

Anesthetic efficacy and safety of ropivacaine 0.75% versus bupivacaine 0.5% for spinal anesthesia in patients undergoing lower limb orthopedic surgery



Pratiti J Gohil¹, Pankti Panchal², Gauri M Panjabi³, Jinal J Gohil⁴, Ushma H Thakar⁵, Raghav R Rathi⁶

¹Assistant Professor, ²Senior Resident, ³Associate Professor, ^{5,6}Resident Doctor, Department of Anaesthesia, Smt. NHL Municipal Medical College and SCL Hospital, Ahmedabad, ⁴Senior Resident, Department of Anaesthesia, Pandit Dindayal Upadhyay Medical College, Rajkot, Gujarat, India

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ABSTRACT

Background: Ropivacaine, a new amino-amide local anesthetic agent, is similar in chemical structure to bupivacaine. The low solubility of ropivacaine leads to greater sensory-motor differentiation by blocking sensory nerve fiber more readily than motor nerve fibers. Early recovery of motor function is associated with decreased incidence of venous thromboembolism and early mobilization. **Aims and Objectives:** The present study aimed to compare the anesthetic efficacy and safety of hyperbaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5% in spinal anesthesia in patients undergoing lower limb orthopedic surgery. **Materials and Methods:** A total of 60 patients aged between 18 and 60 years of either sex, ASA I and II, undergoing elective lower limb orthopedic surgery were randomly divided into two groups, ropivacaine (R) and bupivacaine (B) group. Group R received 3 mL of 0.75% hyperbaric ropivacaine and group B received 3 mL 0.5% hyperbaric bupivacaine intrathecally. The efficacy in terms of onset and duration of anesthesia, quality of anesthesia, and hemodynamic and safety in terms of complications were noted. **Results:** Group R produced faster onset of sensory block (ropivacaine 2.6 ± 0.53 min; bupivacaine 3 ± 0.56 min; $P < 0.006$) and the mean duration of sensory block was significantly lesser compared to Group B (Ropivacaine 121.16 ± 7.73 min; Bupivacaine 180.34 ± 11.56 min; $P < 0.0001$). Patients in Group R has significantly more rapid recovery of a motor blockade than Group B (ropivacaine 149.5 ± 8.64 min; bupivacaine 210.17 ± 13.19 min; $P < 0.0001$). **Conclusion:** Hyperbaric ropivacaine 0.75% was found to be a comparable alternative to hyperbaric bupivacaine 0.5% in patients undergoing lower limb orthopedic surgery.

Key words: Hyperbaric ropivacaine; Hyperbaric bupivacaine; Lower limb orthopaedic surgery

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INTRODUCTION

One of the most important properties of a long-acting local anesthetic is to reversibly inhibit the nerve impulses, thus causing a prolonged sensory or motor blockade appropriate for anesthesia in different types of surgeries.¹

Bupivacaine is a well-established long-acting regional anesthetic, which like all amide anesthetics has been

associated with cardiotoxicity when used in high concentration or when accidentally administered intravascularly.^{2,3}

Ropivacaine is a long-acting regional anesthetic that is structurally related to bupivacaine. It is a pure S(-) enantiomer, unlike Bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.¹

Address for Correspondence:

Dr. Pratiti J Gohil, Assistant Professor, Department of Anaesthesia, Smt. NHL Municipal Medical College and SCL Hospital, Ahmedabad, Gujarat, India. **Mobile:** +91-9662814661. **E-mail:** pratiti839@gmail.com

The low solubility of ropivacaine leads to greater sensory-motor differentiation by blocking sensory nerve fiber more readily than motor fiber. Early recovery of motor function is associated with decreased incidence of venous thromboembolism, early mobilization, and shorter hospitalization.^{4,5}

Intrathecal ropivacaine was found to be safe, having a shorter duration of action and lesser incidence of transient neurological symptoms than bupivacaine, further, it is less cardiotoxic than bupivacaine.⁶

Ropivacaine was approved for intrathecal administration by European Union in 2004.⁷ Hyperbaric 0.75% ropivacaine is the newer drug available for intrathecal use. Hence, the study was designed to compare the anesthetic safety and efficacy of hyperbaric ropivacaine 0.75% versus bupivacaine 0.5% in spinal anesthesia in patients undergoing lower limb orthopedic surgeries.

Aims and objectives

1. Block characteristics-motor and sensory
2. Analysis of hemodynamic parameters
3. Quality of intraoperative anesthesia
4. Intraoperative and postoperative side effects and complications if any.

MATERIALS AND METHODS

After approval of the institutional review board committee, a prospective, randomized, double-blinded study was conducted on 60 adult patients, of ASA I and II, aged between 18 and 60 years undergoing elective lower limb orthopedic surgery under spinal anesthesia. Written informed consent to participate in the study was taken. A routine pre-anesthetic check-up with necessary investigations was done.

Patients with known allergy to any drugs, contraindication to neuraxial block, and those patients in whom informed consent could not be obtained were excluded from the study.

Patients were divided randomly by odd n even method into two equal groups (n=30), group R (ropivacaine) and group B (bupivacaine).

On the night before the operation, all the patients received tablet ranitidine 150 mg and tablet of alprazolam 0.5 mg. On arrival a suitable peripheral intravenous (IV) assessment was performed with an 18-gauge canula. Preloading was given 8–10 mL/kg of ringer lactate over 10–15 min.

In the operation theater, standard monitors such as electrocardiogram, non-invasive arterial blood pressure,

and pulse oximetry (SPO₂) were attached, and baselines reading were noted.

Under all aseptic precautions, the subarachnoid blocks were performed using 23G Quincke spinal needle with the patient in the sitting position at L3-L4 intervertebral space. Group R received 3 mL hyperbaric 0.75% ropivacaine and Group B received 3 mL of hyperbaric 0.5% bupivacaine intrathecally. The patients were made supine immediately and readings of BP, HR, and MAP were taken.

Sensory Block characteristics were noted through pinprick method and motor through modified Bromage scale. The onset of sensory block was taken as the time from injection of anesthetic solution to the loss of sensation to pinprick at T10 level. The maximum level of sensory block and time required for it was noted. Motor block was assessed using a modified Bromage scale by asking the patient to flex the limb at the hip, knee, and ankle joints.

Grade 0: No paralysis

- Grade 1: Inability to raise extended leg, can bend knees
- Grade 2: Inability to bend the knee, can flex ankle
- Grade 3: No movement.

The onset time of motor block was taken as the time to acquire a complete motor block (grade 3) after the intrathecal injection of local anesthetic. Then, the assessment was continued until complete regression of motor block in the lower limbs and sensory block to S1.

Vitals parameters such as heart rate, mean arterial pressure, SPO₂ will be recorded at baseline, after spinal anesthesia every 2 min for 15 min and then at an interval of 15 min throughout surgery. Quality of intraoperative anesthesia will be assessed using “Four grade scale” which is defined as:

- Excellent: No supplementary sedative or analgesia is required
- Good: Only sedative required
- Fair: Both sedative and analgesia required
- Poor: General anesthesia and tracheal intubation required.

Complications such as hypotension, bradycardia, nausea, vomiting, and shivering were recorded intraoperative and postoperative if any. Hypotension, defined as a fall in systolic blood pressure >20% from the baseline was treated with IV injection of mephentermine 3 mg or IV fluids or both based on requirements. A fall in heart rate <60 beats/min was considered bradycardia and treated with injection atropine 0.3 mg IV.

Statistical analysis

Results are expressed as mean value±standard deviation (SD). Continuous data were compared with t-test analysis and categorical data were assessed with Chi-square test. All data were analyzed using a statistical package of social sciences (SPSS software version 20). Results were considered significant if $P < 0.05$ and highly significant if $P < 0.001$.

RESULTS

The characteristics of the two groups were comparable in terms of age, sex, ASA status, and duration of surgery as shown in Table 1.

The mean onset of sensory block at T10 level was 2.6 ± 0.53 min in group R (Ropivacaine) and 3 ± 0.56 min in group B (Bupivacaine) and $P = 0.006$ (Table 2). The time required to achieve maximum level of sensory block was 7.96 ± 0.82 in group R and 8.39 ± 1.24 in group B. $P = 0.11$ (Table 2).

The mean duration of sensory block was shorter in ropivacaine group (121.16 ± 7.73 min) than with bupivacaine group (180.34 ± 11.56 min; $P = 0.000$). The maximum sensory block height achieved in ropivacaine was T5 and bupivacaine was T6 (Table 2).

The mean onset of motor block in group R was 4.33 ± 0.81 min and 4.67 ± 0.71 min in group B $P = 0.08$. Time required to complete recovery of motor block in the bupivacaine group was (210.17 ± 13.19 min) compared to ropivacaine (149.5 ± 8.64 min; $P = 0.0001$) (Table 2).

Intraoperative quality of anesthesia was excellent in 22 (73%) patients in group R and 20 patients (66%) in group B. Good quality of anesthesia was in 5 (17%) patients

in group R and 6 (20%) patients in group B. Fair quality of anesthesia in 3 (10%) patients in group R and 4 (14%) patients in group B noted (Table 3).

In both the groups patients were remain stable intraoperatively in terms of heart rate and mean blood pressure as shown in Graphs 1 and 2, respectively.

Hypotension was the most common side effect in both groups. Hypotension was noted intraoperatively in 5 patients (16%) in group R and 7 patients in group B (23%) which was treated by medications. Intraoperatively, shivering was noted in 3(10%) patients in group R and 6(20%) patients in group B.

Table 1 shows demographic profile of both the groups. The mean age in group R (ropivacaine) was 42.331 years and 37.5 years in group B(bupivacaine). In group R, 14 male and 16 female patients were there and in group B 18 male and 12 female patients were there. Group R included 28 patients of ASA I and 2 patients of ASA II. Group B included 26 patients of ASA I and 4 patients of ASAII. The mean duration of surgery was 101.83 ± 8.55 min in group R and 104.31 ± 10.58 min in group B ($P < 0.05$). The difference was not significant in both the groups.

Table 2 shows block characteristics in both groups. The time required to onset of sensory block up to T₁₀ was 2.6 ± 0.53 min in group R and 3 ± 0.56 min in group B ($P = 0.006$) which was statistically significant.

Time required to achieve the maximum level of sensory block was 7.96 ± 0.82 min in group R and 8.39 ± 1.24 min in group B ($P = 0.11$) which was statistically not significant.

Time required to onset of motor block was 4.33 ± 0.81 min in group R and 4.67 ± 0.71 min in group B ($P = 0.08$) which was statistically not significant.

Table 1: Demographic data

Patient data	Group R (Ropivacaine) (n=30)	Group B (Bupivacaine) (n=30)	P-value
Age (years)	42.331	37.50	0.109
Gender male/female	14/16	18/12	0.301
ASA grade (I/II)	28/2	26/4	0.301
Duration of surgery (min)	101.83±8.55	104.31±10.58	0.32

Table 2: Block characteristic

S. No.	Efficacy endpoints	Time in minutes (mean±SD)		
		Group R	Group B	P-value
1	Time required to onset of sensory block up to T ₁₀	2.6±0.53	3±0.56	0.006
2	Time required to achieve maximum level of sensory block	7.96±0.82	8.39±1.24	0.11
3	Time required to onset of motor block (Bromadje scale)	4.33±0.81	4.67±0.71	0.08
4	Time required to complete recovery from sensory block to S1	121.16±7.73	180±11.56	0.0001
5	Time required to recover from motor block (Bromadje 0)	149.5±8.64	210±13.19	0.0001

Table 3: Quality of intraoperative anesthesia

Grade scale	Number of patients	
	Group R (%)	Group B (%)
Excellent	22 (73)	20 (66)
Good	5 (17)	6 (20)
Fair	3 (10)	4 (14)
Poor	0	0

Time required to complete recovery from sensory block to S1 was 121.16 ± 7.73 min in group R and 180 ± 11.56 min in group B ($P=0.0001$) which was statistically significant.

Time required to recovery from motor block was 149.5 ± 8.64 min in group R and 210 ± 13.19 min in group B ($P=0.0001$) which was statistically significant.

Table 3 shows quality of intraoperative anesthesia in both groups. The excellent grade was 73% in group R as compared to 66% in group B. Good grade was 17% in group R and 20% in group B. The fair grade was 10% in Group R and 14% in Group B.

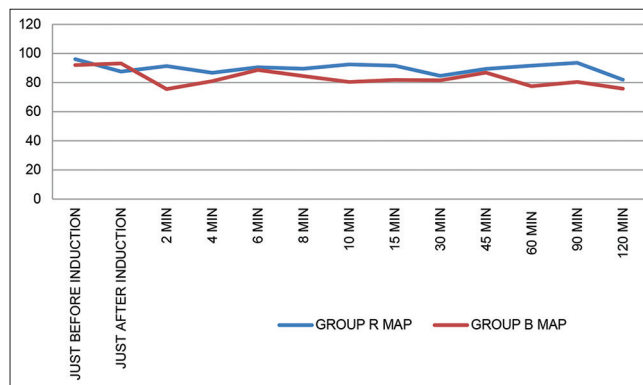
Graph 1 shows intraoperative changes in mean arterial blood pressure in group R and group B at intervals. Both the groups in terms of mean arterial blood pressure intraoperatively were stable and comparable and the difference was not significant ($P<0.05$).

Graph 2 shows intraoperative changes in mean heart rate in group R and group B at intervals. Both the groups in terms of mean heart rate intraoperatively were stable and comparable and the difference was not significant ($P<0.05$).

DISCUSSION

Ropivacaine, a newer amino-amide local anesthetic agent similar to bupivacaine in chemical structure, but 30-40% less potent than bupivacaine has been well-studied for spinal anesthesia.⁹ Intrathecal use of hyperbaric Local anesthetic agents has become more popular as they produce predictable block characteristics and reliable Spinal anesthesia. Earlier studies with isobaric ropivacaine reported to have variable or inadequate block patterns for surgery and confirmed that the addition of glucose to the solution of ropivacaine has better effects.⁹ Considering the essentiality of hyperbaric ropivacaine, after an extensive process of obtaining patent, animal toxicity studies and clinical phase III trial 0.75% hyperbaric ropivacaine was launched which is equipotent with 0.5% bupivacaine.¹⁰⁻¹⁴

In our study, the time required to onset of sensory block up to T10 was less in ropivacaine compared to the bupivacaine group. Being less lipophilic, ropivacaine penetrates less into



Graph 1: Intraoperative mean blood pressure



Graph 2: Intraoperative mean heart rate

large, myelinated motor fibers; therefore, it has selective action on the pain-transmitting A delta and C nerves rather than A beta fibers, which are involved in motor function.¹⁵⁻¹⁷ Thus, ropivacaine shows more selective sensory versus motor blockage than the more lipophilic bupivacaine.¹ Kallio et al.,² while comparing hyperbaric and plain ropivacaine reported that intrathecal hyperbaric ropivacaine 15 mg resulted in faster onset, greater success rate of analgesia at the level of T10 dermatome and faster recovery of block. This is in contrast to some earlier studies Erturk et al.,¹⁰ and Bigat et al.,⁸ who found earlier sensory onset in the bupivacaine group.

We observed that in our study time required for complete recovery of motor and sensory block was faster in the ropivacaine group compared to the bupivacaine group. Similar observations were found in Luck et al.,⁷ and Whiteside et al.⁴

In our study, there is no statically significant difference observed in intraoperative quality of anesthesia in both the groups. Both groups provide excellent quality of anesthesia. Similar results were seen in Osama-Al-Abdulhadi et al.,¹¹ and Luck et al.,⁷ who also found an insignificant difference in quality of anesthesia between the ropivacaine and bupivacaine groups.

The intraoperative and postoperative complications did not differ significantly between both the groups.

Limitations of the study

However, our study was not without limitations. We did not standardize the dose based on age, height, and weight.

CONCLUSION

A solution of ropivacaine that is hyperbaric (0.75%) to the cerebrospinal fluid can be used to provide reliable spinal anesthesia that is comparable to that of hyperbaric (0.5%) bupivacaine in terms of quality of block, but with shorter duration of sensory and motor block, comparable quality of anesthesia and hemodynamic profile.

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Authors Contribution:

PJG- Concept and design of the study, prepared first draft of manuscript; **PP-** Interpreted the results; reviewed the literature and manuscript preparation; **GMP-** Concept, coordination, preparation of manuscript; **JJG-** Statistical analysis and interpretation; **UHT-** Prepared draft of manuscript; **RRR-** statistical analysis.

Work attributed to:

Department of Anaesthesia, Smt. NHL Municipal Medical College and SCL Hospital, Ahmedabad, Gujarat, India.

Orcid ID:

Dr. Pratiti J Gohil - <https://orcid.org/0009-0000-1719-7725>
Dr. Pankti Panchal - <https://orcid.org/0009-0005-6967-5684>
Dr. Gauri M. Panjabi - <https://orcid.org/0000-0002-2500-5698>
Dr. Jinal J. Gohil - <https://orcid.org/0009-0005-6134-7459>
Dr. Ushma H Thakar - <https://orcid.org/0009-0004-0548-8735>
Dr. Raghav R Rathi - <https://orcid.org/0009-0001-3505-2623>

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