Comparison of Fascia Iliaca Compartment Block with Intramuscular Diclofenac Sodium Acute Pain Relief in Emergency Room in patients with Fracture Femur

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ABSTRACT

Introduction: Fracture of femur occurs commonly in adult population following major trauma. The condition is not only severely painful unless immobilized, but also leads to massive hemorrhage and shock states if not treated early. This prospective randomized trial was undertaken to compare the efficacy of fascia illiaca compartment block in providing pain relief when compared to conventional method of pain relief by administering NSAID in emergency department settings.

Material and Methods: After institutional ERB approval, 60 cases that presented to emergency department with suspected fracture femur were randomized in two groups to receive fascia illiaca compartment block or intramuscular diclofenac sodium. The results were compared in terms of VAS score at rest and after 15 degrees hip flexion and the duration of analgesia post-procedurally.

Results: The VAS score were significantly lower and the duration of analgesia was significantly greater in patients managed with fascia illiaca block compared to intramuscular diclofenac injection.

Conclusion: The pain following fracture of femur can be managed more effectively using simple technique like fascia illiaca block with minimal discomfort and side-effects than diclofenac sodium.

Keywords: Fascia illiaca compartment block, diclofenac sodium, acute pain services, fracture femur

INTRODUCTION

Patients with fracture femur are in severe pain upon arrival at emergency department (ED). The pain is further aggravated during movement for orthopedic examination, radiological investigations and shifting to operation theatre or ward. Pain treatment in elderly patients with fracture femur is traditionally based on systemic opioids or more commonly non-steroidal anti-inflammatory drugs like intramuscular diclofenac.2 Use of opioids is associated with side-effects like hypotension and urinary retention especially in frail and elderly patients while the use of intramuscular diclofenac my lead to gastritis, gastrointestinal bleeding and inadequate analgesia.3 Nerve blocking techniques for providing analgesia in fracture femur cases include femoral nerve block, 3-in-1 block and epidural catheter placement. Disadvantages of neuraxial block are the potential for motor blockade that makes the ambulation difficult or impossible and sympathetic blockade that may lead to hypotension and cardiovascular instability.4

Peripheral nerve block involves the injection or infusion of a short or long-acting local anaesthetic (LA) along the peripheral sensory nerve, motor and sympathetic nervous plexus. Peripheral nerve blocks including femoral nerve block require elicitation of paresthesia or use of nerve stimulator making them technically demanding and expensive. 5,6

Fascia iliaca compartment block (FICB) is a safe, effective and easily learned procedure. It results in blockade or femoral nerve, obturator nerve and lateral cutaneous nerve of thigh with a single injection without eliciting paresthesia. The FICB is devoid of any major side effects. Only a single case of transient polyneuropathy following FICB has been reported till date.

However, there is paucity of FICB literature in context to Indian population. Therefore, the present prospective, randomized study was designed to evaluate the analgesic efficacy of single-shot FICB for acute pain management and to compare it with intramuscular diclofenac sodium in adults with fracture femur in the emergency department.

MATERIAL AND METHODS

After obtaining approval from institutional ethics committee and written informed consent, 60 patients of either sex belonging to ASA physical status I/II, aged between 50-70 years with suspected fracture femur were included in this study just after their arrival in the emergency department. Patients with history of chronic opioids or NSAID treatment or within the last 6 hours, any substance abuse, body mass > 35, infection or open wound at injection site, psychoneurotic disease or neurologic deficit, haemodynamic instability, associated head injury, allergies to local anaesthetics, Glasgow coma score < 15, blood coagulopathy or on anti-coagulant medication were excluded from the study.

Patients were randomly assigned to one of the two groups of thirty each using a computer generated randomization chart. Group F patients (n=30) received FICB with 0.5% bupivacaine (0.4ml/kg ideal body weight diluted with 0.9% saline to make a total amount 40 ml) and Group D patients received 75 mg diclofenac sodium intramuscularly. The diagnosis of fracture femur was based on trauma mechanism, thigh pain and deformity. Patient's height was measured in centimeters

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How to cite this article: Jagdish Dureja, Gunjan Chaudhry, Surya, Sangeeta Dureja. Comparison of fascia iliaca compartment block with intramuscular diclofenac sodium acute pain relief in emergency room in patients with fracture femur. International Journal of Contemporary Medical Research 2016;3(4):1119-1122.

and ideal body weight was calculated as under:

Males Weight = Length (cm) - 100Females Weight = Length (cm) - 105

After proper disinfection, a skin wheal was raised with 23G needle by infiltrating 1 ml 2% lignocaine. The puncture site was marked 1 cm caudal to junction of lateral one-third with medical two-thirds of the inguinal ligament (Fig. 1).

The plexus block needle was inserted and advanced at a 90 degree angle to the skin. The first loss of resistance was felt as the needle's tip crossed the fascia lata. The needle was advanced further at the same angle until the second loss of resistance was felt as the fascia iliaca was pierced. The angle to the skin was then decreased to 30 degrees and the needle was advanced 1 cm cephalad (Fig. 2).

The drug was injected after negative aspiration of blood to rule out intravascular needle placement, over one minute period and firm pressure was applied manually, just distal to the puncture site. If there was swelling in the groin after injection, the region was massaged. Both of these manipulations were performed to encourage cephalad distribution of the injected solution.

The procedure time was the time taken from point of disinfection to the withdrawal of needle after drug administration. The intensity of pain was measured on a 10 cm Visual Analogue Scale (VAS) in which 0 represented no pain and 10 represented the worst possible pain. VAS was recorded just before the block then at 10 minutes intervals till 30 minutes and 1 hour after the procedure at rest. VAS was also recorded with passive hip flexion of approximately 15 degree at 30, 60 minute after the procedure as well as before the procedure. Sensory block was evaluated using cold perception loss in the lateral, medical and internal part of the thigh at 0, 10, 20 and 30 minute after the intervention in group F. Similarly, in this Group, response to pin prick was noted in the lateral, medical and internal part of the thigh. A complete block was defined as block in all the three parts of the thigh (lateral, medical, internal), a partial block was defined as a block in one or two parts, and a block failure was defined as no sensory block in any part of the thigh. In case of block failure, rescue analgesia was provided with intramuscular morphine 0.1 gm/kg body weight and the patient was excluded for further comparison. Thirty minutes after performing the block, the patients were taken to radiology department for X-ray confirmation of the fracture.

Any adverse effects, if any like nausea, vomiting, toxicity to local anaesthetic, haematoma formation, etc. was noted. Systolic blood pressure less than 90 mmHg or more than 20 % decrease as compared to baseline value was considered as significant hypotension, while heart rate below 50 beats per minute or more than 20% decrease as compared to baseline was taken as bradycardia and managed accordingly. Total duration of analgesia was taken as the time from the loss of cold perception to the demand for more analgesia by the patient in FICB group. In group D, it was the time from injection to the demand for more analgesia after a relatively pain free interval.

Demographic data and VAS was expressed as median and 25th to 75th percentile (interquartile range, IQR). Test for significant differences between groups was done with

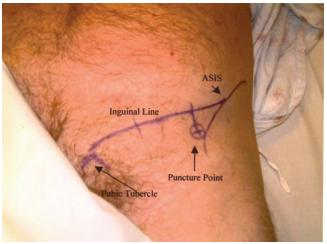


Figure-1: Surface Landmarks for FICB



Figure-2: Needle insertion technique for FICB (pen holding fashion)

Mann-Whitney U test. The comparisons of efficacy according to sensory spread were done with Wilcoxon test. A value of P<0.05 was considered statistically significant. All data analysis was conducted with SPSS for Windows version 16.1 (SPSS Inc., Chicago, II).

RESULTS

1/3.

A sixty patients of either sex between 50-70 years of age having ASA physical status of grade I and II were evaluated in this prospective randomized trial with suspected fracture femur. Group F (n=30) received Fascia iliaca compartment block with 0.5% bupivacaine (0.4 ml kg⁻¹ dead body weight diluted with 0.9% saline to make a total amount 40 ml). Group D (n=30) received 75mg intramuscular diclofenac sodium in the gluteal region.

Both the groups were statistically comparable regarding age, height, weight and sex distribution. (P> 0.05). (Table-1) All the patients had a femoral fracture which was confirmed on radiological investigation. Out of total 30 patients in group F, 22 patients (73.3%) had fracture in upper third, 5 patients (17.7%) middle third and in the remaining 3patients (10%) lower third of femur was fractured. (Fig. 1) out of group D 28 patients had # upper 1/3 and 2 patient had # middle

Demographic Data	Group F (n=30)	Group D (n=30)	P-value	
Mean Age (Range) (in years)	61 (57-67.25)	61.5 (54.75-68)	0.70	
Gender (M/F)	18/12	17/13	0.56	
Mean Weight (Range) (in Kg)	64.5 (53-75)	61 (56-70)	0.92	
Mean Height (Range) (cm)	164.5 (157-175)	163 (158-170)	0.52	
ASA Grading I/II	17/13	12/18	0.62	
Values have been mentioned as median (interquartile range)				
Table-1: Demographic Distribution				

Group	Before	10 min+	20 min+	30 min+	60 min+
F	8	7	3	2	1
D	7.5	7	5	3	3
P-value	0.710	0.837	0.001	0.000	0.000

All values are median values of VAS score in the respective group.

Table 2: The Comparison of VAS score before and after the intervention in between the two groups at rest

Group	Before	30 min+	60 min +	
F	9	2	1	
D	9	6	6	
P-value	0.871	0.000	0.000	

All values are median values of VAS score in the respective group.

Table-3: The comparison of VAS scores before and after 15° passive hip flexion in between the two groups

	Group F	Group D	P value	
Time (in hours)	9 (8-10.2)	5.5 (4.8-7)	< 0.01	
Table-4: Duration of Analgesia				

Quality of block

Complete block was registered in 25 of total 30 (83.3%) patients in group F, partial in four cases and failed in one case. The medical part of thigh corresponding to femoral nerve sensory distribution was blocked in 80% cases at 10 minute and in 96.7% cases at 30 minute after FICB. The lateral part of thigh was blocked in 70% cases after 10 minutes and in 83% of the case after 30 minutes. The internal part of thigh which is supplied by obturator nerve was blocked in 56.7% cases at 10 minute and in 80% of the cases after thirty minutes. There was no change in sensory blockade between 30 minute and 60 minutes after performing FICB suggesting that peak sensory blockade was achieved at or before 30 minutes after the block. However, the pain scores improved further in FICB group after 60 minutes when compared to that after 30 minutes. There was no difference in pain relief when compared to different location of femoral fracture i.e. upper, middle of lower third of femur.

The VAS scores before the procedure at rest (median values) were statistically comparable in both the group i.e. 8 (7-8) in FICB and 7.5 (7-8) in diclofenac group (p=0.756). After 10 minutes of intervention, the median VAS score was same in both the groups i.e. 7 (p=0466). After 20 minutes, in group F, median VAS score was 3 (2-3) and 5 (5-6.2) in diclofenac group. There was a statistically significant difference when these groups were compared (P=0.01). After 30 minutes the VAS score was 2 (1-2) in group F and 3 (1.8-3.6) in group D

with P-value <0.01. After 60 minutes, median VAS score for group F was 1 (1-1.3) and 3 (2-3) for group D with P<0.01. (Table 2).

Pain assessed by VAS score with passive hip flexion before the procedure was same in both the groups i.e. (8-9). After 30 minutes, it was 2 (2-3) in group F and 6 (5-7) in group D. The difference was a statistically significant when these groups were compared (P < 0.01) (Table 3).

All values are median values of VAS score in the respective group.

The duration of analgesia was significantly longer in group F than diclofenac group when both the groups were statistically compared P < 0.01 (Table 4).

The median time of completion of FICB technique was 4 minutes (3m 55s- 4m 25s) with minimum of 3minutes and 30 seconds and a maximum of 5 minutes 15 seconds. No side-effects (hypotension, bradycardia, signs or symptoms of local anaesthetic toxicity, vascular punctures and paresthesia) were observed in FICB group. However, in diclofenac group two patients reported abdominal pain while another two had an episode of vomiting within an hour of intramuscular injection (table 5).

DISCUSSION

Bone fractures are very painful and inadequate pain relief causes deleterious effects on all body systems by increasing blood levels of stress hormones. Adequate pain relief is also important in modifying the physiological stress response. Provision of effective analgesia is important not only for humanitarian reasons but also because pain may have negative impact on recovery.

Adequate pain relief benefits the patient not only by reducing metabolic and endocrine stress response, but also by decreasing incidence of pulmonary, cardiovascular and thrombo-embolic complications. Unmanaged pain, both acute and chronic, can affect mental status and might precipitate delirium, especially in elderly patients with hip fractures.^{8,9}

The present study had a success rate of (83.3%) for FICB. Review of literature revealed a range of successful blocks from 67-96%. 7,14,16 Hence, the percentage of successful blocks in the present study was comparable to literature. Study done by Reavley *et al*¹⁰ and Walace *et al*¹¹ compared the efficacy of iliaca block with 3-in-1 block and found that FIB was superior in terms of duration of post-operative analgesia and reductions in analgesic consumption. Complete block was registered in 25 of total 30 (83.3%) patients in FICB group, it was partial in four cases and there was no effect in one case. Complete block primarily depends upon whether the obturator nerve is blocked-which may be difficult to obtain and unpredictable. The difficulty is that, although injected anaes-

Group	Hypotension	Bradycardia	Perioral numb-	Nausea, vom-	Paresthesia, vas-	Abdominal pain
			ness, convulsion	iting	cular puncture	
F	Nil	Nil	Nil	Nil	Nil	Nil
D	Nil	Nil	Nil	2	Nil	2
Table-5: Side effects in both the groups						

thetic entering the iliac fascia blocks the femoral and LFC nerves, sufficient anesthetic do not always migrate proximally to block the obturator nerve, which lies on the internal edge of the psoas muscle in a separate plane. 12-14 However, this success rate can be further improved with use of ultrasound guided FICB and modified FICB. In FICB, sensory block of inner part of thigh is an early predictor of optimal pain relief for femur fractures. In patients with a proximal femur fracture, hip flexion is usually limited to 15 degrees. However after a successful FICB, hip flexion can increase up to 53 degrees due to analgesia and relaxation of the quadriceps muscle. 15 We analyzed the VAS scores prior and later to hip flexion in both the groups to evaluate the efficacy of both the interventions, but did not evaluated the increase in hip flexion as an end-point in our study as was done by Dochez et al.15

Total time to Performa the FICB was (median) 4 minutes which was comparable with other studies (4 to 5 minutes). ¹⁶⁻¹⁸ FICB provides an additional margin of safety since the needle is inserted into an area away from the femoral nerve and vessels. ¹⁹ No clinically significant adverse effect was reported with FICB. No clinically significant side-effect was observed in FICB group in our study, while in diclofenac sodium group 2 patients had nausea and vomiting and two other registered complains of abdominal pain. This can be explained by drug induced gastritis which is a well known and common side-effect of diclofenac sodium. ²⁰

A limitation of this study is that the effectiveness of the block is not tested by independent observers. However, due to practical and logical reasons it was not possible to add multiple observers as this could have lead to observer bias.

CONCLUSION

In conclusion this study demonstrated that FICB is a simple, inexpensive and effective method of emergency department analgesia for cases presenting with fractures of femur.⁷

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Source of Support: Nil; Conflict of Interest: None

Submitted: 23-02-2016; Published online: 23-03-2016