

Evaluation of 0.5 % Hyperbaric Ropivacaine Versus 0.5 % Hyperbaric Bupivacaine for Elective Surgery under Spinal Anaesthesia - A Comparative Study

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Abstract

Original Research Article

In this prospective randomized control study, we compared the clinical efficacy and safety of equal doses (15 mg) of 0.5% Hyperbaric Ropivacaine with 0.5 % Hyperbaric Bupivacaine for lower torso surgeries under Spinal Anaesthesia. After Ethical Committee clearance and obtaining informed written consent from the patient, 80 patients of ASA 1 and 2 of age group 25-50 years posted for lower torso surgeries in Government. Mohan Kumaramangalam Medical College were included. Study population was divided into 2 groups- GROUP B(Patients in this group received intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Bupivacaine) GROUP R(Patients in this group received intrathecal 15 mg (3 ml) of 0.5% Hyperbaric Ropivacaine which is prepared aseptically immediately before injection by adding 1 ml (250 mg) of autoclaved 25% dextrose ampoule (10 ml) to 2 ml of commercially available sterile preservative free isobaric solution of 0.75% Ropivacaine).From our study we conclude that the duration of sensory block and motor block in patients receiving 0.5 % hyperbaric Ropivacaine was less when compared to the patients receiving 0.5 % hyperbaric bupivacaine

Keywords: Spinal Anaesthesia, 0.5% Hyperbaric Ropivacaine, 0.5% Hyperbaric Bupivacaine.

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INTRODUCTION

"Cocainization of the spinal cord" was first described by August Bier in 1899. Cocaine - the drug which leads to the discovery of spinal anaesthesia, had many side effects and eventually Lignocaine became the preferred drug. Later 5% Lignocaine heavy was reported to cause transient neurological symptoms and it was withdrawn from regular use. Since then Bupivacaine has been the most widely used drug for Spinal anaesthesia.

Three decades ago, some patients who received Bupivacaine developed life threatening arrhythmias, which were refractory to treatment. On notifying this life threatening cardiotoxicity of Bupivacaine, the search for newer, safer local anaesthetic drugs began. An important aspect of this cardiotoxicity is that, it is related to the stereospecificity of Bupivacaine with the 'S' isomer having very less cardiotoxic potential compared to the 'R' form. To

overcome this side effect, Ropivacaine a long lasting drug with less cardiotoxicity was discovered.

Ropivacaine, a newer amino - amide local anesthetic agent similar to Bupivacaine in chemical structure, which is 30-40% less potent than Bupivacaine has been well-studied for spinal anaesthesia. The preliminary studies evaluated the efficacy and safety of isobaric Ropivacaine for neuraxial blockade. Intrathecal Ropivacaine was found to be safe, having shorter duration of action than Bupivacaine and lesser incidence of transient neurological symptoms (TNS) as compared with intrathecal Lignocaine. Intrathecal use of hyperbaric Local Anaesthetic agents has become more popular as they produce predictable block characteristics and reliable Spinal Anaesthesia.

Presently only isobaric preparations of Ropivacaine are commercially available for the reason of difficulty in maintaining the pharmacological stability of hyperbaric solutions for clinical use.

In this prospective randomized control study, we are comparing the clinical efficacy and safety of 0.5% Ropivacaine (made hyperbaric by the addition of desired dose of dextrose from autoclaved 10 ml ampoule of 25% dextrose) with commercial hyperbaric 0.5% Bupivacaine using equal doses (15 mg) and to assess the suitability of Ropivacaine as an alternative to Bupivacaine for intermediate duration of surgeries under Spinal Anaesthesia.

AIM OF THE STUDY

To compare the clinical efficacy and safety of equal doses (15 mg) of 0.5% Hyperbaric Ropivacaine with 0.5 % Hyperbaric Bupivacaine for lower torso surgeries under Spinal Anaesthesia.

MATERIALS AND METHODOLOGY

Study centre

Government Mohan Kumaramangalam Medical College, Salem

Study design

Interventional study

Patient selection

Ethical committee approval and informed written consent from patients involved in this study are obtained before starting this study.

Study design

Prospective randomized control study, single blinded.

Randomization

Patients were randomly allocated into two groups by slips in a box technique.

Study population

80 Patients

SAMPLE SIZE CALCULATION

The sample size was calculated based on the similar previous studies. Considering the power of the study as 80 % , type – I error rate (alpha) as 5 % and a superiority margin between the two groups as 25 % ,the sample size of this study was calculated to be 80 patients.

n = the sample size in each of the groups
 μ_1 = population mean in treatment Group 1
 μ_2 = population mean in treatment Group 2
 $\mu_1 - \mu_2$ = the difference the investigator wishes to detect
 σ^2 = population variance (SD)
 a = conventional multiplier for alpha = 0.05
 b = conventional multiplier for power = 0.80

$$n = \frac{2 [(a + b)^2 \sigma^2]}{(\mu_1 - \mu_2)^2}$$

Sample size calculation

MATERIALS

25 gauge Quincke spinal needle.

Table-1: Comparison of mean age between study group (N=80)

Parameter	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Age (Mean ± STD)	36.78 ± 9.885	41.93 ± 12.275	0.042

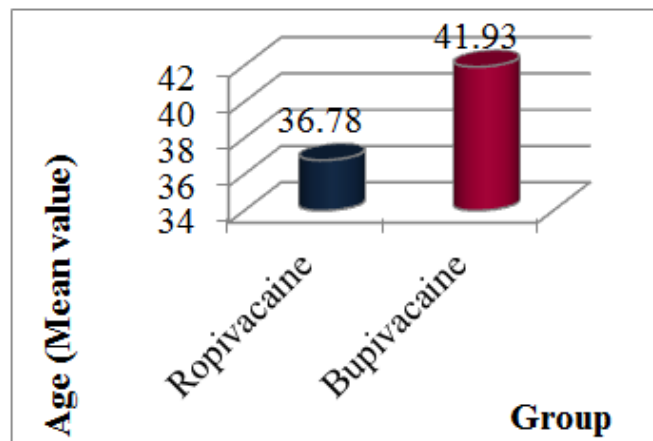


Fig-1: Bar chart of Comparison of mean age between Study group (N=80)

Table-2: Comparison of gender with study group (N=80)

Gender	Group		Total
	Ropivacaine	Bupivacaine	
Male	21	24	45
Percentage	52.5%	60%	56.3%
Female	19	16	35
Percentage	47.5%	40%	43.8%
Total	40	40	80
Chi square	0.457		
P value	0.499		

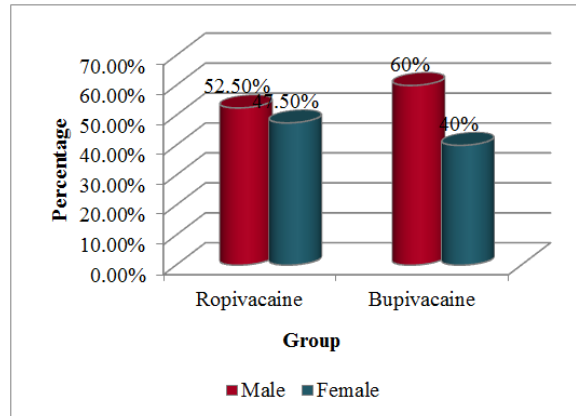


Fig-2: Cluster bar chart of comparison of gender between study group (N=80)

Table-3: Comparison of mean time to onset of sensory block (in minutes) between study group (N=80)

	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Time to onset of sensory block (in minutes)	4.00 ± 0.784	3.00 ± 0.679	<0.001

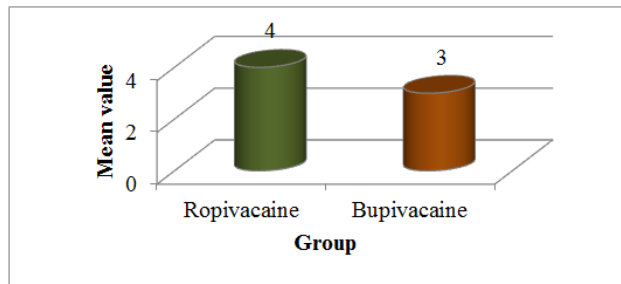


Fig-3: Bar chart of comparison of mean time to onset of sensory block (in minutes) between study group (N=80)

Table-4: Comparison of mean time to peak sensory block (in minutes) between study group (N=80)

Parameter	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Time to Peak sensory block(in minutes)	13.45 ± 0.846	14.53 ± 0.987	<0.001

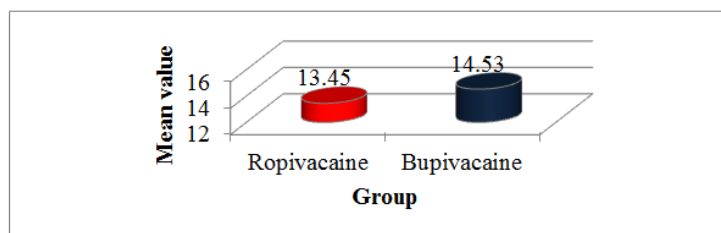


Fig-4: Bar chart of comparison of mean time to peak sensory block (in minutes) between study group (N=80)

Table-5: Comparison of mean duration of sensory block (in minutes) between study group (N=80)

	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Duration of Sensory Block (in minutes)	154.18 ± 6.176	190.05 ± 6.801	<0.001

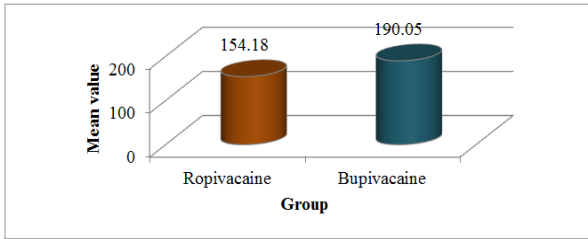


Fig-5: Bar chart of comparison of mean time to peak sensory block (in minutes) between study group (n=80)

Table-6: Comparison of mean time to complete motor block (in minutes) between study group (N=80)

	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
TOM	14.18 ± 1.059	11.58 ± 1.035	<0.001

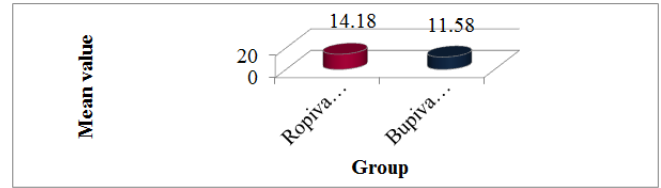


Fig-6: Bar chart of comparison of mean time to complete motor block (in minutes) between study group (N=80)

Table-7: Comparison of mean duration of motor block (in minutes) between study group (N=80)

	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Duration of Motor Block (in minutes)	122.53 ± 5.174	189.25 ± 8.566	<0.001

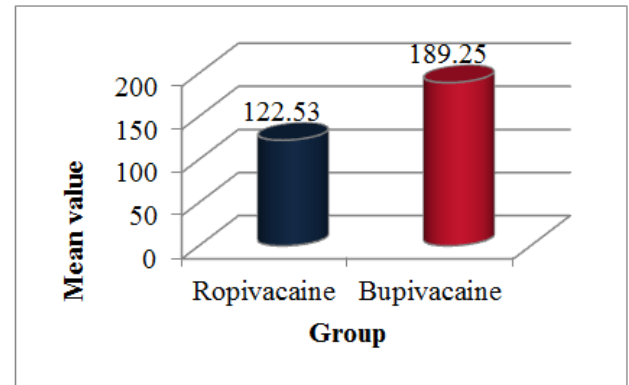


Fig-7: Bar chart of comparison of mean duration of motor block (in minutes) between study group (N=80)

Table-8: Comparison of mean arterial pressure between study group (N=80)

Mean Arterial pressure	Group		Unpaired t test P value
	Ropivacaine (N=40)	Bupivacaine (N=40)	
Preoperative	95.18 ± 8.54	92.58 ± 7.45	0.151
1 min	90.21 ± 7.38	88.24 ± 6.93	0.223
3 min	85.44 ± 7.00	82.02 ± 4.91	0.013
5 min	82.22 ± 7.63	78.28 ± 5.49	0.010
10 min	82.62 ± 6.47	80.36 ± 6.54	0.125
15 min	83.22 ± 6.56	80.94 ± 6.12	0.113
30 min	85.12 ± 5.76	82.36 ± 4.21	0.017
45 min	87.57 ± 5.31	84.33 ± 3.53	0.002
60 min	90.40 ± 5.86	89.07 ± 4.53	0.258
75 min	92.72 ± 4.88	88.90 ± 3.0	<0.001
90 min	94.73 ± 5.35	90.20 ± 3.78	<0.001
120 min	95.68 ± 6.53	92.52 ± 4.58	0.014

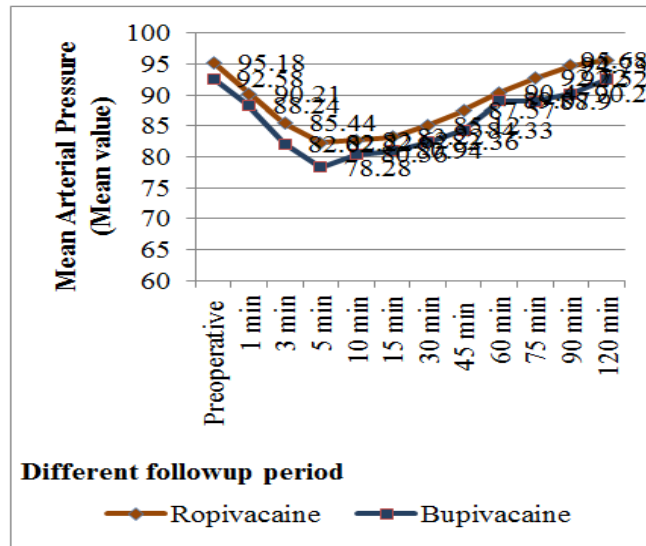


Fig-8: Trend line diagram of comparison of mean arterial pressure between study group =80)

Table-9: Comparison of Side effects with study group

Adverse effects	Group R Ropivacaine (n=40)	Percentage	Group B Bupivacaine (n=40)	Percentage
Hypotension	7	17.5 %	11	27.5 %
Bradycardia	3	7.5 %	5	12.5 %
shivering	4	10 %	5	12.5 %
Nausea	4	10 %	8	20 %
GA supplementation	0	0	0	0

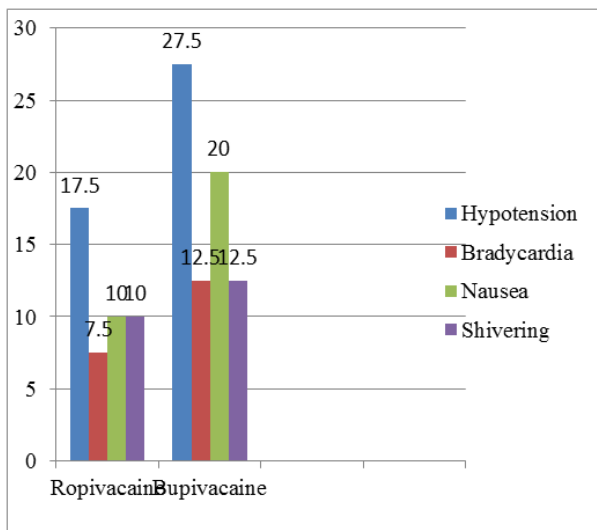


Fig-9: Cluster bar chart of comparison of side effects between study groups

Drugs: 0.5 % Hyperbaric Bupivacaine and 0.75% Isobaric Ropivacaine (Ropin 0.75 in 10 ml ampoule). Injection Dextrose 25 % ampoule (10ml), Emergency drugs and crystalloids, Monitors: ECG, NIBP, SPO2, PR

RESULTS

A total 80 people were included in the final analysis.

DISCUSSION

Early 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 as with other drugs used for Spinal anaesthesia.

It reduces the proportion of a limited block or more extensive block which has been previously reported from studies on both tetracaine and bupivacaine.

As hyperbaric ropivacaine is not available commercially, addition of glucose 3-10% to ropivacaine has been used and studied for surgeries under Spinal Anaesthesia.

In our study, the concentration of dextrose (83 mg/ml, 8.3%) used is similar to that of commercially available hyperbaric bupivacaine (80 mg/ml, 8%). We used readily available 25% 10 ml dextrose ampoules, autoclaved to prevent the risk of bacterial contamination. It is known that ropivacaine is 30-40% less potent and effects are short lived than bupivacaine making it advantageous for short to intermediate duration of surgeries or ambulatory surgeries.

We observed that ropivacaine significantly produced slower onset but shorter time to peak effect (4.0 ± 0.784 min, 13.45 ± 0.846 min) than bupivacaine

(3.0 ± 0.679 min , 14.53 ± 0.987 min); however, level of sensory block achieved was similar and duration of sensory block was significantly lesser with ropivacaine (154.18 ± 6.176 min).

The onset of pinprick analgesia at T10 was more rapid in bupivacaine Group B than in ropivacaine Group R ($P < 0.001$).

However, the time to (peak) maximum extent of cephalad spread and the level achieved were similar in both groups. The mean duration of sensory block was shorter in Group R (154.18 ± 6.176) than in Group B (190.05 ± 6.801) [$P < 0.001$].

The time to maximum motor blockade was statistically similar ($P < 0.001$) and duration of motor blockade was greater in Group B (189.25 ± 8.566) than in Group R (122.53 ± 5.174). [$P < 0.001$].

In bupivacaine group 11 (27.5%) patients and in ropivacaine group 8 (17.5 %) patients required ephedrine for hypotension ($P > 0.05$). No significant difference in the incidence of bradycardia was observed in two groups and they responded easily to injection atropine. Four patients in Group R and five patients in Group B developed shivering which was managed conservatively.

The findings were similar to the study carried out in elective surgeries under Spinal Anaesthesia by Whiteside [2] and others who observed onset time of 5 and 2 min with 3 ml of 0.5% hyperbaric ropivacaine and bupivacaine in 5% and 8% glucose respectively.

We observed that ropivacaine has a less potent effect on motor nerves and the degree of sensory-motor separation is more as compared with bupivacaine, but can produce reliable Spinal Anaesthesia, which has been supported by similar observations of other studies.

The findings were similar to the study carried out by Whiteside [2] and others, who observed mean onset time of motor blockade of 15 min and 10 min and total duration of around 90 min and 180 min with similar dose of hyperbaric ropivacaine and bupivacaine respectively.

Luck et al. [8] also observed less degree and duration of motor blockade, lower incidence of Bromage score of grade III in 63% with hyperbaric 0.5% ropivacaine as compared to 90% with 0.5% bupivacaine, with the similar dose of 3 ml with 30 mg/ml of glucose.

We also noted that compared to bupivacaine ropivacaine group had good sensory blocks, favorable recovery profile of sensory/motor blockade and shorter time to first micturition. These features of ropivacaine are beneficial for ambulatory surgery.

Hyperbaric lignocaine 5% has been used as a short-acting agent for ambulatory Spinal Anaesthesia, but currently its use is restricted due to a high incidence of TNS.

We found no evidence of any late sequelae such as backache or other transient symptoms in this study as with previous studies of ropivacaine. Hence, ropivacaine can be a safer alternative for ambulatory surgeries.

SUMMARY

80 patients of ASA I and II posted for elective lower torso procedures were grouped into Group R (Ropivacaine) and Group B (Bupivacaine) of 40 each and Spinal anaesthesia was performed to compare the following variables between two groups. Time to onset of Sensory block, Time to peak Sensory block, Duration of Sensory block, Time to Complete Motor block, Duration of Motor block, Intraoperative Haemodynamics and Complications

The study showed the following results

The onset of sensory and motor block was nearly same in both the groups. The time to peak sensory and motor block was similar in both groups.

The duration of sensory block and motor block was less in Ropivacaine group when compared to Bupivacaine Group.

There were not much significant hemodynamic variations in both groups. Incidence of complications was less in Ropivacaine group.

CONCLUSION

From our study we conclude that the duration of sensory block and motor block in patients receiving 0.5 % hyperbaric Ropivacaine was less when compared to the patients receiving 0.5 % hyperbaric bupivacaine. The onset of sensory and motor block was nearly same in both the groups. Incidence of Complications like hypotension and bradycardia were less in Ropivacaine group. Ropivacaine is comparable to the readily available hyperbaric 0.5% bupivacaine (in 8% glucose) in terms of quality of block, but with a shorter recovery profile, it is a useful agent for Spinal Anaesthesia for intermediate duration of surgeries.

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