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Original Research Article

A Comparative Evaluation of Hyperbaric Ropivacaine 0.5% (18mg) versus Hyperbaric Bupivacaine 0.5% (18mg) for Elective Lower Abdominal Surgery under Spinal Anaesthesia

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Abstract:

Background: Ropivacaine is a novel long-acting amide local anaesthetic that is comparable to bupivacaine in terms of its structure and pharmacodynamics. ln comparison to bupivacaine, ropivacaine has a reduced propensity to affect the central nervous system and a lower cardio-toxicity.

Aims and Objectives: The aim of our study was to compare and assess the effectiveness and compare the block characteristics of hyperbaric ropivacaine 0.5% (18mg) versus hyperbaric bupivacaine 0.5% (18mg) for elective lower abdominal surgeries under spinal Anaesthesia.

Materials & Methods: After approval of Institutional Ethical Committee, this prospective comparative study was conducted on 60 patients aged 18-60 years posted for elective lower abdominal surgeries under spinal anaesthesia after taking informed consent. Patients were randomly divided into two groups; Group B: received 18 mg (3.6 ml) of 0.5% Hyperbaric Bupivacaine intrathecally, while Group R received 18 mg (3.6 ml) of 0.5% Hyperbaric Ropivacaine, prepared aseptically by adding 1.2 ml (300 mg) of autoclaved 25% dextrose from a 10 ml ampoule to 2.4 ml of commercially available sterile preservative-free isobaric 0.75% Ropivacaine solution immediately prior to injection. The onset time for sensory, motor blockade, duration of anaesthesia and duration of analgesia, VAS score were observed in both the groups. The haemodynamic variables and any untoward side effects were noted in both groups.

Result: The onset of sensory and motor blockade was similar in both groups. Hemodynamic variables were found to be more stable in the Ropivacaine group.

Conclusion: Hyperbaric Ropivacaine demonstrated comparable block quality to commonly used hyperbaric 0.5% bupivacaine when administered intrathecally for elective lower abdominal surgeries under spinal anesthesia.

Keywords: Analgesia; Bupivacaine; Hyperbaric; Ropivacaine; Spinal anesthesia.

Introduction

Spinal anaesthesia is the procedure that is utilized most frequently for lower abdominal operations since it is both incredibly cost-effective and simple to administer. In light of the controversy and uncertainty that surrounds the application for spinal lignocaine; hyperbaric bupivacaine (0.5%) has supplanted lignocaine as the medication of choice for the safe administration of spinal anaesthesia. [1] Newer LA drug, hyperbaric ropivacaine, is well-known for its ability to safely administer spinal anaesthesia. In comparison to bupivacaine, ropivacaine has a reduced propensity to affect the central nervous system and a lower cardio-toxicity. [2] In vivo studies have shown that ropivacaine, when administered at the same concentration as bupivacaine, is less effective and has a shorter duration of motor block than bupivacaine. [3] The use of hyperbaric LA agents administered intrathecally has gained popularity due to the fact that these agents create predictable block characteristics and reliable SA. [4,5] At the moment, the only commercially available preparation of ropivacaine is isobaric preparation. This is due to the fact that it is difficult to maintain the pharmacological stability of hyperbaric solution. Hyperbaric solution produced by adding

the necessary amount of dextrose from an autoclaved ampoule containing 10 ml of dextrose at a concentration of 25 percent. [1] Consequently, the purpose of this study was to evaluate the clinical efficacy of 0.5% ropivacaine (18 mg), which was made hyperbaric by adding the desired dose of dextrose from an autoclaved 10 ml ampoule containing 25% dextrose, in comparison to the clinical efficacy of commercial hyperbaric 0.5% bupivacaine, which was administered in equal doses (18 mg) of almost similar specific gravities.

Aim and Objectives

The aim of our study was to compare and assess the effectiveness and compare the block characteristics of hyperbaric ropivacaine 0.5% (18mg) versus hyperbaric bupivacaine 0.5% (18mg) for elective lower abdominal surgeries under spinal Anaesthesia.

Materials & Methods

The study was done as a hospital based prospective comparative study at the Department of Anaesthesiology, Sri Siddhartha Medical College and Research Centre, located in Tumkur, Karnataka, India. Patients aged 18-60 years, classified as ASA Class I & II, who were undergoing elective lower abdominal surgery under spinal anesthesia, were recruited for the research after obtaining clearance from the institutional ethics committee (Ref No.: SSMC/MED/IEC-129/July-2022) and informed consent from the patients. Patients with pre-diagnosed systemic illness, gross spinal abnormality, localized skin infection, coagulation disorders, pregnant or lactational mothers, narcotic abusers, or unwilling to give consent were excluded from the study.

Sample size calculation was done by employing Purposive sampling technique & the formula for calculating the sample size was $n = 2[Z(1-\alpha/2) + Z(1-\beta)]2x\sigma2/d2$. The minimum sample size required after considering the non-response rate of 10%, the total sample size required was 22 in each group (total = 44). Therefore, sample of 30 in each group was considered for this study.

All the selected 60 patients were allocated randomly into two groups after pre-anaesthetic evaluation and routine work-up.

- **Group B:** received 18 mg (3.6 ml) of 0.5% Hyperbaric Bupivacaine intrathecally,
- **Group R:** received 18 mg (3.6 ml) of 0.5% Hyperbaric Ropivacaine, prepared aseptically by adding 1.2 ml (300 mg) of autoclaved 25% dextrose from a 10 ml ampoule to 2.4 ml of commercially available sterile preservative-free isobaric 0.75% Ropivacaine solution immediately prior to injection.

On the operation table, routine monitoring of non-invasive blood pressure (NIBP), heart rate, electrocardiography (ECG), oxygen saturation (Spo2), end-tidal CO2 (EtCO2) was started & vital parameters were recorded throughout the intraoperative period and at the end of surgery.

Spinal anaesthesia was administered under strict aseptic conditions, and once clear cerebrospinal fluid (CSF) flow was confirmed, 18 mg of 0.5% Hyperbaric Bupivacaine or Ropivacaine was administered. Time of onset of sensory blockade, the height of sensory blockade, motor blockade as per Bromage scale, total duration of sensory blockade and motor blockade, quality of analgesia (visual analogue score), two-segment sensory regression time, time to first rescue analgesic, and number of rescue analgesics in 24 h were also monitored.

Observation parameters:

1. Onset time of sensory blockade (Time to reach T10 dermatome level)
2. Total duration of sensory blockade (Time until regression to L1 dermatome level)
3. Time to achieve complete motor blockade (Time taken to reach Bromage score 3)
4. The vital signs were recorded at specific intervals: 1, 3, 5, 10, 15, 30, and in the recovery room after the subarachnoid blockade.
5. Any side effects that occurred intraoperatively or during the postoperative period were noted.

Statistical Analysis: Descriptive statistical analysis was carried out by mean and standard deviation for quantitative variables and frequency and percentages for categorical variables. The association between categorical variables was analyzed by using the chi-square test. Repeated measures and ANOVA was applied to test for difference in parameters at different time intervals. Statistical software SPSS version-20 was used for the analysis.

Result

Demographic data: The age, weight, height and duration of surgery were comparable in both groups. **[Table 1]**

Table 1: Demographic data

Variables		Group B (Mean)	Group R (Mean)	P value
Age (in years)		41.37	46.00	0.33 **(NS)**
Gender (M:F)		7:21	15:15	0.30 **(NS)**
Weight (Kg)		57.87	57.10	0.15 **(NS)**
Height (cm)		152.80	151.30	0.41 **(NS)**
ASA I	I	18	16	>0.05 **(NS)**
	II	12	14	

NS- Not Significant (p>0.05)

Haemodynamic variables: Changes in vital parameters shown in graph 1-4.

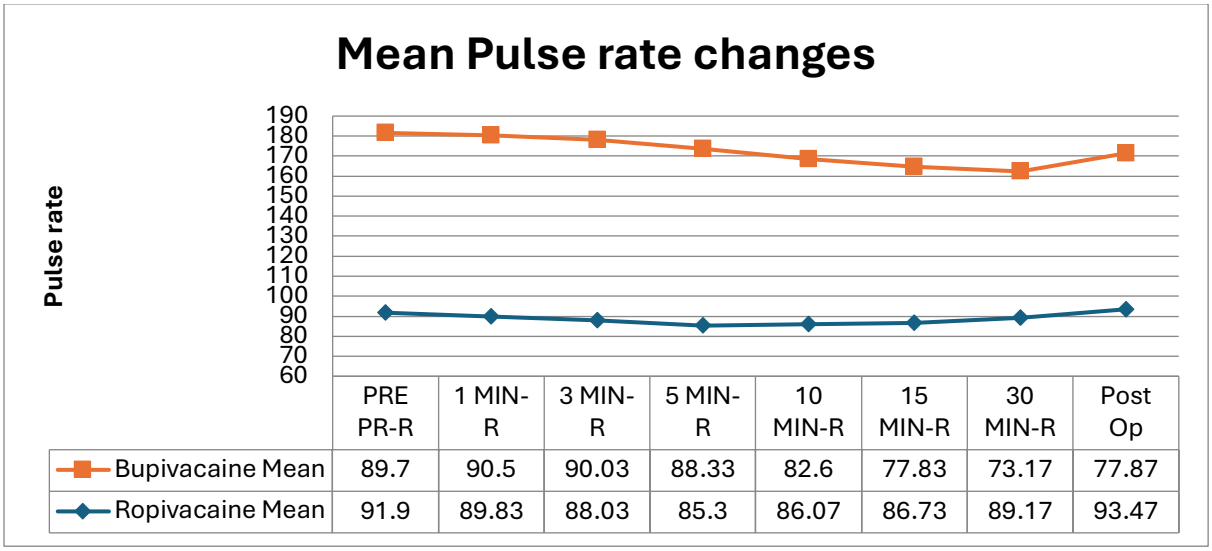


Figure 1: HR variability

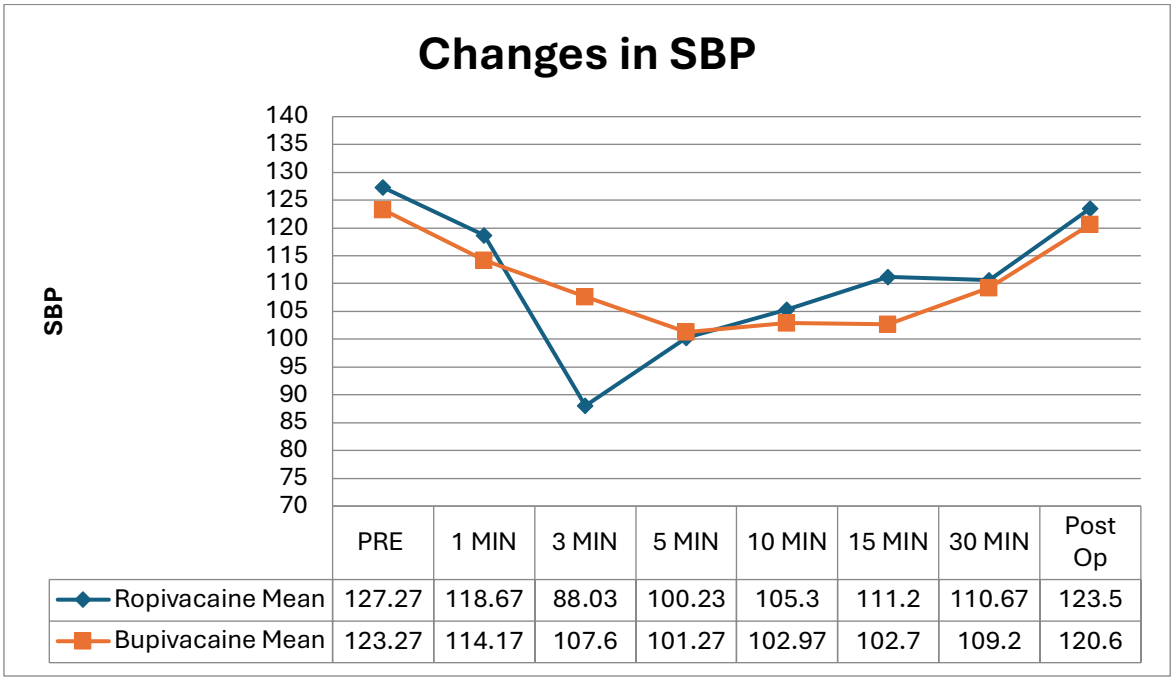
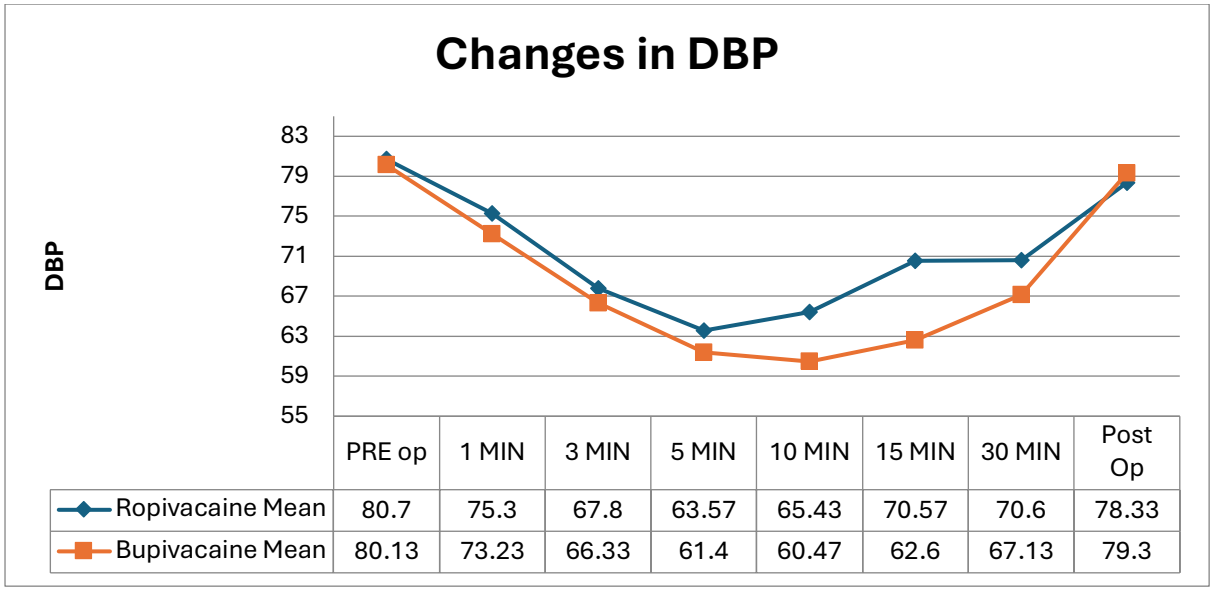


Figure 2: SBP variability



Graph 3: DBP variability

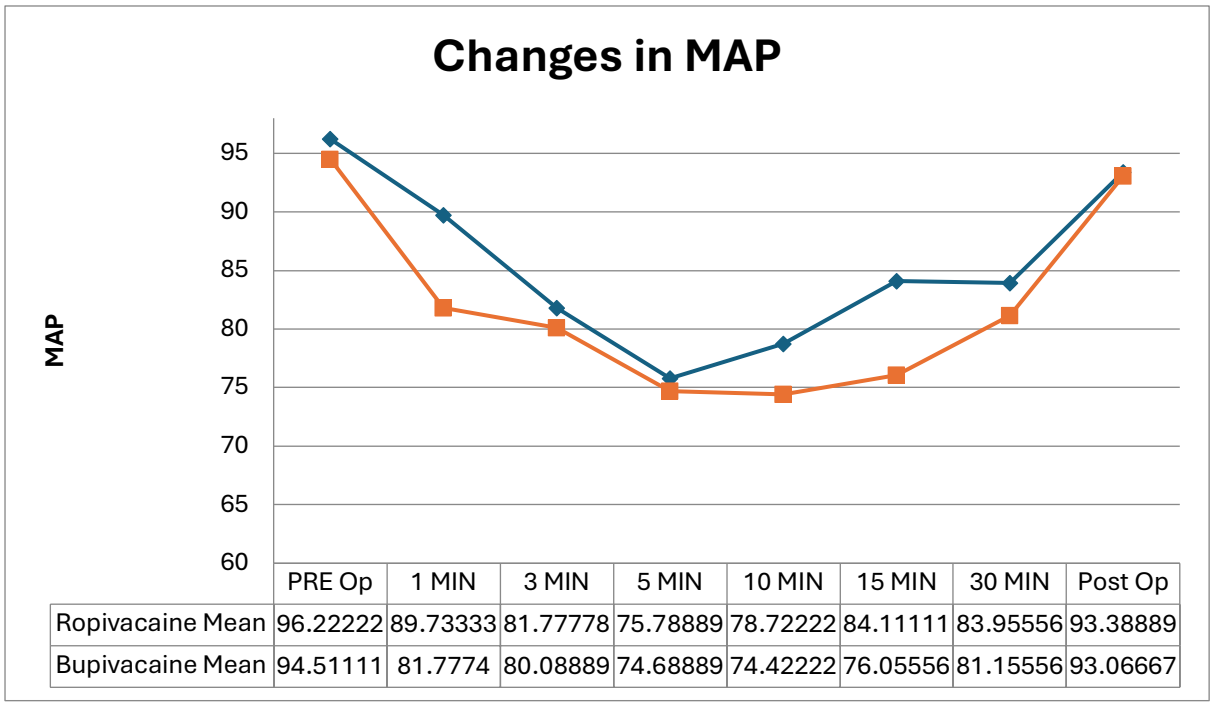


Figure 4: MAP variability

Variations in Heart rate (P=0.000) and mean arterial pressure (P=0.007) between both the groups were found statistically significant. Variations in systolic and diastolic blood pressure among both the groups were comparable (P>0.05). **[Table 2]**

Table 2: Hemodynamic variables

Variables	Groups	F-Value	P-Value
Changes in HR	Group B	40.951	.000
	Group R		
Changes in SBP	Group B	7.56	.007
	Group R		
Changes in DBP	Group B	7.537	.007
	Group R		
Changes in MAP	Group B	7.674	.01
	Group R		

Onset of sensory and motor blockade: In the present study, the mean sensory block onset time didn't differ significantly between the groups (P>0.05). But the comparison of mean motor block onset time as well as duration of sensory and motor block among both the groups was found to be statistically significant (P<0.001). The time to rescue analgesia was found to be longer in Bupivacaine group when compared to Ropivacaine group, 258.33 vs. 176.57, (P<0.001). **[Table 3]**

Table 3: Block characteristics & time to rescue analgesia

Variables	Group B (Mean±SD)	Group R (Mean±SD)	P value
Onset of Sensory blockade (mins)	4.00±0.80	7.13±0.99	0.43 **(NS)**
Onset of Motor blockade (mins)	7.30±1.17	14.00±1.80	0.03 **(S)**
Duration of Sensory blockade (mins)	194.57±9.91	154.90±7.87	<0.001 **(S)**
Duration of Motor blockade (mins)	181.30±6.53	127.03±5.52	<0.001 **(S)**
Time to rescue analgesia (min)	258.33±18.50	176.57±8.34	<0.001 **(S)**

NS- Not Significant (p>0.05), S- Significant (p<0.05)

Side-effects: Incidence of side-effects between Ropivacaine and Bupivacaine were statistically significant (P<0.05). **[Graph 5]**

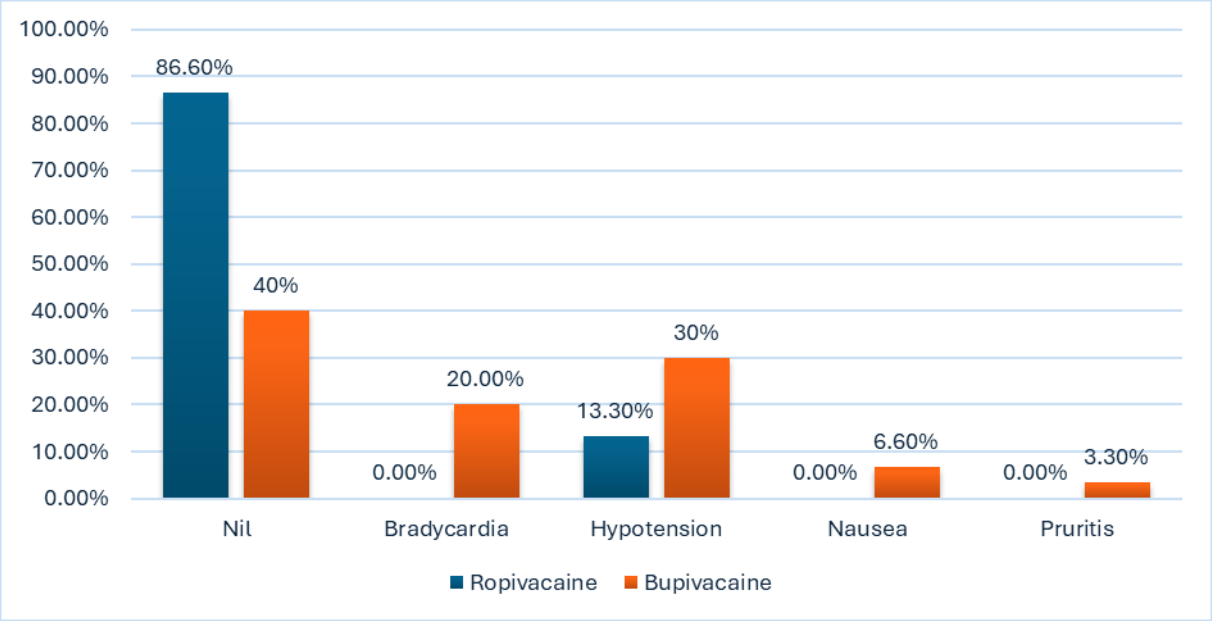


Figure 5: Side-effects

Discussion

Spinal anaesthesia is an effective method for performing gynecological, urological, and orthopedic procedures, which are the most common types of surgeries that fall under this category. [6,7] In addition, the majority of these instances are of short duration, lasting less than three hours. Therefore, the strong motor block and urine retention that are often generated by intrathecal bupivacaine are not required for these cases. [8,9] To put it another way, bupivacaine is not sufficient to meet the requirements of the increasing number of day-care procedures. [6-10]

Following the discovery that 5% hyperbaric lignocaine, which had been utilized in the past for the purpose of providing short-term spinal anaesthesia, was shown to be neurotoxic, it was removed from clinical usage.[50-4] In light of these neurological issues, anaesthetists have been searching for a more recent local anaesthetic drug that is capable of providing a spinal block that is effective enough to fulfill the needs of surgical procedures while also having a minimal risk for toxicity and a shorter duration of action. The shorter duration of action that it possesses would be advantageous for day-care situations since it would make it possible to achieve the discharge requirements earlier. Ropivacaine, a recently developed local anaesthetic drug, has the potential to be an advantageous substitute for low-dose bupivacaine spinal anaesthesia during surgical procedures.[11,12]. According to the findings of our research, there was no discernible difference between the two groups in terms of the mean height of sensory block (T6) when both groups received the same dosages of hyperbaric bupivacaine and hyperbaric ropivacaine. [3] In agreement with the

findings of the research conducted by Gautier et al., which evaluated the effects of equivalent dosages of ropivacaine 8 mg (4 ml of 0.2%) and bupivacaine 8 mg (4 ml of 0.2%), the researchers found that the level of sensory block was comparable in both groups (T8). Our findings were also consistent with research conducted by McDonald et al [13], Whiteside et al [55], Chung et al [14]. Although Dar et al [4] and Gupta S et al [15] showed that the mean onset of sensory block (6 ± 1.3 min vs. 3 ± 1.1 min; P < 0.001) and motor block (13 ± 1.6 min vs. 9 ± 1.3 min; P < 0.05) was significantly slower in ropivacaine group as compared to bupivacaine group.

During the course of our research, we discovered that there was a statistically significant difference in the duration required to establish grade 3 motor blockades, as well as the entire duration of the motor blockade. However, we discovered that ropivacaine resulted in a lower degree of motor block, which reversed more quickly than bupivacaine (P<0.001). Our results were consistent with Gautier et al [16], McDonald et al [13], Chung et al [14], Ramesh Ghimere et al [17] and Dar et al [3].

Our research findings indicate a significant difference in heart rate and mean arterial pressure between the two groups (p<0.05). In 2003, Whiteside and colleagues conducted a study that is consistent with the findings of our own research. They found that the cardiovascular alterations in both groups were significantly different from one another. [11] According to Chung et al. [14], hypotension was the most common side effect in both groups. According to the study by Feroz Ahmad Dar et al. [18], there was a significant difference in the incidence of hypotension between the bupivacaine and ropivacaine groups (P < 0.001). The study found that the incidence of hypotension was significantly higher in the bupivacaine group compared to the ropivacaine group. According to Gupta S et al [15], the incidence of hypotension was significantly different between the two groups. While 36.6% of patients in the bupivacaine group experienced hypotension, only 13.3% of patients in the ropivacaine group experienced hypotension (P=0.01). This indicates a statistically significant difference in the incidence of hypotension between the two groups, with ropivacaine having a lower incidence of hypotension.

Limitation of study: Due to the fact that the majority of our patients required catheterization in order to have surgery, one of the limitations of our study was that we were unable to comment on the status of passing urine. As a result, we have arrived at the conclusion that hyperbaric ropivacaine offers a block that is equivalent to that of hyperbaric bupivacaine, but with a shorter duration of action and less hypotension.

Conclusion

Hyperbaric Ropivacaine has been shown to have similar block quality as the commonly used hyperbaric 0.5% bupivacaine when given intrathecally for elective lower abdominal surgeries under spinal anaesthesia. However, it has the advantage of a faster recovery profile, making it a favorable option for spinal anaesthesia in surgeries of intermediate surgical duration.

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