



Original Research Article

Comparative evaluation of intrathecal preservative free isobaric 0.5% ropivacaine with isobaric 0.5% bupivacaine in patients undergoing lower abdominal surgeries

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ABSTRACT

Background: Spinal anaesthesia is the frequently used central block used in a surgical procedure. Different local anaesthetic drugs used in spinal anaesthesia differ in their analgesic property, lipid solubility, protein binding, pKa, and degree of spread, the baricity of solution being one of the primary determinants of spread of solutions.

Aims: To compare and evaluate the anaesthetic profile of preservative free 0.5% isobaric ropivacaine and bupivacaine in patients undergoing lower abdominal surgeries.

Materials and Methods: The clinical study enrolled 100 patients posted for lower abdominal surgeries under spinal anaesthesia. All the patients were then randomized and received either isobaric preservative free 3ml(15mg) of 0.5% bupivacaine (Group A, n=50) or 3ml(15mg) of 0.5% ropivacaine (Group B, n=50). Onset and duration of sensory and motor blocks, haemodynamic changes and any other side effects were noted.

Results: Demographic variables between the two groups were not significant. Onset of sensory block was delayed in ropivacaine group B (4.80 ± 0.92 vs 4.35 ± 0.88 min, $p < 0.05$) than group A, whereas duration was found to be significantly more in group A (170.29 ± 14.14 vs 155.77 ± 13.97 min, $p < 0.05$) than group B. Onset of motor block was also earlier in group A than group B with p value < 0.05 , whereas duration was significantly shorter in group B (140.08 ± 16.58 vs 160.95 ± 15.74 min). The two groups were comparable in maximum level of blockade reached and haemodynamic parameters. Incidence of hypotension and bradycardia was significantly less in ropivacaine group.

Conclusion: This study establishes that ropivacaine produces good sensory block and is more stable hemodynamically with lesser side effects.

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1. Introduction

The interest in regional anaesthesia technique has been increasing and decreasing in the past but revival and re-evaluation of different techniques and drugs has provided a predictable intra-operative and postoperative course aiding in smooth transition from surgery to recovery. Local anaesthetic agents are drugs which in clinical dosages produce reversible blocks by impeding pulse transmissions in peripheral nerves, spinal roots and nerve endings. The degree of spread of local anaesthetic solutions is dependent

upon many factors, baricity (being the ratio of the density of the solution to the density of CSF) of the solution being one of the primary determinant. Traditionally, solutions of hyperbaric lignocaine and bupivacaine were used in spinal anaesthesia but their potential neurotoxicity and cardiotoxicity respectively, poses a great matter of concern.¹ Intrathecal bupivacaine has low incidence of postoperative complications² but higher doses are associated with higher incidence of complications, greater delay in patient discharge and increased hospital stay.³ Many studies have shown that hyperbaric solutions produce more extensive cephalad spread than isobaric solutions and the onset of spinal block is more rapid with isobaric than

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with hyperbaric bupivacaine.

Latest clinical studies of local anaesthetics have been a direct sequel of cardiotoxicity of bupivacaine which is an acute life-threatening condition.¹ The newer drug ropivacaine is an amino-amide, a propyl derivative and pure S-enantiomer of bupivacaine with an enantiomeric purity of 99.5%.⁴ Researchers found that ropivacaine is less cardiotoxic on a milligram basis than bupivacaine because of its reduced lipophilicity.⁵

When we searched the literature, we found that hyperbaric ropivacaine and hyperbaric bupivacaine have been vastly studied and compared, but ropivacaine is available only as an isobaric preparation in market and, hence, when its hyperbaric solution is required, it needs to be freshly prepared by addition of dextrose. But mixing of dextrose to the solution has to be done very cautiously because it increases the chances of infection. So, we intended to use isobaric ropivacaine because of the issues related to the preparation of hyperbaric ropivacaine which is either due to breach in sterility at any level of drug making process or time used to make it in a sterile way. However, many anaesthesiologists still hesitate to use the isobaric ropivacaine because of its unpredictable spread and earlier regression. Considering the difference in anaesthetic efficacy of isobaric ropivacaine to isobaric bupivacaine the results are controversial in spinal anaesthesia, it is in this context that the present study was done to compare and evaluate the anaesthetic safety and efficacy of these two drugs in patients who were posted for lower abdominal surgeries.

2. Materials and Methods

After approval by the institutional ethical committee and an informed written consent, present study was carried out in a single blind randomized and in a controlled manner in 100 patients of either gender, ASA grade 1 and 2 between 20 to 60 years of age who were posted for lower abdominal surgeries under spinal anaesthesia.

A detailed preoperative check-up was done one day before the surgery was planned. All the patients were then randomized to receive either preservative free 3ml(15mg) of 0.5% bupivacaine (Group A, n=50) or preservative free 3ml(15mg) of 0.5% ropivacaine (Group B, n=50). An intravenous line was secured in all patients and 10ml/kg of isotonic saline was given before subarachnoid block in the preoperative room. Patients were shifted to operation table and were monitored for heart rate (HR), lead II, V on electrocardiogram, pulse oximetry (SpO₂) and blood pressure (BP). Baseline parameters were recorded before giving subarachnoid block. A subarachnoid block was performed using midline lumbar approach with patient in sitting position using Quinckie's spinal needle 26 G in L3-4 interspace. Then patients were made supine.

2.1. Parameters monitored

Onset of sensory block was assessed from the time of injecting the drug till complete analgesia was achieved at the level of lower border of umbilicus.

Level of sensory block was checked and tested bilaterally by pinprick method (20gauge hypodermic needle) at one-minute interval for seven minutes and then at 10 and 15 minutes. Maximum level achieved was noted at 15 minutes. C5-6 was used as baseline point for normal sensation. Duration of sensory block was taken as the time from the onset of sensory block to the time taken for regression to the two lower levels as compared to that at the onset.

The onset of motor block was determined every one minute till complete motor block (grade 3) was achieved as per Modified Bromage scale. Duration of motor block was taken as the time from complete motor block to the time when the patient was able to flex knees that is Grade I on Bromage scale.

Table 1:

Grade 0	No motor block
Grade I	Inability to raise legs
Grade II	Inability to flex knees
Grade III	Inability to flex ankle joint

Monitoring of hemodynamic parameters (HR, SBP, DBP) was done every one minute for 5 minutes, then every 3 minutes for next 15 minutes, every 5 minutes for next 40 minutes and lastly every 10 minutes till end of the surgical procedure. Any side effects such as hypotension, bradycardia, nausea, vomiting were written down. Hypotension was considered as fall in SBP >20% from baseline.

2.2. Statistical analysis

The data was analysed with the help of computer software MS EXCEL and SPSS12.0 for windows. Outcomes were reported as percentages for qualitative variables and mean and standard deviation for quantitative variables. Unpaired t test / chi square tests were employed for evaluating any statistical significance between the two groups. A p value of < 0.5 was considered as statistically significant. Unpaired t test and chi square test were employed.

3. Results

Both the groups were comparable in demographic data (Table 2).

Mean onset of sensory block was slower in the ropivacaine group and this difference was found to be statistically significant. The duration of sensory block was found to be significantly more in the bupivacaine group than in the ropivacaine group as shown in Table 3.

Table 2: Demographic data

		Group A (n=50)	Group B (n=50)	p value
Age (in Years)		42.3±11.5	43.1±11.5	0.7
Sex	Males	13	12	1.00
	Females	37	38	

Age is expressed in mean ± SD

Table 3: Characteristics of block

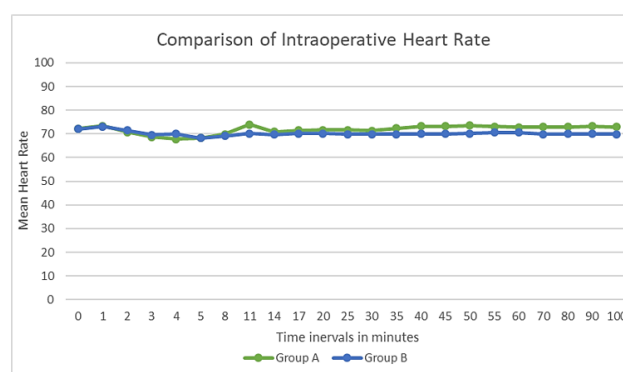
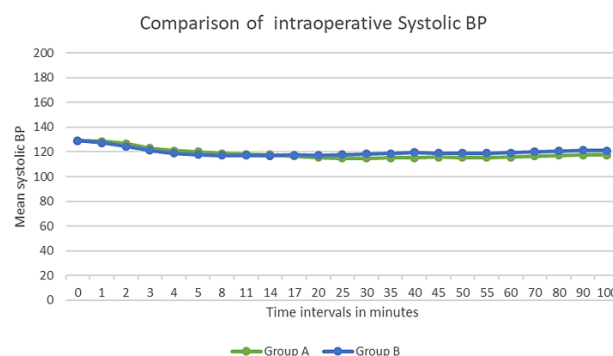
Time (in minutes)	Group A	Group B	p value
Onset of sensory block	4.35 ± 0.88	4.80 ± 0.92	0.017
Duration of sensory block	170.29 ± 14.14	155.77 ± 13.97	0.000
Onset of motor block	5.52 ± 0.75	5.91 ± 0.84	0.018
Duration of motor block	160.95 ± 15.74	140.08 ± 16.58	0.000

Data is presented in mean± SD

The onset of motor block was earlier in bupivacaine group as compared to ropivacaine group and this difference was found to be statistically significant. The duration of motor block was almost 20 minutes shorter in the ropivacaine group and this difference was found to be highly significant as shown in Table 3. The two groups were comparable in the maximum level of blockade reached at 15 minutes. The maximum cephalad spread of sensory block achieved in both the groups at 15 minutes was T₄. The maximum level achieved and distribution are shown in Table 4.

The baseline hemodynamic parameters were found to be comparable in both the groups. While comparing heart rates of the two groups there was a fall from the baseline values but it was statistically comparable throughout the study period (Figure 1). In Group A, SBP and DBP remained decreased till 100 minutes and 60 minutes respectively, whereas in Group B the SBP and DBP remained decreased till 100 minutes and 55 minutes respectively. Intergroup comparison of SBP showed that there was a significant decrease in readings from 40 minutes onwards in the bupivacaine group with $p < 0.05$ i.e SBP was significantly lesser in the bupivacaine group when it was compared to ropivacaine group after 40 minutes (Figure 2). While analysing the variations in DBP in both the groups, there was no significant difference in readings at any of the time intervals (Figure 3).

Incidence of hypotension was 24% in Group A and 16% in Group B, which was statistically significant ($p=0.04$). Incidence of bradycardia was 14% in Group A and 6% in Group B which was statistically significant ($p=0.03$). Incidence of nausea and vomiting was comparable in both the groups ($p > 0.05$). The failure rate to achieve adequate analgesia was 6% in both the groups.

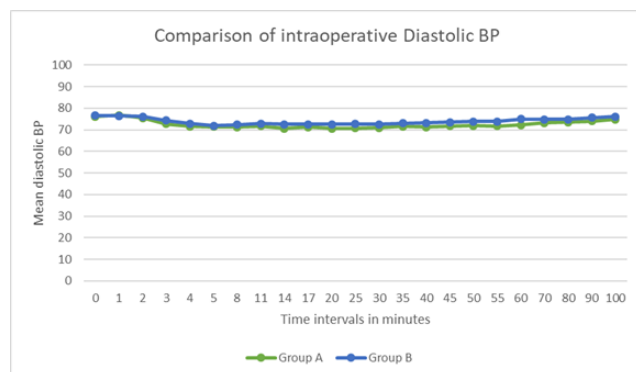
**Fig. 1:** Comparison of intraoperative heart rate**Fig. 2:** Comparison of intraoperative systolic blood pressure

4. Discussion

Ropivacaine in isobaric form is effective and safe for regional anaesthetic techniques such as epidural, brachial plexus blocks and spinal anaesthesia as there is ample clinical data present to show its effect.^{6,7} It can be safely used when anaesthesia of a similar quality but of a lesser period than that of bupivacaine or levobupivacaine is demanded.⁸ We chose isobaric ropivacaine and isobaric

Table 4: Maximum level of block at 15 minutes

	Group A		Group B	
	No. of patients	% age	No. of patients	% age
T4	05	10	05	10
T6	14	28	17	34
T8	20	40	18	36
T10	08	16	07	14

**Fig. 3:** Comparison of intraoperative diastolic blood pressure

bupivacaine in equivalent doses and concentration to rule out any bias.

Our results regarding onset of sensory block showed that onset is earlier with bupivacaine which are in accordance with other studies.^{9–11} This could be because of the lesser lipid solubility of ropivacaine which causes this drug to penetrate the large myelinated A fibres more slowly than the more lipid soluble bupivacaine. Although, Reetu Verma et al¹² on comparing 0.75% isobaric ropivacaine with 0.5% bupivacaine found no difference in onset of sensory block, however this could be accredited to higher concentration of ropivacaine used by them. Our results are in contrast to DA McNamee et al¹³ who in their study found no significant difference in the onset of motor and sensory blocks between the two groups. Though they demonstrated shorter time to onset of sensory block at T₁₀ being 2 minutes in both the groups with an equivalent dose of 17.5mg.

In our study duration of sensory block was significantly longer in bupivacaine group (170.29 ± 14.14 min) than in ropivacaine group (155.77 ± 13.97 min) as was claimed by many previous studies,^{11,13} although study conducted by Nalini A et al¹⁰ found duration of sensory block to be 14.5 ± 34.8 minutes with ropivacaine and 15.2 ± 9.1 minutes with bupivacaine which was not significant. Whereas more duration of sensory block with ropivacaine was shown by Reetu Verma et al¹² (315 ± 38.5 minutes) as compared to bupivacaine (296.2 ± 25 minutes) because of the higher concentration of ropivacaine (0.75%) used by them. Gautier et al¹⁴ found that 8 mg of bupivacaine was of equal potency to 12 mg of ropivacaine when they compared 4 ml of intrathecal hyperbaric bupivacaine 0.2% (8mg) with 4 ml of

different concentrations i.e. 0.2, 0.25, 0.3, 0.35% hyperbaric ropivacaine (8,10,12,14mg) in patients undergoing knee arthroscopy. The varied results in the above-mentioned studies could be due to difference in the dosages used, baricity of the drug solution and the population studied.

Onset of motor block in our study was found to be faster in bupivacaine group than ropivacaine group and is in accordance with studies conducted by J B Whiteside et al⁹ and Nalini et al¹⁰ and in contrast to various studies.^{11,13,15} This could be because of the different doses and concentrations of the drugs used by them.

Our study revealed longer duration of motor blockade in bupivacaine group (160.95 ± 15.74 min) as was shown by other studies.^{10,12,13} In contrast, Hema et al¹⁵ and Malinovsky JM et al¹⁶ found no difference whereas Kumar SS et al¹¹ found bupivacaine to be superior. They also concluded that isobaric bupivacaine should be opted over isobaric ropivacaine for day care short duration surgeries. However, these findings do not correlate with our results where we found ropivacaine to be more effective owing to the fact that they used different concentration and volumes of the two drugs. As we had used equivalent doses and concentration of the two drugs in our study and still found ropivacaine to be better than bupivacaine, this could prove that there is difference in potency of the two drugs when given by intrathecal route.

There was no significant difference in the maximum level of blockade achieved in both the groups with the highest level obtained at 15 minutes in both the groups being T₄ in our study as was also found by M Montouvalou et al⁸ while Mc Namee et al¹³ found the maximum sensory levels to be up to cervical dermatomes. This disparity can be explained by the fact that we noted the maximum levels achieved at 15 minutes only and the volume of drug used in the above-mentioned study was more than that used in our study. Our results were in contrast to those by Kessler P et al⁷ and Malinovsky et al¹⁶ who found sensory blockade higher in bupivacaine group and may be explained by the difference in the method of assessment.

In our study there was significant decrease in heart rate in both the groups with no intergroup differences. Study also enumerated that bradycardia was more common in bupivacaine group (14%) than in the ropivacaine group (6%). Thus, showing that bupivacaine is more hemodynamically unstable than ropivacaine as was found by M Mantovalou et al⁸ and P Gautier et al¹⁷ whereas

study by Kessler P et al⁷ found no difference in incidence of bradycardia. Reduced potential for CNS and cardiotoxicity is associated with ropivacaine when it is compared to bupivacaine because of its less penetration into large myelinated motor fibres owing to its inherent property of less lipid solubility. Moreover, ropivacaine is highly selective for pain transmitting nerve fibres than motor function fibres.

While comparing changes in SBP in present study, there was a difference in readings from 40 minutes onwards with the bupivacaine group showing significantly lower values. Incidence of hypotension was also statistically significant between the two groups. This finding correlates with the fact that the sympathectomy caused by spinal anaesthesia produces hemodynamic changes which nonetheless are more with bupivacaine. Our findings are consistent with those of M Mantouvalou et al⁸ and S Suresh Kumar et al.¹¹ However, many studies in literature have found no clinically significant differences in hemodynamic parameters between isobaric ropivacaine and bupivacaine.^{7,16,17}

The overall incidence of nausea was similar in both the groups in our study as was found by DA McNamee et al¹³ and P Gautier et al.¹⁷ None of our patients vomited. We also found that four patients who had nausea also had coincident hypotension which is in accordance with the study conducted by Randall et al¹⁸ who found that occurrence of hypotension during spinal anaesthesia led to almost twofold increase in the odds of developing nausea.

In our study, the failure rate to achieve adequate and desirable analgesia with both the drugs was 6%. Similarly, Van Kleef et al¹⁹ reported a failure rate of 5% as against Wahedi et al²⁰ who reported that 20% patients had inadequate analgesia in abdominal surgeries with intrathecal ropivacaine.

5. Conclusion

In conclusion this study establishes that 0.5% isobaric ropivacaine has rapid onset, produces good sensory blockade and is more stable hemodynamically with lesser side effects in comparison to 0.5% isobaric bupivacaine. Hence, commercially available 0.5% isobaric ropivacaine can be safely used for lower abdominal procedures.

6. Source of Funding

None.

7. Conflicts of Interest

There are no conflicts of interest.

References

- Albright GA. Cardiac arrest following regional anaesthesia with etidocaine or bupivacaine. *Anesthesiol.* 1979;51:285–7.
- Pollock JE, Neal JM, Stephenson CA, Wiley C. The importance of surgical positioning and anaesthetic concentration in the incidence of transient radicular irritation. *Anesthesiol.* 1995;83:824.
- Chambers WA, Edstrom HH, Scott DB. Effect of baricity on spinal anaesthesia with bupivacaine. *Br J Anaesth.* 1981;53(3):279–82.
- McClure JH. Ropivacaine. *Br J Anaesth.* 1996;76(2):300–7.
- Åkerman B, Hellberg IB, Trossvik C. Primary evaluation of the local anaesthetic properties of the amino amide agent ropivacaine (LEA 103). *Acta Anaesth Scand.* 1988;32(7):571–8.
- McClellan KJ, Faulds D. Ropivacaine- an update of its use in regional anaesthesia. *Drugs.* 2000;60:1065–93.
- Kessler P, Eichler A, Wilke HJ, Strouhal U, Bremerich D. Intrathecal ropivacaine vs. bupivacaine in lower abdominal gynaecological procedures. *Eur J Anaesth.* 2001;18(Supplement 21):86.
- Mantouvalou M, Ralli H, Arnaoutoglou G, Tziris G, Papadopoulos. Spinal anaesthesia: Comparison of plain ropivacaine, bupivacaine and levobupivacaine for lower abdominal surgery. *Acta Anaesth Belg.* 2008;59:65–71.
- Whiteside JB, Burke D, Wildsmith JAW. 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(3):304–8.
- Nalini A, Kuragayala U, Bhimeswar MV. A comparative study of intrathecal 0.5% isobaric ropivacaine vs 0.5% isobaric bupivacaine in lower abdominal surgeries. *IJCMR.* 2016;3(11):3124–3127.
- Kumar SS, Talwar V, Gupta P, Gogia AR. Comparison of the efficacy of intrathecal isobaric ropivacaine and bupivacaine in day care knee arthroscopy: A randomized controlled trial. *Anesth Essays Res.* 2018;12(4):859–64.
- Verma R, Mehrotra S. Comparison between intrathecal isobaric bupivacaine 0.5% with isobaric ropivacaine 0.75% for lower limb orthopaedic surgeries: a double blind randomized controlled study. *Int J Contemp Med Res.* 2017;4(4):868–71.
- McNamee DA, McClelland AM, Scott S, Milligan KR, Westman L, Gustafsson U. Spinal anaesthesia: comparison of plain ropivacaine 5 mg ml⁻¹ with bupivacaine 5 mg ml⁻¹ for major orthopaedic surgery. *Br J Anaesth.* 2002;89(5):702–6.
- Gautier PE, Kock MD, Steenberge AV, Poth N, Lahaye-Goffart B, Fanard L, et al. Intrathecal ropivacaine for ambulatory surgery: comparison between intrathecal bupivacaine and ropivacaine for knee surgery. *Anesthesiol.* 1999;91(3):1239–45.
- Gupta H, Amilkanthwar S. 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. *Int J Res Med Sci.* 2016;4:3134–40.
- Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A, et al. Intrathecal Anaesthesia: Ropivacaine Versus Bupivacaine. *Anaesth Analg.* 2000;91(6):1457–60.
- Gautier P, Kock MD, Huberty L, Demir T, Izydorczak M, Vanderick B. Comparison of the effects of intrathecal ropivacaine, levobupivacaine, and bupivacaine for Caesarean section. *Br J Anaesth.* 2003;91(5):684–9.
- Carpenter RL, Caplan RA, Brown DL, Stephenson C, Wu R. Incidence and risk factors for side effects of spinal anaesthesia. *Anesthesiol.* 1992;76(6):906–16.
- Kleef JWV, Veering B, Burm AG. Spinal anaesthesia with ropivacaine: A double blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing minor lower limb surgery. *Anaesth Analg.* 1994;78:1125–30.
- Wahedi W, Nolte H, Klein P. Ropivacaine in spinal anaesthesia. *Anaesth.* 1996;45:737–44.

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