

COMPARISON OF THE CLINICAL EFFECT OF INTRATHECAL HYPERBARIC 0.75% ROPIVACAINE AND 0.5% BUPIVACAINE FOR LOWER ABDOMINAL SURGERIES IN ADULT PATIENTS

Roopal R Garaniya¹, Jagruti R Satasia², Kamala H Mehta³, Divyakumari R Chauhan⁴, Vandanaba L. Rathod⁵, Vishnudharan K⁶

Received : 07/05/2023
Received in revised form : 28/06/2023
Accepted : 08/07/2023

Keywords:

lower abdominal surgery; spinal anaesthesia; ropivacaine, bupivacaine.

Corresponding Author:

Dr. Roopal R Garaniya,

Email: roopalgaraniya@gmail.com.

DOI: 10.47009/jamp.2023.5.4.72

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (4); 349-353



¹Assistant Professor, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

²Associate Professor, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

³Professor, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

⁴3rd Year Resident, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

⁵1st Year Resident, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

⁶1st Year Resident, Department of Anaesthesia, S.C.L Hospital, Smt. N.H.L Municipal Medical College, Ahmedabad, Gujarat, India.

Abstract

Background: Spinal anaesthesia is a most common anaesthetic technique for lower abdominal surgeries. This prospective observational study was done to evaluate the clinical effect of intrathecal hyperbaric ropivacaine versus hyperbaric bupivacaine for these surgeries. **Methods:** Sixty patients between 18 to 65 years with ASA I-II posted for lower abdominal surgeries were randomly divided into two groups; patients in group R received 3ml 0.75% ropivacaine while in group B received 3ml 0.5% bupivacaine. Hemodynamic parameters, sensory and motor block characteristics, quality of muscle relaxation and associated side effects were compared. **Results:** Mean arterial blood pressure (MAP) were significantly less during 10 to 30 minutes after induction in patients in group B than in patients in group R. Onset of sensory blockage in ropivacaine group was more than in group B (p value <0.0001), in group R time required for this maximal blockage (14.2±1.51 min) was significantly higher than in group B (10.03±1.22 min). In group R, total duration of sensory blockage (160.5±41 min) was less than patients in group B (196.6±40) (p value 0.001). patients in group R had less duration (124.3±32.3 min) of motor block than in patients in group B (160.5±36.4) (p value 0.0001). **Conclusion:** Quality of muscle relaxation was comparable in both the groups. Hence hyperbaric ropivacaine is safe and hemodynamically stable with faster recovery while quality of muscle relaxation is equivalent to bupivacaine.

INTRODUCTION

In various types of regional anaesthesia, spinal anaesthesia is one of the most common, cost effective, relatively safe and easy to perform technique. It provides rapid and reliable anaesthesia with adequate muscle relaxation with lower chances of systemic and metabolic disturbances.^[1-3]

Local anaesthetic drugs commonly used for spinal anaesthesia are lignocaine, bupivacaine and ropivacaine.^[4,5] Use of lignocaine is bounded because occurrence of transient neurological symptoms (TNS) with intrathecal administration, incidence of TNS ranges from 0% to 37%.^[6-8]

Bupivacaine is most commonly used local anaesthetic drug for spinal anaesthesia. Use of bupivacaine is associated with neurotoxicity, cardio toxicity and prolongation of motor block.^[9]

Ropivacaine is a relatively newer long acting amide local anesthetic, a pure S-enantiomer of bupivacaine. It is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. The reduced lipophilicity is also associated with decreased potential for central nervous system toxicity and cardio toxicity.

With a shorter duration of action than bupivacaine and a lower frequency of transient neurological

symptoms (TNS) as compared to intrathecal lignocaine, intrathecal ropivacaine is determined to be safe as suggested by various studies.^[10,11]

Intrathecal isobaric ropivacaine used previously and proved to provide adequate level of block for surgeries, faster onset of sensory and motor blockade, lesser duration of motor blockade with good analgesia and stable hemodynamic.^[9]

Comparative study of intrathecal hyperbaric bupivacaine and ropivacaine in elective lower abdominal and lower limb surgery found that hyperbaric ropivacaine can be used to provide reliable spinal anaesthesia in terms of quality of block with faster recovery and minimal side effects.^[12]

Based on the above hypothesis, aim of this study was to evaluate and compare the hemodynamic stability and muscle relaxation during lower abdominal surgery under spinal anaesthesia produced by hyperbaric Ropivacaine with hyperbaric Bupivacaine.

Aims and Objectives of Study

Aim of study is to compare efficacy and safety of intrathecal hyperbaric 0.75% Ropivacaine with 0.5% Bupivacaine in the patients posted for lower abdominal surgeries under spinal anaesthesia with objectives of to observe time to onset and extent of sensory block, time of onset of motor block, duration of motor block, hemodynamic stability, quality muscle relaxation and side effects if any.

MATERIALS AND METHODS

After getting IRB approval and informed and written consent this prospective- observational study was conducted in 60 patients with 30 in each group in our hospital. Age 18 to 65 yrs., either gender, ASA status I-II, posted for lower abdominal surgeries under spinal anaesthesia at our hospital during study period were included in the study. Exclusion criteria were patients (1) with the known case of local anesthetic allergies (2) with coagulopathy (3) who have infection at site of injection (4) with neurological deficits (5) having difficulty to communicate/ neuropsychiatric disorder (6) refusing to participate in the study. Using closed envelope technique Patients were allocated in two groups- group R and B.

Patients in Group R received commercial hyperbaric 0.75% ropivacaine 3ml while in patients in Group B received commercial hyperbaric 0.5% bupivacaine 3ml.

Standard hospital protocol regarding medical optimisation, intravenous line placement, premedication, and antibiotic prophylaxis were followed. After arriving in operation theatre monitors for non invasive blood pressure, electrocardiogram (ECG), and pulse oximetry (SPO2) were attached.

With the patient in the lateral position, under strict aseptic conditions, lumbar puncture performed at the

level of L3 –L4 intervertebral space using a 23-gauge Quincke spinal needle. Once free flow of clear cerebrospinal fluid obtained, study drug for the patient (either bupivacaine or ropivacaine) according to the group they belong were injected over 20 – 30 seconds and patient placed in supine position immediately and gently.

After giving spinal anaesthesia, record of vital parameters such as HR, MAP and SPO2 done at every 5 minutes for 20 minutes, then every 10-minute interval till 90 minutes and then every 30 minute interval till 120 minutes. Intra-operative complications like hypotension and bradycardia, consider as fall in 20% from the baseline value were recorded and managed accordingly.

Sensory block assessment done by using pin prick test.

Time of onset: defined as the time between injections of the drug to the loss of sensation at T12 level.

Maximal sensory block: time between injection and maximal level blockade achieved.

Duration of sensory blockade: period between injection and recovery from sensory blockade to L1 level.

The degree of motor block was assessed using “modified bromage scale”

0 = No block

1 = impaired movements at the hip, with normal knee and ankle movements.

2 = impaired movements at hip and knee with normal ankle movements.

3 = impaired movements at hip, knee and ankle.

Duration of motor blockage: period between injection and achieving bromage scale 0.

Assessment of motor and sensory blockade was done every 2 min. Associated side effects (hypotension, bradycardia and arrhythmias) in the two study groups were recorded.

During surgery, the quality of muscle relaxation was assessed by the surgeon using a three-point scale (1 = excellent, 2 = good, 3 = fair).

Statistical Methods

We used the Statistical Package for the Social Sciences for Windows (SPSS version 20, inc., Chicago, IL, USA). We used chi-square test for categorical values and student’s t-test for numerical values. P values of less than 0.05 was considered significant.

RESULTS

In our study we included 60 patients posted for lower abdominal surgeries, 30 patients in each group. The demographic characteristics of both the groups were presented in Table 1. Demographic data were comparable in both the group. There was no statistical difference in intraoperative HR (heart rate) in both the groups (chart 1) while mean arterial blood pressure (MAP) were significantly less during 10 to 30 minutes after induction in patients in group

B than in patients in group R (chart 2), but none of the patients in group B required inotropic support. Table 2 shows sensory and motor block characteristics. Onset of sensory blockage in ropivacaine group was more than in group B (4.42 ± 1.33 min, 2.9 ± 0.75 min, p value <0.0001). We achieved maximal T6 sensory blockage in both groups but in group R time required for this maximal blockage (14.2 ± 1.51 min) was significantly higher than in group B (10.03 ± 1.22 min) (p value <0.0001). Patients in group R had total duration of sensory blockage was (160.5 ± 41

min) which was significantly lower than patients in group B (196.6 ± 40) (p value 0.001). There was no difference between two groups in term of onset of motor block, but patients in group R had less duration (124.3 ± 32.3 min) of motor block than in patients in group B (160.5 ± 36.4) (p value 0.0001). Quality of muscle relaxation was comparable in both the groups (table 3). Incidence of side effects was describe in table 4, there was no statistical difference in incidence of side effects in both the groups.

Table 1: Demographic parameters

Variables	Group R (MEAN \pm SD)	Group B (MEAN \pm SD)	P value
Age (years)	53.19 \pm 10.40	54.73 \pm 11.36	0.42
Gender (male: female)	17:13	18:12	1.000
ASA Status (I:II)	27:03	26:04	1.000

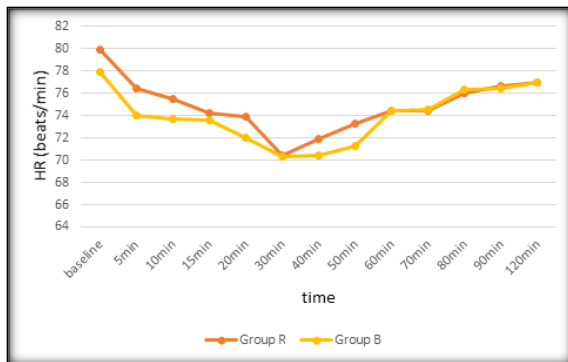


Figure 1: Comparison of heart rate (HR) in two groups

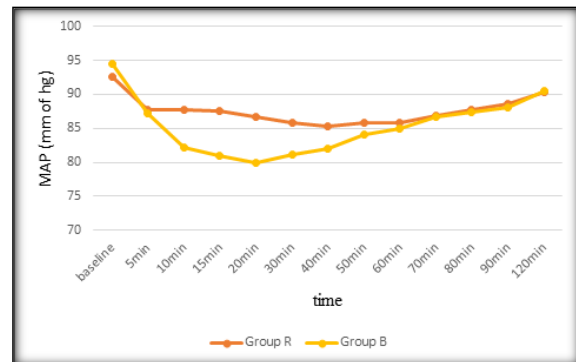


Figure 2: Comparison of mean arterial blood pressure (MAP)

Table 2: comparison of sensory and motor characteristics

Parameters	Time required after induction (in min)		P value
	Group R (MEAN \pm SD)	Group B (MEAN \pm SD)	
Onset of sensory block	4.42 \pm 1.33	2.9 \pm 0.75	<0.0001
Maximal sensory block (T6)	14.2 \pm 1.51	10.03 \pm 1.22	<0.0001
Duration of sensory blockade	160.5 \pm 41	196.6 \pm 40.0	0.001
The degree of motor block (modified bromage scale 3)	9.4 \pm 2.1	8.2 \pm 5.3	0.25 no significant
Duration of motor block	124.3 \pm 32.3	160.5 \pm 36.4	0.0001

Table 3: Quality of muscle relaxation

Parameters	Group R	Group B	P value
	N (%)	N (%)	
Excellent	24 (80%)	25 (83.33%)	
Good	06 (20%)	05 (16.66%)	>0.05
Bad	0	0	

(N= number of patients)

Table 4: Incidence of post-operative side effects

Side effects	Group R	Group B	P value
Hypotension	2	3	
Bradycardia	0	0	
Nausea	0	0	>0.05
Vomiting	0	0	
Shivering	0	0	
Urinary retention	0	1	

DISCUSSION

The subarachnoid block is a very effective anaesthetic technique with a high success rate and good safety profile. Although commonly used local anaesthetics for spinal anaesthesia are highly potent, a search for newer agents is always on in terms of safety, efficacy, toxicity and early recovery than routinely used drugs. However systemic toxicity of local anaesthetic with intrathecal use is not a problem but quality of block, quality of muscle relaxation, hemodynamic stability and side effects are factors to take into account. So newer anaesthetic are being investigated to fulfil this factors.

Ropivacaine, a relatively newer amino-amide local anaesthetic agent, a pure form of the S enantiomer of propyl derivative of pipercoloxylidide. It has low lipid solubility than bupivacaine which may cause this drug to penetrate large myelinated A fibers more slowly so block sensory nerve fibers more readily than motor fibers. Ropivacaine is now gaining popularity due to its reduced cardiovascular and neurotoxic effects.

It has been used extensively for the local infiltration, epidural, and peripheral blocks. However intrathecal use of ropivacaine was limited because hyperbaric ropivacaine is not available commercially and hyperbaric solution provide more reliable spinal anaesthesia compare to isobaric solution. So autoclaved dextrose ampoule and extreme antiseptic care was required to prepare the hyperbaric solution of ropivacaine to avoid the risk of contamination. More ever standard densitometer was not available in every clinical set up so exact specific gravity cannot be estimated.

But now commercial 0.75% hyperbaric ropivacaine is available. So we wanted to conduct this study to compare clinical effect of hyperbaric ropivacaine with hyperbaric bupivacaine.

Onset of sensory block was delayed in ropivacaine group compare to bupivacaine group in our study. Our finding are similar with the study done by Kulkarni et al. and Whiteside and others.^[13,14] But this finding is contradictory with the study done by Bansal S et al, in their study they observed onset of sensory block was less in ropivacaine groups.^[12] That difference might be due to they used higher doses of ropivacaine and bupivacaine in a 3:2 ratio as previous study suggested that ropivacaine is not equipotent to bupivacaine after intrathecal administration.^[15,16,17,18]

We achieved adequate level of sensory block in both the groups but time required to get maximum level of sensory block was delayed and total duration of sensory block was less in group R. Our findings is similar with the other study.^[12,19]

In our study we achieved complete motor blockade, modified bromage score III in both the groups. Mean time to achieve complete motor blockage was comparable in both the groups. Previous study had

also similar findings.^[12] But study done by whiteside observed delayed in getting complete motor block in ropivacaine groups.^[14] This might be as a result of methodological variations in such as variations in dose, baricity, and demographic characteristics in contrast to our study.

Total duration of motor blockade was significantly shorter in patients with ropivacaine groups in this study. This might be due to ropivacaine has a less potent effect on motor nerves and the degree of sensory-motor separation is more as compared with bupivacaine, which has been supported by similar observations of other studies.^[12,13,14]

In our study intraoperative hemodynamic parameters were stable in both groups, but in bupivacaine groups more patients had episodes of hypotension compare to patients in ropivacaine groups during 10 to 30 minutes after induction. A study done by Whiteside et al found that 15% of patients in the hyperbaric ropivacaine group needed ephedrine compared to 70% of patients in the hyperbaric bupivacaine group, which validates our findings of a low prevalence of hypotension in this group.^[14]

Quality of muscle relaxation, assessed by operating surgeons were similar in both the groups. Our findings are similar with study done by other investigators, they found insignificant difference in term of quality of muscle relaxation in both groups.^[20,21] The two groups did not significantly vary in the postoperative side effects.

Our research shows that intrathecally injected hyperbaric ropivacaine delivers sufficient anaesthesia for lower abdominal procedures. While the highest level of sensory block is the same, the onset of sensory block is slower than it is with bupivacaine and motor block that lasts less time than bupivacaine. In term of cardiovascular stability ropivacaine is superior.

On account of this for lower abdominal surgeries ropivacaine can be used successfully with some disadvantage the shorter surgical length may not always match the shorter duration of the motor and sensory block more ever due to less postoperative analgesia.

Limitation

Larger randomised investigations are required to confirm our study's findings due to the limitations of our study's small sample size and single centre trial. More ever we used equal dose of ropivacaine and bupivacaine and previous studies had concluded that ropivacaine is less potent, so further studies required to decide the effective dose of ropivacaine in term of duration of motor and sensory block. We have not used any adjuvant to local anaesthetic which can be address the above disadvantage.

CONCLUSION

In comparison to intrathecal hyperbaric bupivacaine, hyperbaric ropivacaine is safe and hemodynamically

stable with faster recovery while quality of muscle relaxation is equivalent.

REFERENCES

1. Gupta HB, Amilkanthwar SN. A prospective, comparative, observational study of quality of spinal anaesthesia with 0.5% and 0.75% plain isobaric ropivacaine in lower abdomen and lower limb surgeries. *International Journal of Research in Medical Sciences* 2017; 4(8):3134-40.
2. Surekha C, Radha MK, Kumar MS. A comparative study of intrathecal isobaric (0.75%) ropivacaine with isobaric (0.5%) bupivacaine for elective lower abdominal/limb surgeries – a clinical study. *International Journal of Research in Health Sciences* 2014; 2(4):1172-9.
3. Finucane BT, Sandler AN, McKenna J, et al. A double-blind comparison of ropivacaine 0.5%, 0.75%, 1.0% and bupivacaine 0.5%, injected epidurally, in patients undergoing abdominal hysterectomy. *Canadian Journal of Anaesthesia* 1996; 43(5 Pt 1):442-9.
4. Lim Y, Ocampo CE, Sia AT. A comparison of duration of analgesia of intrathecal 2.5 mg of bupivacaine, ropivacaine, and levobupivacaine in combined spinal epidural analgesia for patients in labor. *Anesth Analg* 2004; 98:235-9.
5. Casati A, Moizo E, Marchetti C, Vinciguerra F. A prospective, randomized, double blind comparison of unilateral spinal anesthesia with hyperbaric bupivacaine, ropivacaine, or levobupivacaine for inguinal herniorrhaphy. *Anesth Analg* 2004; 99:1387-92.
6. Horlocker TT. Complications of spinal and epidural anesthesia. *Anesthesiol Clin North Am* 2000; 18:461-85.
7. Johnson ME. Potential neurotoxicity of spinal anesthesia with lidocaine. *Mayo Clin Proc* 2000; 75:921-32.
8. Hampl KF, Schneider MC, Ummenhofer W, Drewe J. Transient neurologic symptoms after spinal anesthesia. *Anesth Analg* 1995; 81:1148-53.
9. Bhat SN, Himaldev, Upadya M. Comparison of efficacy and safety of ropivacaine with bupivacaine for intrathecal anaesthesia for lower abdominal and lower limb surgeries. *Anesth Essays Res* 2013; 7(3):381-5.
10. Hocking G, Wildsmith JA. Intrathecal drug spread. *Br J Anaesth* 2004; 93:568-78.
11. Zaric D, Christiansen C, Pace NL, Punjasawadwong Y. Transient neurologic symptoms after spinal anesthesia with lidocaine versus other local anesthetics: A systematic review of randomized, controlled trials. *Anesth Analg* 2005; 100:1811-6.
12. Bansal S, Ramdev B, Narula P, et al. Comparative evaluation of intrathecal hyperbaric ropivacaine versus intrathecal hyperbaric bupivacaine in elective lower abdominal and lower limb surgery. *IOSR Journal of Dental and Medical Sciences* 2015; 14(4):27-31.
13. Kalpana R Kulkarni, Sunetra Deshpande, Ismail Namazi, et al. A comparative evaluation of hyperbaric ropivacaine versus hyperbaric bupivacaine for elective surgery under spinal anesthesia. *Journal of Anaesthesiology Clinical Pharmacology* 2014; 30: 238-242
14. Whiteside JB, Burke D, Wildsmith JA. Comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery. *Br J Anaesth* 2003; 90: 304-8.
15. McDonnald SB, Liu SS, Kopacz DJ and Stephenson CA, Hyperbaric spinal ropivacaine: a comparison to bupivacaine in volunteers. *Anesthesiology* 1999; 90: 971-7.
16. Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A et al. Intrathecal anesthesia: ropivacaine versus bupivacaine. *Anesth Analg* 91, 2000, 1457-60.
17. Gautier PE, De Kock M, Van Steenberge A, Poth N, Lahaye B, Fanard L et al. Intrathecal ropivacaine for ambulatory surgery: a comparison between intrathecal bupivacaine and ropivacaine for knee arthroscopy. *Anesthesiology* 91, 1999, 1239-45.
18. De Kock M, Gautier P, Fanard L, Hody JL and Lavand'homme P, Intrathecal ropivacaine and clonidine for ambulatory knee arthroscopy: a dose response study. *Anesthesiology* 94, 2001, 574-8
19. Chari V, Goyal A, Sengar P, et al. Comparison between intrathecal isobaric ropivacaine 0.75% with hyperbaric bupivacaine 0.5%: a double blind randomized controlled study. *Anaesthesia, Pain & Intensive Care* 2013; 17 (3):261-6.
20. Al-Abdulhadi O, Biehl D, Ong B and Boker A, Hyperbaric spinal for elective caesarean section – Ropivacaine vs bupivacaine. *MEJ Anesth* 19, 2007, 385 – 397.
21. Luck JF, Fettes PDW and Wildsmith JAW, Spinal anaesthesia for elective surgery: a comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine. *Br J Anaesth* 101, 2008, 705-10.