

A randomized prospective study of comparison of IV Fentanyl vs. femoral nerve block to facilitate administration of subarachnoid block in sitting position for femur fracture surgeries

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Abstract

Background: Providing adequate pain relief not only gives comfort to the patients, but also shown to improve positioning for neuraxial block. Analgesics or femoral nerve block (FNB) are often used to help the patient tolerate pain while positioning for neuraxial block. Femoral nerve block has been shown to be an effective method of analgesia for fractured femoral shaft when it is performed either during pre-hospital management or in the emergency department.

Objective: To compare the analgesic efficacy of femoral nerve block and IV Fentanyl in femur shaft fracture patients for positioning them for neuraxial block.

Methods: An observational study was conducted among 60 patients belonging to ASA grade I and ASA grade II status undergoing surgery for fracture femur. Patients were randomly allocated to either of the two groups with the help of computerized randomization into: Group A: Femoral Nerve Block and Group B: IV Fentanyl. Data was collected by measuring hemodynamic parameters, VAS score at rest and at movement prior to intervention i.e. femoral nerve block or IV Fentanyl, and every 5 min till 30 min after intervention. The investigator was same for all the cases of the study. Data was analyzed using ANOVA test (Windostat Version 8.6 from indostat services, Hyderabad)

Results: Both femoral nerve block and IV Fentanyl provided analgesia. The hemodynamic parameter variations (H.R., SBP, DBP, and MAP) in Fentanyl and femoral nerve block groups were statistically significant after 10 min interval. It was found that in femoral nerve block group no rescue analgesia was required and in IV Fentanyl group 100% rescue analgesia was required.

Conclusion: Femoral nerve block has better analgesic efficacy compared to IV Fentanyl. Hemodynamic parameters are more stable when femoral nerve block was used for analgesia.

Keywords: Femoral nerve block, Efficacy, Fentanyl, Analgesia, Intervention

Introduction

“Pain is what patient says, hurts”. Thus the emphasis is on patient’s experience. It has been described in terms of damage very aptly by the International Association for the Study of Pain (IASP) as “An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.⁽¹⁾

As the periosteum has the lowest pain threshold of the deep somatic structures, fracture of femur is very painful bone injury.⁽²⁾ Repair of femur fracture most commonly involve either internal fixation of the fracture or intra medullary nailing.^(3, 4)

Femoral fractures in patients older than 50 years are mostly pathological whereas in younger patients, they are mostly traumatic. Neuraxial block is preferred over general(GA) as it provides post-operative analgesia, helps in healing, early mobilization and avoids poly pharmacy. As displaced fractures are painful, giving position for neuraxial block is difficult. So, administration of neuraxial block without prior analgesia is challenging.

Providing adequate pain relief not only increases comfort in these patients, but has also been shown to improve positioning for neuraxial block. Analgesics or femoral nerve block (FNB) are often used to help the

patient tolerate position. Femoral nerve block has been shown to be an effective method of analgesia for fractured femoral shaft either during pre-hospital management or in the emergency department^(6, 7) and also provide excellent postoperative analgesia.⁽⁸⁾

In this prospective randomized study, we compared the analgesic efficacy and hemodynamic stability of a femoral nerve block and IV Fentanyl when administered before neuraxial blockade in patients undergoing surgery for fracture shaft of femur.

Material & Methods

A prospective, randomized study was conducted on 60 patients of ASA I and II between the age group of 18-65 yrs undergoing surgical correction of fracture shaft femur under subarachnoid anesthesia. Patients were randomly allocated into two groups with the help of computerized randomization into

Group A: In this group of patients, femoral nerve block was administered 30 minutes before planned subarachnoid blockade.

Group B: In this group of patients, IV Fentanyl 3ug/kg was administered 30 minutes before planned subarachnoid blockade.

Inclusion criteria:

1. All patients undergoing elective surgeries for

femur shaft fractures.

2. Age >18 years and <65 years
3. ASA I & II

Exclusion criteria:

1. Patients with poor GCS
2. Age <18 years and >65 years
3. Patients with liver and renal diseases
4. Patients with known local anesthetic allergy
5. Patients with bleeding tendencies and coagulopathy.
6. Patients with known neuropathy.
7. Patients with skin lesion at block site.

Study procedure: After obtaining Scientific & ethical committee approval and written informed consent, we recruited 60 patients with fractured shaft of femur. On arrival in the anesthesia induction room, a visual analogue pain scale (VAS) (0 - no pain to 10 - maximal pain) was clearly explained to the patients. An IV access was secured and ringers lactate solution was started. All patients were monitored with electrocardiography, pulse oximeter, and non-invasive blood pressure measurement. All patients were given oxygen (6 L/min) via a face mask. Skeletal traction was maintained during the procedure

Patients in the FNB group received FNB guided by a peripheral nerve stimulator (Stimuplex; B Braun, Melsungen, AG). An insulated 50 mm 22 G needle was

introduced 1 cm lateral to the femoral artery and just below the inguinal ligament. When a current 0.2–0.4 mA elicited a quadriceps contraction, 30 ml of Bupivacaine 0.3% (a mixture of 20 ml of Bupivacaine 0.5% and 10 ml of normal saline 0.9%) was injected incrementally after a negative aspiration test.

Patients in the Fentanyl group received IV Fentanyl 3 µg/kg. In both groups, the time when the treatment drug (FNB or Fentanyl) was administered was considered as the starting time and patient was given sitting position for spinal anesthesia 30 min after starting time. If the patient’s pain is greater than 4 according to VAS, rescue analgesic in the form of IV Paracetamol 15 mg/kg was used.

Parameters observed

1. Heart rate
2. Systolic blood pressure
3. Diastolic blood pressure
4. Mean arterial pressure
5. VAS score at rest
6. VAS score at movement of fractured limb
7. Rescue analgesic requirement

Parameters noted on arrival of patient and every 5 min after intervention (FNB or IV Fentanyl) till 30 min.

Statistical analysis: By using ANOVA test (Windostat Version 8.6 from indostat services, Hyderabad)

Table 1: Summary of heart rate (HR) /minute in treatment group

| Hear Rate | Femoral Block | | Fentanyl | | P value | |
|------------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-intervention | 87.60 | 7.96 | 89.13 | 8.43 | 0.472 | Not Significant |
| 5 Minutes | 87.50 | 7.38 | 86.37 | 6.74 | 0.537 | Not Significant |
| 10 minutes | 84.77 | 5.29 | 89.30 | 7.10 | 0.007 | Significant |
| 15 Minutes | 80.83 | 6.24 | 88.70 | 5.81 | 0.000 | Significant |
| 20 Minutes | 78.30 | 5.27 | 88.37 | 5.77 | 0.000 | Significant |
| 25 Minutes | 75.90 | 4.88 | 86.53 | 5.45 | 0.000 | Significant |
| 30 Minutes | 75.67 | 5.44 | 87.30 | 5.86 | 0.000 | Significant |

In FNB group there is decrease in mean heart rate compared to pre-intervention period till 25 min period and stable thereafter. In Fentanyl group there is decrease in mean heart rate at 5 min interval compared to pre-intervention period which again increased after 10 min. Difference in mean heart rate in both the groups after 10 min interval is statistically significant.

Table 2: Summary of systolic blood pressure (SBP) in mmHg

| SBP | Femoral Block | | Fentanyl | | p-value | |
|------------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-intervention | 132.47 | 9.32 | 133.07 | 9.19 | 0.803 | Not Significant |
| 5 Minutes | 132.53 | 7.93 | 133.47 | 7.31 | 0.637 | Not Significant |
| 10 minutes | 129.97 | 7.97 | 134.77 | 4.86 | 0.007 | Significant |
| 15 Minutes | 128.63 | 7.74 | 135.63 | 4.38 | 0.000 | Significant |
| 20 Minutes | 127.50 | 7.98 | 134.80 | 4.21 | 0.000 | Significant |
| 25 Minutes | 126.90 | 7.75 | 134.53 | 4.34 | 0.000 | Significant |
| 30 Minutes | 126.00 | 7.79 | 135.27 | 3.69 | 0.000 | Significant |

From above Table, mean SBP in FNB group decreased gradually after 5min interval while mean SBP in Fentanyl group increased after 5min interval. Difference in mean SBP in both the groups after 10 min interval is statistically significant.

Table 3: Summary of diastolic blood pressure (DBP) in mmHg

| DBP | Femoral Block | | Fentanyl | | p-value | |
|------------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-intervention | 79.23 | 4.36 | 79.23 | 4.92 | 1.000 | Not Significant |
| 5 Minutes | 79.67 | 4.10 | 79.60 | 3.87 | 0.949 | Not Significant |
| 10 minutes | 79.57 | 4.25 | 81.20 | 2.01 | 0.064 | Not Significant |
| 15 Minutes | 78.60 | 3.71 | 80.87 | 1.70 | 0.004 | Significant |
| 20 Minutes | 78.77 | 4.51 | 80.87 | 2.83 | 0.036 | Significant |
| 25 Minutes | 79.10 | 3.93 | 80.97 | 2.03 | 0.026 | Significant |
| 30 Minutes | 78.87 | 4.19 | 80.77 | 1.76 | 0.028 | Significant |

From above Table mean DBP in FNB group increased till 10 min interval and thereafter decreased while in Fentanyl group mean DBP increased after 5min and remained same thereafter. Difference in mean DBP in both the groups after 10 min interval is statistically significant.

Table 4: Mean of mean arterial blood pressure (MAP) in mmHg

| MAP | Femoral Block | | Fentanyl | | p-value | |
|------------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-intervention | 97.00 | 4.90 | 97.20 | 5.00 | 0.877 | Not Significant |
| 5 Minutes | 97.30 | 4.10 | 97.60 | 3.80 | 0.796 | Not Significant |
| 10 minutes | 96.40 | 5.00 | 99.10 | 2.00 | 0.010 | Significant |
| 15 Minutes | 95.30 | 4.50 | 99.10 | 2.10 | 0.000 | Significant |
| 20 Minutes | 95.00 | 5.10 | 98.80 | 2.70 | 0.001 | Significant |
| 25 Minutes | 95.00 | 4.80 | 98.80 | 2.00 | 0.000 | Significant |
| 30 Minutes | 94.60 | 4.90 | 98.90 | 1.70 | 0.000 | Significant |

From the above Table it is seen that MAP mean in FNB group decreased after 10 min while in Fentanyl group MAP mean increased after 10 min and remained same thereafter. Difference in mean MAP in both the groups after 10 min interval is statistically significant.

Table 5: Summary of pain score: VAS Rest

| VAS Rest | Femoral Block | | Fentanyl | | p-value | Significance |
|---------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-operative | 9.00 | 0.00 | 9.00 | 0.00 | 1.000 | Not Significant |
| 5 Minutes | 9.00 | 0.00 | 9.00 | 0.00 | 1.000 | Not Significant |
| 10 minutes | 8.33 | 0.84 | 6.80 | 0.80 | 0.000 | Significant |
| 15 Minutes | 5.33 | 1.35 | 7.30 | 0.80 | 0.000 | Significant |
| 20 Minutes | 3.73 | 1.44 | 7.23 | 0.73 | 0.000 | Significant |
| 25 Minutes | 1.53 | 1.55 | 6.47 | 0.86 | 0.000 | Significant |
| 30 Minutes | 2.40 | 1.65 | 6.33 | 0.84 | 0.000 | Significant |

From above Table mean VAS at rest in FNB group decreased after 10 min interval while mean VAS at rest in Fentanyl group also decreased but remained same thereafter. Mean VAS at rest in FNB group & Fentanyl group at 10min(8.33 & 6.8), 15 min (5.33 & 7.30), 20min(3.73 & 7.23), 25min(1.53 & 6.47) 30 min(2.40 & 6.33) which were statistically significant. That means FNB has better analgesic profile compared to iv fentanyl.

Table 6: VAS Movement

| VAS Mvmnt | Femoral Block | | Fentanyl | | p-value | Significance |
|---------------|---------------|----------|----------|----------|---------|-----------------|
| | Mean | Std. Dev | Mean | Std. Dev | | |
| Pre-operative | 10.00 | 0.00 | 10.00 | 0.00 | 1.000 | Not Significant |
| 5 Minutes | 10.00 | 0.00 | 10.00 | 0.00 | 1.000 | Not Significant |
| 10 minutes | 9.33 | 0.84 | 8.10 | 0.80 | 0.000 | Significant |

| | | | | | | |
|------------|------|------|------|------|-------|-------------|
| 15 Minutes | 6.43 | 1.10 | 8.20 | 0.70 | 0.000 | Significant |
| 20 Minutes | 4.83 | 1.39 | 8.23 | 0.73 | 0.000 | Significant |
| 25 Minutes | 2.50 | 1.63 | 7.47 | 0.86 | 0.000 | Significant |
| 30 Minutes | 3.37 | 1.65 | 7.37 | 0.85 | 0.000 | Significant |

Above Table shows mean VAS at movement in FNB group decreased after 10 min interval while mean VAS movement in Fentanyl group also decreased after 10 min but remained same thereafter. Mean VAS at movement of fractured limb in FNB group & Fentanyl group at 10min, 15min, 20min, 25min and 30min were(9.33 & 8.1), (6.43 & 8.20), (4.83 & 8.23), (2.50 & 7.47) and (3.37 & 7.37) respectively which were statistically significant(p-value 0.000). Difference in mean VAS at movement in both the groups after 10 min interval is statistically significant. That means FNB has better analgesic profile compared to iv fentanyl.

Discussion

In our institute, fracture of femur shaft is operated by closed intra-medullary nailing in anterograde fashion. The patients are placed in the supine position on the fracture table. The surgical incision is made proximal to the greater trochanter to develop the entry hole for the nail. The non-affected limb is often abducted to facilitate the use of the image intensifier. We routinely practice spinal anesthesia (with or without the placement of an epidural catheter). The positioning of these patients to perform neuraxial blockade is often problematic because even a minimal overriding of the fracture ends while positioning is extremely painful. To reduce the pain and avoid further soft tissue trauma, we prefer to maintain femoral traction and perform spinal anesthesia in the sitting position. Despite this practice, administration of a substantial amount of IV analgesics is mandatory during placement of the neuraxial block. Sandby-Thomas et al⁽⁹⁾ reported that the most frequently used agents were midazolam, ketamine, and propofol. Alternative agents were Fentanyl, remifentanyl, morphine, nitrous oxide, and sevoflurane, whereas nerve blocks were used infrequently.

The femoral nerve block has been used successfully in adults for femoral shaft fracture.^(6,7) Capdevilla et al⁽⁸⁾ reported effective and safe analgesia provided by using continuous femoral blocks for bilateral femoral shaft surgery. However, few studies have investigated FNB to facilitate positioning during conduct of regional anesthesia.

Gosavi et al⁽¹⁰⁾ assessed pain during change of position from supine to sitting after FNB with lidocaine; VAS scores were 2.7 ± 1.13 . In our study mean VAS at movement after 30 min of intervention was 3.37 in FNB group and 7.37 in iv fentanyl group.

Arissara Iamaroon et al⁽¹¹⁾ were unable to show benefit of femoral nerve block over IV fentanyl for positioning fracture femur patient for neuraxial block. Salvatore Sia, Francesco Pelusio, et al⁽¹²⁾ concluded that femoral nerve block is better than IV Fentanyl for

giving position for spinal block in femoral shaft fracture surgeries. In their study VAS at positioning for spinal anaesthesia was 0.5 ± 0.5 and 3.3 ± 1.4 in femoral nerve block group and iv fentanyl group respectively with p-value < 0.001 which is statistically significant.

The VAS score (0 – 10) was chosen to evaluate pain in the present study. A VAS score of 0 is no pain and 10 worst imaginable pain. The analgesic effect of femoral nerve block was significantly better than IV Fentanyl. Mean VAS at rest and movement of fractured limb in femoral nerve group at 10, 15, 20, 25 and 30 min were (8.33 & 9.33), (5.33 & 6.43), (3.73 & 4.83), (1.53 & 2.50) and (2.40 & 3.37) while in fentanyl group (6.8 & 8.10), (7.3 & 8.20), (7.23 & 8.23), (6.47 & 7.47) and (6.33 & 7.37) respectively. P- value at all interval was 0.000 which is statistically significant implying that femoral nerve block was more effective in terms of analgesia than iv fentanyl.

The hemodynamic parameter variations (H.R., SBP, DBP, MAP) in Fentanyl and FNB groups are statistically significant after 10 min interval, which implies hemodynamic parameters in FNB group are stable compared to IV Fentanyl group.

In our study, we compared all groups for 30 min. and at the end of 30 min; if VAS score is more than 4, rescue analgesia (IV Paracetamol 15mg/kg) was given. It is found that in femoral nerve block group no rescue analgesia was required and in IV Fentanyl group 100% rescue analgesia was required.

No adverse systemic toxicity of Bupivacaine, such as seizure, arrhythmia, or cardiovascular collapse was noted in the femoral nerve block group. Neither vascular puncture nor paresthesia occurred. No complications, such as hematoma, infection, or persistent paresthesia were observed within 24 hours after the operation. Similarly no adverse effect like nausea, vomiting, and respiratory depression were found in IV fentanyl group.

Conclusion

Fracture shaft femur is painful. Femoral nerve block and IV Fentanyl both are useful in reducing pain to facilitate administration of subarachnoid block in sitting position. Femoral nerve block has better analgesic efficacy compared to IV Fentanyl. IV Fentanyl is inadequate as a sole analgesic agent in fracture femur patient and requires supplementation of other analgesics (i.e. rescue analgesia).

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