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A Prospective Comparative Study of Efficacy of Bupivacaine Alone or in Combination with Dexamethasone in Fascia Iliaca Compartment Block Prior to Subarachnoid Block for Fracture Femur Surgeries

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Abstract

Context: Femur fractures patients are in considerable pain on attempted hip flexion. Fascia Iliaca Compartment Block (FICB) is an effective means of providing analgesia during transit and positioning for spinal anesthesia which also persists postoperatively. *Aims:* To assess the preoperative and postoperative analgesic effect of Dexamethasone as adjuvant to Bupivacaine in FICB. *Settings and Design:* After obtaining ethical committee clearance, minimum sample size calculated from pilot studies was 64. Between Dec 2016–Feb 2017, 70 patients with proximal femur fractures posted for open reduction and internal fixation surgery were recruited for the study. *Methods and Materials:* Patients were randomly distributed into Control and Test Groups 35 patients received USG guided FICB with 28 *ml* 0.25% Bupivacaine + 2 *ml* Normal Saline and remaining received block with 28 *ml* 0.25% Bupivacaine + 2 *ml* (8 *mg*) Dexamethasone 20 *minutes* prior to being moved into position for spinal anesthesia. VAS score is used to assess pain during positioning, and in the postoperative period for duration of analgesia and requirement of rescue analgesics. *Statistical analysis used:* Paired "*t*" test, and ANOVA for parametric data and Fischer's test for categorical data. *Results:* Patients who received Dexamethasone as an adjuvant had significant prolongation of analgesia and required fewer rescue analgesics in the first postoperative day. No significant difference noticed in analgesia while positioning for spinal anesthesia. *Conclusions:* This study shows that FICB (total vol; 30 *ml*) provides preoperative analgesia, and Dexamethasone as adjuvant significantly prolongs the duration of block reducing the need for rescue analgesics over the first postoperative day.

Keywords: Proximal Femur Fractures; Fascia Iliaca Compartment Block; Dexamethasone; Postoperative analgesia.

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Introduction

Femur fractures are severely painful, especially fractures of the proximal femur, which limit mobility at the hip joint making it more difficult for the patient to sit up.[1] Surgical reduction of the fracture and fixation with an implant is the most common treatment modality and these surgeries are usually performed under central neuraxial blockade, frequently spinal anesthesia.[2]

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In the presence of pain, positioning for the neuraxial block is suboptimal and hence requires analgesia either through intravenous opioids or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), or the use of peripheral nerve blocks. Patients also experience a lot of postoperative pain and conventionally require multiple doses of analgesics typically opioids or NSAIDs.

Instead, a single dose of local anesthetic given as a peripheral nerve block prior to surgery can improve patient comfort during transit and positioning in the preoperative period and also provide long lasting analgesia in the postoperative setting.[3] Commonly used nerve block techniques include Femoral nerve block, 3-in-1 block and Fascia Iliaca Compartment Block (FICB). FICB is superior in terms of efficacy, safety and easy administration providing unilateral analgesia, reducing sideeffects, without motor blockade and fewer neurological complications.[3–5]

The duration of analgesia is prolonged by the addition of adjuvants. The efficacy of the glucocorticoid Dexamethasone in prolonging FICB has been studied previously. It has been postulated that steroid injections produce a degree of vasoconstriction, and hence, one theory suggests that the drug acts by reducing local anesthetic absorption. Another theory suggests that dexamethasone potentiates the activity of inhibitory potassium channels on nociceptive C-fibres (*via* glucocorticoid receptors), thereby decreasing their activity.[6] The use of Ultrasonography (USG) guided FICB has been noted to increase the ease of administration and safety of the technique.[7]

Objectives

1. To assess the duration and quality of postoperative analgesia in the first *24 hrs*;
2. To assess preoperative pain relief and patient comfort while shifting into OT and while positioning for anesthesia.

Materials and Methods

Inclusion Criteria

- Patients aged *18–80 yrs*;
- Patients with proximal femoral fractures planned for open reduction and internal fixation;
- Patients with ASA-PS (American Society of Anesthesiologists-Physical Status) Grade 1 and 2.

Exclusion criteria

- Patients refusing to participate in the study;
- Patients weighing <*50 kg*;
- Patients with allergy to local anesthetics, peripheral neuropathy, bleeding diathesis, previous femoral bypass surgery, inguinal hernia, inflammation or infection over injection site;
- Patients with psychiatric disorders and polytrauma.

Sample size

With reference to the previous studies,[8] a sample size was calculated based on SSME calculator available on the website: http://www.Openepi.Com/samplesize/ssmean.Htm using

Level of alpha: 0.05 (two sided);

Power: 0.80 (80%);

Expected mean difference in VAS scores: 4;

Standard deviation between means: 5.5;

Total sample size: 70, with 35 patients in each group.

Procedure

After obtaining Institutional ethical committee approval and informed written consent from the patients, 70 patients were studied. Patients were randomly divided based on computer generated random numbers into one of the Two Groups: Dexamethasone Group (D), and Control Group (B).

Group B: Received *2 ml* of normal saline with *28 ml* of 0.25% Bupivacaine. Total volume- *30 ml*.

Group D: Received *8 mg* dexamethasone made up to *2 ml* with *28 ml* of 0.25% Bupivacaine. Total volume:*30 ml*.

All patients were subjected to preanesthetic evaluation including medical history, physical examination and laboratory tests.

The patients were premedicated with tablet alprazolam *0.5 mg* the night before surgery.

In the preoperative waiting room, patients were put on standard monitoring including Non-invasive Blood Pressure (NIBP), pulse oximetry, electrocardiogram and baseline readings were noted. Baseline VAS (Visual Analogue Scale) score for pain was noted.

USG guided Fascia Iliaca Compartment Block was administered to all patients *30 min* prior to

shifting into Operation Theatre (OT), (Fig. 1). A short beveled, 23G Quincke's spinal needle is used. After puncturing Fascia Iliaca and negative aspiration, *30 ml* of predetermined drug was injected in *5 ml* aliquots over *2–3 minutes*. An expanding anechoic collection just below Fascia Iliaca was the visual confirmation of correct placement of drug, (Fig. 2).

Patients were shifted into the operating room *30 minutes* after administering the block.

All vital parameters, and VAS score for pain were noted when patient was positioned for Subarachnoid block. The SAB was then administered using Inj Bupivacaine 0.5% (Heavy)-*3ml*, and surgery was started after confirming the level of subarachnoid block.

Postoperatively, complaints of pain were assessed using VAS scores for the first postoperative day at immediate postop time, *2, 6, 12, 18* and *24 hrs* postoperatively and scores of '4' or more were given Inj Tramadol *100 mg* IV as rescue analgesia.

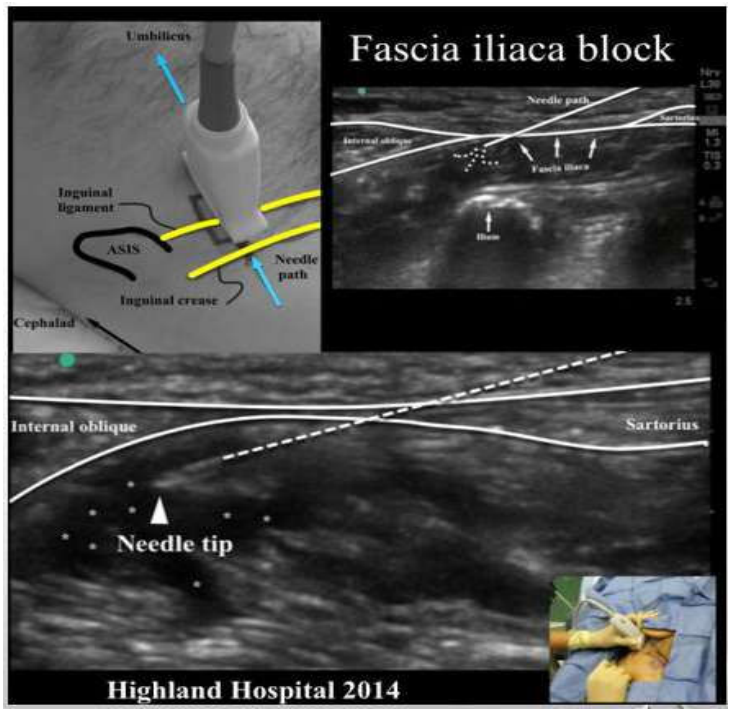

Fig. 1: Ultrasound image of front of thigh at level of groin crease, to demonstrate injection of drug for FICB

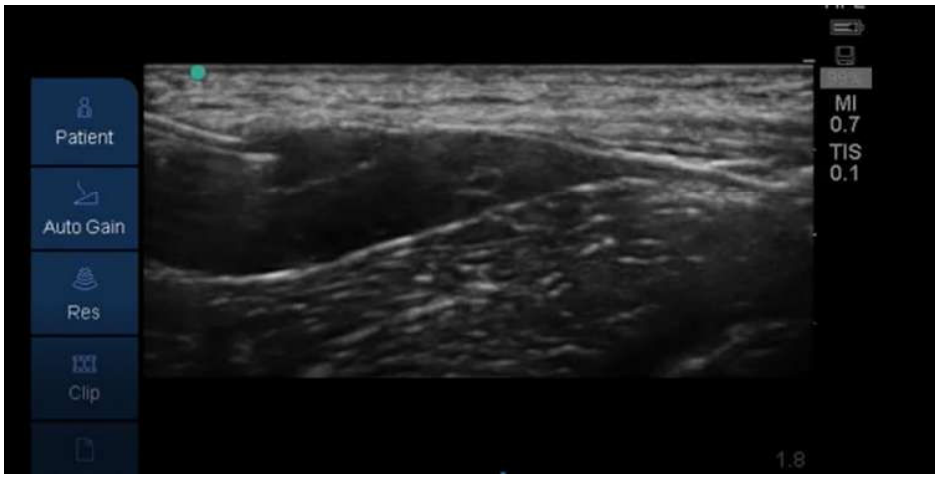

Fig. 2: Ultrasound image demonstrating spreading anechoic shadow- drug deposition in FICB

Statistical Analysis

- Results obtained were analyzed using descriptive statistics.
- Results on continuous measurements are presented on Mean + SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.
- Student *t*-test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two Groups. Inter Group analysis on metric parameters.
- Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more Groups.
- The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment *ver* 2.11.1 were used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables etc.

Significant values: $p < 0.1$.

Results

- Mean time to rescue analgesia in Group B is *5.81 hrs*, and in Group D is *15.98 hrs*, (Fig. 3).
- Mean VAS score in Group B at *6 hrs* and *12 hrs* was 3.95 and 5.57, and in Group D 1.55 and 3.16. VAS scores decreased from 7.16 and 7.21 prior to block to 1.76 and 2.13 *30 minutes* after block in Group B and Group D respectively, (Fig. 4).

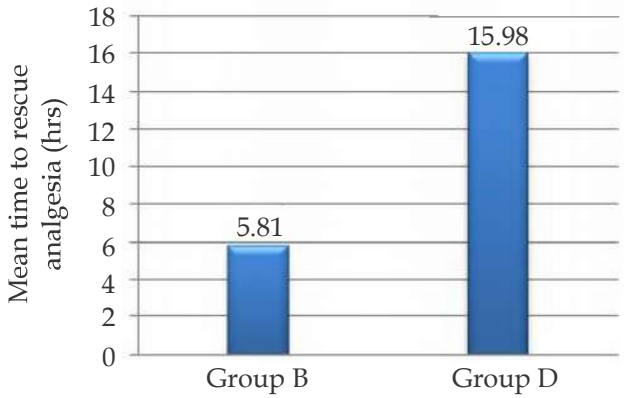

Fig. 3: Bar graph of mean time to rescue analgesia among both groups

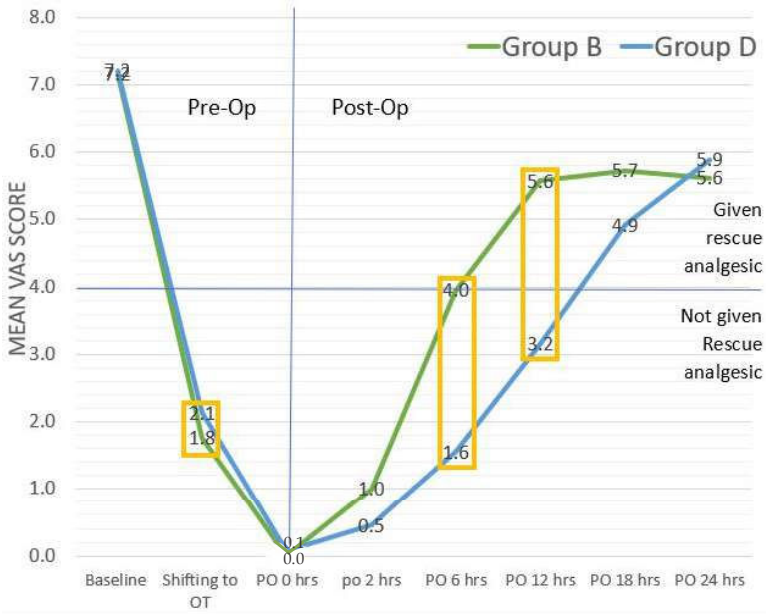

Fig. 4: Ling graph of the mean VAS in both groups in pre- operative and post operative periods

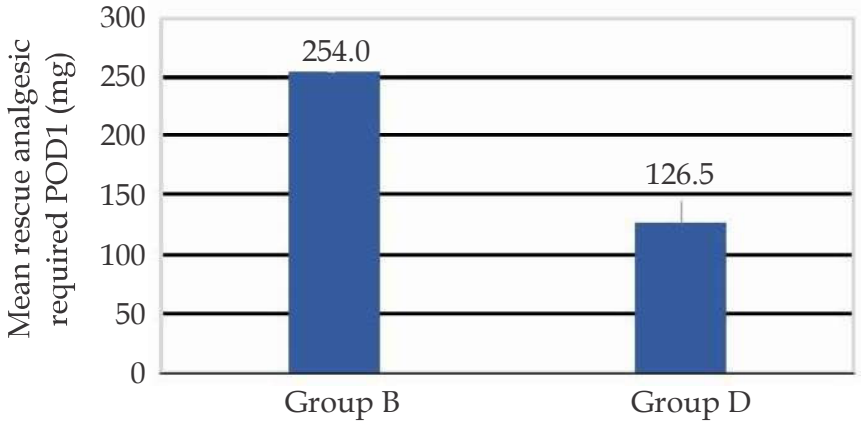

Fig. 5: Bar graph of the average amount of rescue analgesic consumed per patient in first postoperative day across both groups.

- Mean requirement of rescue analgesia (on POD1) in Group B was *254.0 mg* and in Group D was *126.5 mg*, (Fig. 5).
- Mean age being 60.2 and 57.9 in Group B and Group D respectively. $p = 0.6$, (Table 1).
- 62.2% of patients in Group B were male, and 57.9% in Group D, $p = 0.7$ (Table 2).
- 64.9% of patients in Group B were ASA-I, while 50% in Group D are ASA-I, $p = 0.2$ (Table 3).
- No adverse neurological outcome was noted in the study.
- No instances of Local Anesthetic Systemic Toxicity.
- All patients were noted to have recovered normal sensory function over the operated limb at *24 hrs* postoperatively.

Table 1: Age distribution of patients in either groups. p=0

		Drug Group			
		B		D	
		Count	Column n %	Count	Column n %
AGE Category	<50	6	16.2%	6	15.8%
	51–60	13	35.1%	19	50.0%
	61–70	15	40.5%	11	28.9%
	>71	3	8.1%	2	5.3%

Table 2: Gender distribution of patients in either groups. $p = 0.7$

		Drug Group			
		B		D	
		Count	Column n %	Count	Column n %
Gender	Female	14	37.8%	16	42.1%
	Male	23	62.2%	22	57.9%

Table 3: Distribution of patients based on American Society of Anesthesiologist's Physical Status Classes. $p = 0.2$.

		Drug Group			
		B		D	
		Count	Column n %	Count	Column n %
ASA Grade	I	24	64.9%	19	50.0%
	II	13	35.1%	19	50.0%

Discussion

The Fascia Iliaca Compartment block was first described by Dalens *et al*. in 1989 on children using landmark technique as a means to block the Femoral, Lateral Cutaneous and Obturator nerves[9] and was described as providing a consistent block of the femoral and lateral cutaneous nerves, and a block of obturator nerve (4–47%), providing good analgesia for fractures at the hip joint and proximal femur.[9]

It has since been used as a means of analgesia following surgical procedures in the hip, femur and knee, treatment of burns on the thigh and in prehospital treatment of fracture femur.[3,10] It is a safe alternative to the 3-in-1 Block and is more efficacious than the femoral/lateral cutaneous nerve blocks administered individually.[4,11] It has been demonstrated to provide better quality and longer duration of analgesia when compared to intravenous opioids and NSAIDs.[3,4] By administering the block *30 minutes* prior to shifting, patients are comfortable during shifting and positioning[7].

In a study done in 2009, Yun MJ *et al*.[5] found that FICB decreases mean VAS score from 7.4 to 2, compared to IV alfentanil- 7.3 to 3.5. Similarly,

in a study conducted in 2005 on preoperative patients by Candal-Couto JJ, McVie JL *et al*.,[12] the visual analogue scores were found to be improved significantly from 7.2 to 4.6 (SD 2.4). This is comparable to our study where mean VAS score decreased from 7.16 and 7.21 in study and control groups to 1.67 and 2.13 respectively which is statistically significant at $p < 0.0001$. However, there is no significant difference between the two groups ($p = 0.3$), (Fig. 4).

Hence, FICB as a preoperative analgesic, improves patient comfort, but the addition of Dexamethasone doesn't improve the outcome in the preoperative setting. In 2016, Kumie FT *et al*.[4] concluded that the use of FICB provided adequate postoperative analgesia, reduced the total analgesic consumption and prolonged the time to first analgesic requirement after surgery for femur fractures. These findings are similar in our study, where mean rescue analgesic requirement was *254.0 mg* of Inj Tramadol when using Bupivacaine alone in FICB, but only *126.5 mg* of Inj Tramadol when Dexamethasone is added ($p < 0.0001$), (Fig. 5).

This study compares the use of Bupivacaine to Bupivacaine with Dexamethasone in FICB. A similar study conducted by Suresh N, Kiran N, *et al*. in 2014[8] used a total drug volume of *40 ml* and found that the addition of Dexamethasone significantly increases the duration of block. This study uses a total drug volume of *30 ml* as described by Yun MJ, Kim YH *et al*.[5] to assess if the addition of dexamethasone as an adjuvant is useful in reducing the total volume of drug required. It was found that the mean duration of block in the Dexamethasone group was increased to *3 times* that of the Control Group ($p < 0.001$), (Fig. 3). This is similar to the findings of Suresh N *et al*., and is in keeping with previous clinical data, that suggest that the addition of Dexamethasone to peripheral nerve blocks significantly prolongs the duration of block.[8]

Conclusion

FICB with Bupivacaine and Dexamethasone has significant perioperative analgesia and decreases need for rescue analgesia in first postoperative day.

Key Messages

The addition of Dexamethasone to FICB significantly prolongs the quality and duration of analgesia on POD1 while USG guidance reduces the volume required for an adequate block.

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