Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v30i3.2511

EFFICACY OF 0.5% HYPERBARIC BUPIVACAINE VERSUS 0.75% ISOBARIC ROPIVACAINE FOR LOWER LIMB SURGERIES – A COMPARATIVE STUDY

Dr Ravi Teja Vallabha[1], Dr. Upputuri Vijaya Sekhar[2], Dr T Phaneendra Reddy[3], Dr Kiran Karnati[4*]

[1]Associate Professor: Department of Anaesthesiology: Santhiram Medical College and General Hospital: Nandyala, Andhra Pradesh 518001
[2]Assistant Professor: Department of Anaesthesiology: Katuri Medical College and Hospital, Guntur, Andhra Pradesh- 522019
[3]Assistant Professor: Department of Anaesthesiology: Santhiram Medical College and General Hospital: Nandyala, Andhra Pradesh 518501
[4*]Assistant Professor: Department of Anaesthesiology: Katuri Medical College and Hospital, Guntur, Andhra Pradesh- 522019

***Corresponding Author:** Dr. Kiran Karnati
*Assistant Professor: Department of Anaesthesiology: Katuri Medical College And Hospital, Guntur, Andhra Pradesh- 522019

Abstract

BACKGROUND: Ropivacaine, a recently introduced local anaesthetic, has approximately 40% reduced potency compared to bupivacaine. The objective of this study was to compare the clinical effectiveness of hyperbaric 0.75% ropivacaine and 0.5% bupivacaine for spinal anaesthesia during lower limb surgeries.

METHODOLOGY: A randomized double-blinded study was carried out in 60 participants who were divided into 2 groups. Group B were given 2ml intrathecal injection of 0.5% hyperbaric Bupivacaine kg while Group R were given an intrathecal dose of 2ml of 0.75% isobaric Ropivacaine. The variables like time taken for onset of sensory and motor block, duration of the blocks, time taken to reach T10 level were recorded.

RESULTS: Ropivacaine's slower time to motor blockade onset and shorter motor blockade duration compared to Bupivacaine were both highly significant with P value of 0.0001.

CONCLUSION: The utilisation of ropivacaine's recovery profile may prove advantageous in situations when immediate mobilisation is necessary.

INTRODUCTION

The clinical application of spinal anaesthesia predates the breakthrough of orotracheal intubation. Specifically, August Bier introduced spinal anaesthesia into practise in 1898, whereas Franz Kuhn's breakthrough in orotracheal intubation occurred in 1901. only preceding anaesthetic procedures were the ocular topical anaesthesia developed by Carl Koller and the infiltration anaesthesia introduced by Carl-Ludwig Schleich in 1892.[1] Regional methods are commonly utilised as the

primary anaesthetic approach for surgical procedures related to the lower leg. Due to its rapid onset and short duration of action, lidocaine has become the local anaesthetic of choice for lower limb procedures requiring spinal anaesthesia; nonetheless, it is associated with a high prevalence of temporary neurological symptoms.[2] The commonly used medication, 0.5% bupivacaine, is cardiotoxic and causes sustainable motor blockage. The drug Ropivacaine, which is newer in comparison, has a reduced degree of cardiac toxicity. Additionally, it induces a shorter duration of motor blockade[3], hence alleviating the psychological discomfort associated with prolonged immobility following minor lower limb procedures.[4] A prospective, randomized, double-blinded study on two groups of 30 patients each was carried out by Helena Kallio, et al. These patients underwent elective day-care minor lower-limb procedures with spinal anaesthesia, using a 2ml solution of local anaesthetics. One group were given plain Ropivacaine 10mg/ml, while another group were injected with 5mg/ml of plain Bupivacaine. They concluded that ropivacaine resulted in faster recovery from motor blockade, but the duration of sensory blockade was the same in both the groups.[5] Another comparative randomized double-blind study was conducted by Jean-Marc Malinovsky et al,[6] regarding the efficacy of intrathecal ropivacaine versus bupivacaine in 100 patients. The participants were randomised to receive either 10mg of isobaric bupivacaine or 15mg of isobaric ropivacaine for the purpose of transurethral resection of the bladder or prostate with the allocation ratio set at 3:2. They inferred that administration of 15 mg of intrathecal ropivacaine yielded similar motor and hemodynamic effects, albeit with a lower potency of anaesthesia, in comparison to the administration of 10 mg of bupivacaine during endoscopic urological surgery. Hence, the objective of the present study was to evaluate the extent of the sensory and motor blockade caused by 2.0 ml of intrathecal isobaric Ropivacaine 0.75%, as well as any potential toxic side effects, in comparison to 2.0 ml of intrathecal hyperbaric Bupivacaine 0.5% for surgical procedures involving the lower limbs.

MATERIALS AND METHODS

The current study was conducted as a prospective, randomised investigation spanning a duration of two years, specifically from November 2012 to October 2014.The research was conducted on a sample of one hundred participants within the age range of 20 to 50 years. The study was conducted at Narayana Medical College Hospital, Nellore, after approval from the Institutional Ethical committee and obtaining informed consent from each patient. The study participants were aged between 20 – 50 years of either gender, weighing between 50-90 kgs, with their height between 150 to 180 cms and who were posted for elective surgery of lower extremities with American Society of Anaesthesiologists (ASA) grading of I and II were included. The patients with any medical co-morbid conditions involving hepatic, renal, cardiovascular, respiratory, or central nervous systems, those with any local infections at lumbar region, those who were on anti-coagulant therapy, haemoglobin less than 10gm/dl and those with any diseases or deformities involving the spinal cord and vertebral column were excluded for this research. Patients who met the inclusion criteria and provided written informed consent had undergone a pre-anaesthesia checkup and any necessary baseline investigations. A total of one hundred patients were allocated randomly into two groups, with each group consisting of fifty participants. The **Group B** were administered a 2ml intrathecal injection of 0.5% hyperbaric Bupivacaine. **Group R** consisted of fifty patients who were administered an intrathecal dose of 2ml of 0.75% isobaric Ropivacaine.

After all the necessary equipment were prepared and checked in the operation theatre, the patient was given the specific anaesthetic drug based on the randomly assigned group of him/her. All the baseline vitals were monitored post induction. The degree of sensory anaesthesia was determined by assessing the absence of temperature sensation using ice in a test tube placed at the mid clavicular level. Measurements were taken every minute until the anaesthesia extended to the T10 dermatome level, after which measurements were taken every 10 minutes throughout the duration of the procedure. The variables like the time taken for the block to reach T10, maximum height of the block, total duration of analgesia, time for further request of analgesia, time taken for the onset of

motor block, the degree of motor block, total duration of block was recorded. Time until motor block was evaluated minute-by-minute until total motor block occurred, and then every 30 minutes until normal motor function returned, using the Bromage scale (0 = no motor block, 3 = complete motor block of lower limbs).

Statistical Analysis

Mean and Standard deviation were used to describe the distribution of the data. The significance of research parameters on a continuous scale between the two groups has been determined using the Student t test (two-tailed, independent). For the data analysis, SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, and Systat 12.0 were utiliized; for the graphs and tables, Microsoft Word and Excel were used. Statistical significance was attributed to values with a significance level of $p<0.05$.

RESULTS

Table 1 presenting the Onset of Sensory Block at T10

Time in seconds	Group B (n=50)	Group R(n=50)
60 – 120	20(40%)	8(16%)
121 – 180	27(54%)	34(68%)
181 – 240	3(6%)	7(14%)
241 – 300	0	1(2%)

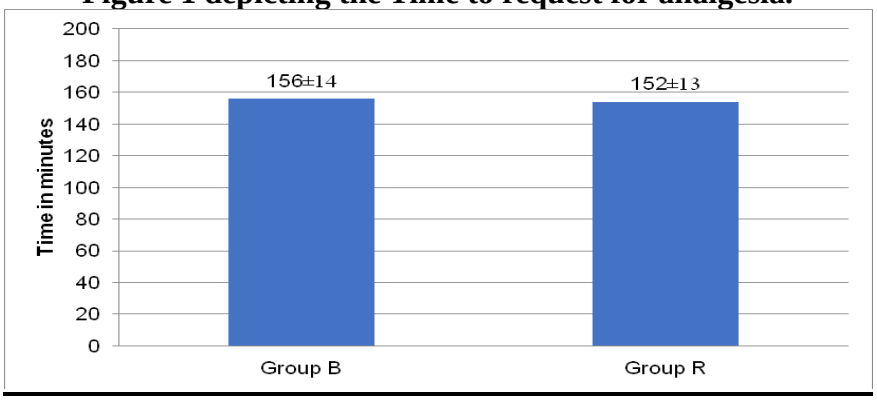
The attainment of sensory blockage at the T10 level occurred within 180 seconds in 94% of patients in group B and 84% of participants in group R. One hundred percent of group B patients and 98% of group R patients had attained up toT10 level by the end of 240 seconds. The average duration of sensory blocking at the T10 level was found to be 142.4.40±37.56 seconds in group B and 154.50±33.66 seconds in group R. However, this difference was not considered clinically or statistically significant, as indicated by a P value of 0.0930.

Table 2 showing the Total duration of sensory block (Regression to S1 level)

Time in minutes	Group B	Group R
60 – 120	3(6%)	5(10%)
121 – 180	37(74%)	44(88%)
181 – 240	10(20%)	1(2%)

The duration of sensory block was seen to exceed 2 hours in 94% of patients in Group B and 90% of subjects in Group R. After a duration of three hours, it was seen that 80% of patients in group B and 98% of participants in group R were making recovery from sensory block. After a duration of 4 hours, all patients belonging to both group B and group R exhibited complete retraction of sensory blockage. The average length of sensory block was 149.30±24.62 minutes for Group B and 141.40±15.52 minutes for Group R. The observed outcome failed to show clinical or statistical significance, as shown by a p-value of 0.06.

Figure 1 depicting the Time to request for analgesia.



As shown in the above figure 1, the mean duration of analgesia in group B was found to be 156.80±14.36 minutes, while in group R it averaged 152.50±13.71 minutes. About 92% of group B and 100% of group R patients both required analgesia within three hours. More than three hours of pain relief were experienced by four patients in group B, but not a single patient in group R.

Table 3 displaying the Onset of Motor blockade.

Time in seconds	Group B	Group R
120 – 240	18 (36%)	0 (0%)
241 – 360	29 (58%)	2 (4%)
361 – 480	3 (6%)	23 (46%)
>480	0 (0%)	25 (50%)

In Group B, the start time of motor block varied from 2 minutes to 8 minutes, but in Group R, it ranged from 4 minutes to 12 minutes. In Group B, motor blockade was observed in 36% of patients within 4 minutes, but no patients in Group R experienced motor blockade within the same time frame. All patients in group B experienced the initiation of motor blockade within 8 minutes, however only 50% of patients in group R had the commencement of motor block within the same duration. In group B, the average time for the beginning of motor blockade was 275.60±61.15 seconds, while in group R, it was 509.8±91.77 seconds. The outcomes observed were found to be both clinically and statistically significant, with a p-value of less than 0.0001.

Table 4 presenting the Duration of Motor Blockade.

Time in minutes	Group B	Group R
60 – 120	26(52%)	50(100%)
121 – 180	24(48%)	0(0%)
181 – 240	0(0%)	0(0%)

In group B, the duration of motor blockade was between 90 and 160 minutes, but in group R, it was between 65 and 110 minutes. After a duration of 120 minutes, it appeared that only 52% of patients in Group B had recovered from motor block, while all patients in Group R had fully recovered from motor block. In group B, the longest period of motor blockade was recorded at 160 minutes (2 patients), while in group R, the maximum duration of motor blockade was 110 minutes (2 patients). The average duration of motor blockade in group B was 119.90±20.66 minutes, whereas in group R it was 84.2±11.26 minutes. The difference between the two groups was found to be statistically significant, with a p-value of 0.0001, indicating both clinical and statistical significance.

Table 5 showing the side-effects of Anaesthetic agents.

Side Effect	Group B	Group R
Hypotension	14(28%)	13(26%)
Bradycardia	6(12%)	4(8%)
Nausea & Vomiting	5(10%)	3(6%)

Fourteen (28%) patients in group B and thirteen (26% patients in group R) experienced hypotension. Six patients (12%) in Group B and 8 patients (8%) in Group R experienced bradycardia. Ten percent of patients in group B and six percent of patients in group R experienced nausea and vomiting. There was no statistically or clinically significant difference in the prevalence of adverse events between the two groups.

DISCUSSION

Sensory block at T10:

In the present study, both drugs produced a safe and effective level of anaesthesia in all patients. In group B, the average time required to achieve sensory blocking at T10 was 142.4.4037.56 seconds,

while in group R, it was 154.5033.66 seconds. Though these findings were not statistically significant.

The present findings were in line with those of Luck J.F et al.[7], who compared the onset of sensory block at T10, the extent of spread, and the mean time to maximum spread of intrathecal hyperbaric solutions of Bupivacaine, Ropivacaine, and Levobupivacaine and found no significant statistical differences between the groups.

Maximum level of Sensory block:
In this study, it was observed that the maximum level of sensory blockade obtained in the ropivacaine group was T5 in 2 patients and T6 in 8 patients. In contrast, the bupivacaine group exhibited a maximum level of sensory blockade up to T6 in 6 patients. There was no statistically significant difference between the two groups in terms of the maximum level of sensory block. The findings of this research were consistent with those of Luck J.F et al.[7], indicating that there was no statistically significant difference between the effects of Bupivacaine and ropivacaine on the maximum cephalad distribution of the drug.

Total duration of Sensory block (Regression of sensory block to S1):
In this research, it was observed that the sensory block exhibited a duration of 2 hours in 94% of patients belonging to group B, whereas 90% of patients in group R shown a similar persistence of the sensory block. The findings of the study demonstrated similar outcomes in both groups, with no observed clinical or statistical significance.

The findings of the current investigation contradict those of Gautier et al.[8], who conducted a comparative analysis of intrathecal Ropivacaine and Bupivacaine in the context of ambulatory surgery. They concluded that there was a statistically significant disparity in the total period of sensory block between Ropivacaine and Bupivacaine. The administration of intrathecal ropivacaine at a dosage of 10 mg resulted in a shorter duration of sensory anaesthesia compared to the administration of bupivacaine at a dosage of 8 mg (152 +/- 44 minutes vs. 181 +/- 44 minutes; $P < 0.05$).

Onset of motor block:
In this study, it was observed that the onset of motor block occurred within a range of 2 to 8 minutes in group B, while in group R, it occurred within a range of 4 to 12 minutes. In group B, the mean time for the beginning of motor blockade was 275.60±61.15 seconds, while in group R, it was 509.8±91.77 seconds. The observed results were found to be both clinically and statistically significant, with a p-value of less than 0.0001.

The findings of the present research regarding the initiation of motor block align with those of Mantouvalou et al.[9] In their investigation comparing plain Ropivacaine, Bupivacaine, and levobupivacaine for lower abdominal surgery, they determined that the Bupivacaine group exhibited a notably quicker onset of motor block compared to the Ropivacaine group ($P < 0.05$).

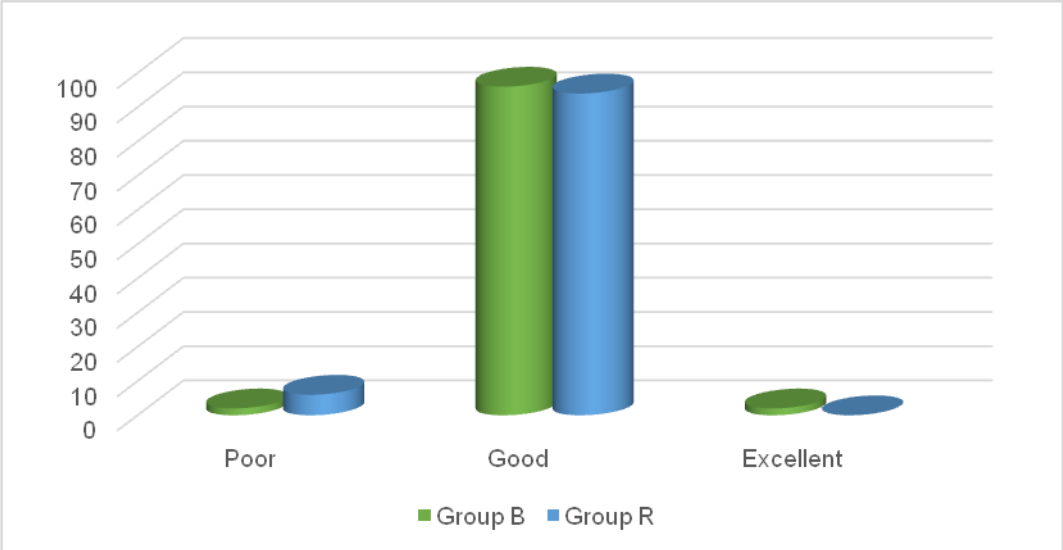
Consistent with the current findings, a study by Gautier et al.[8], comparing the effects of 8mg and 12mg of bupivacaine and ropivacaine for caesarean section found that the average time for the onset of Grade 3 bromage motor block was 9 minutes and 14 minutes, respectively, which was clinically and statistically significant.

Duration of motor blockade:
When comparing groups B and R, the present findings showed that motor blockade lasted significantly longer in group B (119.9020.66 min) than in group R (84.211.26 min; with p0.0001).

The findings of this investigation match with those of the study conducted by Kallio H et al.[10], in which they examined the effects of intrathecal plain solutions of Ropivacaine (15mg) and Bupivacaine (10mg). They reported that the Ropivacaine group exhibited a statistically significant faster recovery from motor block compared to the Bupivacaine group.

Quality of Anaesthesia:
Ninety-eight percent of group B patients and ninety-four percent of group R patients rated the quality of their anaesthetic as good or excellent as shown in the below figure 2.

Figure 2 portraying the quality of anaesthesia.



In the study conducted by Luck J.F et al.[7] and the investigations conducted by Kallio H et al.[10], it was determined that the quality of anaesthesia is good when using both Ropivacaine and Bupivacaine which agree with the outcome of this study.

Side-effects of Anaesthetic agents:
Nausea and vomiting were observed in 10% of patients in the Bupivacaine group and 6% of patients in the Ropivacaine group. In this study, there were no reported incidents of back pain among the patients, which contrasts with the findings of McDonald SB et al.[11] research. They observed a significant occurrence of back pain (28%; P = 0.098) following the administration of intrathecal ropivacaine.

Strengths and Limitations: In this study the clinical effectiveness of ropivacaine versus bupivacaine during spinal anaesthesia for lower limb surgeries was studied keeping the doses in fixed proportions. This was of the few studies which has assessed the onset and duration of sensory and motor blocked and quality of anaesthesia with ropivacaine and bupivacaine. This study has also recorded the side effect profile with each drug which can help in preventing the untoward consequences occurring with these drugs in future. However, this being a randomised controlled double blinded study, it was constrained as selection bias may occur due to chances of non-compliance and withdrawal after randomisation. The external validity of the study was affected due to non-generalizability because of small sample size.

CONCLUSION
The findings of the present study indicated that the intrathecal administration of 15 mg of isobaric Ropivacaine (equivalent to 2 ml of 0.75% concentration) yielded adequate anaesthesia while maintaining stable hemodynamics during surgical procedures involving the lower limbs. However, it

was observed that Ropivacaine exhibited a delayed onset of motor block and a shorter duration of motor block in comparison to Bupivacaine. This difference was statistically and clinically significant, making it a desirable characteristic for facilitating early ambulation, voiding, and physiotherapy. Hence, it can be concluded that Ropivacaine can be preferred over Bupivacaine for spinal surgeries of lower limbs.

REFERENCES

1. Wulf H.F.W. The centennial of spinal Anesthesia Anesthesiology. 1998:89 500-506.
2. Pollock JE, Neal JM, Stephenson CA, Wiley CE. Prospective study of the incidence of transient radicular irritation in patients undergoing spinal anesthesia. Anesthesiology 1996;84:1361-7.
3. Cpogna G, Cellono D, Fusco P, Lyons G, Columb M, relative potencies of bupivacaine and ropivacaine for analgesia in labor Br J Anaesth 1999; 82: 371.
4. Yamashita A, Matsumoto M, Matsumoto S, Itoh M, Kawai K, Sakabe T. A comparison of the neurotoxic effects on the spinal cord of tetracaine, lidocaine, bupivacaine, and ropivacaine administered intrathecally in rabbits. Anesth Analg 2003;97:512- 9.
5. Helena Kallio, Eljas-Veil T.Snall, Sami J.Suvanto, Carl A. Tuomas, Mauri K. Iivonen et al, Spinal hyperbaric ropivacaine fentanyl for day surgery, Regional anaesthesia and pain medicine, Jan/Feb 2005, volume 30, 48-54.
6. Jean-Marc Malinovsky, Florence Charles,Ottmar Kick, MD, Jean-Yves Lepage, Myriam Malinge, Antoine Cozian, MD, Olivier Bouchot, Michel Pinaud, Intrathecal Anesthesia: Ropivacaine Versus Bupivacaine Anesthesia and analgesia, **December 2000** vol. 91 no. 6 **1457-1460.**
7. Luck JF, Fettes PD, Wildsmith JA. Spinal anaesthesia for elective surgery: A comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine. Br J Anaesth 2008;101:705-10.
8. Gautier C, de Kock M, Van Steenberge A, Poth N, Lahaye- Goffart B, Farnard L, Hody JL. Intrathecal ropivacaine for ambulatory surgery. A comparison between intrathecal ropivacaine for knee arthroscopy. Anesthesiology 1999;91:1239-1245.
9. Mantouvalou M, Ralli S, Arnaoutoglou H, Tziris G, Papadopoulos G. Spinal anesthesia: comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. Acta Anaesthesiol Belg. 2008;59(2):65–71.
10. Kallio H, Snäll EVT, Tuomas CA, Rosenberg PH. Comparison of hyperbaric and plain ropivacaine 15 mg in spinal anaesthesia for lower limb surgery. British Journal of Anaesthesia. 2004 Nov;93(5):664–9.
11. McDonald SB, Liu SS, Kopacz DJ, Stephenson CA. Hyperbaric spinal ropivacaine: a comparison to bupivacaine in volunteers. *Anesthesiology* 1999; 90: 971-7.