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A COMPARATIVE STUDY OF INTRAVENOUS FENTANYL AND ULTRASOUND-GUIDED FEMORAL NERVE BLOCK FOR POSITIONING DURING SPINAL ANAESTHESIA IN FEMUR FRACTURE SURGERIES

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ABSTRACT
Objective: To assist in the administration of spinal anesthesia for patients undergoing femur fracture procedures, we conducted comparison research to compare the analgesic efficiency of intravenous fentanyl against ultrasound-guided femoral nerve block (FNB). **Material and Methods:** A group of 112 patients ranging in age from 18 to 70 years old who had ASA Physical Status I and II and were having femur fracture procedures under spinal anaesthesia participated in the randomised, prospective, interventional trial. These individuals were divided into two groups through a random assignment process. Group FENT (n = 56) received Intravenous fentanyl 1 microgram/kilogram (µg/kg) and five minutes before positioning for spinal anaesthetic, group FNB (n = 56) received ultrasound-guided FNB with 20 millilitres (ml), 1.5% lignocaine and adrenaline (1:200,000). **Results:** Comparison of pain scores during positioning using the Visual Analog Scale (VAS) revealed that Group FENT had a score of 1.95 ± 0.585, whereas Group FNB had a score of 0.61 ± 0.562 (p-value 0.001). The FNB group demonstrated superior patient positioning quality. Patient satisfaction was similar in both groups, and no significant side effects were observed. **Conclusion:** FNB offers enhanced analgesia, improved patient positioning, higher patient satisfaction, reduced reliance on additional analgesia, and fewer side effects compared to intravenous fentanyl for spinal anesthesia.

INTRODUCTION
Fracture femur is one of the common orthopaedic problems following trauma in all age groups[1]. It has a bimodal incidence. The prevalence is lower in younger patients and is linked to high-energy trauma, such as falling from a ladder or being in a car accident. Low-energy falls in the home or community are the main cause of injuries among the elderly.

Because periosteal tissue has the lowest pain threshold of deep somatic structure and is densely supplied by nerve fibres of the femoral nerve, femur fractures are brutally painful. The shaft of the femur experiences shear muscle forces, leading to thigh deformation and bone fragment angulations, which complicate the reduction of these fractures during surgery. Therefore, it is crucial to achieve complete relaxation of the Quadriceps muscle,

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which acts on the femur [2]. The recommended method for delivering anaesthetic and muscular paralysis is central neuraxial block, such as subarachnoid block [3]. Correct placement is a necessity for successful spinal anaesthesia. But limb immobility and excruciating pain make it difficult to get in the proper position for this surgery. Providing sufficient pain relief not only enhances patient comfort but also improves the ability to achieve the optimal positioning for spinal anesthesia. Effective pain control would lower the length of hospital stay and the risk of thrombotic events which improves patient's satisfaction [4]. To provide effective analgesia intravenous (IV) analgesics and regional anaesthesia (nerve blocks) are used. IV analgesics such as paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), and opioids are commonly administered for pain management.. Although paracetamol is a powerful and secure analgesic [5], it is insufficient for a large percentage of patients when used alone. Considering the gastrointestinal side effects and nephrotoxicity associated with NSAIDs, they are generally contraindicated in this specific patient population. They might also lead to more bleeding during surgery. Opioids offer a respectable level of analgesia when used to treat static pain, however they are comparatively inefficient for treating dynamic pain [6]. Opioid may cause many undesirable side effects such as confusion, nausea, vomiting, constipation , delirium and respiratory depression along with they have addictive potential which significantly impact post operative rehabilitation. Other IV analgesic likes midazolam, ketamine, propofol also been used to provide analgesia.

Regional analgesia in form of nerve blocks offers an attractive alternative to IV analgesics both for pre, intra and postoperative use. Nerve blocks are providing analgesia those targets on both static and dynamic pain [6]. Femoral nerve block (FNB) effectively reduces intense pain, thereby promoting patient safety. Furthermore, it leads to a shorter duration for performing spinal anesthesia, ensuring a more efficient process [7] with less consumptions of opioid, which consequently reduces the adverse effects of opioids and promotes earlier hospital discharge.

In comparison to the traditional peripheral nerve stimulator technique, ultrasound speeds up the onset and enhances the quality of the block by helping to pinpoint the exact position of the nerve. It also helps reduce the amount of local anaesthetic solution needed and has a greater success rate.

There are contradictory results regarding the superiority of FNB over IV fentanyl. Therefore, we undertook this investigation compares the ability of intravenous fentanyl to facilitate patient positioning for central neuraxial block during femur fracture procedures to ultrasound-guided femoral nerve block (USG) FNB.

MATERIALS AND METHODS

The ethics committee of our institute gave its approval to this work, on the 12th of October 2021 (No. 863/MC/EC/2021). Clinical Trials Registry-India (CTRI) number is CTRI/2021/10/037697.

Sample of 56 cases in each group was calculated at 95.0% confidence and 80.0% power to verify the expected difference of 0.42 ± 0.783in mean VAS score between both groups.

Eligibility Criteria

Inclusion criteria:

1. Patients giving written informed consent.
2. Patients undergoing elective surgery for fracture of femur unable to sit for spinal anaesthesia due to severe pain (VAS > 7).
3. ASA Grade I & II.
4. Patients between 18-70 years of age.

Exclusion criteria:

1. Patients with multiple injuries.
2. Patients with history of known allergic to study drugs.
3. Patients with compromised renal, cardiac and respiratory functions.
4. Patient with general contraindication for spinal anaesthesia.

After confirmation of identity, patient was taken in operation theatre. In the operation theatre fasting status, consent and PAC were checked and standard ASA monitors were connected. Baseline VAS score was assessed by using the visual analogue scale (0= no pain, 10 = maximal pain). Patients were randomized into 2 groups with opaque sealed envelope technique.

Group FENT (n = 56): Patients in the study were administered an intravenous injection of fentanyl at a dose of 1 microgram/kilogram (µg/kg) 5 minutes before positioning for spinal anesthesia.

Group FNB (n = 56): Patients received USG guided FNB 5minutes (min) prior to positioning.

The FNB procedure was performed by one of the two anesthesiologists involved in the study. High frequency (5-12MHz) linear probe was prepared with double gloves technique. Under all aseptic precautions, painting, and draping done. The alignment of the marker was confirmed by positioning the linear ultrasonography probe in the inguinal crease and parallel to the inguinal ligament. A hyper echoic, triangular-shaped object directly lateral to the femoral artery was identified as the femoral nerve. To perform the in-plane needle insertion technique, the 20-gauge needle is inserted at the lateral end of the ultrasound probe, and advance it parallel to the ultrasound beam, in full view, until it approaches the femoral nerve. Then 20 milliliter (ml), a solution of 1.5% lignocaine and adrenaline (1:200,000) was progressively delivered once a negative aspiration test was confirmed. The solution used for injection consisted of 15 mL of 2.0% lignocaine diluted with 5 mL of distilled water.

Effect was checked by pin prick on anterior part of thigh. If VAS score > 3 after 5 minute additional doses of IV fentanyl 0.5µg/kg with a five minute interval given until VAS decreased to < 3 or patients were given a maximum dose of 3 µg/kg of fentanyl, or the dose was limited to achieve a VAS score of 3, whichever came first. If the target VAS score of 3 could not be attained, those patients were excluded from the study. Under strict aseptic measures, spinal anesthesia was administered five minutes after the intervention. The procedure was performed with the patient in a seated position, targeting the L3-L4 space using a 25G Quincke's needle. A total of 2.5mL of 0.5% hyperbaric bupivacaine with 25µg fentanyl was injected. The visual analogue scale (VAS) was used to gauge how painful the positioning for spinal anaesthesia was. The VAS score varied from 0 (the absence of pain) to 10 (the intensity of discomfort). In order to attain a VAS score below 3, further intravenous fentanyl dosages were required, Quality of Patient Positioning range between 0 to 3 where 0 = not satisfactory, 1= satisfactory, 2=good, 3=ideal, Vital parameters, Patient satisfaction (Yes/No), side effects like respiratory depression, sedation, bradycardia, hematoma, local anaesthetic systemic toxicity were assessed.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) software application, version 21 for Windows, was used to do the statistical analytics like chart preparing and calculation. The variables' mean and standard deviation (S.D.) were presented. Categorical data were compared using the Chi-square test, whereas quantitative metric data were analyzed using the unpaired Student's t-test. For all statistical analyses conducted, a p-value of 0.05 was considered statistically significant, which all maintained a significance level of 95.0%.

RESULTS

Randomly chosen for the study were 112, who have ASA physical status I and II patients of either sex, between the ages of 18 and 70, who had posted for femur fracture procedures. Regarding demographic characteristics, the two groups were comparable (Table 1). Heart rate (HR) and oxygen saturation (SpO_2) did not differ statistically substantially between the two groups (p-values 0.172 and 0.481, respectively); however, mean arterial pressure (MAP) was significantly lower in the FENT group 5 minute after the intervention (p-value 0.042) (Table 2). Baseline VAS score (mean ± S.D.) between Group FENT (8.43 ± 0.628) and Group FNB (8.57 ± 0.71) was comparable (p-value 0.262) [Table 3]. VAS score during positioning (mean ± S.D.) for spinal anaesthesia was notably lower in Group FNB (0.61 ± 0.562) compared to the Group FENT (1.95 ± 0.585) (p-value 0.001) (Figure 1, Table 3) .Quality of patient positioning for spinal anaesthesia (mean ± S.D.) was better in Group FNB (2.77±0.467) as compared to Group FENT (1.48±0.66) (p-value 0.001) (Table 3). When comparing patient satisfaction (Yes/No), Group FNB scored higher (56/0) than Group FENT (48/8). (p-value 0.010) [Table 3]. Between the two groups, neither required substantially more IV fentanyl dosages than the other. (p-value 0.156). No major side effects observed in both groups except excessive sedation were seen in four patients in FENT Group (Table 3).

DISCUSSION

Fracture shaft of femur is commonly encountered injury in orthopaedic practice with high rate of morbidity and mortality.

According to Sorenson et al. individuals having general anaesthesia had a higher chance of developing deep vein thrombosis [8]. Regional anaesthetic (RA), according to cochrane review, was related with a lower one-month mortality rate, even if the difference was statistically insignificant [9]. Also, the time to ambulation will be earlier for patients receiving RA. So, the preferred technique of providing anaesthesia in these cases is RA especially Spinal anaesthesia. However, the technique of choice will depend upon anaesthesiologist preference and expertise. In our institute, the technique of choice is spinal anaesthesia unless any contraindication is present. Spinal anaesthesia was quite challenging due to excruciating pain associated with fracture shaft of femur patient due to inability of patient to give optimal positioning for spinal anaesthesia.

Table 1 Demographic data

	Group FENT (n=56)	**Group FNB (n=56)**	**p-value**
Age (Years)	40.14±18.013	37.43±18.179	0.429
Gender (Male/Female)	36/20	40/16	0.544
ASA Physical Status(I/II)	31/25	32/24	1.000
Fracture Site	Number of cases (Group FENT)	Number of cases (Group FNB)	0.978
Neck of Femur	17	19	-
Intertrochanteric	17	18	-
Subtrochanteric	2	1	-
Shaft (Upper Third)	6	7	-
Shaft (Middle Third)	8	6	-
Shaft (Lower Third)	4	4	-
Suprachondylar	2	1	-

Data are presented as Number or mean ± Standard Deviation
FENT=Fentanyl, ASA= American Society of Anesthesiologists, FNB = Femoral Nerve Block

Many methods have been used to alleviate this pain such as pharmacological methods and non-pharmacological methods. Pharmacological methods include various classes of analgesics that include both opioids and non-opioids. Sandby-Thomas et al. found that the most commonly utilized agents for anesthesia induction were ketamine, midazolam, and propofol. Additionally, Fentanyl, remifentanil, morphine, nitrous oxide, and sevoflurane were the agents [3]. Although they are quiet effective in relieving the pain but they are associated with multitude of side effects such as nausea, vomiting, respiratory depression, urinary distension etc. Non pharmacological methods include various types of nerve blocks. It is well known that femoral nerve block (FNB) can be used in a variety of situations to reduce pain brought on by femur fractures [10][11]. In addition., FNB is now used to facilitate patient placement during spinal anaesthesia operations [7][12][13][14]. There were no statistically significant variations in the age, gender, ASA physical status, or fracture site between the two groups in our study (Table 1).

Table 2 Vital parameters

	Group FENT (n=56)	**Group FNB (n=56)**	**p-value**
Baseline HR	87.55±11.109	85.46±12.078	0.764
HR During Positioning	84.70±9.055	88.29±9.322	0.172
HR 5 Minutes after intervention	81.18±9.975	88.34±10.337	0.052
Baseline MAP	96.39±10.124	97.32±7.616	0.584
MAP During Positioning	98.13±7.532	97.55±7.630	0.691
MAP 5 Minutes after intervention	85.70±7.259	88.71±8.254	0.042*
Baseline SpO2	98.71±0.624	98.95±0.773	0.083
SpO2 During Positioning	98.54±0.785	98.64±0.819	0.481
SpO2 5 Minutes after intervention	98.93±0.806	99.02±0.774	0.551

Data are presented as mean ± Standard Deviation
HR=Heart Rate, FNB = Femoral Nerve Block, FENT= Fentanyl, MAP= Mean Arterial Pressure, SpO2 = Oxygen Saturation
* p-value <0.05

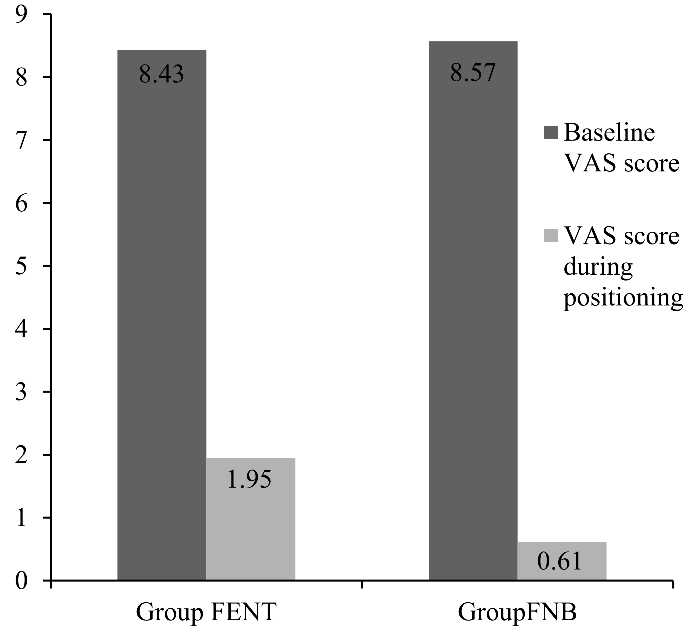
In our study, baseline VAS score was comparable in both groups. VAS score during positioning was 1.95±0.585 in the FENT group and 0.61±0.562 in the FNB group (p-value 0.001) [Table 3]. In comparison to the FENT group, the VAS score during positioning was statistically lower in the FNB group. The pain scores with FNB were significantly lower than those with IV fentanyl in many other studies as well [1][13][15][16][17]. FNB and fentanyl did not significantly vary, according to a study by Lamaroon et al. [7]. He positioned the patients 15 minutes after the block and used 0.3% bupivacaine for FNB. The probable reason was the use of bupivacaine instead of lidocaine. The effect of lignocaine in FNB comes in 5 min however; onset of analgesic effect of bupivacaine is variable and may take 25-30 min for full effect. The most significant result of our study was the superiority of femoral nerve blockage in terms of analgesia when positioned for spinal anaesthesia in cases of femur fracture compared to IV fentanyl. FNB was also linked to the best possible patient placement.FNB was also linked to better patient positioning quality and higher levels of patient satisfaction. (p-value 0.001, 0.010 respectively) (Table 3). Similar finding were observed by some other studies[13][15].

Table 3 VAS Scores, Quality of Patient Positioning, Patient Satisfaction, Additional Doses of IV Fentanyl Requirement, Side Effects

	Group FENT (n=56)	Group FNB (n=56)	p-value
Baseline VAS score	8.43±0.628	8.57±0.71	0.262
VAS score During Positioning	1.95±0.585	0.61±0.562	0.001*
Quality of Patient Positioning (0-3)	1.48±0.66	2.77±0.467	0.001*
Patient Satisfaction (Yes/No)	48/8	56/0	0.010*
Number of Patients required Additional Doses of IV Fentanyl	2	0	0.156
Side Effects: excessive sedation	4	0	0.127

Data are presented as mean ± Standard Deviation or Number
IV= Intravenous, VAS= Visual analog scale, FENT= Fentanyl, FNB = Femoral Nerve Block, * p-value <0.05

In our study, if VAS score was >3 after 5 minutes of intervention, repeated doses of intravenous fentanyl, starting at 0.5 μg/kg, were administered at five-minute intervals until either a VAS score of 3 or a maximum dose of 3 μg/kg was achieved, depending on which condition was met first. The logic for this dosing was to avoid any untoward effects of fentanyl like excessive sedation, hypoventilation or apnea. Almost all our patients got adequate pain relief with FNB or IV fentanyl. Additional doses of fentanyl were given only to 2 patients of the IV Fentanyl group (Table 3). Similar findings were observed in a study done by Sia et al. they found that supplemental fentanyl (50μg) was given to one patient of group IV Fentanyl [13]. Additionally, there were no appreciable differences in the two groups' heart rates or SpO2. However, the MAP of the IV fentanyl group was lower than the FNB group (Table 2).



FENT= Fentanyl, FNB = Femoral Nerve Block

In our study, we observed that sedation was seen only in 4 patients of group FENT. Other side-effects like respiratory depression, bradycardia, hematoma, local anaesthetic systemic toxicity (LAST), intra-arterial injection, hematoma, infection etc. were not seen in our study. Our findings correlated with the study of Vats, et al., they found that excessive sedation was seen in two patients in the FENT group[1]. Ultrasound-guided techniques aid in accurate localization of the femoral nerve and provide real-time visualization of drug deposition, allowing for reduced volumes of local anesthetic during the procedure. Thus, it causes early onset of block, improved success of block along with decreased volume of drug that decreasing the chances of LAST. We used 1.5% lignocaine because of its earlier onset and adrenaline (1:200,000) as an adjuvant for decreasing the probability of toxicity and making its effect long lasting. The dosage of 1μg/kg of fentanyl was taken to get potent and short acting analgesia with minimal risk of opioid related side effects. 5 minutes interval was chosen because it was adequate to establish the effect of lignocaine and fentanyl in all patients.

CONCLUSION

We concluded that ultrasound guided FNB provides earlier onset and better pain relief (in terms of VAS score), optimal patient positioning, more patient satisfaction, hemodynamic stability with minimal volume of local anaesthetic, less need for additional analgesia along with avoiding the side effects of opioids like infection, nerve damage, neuropathy etc. in comparison to IV Fentanyl to facilitate the positioning during spinal anaesthesia in patients undergoing femur fracture surgeries.

FINANCIAL ASSISTANCE
Nil

CONFLICT OF INTEREST
The authors declare no conflict of interest

AUTHOR CONTRIBUTION
Sonali Beniwal examined and assessed research-related data from experiment designs. Mamta Khandelwal assisted in carrying out the operations room studies. The draught of the manuscript was assisted by T Mirthun Thomas. The final manuscript was read and approved by all authors.

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