

Original Research Article

Comparison of ropivacaine alone or with dexamethasone as an adjuvant for reducing pain during positioning for neuraxial blockade with ultrasound-guided fascia iliaca compartment block

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Received: 18 April 2020

Accepted: 13 May 2020

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ABSTRACT

Background: Comparison of ropivacaine alone or with dexamethasone as an adjuvant for reducing pain during positioning for neuraxial blockade with ultrasound-guided fascia iliaca compartment block.

Methods: In this double-blinded study, a total of 60 patients between 18 to 80 years of age, undergoing surgery for hip fracture were enrolled. Patients in Group A received 40 ml of 0.25% ropivacaine +2 ml saline and patients in Group B received 40 ml of 0.25% ropivacaine +8 mg dexamethasone. USG guided FICB and postoperative monitoring was done by the chief investigator who was unaware of group allotted and drug administered.

Results: There is no significant difference in the heart rate between the two groups after 30 min of the block. The variation of systolic blood pressure of both the group for the first 30 min after giving FICB block was not significant ($p>0.05$). The absolute value of diastolic blood pressure (DBP) was significantly lower in Group B compared to group A just before the block, a variation of DBP with time was not significant. There was a gradual improvement of pain score from mean 6.7 in Group A and 6.6 in Group B at 0 min to score of 2 at the end of 30 min in both the group. This improvement was achieved earlier in Group B compared to Group A, although the difference was not significant ($p>0.05$). Vital parameters like HR, SBP, DBP, SpO₂ values were similar in both the groups. No patients in either group required any interventions both pre-operatively and post-operatively. Time of rescue analgesia was noted with the VAS score was significantly more in Group B ($p\leq 0.004$). The incidence of hematoma, accidental intravascular injection, convulsion, and paresthesia were nil in both groups.

Conclusions: Although both the groups had comfortable and pain-free positioning for administering spinal anaesthesia before surgery. USG guided FICB is easy to perform block and give excellent analgesia for positioning and mobilization of hip fracture patients pre and post-operatively both, and dexamethasone as an adjuvant to 0.25% ropivacaine prolong its local anesthetic effect significantly.

Keywords: Dexamethasone, Fascia iliaca compartment block, Neuraxial blockade, Ropivacaine, Ultrasound-guided

INTRODUCTION

Hip fractures are common in frail and elderly populations with multiple comorbidities.¹ Multiple co-morbidities placing them at higher risk for perioperative

complications, especially chest infection and heart failure. Positioning for neuraxial blocks is always challenging because even slight overriding of the fracture end is intensely painful. Most of these patients require a position to exudate neuraxial block. Hence, prior to

neuraxial blockade, analgesia is provided by conventional modes of pain relief like non-steroidal anti-inflammatory drugs (NSAIDs), transcutaneous nerve stimulations (TENS), opioids and also by peripheral nerve blocks such as femoral nerve block, 3 in 1 block and Fascia iliaca compartment block (FICB).²⁻⁴ FICB is not a nerve block but a single shot compartment block where a large volume of local anesthetic agent is deposited beneath fascia iliaca which cover femoral nerve on the medial side, lateral femoral coetaneous nerves on the lateral side, and a short course of obturator nerve in the deeper plane. The use of ultrasound to guide regional blocks is becoming increasingly popular as it increases success rates, shortens block onset time and reduces the number of needle insertions and complications, ultrasound-guided FICB has been practiced in this study and it appears to increase the frequency of sensory loss of all three nerves compared to the landmark technique.⁵⁻⁷ The primary objective was a comparison of pain scores for positioning of the patient for spinal anesthesia in patients with proximal femur fracture in the group with ropivacaine alone and a group receiving ropivacaine with dexamethasone. The secondary objective was to compare the duration and degree of postoperative analgesia (time of first rescue analgesia) in groups.

METHODS

This study was carried out at the tertiary care hospital in India. After approval from the institutional ethics committee, written informed consent was obtained from the patients. Out of a total of 67 patients admitted in the ward during the study period (1st January 2015 to 30th June 2017), 4 patients did not meet inclusion criteria and 3 patients expressed their unwillingness to participate in the study. This prospectively studies studied in a randomized, placebo-controlled, double-blind fashion to evaluate the effect of two drugs for pain relief for patients posting before the neuraxial block and postoperative analgesic requirement. Patients with bleeding disorders, allergy to local anesthetics, peripheral neuropathy, hepatic or renal insufficiency, previous femoral bypass surgery, inguinal hernia, inflammation or infection over the injection site, morbid obesity, patients on previous opioid therapy, psychiatric disorders, poly-trauma and those who refused to participate in the study were excluded from the study.

A total of 60 patients in the American Society of Anesthesiologists (ASA) physical status grade I and II, between 18 to 80 years of age, undergoing surgery for proximal femur fracture were enrolled. According to a computer-generated randomization chart, the patients were assigned to one of the two treatment groups. Patients in Group A received 40 ml of 0.25% ropivacaine +2 ml saline and patients in Group B received 40 ml of 0.25% ropivacaine +8 mg dexamethasone. The test drug was prepared and administered by a nurse who was blinded to drug assignment. Either ropivacaine or dexamethasone was taken and diluted with NS to a

volume of 40 ml in a 50 ml syringe and labeled as ‘TEST DRUG’. Vitals were recorded by blinded treating clinicians (SS). USG guided FICB and postoperative monitoring was done by the chief investigator who was unaware of group allotted and drug administered.

A 22-gauge 100 mm needle (Stimuplex ®, B. Braun, Melsungen, Germany), Sonosite Micromax ® (Sonosite ®, Bothell, WA, USA) needle was used for the study. A simple 10-point visual analogue scale (VAS) score to assess the severity of pain was taken. Each Patient was monitored using electrocardiography (ECG), pulse oximetry (SpO₂) and non-invasive blood pressure (NIBP) every 2 minutes until 30 minutes. Comfort while positioning for spinal anesthesia was noted 30 minutes after FICB using the VAS score. Patients reporting pain scores 4 and above were given IV tramadol (100 mg) as rescue analgesia.

The sample size was calculated using Open-EPI version 2.3.1 software. The sample size was calculated based on the study conducted by Kumar N et al.⁸ Two-sided significance level (1-alpha): 95 with power (1-beta, % chance of detecting): 80 and ratio of sample size, unexposed/exposed: 1. 7Percent of patients who needs 1st rescue analgesia was 17 and 57 in Group A and B respectively. Based on this sample size came to be 23 in each group. Statistical analysis was done using SPSS software 11.0. Data obtained are tabulated in the excel sheet and analyzed. All values are expressed as mean + standard deviation. Chi-square test for proportions in qualitative data. Student’s unpaired t-test for quantitative data. p<0.05 was considered statistically significant.

RESULTS

Demographics were compared and were found out to be comparable (Table 1). Age and weight were comparable in both groups. Most of the patients were of 51-70 years of age range. Group B had a predominantly female population.

Table 1: Demographic profile and baseline clinical characteristics of patients in both the group.

Patient data	Group A (n=30) mean±SD	Group B (n=30) mean±SD	P-value
Age (year)	59.2±14.03	58.9±14.5	0.95
Weight (kg)	63.7±10.3	63.6±5.7	1
Gender M/F	16:14	10:20	
ASA (I/II)	08/22	06/24	

All values expressed as mean ± SD or as expressed otherwise

The mean pulse rate ranged around 72 -75 in both groups. The student’s unpaired ‘t’-test showed that there is no significant difference in the pulse rate between the two groups in 30 min after block. The variation of systolic blood pressure of both the group for the first 30 min after

giving FICB block was not significant ($p>0.05$). The absolute value of DBP was significantly lower in group B compared to Group A just before the block, a variation of DBP with time was not significant (Table 2). SpO₂ was maintained throughout the study period. There was a gradual improvement of pain score from mean 7.69 in Group A and 7.52 in Group B at 0 min to score of 2 at the end of 30 min in both the group. This improvement was achieved earlier in Group B compared to Group A, although the difference was not significant ($p>0.05$).

Vital parameters like HR, SBP, DBP, SpO₂ values were similar in both the groups. No patients in either group required any interventions both pre-operatively and post-operatively. Time of rescue analgesia was noted with a VAS score of four or more in both the groups, and it was significantly more in Group B ($p\leq 0.004$).

The incidence of hematoma, accidental intravascular injection, convulsion, and paresthesia were nil in both groups.

Table 2: Systemic hemodynamic parameters at a different time interval (values expressed as mean±SD or number) during the observation period in two groups.

value		T1	T2	T3	T4	T5	T6	T7
HR	Group A	72.2±5.6	73.6±5.5	72.8±5.01	75.2±5.6	72.8±5.9	73.8±5.01	73.8±5.01
	Group B	72.7±5.51	74.6±5.4	73.96±4.8	75.7±5.4	74.4±4.9	74.9±4.7	74.9±4.7
p-value		0.72	0.48	0.38	0.72	0.26	0.38	0.06
SBP	Group A	125.7±8.4	126.1±7.06	125.7±6.6	126.4±6.4	127±6.2	126±6.5	126±5.3
	Group B	124.8±7.9	126.3±7.9	126.5±6.9	124.3±7.8	125±6.9	126±7.2	126±4.2
p-value		0.36*	0.08*	0.38*				
DBP	Group A	83.7±3.8	82.2±3.18	80.7±3.14	83.1±2.8	82.3±3.1	88.3±3.4	80.1±3.1
	Group B	79.3±7.5	78.5±7.37	77.8±6.77	79±6.9	78.4±6.7	77.3±7.1	77±7.3
P-value		0.01, 2.59*	0.02, 2.3*	1.9*				
SpO ₂	Group A	100	99.9±0.2	99.9±0.2	99.9±0.3	99.9±0.2	100	99.9±0.2
	Group B	99.9±0.19	99.8±0.3	99.8±0.3	99.8±0.2	99.8±0.3	99.8±0.3	100
p-value		0.98*	1.36*	0.41*				
VAS score	Group A	6.7	3.2	2	0.5	1.3	1.5	1.5
	Group B	6.6	3.2	2	0.6	1.2	1.4	1.4
p-value		0.30*	-	-	-0.42*	0.35*	0.39*	0.40*

#T1: baseline (before block), T2: 15 min after successful block, T3: 30 min after block, T4: in the postoperative period, T5: 2 hours in the postoperative period, T6: 4 hours in the postoperative period, T7: 06 hours in the postoperative period, HR: heart rate, SBP- systolic blood pressure, DBP: diastolic blood pressure.

DISCUSSION

The world population is aging; in the future, authors will have more traumatic fractures in old age group patients. With the high incidence of side effects of opioids, NSAIDs in the old age group authors need more trials with appropriate an adjuvant to confirm the efficacy of FICB as pre-operative and post-operative analgesia. Candal-Couto et al, demonstrated that FICB allows patients to be able to tolerate a sitting position with a femoral neck fracture.⁹ Elderly patients with fracture femur are more prone to delirium because of pain and medications. Adequate analgesia not only prevents delirium but also, allows increased mobility and shorter hospital stay.¹⁰ Analgesia provided by femoral nerve blockade and FICB not only have less side effect is compared to commonly used epidural analgesia for postoperative pain but also have a lower incidence of hypotension.¹¹⁻¹³

Study preferred FICB block in these surgeries because it is more effective in blocking the lateral cutaneous nerve of the thigh and femoral nerve.¹⁴ It is not only easy to perform but it is also associated with minimal risk as the

local anesthesia agent is injected at a safe distance from the femoral artery. It is always safe to perform the FICB before spinal anesthesia as the patient can respond during the administration of the local anesthetic and can prevent intraneuronal injections.¹⁵ There are reports of postoperative neuropathy when FICB was attempted after spinal anesthesia. Although, ultrasound guidance is theoretically an attractive means of preventing intraneuronal injection due to real-time imaging of the needle and nerve.

This study examined the effect of dexamethasone on 0.25% ropivacaine for FICB in patients with fracture femur. Authors observed that prolongation of block duration was significantly higher when dexamethasone was added as an additive to plain ropivacaine. This block prolongation was also observed when dexamethasone was combined with mepivacaine for supraclavicular blocks.¹⁶ Similarly Cummings KC et al, also observed that dexamethasone significantly prolonged the duration of ropivacaine and bupivacaine when used for the interscalene block.¹¹ The existing literature supports the clinically important benefit authors observed in this study.

Authors took dexamethasone in this study. The region is that no trial has reported neurotoxicity attributable to dexamethasone till now. Also, in this study, no adverse events were detected. Additionally, epidural corticosteroids have been used safely for a long time in treating patients with radicular pain arising from nerve root irritation dexamethasone, in particular, has been studied as an adjuvant to epidural local anesthetics.¹⁷⁻¹⁸ Steroids administered peri-neutrally are eventually absorbed and produce systemic effects. Given IV several steroids have been shown to improve postoperative pain and reduce postoperative nausea and vomiting.¹⁹⁻²⁰ There were no significant differences in pain score for first 30 min in both the groups, although pain relief was achieved earlier in Group B (ropivacaine with dexamethasone)

The time of rescue analgesia was noted with the VAS score of four or more in both the groups and it was significantly more in Group B (p-value=0.004). This result is in contrast with the Suresh et al study which almost showed the double duration of time of rescue analgesia in the group with dexamethasone as an adjuvant.⁸ The incidence of hematoma, accidental intravascular injection, convulsion, and paresthesia were nil in both groups. Authors have reported zero complications in this study. It might be because of extreme caution and attention given to every detail to avoid intravascular injection or damaging the nerve. Authors always made sure that the needle tip was visible throughout the procedure.

The only limitation in this study is that the intensity of pain of different fractures such as fracture neck femur, trochanteric fracture, shaft femur fracture was not taken into consideration.

CONCLUSION

Although both the groups had comfortable and pain-free positioning for administering spinal anesthesia before surgery. USG guided FICB is easy to perform block and give excellent analgesia for positioning and mobilization of femur fracture patients pre and post-operatively both, and dexamethasone as an adjuvant to 0.25%ropivacaine prolong its local anesthetic effect significantly.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Dubey S, Ambi U, Taank P, Singh S, Marwah V. Comparison of ropivacaine alone or with dexamethasone as an adjuvant for reducing pain during positioning for neuraxial blockade with ultrasound-guided fascia iliaca compartment block. *Int J Res Med Sci* 2020;8:2270-4.