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Original Research Article

EFFICACY AND SAFETY COMPARISON OF 0.5% ROPIVACAINE AND 0.5% BUPIVACAINE PREOPERATIVELY IN FEMORAL NERVE BLOCK FOR PAIN MANAGEMENT AND PLACEMENT WHILE PERFORMING REGIONAL ANESTHESIA IN PATIENTS OF FEMUR INTERTROCHANTERIC FRACTURES: RANDOMIZED CLINICAL ANALYSIS.

Sasank Sekhar Mallick[1], Sansaya Mahapatra[2], Avinash Barpanda[3], Debi Prasanna Behera[4]

[1]Assistant Professor, Department of Critical Care Medicine, Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital, Bhubaneswar, Odisha, India.
[2]Assistant Professor, Department of Critical Care Medicine, Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital, Bhubaneswar, Odisha, India.
[3]Assistant Professor, Department of Critical Care Medicine, Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital, Bhubaneswar, Odisha, India.
[4]Assistant Professor, Department of Emergency Medicine, Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital, Bhubaneswar, Odisha, India.

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Corresponding Author:
Dr. Debi Prasanna Behera
Assistant Professor, Department of Emergency Medicine, Kalinga Institute of Medical Sciences and Pradyumna Bal Memorial Hospital, Bhubaneswar, Odisha, India.
Email: Debi.behera@kims.ac.in

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ABSTRACT

Background: To evaluate the analgesic effect of ropivacaine in comparison with bupivacaine in femoral nerve block (FNB) for positioning of patient for neuraxial block in patients with inter- trochanteric fractures of femur. Design: The study was a prospective single blind two arm randomized clinical trial. Setting:

Materials and Methods: This study was conducted in Dr Balabhai Nanavati Hospital, (Mumbai) a 352 bedded multi-specialty hospital with 12 operation theatres that caters to a large number of patients from different parts of Mumbai as well as Maharashtra. Participants: All patients of ASA grade I, II & III for Routine and emergency surgeries who gave written informed consent in the age group 25 to 80 years with inter-trochanteric fractures of femur. The patients were randomly allocated into two groups of 30 each. Group A – receiving 0.5 % 20 ml bupivacaine, Group B – receiving 0.5% 20 ml ropivacaine. Interventions: Femoral nerve block to patients either with ropivacaine or bupivacaine. Primary outcome: measures the pain score during patient positioning and the time of onset and peak of sensory block.

Results: The difference between the mean onset times of sensory block between the two groups was not statistically significant. (p value of 0.0896). Patients in group B (receiving ropivacaine) had a mean onset time of the sensory block of 3.57 mins and in group A (receiving bupivacaine) it was 3.93 mins. The difference in the mean time taken to achieve the peak of sensory block between the two groups was statistically significant. (P value was less than 0.0001) the mean time taken to achieve the peak of the sensory block in group B (receiving ropivacaine was 17.47 mins as compared to 22.53 mins. in group A (receiving bupivacaine). At the peak of the sensory block the difference of the mean pain scores between the two groups was not statistically significant. (p value of 0.8003) the mean of the pain scores (NRS) for group A (receiving bupivacaine) was 2.00 while the mean of the pain scores(NRS)for group B (receiving ropivacaine) was 2.03. During positioning for neuraxial block the difference of the mean pain scores between the two groups was not

statistically significant. (p value of 0.8003) the mean of the pain scores for group A (receiving bupivacaine) was 2.00 while for group B(receiving ropivacaine) was 2.03. The hemodynamic parameters i.e pulse rate, systolic and diastolic blood pressures and oxygen saturation were stable throughout the study duration and were comparable to their baseline values. These parameters were also comparable between the two study groups i.e group A & B.

Conclusions: 0.5% 20ml of ropivacaine in femoral nerve block is a safe dose allowing anesthetist to produce a fast onset of sensory block, providing quicker and favourable positioning to conduct neuraxial block. Both the drugs have stable hemodynamic profile without any adverse effects or complication so either of the two drugs could be used for peripheral blocks but considering but the increased safety profile of ropivacaine it can be used as a safer alternative to bupivacaine in nerve blocks, especially in compromised cardiovascular patients.

Key Words: Inter-trochanteric fracture, femoral block, Ropivacaine, Bupivacaine.

INTRODUCTION

Pain is defined as "an unpleasant emotional and sensory experience connected to or characterized by actual or potential tissue damage." Good anesthetic practice includes providing appropriate perioperative pain management. Relevant to this work are the variables that influence the kind, severity, and length of pain after surgery. Acute pain management for painful situations, neuralgic pain from injuries or diseases that damage the peripheral nervous system, and cancer-related neurogenic pain are all made easier by peripheral nerve blocks.[2]

Peripheral nerve blocks are ideally suited for lower extremity fractures because of the peripheral location of surgical site and the potential to block pain pathways at multiple levels. In contrast to other analgesic techniques such as systemic analgesics, a properly conducted peripheral nerve block avoids hemodynamic instability and pulmonary complications, helps achieve adequate preoperative and post operative analgesia and facilitates timely,[3,4,5] discharge. Additional advantages are that peripheral blocks are generally not,[6,7] contraindicated in patients on anticoagulants , can be extended for surgical anesthesia, can be used in patients having lumbo-sacral diseases and circumvents the need for airway instrumentation.

Nerve blocks have been purported to result in a reduction of the quantity of parenteral,[8] analgesia administered to control pain or dulcify pain levels. Peripheral nerve blocks can also be used for comfortable positioning in elderly patients for the conduct of neuraxial anaesthesia as a part of management of fracture of femur.[9] Various pharmacological agents have been used to conduct peripheral nerve blocks, bupivacaine being the most popular due to its longer
duration of action.[10] Ropivacaine, a newer local anesthetic agent with greater selectivity for sensory blockade and lower cardiovascular and neurological toxicity, seems to be an attractive alternative.[11,12,13] Previous studies have compared safety and efficacy of bupivacaine and ropivacaine for interscalene block,[14,15,16,17,18,19] brachial plexus block,[20,21,22,23,24,25,26] lumbar pelvic block,[27,28] sciatic nerve block.[27,28] There are very few studies comparing the two drugs on femoral nerve block pre operatively.[9,29] However, there are very few studies comparing bupivacaine and ropivacaine in FNB to provide analgesia for positioning before subarachnoid block in patients with fracture femur.

The present study is designed to compare bupivacaine with ropivacaine in femoral nerve block (FNB) to provide analgesia for positioning before performing subarachnoid block in the sitting position in patients with inter-trochanteric fractures of femur.

MATERIALS AND METHODS

Study setting: This study was conducted in Dr Balabhai Nanavati Hospital, Mumbai. It is a 352 bedded multi-specialty hospital, with 12 operation theatres. The hospital caters to a large number of patients from different parts of Mumbai as well as Maharashtra.

Study population: This study consisted of admitted patients of both sexes having inter- trochanteric fracture of femur posted for surgical intervention who consented for the femoral nerve block.

Study period: December 2011 to November 2013, the study was done during the period of DNB training in the specialty of Anesthesia.

Study design: The study was a prospective single blind two arm randomized clinical trial.

Group A – receiving 0.5 % 20 ml Bupivacaine
Group B – receiving 0.5% 20 ml Ropivacaine

Inclusion Criteria

- All patients, who gave written informed consent in the age group 25 to 80 years with inter-trochanteric fracture of femur
- Patients of ASA grades I, II & III Routine and emergency surgeries

Exclusion Criteria

- Extremes of age (<25 and >80 years)
- History of previous hypersensitivity to the local anesthetic drugs

- Refusal to give written informed consent by the patient
- Patients unable to score their pain
- Local infection
- Neurological & coagulation disorders.

RESULTS

60 instances of intertrochanteric femur fractures that were admitted to the orthopedic wards of Dr. Balabhai Nanavati Hospital in Mumbai between December 2011 and November 2013 make up the research population. As stated in the methods section, these patients were split up into two groups of thirty patients each

- **Group A** receiving 20 ml of 0.5% bupivacaine
- **Group B** receiving 20 ml of 0.5% ropivacaine

The following is the analytical results of all the cases and conclusions drawn from it.

Table 1: Number of subjects allocated to each group table – 1 patient allocation

	Count	Column N%
Gr.A(Bupivacaine)	30	50%
Gr.B(Ropivacaine)	30	50%
total	60	100%

Both the groups had equal number of patients

2. Age Distribution

Table 2: Mean age of patients in the two groups reciving femoral nerve block

	N	Mean Age	Std. Deviation
Gr.A(Bupivacaine)	**30**	**57.67**	**12.152**
Gr.B(Ropivacaine)	**30**	**58.00**	**11.564**

Independent T-Test P value of 0.914

Mean age of the patients who received Bupivacaine was 57.67±12.152 years whereas patients who received Ropivacaine was 58.00±11.564. The age difference between the two groups was not statistically significant. (table 2, graph 1)

1. SEX DISTRIBUTION

Table 3: Percentage of male and female subjects in each group receiving femoral nerve block

		Bupivacaine		Ropivacaine	
		Count	Column N %	Count	Column N %
Sex	Male	12	40.0%	12	40.0%
	Female	18	60.0%	18	60.0%
	Total	30	100.0%	30	100.0%

Pearson Chi-Square Tests (Chi-square value = .000, df = 1, p value = 1.000)

Results are based on nonempty rows and columns in each innermost sub-table. The age difference between the two groups was not statistically significant. Sex distribution in both the groups was equal. (Table 3, graph 1)

2. ASA DISTRIBUTION

Table 4: Percentages of subjects belonging to ASA categories in both the groups receiving femoral nerve block

		Bupivacaine		Ropivacaine	
		Count	Column N %	Count	Column N %
ASA	1	5	16.7%	5	16.7%
	2	19	63.3%	19	63.3%
	3	6	20.0%	6	20.0%
	Total	30	100.0%	30	100.0%

Pearson Chi-Square Tests (Chi-square value = .000, df = 2, p value = 1.000)

Results are based on nonempty rows and columns in each innermost sub table. a. More than 20% of cells in this sub-table have expected cell counts less than 5. Chi-square results may be invalid. ASA distribution in both the groups was equal. (table 4, graph 1)

DISCUSSION

The foundation of sound anesthetic practice is the selection of the optimal local anesthetic drug for peripheral nerve blocks, one that offers stable hemodynamics and sufficient analgesia. Consequently, a medication that acts quickly, lasts a long time, and has low toxicity may be advantageous. Bupivacaine has been the most widely used local anesthetic for peripheral nerve

blocks up to this point. However, due to its broad and variable nerve block latency and increased neuro and cardiac toxicity, it required to be replaced with a medication with a superior anesthetic and safety profile. A novel long-acting local anesthetic is ropivacaine. A notable safety profile,[11,12] and a higher degree of separation between motor and sensory blockage in extradural block were demonstrated by ropivacaine, a pipecoloxylidides group of local anesthetics. However, this may be more of a consequence of relative potency, which may have practical use in peripheral nerve blocks, among other areas. Another benefit of ropivacaine is that, both at equal and equipotent dosages, it has a lower potential for toxicity than bupivacaine. Ropivacaine's recent entry into the Indian market led us to assess the new medication's anesthetic and safety characteristics as well as its clinical comparison with bupivacaine. Due to the relatively high incidence of hip fractures in India, this study examined these two medications in femoral nerve block. According to studies, the FNB approach is a straightforward, affordable, and uncomplicated way to reduce heart rate, anxiety, and discomfort following femoral damage. It also helps with posture during treatment and relieves pain and muscular spasms brought on by fractured bones. of relative potency, which may have practical use in peripheral nerve blocks, among other areas. Another benefit of ropivacaine is that, both at equal and equipotent dosages, it has a lower potential for toxicity than bupivacaine. Ropivacaine's recent entry into the Indian market led us to assess the new medication's anesthetic and safety characteristics as well as its clinical comparison with bupivacaine. Due to the relatively high incidence of hip fractures in India, this study examined these two medications in femoral nerve block. According to studies, the FNB approach is a straightforward, affordable, and uncomplicated way to reduce heart rate, anxiety, and discomfort following femoral damage. It also helps with posture during treatment and relieves pain and muscular spasms brought on by fractured bones. even with the patient's legs in traction, of regional,[3,4,5] anesthesia.

At our facility, femur fractures are frequently treated definitively with neuraxial block. It is quite painful and nearly always necessitates the use of analgesics, which can be systemic or peripheral nerve blocks. Even a small movement during positioning and transit (to execute a subarachnoid blockade) causes the fracture ends to override. Systemic,[4] analgesics are more problematic than peripheral nerve blocks, thus it is best to avoid them in older individuals with femur fractures. In this investigation, a femoral nerve block was administered with 0.5% 20 ml ropivacaine. When compared to the same conc, it was hoped that ropivacaine would offer quicker pain alleviation, higher-quality analgesia with less side effects, and easier, painless placement for neuraxial block. and bupivacaine volume. The sensory block's mean onset time for patients in group B (those getting ropivacaine) was 3.57 minutes, which was somewhat quicker than that of group A (those receiving bupivacaine), which was 3.93 minutes. (p-value = 0.0896) There was no statistically significant difference between the two groups' mean sensory block onset periods. Trivedi L9, who contrasted Ropivacaine with Bupivacaine in femoral nerve block, found similar outcomes. She came to the conclusion that the onset times for sensory block in the Ropivacaine and Bupivacaine groups were comparable since the mean onset time for both groups was less than five minutes and the p value was more than 0.05.

When comparing the start timings of sensory block in brachial plexus block between Ropivacaine and Bupivacaine, Ramamurthy,[21] found that both groups' onset times were similar. In contrast, the beginning time of sensory block in the Ropivacaine group was less than 5 minutes, whereas in the Bupivacaine group it was 13.83+_3.49 minutes, according to a research by Tripathy D20 comparing the two drugs in supraclavicular block. The current investigation, which demonstrates that there is no statistically significant difference in the start time of sensory block for either ropivacaine or buprevacaine, contradicts these findings. This could have happened, though, because of the lower dosage of buprevacaine that was used. Ropivacaine was 0.5% compared to 0.75%.

The average duration to reach the peak of the sensory block was 17.47 minutes for group B (getting ropivacaine) and 22.53 minutes for group A (receiving buprevacaine) (P value was less than 0.0001). There was a statistically significant difference between the two groups' mean times to reach the peak of sensory block. In group B, the apex of the sensory block was reached much early. Comparing 20ml of 0.5% Ropivacaine and Bupivacaine in femoral nerve block, Trivedi L9 also found similar results, concluding that the Ropivacaine group experienced a higher mean duration for the peak of sensory block than the Bupivacaine group.

CONCLUSION

For patients with femur fractures, femoral nerve block is an easy, affordable, and efficient way to offer analgesia prior to neuraxial block. Since steady hemodynamics without neuro and cardio toxicity and a quick onset of sensory block and analgesia peak are crucial objectives in regional anesthesia, we deduce that: In femoral nerve block, 1.0.5% 20ml of ropivacaine is a safe dosage that enables the anesthetist to provide a rapid onset of sensory block, enabling more rapid and advantageous placement for neuraxial block. Ropivacaine and buprevacaine exhibit comparable levels of sensory analgesia in terms of both onset and intensity. Given their stable hemodynamic profiles and lack of side effects or complications, both medications might be employed for peripheral blocks; nevertheless, given the

elevated Roprivacaine's profile of safety in nerve blocks, it can be utilized as a less dangerous substitute for bupivacaine, particularly in individuals with impaired cardiovascular function.

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