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Original Article

A Clinical Comparative Study of Fascia Iliaca Compartment Block with Bupivacaine and Bupivacaine with Dexmedetomidine for Positioning and Duration of Postoperative Analgesia in Fracture Femur under Spinal Anesthesia

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Abstract

Context: Positioning fracture femur cases for sub arachnoid block (SAB) is challenging. Fascia iliaca compartment block (FICB) is low skilled, helps positioning, and provides analgesia. Dexmedetomidine as an adjuvant prolongs analgesia. **Aims:** The aims were to study and compare FICB with bupivacaine and bupivacaine with dexmedetomidine in fracture femur cases with regard to positioning during SAB, duration of analgesia in terms of Visual Analog Scale (VAS), Numerical Rating Scale (NRS), and Patient Satisfaction Score, and assess side effects. **Settings and Design:** This was a randomized, double-blind, prospective study. **Subjects and Methods:** Sixty fracture femur patients were divided into two groups as follows: Group A: FICB with injection bupivacaine 0.25% 38 cubic centimeter (cc) + dexmedetomidine 0.5 μg/kg in 2 cc normal saline (NS) and Group B: FICB with injection bupivacaine 0.25% 38 cc + 2 cc NS. **Statistical Analysis Used:** Data were analyzed using SPSS 22.0 software. Categorical data were processed by frequencies and proportions, whereas continuous data were processed by mean standard deviation. Chi-square test and independent *t*-test were used as tests of significance, considering $P < 0.05$ as statistically significant. **Results:** In Group A, mean VAS score at 5 min (min) was 3.7 ± 0.9 and in Group B it was 4.3 ± 0.7. Similarly, at 15 min, mean VAS score in Group A was 0.4 ± 0.6 and in Group B it was 1.9 ± 0.9. VAS score was significantly high in Group B at 5, 10, and 15 min. Mean time to rescue analgesia in Group A was 838.3 ± 82.7 min and in Group B it was 461.5 ± 36.6 min, which was significant. **Conclusion:** FICB ensures patient comfort during positioning for SAB and provides postoperative analgesia. Dexmedetomidine significantly prolongs postoperative analgesia.

Keywords: Anesthesia, bupivacaine, dexmedetomidine, fascia iliaca compartment block, spinal

Introduction

Spinal anesthesia is a useful technique of anesthesia, especially for lower-limb and lower abdominal surgeries. It offers various advantages such as excellent muscle relaxation for the surgeon and total obtundation of the surgical stress response. It is a safe, reliable, and an inexpensive technique for providing surgical anesthesia and postoperative pain relief in lower-limb and lower abdominal surgeries. The disadvantage of this technique is its limited duration of action. Various adjuvant drugs such as opioids, nonopioids, and α_2-agonists such as clonidine and dexmedetomidine have been added with bupivacaine to improve the quality of perioperative analgesia and also to minimize the local anesthetic dosage requirement, particularly in high-risk patients and in ambulatory procedures.

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Lower-limb surgeries such as fracture femur pose a challenge to anesthesiologists, in that positioning of such cases for spinal anesthesia is often difficult because of excruciating pain. This also presents difficulty in the administration of spinal anesthesia because of inappropriate position of the patient. Even minimal overriding of fracture ends will be extremely painful in these patients. Pain arises from the periosteum of

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bone, which is very sensitive and causes muscle spasm which further displaces fracture ends, worsening the pain.

Hence, there was a need to offer good pain relief to such patients in order to facilitate appropriate positioning for spinal anesthesia. Further, this also offers comfort to the patient and reduces stress response because of pain relief.

Recently, few authors have used fascia iliaca compartment block (FICB) in order to offer analgesia for positioning of patients in fracture femur. The FICB was initially described by Dalens *et al*. using a landmark technique. Advantages of FICB include requirement of low skilled, inexpensive method and can easily be administered using anatomical landmarks to provide perioperative analgesia in patients with fracture femur.[1]

Bupivacaine, a long-acting local anesthetic, has been traditionally used to offer postoperative analgesia. Many additives such as opioids, nonopioids, and α_2-adrenergic agonists such as clonidine are being added with bupivacaine in various nerve blocks.[1] Dexmedetomidine has been added as an adjuvant to local anesthesia in various blocks such as supraclavicular, by various authors, and has been shown to prolong postoperative analgesia as shown in a study done by Agarwal *et al*.[2] Hence, in the present study, we intend to compare FICB with bupivacaine and bupivacaine with dexmedetomidine for positioning and duration of postoperative analgesia in fracture femur under spinal anesthesia.

Objectives of the study

The objective was to study and compare FICB with bupivacaine and bupivacaine with dexmedetomidine in fracture femur under spinal anesthesia with regard to:

1. Positioning of patient during spinal anesthesia in terms of Visual Analog Scale (VAS) and Numeric Rating Scale (NRS) score
2. Duration of postoperative analgesia in terms of VAS and NRS scores
3. Patient Satisfaction Score at the end of the study
4. To assess any side effects such as hypotension, bradycardia, and sedation associated with the drug.

Subjects and Methods

This is a randomized, double-blind, prospective study.

Source of data

The source of data included sixty patients admitted for fracture femur surgeries, done under SAB, at a tertiary referral hospital during January 2016–January 2017.

Method of collection of data

Inclusion criteria

Patients with physical status American Society of Anesthesiologists (ASA) classes I and II, aged between 18–50 years of either sex, and posted for elective surgery of fracture femur under spinal anesthesia were included in the study.

Exclusion criteria (other than those to spinal anesthesia)

Patients with a history of known allergy to any drugs, especially dexmedetomidine and local anesthetics, uncontrolled hypertension, ischemic heart disease, uncontrolled diabetes mellitus, cerebrovascular disease, renal and hepatic diseases, bronchial asthma, and drug and alcohol abuse were excluded from the study.

Sampling procedure

After obtaining approval from the Institutional Ethics Committee and obtaining written informed consent, the study was conducted on sixty patients belonging to physical status ASA classes I and II, aged 18–50 years, and who were scheduled to undergo surgery under spinal anesthesia for fracture femur. A day prior, preoperative visit was made and thorough clinical evaluation was conducted and necessary investigations were ordered and reviewed. Patients were kept nil oral prior to surgery for 8 h and premedication tablet rantac 150 mg and tablet alprazolam 0.25 mg were given at night.

After shifting patients to operation theater, intravenous (IV) cannula with 18G vasofix was secured, and baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation (SpO_2) were recorded.

Patients were randomly allocated to two groups by a computer-generated table.

- Group A received FICB with injection bupivacaine 0.25% 38 cc with injection dexmedetomidine 0.5 μg/kg in 2 cc normal saline (NS)
- Group B received FICB with injection bupivacaine 0.25% 38 cc with 2 cc NS.

FICB was given using anatomical landmark technique and two-pop technique as described by Dalens *et al*.[1]

HR, SBP, DBP, MAP, and SpO_2 were recorded every 5 min for 15 min. After this, patients were positioned for spinal anesthesia and VAS and NRS scores were noted as shown in Figures 1 and 2. After administration of spinal anesthesia, HR, SBP, DBP, MAP, and SpO_2 were recorded every 10 min till the completion of surgery. After surgery, patients were shifted to postanesthetic care unit and hemodynamics was monitored. The time to first postoperative rescue analgesia as evidenced by VAS ≥4 and NRS ≥4 was noted and rescue analgesia in the form of injection diclofenac sodium 1 mg/kg was administered intramuscularly.

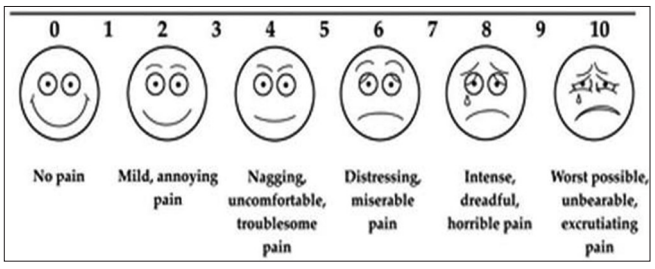

Figure 1: Visual Analog Scale[3]

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At the end of study, Patient Satisfaction Score as adopted by Ittichaikulthol *et al*. was recorded.[4]

This is a numerical score from 1 to 4 as follows:

- 1 – Poor
- 2 – Fair
- 3 – Good
- 4 – Very good.

Any adverse effects such as hypotension, bradycardia, and sedation were recorded. Sedation was assessed using Ramsay's Sedation Score.[5]

Ramsay Sedation Scale

Ramsay Sedation Scale scores are as follows:

1. Patient is anxious, agitated, or restless
2. Patient is cooperative, oriented, and tranquil alert
3. Patient responds to commands
4. Asleep, but with brisk response to light glabellar tap or loud auditory stimulus
5. Asleep, sluggish response to light glabellar tap or loud auditory stimulus
6. Asleep, no response.

Statistical analysis

Data were entered into Microsoft Excel (MS office) data sheet and were analyzed using SPSS 22.0 version software (IBM SPSS Statistics, Somers, NY, USA). Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as the test of significance. Continuous data were represented as mean and standard deviation. Independent *t*-test was used as the test of significance to identify the mean difference between two groups. $P < 0.05$ was considered statistically significant.

Sample size

Sample size was estimated using the mean duration of analgesia in bupivacaine (7.85 ± 1.62) and bupivacaine with other drug (9.875 ± 0.99) as described by Kumar *et al*. and a pilot study, respectively.[6] Using these values at 99% confidence limit and 99% power, a sample size of 14 was obtained in each group. With 10% nonresponse, a sample size of 14 + 1.4 ≈ 16 cases was calculated in each group.

Sample size estimation formula

$$\text{Sample size} = \frac{2SD^2(Z_{\alpha/2} + Z_{\beta})}{d^2}$$

Where *SD* is the standard deviation (from previous studies or pilot study)

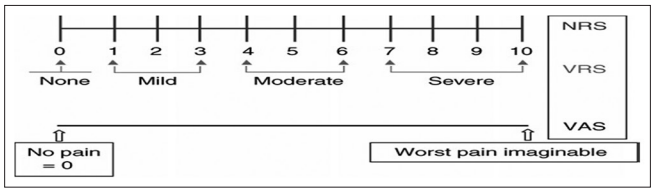

Figure 2: Numerical Rating Scale[3]

$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ (from Z table) at type 1 error of 5%

$Z_{\beta} = Z_{0.20} = 0.842$ (from Z table) at 80% power

d = effect size = difference between mean values.

Using the above-mentioned formula, the sample size was calculated as follows:

$$\text{Sample size} = \frac{2SD^2(1.96 + 0.84)^2}{d^2}$$

$Z_{\alpha/2} = 2.58$ at 99% confidence limit

$Z_{\beta} = 2.33$ at 99% confidence limit.

Results

A total of sixty patients were enrolled in the present study. Thirty patients were randomly selected to be included in each group.

Graphical representation of data

MS Excel and MS word were used to obtain various types of graphs such as bar diagram and line diagram.

$P < 0.05$ was considered statistically significant after assuming all the rules of statistical tests.

Statistical software

MS Excel and SPSS version 22.0 were used to analyze data.

In Group A, mean VAS score at 5 min was 3.7 ± 0.9 and in Group B it was 4.3 ± 0.7. Similarly, at 15 min, mean VAS score in Group A was 0.4 ± 0.6 and in Group B it was 1.9 ± 0.9. VAS score was significantly high in Group B than in Group A at 5, 10, and 15 min with $P < 0.001$ which was considered statistically significant as shown in Table 1.

In Group A, mean NRS score at 5 min was 3.6 ± 0.8 and in Group B it was 3.9 ± 0.7. Similarly, at 15 min, mean VAS score in Group A was 0.3 ± 0.5 and in Group B it was 1.9 ± 1.0. NRS score was significantly high in Group B than in Group A at 10 and 15 min with $P < 0.001$ which was considered statistically significant as shown in Table 2.

Heart rate comparison between two groups at different time intervals

In this study, there was statistically significant difference in mean HR between two groups at various intervals, but there was no significant bradycardia. Mean HR was significantly

Table 1: Visual Analog Scale score comparison between two groups

VAS	Group (mean±SD)		*P*
	Group A	Group B	
5 min	3.7±0.9	4.3±0.7	0.018*
10 min	2.1±0.8	3.6±0.7	<0.001*
15 min	0.4±0.6	1.9±0.9	<0.001*

**P* value statistically significant. SD=Standard deviation, VAS=Visual Analog Scale

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Table 2: Numerical Rating Scale score comparison between two groups

NRS	Group (mean±SD)		*P*
	Group A	Group B	
5 min	3.6±0.8	3.9±0.7	0.116
10 min	2.4±0.9	3.4±0.7	<0.001*
15 min	0.3±0.5	1.9±1.0	<0.001*

**P* value statistically significant. SD=Standard deviation, NRS=Numerical Rating Scale

Table 3: Time to rescue analgesia comparison between two groups

	Group (mean±SD)		*P*
	Group A	Group B	
Time to rescue analgesia (min)	838.3±82.7	461.5±36.6	<0.001*

**P* value statistically significant. SD=Standard deviation

Table 4: Patient Satisfaction Score comparison between two groups

	Group (mean±SD)		*P*
	Group A	Group B	
Patient satisfaction score	3.6±0.5	3.0±0.7	0.001*

**P* value statistically significant. SD=Standard deviation

Table 5: Ramsay Sedation Score comparison between two groups

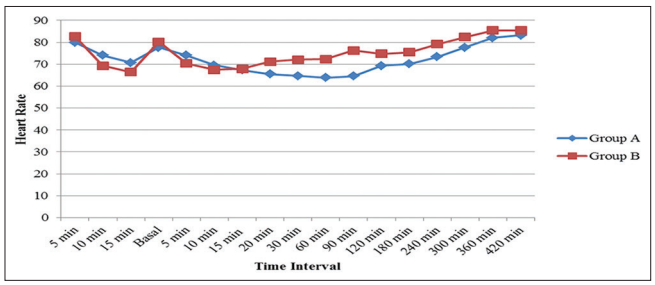
	Group (mean±SD)		*P*
	Group A	Group B	
Ramsay Sedation Score	2.2±0.5	2.0±0.4	0.157

SD=Standard deviation

Table 6: Adverse effects' comparison between two groups

Adverse effects	Group			
	Group A		Group B	
	Count	Percentage	Count	Percentage
Nil	25	83.3	28	93.3
Hypotension	4	13.3	2	6.7
Hypotension + nausea	1	3.3	0	0

χ^2=1.836, df=2, *P*=0.399



Graph 1: Line diagram showing heart rate comparison between the two groups

low initially in Group B and from 20 min HR was significantly high in Group B than in Group A [Graph 1].

Mean arterial pressure comparison between two groups at different time intervals

In this study, there was statistically significant difference in mean MAP between two groups at 10 and 15 min and from 10 to 240 and then to 420 min. At other intervals, there was no significant difference between the two groups. Mean SBP was significantly high in Group B than in Group A as shown in Graph 2.

In the study, there was no significant difference in mean SpO_2 at various intervals which was between 96% and 99%.

In Group A, mean time to rescue analgesia was 838.3 ± 82.7 min and in Group B it was 461.5 ± 36.6 min. This difference in mean time to rescue analgesia was statistically significant as shown in Table 3.

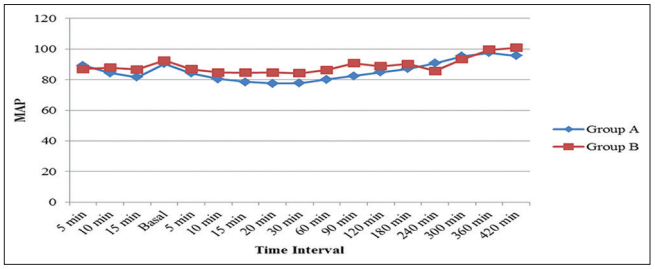
Mean Patient Satisfaction Score in Group A was 3.6 ± 0.5 and in Group B it was 3 ± 0.7. This difference in mean Patient Satisfaction Score was statistically significant as shown in Table 4.

Mean Ramsay Sedation Scale score in Group A was 2.2 ± 0.5 and in Group B it was 2 ± 0.4. This difference in mean Ramsay Sedation Scale score between two groups was not statistically significant as shown in Table 5.

In Group A, 13.3% had hypotension and 3.3% had hypotension + nausea and in Group B, 6.7% had hypotension. There was no statistically significant difference (*P* = 0.399) in adverse effects between the two groups as shown in Table 6.

Discussion

Fracture femur is commonly seen following trauma in young individuals or a trivial fall in the elderly. Fracture shaft of femur poses unusual problems to anesthesiologists. These fractures are extremely painful as the pain arises from the periosteum and are subjected to major muscle forces that will deform the thigh and can angulate the bone fragments further, thus worsening the pain. It will also complicate the intraoperative reduction of the fracture. Hence, all the muscles acting on the femur need to be completely paralyzed. Surgery is the definitive treatment of fracture femur cases. Surgical reduction if done within 2 days of fracture reduces significant morbidity and mortality.[7]



Graph 2: Line diagram showing mean arterial pressure comparison between the two groups at different time intervals

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Spinal anesthesia is a routinely used technique for reduction of fracture in these patients with fracture femur. Positioning of these patients for subarachnoid block becomes extremely challenging. However, any overriding of the fracture ends is extremely painful, and the procedure of patient positioning to perform a spinal block always requires the administration of a large amount of IV analgesics.

Various conventional forms of analgesics such as opioids and nonsteroidal anti-inflammatory drugs (NSAIDS) should be used with caution in patients with comorbidities such as diabetes mellitus or renal dysfunction. NSAIDS may worsen renal function. Opioids have shown to cause significant respiratory depression and other side effects such as drowsiness, nausea, and vomiting.

Femoral nerve block has been shown to be an effective method of analgesia for fractured femoral shaft when it is performed either during prehospital management or in the emergency department and also can provide excellent postoperative analgesia.[1,8] In this prospective randomized study, we compared the FICB with injections bupivacaine and dexmetomedine and injection bupivacaine with NS in fracture femur cases posted for surgery under spinal anesthesia.

Demographic data

Age and gender distribution between the two groups in our study was comparable and was not statistically significant.

Visual Analog Scale and Numerical Rating Scale scores

We studied the efficacy of FICB in fracture femur patients with bupivacaine and bupivacaine with dexmedetomidine in positioning patients for SAB and the duration of postoperative analgesia using VAS scores and NRS scores. This is similar to other studies as described below. In a prospective study done by Kumar *et al*., in fifty patients undergoing surgery for hip fracture, FICB was given preoperatively before spinal anesthesia as it has analgesic property as well as controls surgical stress response.[9] It also helps in positioning for subarachnoid block. In this study, VAS score was assessed before block and after 20 min of block with scales ranging from 0 to 10. Before FICB, average VAS was 7.5 which decreased to an average of 2.94 at 20 min after block, which was statistically significant ($P < 0.01$). During positioning for spinal anesthesia, 46 patients had VAS <4.

In a study by Williams *et al*., patients with femoral neck fracture were divided into two groups, wherein one group received standard preoperative analgesia with paracetamol and opioids as required and the other group received FICB with standard preoperative analgesia.[10] Pain was assessed using VAS score. The VAS score following standard analgesia plus FICB was significantly lower compared to standard analgesia alone ($P = 0.001$). In standard analgesia group, the VAS score reduced after 15 min but was not statistically significant ($P = 0.76$). In patients with standard analgesia plus FICB, the VAS score reduced after 15 min and the analgesia lasted for the entire 8 h.

In a prospective study done on hip fracture patients by Groot *et al*., where 43 patients were administered FICB using anatomical landmark technique as described by Dalens *et al*.,[1,11] FICB was administered by residents with varying levels of experience. Pain levels were assessed at varying intervals following procedure using NRS score. It was shown that there was reduction in pain at the time of admission and patients experienced less pain after the FICB with low NRS scores compared to basal, which was statistically significant ($P = 0.04$). FICB was found to be an efficient, safe, and practical method of reducing pain in hip fracture patients.

In our study, following administration of FICB, VAS scores were assessed at 5, 10, and 15 min interval. In Group A, mean VAS score at 5 min was 3.7 ± 0.9 and in Group B it was 4.3 ± 0.7. Similarly, at 15 min, mean VAS score in Group A was 0.4 ± 0.6 and in Group B it was 1.9 ± 0.9. VAS score was significantly high in Group B than in Group A at 5, 10, and 15 min with $P = 0.018$, $P < 0.001$, and $P < 0.001$, respectively.

Whereas in Group A, mean NRS score at 5 min was 3.6 ± 0.8 and in Group B it was 3.9 ± 0.7. Similarly, at 15 min, mean NRS score in Group A was 0.3 ± 0.5 and in Group B it was 1.9 ± 1.0. NRS score was significantly high in Group B than in Group A at 10 and 15 min with $P < 0.001$. Hence, FICB administered preoperatively helps in effectively positioning the patients for spinal anesthesia by reducing VAS and NRS scores significantly.

Hemodynamic parameters

Heart rate and mean arterial pressure

In our study, we found that the mean HR and MAP in Group A were lower than that in patients of Group B, which was statistically significant, but did not cause any significant bradycardia or associated hypotension. This could be explained as an effect of injection dexmedetomidine added to injection bupivacaine which is known to occur.

In a prospective study done by Paria *et al*., fifty patients posted for hip-and-knee fracture surgeries were administered FICB preoperatively.[12] All patients were co-operative for intrathecal procedure following FICB as it reduced the pain effectively. Hemodynamic fluctuations were absent intraoperatively.

In our study, there was significant difference in mean HR and mean MAP between the two groups at various intervals. Mean HR and mean SBP were significantly low in Group A than in Group B.

Duration of analgesia

Various studies have shown that FICB provides effective postoperative analgesia. In our study, we assessed the duration of postoperative analgesia by measuring the time to rescue analgesia which was administered when the VAS score was ≥4.

Kumar *et al*. in their study on sixty patients with fracture femur administered FICB preoperatively where injection dexamethasone was used as an adjuvant to bupivacaine in one group of patients receiving FICB and the other group receiving

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injection bupivacaine with NS.[6] Duration of analgesia was noted using time to rescue analgesia which was administered when the VAS ≥4. In this study, the duration of analgesia was significantly longer in dexamethasone group which was 16.33 ± 5.69 h when compared to the other group which was 7.85 ± 1.62 h and was found statistically significant with $P < 0.001$.

In a study done by Kumie *et al*. on patients with femur fracture, FICB was given to check its efficacy as a part of multimodal analgesia following surgery.[13] Duration of analgesia was noted using VAS score and request for first analgesia. It was found that VAS scores were less in FICB group. The FICB group had a longer time for the first analgesic request than the control group (417 ± 112.10).

A study done by Wallace *et al*. included sixty patients who were posted for knee arthroscopy procedure.[14] One group of patients were given FICB and the other group of patients received 3-in-1 block. They concluded that longer duration of postoperative analgesia was found with FICB but was not statistically significant. The time to first analgesic request was 497 ± 620 min in the 3-in-1 group and 649 ± 636 min in the FICB group with $P = 0.39$.

In our study, in Group A, mean time to rescue analgesia was 838.3 ± 82.7 min and for Group B, it was 461.5 ± 36.6 min. This difference in mean time to rescue analgesia was statistically significant with $P < 0.001$.

Patient Satisfaction Score

Quality of analgesia was assessed using Patient Satisfaction Score at the end of the study. Various studies have shown excellent patient comfort with good quality and duration of analgesia with FICB.

Wallace *et al*. showed that both FICB group and 3-in-1 block group had lower and similar Patient Satisfaction Scores with a median score of 1 (complete satisfaction). *P* value of Patient Satisfaction Score between the two groups was 0.67 and was not significant.[14]

Rahimzadeh *et al*. found that Patient Satisfaction Score was better in the group of patients who received 0.2% bupivacaine for FICB than 0.3% bupivacaine.[15]

Pandya and Jhanwar found that among patients who received FICB, 76.67% of patients rated it as excellent, 16.66% as good, and 6.67% as poor quality of analgesia, whereas among patients who received 3-in-1 block analgesia, it was rated as excellent, good, and poor by 56.77%, 36.66%, and 6.67% of patients, respectively.[16]

In our study, mean Patient Satisfaction Score in Group A was 3.6 ± 0.5 and in Group B it was 3 ± 0.7. This difference in mean Patient Satisfaction Score was statistically significant. Hence, it is shown that quality of analgesia was better in patients who received FICB with injection bupivacaine and dexmedetomidine than with bupivacaine alone.

Adverse effects

Similar to various other studies, there were no significant adverse effects noted in the study. In our study, in Group A, 13.3% of patients had hypotension and 3.3% had hypotension and nausea and, in Group B, 6.7% had hypotension, which was not statistically significant with $P = 0.399$.[6,11]

Strengths and limitations of study

This block is easy to administer and cost-effective. It reduces pain scores significantly during positioning for spinal anesthesia and prolongs the duration of postoperative analgesia.

The block success with this "feel" technique is sporadic because false "pops" can occur. Ultrasound-guided technique is essentially the same; however, monitoring of the needle placement and local anesthetic delivery assures deposition of the local anesthetic into the correct plane.[17]

Conclusion

We conclude that FICB is safe, easy to perform, and provides effective analgesia without any hemodynamic instability or any adverse effects.

From our study, FICB done prior to spinal anesthesia was found to ensure the following:

- Patient comfort during positioning for subarachnoid block and also provides postoperative analgesia
- Adding dexmedetomidine to plain bupivacaine significantly prolongs postoperative analgesia when compared to plain bupivacaine.

Acknowledgment

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Nil.

Conflicts of interest

There are no conflicts of interest.

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