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Efficacy of Ultrasound-guided 3-in-1 Femoral Nerve Block for Pain Management in Elderly Patients Presenting to the Emergency Department with hip Fractures: A Randomized Controlled Trial

Ramesh Babu Homanna Javali[1], Suraj GB[2], Akkamahadevi P[3], Madhu Srinivasarangan[4], Sriharsha J[5], Nisarg S[6], Adarsh SB[7]

[1]Associate Professor, [2]Resident, [3]Professor, [4,5]Assistant Professor, [6,7]Senior Resident, Department of Emergency Medicine, JSS Medical College and Hospital, JSSAHER, Mysuru, Karnataka 570004, India.

Abstract

Background: Hip fractures in elderly is a common occurrence around the world and is associated with increased morbidity and mortality. Adding to this burden is the inadvertent pain management occurring frequently in the Emergency Department due to the fear of adverse effects of the administered pharmacotherapy. Hence, newly developed, safer Ultrasound guided nerve block modality is the cornerstone in the management of pain in these special populations attending the Emergency Department. *Objectives:* To determine the efficacy of Ultrasound (US)-guided three-in-one femoral nerve block as compared to intravenous opioids alone for analgesia in the elderly patients presenting to the Emergency Department (ED) with hip fractures. *Methods:* This was a single centre, pragmatic randomised controlled open-label trial. Older adults (age>55 yrs) with radiologically confirmed hip fractures were randomized into either of the two treatment arms: US-guided three-in-one Femoral Nerve Block plus Intravenous Morphine (FNB group) vs Intravenous Morphine alone Standard Care (SC group). Pain relief was measured with a 11-point numerical rating scale (NRS). Secondary outcome measures included the amount of rescue analgesia received and occurrence of adverse events (respiratory depression, hypotension, nausea/vomiting). *Results:* Thirty patients in each arm completed the study. There was no significant difference between the two groups with respect to baseline characteristics. There was a significant decrease in pain intensity over time in FNB group ($p<0.001$). The primary outcome measure, SPID over 1 hour was significantly greater in the FNB group [292.0(225-330) vs 106.5(45-195), $p<0.001$]. With regard to second outcome measure, parenteral opioid use, FNB group received significantly less parenteral opioid than those in the SC group [0.8 mg vs 9.5 mg, $p<0.001$]. *Conclusion:* US-guided femoral nerve block as an adjunct to intravenous opioids resulted in: 1) Significantly reduced pain intensity; 2) Decreased amount of rescue analgesia received; 3) Significantly reduced adverse events due to opioids. Hence, our study supports the routine use of US-guided three-in-one femoral nerve block for pain management in hip fractures in the ED.

Keywords: Femoral Nerve Block; FNB group; Numerical rating scale (NRS); SC group; Opioids.

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Corresponding Author: Suraj GB, Resident, Department of Emergency Medicine, JSS Medical College and Hospital, JSSAHER, Mysuru, Karnataka 570004, India.

E-mail: suraj612@gmail.com

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Introduction

Hip fractures are very common, with an incidence of around 1.6 million cases/year worldwide [1]. This high incidence is expected to rapidly increase in the coming decades, driven by population aging [2,3]. It remains one of the most serious injuries that occur in older people [4-6] and is associated with mortality rate of 10% at one month, 20% at four months and 30% at one year [7]. Approximately half of patients who were previously functionally independent become partly dependent, while one third become totally dependent [8].

Hip-fracture patients are in severe pain upon arrival at the emergency department [9,10]. It is well known that control of pain in Emergency Department is often inadequate [11]. Persistent, unremitting pain may adversely affect the body's endocrine (overstimulation of hypothalamic-pituitary-adrenal-axis), cardiovascular (altered insulin and lipid metabolism – increased cardiovascular deaths), immune (adrenal exhaustion and decreased serum levels of glucocorticoids, including cortisol and pregnenolone), neurologic (anxiety, depression, delirium) and musculo-skeletal systems (muscle atrophy, neuropathies, contractures, arthropathies, myopathies and neuropathies) and require aggressive treatment of the pain as well as the resulting complications. Untreated pain is also associated with delirium [12,13]. And thus adequate treatment of pain is a primary goal and should be continued throughout until the patient is pain free [10].

A wide variety of options are available for the treatment of pain; NSAIDs for mild to moderate pain and opioids for severe pain. Despite having effective treatments available for both acute and chronic pain therapy, the treatment of pain can be difficult and is often one of the most challenging and frustrating aspects of the practice of emergency medicine [14-17]. Pain management for moderate pain is usually based on systemic opioids that have many side effects, [18] more commonly, nausea, vomiting and constipation and a few serious side effects like delirium, respiratory depression and death. These are more common particularly among frail, elderly populations [19].

Given the adverse effects of systemic opioids, regional anaesthesia has been advocated as an alternative and/or supplement to conventional treatment [20]. Femoral nerve blocks have been shown to be a safe, fast, and effective means of providing analgesia [21-26]. Use of ultrasound would be expected to improve the success rate of regional techniques and evidence does support this [27]. Anaesthesiology research also suggests that US-guided femoral nerve blocks may be superior to other nerve block techniques in regard to onset of action and amount of anaesthetic required [28,29].

Therefore we set out to determine if the patients who receive ultrasound-guided femoral nerve block have better pain relief when compared with the patients who received parenteral opioids alone. Secondary aim of this study was to determine if femoral nerve block reduces the total dose of parenteral opioids received. Lastly, we aimed to explore the incidence of adverse events.

Materials and Methods

Study Setting

This was a single centre pragmatic randomised controlled open-label trial, performed over a period of 18 months from October 2016 to March 2018 in a the Department of Emergency Medicine of a tertiary care, medical college hospital in South India with an annual ED attendance of 30,000.

Method of Collection of Data

Patient's data was captured on a pre-approved proforma which included demographic details, details of nature and mechanism of injuries, time and place of injury, on-scene-time, pre-hospital time, factors influencing the initial treatment.

We included all patients presenting to the emergency medicine department with age >55 years; radiologically confirmed fracture neck of femur or intertrochanteric fracture or both; pain numeric rating scale >/= 5; normal lower extremity neurovascular examinations and willing to participate in trial.

In patients shifted from other hospital for elective procedure and continued care; patients with altered pain perception – unconscious patients, patients with altered sensorium, severe head injury; known international normalized ratio > 3.0; prior femoral arteryvascular surgery on the same side as the fracture; patients with other significant trauma; hypoxia (pulse oximetry < 92%); hypotension (systolic blood pressure < 100 mm Hg); known hypersensitivity to local anaesthetics ormorphine were excluded from the study.

Study Design

After a valid consent, older adults with confirmed hip fractures satisfying both inclusion and exclusion criteria were randomized using an Internet based program into either of the two treatment arms:

1. Ultrasound guided three-in-one Femoral Nerve Block plus morphine (FNB group)

Or

2. Standard of Care (SC group) - Intravenous (IV) Morphine alone

The dose of the IV morphine was at the discretion of the treating physician with a target of 50% reduction in pain or per-patient request.

Procedure of Femoral Nerve Block

All the procedures were performed by 5 Emergency Physicians out of which 2 were in the consultant grade and the other 3 were ultrasonography-trained Emergency Medicine residents.

The participant was made to lie in a supine position on a standard ED trolley. The US used was Sonosite M-Turbo. The skin was painted with povidone iodine solution and draped. On the side of the affected hip, the US probe was be placed 1 cm distal to the inguinal ligament. The probe was adjusted to identify the femoral vessels and nerve in cross-section (Fig. 1). The nerve was identified as a hyperechoic structure approximately 1 cm lateral to the pulsatileartery. With a 27-gauge needle, a local skin wheal of 2% lignocaine is made 2 cm lateral to the US probe. An 18-gauge needle is used to deposit 2% lignocaine at the site of the skin wheal. At this puncture site, a 22-gauge Whitacre noncutting spinal needle is introduced at a 45-degree angle in plane to the US probe. The needle was visualized by US throughout the procedure to ensure that vascular puncture is avoided and 25 mL of 0.25% bupivacaine injected along the nerve sheath through this needle. The spread of local anaesthetic administered, is confirmed by an expanding hypoechoic area in the correct fascial plane. Immediately following the injection, manual pressure is held for 5 minutes 1 cm distal to the injection site.

Pain intensity (Numerical Rating Scale) and secondary outcome measures (Blood Pressure, Pulse Rate, Oxygen Saturation, Respiratory Rate, amount of rescue analgesia) was measured at time 0, 15 min, 30 min and 60 min post procedure/IV morphine.

Assessment of Pain Relief

We used patient reported pain scores to assess pain relief. Participants reported their pain using an 11-point numerical rating scale (NRS) which ranged from 0 (no pain) to 10 (worst pain imaginable). Baseline NRS scores were measured and repeat measurements were recorded at 15, 30 and 60 minutes post procedure. Summed Pain-Intensity Difference (SPID) over 1-hour study period was taken as the primary efficacy variable and was calculated using the Pain-Intensity Difference (PID).

Statistical Analysis

Data was entered into Microsoft excel data sheet and was analysed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA). Categorical data was represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as means, standard deviations, medians, ranges, and percentages as appropriate. Independent t test was used as test as significance to identify the mean difference between the two quantitative variables. MS excel and MS word were used to obtain various graphs.A p-value of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results

Eighty two patients were screened for the study. Twenty two were excluded; 12 suffered polytrauma due to RTAs; 5 had concurrent head injury with GCS<15; 3 did not give consent for the study; 2 haddistal neuro-vascular deficits. Sixty patients were included in the trial. Thirty patients in each arm completed the study (Fig. 2). The study population aged between 67 – 83 years with a mean age of 75 years. 70% (n=42) of the study population constituted of females. The most common mechanism of injury was accidental falls; 80% (n=48) as opposed to road traffic accidents; 20% (n=12). 76% (n=46) of the patients sustained inter-trochanteric fracture of which 11% (n=7) had comminuted fracture. The rest 24% (n=14) of the population sustained fracture neck of femur, of which 7% (n=4) had comminuted fractures of the neck. Only 12% (n=7) of the subjects had concurrent head injury but none with GCS less than 15. There was no significant difference between the treatment groups with respect to age, sex, mechanism of injury, vital signs (baseline and at 1 hour) and type of fracture. Baseline characteristics are represented

in Table 1. There was no significant difference in pre-intervention mean NRS scores between the two groups (p=0.855)(Table 2).

There was a significant decrease in pain intensityover time in the patients belonging to FNB group (p < 0.001). NRS (which represents the mean pain-intensity) and PID over 1 hour are displayed in Fig. 3 and 4. The primaryoutcome measure of our study, SPID over 1 hour was significantly greater in the FNB group (Table 2). All the individuals in

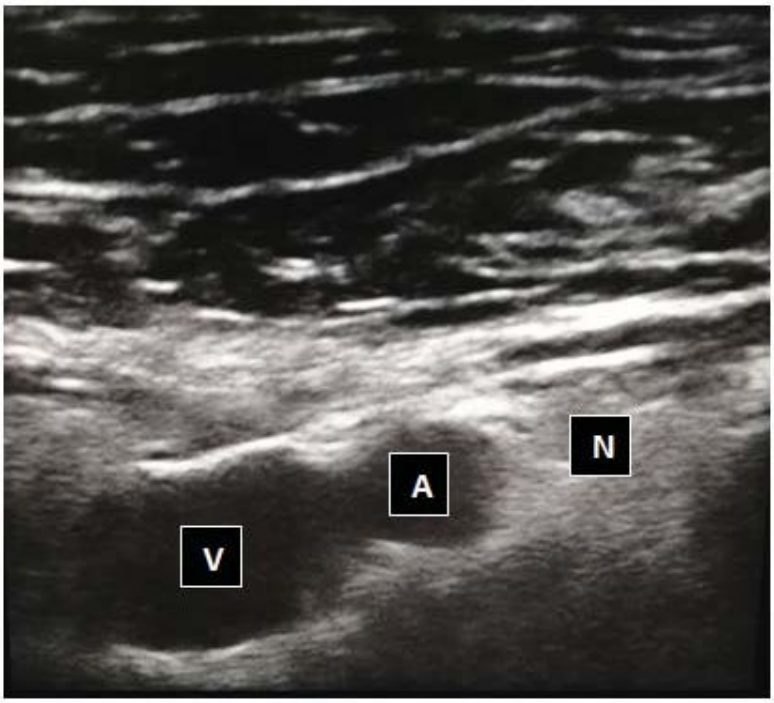

Fig. 1: Femoral Artery (A), Vein (V) and Nerve (N) as seen on ultrasonography

Table 1: Patient Characteristics and Vital Signs by Group Assignment

Characteristics	FNB group	SC group
Age (yr)	74 (55 – 88)	77 (55 - 90)
Female sex, n (%)	21 (70)	21 (70)
Femoral neck fracture,		
– Simple, n (%)	4 (13)	6 (20)
– Comminuted, n (%)	3 (10)	1 (3)
– Total, n (%)	7 (23)	7 (23)
Intertrochanteric fracture,		
– Simple, n (%)	19 (63)	20 (67)
– Comminuted, n (%)	4 (13)	3 (10)
– Total, n (%)	23 (77)	23 23 (77)
Mechanism of injury		
– Self-fall	24 (80)	25 (83)
– RTA	6 (20)	5 (17)
Vital signs		
Initial SBP (mm Hg)	153 (178 -134)	156 (180 - 126)
Initial HR (beats/min)	87 (72-114)	91 (72-112)
Initial RR(cycles/min)	17 (14-21)	17 (14-20)
Initial O_2 sat (%)	97 (91-100)	95 (93-99)
1 hour SBP (mm Hg)	142 (126-170)	147 (88-176)
1 hour HR (beats/min)	76 (62-103)	84 (63-104)
1 hour RR(cycles/min)	15 (13-19)	14 (6-19)
1 hour O_2 sat (%)	95 (81-100)	92 (78-99)

All data are represented as mean (range) unless otherwise specified.

FNB = Femoral nerve block; SC = Standard of Care; SBP = systolic blood pressure; HR = Heart rate; RR = Respiratory Rate; O_2 sat = Oxygen saturation.

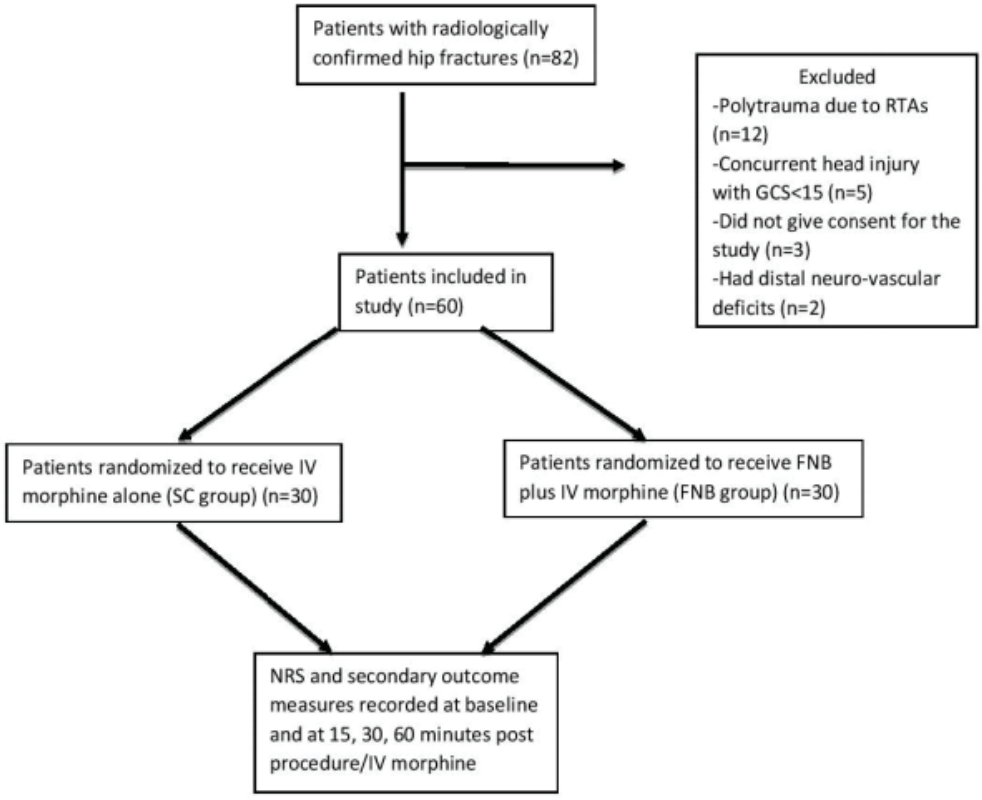

Fig. 2: Study flow diagram.

Table 2: Patient Outcomes by Group Assignment

Outcome	FNB group	SC group	P value
Pain scores (NRS)			
– Baseline	7.4 (6-9)	7.4 (6-9)	0.855
– 1 hour	2.0 (1-3)	4.9 (3-7)	<0.001
SPID	292.0 (225-330)	106.5 (45-195)	<0.001
>33% SPID, n (%)	30 (100)	3 (10)	<0.001
Parenteral analgesia			
– Pre-procedure morphine (mg)	3.0	3.0	
– Rescue morphine (mg)	0.8 (0-6)	9.5 (7-12)	<0.001
Adverse events			
– Hypotension, n (%)	0	4 (13)	0.038
– Respiratory depression, n (%)	6 (20)	10 (33)	0.243
– Nausea/vomiting, n (%)	6 (20)	9 (30)	0.371

All data are represented as mean (range) unless specified otherwise.

FNB = femoral nerve block; SC = Standard of Care; NRS = numeric rating scale; SPID = summed pain-intensity difference.

Hypotension defined as systolic BP < 100 mm Hg; Respiratory depression defined as hypoxia (room air O_2 sat < 92%) or hypopnea (Respiratory Rate < 10 breaths/min) at any time during study period

*Statistically significant ($p < 0.05$).

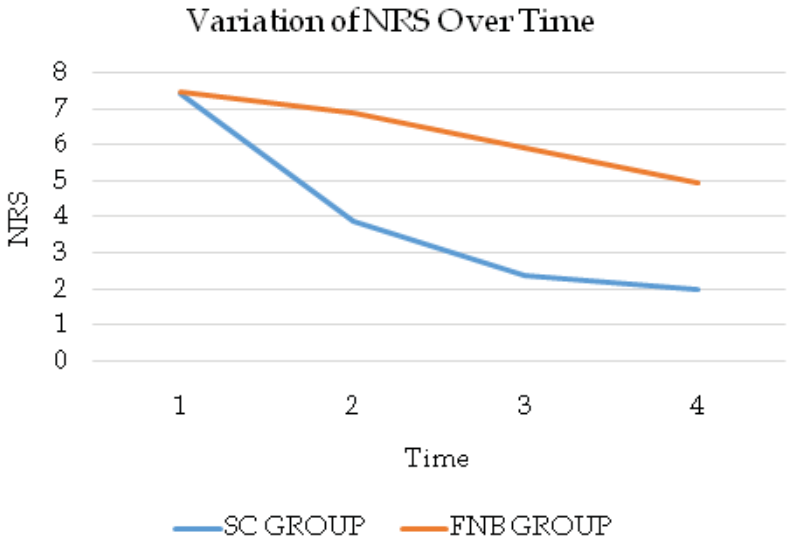

Fig. 3: Variation of Numeric Rating Scale (NRS) over time in FNB group and SC group

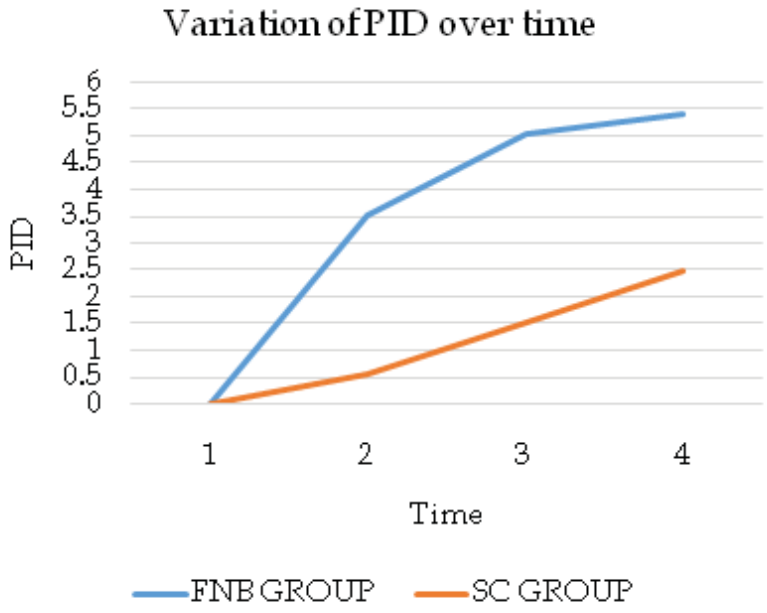

Fig. 4: Variation of Pain Intensity Difference (PID) over time in FNB group and SC group

the FNB group achieved at least 33% reduction in pain intensity over time; 93% (n=28) had at least 60% reduction. In the SC group, only 5% (n=3) individuals achieved a 33% reduction in pain.

With regard to our second outcome measure, parenteral opioid use, patients in the FNB group received significantly less parenteral opioid than those in the SC group (Table 2). Only 5 subjects in Femoral Nerve Block group received rescue analgesia over the study period as opposed to SC group, wherein all the subjects received additional doses of morphine. The range of rescue opioid doses ranged widely, between 7 to 12 mg in the SC group; 20% (n=6) of the participants received 7 mg, 50% (n= 15) received 9 mg and 30% (n=9) received 12mg of rescue dose of morphine. In the FNB group 10% (n=3) received 4 mg and 7% (n=2) received 6 mg of rescue dose of morphine.

However, in terms of occurrence of hypotension, the SC group had 13% (n=4) of participants who suffered hypotension at some stage of the study period which was statistically significant (p=0.038). With regard to occurrence of respiratory depression, and nausea/vomiting, there was no statistically significant difference between the two groups. No other adverse events occurred during the study period.

Discussion

Several studies have used only Visual Analogue Scale (VAS), Numeric Rating Scale (NRS) and Pain-Intensity Difference (PID) for measurement of pain relief [21,22,30,31]. But Summed Pain-Intensity Difference (SPID) is a widely used variable to determine treatment response to analgesics over a relevant period of time and is a better tool as compared to PID. Hence, SPID over 1-hour study period was taken as the primary efficacy variable. It was calculated using the Pain-Intensity Difference (PID) at each time point. The PID was calculated as the change from baseline NRS for each measurement in time. SPID is the summation of the PID at each of the study time points and weighted using the amount of time since the prior assessment.

The benefit of using SPID is that it takes into account individual differences in baseline pain intensity, as well as time. SPID can also be reported as a percentage of maximum possible SPID (% SPID). Maximum possible SPID is the value that would be achieved if the patient were pain free (NRS = 0) for the entire study period. We were interested in the number of patients who achieved a % SPID of 33% [30]. A PID of 33% has been previously established to represent clinically important measurement in pain outcomes [32].

In our study there was a significant decrease in pain intensity over time in terms of decrease in NRS and increase in PID in the patients belonging to the FNB group ($p < 0.001$). Our primary outcome measure, the Summed Pain Intensity Difference over 1 hour was significantly greater in the FNB group ($p < 0.001$). The result of our study correlates with several similar studies done in the ED [21, 22, 30, 32].

Also patients in the FNB group received significantly less parenteral opioids ($p < 0.001$) than those in the SC group. All the patients in the SC group received several additional doses of morphine as compared to only five patients in the FNB group. Several similar studies also concluded that the amount of rescue analgesia received was more in the Standard of Care group as opposed to femoral nerve block group [30-35].

Among a few observed patients, the amount of intravenous opioid administered to the patients awaiting surgery increased as time to surgery increased. It was beyond the scope of the present study to examine the delays caused. However, it shows that FNBs were becoming in effective, long before most of the patients were being transferred to surgery. A better option would be to use a FNB infusion. Studies have identified several benefits of FNB infusions, including: patients being able to 'roll' onto their lateral side; continued use postoperatively for analgesia, allowing comfortable hip flexion; and improved respiratory function, as well as likely elevated mood [36].

With regard to occurrence of respiratory depression, nausea and vomiting, there was no statistically significant difference between the two groups which correlates with several other studies comparing the same secondary outcomes between the femoral nerve block and the Standard of Care groups [37-41]. Hypotension occurred in the standard care group which was statistically significant as compared to the FNB group. This was probably due to the repeated doses of intravenous opioids administered with an intention to achieve at least 50% reduction in pain. However, our study did not have enough power to detect differences in the adverse events. Further work is needed in this regard to characterize whether or not the use of FNBs affects the incidence of adverse events.

Conclusion

Ultrasound-guided femoral nerve block as an adjunct to Standard of Care resulted in; 1) Significantly reduced pain intensity; 2) Decreased amount of rescue analgesia; 3) Significantly prevented the occurrence of hypotension when compared with SC group.

Hip fracture pain managed with intravenous opioids alone, proved to be inferior to femoral nerve block which as an adjunct to the standard care offered effective pain control in our study population,. Also, the femoral nerve block resulted in decreased quantity of the opioid received by the study group and hence had fewer chances of opioids related adverse effects. Hence, our data supports the routine use of femoral nerve block as an adjunct to morphine for pain management in the patients with hip fractures.

Future studies can examine additional outcomes with FNB like development of delirium, time taken for operative intervention, length of stay in the hospital. Subsequent studies can examine continuous (catheter based) femoral nerve block technique for a prolonged pain relief. There is also scope for studies on various other regional nerve blocks for injuries sustained by a patient with polytrauma.

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