ORIGINAL ARTICLE ASIAN JOURNAL OF MEDICAL SCIENCES

To evaluate the efficacy of ropivacaine with dexmedetomidine and ropivacaine with dexamethasone in fascia iliaca compartment block for post-operative pain relief in fracture femur surgeries: A comparative randomized study

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Submission: 12-01-2023 Revision: 02-04-2023 Publication: 01-05-2023

ABSTRACT

Background: Patients with femur fracture experience severe post-operative pain. Fascia iliaca compartment block (FICB) is a safe and effective approach for providing post-operative analgesia. **Aims and Objectives:** The aim of the study was to compare the post-operative pain relief with dexmedetomidine and dexamethasone with ropivacaine in FICB. **Materials and Methods:** This prospective, double-blinded, randomized controlled, and clinical study was done on 105 patients, with ASA physical status I-II, aged between 18 and 70 years, undergoing surgery for femur fracture. Patients were randomly allocated into three groups. All patients received FICB by landmark technique before spinal anesthesia. Group A patients received 38 mL of 0.25% ropivacaine and dexmedetomidine, Group B received 38 mL of 0.25% ropivacaine and dexamethasone and Group C received 38 mL of 0.25% ropivacaine. Patients were assessed for analgesia during positioning and post-operative period using visual analog scale (VAS). Hemodynamic parameters and time for first rescue analgesia were recorded. **Results:** The mean VAS score at 6 h after surgery was 0.74 ± 0.95 in Group A, in Group B 2.26 ± 0.95, and in Group C was 4.23 ± 1.17, which was statistically significant ($P < 0.05$). The time for first rescue analgesia was 13.03 ± 1.79 h in Group-A, 8.31 ± 1.11 h in Group B and 5.94 ± 0.87 h in Group C ($P < 0.001$). **Conclusion:** Addition of dexmedetomidine or dexamethasone to ropivacaine for FICB in femur fracture patients prolongs post-operative analgesia compared to ropivacaine alone.

Key words: Dexmedetomidine; Dexamethasone; Ropivacaine; Fascia iliaca compartment block; Post-operative analgesia

Access this article online

Website: http://nepjol.info/index.php/AJMS

DOI: 10.3126/ajms.v14i5.51389

E-ISSN: 2091-0576

P-ISSN: 2467-9100

INTRODUCTION

A fracture femur is a common injury that is associated with excruciating pain. Surgeries for the fracture femur are generally done under spinal anesthesia, which offers excellent muscle relaxation and near-total attenuation of the surgical stress response.[1] It is a safe and reliable technique for providing surgical anesthesia and post-operative pain relief in the lower limb surgeries. However, the disadvantage of this technique is its limited duration of action. Furthermore, positioning for spinal anesthesia in such cases is difficult due to excruciating pain. Hence, there was a need to provide good pain relief to these patients to facilitate appropriate positioning for spinal anesthesia and to provide post-operative analgesia. Successful pain

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management enhances early ambulation and reduces hospital stays.

Conventional pain treatment (NSAIDs, paracetamol, and opioids) has various side effects.[2] This makes the role of multimodal analgesia more relevant for patients suffering from a femur fracture. Peripheral nerve blocks provide effective unilateral analgesia and reduce the chances of opioid-related and autonomic side effects, producing less motor blockade, and fewer neurological complications.[3]

Fascia iliaca compartment block (FICB) has been shown previously that it provides effective post-operative analgesia for fracture femur when given preoperatively.[4] To improve the quality of peripheral nerve blocks, many adjuvants (such as opioids, non-opioids, clonidine, ketamine, and epinephrine) have been added to local anesthetics.[5,6]

One such agent is dexmedetomidine, it is a potent as well as highly selective alpha-2 adrenergic agonist having a sedative, sympatholytic, and analgesic effect and has been described as a safe and effective additive in many anesthetic applications and analgesic techniques.[7,8] Another agent glucocorticoid, dexamethasone, has also been shown to be effective in a number of clinical studies.[9,10] Steroid produces a degree of vasoconstriction, thereby reducing local anesthetic absorption. Furthermore, it potentiates the activity of inhibitory potassium channels on nociceptive C fibres (through glucocorticoid receptors), thereby decreasing the activity of nociceptive C fibres.[11]

To the best of our knowledge, there are limited studies that have compared the effect of adding dexmedetomidine and dexamethasone to ropivacaine in fascia iliaca block.

Aims and objectives

The aim was to compare the efficacy of dexmedetomidine and dexamethasone as an adjuvant to ropivacaine for post-operative analgesia with FICB in fracture femur surgeries.

Primary objectives

The primary objectives of this study were to assess the duration and quality of post-operative analgesia in the first 24 h.

Secondary objectives

The secondary objectives of this study were to assess pre-operative pain relief and patient comfort while positioning for anesthesia.

MATERIALS AND METHODS

Study design

This study was prospective double-blind randomized study.

Sample size

Sample size is estimated using the mean duration of analgesia with ropivacaine alone (5.37±0.56) and with ropivacaine and dexmedetomidine (6±0.86) based on the study conducted by Bagle et al.[12]

Using these values at 95% confidence interval and 95% power of test, the following sample size formula was used. A sample size of 35 obtained in each group.

Sample size estimation formula was used as:

$$n = \frac{(Z_{\alpha/2} + Z_{1-\beta})^2 \times (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)^2}$$

S_1=0.56
S_2=0.86
μ_1=5.37
μ_2=6
$Z_{\alpha/2}$=1.96
$Z_{1-\beta}$=1.64
So, n=35
So, in each group, 35 samples were taken

Total sample size=105 study participants were included.

Inclusion criteria

The following criteria were included in the study:

1. Consent to participate in study
2. Patients scheduled for fracture femur surgeries under spinal anesthesia.
3. Age group 18–70 years
4. ASA Physical Grade I and II.

Exclusion criteria

The following criteria were excluded from the study:

1. Patient's refusal
2. Uncooperative patient
3. History of any significant pulmonary, cardiovascular, endocrinal, neurological, hepatorenal, psychiatric, or metabolic disease
4. Age below 18 years and above 70 years
5. Patients with allergy to local anesthetics
6. Patients having peripheral neuropathy, bleeding diathesis, femoral bypass surgery, and inguinal hernia
7. Local infection at the site of injection.

After detailed pre-operative assessment and routine physical examination, along with relevant mandatory investigations, the study was conducted on 105 patients belonging to physical status ASA classes I and II, aged 18–70 years, and who were scheduled to undergo surgery under spinal anesthesia for fracture femur.

After shifting the patient to the operating room, an intravenous (IV) cannula with 18 G vasofix was secured, and baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation was recorded.

Patients were randomly allocated to three groups by envelope method: Group A, Group B, and Group C of 35 patients each.

- Group A received FICB with injection of ropivacaine 0.25% 38 cc with injection dexmedetomidine 1 μg/kg in 2 cc normal saline (NS) total volume: 40 mL
- Group B received FICB with an injection of ropivacaine 0.25% 38 cc with an injection of dexamethasone 8 mg (2 mL) total volume: 40 mL
- Group C received FICB with injection ropivacaine 0.25% 38 cc with 2 cc normal saline (NS) total volume: 40 mL.

FICB was given using the anatomical landmark technique and two-pop technique as described by Dalens et al.[13] All vital parameters were recorded. 15 min after administering the block, the quality of pain relief during positioning for spinal anesthesia was assessed subjectively: satisfactory/not satisfactory.[14] The SAB was then administered using Inj. Bupivacaine 0.5% (Heavy)- 3 mL, and surgery was allowed to proceed after the absence of pinprick sensation at or above T10 dermatomal level. During the whole intraoperative period, vital monitoring was done at 15, 30, 60, 90, 120, 150, and 180 min.

After completion of the surgery, patients were shifted to post-operative ward, vital parameters and visual analog scale (VAS) score was noted at immediate post-operative period, 1, 2, 4, 6, 8, 12, and 24 h postoperatively.

Patients were given rescue analgesia of Inj. Tramadol 100 mg IV, whenever they complained of pain or reported VAS more than 4. Time of first administration of rescue analgesic was noted. VAS score was recorded until patient requested for 1st rescue analgesia that was duration of post-operative analgesia.

RESULTS

There were no statistically significant differences in distribution of all demographic characteristics in all the three groups.

At 2 h, 4 h and 6 h postoperatively, Group A has significantly lower VAS score compared to Group B and Group C, while, at 8 h postoperatively, Group B showed highest VAS score compared to both Groups A and B.

DISCUSSION

FICB has been known to block the femoral, lateral femoral cutaneous nerve, and obturator nerve by the central spread of local anesthetic (volume-dependent block).[14] It also provides adequate analgesia for fractures of the proximal femur and hip joint. Since then, it is being used as a technique of analgesia following surgical procedures in hip, femur, knee, and thigh burn treatment. The beneficial effects of FICB over NSAIDS, fentanyl, gabapentin, or other nerve blocks have been studied.[3] A study done by Anaraki and Mirzaei[15] showed that the use of pre-emptive gabapentin when compared with 0.5% bupivacaine in FICB had lower post-operative satisfaction and duration of analgesia. Furthermore, it is a safe and more efficacious alternative compared to the 3-in-1 block as described by the study done by Pandya and Jhanwar,[16] where they compared the fascia iliaca block with a 3-in-1 nerve block and observed that there was a better sensory blockade of a lateral cutaneous nerve of the thigh with FICB.

Table 1 is showing that demographic profile was comparable in our study, between all groups, there was no difference in terms of demographic data (age, weight, sex, and ASA grading) (P>0.050). Similar study done by Dubey et al.,[9] in their study on FICB with ropivacaine alone and with dexamethasone, found similar demographic data which were comparable to our study.

In Table 2, we found that the 97% of patients (34 patients) in both Groups A and B had satisfactory quality of pain relief, while in Group C, 94% (33 patients) of patients reported satisfaction during positioning for spinal anesthesia. However, the difference between the three groups was statistically insignificant (P=0.771). The findings in our study were supported by the study done by Sana et al.,[14] on post-operative pain relief with FICB using dexmedetomidine and dexamethasone with bupivacaine. They also did not observe any significant difference between the group dexamethasone, group dexmedetomidine, and plain bupivacaine in patient positioning during spinal anesthesia which was statistically insignificant (P>0.05).

In Figures 1 and 2, HR, SBP, DBP, MAP, and Spo_2 showed no statistically significant difference among the groups (P>0.05). Our findings correlated with the study conducted by Sabra et al.,[17] on ultrasound (USG)-guided FICB with ropivacaine and dexmedetomidine for post-operative analgesia in hip arthroplasty.

In our study, we assessed and compared the VAS score at different time intervals. The VAS score in our study was higher mostly in Group C (plain ropivacaine) compared to

Table 1: Demographic profile of study participants

Demographic parameter	Group A	Group B	Group C	P-value
Age (years)	45.97±17.78	46.17±17.53	45.57±17.25	0.989
Weight (kg)	65.11±8.99	67.26±9.43	66.89±8.72	0.573
Gender				
Male	12	12	11	0.958
Female	23	23	24	
ASA grade				
I	8	7	6	0.836
II	27	28	29	

Table 2: Pain relief during positioning of Subarachnoid block

Quality of pain relief	Group A versus Group B versus Group C			
	Group A	Group B	Group C	P-value
Satisfactory	34	34	33	0.771
Unsatisfactory	1	1	2	
Total	35	35	35	

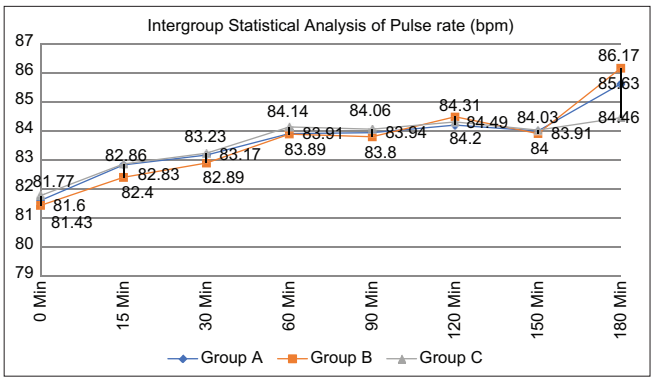

Figure 1: Mean pulse rate

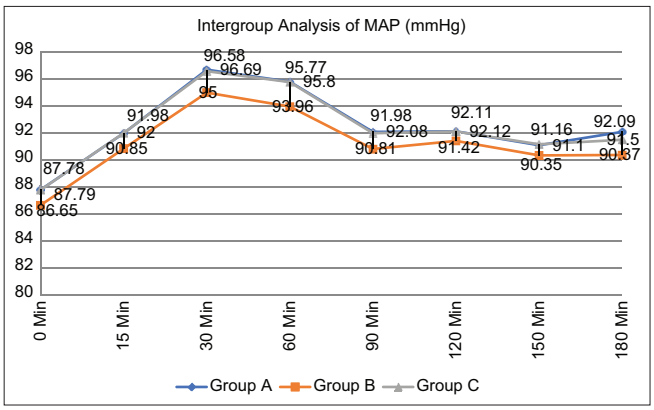

Figure 2: Mean blood pressure

Group B (Dexamethasone with ropivacaine) and Group A (Dexmedetomidine with ropivacaine).

In Table 3, VAS score at 6 h was 0.74±0.95 in Group A, 2.26±0.95 in Group B, and 4.23±1.17 in Group C, P<0.001 which was highly significant between the groups.

Similar results were seen in the study conducted by Sana et al.,[14] on post-operative pain relief with FICB using dexmedetomidine and dexamethasone with bupivacaine, they found out there was statistically significant difference between plain bupivacaine and dexamethasone and plain bupivacaine and dexmedetomidine at 8 and 12 h. In another study conducted by Li et al to determine the post operative analgesia of ropicacaine and dexmedetomidine for USG guided fascia iliaca block after knee arthroscopic surgery, VAS score was much less in dexmedetomidine group as compared to plain ropivacaine alone at 6 h and 12 h after surgery with P<0.05, which was statistically significant.

In Table 4, the time to first rescue analgesia of Group A was 13.03±1.79 h, in Group B was 8.31±1.11 h, and in Group C was of 5.94±0.87 h, P<0.001, which was highly significant. Both dexamethasone and dexmedetomidine can reduce local inflammation and prolong the duration of nerve block through vasoconstriction, while dexmedetomidine additionally inhibits hyperpolarization activated cationic current. It blocks the nerve conduction through C and Aδ fibers.[19,20]

Our study was in accordance with study conducted by Sana et al.,[14] the duration of analgesia in group dexmedetomidine was higher as compared to group dexamethasone. It was 16.17 h in group dexmedetomidine and 12.53 h in group dexamethasone, whereas with plain bupivacaine 0.25%, it was 8.23 h. P<0.001 implying that the difference was highly significant between the groups. They concluded that dexmedetomidine as an adjunct to bupivacaine in FICB provided better post-operative analgesia as compared to dexamethasone.

In another study done by Singla et al.,[21] on parturients who received USG-guided bilateral TAP block, time to first rescue analgesic was 474.30 min in group dexmedetomidine, whereas it was 407.30 min in group dexamethasone. P<0.005, and the difference between the groups was statistically significant. Thus, in their study, addition of dexmedetomidine prolonged the time of first rescue analgesia as compared to dexamethasone.

Table 3: Intergroup statistical analysis of VAS score

Time (h)	Group A versus Group B versus Group C				
	Group A	Group B	Group C	f value	P-value
0	0±0	0±0	0±0		
1	0±0	0±0	0±0		
2	0.06±0.34	0.11±0.47	0.43±0.81	4.200	0.018
4	0.2±0.53	0.34±0.76	2.09±1.4	40.895	<0.001
6	0.74±0.95	2.26±0.95	4.23±1.17	101.413	<0.001
8	1.97±0.89	4.25±1.3	2.6±1.34	35.141	<0.001
12	2.97±1.38	2.5±2.52	0±0	0.341	0.563
24	5±0	0±0	0±0		

Table 4: Intergroup statistical analysis time to rescue analgesia

Time (in hours)	Group A	Group B	Group C	P-value
Time to rescue analgesia (in hours)	13.03±1.79	8.31±1.11	5.94±0.87	<0.001

Sabra et al.,[17] in their study on effectiveness of FICB with ropivacaine and dexmedetomidine in hip arthroplasty, found that the addition of dexmedetomidine to ropivacaine significantly prolonged the mean time for first analgesic requirement as compared to plain ropivacaine. It was 381.91±65.10 min in plain ropivacaine, whereas it was 573.33±95.10 min when dexmedetomidine was added as an adjuvant.

Incidence of nausea and vomiting was 11% (4 patients) in both Groups A and C, whereas 14% in Group B (five patients). Hypotension was observed in 5% (two patients) in Group A and 3% (1 patient) in Group C, whereas none of the patients had hypotension in Group B (P<0.05). Gopal and Krishnamurthy[1] found out that incidence of nausea and hypotension in their study between group bupivacaine was 6.7% and group bupivacaine with dexmedetomidine group was 16.6% which was statistically insignificant (P=0.3).

Limitations of the study

The major limitation of our study was that the investigator was unable to objectively quantify and evaluate post-operative pain, which being a subjective experience can be a major limiting factor in comparing and estimating the effectiveness of various modalities of treatment.

CONCLUSION

Dexmedetomidine when added to ropivacaine prolongs the duration of analgesia and decreases analgesic consumption compared to dexamethasone with ropivacaine.

Duration of Analgesia was - Dexmedetomidine + Ropivacaine > Dexamethasone + Ropivacaine > Ropivacaine

Pre-operative pain relief of patients during positioning for spinal anesthesia was comparable in all three groups. Hemodynamic parameters in all three groups remained stable during whole intraoperative period.

ACKNOWLEDGMENT

We are grateful to the patients undergoing fracture femur surgeries and their family for their cooperation in the study. Besides this, the entire team of Department of Anesthesiology, Gajra Raja Medical College helped a lot in this research work.

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NT- Concept and design of the study, prepared first draft of manuscript; **SB**- Interpreted the results; reviewed the literature and manuscript preparation; **NJ**- Concept, coordination, statistical analysis and interpretation; **MJ**- Preparation of manuscript and revision of the manuscript.

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Source of Support: Nil, **Conflicts of Interest:** None declared.