



# Dexmedetomidine and Bupivacaine Versus Bupivacaine Alone in Ultrasound Guided Fascia Iliaca Compartment Blockade for Femoral Fractures

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## Abstract

**Background:** Pain control is one of the most important issues in femoral fractures. One of the most effective methods is the fascia iliaca compartment block.

**Objectives:** The aim of this study was to compare the efficacy of the addition of dexmedetomidine to bupivacaine on the quality of ultrasound guided blockade of the fascia iliaca compartment in adults undergoing femoral shaft fracture surgery.

**Methods:** This study was a double-blind clinical trial. We studied 60 adults who were hospitalized for a femoral shaft fracture. The patients were divided into two equal groups receiving either bupivacaine alone or bupivacaine and dexmedetomidine for compartment blockade of the iliac fascia. Group allocation was based on the method of randomization from concealed envelopes. Primary outcomes were pain intensity, sedation and analgesic consumption assessed at 1, 2, 6 and 24 hours after surgery in two groups. Data were analyzed using SPSS software.

**Results:** Pain intensity was lower in the dexmedetomidine group 1, 2, 6 and 24 hours after surgery ( $p < 0.05$ ). The sedation score was also higher in the dexmedetomidine group 6 and 24 hours after surgery ( $p < 0.05$ ). The dose of analgesics used by the dexmedetomidine group was significantly lower 6 and 24 h after treatment. No hypotension, respiratory depression and bradycardia occurred in the patients participating in this study.

**Conclusion:** The addition of dexmedetomidine to bupivacaine during ultrasound-guided blockade of the fascia-iliac compartment is associated with reduced pain intensity and improved sedation in patients undergoing femoral fracture surgery.

**Keywords:** Bupivacaine, Dexmedetomidine, Fascia iliaca compartment block, Post-operative pain

## 1. Background

### 1.1. Background

Dexmedetomidine is a selective alpha-2 agonist (1). Some experimental and clinical studies have shown that the addition of dexmedetomidine to bupivacaine increases its efficacy (2-5) without increasing neurotoxicity.

### 1.2. Statement of the problem

Few studies have investigated the combination of dexmedetomidine with other nerve block drugs.

Some studies have attempted to demonstrate the benefit of dexmedetomidine as an adjuvant to local anesthetics in neuraxial anesthesia (6,7). Nerve blocks are performed for femoral fractures due to excessive pain. Some studies have shown that the duration of nerve blocks is prolonged by combining dexmedetomidine with bupivacaine (8) but, there are insufficient studies in this area and further clinical evidence is needed to support the use of this drug (9). Although many studies have suggested the use of dexmedetomidine as an adjuvant in nerve block, the side effects of the drug have not been evaluated in these studies (10). A 2012 study investigated the

effect of combining these two drugs in children with femoral fracture. In this study, the combination of dexmedetomidine with bupivacaine was compared with bupivacaine alone. The use of dexmedetomidine was associated with a lower sevoflurane concentration during the procedure, higher sedation points, a longer postoperative pain-free period and a lower use of rectal paracetamol after the procedure. Agitation was reported in a few cases. In addition, respiratory depression, bradycardia, hypotension or itching were not reported in any patient in either group (11). Only a few studies are available on the combination of dexmedetomidine with bupivacaine in adults. Li et al. conducted a study to evaluate the efficacy of adding dexmedetomidine to ropivacaine in compartment blockade of the iliac fascia during knee arthroscopy in adults. Their conclusion was the superiority of the combination of dexmedetomidine and ropivacaine (12).

Many studies focused on the effect of dexmedetomidine on local anesthetics in a variety of regional anesthesia such as supraclavicular or infraclavicular in adult upper limb surgery and came to similar results (13,14).

## 2. Objectives

This study was conducted to investigate the effect of adding dexmedetomidine to bupivacaine in ultrasound guided compartment blockade of the iliac fascia in adults with femoral shaft fractures undergoing surgery. The specific aims were to compare pain intensity, sedation score, analgesic dose used and drug-related side effects in the bupivacaine group and the bupivacaine plus dexmedetomidine group during ultrasound guided fascia iliaca compartment block.

## 3. Methods

### 3.1. Study design and setting

This study was conducted at Shahid Mohammadi

Hospital in Bandar Abbas, Iran. This study was a double-blind clinical trial involving 68 adults over 18 years of age with ASA I and II with a femoral shaft fracture were enrolled in this trial but, 8 of whom discontinued the study, and a final analysis was applied to 60 patients (30 each group). (Figure 1).

### 3.2. Sample size and sampling method

A total of 68 adults were included in the study. We designed a prospective, randomized blind study. The sample size was calculated using the mean VAS score of 1.45 on day 6 after surgery in the dexmedetomidine group of the study by Li Y et al (12). The patients were divided into two groups. Group assignment was based on the method of random drawing from concealed envelopes.

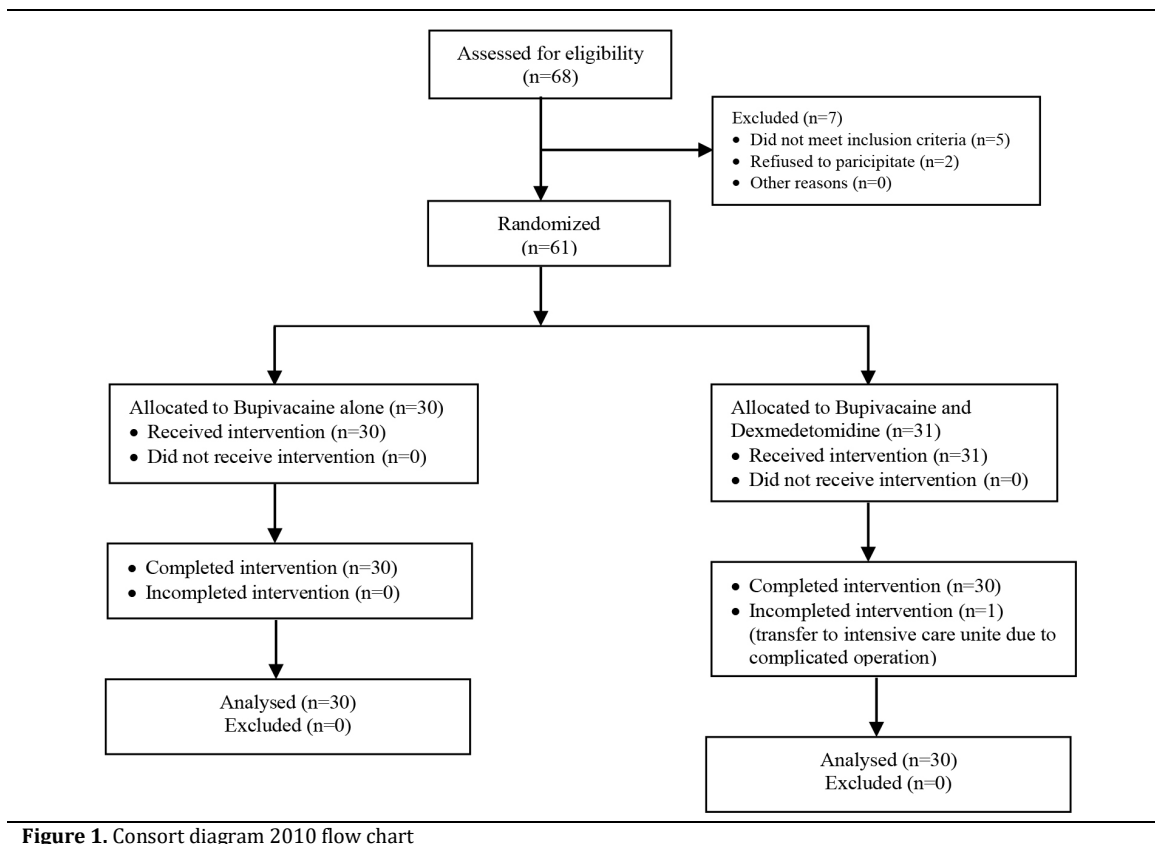


Figure 1. Consort diagram 2010 flow chart

### 3.3. Inclusion and exclusion criteria

All patients with femoral shaft fracture who were older than 18 years and had completed the informed consent form were included in the study. Exclusion criteria were drug allergies, neurological diseases, coagulation disorders, infections at the site of the block, multiple traumas and a history of opioid addiction.

### 3.4. Ethical issues

Informed consent to participate in the study was obtained from all patients, and those unwilling to participate were excluded. Patients information was

kept confidential. The study was conducted after approval by the university ethics committee and registration at ClinicalTrials.gov with the identifier ClinicalTrials.gov: NCT02658760.

### 3.5. Data Collection

All patients who entered the operating room and were placed on the bed were operated on under standard monitoring of electrocardiogram, pulse oximetry and blood pressure. Baseline hemodynamic parameters were recorded in all patients. Patients in both groups received the same anesthesia. A preanesthetic dose of 2 mg midazolam and fentanyl at a

dose of 2 micrograms per kg was used in all patients. Anesthesia was induced with propofol at a dose of 2 mg per kg and then with atracurium at a dose of 0.5 mg per kg. Anesthesia was continued with propofol at a dose of 100 micrograms per kg body weight per minute. Analgesia was prepared with a morphine injection of 0.05 mg per kg. Remifentanyl was administered to all patients at a dose of 2 micrograms per kg. Remifentanyl is a short-acting drug whose effect lasts until the start of Intervention in both groups and would not affect the results. After surgery in the recovery room, the control group (Group A) received 30 ml of bupivacaine 0.25% (Marcaine 5mg/ml, AstraZeneca, Sweden) with a placebo (normal saline). The study group (group B) received the same dose of bupivacaine for FICB in combination with dexmedetomidine (Precedex 200micgm/ml, Hospira, USA) at a dose of 2 micrograms per kg body weight. The block was performed under ultrasound guidance (Ezono devices and probes linear 10 MHz). The person performing all blocks was unaware of the postoperative assessments.

### 3.6. Research tools

After the nerve block, the pain level was measured using a VAS scale from zero to 10 at 1, 2, 6 and 24 hours after surgery. According to this scale, the patient is asked to indicate the intensity of the pain. The highest pain is rated as 10 and the lowest as zero. If the VAS score was greater than 3 after the nerve block, they received the same dose of analgesic (0.5 mg pethidine per kg body weight) and the data were recorded. In all patients, vital signs were examined before and after surgery (e.g. databases), the duration of postoperative analgesia was drawn until the first dose, the occurrence of side effects such as hypotension (systolic blood pressure below 90 mm mercury column), bradycardia (heart rate below 60 beats per minute) and respiratory depression (respiratory rate below 12 beats per minute) was investigated in the above-mentioned hours. Sedation was assessed according to the Ramsay's Sedation Scales criteria, which ranged from 1 to 6. The above information was recorded in a checklist prepared by the researcher who was unaware of the group

assignment. Demographic characteristics such as age, weight, gender, height and BMI were also recorded in this checklist.

### 3.7. Analysis Information

The primary outcome was the VAS 6 hours after surgery, while other outcomes (sedation and analgesic consumption) were considered secondary outcomes. Data were analyzed using IBM SPSS statistical software and descriptive statistics such as mean and standard deviation, frequency of tests and percentage of tests, and independent samples t-test or chi-square. In this study, the p-value was considered statistically significant at less than 0.05.

## 4. Results

### 4.1. Demographic Data

This study involved 60 patients, of whom 10 (16.6%) were female and 50 (83.3%) were male and 30 patients (50%) were in the bupivacaine alone group (A) and 30 (50%) in the bupivacaine and dexmedetomidine group (B). The average age of the patients was  $37.36 \pm 20.18$  years, the average height was  $169.53 \pm 8.97$  cm, the average weight was  $67.38 \pm 13.19$  kg, and the average BMI was  $23.32 \pm 3.66$  kg/m<sup>2</sup>. Table 1 compares the demographic information between the two groups.

**Table 1:** Comparison of demographic variables between two groups

Variable	Group A	Group B	P-value
Age (yr.)	40.6 ± 22.2	34.2 ± 17.8	0.25
BMI	23.4 ± 4.3	23.2 ± 2.9	0.84
Height (Cm)	171.1 ± 10.9	167.9 ± 6.3	0.21
Weight (Kg)	69.1 ± 16.1	65.7 ± 9.5	0.36
Gender	F	4 (13.3%)	0.5
	M	24 (80%)	26 (86.6%)

### 4.2. Main Findings

Table 2 compares the pain intensity, sedation score, and dosage of analgesics used by the two groups.

None of the subjects in our study experienced complications such as respiratory depression, hypotension or bradycardia.

**Table 2.** Comparison of pain severity, sedation score, and dosage of analgesics used by two groups

Variable	Group A	Group B	P-value	
Pain severity (VAS)	Baseline	4.23 ± 2.81	3.15 ± 2.09	0.039
	After 1 hour	0.5 ± 1.06	0.03 ± 0.19	< 0.001
	After 2 hours	1.23 ± 0.65	0.26 ± 0.66	< 0.001
	After 6 hours	3.38 ± 0.63	1.34 ± 0.56	< 0.001
	After 24 hours	5.46 ± 1.10	3.38 ± 1.29	< 0.001
Sedation score (Ramsay)	Baseline	1.07 ± 0.27	1.19 ± 0.40	0.232
	After 1 hour	2.03 ± 0.19	2	0.327
	After 2 hours	2	2	-
	After 6 hours	1.15 ± 0.36	2	< 0.001
	After 24 hours	1.03 ± 0.19	1.53 ± 0.5	< 0.001
Analgesic dosage (mg)	Baseline	25 ± 14.4	18 ± 16.95	0.115
	After 1 hour	0	0	-
	After 2 hours	0	0	-
	After 6 hours	22.11 ± 8.14	0	< 0.001
	After 24 hours	38.46 ± 14.54	17.30 ± 11.76	< 0.001

## 5. Discussion

### 5.1. Intensity of Pain

According to the results of this study, pain intensity was lower in the dexmedetomidine group than in the control group. We used a visual analog scale to measure pain. Similar studies have shown the efficacy of dexmedetomidine with bupivacaine in nerve blocks. The 2014 study by Agrawal et al. showed that the onset of numbness was shorter in the dexmedetomidine group than in the control group and the duration of anesthesia was also longer in these subjects (13). However, their study examined the supraclavicular brachial plexus block, whereas our study performed an iliac fascia block. The pain scale used, in our study was the Visual Analog Scale, which differs from the scale used in the Agrawal study. The onset of anesthesia and the duration of anesthesia were taken into account in this study.

Similar results were also reported in the study by Ammar et al. The results of this study showed that the duration of anesthesia was longer in the dexmedetomidine group. Pain was also less in this group than in the control group (14). In Ammar's study, however, an infraclavicular plexus block was performed, which differs from my study.

The study by Halder and colleagues investigated subarachnoid block during lower limb surgery. The results of this study showed that pain intensity was lower in patients treated with dexmedetomidine than in the control group. The duration of the motor and sensory blocks was significantly longer in the dexmedetomidine-treated patients than in the control group. First-time analgesic consumption in the dexmedetomidine group was later than in the control group (15).

Helal and colleagues studied dexmedetomidine in femoral-sciatic block and came to a similar conclusion. In this study, the onset of sensory and motor block was shorter and the duration of sensory and motor block was longer in the dexmedetomidine combination with bupivacaine (16).

The results of these studies confirm the results of our study with regard to pain intensity and duration.

Attia and Zein showed better results with adding a combination of Ketamin and Dexmedetomidine as an adjuvant to bupivacaine in FICB recently (17).

Hua et al. investigated the effect of adding dexmedetomidine to ropivacaine for FICB in elderly patients who were candidates for hip replacement surgery with general anesthesia. They found the same results in terms of pain control and a better mental condition in the dexmedetomidine group (18).

Kundra et al. showed a sparing effect in opioid consumption after the addition of dexmedetomidine to ropivacaine in FICB after hemiarthroplasty. This is consistent with our study (19).

### 5.2. Patients sedation points

In this study, sedation scores were higher in the dexmedetomidine group than in the control group 6 to 24 hours after the start of the study. The Ramsay scale was used to measure sedation in our study. In the same study, Agrawal and colleagues also showed that sedation was better in patients receiving dexmedetomidine than in the control group (13).

Similarly, the study by Ammar and colleagues showed that long-term sedation was better in patients in the dexmedetomidine group than in the control group (14).

The study by Helal et al. showed a longer duration of anesthesia in the patients who received a bupivacaine-dexmedetomidine combination (16).

Li Y et al. found in their study that pain was less in the dexmedetomidine group than in the other groups 6 and 12 hours after surgery, but the sedation score was the same in both groups. The difference in sedation results could be due to the use of a low dexmedetomidine dose of 1 compared to 2 micrograms/kg in our study (12).

### 5.3. The Number of Injections and Total Dose of Analgesic

In our study, the number of analgesic injections in the dexmedetomidine group 6 and 24 hours after the start of the study was significantly lower than in the control group. The total dose of analgesic was significantly lower in the dexmedetomidine group than in the control group 6 and 24 hours after the start of the study.

In the study by Ammar and his colleague, the dose of morphine required was also lower in the dexmedetomidine group than in the control group (14).

In a study conducted by Halder and colleagues, the need for analgesics was also lower in patients treated with dexmedetomidine than in the control group (15).

### 5.4. Complications

None of the subjects in our study experienced complications such as respiratory depression, hypotension or bradycardia. In the Agrawal study, bradycardia was reported in only one case in the dexmedetomidine group (13). In a similar study, Halder and colleagues also reported no adverse effects in either group (15). In the study by Helal and colleagues, 6 patients in the dexmedetomidine group were reported to have bradycardia, whereas this was not the case in the control group (16). Their study was conducted in below-the-knee surgery. This may be the reason for the differences in the results.

### 5.5. Recommendations

In this study, fascia-iliac block was performed with dexmedetomidine and bupivacaine. It is

suggested that similar studies be considered following our study. If possible, a multicenter study with a larger sample size should be conducted. Other side effects are considered except hypotension and bradycardia and respiratory depression. In addition, we recommend using other dosages of dexmedetomidine in future studies. It is also important to investigate the duration of anesthesia, the duration of motor block and the speed of onset of sensory and motor block.

### 5.6. Limitations

In our study, common complications such as hypotension, bradycardia and respiratory depression were investigated, but less common or less important side effects of these drugs were not investigated. If the study had been conducted with a larger sample size, other complications could have been taken into account. Another limitation of this study was that the onset of numbness and the duration of analgesia were not assessed.

## 6. Conclusion

The combination of dexmedetomidine with bupivacaine in compartment block of the iliac fascia is associated with less pain intensity, better sedation and less analgesic injection. We recommend the use of dexmedetomidine in combination with bupivacaine for ultrasound guided fascia iliaca compartment block.

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## Footnotes

**Conflicts of Interest:** None to declare.

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**Ethical Statement:** IR.Hums.

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