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Research Article

A Comparative Evaluation of Intrathecal 0.75% Hyperbaric Ropivacaine versus Intrathecal 0.5% Hyperbaric Bupivacaine for Elective Infraumbilical Surgeries

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ABSTRACT

Background: With the current emphasis on ambulatory surgeries, bupivacaine has limited usefulness. Ropivacaine has low lipid solubility and is less cardiotoxic and neurotoxic than bupivacaine. It is gaining popularity because of its recovery profile. Hence, we designed a study to compare the clinical efficacy of 3 mL of 0.75% hyperbaric ropivacaine versus 3 mL of 0.5% hyperbaric bupivacaine under spinal anaesthesia for elective infraumbilical surgeries.

Aim: To compare the clinical efficacy of 3ml of 0.75% hyperbaric ropivacaine versus 3ml of 0.5% hyperbaric bupivacaine under spinal anaesthesia for elective infraumbilical surgeries.

Material and Methods: After approval from the institutional Ethics Committee, 80 adults aged 18-70 years with ASA I and II grades who presented for elective infraumbilical surgeries under spinal anaesthesia and fulfilled the inclusion criteria were enrolled in this study. According to the randomisation, patients were divided into two groups of 40 each. They received an intrathecal injection of 0.75% hyperbaric ropivacaine (3 mL) in group A or 0.5% hyperbaric bupivacaine (3 mL) in group B. Vital signs were monitored, and block parameters were observed. Adverse events and the time to first micturition were noted. The data were presented as means with standard deviations and frequencies with percentages. The data were analysed using statistical software SPSS version 21.

Result: Ropivacaine produced a slower mean onset of sensory block (11.55 vs 6.63 mins; $p<0.01$), and the mean total duration of sensory block was significantly shorter (234.75 vs 288.75 mins; $p<0.01$) as compared to bupivacaine. Patients in the bupivacaine group achieved a higher level of peak sensory block (p-0.048). The onset of motor block was significantly slower (10.45 vs 6.3 minutes; $p < 0.01$) and the duration was shorter (206.25 vs 258.75 minutes; $p < 0.01$) in the ropivacaine group. Post the induction, SBP and MAP were significantly lower in the bupivacaine group as compared to ropivacaine from the 4th min onwards till the 15th min ($p<0.01$), and DBP was substantially lower in the bupivacaine group as compared to ropivacaine from the 2nd min onwards till the 15th min ($p<0.01$). The time to first micturition was significantly faster with ropivacaine compared to bupivacaine (357.87 vs 403.97 minutes; $p < 0.01$).

Conclusion: The study concludes that 0.75% hyperbaric ropivacaine, despite its slower onset of action, can serve as a good alternative to 0.5% hyperbaric bupivacaine for spinal anaesthesia in elective infraumbilical surgeries of short to intermediate duration, offering the added advantages of earlier recovery and more stable hemodynamics.

Keywords: Day Care Surgeries, Haemodynamics, Local Anaesthetics, Spinal Anaesthesia.

INTRODUCTION

Spinal anaesthesia is a safe technique that provides rapid and reliable anaesthesia with muscle relaxation while causing fewer systemic and metabolic disturbances. 0.5% hyperbaric bupivacaine has been widely utilised for spinal anaesthesia. It induces an intense and prolonged motor blockade, making it

inappropriate for use in ambulatory anaesthesia [1]. Significant limitations of the use of bupivacaine are its neurotoxicity and cardiotoxicity. Therefore, a search for new local anaesthetics was initiated to assess their suitability for day care anaesthesia. Ropivacaine is a relatively new aminoamide local anaesthetic. It is the first S (-) enantiomer of bupivacaine and appears to be less potent and causes a less intense motor block of a shorter duration compared to bupivacaine [2-4]. Additionally, Ropivacaine has less cardiovascular and central nervous system toxicity than bupivacaine [5]. Since daycare surgeries are a rapidly growing and widely accepted form of healthcare, Ropivacaine is a favourable local anaesthetic for these surgeries because it allows for earlier postoperative mobilisation [6]. Studies on Ropivacaine have been conducted for local infiltration, epidural, and peripheral nerve blocks. There is limited data on the intrathecal use of ropivacaine, particularly comparing hyperbaric 0.75% ropivacaine with other local anaesthetics. Our study aims to compare the clinical efficacy of 0.75% hyperbaric Ropivacaine with that of 0.5% hyperbaric Bupivacaine under spinal anaesthesia for elective infraumbilical surgeries.

MATERIAL AND METHODS

A prospective, double-blinded, randomised clinical study was conducted at the Department of Anaesthesiology, Jagjivan Ram Railway Hospital, Mumbai, from August 2022 to July 2023, following approval by the Institutional Ethics Committee [IEC/JRH/12/08/2022].

Sample Size Calculation: To evaluate the block characteristics with intrathecal hyperbaric ropivacaine and bupivacaine, the mean duration of sensory block observed in a previously published study[10] was considered for sample size calculation using the formula $\eta = (Z)^2(S.D.)^2/L^2$.This calculation was based on the assumption of α (type 1 error) =15%, β (type 2 error) =20% and power of study = 80% to detect a difference of 35%, where η is the sample size, z = 1.96 at a 95% Confidence interval, L is the permissible error in the estimate of the new mean (5-20% of the mean) and S.D. is the standard deviation. A total of 40 patients were enrolled per group, with written informed consent obtained and explained in their language to account for possible dropouts.

Inclusion Criteria

1. Adult patients aged between 18-70 years (both inclusive) of either sex.
2. Patients of ASA (American Society of Anaesthesiologists) physical status Grade I and II
3. Patients with height between 150 cm - 180cm.
4. Patients weighing between 45kg to 80kg.
5. A patient who has given valid informed written consent.
6. Patient undergoing elective infraumbilical surgery.

Exclusion Criteria

1. ASA grade III, IV, and V
2. Patient's refusal
3. Patients with contraindications for spinal anaesthesia.
4. Female subjects who are pregnant or lactating
5. Known hypersensitivity to any of the study drugs.
6. Lack of informed written consent

A total of 80 patients meeting the inclusion criteria were selected for the study and randomly divided in double-blind fashion using computer-generated numbers into two groups with 40 patients in each group:
Group A: Administered a 3 ml intrathecal dose of 0.75% hyperbaric Ropivacaine.
Group B: Administered a 3 ml intrathecal dose of 0.5% hyperbaric Bupivacaine.
An anaesthetist not involved in the intraoperative management or postoperative assessment prepared the intrathecal injection under strict aseptic precautions in an unlabelled syringe. The patient, the surgeon, the in-charge anaesthesiologist responsible for the intra-operative care, and the individual who performed the postoperative evaluations were blinded to the patient group assignment. Group allocation was concealed in sealed, opaque envelopes and was opened by an anaesthesiologist not involved in the intraoperative or postoperative care of the patients.
A total of 85 patients were selected, out of which two were excluded because they did not meet the inclusion criteria, and three did not provide consent. A total of 80 patients were included in the study. The Consolidated Standards of Reporting Trials (CONSORT) flowchart has been presented in [Table/Fig-1]. They were observed for the Onset and duration of sensory and motor block, the Peak sensory

level achieved, the time to reach the peak level, and the Degree of motor block achieved as primary objectives. Secondary objectives included hemodynamic changes, the frequency of adverse events, and time to first micturition.

Study Procedure

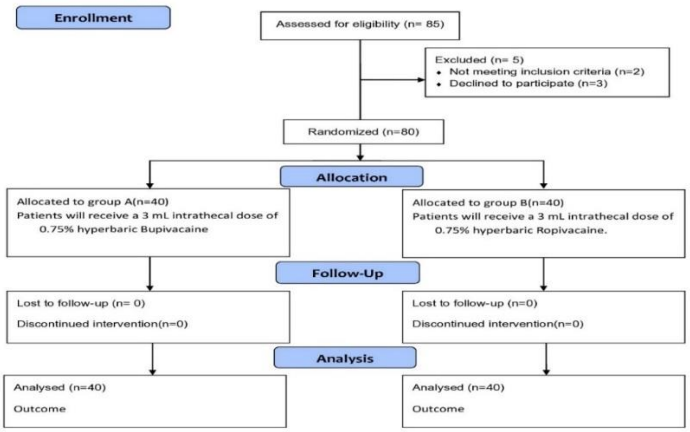
For anxiety relief, patients were prescribed 0.25 mg to 0.5 mg of alprazolam tablets to be taken at night before surgery. Patients were kept nil per oral from midnight before surgery. On the day of surgery, the patient was taken to the O.T. The multi-channel monitor was attached, and baseline parameters, including pulse rate, blood pressure (systolic, diastolic, and mean), electrocardiography (leads II and V), and SpO2, were recorded. An intravenous line was established using a 20G size intravenous cannula, and preloading was done in every patient (using 8 ml of crystalloid/kg of body weight). Under all aseptic precautions, the subarachnoid blocks were performed using a 25G Quincke spinal needle with the patient in the sitting position at L3-L4 or L4-L5 intervertebral space, and the appropriate local anaesthetic drug was injected. The patients were made supine immediately afterwards. The development of the block was recorded by an investigator who was blind to the nature and type of solution injected. The extent of sensory block (analgesia to pinprick), and degree of lower limb motor block, were recorded at 2 min intervals for the first 10 minutes post-injection and at 5 min intervals thereafter until 30 mins after which assessment was performed every 10 mins intervals until 60 mins and then at 15 min intervals until 120 mins thereafter every 30 mins until complete regression of the sensory level and motor blockade of grade 0 on Bromage scale was observed. During surgery, hemodynamic monitoring was performed at 2-minute intervals for the first 10 minutes, then at 5-minute intervals until 30 minutes, and thereafter every 15 minutes until the surgery was completed. The onset of sensory block at the T-10 level was defined as the time from the injection of the anaesthetic solution to the loss of sensation to pinprick. Complete recovery of sensory block was defined as the presence of painful sensations on the pinprick at the S1 dermatome level, and the time was recorded. Motor block was assessed using James modified Bromage scale used by asking the patient to flex the limb at hip, knee, and ankle joints (Grade 0: full movement, Grade 1: Inability to raise extended leg, can bend knee, Grade 2: Inability to bend knee, can flex ankle, Grade 3: No movement). The onset time of the motor block was defined as the time to achieve a complete motor block (Grade 3) after intrathecal injection of local anaesthetic, and the total duration was defined as the time to recover completely from the motor block. Bradycardia was defined as a pulse rate < 60/min and was treated with an injection of atropine 0.6mg. Hypotension (a fall in systolic blood pressure of >30% from baseline) was recorded and treated with an IV bolus of 5 mL/kg of Ringer's lactate, followed by an injection of mephentermine 3 mg in intermittent boluses as needed. Fluids were administered to replace intraoperative losses. After surgery, patients were encouraged to mobilise under supervision only when the sensory block had regressed beyond S1, and the time to first micturition was noted. All patients were visited at 24 h and telephoned twice a week later to identify any adverse sequelae.

RESULTS

In this double-blind prospective study, there was no significant difference between the study groups in terms of age, gender distribution, ASA grade, weight, height, or duration of surgery ($p>0.05$) [Table/Fig-2]. Both groups were comparable at baseline in terms of mean heart rate [Table/Fig-3]. The difference remained non-significant throughout the study period ($p>0.05$). Both groups also showed comparable baseline values for mean SBP, DBP, and MAP [Table/Fig-4]. After induction, SBP and MAP were significantly lower in the bupivacaine group compared to the ropivacaine group from the 4th minute onward until the 15th minute ($p<0.01$), and DBP was significantly lower in the bupivacaine group from the 2nd minute until the 15th minute ($p<0.01$). The differences were not significant thereafter, through the end of the study period ($p > 0.05$). Both groups had comparable baseline mean oxygen saturation [Table/Fig. 5], and the difference remained non-significant throughout the study ($p>0.05$). Characteristics of the subarachnoid block (SAB) are provided in [Table/Fig-6]. The mean onset of sensory block at the T10 level was significantly faster (6.63 vs. 11.55 minutes; $p<0.01$), and the duration was significantly longer (288.75 vs. 234.75 minutes; $p<0.01$) with bupivacaine compared to ropivacaine. Additionally, the mean time to reach peak sensory level was significantly shorter in the bupivacaine group (13.60 vs. 19.00 minutes; $p < 0.01$). The T4 level was achieved in 5% of

bupivacaine cases and 0% of ropivacaine cases. In comparison, T6 levels were reached by 42.5% and 22.5%, and T8 levels by 50% and 65%, respectively, indicating that more cases in the bupivacaine group achieved higher sensory blocks (p = 0.048). The mean time to onset of motor block was significantly shorter with bupivacaine (6.3 vs. 10.45 minutes; p<0.01), and the duration was longer (258.75 vs. 206.25 minutes; p<0.01). Most patients achieved Bromage grade 3 motor blockade. There was no significant difference between the groups in the degree of motor blockade achieved (p=1.0). Both groups were similar in terms of adverse events [Table/Fig. 7], with no significant difference (p>0.05). Bradycardia was observed in 20.0% of patients receiving bupivacaine and 7.5% receiving ropivacaine. Hypotension occurred in 10% and 5% of cases, respectively. Post-operative nausea and vomiting (PONV) occurred in 2.5% of the bupivacaine group and none in the ropivacaine group. Both groups experienced post-dural puncture headache (PDPH) and backache (PDPB) at a rate of 2.5% each. No neurological symptoms were observed, and no patient required supplementation with GA. The time to first micturition was significantly earlier in the ropivacaine group (357.87 vs. 403.97 minutes; p<0.01) [Table/Fig. 8].

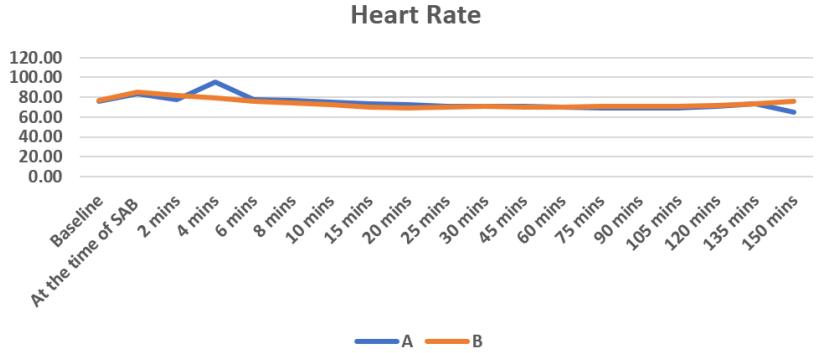
[Table/Fig-1]: CONSORT Flowchart of the Study



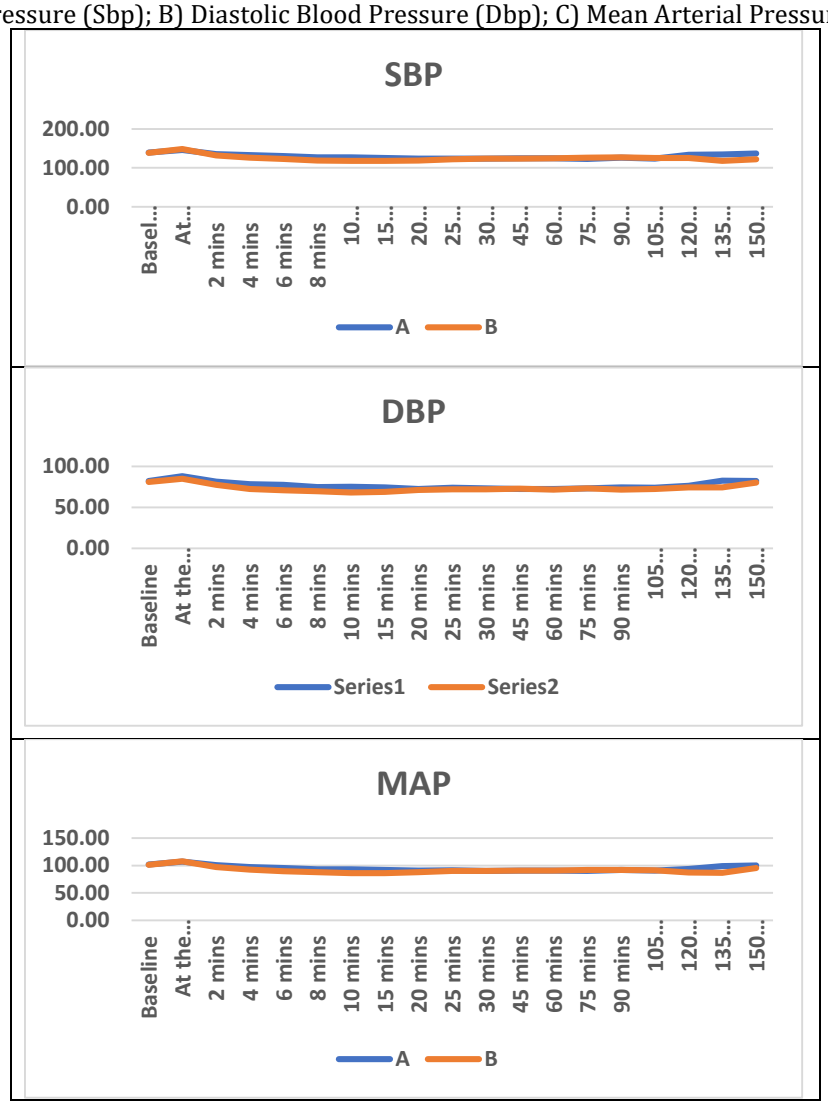
[Table/Fig-2]: Patient Characteristics and Duration of Surgery

Demographic Profile And Duration Of Surgery	Group A Ropivacaine (N = 40)	Group B Bupivacaine (N = 40)	Analysis Of Variance Test P- Value
Age In Years (Mean)	51.05	53.00	0.56
Gender M/F	32/8	32/8	1.0
ASA (I/II)	18/22	14/26	0.49
Weight (In Kg)	66.45	67.75	0.49
Height (In Cm)	166.28	164.88	0.32
Duration Of Surgery (Mins)	89.38	100.13	0.105

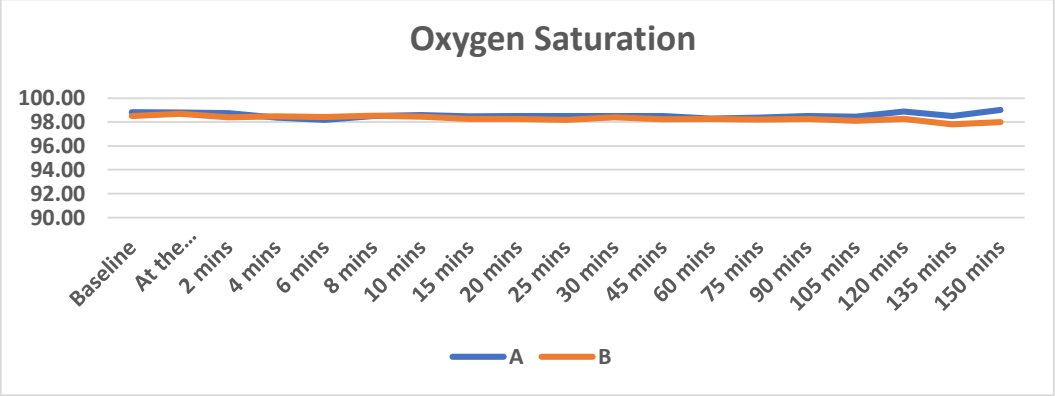
[Table/Fig-3]: Mean Heart Rate between Study Groups at Various Time Points



[Table/Fig-4]: Chart Showing Comparison of Haemodynamic Data between Both Groups. A) Systolic Blood Pressure (Sbp); B) Diastolic Blood Pressure (Dbp); C) Mean Arterial Pressure (Map)



[Table/Fig-5]. Mean Oxygen Saturation between Study Groups at Various Time Points

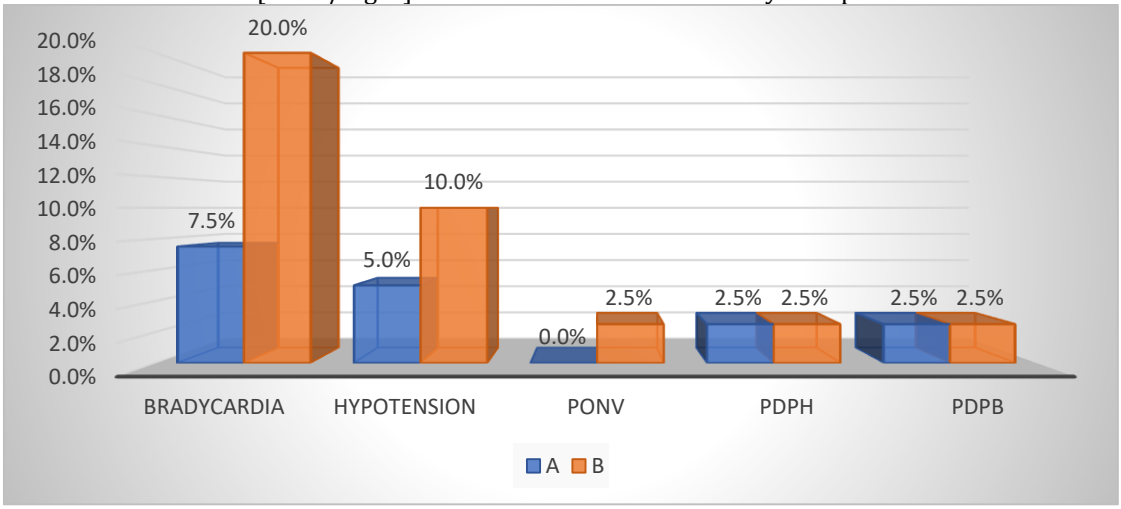


[Table/Fig-6]: Characteristics of Subarachnoid Block (SAB)

Observations of SAB	Group A (n = 40)	Group B (n = 40)	P value
Onset time of sensory block (min)	11.55	6.63	<0.01
Time to peak sensory block (min)	19.00	13.60	<0.01

Peak sensory level achieved at (n, %) T4 T6 T8 T10	 0 (0) 9 (22.5) 26 (65.0) 5 (12.5)	 2 (5) 17 (42.5) 20 (50.0) 1(2.5)	0.048
Duration of sensory block (min)	234.75	288.75	<0.01
Onset time of motor block (min)	10.45	6.30	<0.01
Duration of motor block (min)	206.25	258.75	<0.01
Degree of motor blockade (n,%) Bromage grade 1 Bromage grade 2 Bromage grade 3	 0 (0) 1 (2.5) 39 (97.5)	 0 (0) 0 (0) 40 (100)	1.0

[Table/Fig. 7]: Adverse Events Between Study Groups



[Table/Fig. 8]: Mean Comparison of Time to First Micturition among Study Groups

Parameter	Group	N*	Mean	p- value
Time to First micturition (mins)	A	38	357.87	<0.01
	B	31	403.97	

DISCUSSION

Spinal anaesthesia is crucial for successful outcomes in emergency and elective surgeries due to its comfort and high success rate. Choosing the right local anaesthetic is essential, as it should have minimal effects on vascular parameters, such as heart rate and mean arterial pressure, and a rapid wearing-off effect on sensory and motor functions, thereby reducing hospital stay. Bupivacaine, a long-acting local anaesthetic, has been linked to delayed hospital discharge, and it also warrants being used with caution due to its cardiotoxic potential. Ropivacaine, a newer local anaesthetic, has a wide safety margin. Its low lipid solubility makes it less cardiotoxic and neurotoxic, with an early recovery profile, making it ideal for patients who need early postoperative mobilisation. Hence, it can prove to be suitable for daycare surgeries.

A present hospital-based comparative study aimed to compare the clinical efficacy of 3 mL of 0.75% hyperbaric ropivacaine versus 3 mL of 0.5% hyperbaric bupivacaine under spinal anaesthesia for elective infraumbilical surgeries. A total of 80 cases were divided into two groups of 40 each: Group A: received intrathecal injection of 3 ml of 0.75%hyperbaric ropivacaine, and Group B: received intrathecal injection of 3 ml of 0.5%hyperbaric bupivacaine. Both groups were comparable in terms of baseline characteristics, including age,

gender, ASA grade, and duration of surgery (P > 0.05). In this study, we assessed which of the two agents does not significantly affect the hemodynamic parameters. In comparison, the mean heart rate at baseline and during surgery was comparable between the bupivacaine and ropivacaine groups (p>0.05). Mean SBP, DBP, and mean arterial pressure at baseline were also comparable between the bupivacaine and ropivacaine groups. However, post the induction, SBP and MAP were significantly lower in the bupivacaine group as compared to ropivacaine from the 4th min onwards till the 15th min (p<0.01); also, DBP was significantly lower in the bupivacaine group as compared to ropivacaine from the 2nd min onwards till the 15th min (p<0.01). Both groups were comparable at baseline in terms of mean oxygen saturation. The difference was non-significant throughout the study period (p>0.05). Kharat PA et al. [7] found no significant difference in hemodynamic parameters, except for lower diastolic and mean pressures in group B (p < 0.05). The results of the study by Whiteside et al. [2] also showed that hyperbaric ropivacaine provides reliable spinal anaesthesia with stable hemodynamic parameters and less hypotension compared to bupivacaine. Joshi R et al. (2022) [8] found in their study that the mean arterial pressure was significantly higher with ropivacaine compared to bupivacaine throughout all time intervals, and vasopressor use was lower with ropivacaine. Purohit S et al. [9] in a similar study observed that hemodynamics were stable in Group R as compared to Group B. A significant difference was found in terms of hypotension (12% vs. 4%; p < 0.05) in the bupivacaine group compared to the ropivacaine group. Three patients in the bupivacaine group required an injection of mephentermine 3 mg IV intraoperatively to correct hypotension, while none required it in the ropivacaine group. In our study, the main focus was on both sensory and motor block parameters. It was found that, based on the sensory block assessment, the mean onset of sensory block was slower with ropivacaine (11.55 minutes vs 6.63 minutes; p < 0.01) and the duration was shorter (234.75 minutes vs 288.75 minutes; p < 0.01) compared to bupivacaine. Kulkarni KR et al. [10] in a similar study observed that ropivacaine resulted in a slower onset of sensory block (4.5 min vs. 3.2 min for bupivacaine; P < 0.05) and a significantly shorter mean total duration of sensory block (155 min vs. 190.5 min for bupivacaine; P < 0.05). Somjit Chatterjee et al. [11] in another similar study observed that hyperbaric Ropivacaine 0.75% provided effective and adequate spinal anaesthesia with later onset and shorter duration of sensory block. In the present study, peak sensory block was achieved at T4 in 5% and 0% of bupivacaine and ropivacaine cases. In comparison, T6 levels were reached by 42.5% and 22.5% of cases, and T8 levels in 50% and 65% of cases, respectively. Thus, a higher extent of sensory block was achieved in more cases of group B (p = 0.048). Whiteside B et al. [2] found in their study that the maximum block height achieved was significantly higher in the bupivacaine group than in the ropivacaine group. (P<0.001). In our study, the mean time to achieve peak level was also faster in the bupivacaine group as compared to the ropivacaine group. (13.60 vs 19.00 mins; p <0.01). Kharat PA et al.[7] In their study, the researchers observed that the onset of sensory block was faster with bupivacaine (p < 0.05) and that the time to maximum extent of cephalic spread was shorter in Group B (p < 0.05).In this study, the mean time to onset of motor block was significantly faster (6.3 vs 10.45 minutes; p < 0.01) and the duration was longer (258.75 vs 206.25 minutes; p < 0.01) with bupivacaine compared to ropivacaine. The peak motor block level achieved was a Bromage level 3 in most cases (p < 0.1). Dar et al. [12] observed a significant delay in the onset of motor block (13 ± 1.6 min vs. 9 ± 1.3 min; P < 0.05) in the ropivacaine group in their study. The ropivacaine group had a shorter motor block duration (126 ± 9.2 min vs. 174 ± 12.6 min; P < 0.05) as compared to the bupivacaine group. Purohit S et al. [9] observed that the motor block was also delayed in terms of onset and duration for the Ropivacaine group compared to the Bupivacaine group. Bigat Z et al. [13] in their study on cases undergoing arthroscopic knee surgery also observed that the onset of sensory block and motor block was significantly earlier in group B compared with group R (p < 0.05). The duration of the sensory block and motor block was significantly shorter for group R compared with group B (p < 0.05). The findings of this study are largely in line with most other published data. Luck et al. [14] administered equal doses of hyperbaric bupivacaine, ropivacaine, and levobupivacaine (15 mg) intrathecally for elective surgery. Their study showed that ropivacaine provided shorter duration spinal anaesthesia compared to the

other two drugs. The study concluded that the recovery profile of ropivacaine is useful for early mobilisation. Ghimire et al. [15] concluded that hyperbaric Ropivacaine 0.5% provides a reliable subarachnoid block of shorter duration than hyperbaric Bupivacaine 0.5% ($p < 0.05$). Subba S et al. [16] compared the efficacy and safety of 0.5% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine in spinal anaesthesia. The onset of motor block in the Bupivacaine Group was faster compared to the Ropivacaine group. Regression of sensory and motor blocks both were faster in the Ropivacaine group. Memon N et al. (2015) [17] found in their study that the mean duration of sensory blockade and motor blockade was longer in Group B (160.60 ± 17.27 and 141.0 ± 19.44) compared to Group R (132.23 ± 16.47 and 116.73 ± 5.97). López-Soriano F et al. (2002) [18]in their study found that ropivacaine had shorter durations of motor (68.9 +/- 22.9 min) and sensory (127.0 +/- 24.3 min) blocks compared to bupivacaine (133.3 +/- 29.4 and 174.9 +/- 25.5 min, respectively). In the present study, both groups were comparable in terms of adverse events noted, with no significant difference ($p > 0.05$). Kulkarni KR et al. [10] observed insignificant hemodynamic changes between groups ($P > 0.05$) in their study. Hypotension occurred in 27.5% of patients in the bupivacaine group compared to 20.0% in the ropivacaine group. Bradycardia occurred in 10.0% of patients in the bupivacaine group compared to 7.5% in the ropivacaine group. Backache occurred in 15% of patients in the bupivacaine group compared to 10% in the ropivacaine group. The incidence of post-dural puncture headache was the same in both groups at 5%. Al-Abdulhadi O et al. (2007) [19] found no difference in side effects between the two groups in their study. Srivastava et al. [20] observed similar incidence rates of hypotension and other side effects in both groups. Tarkase AS et al. [21] observed in their study that intraoperative and postoperative side effects, such as nausea, vomiting, and PDPH, were minimal and comparable in both groups. Nausea was observed in 2 (4%) patients in group R and 4 (8%) patients in group B, while vomiting was noted in 1 (2%) patient in group R and 2 (4%) patients in group B. In the present study, the time to first micturition was significantly earlier with ropivacaine compared to bupivacaine (357.87 vs 403.97; $p < 0.01$). Kulkarni KR et al. [10] in a similar study observed that patients in the ropivacaine group were able to pass urine sooner than those in the bupivacaine group (257.27 ± 43.75 minutes vs 358.12 ± 46.93 minutes; $P < 0.05$). Whiteside B et al.5 aimed to compare the clinical efficacy of hyperbaric ropivacaine with that of the commercially available hyperbaric preparation of bupivacaine. The time to first micturition was significantly faster with ropivacaine compared to bupivacaine (276.0 vs 340.5 minutes; $p < 0.01$). Purohit S et al. [9] in a similar study observed that patients receiving Ropivacaine had faster recovery in terms of mobilisation (Group R vs. B- mean 253.5 min vs. 331 min) and time to micturate (Group R vs. B- mean 276 min and 340.5 min).

Limitation(s)

There were limitations to the study, including a limited number of participants and the study being conducted at only one centre. Additionally, the dosing of Bupivacaine and Ropivacaine was constant, and high or low doses were not assessed. Future multicentre studies in India will help validate our findings before they can be accepted and generalised.

CONCLUSION

Hyperbaric ropivacaine 0.75% provided effective and adequate spinal anaesthesia. Though the onset of block is faster with bupivacaine, ropivacaine leads to more rapid recovery of patients, which enables early ambulation. Also, Ropivacaine is associated with fewer episodes of hypotension compared to Bupivacaine, especially in the first 15 minutes post-induction. We thus conclude that 0.75% hyperbaric ropivacaine can be used as a good alternative to 0.5% hyperbaric bupivacaine for spinal anaesthesia in elective infraumbilical surgeries of short to intermediate duration, with the added advantage of early recovery and stable hemodynamics.

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