Original Research Article

Comparison of Ultrasound Guided Femoral Nerve Block And Parenteral Tramadol In Acute Trauma Patients With Fracture Femur: An Observational Study

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Abstract

Aim: The aim of present study is to compare the analgesic effects of USG guided femoral nerve block (FNB) with parenteral tramadol in patients with fractured femur shaft. **Methodology**: This prospective randomized observational study was carried out in the Department of Anaesthesiology and Critical care, Dr. S.N. Medical College, Jodhpur and associated group of hospitals after getting approval from ethical committee. In our study total 60 patients were enrolled and divided randomly into two groups. One group received Femoral Nerve Block **(Group R-** 0.5% **ropivacaine**) and other group received intravenous tramadol (**group T**). A written and informed consent was taken from the patient after explaining the procedure to the patient. Patients were observed for onset and duration of analgesia, hemodynamic and respiratory parameters changes, side effects or complications of study drugs and block. **Results:** it was observed that FNB with ropivacaine provides earlier and prolonged duration of analgesia as compared to intravenous tramadol. The reduction in rescue analgesia might be due to prolonged and better analgesia provided by ropivacaine in R group. None of our patients in both the study groups experienced haemodynamic unstability. **Conclusion:** The USG guided Femoral nerve block with 0.5% ropivacaine is safe, simple and effective method for relieving intense pain due to femur shaft fracture. No systemic side effects were observed and haemodynamic stability was also well maintained in patients with moderate general condition.

Key word: Femoral nerve block, ropivacaine, tramadol, rescue analgesia

Introduction

Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in term of such damage"[1].

Fracture femur is excruciatingly painful and pain arises from the periosteum because the periosteal tissue is richly supplied by nerve fibers from femoral nerve and has lowest pain threshold among the deep somatic structures. If patient is in severe pain that causes spasm of the thigh muscles, leading to the displacement of the broken bone ends and so, add on to a vicious cycle of more pain and consequent spasm. This produce a state of neurogenic shock which might aggravate an already existing hypovolumic shock from occult blood loss into the thigh at the fracture site.

Regional anaesthesia is effective in alleviating pain due to trauma, and it has the advantage of producing localized but complete pain relief, while avoiding the side effects of systemic analgesics or anaesthetics. These methods can be carried out during prehospital care and in the preoperative setting[2]. Previous studies have been done to show the efficacy of fascia iliaca compartment block and femoral nerve block to alleviate pain of femur fractures. The femoral nerve block (FNB) is the very simple peripheral nerve block, shorter learning curve and contraindicated in only certain conditions such as known hypersensitivity to local anesthetic agents or the presence of a vascular or neurological problem in affected limb[3]. FNB can significantly decrease the acute pain of a diaphyseal or distal femoral fracture and fracture neck of femur.

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Profound analgesia is obtained without the adverse effects associated with systemic intravenous analgesics (i.e., respiratory depression, hemodynamic effects, or obtundation of consciousness). This block is also very successfully used to facilitate positioning for placement of neuraxial block in the operating room (OR)[4]. FNB increases comfort and also been shown to improve positioning for a spinal block in such patients[5]. FNB can be carried out with landmark guidance using nerve stimulator or ultrasound guidance[6,7].

In the emergency department, the use of a nerve stimulator for femoral nerve block would result in muscular contraction that would cause increased pain and would risk fracture displacement. Ultrasound guided FNB may be considered as a safe and effective alternative to electrical nerve stimulation. Despite having a definitive advantage of clearly locating the nerves and negating the side effects caused by the nerve stimulator, the clarity of the image obtained can be obscured due to the presence of edema and subcutaneous air leading to block failure[8].

Ultrasound guidance has been shown to decrease the dose of ropivacaine 0.5% required to block the femoral nerve by 42% as compared with the nerve stimulation guidance[9]. Ropivacaine has emerged as a safer anesthetic for local and regional anesthesia (RA) and has replaced previously used anaesthetic drugs[9].

Systemic analgesic options for fracture femur includes paracetamol, NSAIDs, weaker opioids such as tramadol and stonger opioids.

Safe and effective provision of pain management is one of an essential part and primary goal of initial emergency management of fractured femur in ED. There are limited data to establish the benefit of one form of anesthetic over the other. The objective of this prospective study was to compare the analgesic effects of FNB with intravenous (I.V.) tramadol in patients with fracture femur and to compare the rescue analgesic requirements in both groups.

Materials and methods

Source of data

This prospective randomized observational study was carried out in the Department of Anaesthesiology and Critical care, Dr. S.N. Medical College, Jodhpur and associated group of hospitals (Mathura Das Mathur Hospital and Mahatma Gandhi Hospital) after getting approval from ethical committee. In our study total 60 patients patients were enrolled and divided randomly into two group. A written and informed consent was taken from the patient after explaining the procedure to the patient.

Sample size calculation and statistical analysis

Sample size calculation was based on previous study **Arash Forouzan et al 2015[10]** with visual analogue scale (pain score). The mean score was 2.95±2.75 score FNB group as compared to 5.20±3.25 score in F+D group at α of 0.05 and power of the study (1− β2) at 80%, to detect a minimum of mean 2.25score difference between the two groups, the sample size was calculated to be approximately 30 in each group total 60 patients.

All statistical analysis was performed by using SPSS 22.0 software package (SPSS Inc., Chicago, IL, USA). Yates continuity correction test *(Chi square test), Fisher's exact test was used for comparison of qualitative data. All data was summarized as mean ± SD for continuous variables, numbers and percentages for categorical variables. A $p < 0.05$ was accepted as statistically significant.

Inclusion criteria

- Age group of 18 –60 years of both sex
- ASA grade I and II
- Femoral fracture patients, who were hemodynamically stabilized, didn't receive pain killers in last 6 h and their pain score was higher than five based on visual analogue scale.

Exclusion criteria

Patient's or relative's refusal

- Known hypersensitivity/ allergy to amide local anesthetics
- Opioid addicts
- Any chronic systemic illness
- Bleeding diasthesis
- Anatomical abnormality
- Any infection at the regional site
- Pregnant women
- Pre existing peripheral neuropathy or neurological deficits
- Taken analgesic already.
- Cardiac or respiratory instability.
- Head trauma and GCS<14.
- Ongoing cardiac attack, renal failure disease
- Mental disorders, communication failure
- Use of analgesics for premedication

Methodology

The complete procedure was thoroughly explained to the patients and informed consent taken from all of them. The patients were divided into 2 groups based on the random number table. The patients were allocated by computer-generated random numbers into two groups each contain 30 patients. One group received Femoral Nerve Block **(Group R**) and other group received intravenous tramadol (**group T**). Blood pressure, pulse rate and respiratory rate were recorded. A total of 60 patients were studied as they present in an emergency ward.

Group 1 (Group R) - 30 patients received an USG guided FNB with 15 ml of 0.5% ropivacaine.

Group II (Group T) - 30 patients received iv tramadol 2mg/kg dose + 20 ml normal saline over 10 minutes.

After 30 min, if severity of pain was equal to or more than 5 VAS then Inj PCM 10 mg /kg iv was given as rescue analgesia. If any degree of pain persisted after 60 min, another analgesic was used.

The onset and efficacy of block, duration of analgesia, and the occurrence of side effects and complications was recorded. The efficacy of the block was evaluated by assessment of sensory block by a pinprick method and comparing pre block and post block VAS. The degree of sensory block was graded as: 0 = Normal sensation, 1 = Blunted sensation (analgesia) and 2 = Absence of sensation (anesthesia). The VAS was recorded at 5, 10 min after FNB, at radiological examination and traction application. The supplemental analgesic was given when VAS reached 5 or more. Duration of analgesia was considered as the time from placement of the block till injection of rescue analgesic. The patient acceptance was noted by interviewing 24 h after the procedure by using three point score: (1 = Good, 2 = Fair, and 3 = Poor).

Results

Table 1: Post intervention VAS score changes in both groups

Time	VAS score in Group R [Ropivacaine]	VAS score in Group T [Tramodol]	P value
Pre intervention	9.56±0.56	9.76±0.50	0.154
Post intervention			
5 minutes	4.86±1.10	8.60±0.72	<0.0001
10 minutes	1.36±0.99	6.96±0.85	<0.0001
15 minutes	1.00±0.98	4.43±0.62	<0.0001
30 minutes	0.96±0.92	1.53±0.50	0.004
60 minutes	1.10±1.12	0.40±0.67	0.004
120 minutes	1.33±1.06	0.53±0.93	0.003
180 minutes	2.60±0.81	3.26±0.52	0.0004
240 minutes	3.06±0.90	5.26±0.63	<0.0001
300 minutes	2.86±0.77	5.66±0.57	<0.0001
360 minutes	3.10±0.99	----	NA

As shown in **table 1**, Pre intervention VAS score in R & T group was 9.56±0.56 & 9.76±0.50 respectively. VAS score at 5 min after the block was significantly decreased to 4.86±1.10 in group R and 8.60±0.72 in group T as compared to basal value.

On inter group comparison, basal VAS score was similar in both groups but after intervention decrease in VAS score was more in group R as compared to group T. The VAS score remained significantly at low level in group R as compared to group T till 360 min after the intervention & difference was statistically significance (P<0.05).

Table 2: Onset of analgesia (min)

Time (in min.)	Onset of analgesia in Group R [Ropivacaine]	Onset of analgesia in Group T [Tramodol]	Total
0 – 5	28	01	29
5 – 10	02	29	31
Mean±SD	**4.40±0.81**	**9.00±1.17**	**<0.0001**

Table 2 shows onset of analgesia in group R and group T which was 4.40±0.81 min and 9.00±1.17 min respectively. The onset of analgesia was earlier in group R as compared to group T and the difference was statistically significant (P<0.05).

Table 3: Duration of analgesia

Duration of analgesia (in minutes)	Group R [Ropivacaine]	Group T [Tramodol]	Total
200 – 300	02	30	32
301 -400	10	00	10
> 401	20	00	20
Mean±SD	**396.70±40.21**	**264.60±8.18**	**<0.0001**

As depicted in **table 3**, the duration of analgesia was significantly longer in group R (396.70±40.21min) than group T (264.60±8.18min) & difference was highly significant (P < 0.05).

Table 4: VAS Score at Procedure

	Group R	Group T
At the time of radiological examination	0.93±0.98	0.60±0.96
At the time of traction application	1.00±1.01	0.66±0.92

As shown in **table 4**, at the time of radiological examination, the mean VAS score in group R and group T was 0.93±0.98 and 0.60±0.96 respectively which was significantly lower as compared to pre intervention basal VAS score which was 9.56±0.56 and 9.76±0.50 in group R & T respectively.

At the time of traction application, the mean VAS score in group R and group T was 1.00±1.01 and 0.66±0.92 respectively which was significantly lower as compared to pre intervention VAS score.

Table 5: Number of Rescue Analgesia in 24 Hr

No of rescue analgesia in 24 hr	Group R		Group T	
	No of patients	Percentage %	No of patients	Percentage %
0	0	0	0	0
1	O	0	0	0
2	5	16.66	0	0
3	20	66.66	5	16.66
4	5	16.66	16	53.33
5	0	0	9	30
mean±SD	3.00±0.58		4.13±0.68	
P value	<0.05			

As shown in **table 5**, in R group out of 30 patients, 5 patients received two doses of rescue analgesic, 20 patients received 3 doses of rescue analgesic and 5 patients received 4 doses of rescue analgesic in 24 hr while in T group 5 patients received 3 doses of rescue analgesic, 16 patients received 4 doses of rescue analgesic and 5 patients received 5 doses of rescue analgesic in 24 hr after the intervention.

Mean doses of rescue analgesic in R group & T group was 3.00±0.58 & 4.13±0.68 respectively and difference was statistically significant (P<0.05).

Discussion

Relieving pain is one of the fundamental responsibilities of medical practitioners and is usually a primary goal of patients admitted in emergency department. The incidence of femoral, particularly diaphyseal, fractures due to severe trauma is more in young men. Patients younger than 40 are more likely to sustain high energy trauma (eg, motor vehicle crash) and fracture the mid-shaft of the femur, in comparison to those over 40 are more likely to sustain low energy trauma (eg, fall) and fracture the proximal third of the femur[11]. Diaphyseal fracture (femur shaft fracture) result from significant force transmitted from direct blow or from indirect force directed at knee .

Evaluation of trauma patients done according to “Advanced trauma life support (ATLS)” initiated and after that in emergency department stabilization of vitals is given priority specially managing or preventing hypotension and resuscitated with intravenous fluids.

As early definitive stabilization, within 24 hours, has been associated with decreased risk of thromboembolism, pulmonary complications, and shorter length of stay as compared to delayed fixation[12,13,14]. In our institute its usually done with in 6 hrs if not contraindicated.

An ideal analgesic technique should provide relief of pain without change of consciousness or personality. It should have localized effect, i.e. only at site where actual analgesia is required and should not produce systemic side effects like nausea, vomiting, hypotension and respiratory depression.

In this context, regional analgesia given by femoral nerve block may provide satisfactory analgesia for long duration and is an attractive option in fracture shaft femur for this purpose.

Regional analgesia is also advantageous because of minimal toxicity from local anaesthetics, less nausea, prolonged period of analgesia and reduced requirement of rescue analgesic drug. Effects of drugs are limited to the part of the body.

Block characteristics

Onset of analgesia

Our study had shown that onset of block was faster in group R than in group T, which was 4.40±0.81 min and 9.00±1.17 min respectively (**Table 2**). The difference was statistically significant (P<0.05). Our observations were consistent with the results of some previous studies.

Ronchi L et al (1989)[15] evaluated the blockade of femoral nerve with 0.5 % bupivacaine. After FNB onset of analgesia was 8.0±3.5 min. **Somvanshi et al (2015)**[16] evaluated the FNB with 0.5% ropivacaine for acute pain relief in patients with fracture shaft femur in ED. They found that the onset of analgesia occurred in 5.34±1.10 min after the block. **Hemant Kumar et al (2019)**[17] compared FNB with ropivacaine (R) and ropivacaine with dexmedetomidine (D) found that onset of analgesia with ropivacaine (R) was 4.6±1.1 min. **Grossbard GD et al (1979)**[18] evaluated FNB with 0.5% bupivacaine and found that onset of analgesia was 2.97 ± 0.95 minutes. **Haddad FS et al (1995)**[19] compared FNB with 0.25% bupivacaine systemic analgesia in extracapsular femoral neck fracture with found that the mean time of onset of analgesia in femoral nerve block was 3.9+1.15 minutes.

Minor difference among studies regarding onset of analgesia can be explained by variation in volume and concentration of drugs used. It is theorized that more than two consecutive nodes of ranvier of nerve must be in contact with local anaesthetic to block the conduction in that nerve and achievement of surgical analgesia after local anaesthetic solution has been injected depend upon the concentration gradient between the injection site and the nerve, the distance between the two and the rate of absorption from the injection site.

VAS score

As depicted in **table 1**, our results have shown that significant fall in VAS score occurred after 5mins in group R 4.86±1.10 and in group T

8.60±0.72. The VAS score at 15 minutes in group R 1.00±0.98 and in group T 4.43±0.62. VAS score at 30 minutes in group R 0.96±0.92 and in group T 1.53±0.50.

This shows that onset of analgesia starts after 5 minutes in case of femoral nerve block with ropivacaine while peak of analgesia was found after 15 minutes. With the use of intravenous tramadol, VAS score started decreasing after 15 minutes and peak action was after 30 minutes.

As shown in **table 4**, patients had good analgesia during radiological examination & traction application as evident by lower VAS score in both the groups. In group R VAS at radiological examination and at time of traction application 0.93±0.98, 1.00±1.01 and in group T 0.60±0.96, 0.66±0.92 respectively. This relief of pain allowed us comfortable transportation of patients and positioning of the patients during radiological examination.

Kullenberg B et al (2004)[20] studied that "three in one block" with 30 ml of ropivacaine in dose of 7.5 mg/ml and found that VAS of 6, which was reduced to VAS score 2 after the block. **Somvanshi et al (2015)**[16] studied FNB with 15 ml of 0.5% ropivacaine in fracture shaft femur and found that VAS score significantly decrease from 9.12±0.9 (preblock) to 1.84±1.25 (10 min after the block). **Reddy ED et al (2016)**[21] compared the FNB with IV fentanyl to relieve the pain during the positioning of the hip for the spinal anaesthesia before surgery. They found that the VAS score 15 min after analgesic in FNB group was 3.1±2.1 as compared to 3.9±1.9 in IVF group and during the positioning VAS score were 6.2±2.1 and 7.2±2.7 in FNB group and IVF group respectively. Patient satisfaction was 32 and 26 respectively in the FNB and IVF groups.

The above studies corroborate with the result of present study that there is a significant decrease in VAS scores in patient with fracture of femoral shaft and neck femur who received femoral nerve block.

Similar results of decreased VAS score after the femoral nerve block were also found by **Hemant Kumar et al (2019)**[17] **, Arvinder Pal Singh et al (2016)**[22]**, Arash Forouzan et al (2015)**[23]**, Damon Taherzadeh et al (2015)**[16], **Mutty CE et al (2007)**[24] & **Sia S et al (2004)**[25].

Duration of Analgesia

Duration of analgesia in group R & group T was 396.70±40.21 min and 264.60± 8.18 min respectively (**Table 3**). Duration was significantly longer in group R as compared to group T ($P < 0.001$).Results depicts that duration of analgesia was prolonged with ropivacaine in FNB as compared to intravenous tramadol. Our observations were consistent with the results of some previous studies.

Somvanshi et al (2015)[16] evaluated FNB with 0.5% ropivacaine 15 ml in fracture shaft femur. The duration of analgesia observed was 227±63.99 min. **Hemant Kumar et al (2019)**[17] compared FNB with ropivacaine (group R) and ropivacaine with dexmedetomidine (group D) found that duration of analgesia in group D & group R was 744.33±179.6 min and 263±67 min respectively .

Number of Rescue Analgesia

In 24 hr post block period consumption of rescue analgesic was significantly lower in R group than in group T. Mean consumption of rescue analgesic in R group & T group was 3.00±0.58 & 4.13±0.68 (**Table 5**) respectively and difference was statistically significant ($P<0.05$). The reduction in rescue analgesia might be due to prolonged and better analgesia provided by ropivacaine in R group.

Patient Acceptance and safety of USG guided FNB

In present study when patients interviewed after 24 hour of the procedure, in R group out of 30 patients, 22(73%) patients graded the femoral nerve block as good, and only 7(23%) patients graded it as fair, & none of patients found it poor while in T group out of 30 patients 14(46.66%) good, 15(50%) patients graded it as fair and only 1(3.33%) patients graded it poor. Similarly **Gjessing J. and Harley N. (1969)**[26]**, Berry F. R (1977)**[27]**, Mc Glone R et al (1987)**[28] & **Basant kumar et al (2016)**[29] also found 80-90% of the patient acceptability of the technique.

Quality of analgesia was much better in patients who had FNB with ropivacaine as evident by early onset and prolonged duration of effective analgesia along with less requirements of rescue analgesics. The femoral nerve block is safe, simple and effective method in relieving pain and muscle spasm caused by fracture bone. No systemic side effects were observed and haemodynamic stability was also well maintained in patients with moderate general condition. Similar results were found about safety of USG guided FNB by **Madhvi Buddhi et al (2018)**[30]**, Damon Taherzadeh et al (2015)**[16], **Beaudoin FL et al (2013)**[31]**, Steve C. Christos et al (2010)**[32], **Beaudoin et al (2010)**[33], **Casati et al (2007)**[34].

Conclusion

USG guided Femoral nerve block with 0.5% ropivacaine is safe, simple and effective method for relieving intense pain due to femur shaft fracture in emergency department as compared to standard analgesics used in current practice. Implementation of femoral nerve blocks into routine clinical practice could improve the quality of care provided to the patients experiencing pain in femur shaft fracture in emergency department.

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