

Femoral Nerve Block versus Intravenous Fentanyl in Adult Patients with Proximal Femur Fracture: A Comparative Cross-Sectional StudyArchana Sengar¹, Priya Majumdar², Manish Shivani³, Chandra Shekhar Mishra⁴,
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Abstract:**Background:** Femoral fractures are linked to elevated mortality rates and reduced functionality. This study aimed at comparing the pain-relieving impacts of Femoral Nerve Block (FNB) with intravenous (IVF) fentanyl before positioning for a spinal block in individuals with femur fractures.**Material and Methods:** This was a single centre, hospital, inpatient-based comparative, cross-sectional study conducted over a period of 18 months by enrolling a total of 60 patients. FNB group were given Femoral Nerve Block with 10 ml of 0.5% bupivacaine and IVF group were given intravenous fentanyl 1 microgram/kg.**Results:** Overall, there were 23 (38.3%) female and 37 (61%) male participants ($p = 0.426$). The mean time from procedure completion to completing spinal anaesthesia given FNB and IVF was 9.9 minutes and 11.1 minutes, respectively (p -value < 0.001). The median pain score among the participant given IVF (VAS = 3.5) was higher than participants given FNB (VAS = 2) ($p = 0.034$). A higher proportion of participants given FNB rated their experience as either satisfactory and/or very satisfactory than those given IVF ($p = 0.049$). A higher proportion of anaesthesiologists rated their experience as either satisfactory and/or very satisfactory while inducing SA for participants given FNB ($p = 0.642$).**Conclusion:** Femoral Nerve Block (FNB) proved to be a successful and secure approach for preparing femur fracture patients for a spinal block, especially those undergoing spinal anesthesia while in a seated position. The implementation of femoral nerve block can lead to a decrease in pain intensity and a reduced requirement for additional pain relief. Additionally, fewer negative effects on the body are linked to this approach, and the procedure itself does not present higher inherent risks.**Keywords** Proximal Femur Fracture (PFF), Femoral Nerve Block (FNB), Intravenous fentanyl (IVF).

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Introduction

Globally, the femur is among the top five bones of the body that is fractured in any type of accident[1]. Further, among elderly persons, the femur is the commonest long bone to get fractured[1–3]. Also, the incidence of femur fracture will continue to increase as the population ages[1,2]. The umbrella term Proximal Femur Fracture (PFF) also includes the commonly used phrase ‘hip-fracture’, referring to the involvement of femur just distal to the articular cartilage of the hip joint[4].

Among the elderly, fracture of the femur is the result of accidental fall whereas among non-elderly adults the fracture of the femur is secondary to the high energy trauma(2,5). There are several modalities for the treatment of femur fracture (including hip fracture) depending on the type and location of the fracture[6]. Most proximal femur fracture cases

require surgical interventions including individuals requiring emergency surgery[6,7]. Surgical treatment for proximal femur includes fixation of fracture (screws, pins, nails, or plates etc.) or replacing the damaged part of the femur (e.g., head or neck)[7].

The surgical management of proximal femur fracture can be conducted either under general or regional anaesthesia[8–10]. Regional anaesthesia includes neuraxial anaesthesia (spinal or epidural) or peripheral nerve blocks. A systematic review by Guay et al. (2018) concluded that there is no difference in the all-cause 30-day mortality rates among the patients who underwent repair of hip fracture either in the regional or general anaesthesia[11]. Even though the evidence shows a lack of superiority of regional anaesthesia over

general anaesthesia for hip surgery, neuraxial anaesthesia is still equally preferred by surgeons and anaesthesiologists for surgical repair of proximal femur fracture[8,9,12]. There are several reasons for the same including the request from patients to remain awake during the surgery. Additionally, regional anaesthesia is also associated with fewer complications in comparison to general anaesthesia[13–17]. Guay et al. from their meta-analysis concluded that the risk of deep venous thrombosis is higher among those who were operated on under general anaesthesia[11].

However, surgical repair of proximal femur fracture including hip fracture under spinal anaesthesia possesses several unique problems. The most appropriate position to give spinal anaesthesia is the 'lateral decubitus' or 'sitting' position[4]. Fracture of any bone including the femur is a very painful experience. The severity of pain is further exacerbated by the movement of patients e.g., shifting to healthcare facilities including operation theatre. Additional injury to other parts of the body further compounds the degree of pain experienced by patients. The pain is also accompanied by tachycardia, increased blood pressure and anxiety (secondary to the release of catecholamines) [18,19]. Collectively, the pain and other associated conditions make patients very uncooperative for inducing anaesthesia. During the induction of neuraxial (spinal and epidural) anaesthesia, a patient is supposed to stay still to prevent injury to surrounding organs during the injection[20]. This possesses a dilemma for anaesthesiologists. On one hand, there is a tendency to avoid general anaesthesia (especially among elderly patients) on another hand inability to maintain a still posture creates difficulty for inducing spinal anaesthesia. One logical solution to this dilemma is to reduce or eliminate the pain without making the patients unconscious. Towards this end, anaesthesiologists have tried several strategies.

For these special circumstances, clinical researchers have experimented with injectable analgesics (including opioids), nerve blocks, and alternative positions to induce spinal anaesthesia[8,18,21]. The primary advantage of using a systematic analgesic is that it has a generalised effect all over the body, thereby providing overall pain relief in case a patient has additional injuries. The sensory innervation of the proximal femur and a variable portion of the intra-capsular neck of the femur arises from the femoral nerve[22]. Therefore, anaesthesiologists have also experimented with peripheral nerve blocks particularly femoral nerve block (along with sciatic nerve block) to provide pre-spinal analgesia for various types of fractures of the femur[23–25]. However, the empirical evidence comparing the various dimensions of clinical outcomes viz. analgesic effectiveness, side effects profiles,

haemodynamic stability, quality of spinal blockage, and patient satisfaction with the procedure are mixed[4]. Although many published works of literature have investigated the analgesic effectiveness of femoral nerve block and intravenous fentanyl for the positioning of the patients before spinal anaesthesia, there is no consensus on the appropriateness of these methods, especially about the patient's satisfaction.

Therefore, this study aimed at comparing the pre-, intra-, and postoperative clinical outcomes among patients with proximal fracture of the femur who were given either femoral nerve block or intravenous Fentanyl for positioning before inducing spinal anaesthesia.

Material and Methods:

Study Design: This was a single centre, comparative, observational, cross-sectional study.

Study Settings: The present study was conducted at the Department of Anaesthesiology, LN Medical College, Bhopal. It is a tertiary care institute. The data collection for the present study was initiated after the research protocol was approved by the Institute's Ethical Committee on Human Research.

Study Duration: The total duration of the study was 18 months; from to March 2021 to September 2022.

Study Outcomes: Pain experienced by participants (The pain was measured using the Visual Analogue Scale score); Satisfaction among patients and Satisfaction among anaesthesiologists.

Sample Size Calculation: Using the prescribed formula for simple prevalence/proportion, the minimum required sample size for this study was calculated as 60 (30 in each group).

Study Groups

Group FNB: Participants in the FNB group were given Femoral Nerve Block with 10 ml of 0.5% bupivacaine.

Group IVF: Participants in the IVF group were given intravenous fentanyl at the dose of 1 microgram per kilogram of body weight.

Participants' recruitment: The participants were recruited into the study after verifying that they fulfilled the following selection criteria.

Inclusion Criteria:

1. Patients of all genders.
2. Patients belonging to either grade I, II, and III of the American Society of Anaesthesiologists.
3. Patients giving written informed consent to participate in the study.

Exclusion Criteria:

1. Contraindication to spinal anaesthesia,

2. Patients with ASA physical status IV or more,
3. Patients who are allergic to any of the test drugs,
4. Patient's refusal to participate in the study.

Informed Consent: The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. All the questions from participants about the study, drug, procedure, risk, and data privacy were answered. The participants were informed and explained that they have the right to withdraw from the study at any point in time. Thereafter, willing participants were asked to sign the consent form.

Data Collection: The data were collected in a paper-based questionnaire. The questionnaire was approved by the ethical committee before starting data collection. The questionnaire had 4 parts as follows:

1. Part 1: Demographics, Medical history, & Clinical examination.
2. Part 2: Pre-anaesthetic check-up & findings of investigations.
3. Part 3: Intra-operative details.
4. Part 4: Postoperative details.

Observation Tables

To recruit participants for the present study, the principal investigator approached a total of 78 patients: 8 patients refused to participate in the study, 10 patients were excluded, and the remaining 60 patients were enrolled in the present study.

As mentioned earlier, 30 participants received intravenous Fentanyl (Group IVF) and 30 participants were given Femoral Nerve Block (Group FNB). The study observations and results of statistical analysis are presented in the following sections.

Table 1: Distribution of Participants by Gender (N = 60)

Gender	Group				P-Value
	IVF		FNB		
	n	%	n	%	
Age					
Mean (±SD)	58.8 (±9.07)		60.9 (±6.50)		0.3072
Median	59.5		60.5		
Range	45 73		47 78		
Gender					
Female	13	43.3	10	33.3	0.426
Male	17	56.7	20	66.7	
ASA Grade					
I	3	10	1	3.3	0.572
II	16	53.3	18	60.0	
III	11	36.7	11	36.7	
Time from Injury to Surgery (hours)					
Mean (±SD)	59.5 (21.35)		76.0 (31.17)		0.019
Median	57.1		76.5		
Range	26.88 107.52		31.36 150.08		
Site of the Fracture					
Neck	11	36.7	11	36.7	-
Shaft	6	20.0	7	23.3	
Distal	2	6.7	0	0.0	

Table 2: Distribution of Participants by Time to Positioning (N = 60)

Time (Seconds)	Group				Total	
	IVF		FNB		n	%
	n	%	n	%		
Time to positioning						
Mean (±SD)	267.8 (15.23)		237.9 (21.37)		T = 6.23 P- value < 0.001	
Median (IQR)	269		238			
Range	228 296		204 299			
Time to complete Spinal block						
Mean (±SD)	11.08 (1.25)		9.86 (2.35)		t = 15.202 p < 0.001	
Median (IQR)	11.1		9.9			
Range	10.41 - 11.55		9.3 - 10.88			

Table 3: Group Wise Distribution of Pain during Positioning (N = 60)

VAS Score	Group		
	IVF (n, %)	FNB (n, %)	Total (n, %)
0	1	2	3
	3.33	6.67	5.00
1	2	3	5
	6.67	10.00	8.33
2	8	13	21
	26.67	43.33	35.00
3	12	9	21
	40.00	30.00	35.00
4	7	3	10
	23.33	10.00	16.67
Total	30	30	60
	100.00	100.00	100.00
VAS score			
Median	3.5	2	-

Table 4: Distribution of Study Participants Based on the Patient's Satisfaction Score (N=60)

Satisfaction Score	Group: IVF		Group: FNB		Chi Sq.	P-value
	n	%	n	%		
V. Dissatisfied	0	0.0	0	0.0	7.8425	0.049
Dissatisfied	3	10.0	0	0.0		
Neutral	9	30.0	4	13.3		
Satisfied	13	43.3	14	46.7		
V. Satisfied	5	16.7	12	40.0		
Median	Satisfied		Satisfied			

Table 5: Distribution of Satisfaction Score among Anaesthesiologists (N=60)

Satisfaction Score	Group: FNB		Group: IVF		Chi sq.	P-value
	n	%	n	%		
V. Dissatisfied	0	0.0	0	0.0	0.887	0.642
Dissatisfied	0	0.0	0	0.0		
Neutral	8	26.7	5	16.7		
Satisfied	13	43.3	15	50.0		
V. Satisfied	9	30.0	10	33.3		
Median	Satisfied		Satisfied			

Results

Overall, the mean and median age of the participants was 59.8 and 60 years, respectively. Further, most of the patients were aged more than 60 years (48.3%). Groupwise, among the participants given FNB, the mean and the median age of the participants were 60.9 and 60.5 years, respectively. Further, the mean and the median age of the participants given IVF were 58.8 and 59.5 years, respectively (p-value = 0.307).

Overall, there were 23 (38.3%) female and 37 (61%) male participants (p = 0.426). Most of the participants were admitted to the hospital after 3 days (>72 hours) after the incident. The mean time from incident to admission to the hospital among those given IVF and FNB was 59.5 and 76 hours, respectively (p = 0.019). Among the participants given IVF before spinal anaesthesia, 10%, 53.3%, and 36.7% were categorised as ASA grade I, II, and III respectively. Among the participants given FNB:

3.3%, 60.0%, and 36.7% were categorised as ASA grade I, II, and III respectively.

The mean time from procedure completion to positioning among participants given FNB and IVF was 238 and 269 seconds, respectively (p-value < 0.001). The mean time from procedure completion to completing spinal anaesthesia among participants given FNB and IVF was 9.9 minutes and 11.1 minutes, respectively (p-value < 0.001).

The satisfaction was measured concerning the pain and overall comfort while changing the position for inducing spinal anaesthesia. A higher proportion of participants given FNB rated their experience as either satisfactory and/or very satisfactory than those given IVF. More importantly, the distribution of the satisfaction score was statistically significant among participants (p = 0.049). A higher proportion of anaesthesiologists rated their experience as either satisfactory and/or very satisfactory while inducing SA for participants given FNB. However, the

distribution of the satisfaction score was statistically nonsignificant ($p = 0.642$).

Statistical Analysis Plan:

Null Hypothesis: Femoral nerve block with bupivacaine is equal in effect to intravenous fentanyl for positioning in patients undergoing spinal anaesthesia in fracture femur surgery.

Alternate Hypothesis: Femoral nerve block with bupivacaine is better in effect to intravenous fentanyl for positioning in patients undergoing spinal anaesthesia in fracture femur surgery.

The primary outcome was the median VAS score among the participants in the two groups at prescribed time points during the study. All the data were collected in a paper-based data collection form. Thereafter, the data were coded and entered in Microsoft Excel. The coded data were imported into Stata 17.1 version for analysis. For the continuous data, the author calculated the mean, median, mode, standard deviation, and inter-quartile range. Quantitative data confirming the properties of the normal distribution are presented as means \pm standard deviation. For discrete data, the author calculated and reported frequency, proportion, and percentage. Continuous variables in the two comparison groups were analysed using a student's t-test. Categorical variables were analysed using chi-square (χ^2) tests. A P-value < 0.05 was considered statistically significant (26–30). **Funding:** There was no funding for this study. The participants were not paid any type of fees/incentives/freebees to participate in the study.

Discussion

Either regional or general anaesthesia can be used for the surgical treatment of femur fractures [11–13]. According to Parker et al. (2004), regional anaesthesia for hip surgery was linked to reduced fatality rates than general anaesthesia [14]. For surgical repair of a proximal femur fracture, both anaesthesiologists and surgeons continue to choose neuraxial anaesthesia [11,12,17]. The request from patients to stay awake during the procedure is one of several causes for the same. According to Guay et al meta-analysis's those who underwent general anaesthesia for surgery have a greater chance of developing deep vein thrombosis [16]. However, under spinal anaesthesia, surgical repair of femur fractures, particularly hip fractures, has certain special issues. More than half of all femur fracture patients report moderate to severe pain while at rest [4]. The movement of patients, such as moving to a hospital's operating room, exacerbates the degree of pain even more. The degree of pain that patients suffer is further exacerbated by additional injuries to other body regions [23,24]. The combination of the pain and other related issues makes people exceedingly difficult when it comes to administering anaesthesia. Anaesthesiologists have experimented

with a number of methods to do this. In order to do this, we compared the pre-, intra-, and postoperative clinical results in 60 femur fracture patients who received either a femoral nerve block or intravenous fentanyl for placement prior to inducing spinal anaesthesia.

In the present study, the median pain score was similar (VAS=8) among the participants in the two-study group. In addition, the distribution of VAS score among the participants who were given either IVF or FNB was statistically insignificant ($p = 0.087$). After the giving FNB and IVF in respective groups, the median pain score among the participant given IVF (VAS = 3.5) was higher than participants given FNB (VAS = 2) ($p = 0.034$). Although, the maximum pain score (VAS=4) was similar in both the groups, however, 23% participants in IVF group experienced this level pain in comparison to 10% patients in the FNB group. Moreover, 2 (6.7%) and 1 (3.3%) patient did not complain of any pain (VAS=0) in FNB group and IVF group, respectively. Further, about 10% of the participants given IVF experienced significant pain that required additional doses of analgesia. None of the participants given FNB required additional analgesia.

Most of the other studies assessing the effectiveness of FNB and IVF for positioning during spinal anaesthesia also reported similar findings. FNB outperformed IVA in a meta-analysis conducted by Hsu YP et al., (2019) containing a total of 10 trials involving 584 individuals(4). Within 30 minutes, FNB resulted in noticeably decreased pain levels during placement for SA. Moreover, a total of 500 individuals in eight RCT revealed that FNB also decreased the time required to execute SA in comparison to IVA.

Similar to their observations, we also observed in present study that time to positioning for SA was significantly lower among patients given FNB. More specifically, the mean time from procedure completion to positioning among participants given FNB and IVF was 238 and 269 seconds, respectively (p -value < 0.001). Hsu YP et al. concluded that for patients with femur fractures who need to be positioned for a spinal block, FNB is a useful technique that offers noticeably greater analgesia, especially for those who undergo SA while sitting. Additionally, FNB created no significant hemodynamic instability and needed less time for SA. It also had lower postoperative opioid doses and improved physician and patient satisfaction.

Jadon et al., reported that pain score during the positioning for spinal anaesthesia in FNB were significantly lower than fentanyl[31]. Many other studies also reported significantly low pain scores with FNB compared to IV fentanyl. Sia S et al., and Gosavi et al. reported that visual analogue scale

values during positioning were lower in group FNB group versus IVF group ($P < 0.001$). Reddy et al., 2016 also reported that the femoral nerve blocker, lignocaine to be significantly better than fentanyl for the positioning of the hip for surgery with the VAS scores being significantly lower. Singh AP et al., 2016 reported that both FNB and IVF provided good analgesia, but it was better with FNB[32]. They attributed these findings to the fact that FNB produced relaxation of the quadriceps muscle and hence provided better analgesia for positioning and a shorter time to perform spinal anaesthesia. Schiferer et al. demonstrated that FNB provided better analgesia after femoral trauma[33]. Both Bakers F et al., and Yun MJ et al., reported that nerve guided FNB was more effective than IV[4,34] Fentanyl when used for facilitating lateral position to perform sub-arachnoid block in elderly patients undergoing surgery for the neck of femur fractures.

In contrast to our study, Iamaroon et al. did not find any significant difference between FNB and fentanyl[35]. This difference could be attributed to the concentration of bupivacaine used in the present study and frequency of dosage of IV fentanyl. In the present study we used bupivacaine in 0.5% concentration and Iamaroon et al. used 0.3% bupivacaine for FNB and positioned the patients 15 min after block. We positioned the patients after 30 minutes of the block.

The lower pain during positioning can be reflected in several way. For example, patients feeling no or less pain during positioning are more cooperative thereby increasing the chance of successful induction with SA in first attempt. In the present study, among the participants given IVF, 83.3%, 13.3%, and 3.3% required one, two, and three attempts, respectively. Among the participants given FNB, 93.3%, and 6.7%, required one, and two attempts, respectively. This is further reflected in the satisfaction perceived by both patient undergoing surgery and anaesthesiologist inducing SA. In the present study, we measured the satisfaction concerning the pain and overall comfort while changing the position for inducing spinal anaesthesia. A higher proportion of participants given FNB rated their experience as either satisfactory and/or very satisfactory than those given IVF ($p = 0.049$). Further, a higher proportion of anaesthesiologists rated their experience as either satisfactory and/or very satisfactory while inducing SA for participants given FNB, however, the difference was statistically nonsignificant ($p = 0.642$).

Hsu YP et al., from their meta-analysis of 5 RCTs concluded that both anaesthesiologist as well as the patients preferred FNB for positioning in comparison IVF[4]. A total of 264 anaesthesiologist included in 5 RCT expressed higher satisfaction level with FNB, (Standard Mean Difference= 0.91;

95% CI: 0.60 to 1.21, $p < 0.05$; $I^2 = 26\%$). Further 336 patients in 5 RCT also preferred FNB over IVF (Odds Ratio 6.24; 95% CI: 2.78 to 14.03, $p < 0.05$; $I^2 = 0\%$). Jadon et al., also reported that FNB was associated with greater patient satisfaction. Reddy et al., (2016) also reported the analgesic effect of FNB was better than that of IVF resulting in significantly more satisfaction among patients. Similarly, Singh AP et al., 2016 also reported that satisfaction score was better with FNB at all times during their study. Durrani et al., 2013 also reported higher acceptance by patients in FNB. They also reported higher satisfaction among anaesthesiologist because of better quality of positioning with FNB(36). Bantie et al., 2020 reported that a significantly lower patient acceptance in IVF group than both FNB groups ($P=0.001$)[37].

Conclusion

Based on the empirical evidence collected and analysed in the present study, the author is of the firm opinion that Femoral Nerve Block was superior to Intravenous Fentanyl in every aspect for positioning for spinal anaesthesia among patients being operated for femoral fracture. FNB was associated with better analgesia, lack of systematic side-effects; all culminating in higher satisfaction both among patient and anaesthesiologist. The only disadvantage of femoral nerve block was the significantly more waiting time for the onset of action, thereby, making femoral nerve block unsuitable for emergency surgeries.

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