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Original Article

Anaesthesia Section

Effectiveness of Femoral Nerve Block versus Intravenous Nalbuphine in Positioning of Patients with Intertrochanteric Fractures for Spinal Anaesthesia: A Randomised Clinical Study

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ABSTRACT

Introduction: Femoral fracture is a common entity in all age groups. It is more common in elderly, and is a painful condition. Various modalities like peripheral nerve blocks, intravenous opioids can mitigate the pain associated with it, which is deterrent to ideal patient positioning for spinal anaesthesia.

Aim: To compare the effectiveness of Femoral Nerve Block (FNB) versus Intravenous Nalbuphine (IVN) in positioning of patients with intertrochanteric fracture for spinal anaesthesia.

Materials and Methods: A randomised clinical study was conducted in 70 patients of American Society of Anaesthesiologists (ASA) physical status I and II, with intertrochanteric fractures posted for surgery under subarachnoid block. Group IVN received intravenous Nalbuphine at dose of 0.1 mg/kg, and Group FNB received femoral nerve block with 20 mL of 0.2% ropivacaine 15 minutes, prior to positioning of patients for subarachnoid block. The ease of patient positioning was assessed by the pain relief observed during positioning for spinal anaesthesia, and by means of anaesthesiologist satisfaction score. Time taken to position the patients during spinal anaesthesia, and patient satisfaction scores were also measured. Independent 't' test and Mann-Whitney U test were used for the analysis.

Results: The Visual Analogue Scale (VAS) score achieved during positioning of patients for subarachnoid block was significantly better in FNB (3.87±0.99), as compared to IVN (5.09±1.23). No significant differences were observed between both the groups regarding anaesthesiologist satisfaction score, (p=0.11). Time taken for positioning of patients for spinal anaesthesia in seconds (p=0.69), and patient satisfaction score (p=0.08) were also comparable between both groups of patients.

Conclusion: FNB is more effective for positioning of patients of intertrochanteric fractures for spinal anaesthesia. Although either of the techniques can be adopted for improving patient care, FNB may have an edge over IVN.

Keywords: Femoral fracture, Pain relief, Patient positioning, Subarachnoid block

INTRODUCTION

In proximal femur fractures surgical fixation is undertaken early to enhance quicker recovery of elderly patients, and help prevent major complications of prolonged immobilisation like pneumonia and deep vein thrombosis. Administering anaesthesia to this population poses multiple challenges to the anaesthesiologist because of presence of multiple factors-one of them being pain and thus is unsuitable for regional anaesthesia. Bone pain is derived from noxious stimulation of the periosteum or bone marrow. Adequate pain management is necessary to avoid severe psychological distress in patients [1].

Subarachnoid block is the preferred technique and correct positioning is a prerequisite [2]. There is inadequate evidences comparing the use of opioids (like nalbuphine) and FNB to recommend one technique over the other and as so far there is only one study by Durrani HD et al., they compared FNB using 15 mL lignocaine with adrenaline versus a fixed dose of 6 mg IVN [3]. They observed that VAS score during positioning was significantly less in FNB versus IVN time taken to perform spinal block was shorter and quality of patient positioning was also better in FNB as compared to IVN.Thus,the femoral nerve block was more effective than IVN and improved patient positioning for administration of spinal anaesthesia.

The present study aimed to evaluate the effectiveness of FNB using 0.2% ropivacaine versus IVN 0.1 mg/kg for positioning of patients with intertrochanteric fracture surgery under spinal anaesthesia. The primary objective was to assess the ease of patient positioning for spinal anaesthesia which was elicited by the degree of pain relief (VAS score) achieved during patient positioning, and by anaesthesiologist satisfaction score. The secondary objective was to assess the time taken in seconds for patient positioning prior to spinal anaesthesia and patient satisfaction score.

MATERIALS AND METHODS

The randomised clinical trial was conducted in the Department of Anaesthesiology at Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India. The duration of study was from September 2019-September 2021 (two years). The Institutional Ethics Committee (IEC) had approved the study (IEC No: KIIT/KIMS/IEC/131/2019), and it is also registered in the Clinical Trial Registry of India (CTRI/2019/10/021579). Written informed consent was obtained from every patient prior to study.

Inclusion criteria: Subjects of age 18-80 years of either gender, ASA I, II category, scheduled for intertrochanteric fracture surgeries under central neuraxial blockade were included.

Exclusion criteria: Subjects with any contraindications for central neuraxial blockade, femoral nerve blockade or use of opioids/local anaesthetics. ASA III and IV patients, history of polytrauma, infection over injection site and refusal for participation were excluded.

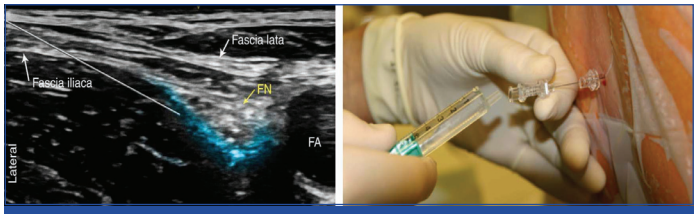
Sample size calculation: Sample size was calculated with reference to the study by Durrani HD et al., [3]. The quality of patient positioning score during spinal anaesthesia as depicted by mean±Standard Deviation (SD) was (2.45±0.55) in FNB group and (1.88±0.80) in the IVN group of patients. Assuming this reference values d=0.83, the

minimum required sample size at 5% level of significance and 80% power was atleast 32 in each group. Taking attrition at 10%, total 70 patients were included in present study i.e., 35 in each group.

Seventy subjects were randomised into two groups by means of computer generated random number table in a ratio of 1:1. Patient allocation was done using opaque sealed envelope technique.

Study Procedure

The IVN in a dose of 0.1 mg/kg was administered to one group of patients and the other group patients were administered ultrasound guided FNB. Nalbuphine 1 mg was diluted to 10 mL with distilled water and was administered in dose 0.1 mg/kg intravenously to the respective group of patients. Ultrasound guided FNB with 20 mL of 0.2% ropivacaine was given, using high frequency (5-12 MHz), linear (Sonosite Edge II ultrasound system FUJIFILM Medical system, USA) probe to visualise the femoral nerve immediately lateral to the femoral artery. USG probe was placed in the inguinal crease parallel to the inguinal ligament. Using the in plane technique of needle placement the stimuplex 10 cm needle was advanced parallel to the USG beam lateral to femoral artery pulsation until it reached the femoral nerve. Local anesthetic 20 mL 0.2% ropivacaine was deposited around the femoral nerve and its spread was visualised on the ultrasound screen. The anaesthesiologist who performed the subarachnoid block administered the femoral nerve block. [Table/Fig-1] and [Table/Fig-2] depict the ultrasonography, and procedural images. The study was not blinded. There were no complications like inadvertent vascular injury, or local anaesthetic toxicity or residual femoral nerve neuropathy while performing FNB.



[Table/Fig-1]: Femoral nerve block under USG guidance.
[Table/Fig-2]: Sitting position for spinal anaesthesia.

Either of the procedures was performed 15 minutes prior to positioning for spinal anaesthesia. Thereafter, under strict aseptic conditions, subarachnoid block was given at L3-L4 or L2-L3 level using midline approach in sitting posture with 0.5% hyperbaric bupivacaine 3 mL. The time taken to perform the subarachnoid block was within 2-3 minutes. Then, haemodynamic variables-Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial pressure (MAP), peripheral oxygen saturation (SpO_2) were monitored before procedure and at time intervals of 2 minutes, 5 minutes, 10 minutes, 15 minutes, 20 minutes after procedure.

The primary study outcome was to measure ease of patients positioning as assessed by pain relief using VAS score before procedure and during positioning for subarachnoid block, and by anaesthesiologist satisfaction score (0-4) (0-Not satisfactory; 1-satisfactory; 2-good; 3-optimal; 4-excellent) during patients positioning [3].

The secondary outcome was to assess:

a) Time duration (seconds) for positioning for the spinal anaesthesia.

b) Satisfaction of patient was also recorded as binary variable yes/no.

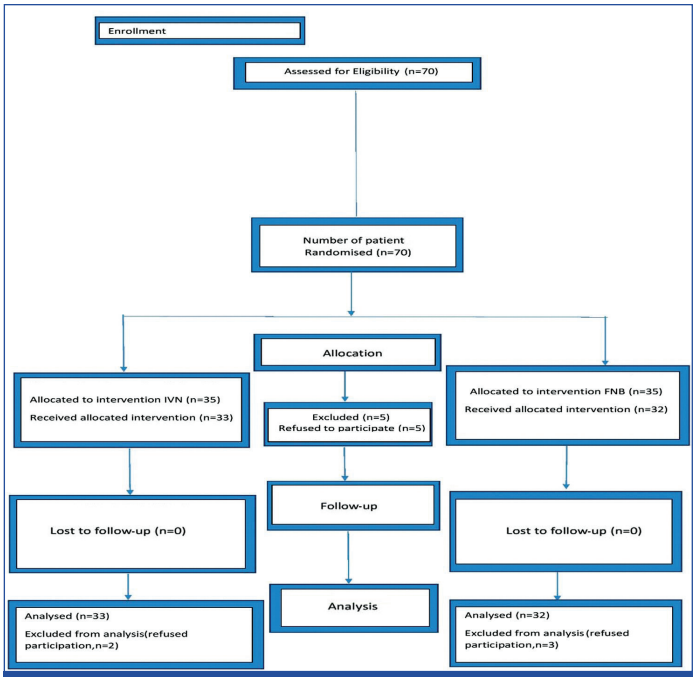
STATISTICAL ANALYSIS

Statistical analysis was done by using the International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) software version 23.0. Data for continuous variable was presented as mean±SD or Median Interquartile Range (IQR) and the categorical variables were presented as frequency and percentage. Independent t-test/Mann-Whitney U test was done to compare the continuous variables based on the distribution of data. Chi-square/Fisher's-Exact test was done to check the association between two categorical variables. The p-value <0.05 was considered as statistically significant. The data was checked for normality using Kolmogorov-Smirnov and Shapiro-Wilk test.

RESULTS

A total of 70 patients who satisfied inclusion criteria were assessed and randomised for study, 35 in each group. Two subjects in IVN Group and three in FNB Group refused participation and were excluded. The total number of participants who had received intervention was 33 in IVN group, and 32 in FNB group [Table/Fig-3].

The distribution of age and gender was similar across IVN and FNB groups (p>0.05) [Table/Fig-4].



[Table/Fig-3]: CONSORT diagram.

Variables	IVN	FNB	p-value
Age median (min-max) (years)	70 (40-80)	68 (25-85)	0.67
Sex			
Female	15	20	0.17
Male	18	12	

[Table/Fig-4]: Demographic data.
Mann-Whitney "U" test

VAS score was significantly less in FNB group of patients during positioning. The ease of patient positioning between both group as assessed by VAS during positioning was highly significant (p>0.001). The time taken for positioning of patients for spinal anaesthesia (in seconds) showed no statistical difference between both groups (p=0.69). Also, the time taken to perform spinal anaesthesia (in seconds) showed no statistically significant difference between both groups (p=0.25). Anaesthesiologist satisfaction in FNB group and IVN group was also comparable (p=0.11). Patient satisfaction between FNB group and IVN group is also similar between both groups (p=0.08) shown in [Table/Fig-5].

[Table/Fig-6] shows the comparison of vital parameters between the two groups. All these haemodynamic variables were not statistically significant between groups before procedure (p>0.05). During positioning (at 15 minutes) mean value of all these parameters was also similar between the two groups except MAP. MAP in IVN group during positioning was significantly higher as compared to FNB group (91.42±14.44 vs 81.74±17.08; p-value <0.05).

Variable		IVN	FNB	p-value (Independent t-test)
VAS before procedure (Mean±SD)		8.15±0.97	8.13±0.88	0.92
VAS during positioning (ease of patient poisoning) (Mean±SD)		5.09±1.23	3.87±0.99	<0.001
Time taken for positioning (Sec) (Mean±SD)		12.79±9.16	11.94±7.99	0.69
Time taken to perform spinal Anaesthesia (Sec) (Mean±SD)		122.06±44.89	146.52±110.68	0.25
Anaesthesiologist satisfaction score, n (%)	Satisfactory	4 (12.1)	2 (6.25)	0.11
	Good	9 (27.3)	7 (21.87)	
	Optimal	18 (54.5)	14 (43.76)	
	Excellent	2 (6.1)	9 (28.12)	
Patient satisfaction, n (%)	Yes	23 (69.7)	28 (87.5)	0.08
	No	10 (30.3)	4 (12.5)	

[Table/Fig-5]: Comparison of data between two groups.

Variable	IVN (Mean±SD)	FNB (Mean±SD)	p-value (Independent t-test)
HR before procedure	87.70±13.42	86.23±14.25	0.672
HR during positioning	85.52±13.66	83.10±11.99	0.456
MAP before procedure	97.76±9.95	97.26±11.30	0.852
MAP during positioning	91.42±14.44	81.74±17.08	**0.017**
SBP before procedure	139.42±14.13	131.84±25.74	0.146
SBP during positioning	125.39±24.29	118.23±17.25	0.181
DBP before procedure	83.36 ±11.93	80.35±11.23	0.304
DBP during positioning	78.15±13.07	72.61±14.4	0.112
SpO_2 before procedure	98.45±1.502	98.35±1.68	0.803
SpO_2 during positioning	95.39±15.43	97.81±1.88	0.391

[Table/Fig-6]: Comparison of vital parameters.

DISCUSSION

Spinal anaesthesia is the preferred technique for femur fracture surgeries, as it is more advantageous than general anaesthesia in providing early mobility, less chances of deep vein thrombosis and helps avoid respiratory complications associated with old age. For improving positioning for subarachnoid block, though opioids are common in use, they are not devoid of adverse effects like cognitive impairment, respiratory depression and vomiting, urinary retention especially in the elderly. Alternatively, peripheral nerve blocks like FNB, fascia iliaca compartment block are practiced for better pain relief and to improve patient positioning. They can be performed through techniques like landmark guided approach, use of peripheral nerve stimulator or ultrasound for identification of nerves. FNB when guided by ultrasound aids in getting the exact location of the nerve, hence, helps reducing the volume of local anaesthetic solution, hastens the onset and improves the quality of block compared to conventional peripheral nerve stimulator technique [4]. Some researchers found no statistically significant difference between both the groups with respect to age, similar to the present study [5,6]. FNB provides better analgesia for patient positioning in subarachnoid block. Utility of this FNB, administered 15 minutes prior to positioning of patients, is well-proved in terms of its analgesic efficacy. This is well supported by several other studies [3,5,7,8]. However, Iamaroon A et al., did not find any significant difference in the VAS scores or benefit of FNB over i.v. fentanyl [9]. They used 0.3% bupivacaine for FNB and positioned the patients 15 minutes after block. In the present study, 0.2% ropivacaine and IVN was used. The present authors chose to compare the concentration of local anaesthetic (0.2% ropivacaine) versus the mentioned dose of IVN (0.1 mg/kg b.w) as per Institutional practice and availability of drugs.

The most important finding in the present study was the ease of patient positioning as also assessed by the anaesthesiologists. It was better in the FNB group when compared to IVN group was comparable. These results however, do not corroborate with some studies, which revealed quality of patient positioning was better with peripheral nerve blocks. [7,10-13]. These authors used different concentration of local anaesthetics and shorter-acting opioids like fentanyl.

The optimal position achieved to perform subarachnoid block in both the groups was due to quick onset of action of drugs (ropivacaine and nalbuphine) which provided adequate analgesia after similar time interval. In this study, the authors chose the sitting position for subarachnoid block as this is an institutional practice and was easier to identify the landmarks. A similar study concluded that, fascia iliaca compartment block enables better hip flexion and helps to improve the ability for adequate sitting position during subarachnoid block [14].

The difference in patient satisfaction was also statistically insignificant between both the groups (p=0.08). These results are dissimilar to the studies by Singh AP et al., Purohit S et al., where better patient satisfaction score was achieved in FNB group [15,16]. The difference in results is due to use of different concentration of local anaesthetics and short acting opioids.

The time taken for positioning (in seconds) of patients between both the groups had no statistically significant difference (p=0.69) too. In addition, the difference in time taken to perform subarachnoid block (time from beginning of positioning to end of spinal) between both groups was statistically insignificant (p-value=0.25). This indicates that both techniques reduce the time taken for administering subarachnoid block equally. Durrani HD et al., also proved that though statistically significant, clinically, time to perform spinal in FNB group was not significantly shorter than IVN group [3]. Purohit S et al., suggested that FNB produced relaxation of the quadriceps muscle, provided better analgesia for positioning and a shorter time to perform spinal anaesthesia [16]. The difference in the present study results, related to the time taken for performance of subarachnoid block, might be due to delay between trauma and surgery which may have had an unpredictable effect on pain in these patients. Reasons for delay in surgery include waiting for preoperative test results, medical stabilisation and availability of the surgeon or operating room. Most of the studies were conducted on all types of femur fracture surgery and hip fracture, but the present study specifically considered intertrochanteric fractures.

With respect to haemodynamic parameters, the present study findings corroborate with the results of Yun MJ et al., [17]. However, the mean arterial pressure was found to be significantly lower after 15 minutes of study intervention in both the groups (p=0.017). Adequate pain relief measures provided well controlled haemodynamics.

Limitation(s)

The patients were not followed-up for postoperative pain relief. So, the total consumption of analgesics for pain relief was not assessed over 24 hours. Neither the patients nor the principal investigator, was blinded in the study which could have lead to observer bias. Also, the time interval between occurrence of trauma and execution of surgery was not uniform among the patients.

CONCLUSION(S)

In terms of pain relief prior to and after positioning of patients of intertrochanteric fractures for subarachnoid block, FNB is more effective than IVN. In terms of other parameters (like haemodynamics, patient satisfaction, time taken for positioning, time taken to perform subarachnoid block), both FNB and IVN are equally efficacious. This study, compared both the techniques and can help in formulating an approach to make patient positioning comfortable and pain

free during administration of central neuraxial block. Hence, it is recommended, that, either of the techniques can be adopted for providing better care of such patients in a tertiary healthcare centre, although FNB may have an edge over IVN.

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