

A Comparative Study on Acute Pain Management at Emergency Room in Traumatic Hip Fracture Patients Using Ultrasound Guided Fascia Iliaca Block Versus Standard Pain Relief Care- A Randomized Clinical Study

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ABSTRACT

On arrival pain relief helps the patient to get mobilized easily for the early radiological examinations and undergo bedside procedures. As the first stage of care and preoperative optimization of hip fracture patients, prompt deployment of multimodal analgesic protocols in the emergency departments is crucial. In this setting, initial interventional analgesic approaches have been shown to reduce procedural sedation and analgesia (PSA), opioid consumption, as well as the associated delirium and opioid- related side effects which is being routinely followed in many accident and trauma care centres. It has its own consequences, like compromised hemodynamic and airway. Such patients require close monitoring before and after the procedure for several hours, before being transferred or discharged from the emergency department (ED). Ultrasound-guided peripheral nerve block is an effective alternative that uses minimal quantities of local anaesthetic and requires minimal monitoring.

Keywords: Acute Pain Management, emergency department, procedural sedation and analgesia, Ultrasound-guided peripheral nerve block)

1. INTRODUCTION

On arrival pain relief helps the patient to get mobilized easily for the early radiological examinations and undergo bedside procedures. As the first stage of care and preoperative optimization of hip fracture patients, prompt deployment of multimodal analgesic protocols in the emergency departments is crucial. In this setting, initial interventional analgesic approaches have been shown to reduce procedural sedation and analgesia (PSA), opioid consumption, as well as the associated delirium and opioid- related side effects which is being routinely followed in many accident and trauma care centres. It has its own consequences, like compromised hemodynamic and airway. Such patients require close monitoring before and after the procedure for several hours, before being transferred or discharged from the emergency department (ED). Ultrasound-guided peripheral nerve block is an effective alternative that uses minimal quantities of local anaesthetic and requires minimal monitoring.

Ultrasound-guided nerve blocks have been frequently described in the anaesthesiology literature and have proven to be more effective than standard landmark approaches. Many studies have proven that ultrasound- guided nerve blocks are effective in providing acute pain relief in emergency departments. Pain management in the ED is a critical skill and one of the vital elements in the overall patient care

Aim of the Study

The aim of the study is to compare the analgesic efficacy of ultrasound guided fascia iliaca nerve block versus standard pain relief care in traumatic hip fracture patients at emergency room.

Objectives of the Study

Primary Objectives:

- To evaluate onset and efficacy of pain relief.
- To evaluate effectiveness of pain control for a period of 12 hours.

Secondary Objectives:

- To assess the hemodynamic variations.
- To assess the ease of examination and mobilization for radiological examinations.
- To assess the patient's psychological status and co-operation for the further treatment.
- To assess the need for rescue analysics.

Visual Analogue Scale (VAS) used for assessing pain

Methods:

A Prospective, Randomized, Single-blind, Controlled study conducted on sixty patients presenting with traumatic were randomly assigned into two groups computer generated grouping using sealed envelope technique.

- Group NB Ultrasound guided fascia iliaca block with 40 ml of inj.
- 0.25% Bupivacaine -weight based allowable dosage 3mg/kg.
 - Group SC standard care provided with IM NSAIDS (diclofenac) 1mg/kg and intravenous paracetamol 15MG/KG repeated 12th hourly.

Inclusion Criteria:

 patients of age years to 65yrs, ASA ps I, II, III who had traumatic hip fracture patients. national early warning score of 0-6 were included. patient who had refused to give consent and who are hemodynamically unstable were excludedI.

Sample Size Calculation

 $n = z^2 pq / e^2$

n = Sample size

Z = Z score (95% CI=1.96)

P = proportion of population, q = (1-p), e = precision

p= 2.04 (based on previous literature available where pain severity score after block was observed.)

On applying the above formula sample size n = 31 which is approximately 30 in each group.

2. METHODOLOGY

The aim of the study is to compare the analgesic efficacy of ultrasound guided fascia iliaca nerve block versus standard pain relief care in traumatic hip fracture patients at emergency room.

Sixty patients presenting with traumatic hip fractures were randomly assigned into two groups.

- Group NB- Ultrasound guided suprainguinal fascia iliaca block with 40ml of inj 0.25 % Bupivacaine -weight based allowable dosage 3mg/kg.
- Group SC- standard care provided with IM NSAIDS (diclofenac) 1mg/kg and intravenous paracetamol 15MG/KG repeated 12th hourly.

Monitoring:

Non-invasive blood pressure monitor, pulse oximeter, ECG, temperature probe is connected to the patient and the base line values are recorded.

On arrival pain intensity was assessed using Visual analogue scale. Vitals –Heart rate, blood pressure, Oxygen saturation, Respiratory rate, oxygen requirement and temperature were measured and plotted in NEWS-2 assessment chart. Patient with NEWS score aggregate of 0-6 were included in the study. Patients were randomized into two groups GROUP NB who received single shot ultrasound guided fascia iliaca with inj.0.25% bupivacaine not exceeding the weight based allowable dosage limits 3mg/kg and the second GROUP SC- standard pain relief care provided with IM NSAIDS diclofenac 1mg/kg + intravenous paracetamol 15mg/kg. procedure pain intensity was assessed using visual analogue score at time zero,15 mins,30 mins,45 mins,1 hour and every hour up to 12 hours. Hemodynamic parameters were measured and plotted in NEWS-2 chart and monitored at time zero,15 mins,30 mins,45 mins,1 hour and every hour up to 12 hours. The rescue analgesia was given with intravenous Fentanyl 2 mcg/kg, when the pain intensity on visual analogue scores raises above 8 and time of first rescue analgesia was noted.

The study outcomes were observed and entered in the Master Chart; statistical analysis was done from the results obtained. The observation and results were discussed in the following pages.

3. OBSERVATIONS AND RESULTS

Statistic Tools

Results were expressed as mean and standard deviation. All statistical analysis were done using SPSS for window version 21.0. For quantitative variants, independent t-test was used for comparison. Similarly for qualitative variants the chi-square test and Fisher's exact test was used for comparison. A p-value of less than 0.05 was considered statistically significant.

Results:

Both the group were similar with respect to demography (Table 1)

Table 1: demography

	Group-NB(n=30)	Group-SC(n=30)		
	Mean±SD	Mean±SD	P-value	
Age (in years)	47.10±14.56	47.93±12.74	1.127	
Gender	18(60%)	17(56.67%)	0.793	
Male	18(00%)	17(50.0770)		
Female	12(40%)	13(43.33%)		
ASA I	11(36.67)	13(43.3%)		
ASA II	11(36.67)	14(46.67%)	0.247	
ASA III	8(26.6)	3(20%)		
Weight (kg)	69.30±6.74	69.13±7.55	0.927	

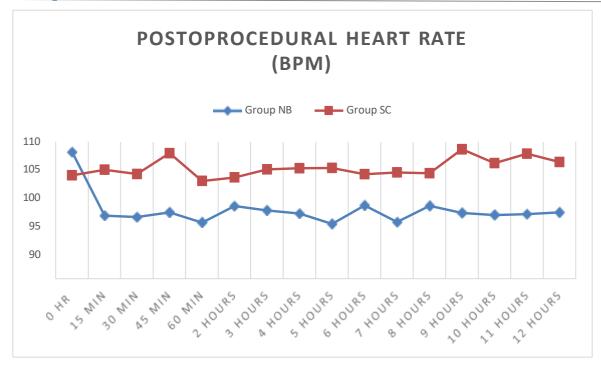


Fig.1.Postprocedural Heart Rate

The heart rate and Mean Arterial pressure between two groups(Fig1) were statistically significant from the time Zero. The mean Heart rates and MAP were significantly higher in the patients who received the standard pain relief care

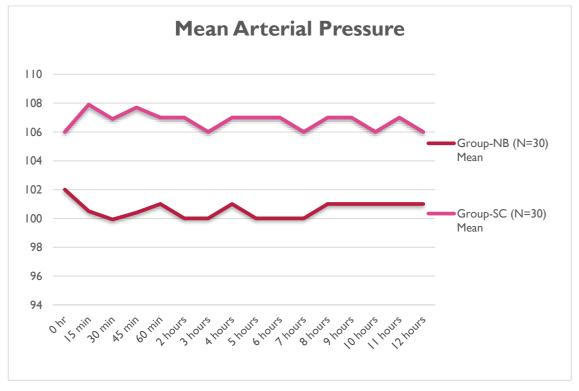


Fig.2. Mean Arterial pressure

The mean arterial blood pressures between two groups were statistically significant from the time Zero. The mean MAPs were significantly higher in the patients who received the standard pain relief care.

Table 2: Visual Analogue Scale

VAS	Group-NB (N=30)				P-value	
	Mean	SD	Mean	SD		
0 hr	9.67	0.76	9.6	0.81	0.7312	
15 min	6.8	2.0	9.1	1.0	<0.0001	
30 min	4.06	1.8	7.9	0.36	<0.0001	
45 min	2.8	2.07	6.46	0.86	<0.0001	
60 min	1.80	1.92	5.97	0.18	<0.0001	
2 hours	0.80	2.07	6.03	0.18	<0.0001	
3 hours	1	2.08	7.33	0.96	<0.0001	
4 hours	2	1.82	7.47	0.9	<0.0001	
5 hours	2.80	2.07	6.13	0.51	<0.0001	
6 hours	4.53	1.38	6.13	0.51	<0.0001	
7 hours	6.33	1.18	7	1.11	0.072	
8 hours	7.97	0.18	7.47	0.90	0.0042	
9 hours	6.33	0.73	7.97	0.18	<0.0001	
10 hours	6.53	1.38	8.03	0.18	<0.0001	
11 hours	7.1	1.5	8.1	0.4	0.0008	
12 hours	8.3	0.7	8.1	0.4	0.179	

The pain scores measured by visual analogue scale (Table 2) between two groups were statistically significant from the time Zero. The mean VAS scores were significantly lower in the patients who received the fascia iliaca block. Hence there is significant pain relief with Fascia Iliaca Block when compared standard pain relief care.

Table 3. patient characteristics

Ease of examination & Mobilization	Group-NB (N=30)		Group-SC (N=30)		P-value	
(VAS)		%	n	%	r varue	
Bad/Painful 9VAS>7)	4	13.3	30	100	<0.00001	
Good/Painless(VAS 4-6)	12	40	0	-		
Excellent/Painless (VAS <3)	14	46.7	0	-		
Mean time for First Rescue Analgesia (in hours)	6.83	2.68	3.33	0.48	<0.0001	
Psychological Status (Calm/Restless / Agitated) Calm	23	76.7	3	10	<0.00001	
Restless	3	10	21	70		

Ease of examination & Mobilization	Group-NB (N=30)		Group-SC (N=30)		P-value
(VAS)		%	n	%	i -varue
Agitated	4	13.3	6	20	
Feedback on pain relief (Bad / Good / Excellent) Excellent		16.7	0	0	<0.00001
Good	21	70	0	0	
Bad	4	13.3	30	100	
Block Success / Failure Success	26	86.6	30	100	<0.00001
Failure	4	70	-	0	

4. DISCUSSION

Delayed recovery is main consequence of inadequate pain relief in patients suffering from hip fractures. The current standard of care followed for patients in the ED suffering with acute hip fracture pain is intravenous opioids. Opiates often have severe neurological effects in the elderly because of the high prevalence of pre-existing cognitive deficits and vascular neurological disorders. Opiates cause severe constipation and nausea (vomiting, along with neurological deficit, may lead to lifethreatening aspiration pneumonia). In addition, opiates may have harmful and depressive cardiovascular and respiratory effects.

In order to reduce such problems, the standard of care in many parts of the world is to utilize parenteral nonsteroidal anti-inflammatory medications (NSAIDs) as the first-line drug in patients with hip fracture rather than narcotics. NSAIDs, on the other hand, predispose patients to

gastrointestinal bleeding, increasing anemia and increasing the amount of transfusions; this, in turn, can induce various types of renal damage and refractory hypertension.

In my study the age distribution in Group-NB was from 19 years to 65 years and in Group-SC was 17 years to 65 years. The mean age and distribution (47.10 ± 14.56 years in Group-NB; 47.93 ± 12.74 years in Group-SC) in both groups were similar and are **not statistically significant** with p-value >0.05.

Similarly, out of the 60 patients included in the study, 35 were males and 25 were females. Among the 30 patients in Group-NB, 60% were males and 40% were females, while in Group-SC, 56.67% were males and 43.33% were females. Their distribution was similar in both the groups and was **not statistically significant** with p-value >0.05. Out of the 60 patients, 24 were ASA PS-I, 25 were ASA PS-II and 11 were ASA PS-III. Among the 30 patients in Group-NB, 36.67% were PS-I, 36.37% were PS-II and 26.6% were PS-III, while in Group-SC, 43.3% were PS-I, 46.67% were PS-II and 10% were PS-III. Their distribution was similar in both the groups and was **not statistically significant** with p-value>0.05. This distribution was similar to the studies conducted by Monzon et al¹, Groot et al², Pasquier et al³

Weight Distribution

In our study it is observed that the mean weight and distribution (69.30 ± 6.74 kgs in Group-NB; 69.13 ± 7.55 kgs in Group-SC) in both groups were similar and are **not statistically significant** (p>0.05).

Preprocedural Pain Score Evaluated Using Visual Analouge Scale

In my study the patients pain score after arriving at the ED is measured using the visual analogue scale between two groups and it was **not statistically significant** and hence both groups were comparable. The p-value of pain score was 0.731 as per independent t-test. The studies conducted by Monzon et al¹, Reavley et al⁴, Haines et al⁵, Chen et al⁵ evaluated the patients pain after arriving at emergency room using the visual analogue scale which is similar to my study.

Postprocedural Pain Score Evaluated Using Visual Analouge Scale

In our study post procedural pain score was evaluated using visual analogue scale at time Zero (time of drug injection), 15 mins, 30 mins, 45 mins, 1 hour and hourly for 12 hours between two groups and analyzed using independent t-test and it is **statistically significant** with p value <

0.05. The mean VAS scores were significantly lower in the patients who received the fascia iliaca block. Hence there is

significant pain relief with Fascia Iliaca Block when compared standard pain relief care.

The studies conducted by Manzon et al¹, Reavley et al⁴, Haines et al⁵, Chen et al⁶ concludes that there is significant decrease in post procedural VAS scores following fascia iliaca block at all times analyzed periodically due to significant pain relief which is concordant to our study.

Hemodynamic Variations:

In our study hemodynamic parameters like blood pressure, heart rate and oxygen saturation and demand, respiratory rate and temperature was measured on arrival to the ED, time Zero (time of drug injection), 15 mins, 30 mins, 45 mins, 1 hour and hourly for 12 hours between two groups and recorded in NEWS-2 chart.

Pre-Procedure Hemodynamics:

The preprocedural hemodynamics recorded in National Early Warning Score-2 (NEWS-2 chart) over a period of 12 hours between two groups was **statistically not significant** and hence both groups were comparable in terms of their preprocedural hemodynamics with no specific clinical significance. The p-values of the HR, SBP, DBP, MAP AND SATURATION and were 0.06, 0.367, 0.182, 0.237, 0.843 respectively.

Post Procedural Heart Rate

In our study the heart rate observed and recorded over a period of 12 hours between two groups were **statistically significant** from the time Zero after the drug injection. The mean heart rates were significantly lower in the patients who received ultrasound guided fascia iliaca block compared to the patients who received the standard pain relief care with mean P-value

<0.05 as per independent t-test. The findings of our study is similar to the study conducted by Chen et al⁶.

Postprocedural Blood Pressure

In our study it is observed that the systolic blood pressure (SBP) and diastolic blood pressure (DBP), mean arterial pressure (MAP) measured over the time line of 12 hours between two groups were analyzed using independent t-test and it is **statistically significant** from time Zero.

The mean SBP, DBP and MAP were significantly lower in the patients who received Fascia iliaca block when compared to the standard pain relief care. The P-value is <0.05 as per independent t-test.

This finding of significantly lower mean SBP, DBP and MAP in the patients who received fascia iliaca block is in accordance with the study conducted by Chen et al⁶ and Monzon¹ et al.

Duration of Pain Relief

In my study the pain score was assessed using visual analogue scale and recorded over a period of 12 hours, it is observed that there is **statistically significant** difference in the total duration of analgesic effect. The mean duration of analgesia in Group-NB was 6.83 ± 2.68 hours, while it was 3.33 ± 0.48 mg in Group-SC. There is **significantly higher duration of effective analgesia in patients with ultrasound guided Fascia iliaca block when compared to standard care of pain relief.**

This finding of significant higher duration of effective analgesia provided by ultrasound guided fascia iliaca block is similar to the findings of the studies done by Elkhodair et al⁷, Foss et al⁸, Groot et al⁹, Haines et al⁴, Chen et al⁶.but Monzon et al¹ with the results of his study concluded that parenteral NSAIDs are very effective as analgesics after hip fractures in elderly patients and fascia-iliaca regional blocks are nearly as effective for up to about 8 hours after administration

Mean Time for First Rescue Analgesia

From the results of our study observed and recorded over a period of 12 hours, it is observed that there is **statistically significant** difference in the meantime for the requirement of first rescue analgesia (Intravenous Fentanyl). The mean time for rescue analgesia in Group-NB was 6.83 ± 2.68 hours, while the same was 3.33 ± 0.48 hours in Group-SC. The result of this study is in accordance with the studies conducted by Ridderikhof et al¹¹, Groot et al⁹, Wathen et al¹.

Ease of Examination & Mobilisation

In my study it is observed that the ease of examination and mobilization from time zero, post procedural pain relief in the emergency room was analyzed. There is **statistically significant** better ease of mobilization in patients who received Ultrasound guided fascia iliaca block than those who received the standard pain relief care. The result of this study is in concordance to the studies conducted by Wennberg et al¹², Steenberg et al¹⁴ and Pasquier et al¹³

Feedback on Pain Relief

Feedback given by the patients from time zero, post procedural pain relief in the emergency room was observed and analyzed. 70% and 16.7% gave good and excellent feedback on pain relief in Group NB, while 100% patients gave bad feedback in group SC, 13.3% in Group-NB gave bad feedback due to a failed block.

Block Success / Failure Rate

Of the 30 patients who were given the ultrasound guided Fascia iliaca block in my study, there were 4 failures. This when compared with the standard care for pain relief with Chi-square test with Yate's correction showed a p-value of 0.12, which is **not statistically significant.**

Post Procedure Complications:

There were no specific complications observed with a small number of samples in our study. There is a possibility of complications like respiratory and cardiovascular depression, nausea, vomiting, pruritis and chest wall rigidity with opioid usage. Hypersensitivity to the drugs used can also be a possibility.

The vitals of the patients every hour has been recorded in NEWS- 2 scoring chart and the aggregate score has been recorded and it could help to escalate the patient for more intensive monitoring and resuscitation whenever needed.

Local anaesthetic systemic toxicity is also an expected complication since facia iliaca is a fascial plane block, a large quantity of drug is being injected, however the usage of ultrasound reduces the undesired vascular injections.

Limitations of the Study:

In our study, we have given a single shot ultrasound guided fascia iliaca block and it provided adequate analgesia for a mean period of 6.83 ± 2.68 hours. It would be better if continuous facia iliaca catheter is placed, so that the analgesia can be prolonged from hours to days with a continuous infusion of local anaesthetic.

5. CONCLUSION

We conclude that ultrasound guided fascia iliaca block given to traumatic hip fracture patients suffering from acute pain at the emergency room provides faster onset, effective, superior and longer duration of analgesia, better hemodynamic stability when compared to the standard pain relief care.

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Dr. Thanigaivasan muralidhasan, Dr. Kannan. S, Dr. S. Bhuvana, Dr. Udhayanan

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