Original Research Article

Comparative Study of Analgesic Efficacy of Ultrasound Guided Femoral Nerve Block Versus Intravenous Fentanyl Injection in Fracture Femur Patients at Emergency Department

Abstract

Background: ~~Fentanyl belongs to phenylpiperidine family that is used to control acute pain and is 50-100 times more potent than morphine with fewer side effects also can be used as analgesia in fracture femur.~~ The aim of this work was to evaluate the analgesic efficacy of ultrasound guided femoral nerve block compared with intravenous (IV) fentanyl in fractures of the femur in patients presented to Emergency Department (ED).

Methods: This prospective, comparative, (blinded, randomized controlled clinical trial) was conducted on fifty patients with femur fracture. Patients were divided into two equal groups: group A underwent ultrasonography-guided femoral nerve block and group B given IV fentanyl 2 µg/kg). All patients underwent initial resuscitation. Intra-venous (IV) access with wide bore cannula and baseline investigation were obtained. Patients underwent X-ray imaging for diagnosis of femur fracture and FAST (Focused Assessment with Sonography for Trauma) scan on presentation at ED by ED trained physicians.

Results: There is significant difference in group B as regard to peripheral oxygen saturation (SpO_2)and Systolic blood pressure (P <0.001 and 0.013 respectively). VAS (median ± SD) was lesser in group A 4.16 ± 2.12 VS 4.96 ± 2.05 in group B. Pain intensity difference was significant decrease group A over time (P= 0.032). Requesting analgesia and rescue analgesia were insignificant different between two groups

Conclusions : Both femoral nerve block and IV fentanyl are effective in relieving pain in patients with femur fractures. but femoral nerve block provides better and intense analgesia,

and major pain intensity difference in less time. Moreover, use of FNB had fewer side effects and more ~~Hemodynamics~~ hemodynamicsstability as compared to opioids.

Keywords: Analgesia, Femoral nerve block, ~~Intravenous~~ fentanyl, Fracture femur, Emergency.

Introduction:

~~The femur is the longest, strongest, and heaviest tubular bone in the human body and one of the principal load bearing bones in the lower extremity [1].~~

Fracture femur is one of the most common orthopedic emergencies [2, 3]. These fractures are very painful and need immediate adequate analgesia [4, 5].

Generally displaced fractures are very painful and do not allow the patient to move. Fracture of femur is a particularly painful because its periosteum has lowest pain threshold of the deep somatic structure [6, 7]. Therefore, pain assessment should be performed on hospital admission and the appropriate level of analgesic therapy should begin as soon as possible [8, 9].

As pain management is increasingly being used in the Emergency Department (ED) for a variety of musculoskeletal presentations [10], Opioid analgesics are used as a first-line drug for acute pain relief [11].

~~Various analgesics such as NSAIDS also are commonly used to treat pain in those patients. Analgesics are associated with adverse effects like nausea, vomiting, drowsiness, dry mouth, miosis, orthostatic hypotension, urinary retention, and constipation.~~ Systemic opioids are associated with respiratory depression, cough suppression, rigidity, and pruritus [12].

An alternative to systemic analgesia is peripheral nerve blockade. Femoral nerve block has been used to provide analgesia in patients with hip and femur fractures in emergency department [6].

It can reduce pain and opioid requirement in the preoperative period. They are also used as adjuncts to spinal and general anesthesia and should always be considered when the latter is

administered [13].The use of ultrasound can improve the efficacy and safety of the femoral nerve block as it is available, accessible, and precisely visualize the femoral neuro-vascular anatomy [14].

~~Fentanyl belongs to phenylpiperidine family that is used to control acute pain and is 50-100 times more potent than morphine with fewer side effects also can be used as analgesia in fracture femur [15].~~

The aim of this work was to evaluate the analgesic efficacy of ultrasound guided femoral nerve block compared with intravenous fentanyl in fractures of the femur in patients presented to Emergency Department.

Patients and Methods:

This prospective, comparative, (blinded, randomized controlled clinical trial) was conducted on fifty adult patients with femur fracture diagnosed with an x-ray and with recent trauma.

Written Informed consent was obtained from all patients (from the relatives in case of patients with altered mental status). The study was approved by the Ethics Committee of the Faculty of Medicine, Tanta University, Egypt.

Exclusion criteria were pregnant patients, with poor Glasgow Coma Score (GCS) below 12 or with dementia, mental illness, and severe communication difficulties e.g., strokes, with groin infections or gross obesity, the presence of contraindications for regional nerve block, pain caused by comorbidities, and contraindications to surgery or anesthesia, or known hypersensitivity to local anesthetics or fentanyl, patient with bleeding tendencies and coagulopathy disorders. International normalized ratio > 3.0, hypoxia (pulse oximetry < 92%), hypotension (systolic blood pressure < 100 mm Hg), prior femoral artery vascular surgery on the same side of the fracture and Patients with critical conditions where enrolment was considered a hindrance to formal diagnostics or interventions.

Patients were divided into two equal groups: group A underwent ultrasonography-guided femoral nerve block and group B given intravenous fentanyl 2 micro-grams/kg.

All patients in this study underwent initial resuscitation on arrival to the resuscitation room where the monitors were attached to them and vital data in the form of heart rate and non-invasive blood pressure measurement were recorded and ~~o_2~~ O_2 saturation by pulse oximetry. Intra-venous (IV) access with wide bore cannula and baseline investigation of blood for complete blood count (CBC), renal function tests (RFTs), liver function tests (LFTs), and coagulation profile were obtained. Full medical and surgical history was obtained from patients and their relatives then thorough full clinical examination including extremities examination indicating femur fracture. Any suspicious history should be observed and reported. Hematoma and soft tissue swelling are often seen as indirect evidence around fracture sites. Patients underwent X-ray imaging as a gold standard test for diagnosis of femur fracture and **FAST** (Focused Assessment with Sonography for Trauma) scan on presentation at ED by ED trained physicians.

Assessment of patient's pain scores using Visual Analogue Scale (VAS) before intervention at rest as well as at movements was noted. Patients were randomized by the sealed envelope technique and allocated into two groups. Group A patients were subjected to ultrasonographic guided femoral nerve block.

Rescue analgesia: VAS score greater than 4 after 30 min, rescue analgesia done in the form of intravenous fentanyl 0.5 mic/kg was administered and re-assessed again for pain and vital data.

Group B patients received 2 microgram/kg intravenous fentanyl before reduction of the fractured femur then reduction done by senior orthopedic surgery resident..

Statistical Analysis:

Data were fed to the computer and analysed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 0.05% level. The used tests were: Chi-square test for categorical variables, to compare between different groups, Fisher's Exact or Monte Carlo correction for chi-square when more than 20% of the cells have expected count less than 5, Student t-test for normally distributed quantitative variables, to compare between two studied groups, Mann Whitney test for abnormally distributed quantitative variables, to compare between two studied groups and Friedman test for abnormally distributed quantitative variables, to compare between more than two periods or stages and Post Hoc Test (Dunn's) for pairwise comparisons.

Results:

Age, sex and general examinations were no statistically significant difference between both groups. Femur fracture was no significant difference between 2 group. Complications were no significant difference between 2 groups. Table 1~~Table 1~~

Table 1: Comparison between the two studied groups according to demographic data, general examinations, mode of trauma and complications

Demographic data	Group A (n = 25)	Group B (n = 25)	Test of sig.	p
Age (years)	30.20 ± 11.20	33.60 ± 10.72	t=1.097	0.278
Sex				
Male	18 (72%)	20 (80%)	χ^2= 0.439	0.508
Female	7 (28%)	5 (20%)		
Comorbidities				
No	14 (56%)	12 (48%)	χ^2= 5.687	^{MC}p= 0.787
HTN	1 (4%)	2 (8%)		
DM	3 (12%)	2 (8%)		
Cardiac	0 (0%)	1 (4%)		
Asthmatic/copd	1 (4%)	2 (8%)		
Malignancy	1 (4%)	0 (0%)		
DCL	3(12%)	1 (4%)		
CKD	0 (0%)	1 (4%)		
addiction	2 (8%)	4 (16%)		
Body weight (kg)	72.60 ± 13.81	75.60 ± 15.79	t=0.715	0.478
***BMI (kg/m^2)**	24.10 ± 5.04	23.46 ± 4.46		
Previous operation	6 (24%)	6 (24%)	χ^2=0.000	1.000

general examinations				
Pulse	105.68 ± 17.35	102.16 ± 19.08	t= 0.683	0.498
SPO2	96.32 ± 2.10	96.28 ± 2.01	t=0.069	0.945
Systolic Bl. Pr.	108.72 ± 17.34	108.72 ± 17.34	t = 0.000	1.000
Diastolic Bl. Pr.	68.20 ± 13.61	68.0 ± 12.58	t = 0.054	0.957
Respiratory rate	27.40 ± 3.75	27.24 ± 3.77	t = 0.150	0.881
Edema -at fractured side-	9 (36%)	9 (36%)	$\chi 2$= 0.000	1.000
Neuro-vascular limb supply				
Not intact	1 (4%)	0 (0%)	$\chi 2$= 2.751	MCp= 0.230
Intact	22 (88%)	25 (100%)		
Could not be assessed	2 (8%)	0 (0%)		
Hematoma				
Rt LL	10 (40%)	10 (40%)	$\chi 2$= 0.481	MCp= 1.000
Lt LL	13 (52%)	14 (56%)		
Rt and Lt LL	2 (8%)	1 (4%)		

Mode of trauma	**Group A (n = 25)**		**Group B (n = 25)**		$\chi 2$	^{MC}**p**
	No.	**%**	**No.**	**%**		
RTA	16	64.0	20	80.0	1.969	0.527
FFH	8	32.0	4	16.0		
Direct trauma	1	4.0	1	4.0		
Complications					χ^2	^{FE}**p**
Nil	25	100.0	22	88.0	3.191	0.235
Complication	0	0.0	3	12.0		

X^2: Chi square test, MC: Monte Carlo test, t: Student t-test, SD: Standard deviation, IQR: Inter Quartile Range, p: p value for comparing between the studied

There is significant difference in group A as regard to Pulse and Respiratory rate in pre ad post-intervention with P value <0.001. There is significant difference in group B as regard to SpO_2 and Systolic BP with P value <0.001 and 0.013, respectively. There was significant difference between group A and group B as regard SpO_2 post-intervention with P value 0.021. There is significant difference between group A and group B as regard respiratory rate with P value 0.003.Table 2~~Table 2~~

Table 2: Comparison between the two studied periods according to general examinations as a baseline values and post-intervention.

General examinations		Baseline	post-intervention	t	p
Pulse	**Group A (n = 25)**				
	Min. – Max.	66.0 – 140.0	70.0 – 113.0	5.920*	<0.001*
	Mean ± SD.	105.68 ± 17.35	94.0 ± 11.27		
	Median (IQR)	103.0 (96.0 – 118.0)	92.0 (87.0 – 103.0)		
	Group B (n = 25)				
	Min. – Max.	66.0 – 140.0	57.0 – 140.0	1.314	0.201
	Mean ± SD.	102.16 ± 19.08	100.88 ± 20.65		
	Median (IQR)	100.0 (90.0 – 110.0)	100.0 (88.5 – 113.5)		

SpO_2	**Group A (n = 25)**				
	Min. – Max.	92.0 – 99.0	97.0 – 99.0	1.809	0.083
	Mean ± SD.	96.32 ± 2.10	88.7 ± 26.49		
	Median (IQR)	96.0 (95.0 – 98.0)	96.0 (94.5 – 98.0)		
	Group B (n = 25)				
	Min. – Max.	92.0 – 99.0	86.0 – 98.0	4.381*	<0.001*
	Mean ± SD.	96.28 ± 2.01	94.76 ± 2.85		
	Median (IQR)	97.0 (95.0 – 98.0)	96.0 (94.0 – 96.5)		
Systolic	**Group A (n = 25)**				
	Min. – Max.	90.0 – 150.0	90.0 – 150.0	0.000	1.000
	Mean ± SD.	108.72 ± 17.34	108.72 ± 16.09		
	Median (IQR)	108.0 (95.0 – 120.0)	108.0 (97.5 – 120.0)		
	Group B (n = 25)				
	Min. – Max.	90.0 – 150.0	90.0 – 135.0	2.671*	0.013*
	Mean ± SD.	108.72 ± 17.34	104.52 ± 12.96		
	Median (IQR)	108.0 (95.0 – 120.0)	100.0 (92.5 – 112.5)		
Diastolic	**Group A (n = 25)**				
	Min. – Max.	50.0 – 100.0	50.0 – 90.0	1.095	0.284
	Mean ± SD.	68.20 ± 13.61	67.20 ± 12.08		
	Median (IQR)	70.0 (60.0 – 75.0)	70.0 (60.0 – 75.0)		
	Group B (n = 25)				
	Min. – Max.	50.0 – 100.0	50.0 – 100.0	0.000	1.000
	Mean ± SD.	68.0 ± 12.58	68.0 ± 12.58		
	Median (IQR)	65.0 (60.0 – 75.0)	65.0 (60.0 – 77.0)		
Respiratory rate	**Group A (n = 25)**				
	Min. – Max.	22.0 – 36.0	19.0 – 32.0	6.458*	<0.001*
	Mean ± SD.	27.40 ± 3.75	23.92 ± 3.73		
	Median (IQR)	26.0 (25.0 – 30.0)	23.0 (21.5 – 26.0)		
	Group B (n = 25)				
	Min. – Max.	22.0 – 36.0	22.0 – 36.0	0.000	1.000
	Mean ± SD.	27.24 ± 3.77	27.24 ± 3.77		
	Median (IQR)	26.0 (24.0 – 28.0)	26.0 (24.0 – 29.0)		

t: Paired t-test, p: p value for comparing between the studied periods, *: Statistically significant at $p \leq 0.05$

Movement of fractured limb between group A and group B at 10-minute post-intervention period shows P= 0.043 and hence the difference is significant. VAS was lesser in group A than group B. Table 3~~Table 3~~

Table 3:Comparison between the two studied groups according to VAS score and Patient satisfaction

VAS score	Group A (n = 25)	Group B (n = 25)	U	p
VAS score	**Median (IQR)**	**Median (IQR)**		
Pre score	9.0 (8.0 – 9.0)	9.0 (8.0 – 9.0)	285.0	0.577
After blocking	9.0 (8.0 – 9.0)		–	–
5 min	7.0 (6.0 – 9.0)	7.0 (6.0 – 8.0)	297.5	0.765
10 min	3.0 (3.0 – 4.0)	5.0 (4.0 – 5.0)	210.50*	0.043*
15 min	3.0 (3.0 – 4.0)	4.0 (3.0 – 5.0)	221.50	0.071
20 min	3.0 (3.0 – 4.0)	4.0 (3.0 – 5.0)	239.0	0.143
25 min	3.0 (3.0 – 4.0)	4.0 (3.0 – 5.0)	244.50	0.175
30 min	3.0 (3.0 – 4.0)	4.0 (3.0 – 5.0)	256.0	0.259

Patient satisfaction	N (%)	N (%)	χ^2	**p**
Satisfied with the result	24 (96.0 %)	20 (80.0%)	3.030	$^{FE}p=0.189$
Not satisfied	1 (4.0%)	5 (20.0%)		

Data are presented as Median (IQR). U: Mann Whitney test, SD: Standard deviation, IQR: Inter Quartile Range, p: p value for comparing between the studied groups, *: Statistically significant at $p \leq 0.05$, **Group A**: In

this group (twenty-five patients) ultrasonography guided femoral**,** nerve block was performed and re–assessed, **Group B**: In this group (twenty-five patients) with intravenous fentanyl 1–2 micrograms/kg will be administered slowly and re–assessed.

Pain intensity difference was significant decrease group A over time (P= 0.032). Figure 1~~Figure 1~~

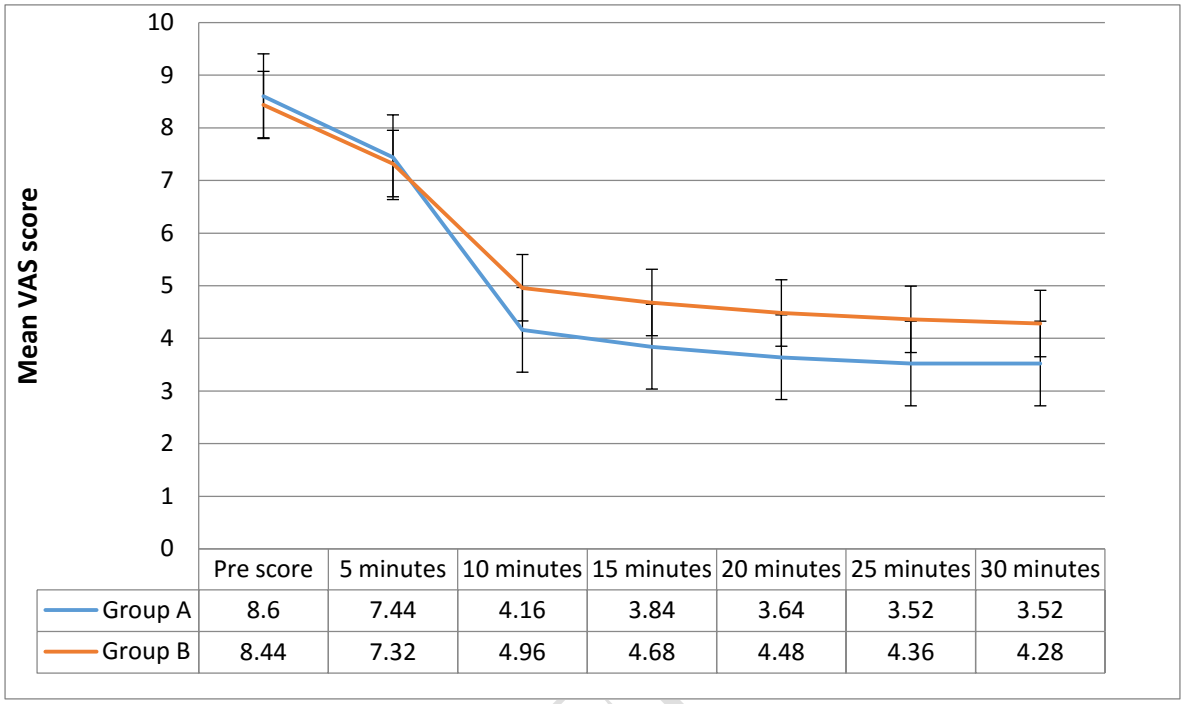

Figure 1: Change of PID over time in both groups

There was inverse relationship between PID and BMI in group A which represents a significant difference (P = 0.041). Requesting analgesia and rescue analgesia were insignificant different between two groups.Table 4~~Table 4~~

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Table 4:Comparison between the PID and BMI in group A and according to requesting analgesia and rescue analgesia.

	Major (n=17)		**Moderate (n=7)**	**Minimal (n=1)**	**F**	**p**
BMI					3.722	0.041*
Min. – Max.	17 - 29		20.5 - 34	34.5		
Mean ± SD.	22.8 ± 4.07		25.7 ± 5.63	34.5		
	Group A (n = 25)		**Group B (n = 25)**		χ^2	**p**
	No.	**%**	**No.**	**%**		
Requesting analgesia-rescue analgesia	4	16.0	8	32.0	1.754	p= 0.185

, *: Statistically significant at p ≤ 0.05, **Group A**: In this group (twenty-five patients) ultrasonography guided femoral**,** nerve block was performed and re–assessed, **Group B**: In this group (twenty-five patients) with intravenous fentanyl 1–2 micrograms/kg will be administered slowly and re–assessed, F = ANOVA

There is no significant relation founded between comorbidities and PID in both groups. Table 5~~Table 5~~

Table 5: Comparison between the PID and comorbidities in both groups

comorbidities	Major (n=27)	Moderate (n=17)	Minimal (n=2)	No difference (n=4)	χ^2	^{MC}p
No	13	13	0	0	38.682	0.104
	48.1%	76.5%	0.0%	0.0%		
HTN	2	1	0	0		
	7.4%	5.9%	0.0%	0.0%		
DM	5	0	0	0		
	18.5%	0.0%	0.0%	0.0%		
Cardiac	0	1	0	0		
	0.0%	5.9%	0.0%	0.0%		
Asthmatic/COPD	2	1	0	0		
	7.4%	5.9%	0.0%	0.0%		
Malignancy	1	0	0	0		
	3.7%	0.0%	0.0%	0.0%		
DCL	1	1	1	1		
	3.7%	5.9%	50.0%	25.0%		
CKD	1	0	0	0		
	3.7%	0.0%	0.0%	0.0%		
Addiction	2	0	1	3		
	7.4%	0.0%	50.0%	75.0%		

Discussion:

Femoral fractures are one of the most common types of fractures, especially in the elderly. Therefore, the fracture femur is a global problem. The incidence of hip fractures worldwide has been estimated to be 1.26 million in the 1990s and are predicted to increase to 2.6 million by 2025 and increase to 4.5 million by 2050 [16].

As a result, most of the patients with femoral fractures are in considerable pain, therefore, they should be given proper and adequate pain management before positioning, transforming and immobilization [17].Use of different regional blocks has been well described for acute pain management of femur fracture and has shown to decrease opioid requirements [18].

This study showed that there was significant difference between 2 groups as regard VAS score at 10 min and showed that there was significant difference as regard VAS score in each group between pre and each other period.

Vats [19] showed that visual analog scale during positioning (median ± SD) was lesser in group FNB: 1.72±0.783 versus FENT. 2.14± 0.92 (P = 0.022). Time required to perform any special maneuver (mean ± SD) was shorter in group FNB: 2.30 ± 0.61 min versus 3.29 ± 0.95 min (P = 0.000). Quality of patient positioning (mean rank) was higher in group FNB 59.62 versus FENT. 41.38 (P = 0.000). Similarly, **Reddy** [20] showed that the time for anesthesia was significantly lower in the FNB group as was the pain scores after 15 mins of analgesic. Even during the positioning of the hip, the pain scores were significantly lesser. Moreover, **Gosavi** [21] assessed pain during change of position from supine to sitting after FNB with lidocaine; VAS scores were 2.7 ± 1.1.13.

This study showed that there was no significant difference between 2 groups as regard patient pain and satisfaction. Similar results obtained in **Vats** [19] that showed that patient satisfaction was same in both groups. No patient required additional dose of fentanyl. Excessive sedation was seen in 2 patients in FENT group that was include 50 patients. However, **Reddy** [20] showed that a greater number of patients was satisfied after the FNB analgesic as compared to the satisfaction after IVF. Also, **Szucs** [22] showed that overall satisfaction recorded at the 72-hour time point was greater in group 2 (FNB).

This study showed that there was no significant difference between 2 groups as regard general examinations (Baseline-vital measures-). Similarly, **Beaudoin** [12] showed that there was no significant difference between treatment groups with respect to vital signs (baseline). **Ranjit** [9] showed that Systolic and diastolic blood pressures and heart rates, before positioning spinal anesthesia were comparable among the groups.

Patients who received fentanyl experienced fall in oxygen saturation, indicating that this might not be the choice of analgesia for elderly patients and those who already have any cardio-respiratory compromise. Similar to our result, **Ranjit** [9] showed that Systolic and diastolic blood pressures and heart rates, during positioning and 5 minutes after spinal anesthesia were comparable among the groups. SpO2 was significantly lower in IVF group during positioning (95 vs 97; p<0.001) and 5 minutes after (95 vs 98; p<0.001). However, none of the patents in either group had their oxygen saturation below 90%.

However, **Buddhi** [23] showed that difference in the heart rate at 5 minutes post intervention is insignificant and difference in the heart rate at 10 minutes post intervention is insignificant and difference in the heart rate at 15 minutes post intervention is significant and difference in the heart rate at 25 minutes post intervention is significant. Also, **Beaudoin** [12] Showed that there was no significant difference between treatment groups with respect to vital signs (at 4 hours).

Vats [19] showed that there was no significant change noticed in HR between two groups (P = 0.622); however, mean arterial pressure (MAP) was significantly lower in FENT group 5 min after the intervention (P = 0.0081).

This study showed that according to Rescue analgesia /timing, four patients in the FNB group received rescue analgesia, compared with 8 patients in the FENT group While majority of the patients did not receive rescue analgesia was in the first group. **Ranjit** [9] showed that to achieve a target VAS of 4 before positioning, three patients in each group needed rescue fentanyl.

Buddhi [23] showed that patients showed break through pain in fentanyl group and required additional analgesics whereas in femoral block no additional analgesic were required.

This Study showed that there was no significant difference between 2 groups as regard complications. Side effects like pruritus, nausea, vomiting, and excessive sedation were noted

in three patients in fentanyl group but none in femoral block group. No intervention needed for that. No systemic side effects like toxicity of bupivacaine and lignocaine, such as convulsions, arrhythmia or circulatory collapse was noted in the femoral nerve group. Neither neuro-vascular injury occurred nor complications, like hematoma, infection or persistent paresthesia were observed. Similarly, **Vats** [19] showed that Excessive sedation was seen in 2 patients in FENT group that was include 50 patients.

However, **Iamaroon** [24] showed that there are no complications were observed within 24 hours after the operation. Also, **Sia** [25] showed that there are no complications were observed during postoperative examination.

We agreed with **Buddhi** [23] that the only disadvantage noted in femoral nerve block group was the additional cost for needle, local anesthetic mixture and need of US machine.

This study was limited by the time from trauma to our intervention as it was long in both groups, and this would have influenced the results. Reasons for delay until intervention include waiting for test results, medical stabilization, and timely consultation. Future research should include time from trauma to intervention in the study design and patients should be randomized and stratified equally in each treatment group. Also, it was limited by the small sample size. So, we suggest that involvement of more population in samples will improve the quality of the evidence. Last, we did not examine outcomes beyond the ED, the affect adverse outcomes, morbidity, and mortality. This was beyond the scope of this initial study.

Conclusion:

Both femoral nerve block and intravenous fentanyl are effective in relieving pain in patients with femur fractures. but femoral nerve block provides better and intense analgesia, and major pain intensity difference in less time. Moreover, use of FNB had fewer side effects and more Hemodynamics stability compared to opioids.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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