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A Comparative Study Of Intrathecal 0.5% Hyperbaric Bupivacaine And Intrathecal 0.75% Hyperbaric Ropivacaine In Lower Abdominal Surgeries.

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Abstract:
Background*: Spinal anaesthesia has been widely used since its introduction in 1898 due to its safety and advantages over general anaesthesia. However, traditional agents like bupivacaine have some disadvantages, including cardiovascular effects and longer duration of action. Ropivacaine has emerged as a potential alternative with reduced cardiovascular toxicity. The study was aimed to compare the efficacy and suitability of 0.75% hyperbaric ropivacaine with 0.5% hyperbaric bupivacaine in patients undergoing lower limb and endoscopic urological surgeries, evaluating onset, quality, duration of block, and incidence of complications.*
Materials and Methods*: A prospective randomized trial was conducted with 130 patients (65 per group) aged 16-60 years, ASA grades 1 & 2. Group B received 3.0 ml of 0.5% hyperbaric bupivacaine, while Group R received 3.0 ml of 0.75% hyperbaric ropivacaine. Onset of anaesthesia, quality of block, duration, hemodynamic parameters, and complications were assessed.*
Results*: Ropivacaine showed faster sensory and motor recovery, better hemodynamic stability, and fewer side effects compared to bupivacaine. The onset of sensory block was slightly faster with bupivacaine (2.17 vs 2.54 minutes), but ropivacaine had a shorter duration of sensory (114.7 vs 158 minutes) and motor block (112 vs 130 minutes). Ropivacaine group experienced less hypotension (4.6% vs 7.7%) and no bradycardia or vomiting compared to the bupivacaine group.*
Conclusion: *Hyperbaric ropivacaine 0.75% was found to be a comparable and safer alternative to hyperbaric bupivacaine 0.5% for patients undergoing lower abdominal surgery, offering faster recovery and better hemodynamic stability.*
Key Word*: Intrathecal; Hyperbaric Bupivacaine; Hyperbaric Ropivacaine; Postoperative analgesia.*

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I. Introduction

Spinal anaesthesia is a commonly used central neuraxial blockade often applied for lower abdominal, pelvic, and lower limb surgeries to reduce postoperative complications. Local anaesthetic agents like bupivacaine, levobupivacaine, and ropivacaine are extensively used in neuraxial nesthesia. Bupivacaine and ropivacaine both belong to the amide group of local anesthetics. However, bupivacaine is associated with higher cardiotoxicity. Ropivacaine, a pure s-enantiomer, offers the advantage of producing a more selective blockade, resulting in less motor impairment. This characteristic may facilitate early ambulation, reducing the risk of deep vein thrombosis and providing other ambulation-related benefits [1]. In terms of the minimal local anaesthetic concentration, ropivacaine demonstrates comparable potency to bupivacaine at higher dosages but exhibits lower potency at lower dosages. Consequently, when administered in a 1.5:1 ratio with bupivacaine, ropivacaine achieves a comparable level of block quality with fewer associated side effects [2].

Hyperbaric solutions are considered more predictable due to their wider and more directive distribution with lower interpatient variability [3]. Originally available only as an isobaric preparation, ropivacaine necessitates the addition of dextrose to create a hyperbaric solution when needed. However, caution is advised during the manual mixing of dextrose, as it may pose a risk of infection. Notably, ropivacaine is now commercially available as a hyperbaric solution. Nonetheless, limited evaluations are comparing the effects of 0.75% ropivacaine hyperbaric to those of equipotent hyperbaric bupivacaine, i.e., 0.5%, making it challenging to conclusively assert the advantages and disadvantages of one drug over the other.

The primary objective of the current study was to assess the efficacy of 0.75% ropivacaine hyperbaric compared to 0.5% bupivacaine hyperbaric in terms of the onset and duration of sensory and motor block. We also assessed safety by measuring the adverse effects among patients undergoing infra-umbilical surgery.

II. Material And Methods

This prospective randomized controlled double blind study was carried out on patients of Department of general anesthesia at Katihar Medical College, Katihar, Bihar for 1.5 year after the approval from ethical committee. A total 130 adult subjects (both male and females) of aged ≥ 18, years were enrolled for in this study.

Study Design: Prospective randomized controlled double blind study

Study Location: Department of Anaesthesiology And Critical Care of Katihar Medical College, Katihar

Study Duration: August 2022 – February 2023 (18 Months)

Sample size: 130 patients.

Sample size calculation: Our sample size calculation was based on study by Singh S.et al. In this study the time to achieve T10 sensory block was 2.5+- 1.3mins in bupivacaine group and 3.2 +- 1.5 in ropivacaine group with alpha value of 5% and beta value of 20% (power = 80%) . Sample size was calculated to be 63 in each group so we included 65 patient in each group .

Subjects & selection method: Adult patients of both sexes, aged between 16 to 60 years, ASA grades 1 & 2 posted for lower limb and endoscopic urological procedures 130 patients had been randomly divided in two groups. First group received 3.0 ml of 0.5% bupivacaine (hyperbaric). Second group received 3.0 ml of 0.75% ropivacaine (hyperbaric).

Inclusion criteria:
1. Age 16-60 yrs
2. ASA grades 1 & 2
3. Posted for lower limb and endoscopic urological procedures

Exclusion criteria:
1. Pregnancy / lactating mothers
2. Known drug allergy to local anesthetic agents
3. Surgery planned as emergency (planned as immediate life or limb saving measure)
4. Having back pain or having medicines at any time prior to surgery
5. Having nausea, vomiting or having medicines at any time prior to surgery
6. Previously taken part in any other research project / clinical trial in last six months.

Procedure methodology

Preoperatively-A thorough pre-anaesthetic assessment and classification as per ASA status been conducted two days to a week prior to operation. The patients was given premedication of 0.25 mg of alprazolam at bedtime on the pre operative night. A fasting period of 10 hours was ensured for all patients. Written informed consent was taken from all patients. The patients were explained about the anaesthetic procedure and the possible complications thereof during an evening pre-anaesthetic visit. The patients were told that they may leave the study if they wish at any time.

On day of surgery- Patients were preloaded with 15 ml/kg of Ringer's Lactate which was to be started 10 minutes before giving the block. Inside the operating room, standard monitors connected for continuous monitoring of pulse, BP, oxygen saturation (SpO2) and ECG. The patients were given subarachnoid block using 25 or 27 G spinal needle (Quincke tip) under full aseptic measures. The block was performed in sitting position. The patient was immediately made supine. Assessments of sensory loss and motor block scores were made 2 and 3 min, respectively, after the spinal injection.

Any patient with partial or incomplete block was excluded from the study. Analgesia was assessed on both sides of the trunk in the anterior axillary line, on the legs, and on the perineum by pinpricks using a short bevel 25-gauge needle. Analgesia was defined as a lack of sharp sensation to pinprick. Onset of anaesthesia was marked by achieving a dermatomal block of T10- T12 (sensory loss to pin prick sensation at these levels). The maximum cephalic height of block and the time interval to achieve it was recorded by loss of pin prick sensation at these levels. Quality of anaesthesia was judged by the assessment of the patient at the time of skin incision, given as:-

a. Excellent: patient was unaware of painful sensations, not complaining or moving limb at the time of skin incision/ painful procedure. No pain or discomfort experienced during the course of surgical procedure. Surgeon did not complain about the anaesthesia

b. Very good: patient could appreciate skin incision/ painful procedure but without moving lower limb and endoscopic urological surgeries and did not complain pain or discomfort during the surgical procedure.
c. Good: same as 'Very good' but complaining of pain or discomfort during surgery requiring analgesic supplementation.

During the surgery, regular recordings of heart rate, systolic, mean and diastolic blood pressure was taken every 3 minutes in the first thirty minutes of surgery and every 10 minutes thereafter till the surgery was concluded. Assessments of sensory loss and motor block scores were made 2 and 3 min, respectively, after the spinal injection, subsequently at 5-min intervals during the first 15 min, then at 15-min intervals between 30 and 120 min, and thereafter at 30-min intervals until complete recovery. Complaints of chest discomfort, nausea, vomiting, and alteration of sensorium were watched for. The same was recorded every hour for the first six hours. Similarly regression of the block to S2 level was recorded by pin prick method to determine the duration of the block.

Fall of the SBP >20 % of baseline or DBP >10 % considered as hypotension. Hypotension was treated with intermittent boluses of Inj Mephentermine 6 mg intravenously. HR >20% of baseline was considered as tachycardia. Any fall in HR to less than 50 beats per minute or a fall in HR causing a 20% decrease in blood pressure was considered as bradycardia and was treated with Inj atropine 0.6 mg IV. Post operative side effects like nausea, vomiting, urinary retention and transient neurological deficit in limbs were noted.

The time taken for requirement of first rescue analgesia in the post operative period was recorded. Inj Diclofenac 75 mg IM was given for rescue analgesia.

Post operative headaches was managed with IV and oral fluids as permitted. Inj Diclofenac 75 mg IM was given. Post operative nausea and vomiting was managed with reassurance and Inj Ondansetron 4 mg IV.

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

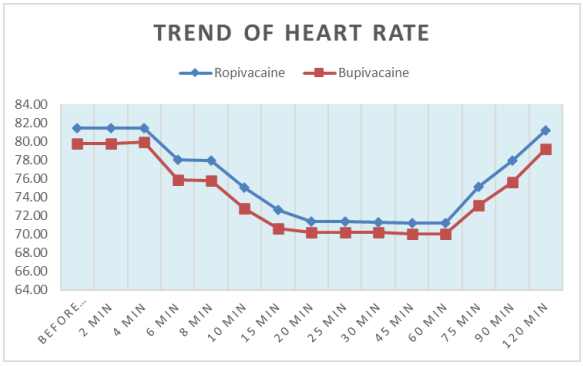
The proportion of males was higher in our study as compared to females while the distribution of gender was similar in both the groups. Females were 40% in group B as compared to 43% in group R.

Table no 1: Descriptive statistics showing Mean, Standard Deviation and Comparison of means between age, weight, and height of both groups

Group Statistics	Group	N	Mean	Std. Deviation	Std. Error Mean	p-value
Age	B	65	34.000	10.7735	1.9670	
	R	65	39.133	11.7407	2.1435	0.83
Weight (kg)	B	65	61.767	8.7363	1.5950	
	R	65	62.233	7.5370	1.3761	0.23
Height (m)	B	65	1.6817	.08562	.01563	
	R	65	1.6557	.05952	.01087	0.04

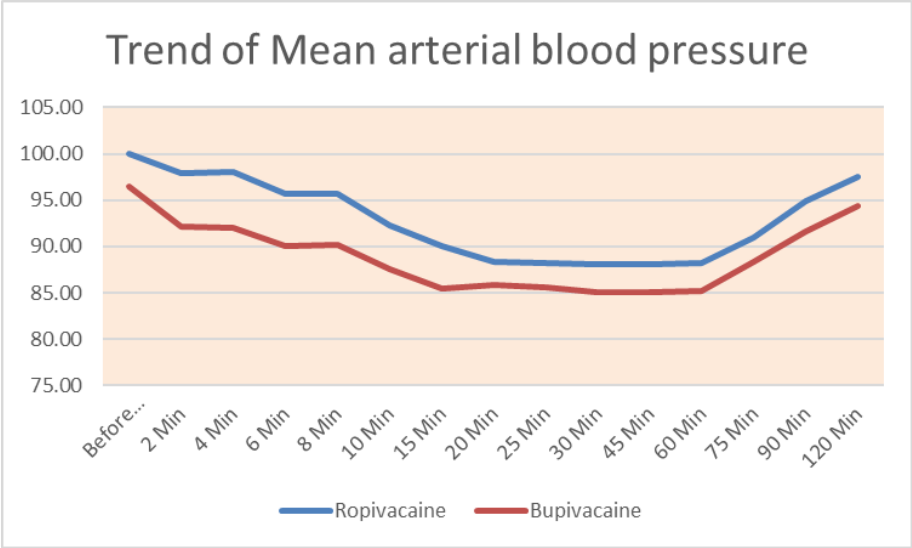
The mean age was 34 years in Bupivacaine group and 39.1 years in Ropivacaine group. There was no statistical difference in both. The mean weight was 61.7 kg in Bupivacaine group and 62.2 kg in Ropivacaine group. There was no statistical difference in both. The mean height was 1.68m in Bupivacaine group and 1.65m in Ropivacaine group. There was statistical difference in both. (Table 1)

Figure 1: Line diagram showing trend of heart rate (mean) in both groups over 2 hours



The mean heart rate in both the groups was within physiological range at all the times during the study. The mean heart rate was also statistically similar in both the groups during the study period (p-value>0.05). The mean heart rate was lower in group B as compared to group R. (Figure 1)

Figure 2: Line diagram showing trend of mean arterial blood pressure (mean) in both groups over 2 hours



The average mean arterial blood pressure was lower in Group B at all the times as compared to Group A.

There was statistically significant difference in average mean arterial blood pressure at all points of the study except 20 and 25 minutes. (Figure 2)

Table no3: Shows Percent Change in Lipids,(mg/dL) on a regular dose of Rosuvastatin 20mg for 6weeks. Total Cholesterol (TC)level reduced by(-26.49%), Low-density lipoproteins cholesterol(LDL-C) went down by (-37.28%), Triglyceride reduced to(-17.3%), Non-HDL-C went down by(-29.71%),after 6 weeks of medication. While there had been a reduction in the undesirable Lipids due to the above medication ,there was a positive upwards change in the desirable Lipids like high-density lipoprotein cholesterol (HDL-C) which improved by (+8.17%), Further, Fasting blood glucose, FBG, mg/dL level were reduced by (-37.95%). and HbA1c, % hemoglobin A1C test which measures blood sugar control over the preceding three months had also gone down by(-11.00%). The desirable alterations in respect of all the above parameters which were attributable to the above medication, were statistically significant, P<0.001---0.033.

Table no 2 : Mean distribution of onset of sensory and motor blockade, grade of motor blockade and duration of blockade in both the groups during surgery and post operatively

	Group	N	Mean	Std. Deviation	Std. Error Mean	p-value
Onset of Sensory Block at T10 (min)	R	65	2.54	.21	.047	.001
	B	65	2.17	.19	.043	
Onset of Motor Block Bromage-3 (min)	R	65	3.75	.19	.043	.001
	B	65	3.09	.23	.052	
Duration of Sensory Blockade(min)	R	65	114.70	3.197	.71	0.00
	B	65	158.55	7.53	1.68	
	R	65	112.10	4.87	1.09	0.00

Duration of Motor Blockade (min)	B	65	130.70	9.02	2.01	
Duration of Analgesia (min)	R	65	205.4	3.43	.76	0.00
	B	65	250.75	5.91	1.32	

The onset of sensory block was earlier in Group B by 37 seconds. The onset of sensory block in group B was 2.17 minutes and 2.54 minutes in group R. the onset of motor block in group R was 3.75 minutes which was statistically higher in group R. the duration of sensory blockade was 114.7 minutes in group R and 158 minutes in group B. The duration of motor block was 112 minutes in group R and 130 minutes in group R. The total duration of analgesia in group R was 205 minutes which was lower than group B with 250 minutes of analgesia. (Table 2)

Figure 3: Bar diagram showing distribution of mean duration of blockade in both the groups.

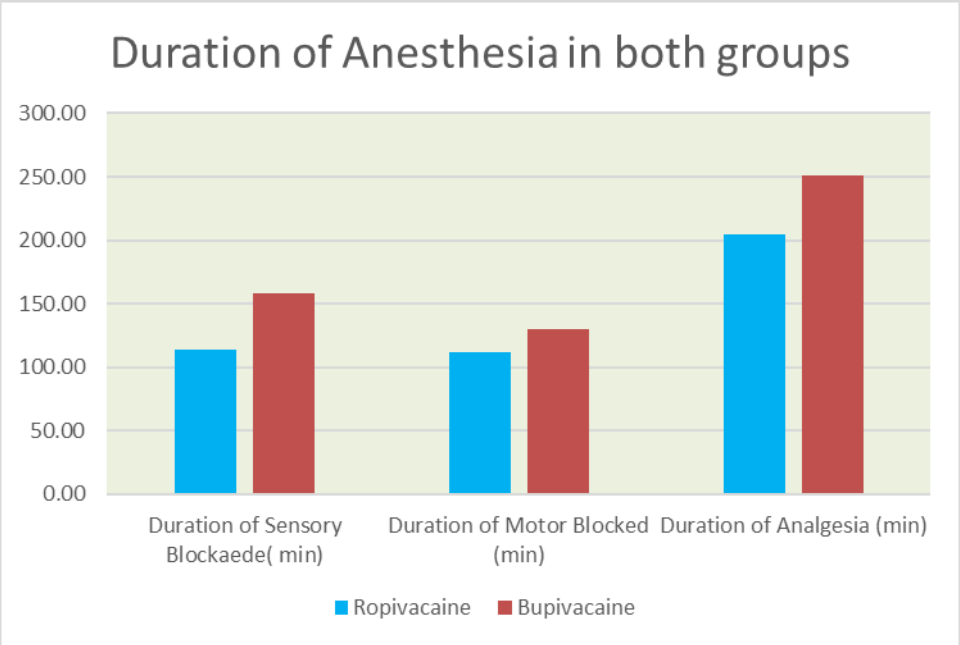


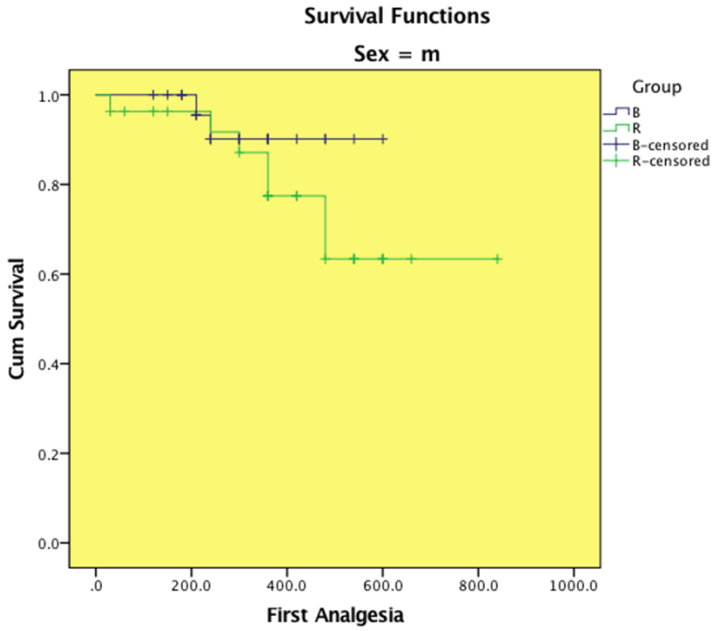
Table 3: Descriptive statistics on two point regression duration and first analgesia time in both the groups

Group Statistics	Group	N	Mean	Std. Deviation	Std. Error Mean	p-value
S2 Regression	B	65	227.00	56.0880	10.2402	
	R	65	150.00	63.0271	11.5071	0.93
First Analgesia	B	65	300.00	127.7659	23.3268	
	R	65	409.00	212.4950	38.7961	0.01

The time taken for two spinal regression was 227 minutes in group B and 150 minutes in group R. The time required for first analgesia was 300 minutes in group B and 409 minutes in group R. The time required for first analgesia was 300 minutes in group B and 409 minutes in group R. (Table 3)

Hypotension was observed in 7.7% of patients in group B and 4.6% patients in group R. Bradycardia was observed in 6.2% of patients in group B and 0% patients in group R. Vomiting was observed in 6.2% of patients in group B and no patients in group R. Backpain was observed in 7.7% of patients in group R only. Headache was observed in 9.2% of patients in group B and 7.7% patients in group R

Figure 4: Survival plot comparing usage of first analgesia given in both groups.



Overall Comparisons[a]			
	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	1.239	1	.266
Test of equality of survival distributions for the different levels of Group.[a]			
a. Adjusted for Sex.			

The survival curve shows similar interval of usage of first analgesia in both the groups. (Figure 4)

IV. Discussion

Spinal anesthesia is the most popular regional anesthetic technique for lower extremity and lower abdominal surgery (4). Bupivacaine 0.5% is commonly used for intrathecal use. Recently, new long-acting local anesthetics (ropivacaine and levobupivacaine) have been introduced into clinical use (5). Ropivacaine is the pure S (-) enantiomer of propivacaine. It has a reduced potential for cardiotoxicity and neurotoxicity with accidental intravenous injection or toxic dose thresholds and is therefore claimed to be safer than the racemic formulation bupivacaine (6) Ropivacaine is less lipid soluble than bupivacaine. Therefore, it penetrates less myelinated motor fibers and thus causes less motor inhibition than sensory inhibition. Their purported advantages include reduced overdose-induced cardiotoxicity and a more specific effect on sensory than motor nerve fibers (7). Ropivacaine 0.75% was recently hyperbaric by adding dextrose for intrathecal use. It is less effective than bupivacaine when used in low doses, such as for epidural analgesia or spinal anesthesia. However, at high doses, such as when used to block the peripheral nervous system, the efficacy and potency of these agents appear to be similar. Against this background, we decided to investigate the efficacy of intrathecal ropivacaine (0.75%) and intrathecal bupivacaine 0.5% in spinal anesthesia for lower abdominal surgery

We recruited 130 patients (65 patients in each group) of ASA grade 1 and 2 between the age group of 16 to 60 years undergoing elective lower abdominal surgeries under spinal anaesthesia and they were randomized to receive 3ml of hyperbaric bupivacaine at L1-L2 interspace in Group A or 3ml hyperbaric Ropivacaine in Group B.

The mean age was 34 years in Bupivacaine group and 39.1 years in Ropivacaine group. There was no statistical difference in both similar to findings of Kulkarni KR et al (7) with mean age of 36.4 years in group R and 38.55 years in group B. The mean weight was 61.7 kg in Bupivacaine group and 62.2 kg in Ropivacaine group. There was no statistical difference in both. The mean height was 1.68m in Bupivacaine group and 1.65m in Ropivacaine group. There was statistical difference in both. The proportion of males was higher in our study as compared to females while the distribution of gender was similar in both the groups. Females were 40% in group B as compared to 43% in group R. Mahajan MH et al (8) had also unequal distribution of genders in both the groups by 4:1.

The mean heart rate in both the groups was within physiological range at all the times during our study. The mean heart rate was also statistically similar in both the groups during the study period (p-value>0.05). Kharat PA et al (9) found that the heart rate was low in group R as compared to group B ($p<0.05$) on regression of block.

The mean systolic blood pressure was within physiological range during the study period in both the groups. There was statistically significant difference in mean systolic blood pressure at baseline, 5 minutes and 10 minutes. It was higher in group R as compared to group B in our study. The mean diastolic blood pressure was lower in Group B at all the times as compared to Group R. there was statistically significant difference at initial 15 minutes of the study period. Similar to findings of Kharat PA et al (9) where the diastolic BP was low in group B. The average mean arterial blood pressure was lower in Group B at all the times as compared to Group A. Similar to findings of Kharat PA et al (9) where the MAP was low in group B. There was statistically significant difference in average mean arterial blood pressure at all points of the study except 20 and 25 minutes. The mean SpO2 level in both the groups was similar during the study period.

In our study, the onset of sensory block was earlier in Group B by 37 seconds. The onset of sensory block in group B was 2.17 minutes and 2.54 minutes in group R. the onset of motor block in group R was 3.75 minutes which was statistically higher in group R. the duration of sensory blockade was 114.7 minutes in group R and 158 minutes in group B. The duration of motor block was 112 minutes in group R and 130 minutes in group R. The total duration of analgesia in group R was 205 minutes which was lower than group B with 250 minutes of analgesia.

In spinal anesthesia for major orthopedic surgery, McClellan KJ et al. (10) investigated and compared equivoque (3.5 mL) plain ropivacaine 5 mg/mL with bupivacaine 5 mL/mL. They discovered that the two groups did not significantly differ in the speed at which motor and sensory block started. Nonetheless, the ropivacaine group's median motor block duration was noticeably shorter.

In spinal anesthesia for lower abdominal and lower limb surgeries, Surekha et al. (11), compared equivoque (2.2 mL) isobaric Ropivacaine 0.75% against isobaric Bupivacaine 0.5%. They discovered that while ropivacaine produced a sensory block of comparable quality, the motor block onset and duration were significantly shorter with ropivacaine, and it also had better hemodynamic stability.

Intrathecal equivoque (3 mL) 0.75% isobaric ropivacaine was tested by Adhikari et al. (12) against lower abdominal procedures, 0.5% isobaric bupivacaine was used. Similar sensory block features were observed in both groups, with the ropivacaine group showing a decreased incidence of hypotension and bradycardia and a considerably earlier motor recovery.

In a study conducted during spinal anesthesia, Olapour et al. (13) compared the effects of 15 mg 1% ropivacaine and 10 mg 0.5% Bupivacaine during caesarian delivery. They discovered that the duration of sensory and motor blockade caused by Ropivacaine was much longer than that of Bupivacaine, with a much longer onset time. The bupivacaine group had significantly greater heart rates, but there was no difference in the systolic and diastolic pressure in either group.

In lower limb and lower abdomen procedures, Chari et al. (14) compared the effects of 22.5 mg isobaric 0.75% ropivacaine with 15 mg of hyperbaric 0.5% bupivacaine intrathecal and observed that sensory and motor onset was significantly slower with significantly shorter motor duration in ropivacaine group than Bupivacaine group.

On the other hand, both groups' analgesic duration and hemodynamic characteristics were similar.

In lower limb and lower abdomen procedures, Purohit et al. (15) compared the intrathecal use of 3 mL hyperbaric ropivacaine and 3 mL hyperbaric bupivacaine. They discovered that the ropivacaine group experienced an early motor recovery and a considerably delayed onset of sensory and motor features compared to the bupivacaine group. Additionally, they discovered that while more patients in the bupivacaine group needed therapy for hypotension, the hemodynamic parameters were more stable in the ropivacaine group.

For infraumbilical operations, Kulkarni et al. (7) compared the intrathecal administration of 15 mg of 0.5% hyperbaric ropivacaine with that of 0.5% hyperbaric Bupivacaine. They discovered that the onset of sensory block was delayed by ropivacaine (4.5 min versus 3.2 min for bupivacaine; $P < 0.05$).

In our study, the onset of sensory block in group B was 2.17 minutes and 2.54 minutes in group R with p-value of 0.00. the difference in observations could be due to difference in concentration of ropivacaine. However, in our case also the mean onset of sensory block was lower in group B.

According to Kulkarni et al. (7), there was a significant difference in the mean total duration of sensory block (ropivacaine 155 min; bupivacaine 190.5 min; $P < 0.05$). The duration of sensory block in our study was 114 minutes for ropivacaine and 158 minutes for the bupivacaine group.

Kulkarni et al (7) Patients in the ropivacaine Group R exhibited substantially more rapid recovery from the motor blockade (ropivacaine120 min; bupivacaine 190 min; $P < 0.05$) and in our study duration of motor block was 112 minutes in group R and 130 minutes in group R.

For lower abdominal surgeries, Kharat et al. (9) compared 4 mL of 0.5% hyperbaric Bupivacaine with 0.5% hyperbaric ropivacaine administered intrathecally. They discovered that the bupivacaine group had significantly earlier onset and longer peak sensory level duration than the ropivacaine group. with comparable level of cephalic spread of drug in both groups. They also found that ropivacaine gave a lesser degree of motor

block with faster regression than bupivacaine. There was no significant difference in hemodynamic parameters except that diastolic and mean pressures remained on a lower side in bupivacaine group.

The time taken for two spinal regression was 227 minutes in group B and 150 minutes in group R in our study. however, there was no difference in mean time to two segment sensory regression in min in group B being 64 min versus group R with 62 minutes in study by Mahajan MH et al (8). Similarly, the time required for first analgesia was 300 minutes in group B and 409 minutes in group R. in study by Mahajan MH et al (8), time of first onset of pain was 110 min in group R and 108 min in group B

In our study, Hypotension was observed in 7.7% of patients in group B and 4.6% patients in group R, in study by Kulkarni KR et al (7) , hypotension was observed in 20% Group R and 27.5% group B. In our study, Bradycardia was observed in 6.2% of patients in group B and 0% patients in group R while 10% in group B in study by Kulkarni KR et al (7) in study by Similar to findings of Kharat PA et al (9) 20% cases had hypotension in group B and 5% in group A which was similar to findings of our study. Bradycardia was found in 14% in group B and 17% in group R by Kharat PA et al (9) which was higher than our observation due to difference in dosage of drug.

Vomiting was observed in 6.2% of patients in group B and no patients in group R. Similarly, Backpain was observed in 7.7% of patients in group R only which was 10% in group R. Headache was observed in 9.2% of patients in group B and 7.7% patients in group R

Limitations:

Since the majority of our patients required catheterization for surgery, one of the limitations of our study was that we were unable to remark on the patients' ability to pass urine. Additionally, the sample size was small in our study and it was a single centric study. Thus, a multicentric study with large sample size is required for external validity of our study. Moreover, there should be a rationalization of density measurement should be done for hyperbaric solutions.

V. Conclusion

First and foremost, we draw the conclusion that a superior hemodynamic profile and a slower onset and comparable duration of sensory block are produced by intrathecal 0.75% hyperbaric ropivacaine than by motor block. Furthermore, we noticed that in earlier research, the motor block pattern was not enhanced by raising the intrathecal hyperbaric ropivacaine concentration to 0.75%. Extra intravenous supplemental sedation may improve the tolerability of motor block features.

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