

# Comparing Two Different Doses of Clonidine as an Adjuvant to Bupivacaine in Blind Fascia Iliaca Compartment Block Preoperatively in Patients Posted for Femur Fractures

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## Abstract

**Background:** Femur fractures occur commonly due to trauma and cause excruciating pain causing difficulty in the positioning of a patient during spinal anesthesia. Fascia iliaca compartment block is an easy, bedside procedure for pain relief of such a patient. Addition of clonidine to local anesthetic agent improves the quality of analgesia.

**Aims:** The aim of the study was to study the effect of two different doses, 50 µg and 100 µg of clonidine as an adjuvant to bupivacaine in blind fascia iliaca compartment block orthopedic patients with a femur fracture.

**Methods:** A total of 120 adult patients of either sex, belonging to American Society of Anesthesiologists (ASA) physical status Class I and II, admitted in an orthopedic ward with femur fractures were randomly divided into three groups. The patients in Group I (control) received 39ml of 0.25% bupivacaine + 1 ml of normal saline, in Group II received 39 ml of 0.25% bupivacaine + 50 µg of clonidine diluted to 1 ml, and in Group III received 39 ml of 0.25% bupivacaine + 100 µg clonidine diluted to 1 ml. The demographic characteristics, hemodynamic parameters, ASA physical status, visual analog scale (VAS) scores, onset of analgesia, duration of analgesia, number of rescue analgesics, and any side effects and patient satisfaction during positioning for spinal anesthesia were noted.

**Results:** VAS scores till 24 h were lower in clonidine groups. The onset of analgesia was also reduced in clonidine groups. The mean duration of analgesia in Group I was 5.4 ± 0.6 h, 11.5 ± 0.3 h in Group II, and 16 ± 0.4 in Group III. The total number of rescue analgesics consumed in Group I was 4.5 ± 0.5, 3.2 ± 0.8 in Group II, and 2.8 ± 0.7 in Group III. The patient satisfaction during positioning for spinal anesthesia after the fascia iliaca compartment block was satisfactory in 30 patients in Group I, 34 patients in Group II, and 35 patients in Group III.

**Conclusions:** We conclude that the use of 50 µg clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block for femoral fracture patients as a component to multimodal analgesic approach for effective pain relief.

**Key words:** Bupivacaine, Clonidine, Fascia iliaca compartment block

## INTRODUCTION

Femur fractures occur commonly due to trauma and cause acute pain in the perioperative period. Patient presents with

pain, swelling, and restricted movements.<sup>[1]</sup> The patient may require surgical intervention such as closed reduction, open reduction and internal fixation, dynamic hip screw fixation or hip arthroplasty, and among others.<sup>[2]</sup> These procedures require neuraxial anesthesia for which optimum positioning is critical in the pre-operative period, but the presence of pain makes the management difficult.

Fascia iliaca compartment block is a simple, bedside, blind underrated procedure used to provide analgesia in the perioperative period for patients with a femur fracture. It

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blocks the femoral, lateral cutaneous nerve of thigh and obturator nerve in a single shot.<sup>[3]</sup> It was first performed by Dalen *et al.*, in 1989, where he compared it with 3 in 1 block in pediatric patients.<sup>[4]</sup>

Clonidine, an  $\alpha_2$  agonist is a widely used adjuvant with local anesthetics to prolong the duration of analgesia. It acts by sympatholysis and direct inhibitory effect on peripheral nerve conduction by A and C fibers.<sup>[5]</sup>

We intended to evaluate the efficacy of clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block specifically for femur surgeries.

## MATERIALS AND METHODS

The present study was undertaken in a tertiary care hospital as a prospective, randomized, double-blind study after approval by hospital ethics committee. A written informed consent was taken from all the patients participating in the study. A total of 120 adult patients of either sex, aged between 18 and 60 years, belonging to American Society of Anesthesiologists (ASA) physical status Class I and II, admitted in an orthopedic ward with femur fractures were randomly divided into three groups. The patients in Group I (control) received 39ml of 0.25% bupivacaine + 1 ml of normal saline, in Group II received 39 ml of 0.25% bupivacaine + 50  $\mu$ g of clonidine diluted to 1 ml, and in Group III received 39 ml of 0.25% bupivacaine + 100  $\mu$ g clonidine diluted to 1 ml. The total volume of drug used in all the three groups was 40 ml. Clonidine was measured in an insulin syringe. The anesthesiologist preparing the drug was not involved in patient care, and the patients were also blinded to the group they were in. Patients having an allergy to local anesthetics, infection at the injection site, bleeding diathesis, having systemic coexisting diseases predisposing to altered sensation such as diabetes mellitus and neuropathies and having any contraindication to regional anesthesia were excluded from the study.

A thorough preanesthetic evaluation including baseline relevant investigations was done before surgery. During preanesthetic evaluation, patients were explained about visual analog scale (VAS) and about its use as a tool for measuring pain which consisted of 100 millimeters line with "0" equaling no pain at all and, "10" being worst pain. Patients were also explained about the procedure of fascia iliaca compartment block, the drugs being used and the possible side effects. Patients were kept nil orally 6 h before surgery. Patients were not premedicated to avoid any bias. After being shifted to operation theater baseline, vital parameters comprising heart rate (HR), systolic and diastolic blood pressure (SBP/DBP), peripheral oxygen

saturation (SpO<sub>2</sub>), and respiratory rate (RR) were recorded. Intravenous access was secured with 18G cannula and patient was preloaded with 10 ml/kg of ringer lactate. The patient was placed supine on the OT table under proper illumination. Under all aseptic precautions, fascia iliaca compartment block was performed using landmark technique as described by Dalens *et al.*<sup>[4]</sup>

The landmark of this technique was a line drawn between the anterior superior iliac spine and the pubic tubercle along the deep inguinal ligament. The site of needle insertion is 1 cm below the junction of lateral one-third and medial two-third of this line. 23 G short beveled needle was inserted vertically till 2 pops were appreciated - the first pop and the second pop occurred when fascia iliaca and fascia lata were pierced, respectively. After negative aspiration, 40 ml of the prepared drug was injected, and the injected area massaged to ensure adequate spread.

After the block, vital parameters such as HR, SBP, DBP, RR, and SpO<sub>2</sub> were monitored every 5 min for initial 20 min and then every 30 min intraoperatively and later at 4 h, 8 h, 12 h, and 16 h. Analgesia was assessed by VAS scale at 1 h, 2 h, 6 h, 12 h, and 24 h. The onset of analgesia was defined as the time taken from injecting drug for fascia iliaca compartment block to VAS <3 to pinprick sensation at the cutaneous distribution of femoral nerve and lateral cutaneous nerve of thigh. The duration of analgesia was defined from time of giving block to the first request for rescue analgesic. For rescue analgesia, tramadol 100 mg was given intravenously. The patient satisfaction during positioning for spinal anesthesia was graded as satisfactory or non-satisfactory.

Patients were observed for any possible side effects such as nausea, vomiting, hypotension (defined as SBP <90 mm of Hg), sedation, bradycardia (defined as HR <50/min), and local anesthetic toxicity. All observations were collected by an anesthesiologist who was blinded to group allocation.

The collected data were analyzed using Statistical Package of the Social Sciences software version 20. The normally distributed variables were analyzed using student's *t*-test, categorical variable using Fischer's exact *t*-test, or Chi-square test. Analysis of variance was used to determine any statistically significant difference in means of two or more groups. *P* < 0.05 was considered statistically significant.

For sample size calculation, we assumed an alpha error of 5% and dropout rate at 10%. The power of the study was kept at 90%. Therefore, to achieve an effect size of at least 30% in VAS scores, the sample size was selected as 40 in each group.

The primary outcome of our study was to see the effect of the combination of clonidine and bupivacaine on duration and quality of analgesia. The secondary outcomes were pain scores, hemodynamic parameters, patient satisfaction during positioning for spinal anesthesia and adverse effects.

## RESULTS

There are no significant differences in the demographic profile of patients in three groups. [Table 1].

The mean age of patients in Group I was  $52 \pm 11.1$ , Group II was  $50 \pm 13.2$ , and Group III was  $49 \pm 12.4$  years. There were 28 males and 12 females in Group I, 30 males and 10 females in Group II, and 26 males and 14 females in Group III. The mean height of patients in Group I was  $165 \pm 4.8$ , in Group II was  $163 \pm 5.1$ , and in Group III was  $166 \pm 4.2$  cm. The mean weight of patients in three groups was also comparable -  $66 \pm 6.2$  kg in Group I,  $68 \pm 5.9$  kg in Group II, and  $65 \pm 7.7$  kg in Group III. There was no significant intergroup variation regarding ASA physical status.

The baseline VAS scores in the three groups were comparable. At 12 h, the mean VAS score of Group I was  $6.8 \pm 0.26$ , Group II was  $4.2 \pm 0.32$ , and  $4.0 \pm 0.28$  Group III. At 24 h, the mean VAS score was  $8.12 \pm 0.30$  in Group I,  $5.8 \pm 0.12$  in Group II, and  $5.6 \pm 0.9$  in Group III. The difference in mean VAS score between Group I and rest of the groups was highly significant ( $P < 0.05$ ), while there was no statistically significant difference between Group II and Group III [Table 2].

The time for onset of analgesia in Group I was  $20.5 \pm 2.2$ ,  $16.8 \pm 2.6$  in Group II, and  $15.9 \pm 2.0$  in Group III. The difference in onset of analgesia between Group II and Group III was not significant. The mean duration of analgesia in Group I was  $5.4 \pm 0.6$  h,  $11.5 \pm 0.3$  h in Group II, and  $16 \pm 0.4$  in Group III. The difference between the groups was statistically significant. The total number of rescue analgesics consumed in Group I was  $4.5 \pm 0.5$ ,  $3.2 \pm 0.8$  in Group II, and  $2.8 \pm 0.7$  in Group III. The difference between Group I and the clonidine groups was statistically significant while the difference in Group II and Group III was not statistically significant [Table 3].

The patient satisfaction during positioning for spinal anesthesia after the fascia iliaca compartment block was satisfactory in 30 patients in Group I, 34 patients in Group II, and 35 patients in Group III which was not significant statistically [Table 4].

There was no statistically significant difference among hemodynamic parameters, RR, and oxygen saturation.

The side effects were noted in all the three groups. No patient reported nausea/vomiting or respiratory depression or local anesthetic toxicity. Hypotension occurred in 1 patient in Group I, 2 patients in Group II, and 4 patients in Group III which was statistically not significant. Bradycardia occurred in 3 patients in Group III which was statistically significant, 2 patients in Group II and 3 patients in Group III were sedated which was statistically significant when compared between Group I and Group III [Table 5].

**Table 1: Demographic profile**

Parameter	Group I	Group II	Group III
Age (years)	52±11.1	50±13.2	49±12.4
Sex (M/F)	28/12	30/10	26/14
Height (cm)	165±4.8	163±5.1	166±4.2
Weight (kg)	66±6.2	68±5.9	65±7.7

**Table 2: VAS score**

Time (h)	Group 1	Group II	Group III
Baseline	7.9±1.2	8.32±0.9	8.0±1.4
2	4.6±2.0	3.5±1.0	3.3±0.42
4	4.5±0.4	3.62±0.29	3.56±0.32
6	4.5±0.39	3.8±0.34	3.6±0.22
12	6.8±0.26	4.2±0.32	4.0±0.28
24	8.12±0.30	5.8±0.12	5.6±0.9

VAS: Visual analog scale

**Table 3: Analgesia assessment**

Parameters	Group I	Group II	Group III
Onset of analgesia (min)	20.5±2.2	16.8±2.6	15.9±2.0
Duration of analgesia (h)	5.4±0.6	11.5±0.3	16±0.4
No. of rescue analgesics in 24 h	4.5±0.5	3.2±0.8	2.8±0.7

**Table 4: Patient satisfaction during positioning for spinal anesthesia**

Parameters	Group I	Group II	Group III
Satisfactory	30	34	35
Non satisfactory	10	06	05

**Table 5: Adverse effects**

Parameters	Group I	Group II	Group III
Nausea/vomiting	0	0	0
Hypotension	1	2	4
Bradycardia	0	0	3
Sedation	0	2	5
Respiratory depression	0	0	0
Local anesthetic toxicity	0	0	0

## DISCUSSION

Fascia iliaca compartment block was first described by Dalen *et al.*, in children for hip surgeries, femur fractures, and treatment of burns on thigh.<sup>[4]</sup> It has been found to be a very easy, safe bedside procedure as the site of injection is far from the neurovascular bundle.<sup>[6]</sup>

Femoral fractures are extremely painful, and analgesia is mainly by systemic administration of nonsteroidal anti-inflammatory drugs or opioids as per the local institutional protocol. A study demonstrated that of all patients presenting to the emergency department of a hospital, 36% received no analgesia, 7% received nonopioids, and rest 57% received opioids.<sup>[7]</sup>

We intended to use fascia iliaca compartment block by anatomical landmark technique to such patients and assess pain relief with bupivacaine alone or bupivacaine with clonidine in two different doses. Clonidine, a centrally acting  $\alpha_2$  agonist, causes peripheral effects through inhibition of the hyperpolarization-activated cation current ( $I_h$  current) especially on C-fibers (pain fibers) than  $A\alpha$ -fibers (motor fibers), resulting in more sensory blockade.<sup>[8]</sup>

The baseline VAS scores in all the groups were similar. There was a significant reduction in VAS scores in patients receiving fascia iliaca compartment block. The reduction was more significant in the clonidine groups (mean VAS score was  $4.2 \pm 0.32$  in Group II and  $4.0 \pm 0.28$  in Group III) where VAS scores remained  $<5$  even at 12 h of giving block. Similar results were documented in a study done by Tomar *et al.* where they found lower VAS scores till 24 h in clonidine groups.<sup>[9]</sup> We conducted this study with same doses and drug composition but the sample size was doubled, and the block was given specifically to femur fracture patients.

The onset of analgesia was significantly reduced in clonidine groups as compared to the control group. The difference in onset time between Group II and Group III was not statistically significant. Clonidine is known to shorten the onset of action of local anesthetic by its effect on descending noradrenergic tract in the spinal cord which plays an important role in pain modulation.<sup>[10]</sup>

The duration of analgesia was also prolonged in clonidine groups. Group I patients who received only bupivacaine were pain-free for  $5.4 \pm 0.6$  h. Patients who received clonidine had a significant extended duration of analgesia -  $11.5 \pm 0.3$  h in Group II and  $16 \pm 0.4$  h in Group III. The average number of rescue analgesics used in 24 h in Group I was  $5.5 \pm 0.5$  which was significantly higher than that consumed in clonidine groups ( $3.2 \pm 0.8$  in Group II and  $2.8 \pm 0.7$  in Group III). This shows that

clonidine prolongs the duration of analgesia and hence consumption of rescue analgesics was also reduced. Monzon *et al.* also found prolongation of the duration of analgesia up to 8 h after single shot fascia iliaca compartment block.<sup>[11]</sup> The analgesic action of clonidine in combination with local anesthetic agents for the peripheral neuraxial block has been widely accepted.<sup>[12,13]</sup>

We also evaluated patient satisfaction during positioning for spinal anesthesia and found that there was no intergroup statistically significant difference among all the groups signifying that fascia iliaca compartment block significantly reduces pain during positioning. Candal-cauto *et al.* also demonstrated that fascia iliaca compartment block causes femoral neck fracture patients to tolerate sitting position which they assessed using an objective sitting score.<sup>[14]</sup>

Patients were observed for any side effects. None of the patients in any group had any nausea and vomiting or respiratory depression or any features of local anesthetic toxicity. Patients in Group III demonstrated increased incidence of hypotension, bradycardia, and sedation. This can be attributed to a higher dose of clonidine used.

A major limitation of our study was that we did not use ultrasound-guided block technique as there was no availability of ultrasound machine at our center. We also did not study dose-response relationship of clonidine to find out the lowest possible dose of clonidine which would increase the duration of analgesia without causing any systemic side effects.

## CONCLUSION

We conclude that fascia iliaca compartment block is a very safe, easy to perform bedside pre-operative block for femur fracture patients. Addition of even a small dose of  $50 \mu\text{g}$  clonidine increased the duration of analgesia without significant side effects while  $100 \mu\text{g}$  clonidine was associated with increased sedation and bradycardia. We recommend the use of  $50 \mu\text{g}$  clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block for femoral fracture patients as a component to multimodal analgesic approach for effective pain relief.

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