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"TO STUDY THE COMPARISON BETWEEN INJ. ROPIVACAINE 0.75% AND INJ. BUPIVACAINE 0.5% FOR LOWER ABDOMINAL & LOWER LIMB SURGERY IN SPINAL ANAESTHESIA"

Anaesthesiology

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ABSTRACT

Introduction- Spinal anesthesia is a neuraxial anesthesia technique in which local anaesthetic is placed directly in the intrathecal space (subarachnoid space). This activity reviews the technique, contraindications, indications of spinal anesthesia and highlights the role of the interprofessional team in the management of these patients. It is used in the surgeries which involve lower limbs and lower abdomen. Ropivacaine acts as potent, long-acting amino amide with a high pKa and limited lipid solubility. Bupivacaine has been showing poor safety profile with cardiovascular system while ropivacaine offers a wide margin of safety. The study aimed to evaluate 0.75% ropivacaine and 0.5% bupivacaine heavy given intrathecally in terms of onset, and duration for lower abdominal and lower extremity surgeries. **Methodology-** The study was conducted at Dr.D.Y. Patil Hospital & Research Institute, Kolhapur from January 2022 to December 2022. Patients were evaluated and educated about the merits and de-merits of the study and were selected based on inclusion and exclusion criteria. Total of 60 patients was included for the study which were divided into two groups and were given Inj. bupivacaine (H) 0.5% 4 cc or Inj. Ropivacaine (H) 0.75% 4 cc for lower abdominal or lower limb surgery under Spinal anesthesia. **Result-** Ropivacaine produces a late sensory block, early regression, and a shorter total duration of the sensory blockade as compared to bupivacaine. Ropivacaine causes the late onset of motor blockade, with less degree and total duration of the motor blockade as compared to hyperbaric bupivacaine. **Conclusion-** Ropivacaine can provide predictable and reliable spinal anaesthesia than commercially available hyperbaric bupivacaine.

KEYWORDS

Anaesthesia, bupivacaine, ropivacaine, lower limb, lower abdomen

INTRODUCTION-

Spinal anaesthesia is the injection of local anaesthetic into the subarachnoid space. It is a simple technique that can be used to provide surgical anaesthesia for procedures involving the abdomen, pelvis, and lower limbs. [1] For surgeries on the lower limbs and the lower abdomen, subarachnoid blocks are frequently employed. Several variables affect how local anaesthetics move throughout the cerebrospinal fluid (CSF), but baricity (density), amount (mg), concentration, and volume of local anaesthetic (LA) are considered to be the main variables. [2-4] The long-acting local anaesthetic bupivacaine, an amino amide, has been used in clinical situations for more than 20 years. Numerous clinical investigations have been conducted to determine the effects of the central neuraxial blockade, including when it first occurs, the height of the block, how long it lasts, and the quality of the motor and sensory blockade at various volumes, bariatric concentrations, etc. [4-8]

The local anaesthetic ropivacaine is a potent, long-acting amino amide with a high pKa and limited lipid solubility. It is synthesized as a 99.5% pure s-enantiomer and is a monohydrate of the hydrochloride salt of 1-propyl' 2'-6'-pipecoloxylidide .[9] Bupivacaine has been displaying a poor safety profile in the cardiovascular system, whereas ropivacaine offers a broader safety margin while maintaining the desired pharmacodynamics features. [10,11] Compared to equal concentrations of racemic bupivacaine, ropivacaine is less cardio toxic and has a substantially greater threshold for central nervous system toxicity. [12-14] Compared to motor nerves, sensory nerves are thought to be blocked by ropivacaine to a greater extent [15,16], with a shorter duration of motor blockage and faster postoperative recovery of motor function as a result. It has been demonstrated that the hyperbaric ropivacaine preparation results in a slower onset and less severe sensory blockage than the commercial bupivacaine preparation [6].

Most of the studies in the literature are the comparison between 0.5% bupivacaine and 0.5% ropivacaine and a comparison between 0.75% ropivacaine and 0.5% bupivacaine.[17, 18] Ropivacaine shows a slower onset of sensory and motor blockade, and also its action is shorter in duration.[19] 0.75% Hyperbaric ropivacaine is recently launched in India thus there are only a few Indian studies performed regarding the comparison between 0.5% bupivacaine and. 0.75% hyperbaric ropivacaine.[20] The study aimed to evaluate 0.75% ropivacaine and 0.5% bupivacaine heavy given intrathecally in terms of onset, and duration for lower abdominal and lower extremity surgeries.

MATERIALS & METHODS-

The study was conducted at Dr.D.Y. Patil Hospital & Research Institute, Kolhapur after receiving all the necessary ethical permissions from the Institutional Ethics Committee. The time period of the study was from January 2022 to December 2022. Patients will be evaluated and educated about the merits and de-merits of the study. Patients from the age group of 18-65 years old, those who had planned to undergo spinal anesthesia for lower abdominal and lower limb surgeries, with Body Mass Index (BMI) 18-35 kg/m2 and those who signed informed consent were included for the study. Whereas, patients with h/o failed spinal anesthesia in past, having massive cardiac disorder, unstable hemodynamics, pregnant patients, willing to know about the receiving drug, and converted to general anaesthesia were excluded from the study. The sample size taken for the study was 60 patients and were randomly divided into two groups of 30 patients each that is Group B and Group R. Each patient will receive Inj. bupivacaine (H) 0.5% 4 cc or Inj. Ropivacaine (H) 0.75% 4 cc for lower abdominal or lower limb surgery under Spinal anesthesia. Every patient will be monitored on different parameters such as, motor blockade by modified bromage scale, sensory blockage with pinprick method and autonomic blockade by measuring heart rate and blood pressure. Proportion Test will be applied at the end of the study for statistical analysis.

MODIFIED BROMAGE SCALE

Bromage 0	Subject is able to move his hip, knee & ankle and is able to lift his leg against gravity.
Bromage 1	Subject is unable to lift his leg against gravity but is able to flex his knee and ankle.
Bromage 2	Subject is unable to flex his hip & knee, but is able to flex his ankle.
Bromage 3	Subject is unable to flex his hip, knee and ankle but is able to move his toes.
Bromage 4	Complete Paralysis

RESULTS-

Age & Sex Distribution-

The mean age of the group B and group R subjects was 38.46±17.97 years and 44±14.74 years respectively. There was no difference between the mean ages when compared between groups. In group B

most of the patients (36.66%, n=11) were in the 18-28 years of age category followed by 29-44 years (26.66%, n=8), 46-60 years (23.34%, n=7), and 61-65 years (13.34%, n=4). Whereas, in group R majority of participants belonged to the 46-60 years of age category (40%, n=12) followed by 29-44 years (26.66%, n=8), 18-28 years (20%, n=6), and 61-65 years (13.34%, n=4).

In both groups, males were predominantly present compared to females (group B 63.34% and group R 76.66%).

Comparison of body temperature between groups-
There was no significant difference in the mean body temperature when compared between the groups at baseline, 0th min, 5th min, 10th min, 20th min, 30th min, 40th min, 50th min, 60th min, and 70th min time intervals (P>0.05). A detailed comparison of body temperature according to time intervals is depicted in table 1.

Table 1. Comparison Of Body Temperature Between Groups

Time intervals (minutes)	Body temperature (mean±SD)		P value
	Group B	Group R	
Baseline	35.89±0.94	35.84±0.91	0.7976
0	35.82±0.75	35.81±0.73	0.9452
5	35.76±0.79	35.78±0.72	0.9055
10	35.71±0.84	35.75±0.78	0.8510
20	35.70±0.87	35.65±0.84	0.8119
30	35.72±0.84	35.66±0.84	0.7949
40	35.69±0.93	35.64±0.88	0.8448
50	35.73±0.81	35.75±0.75	0.9221
60	35.75±0.80	35.77±0.80	0.9250
70	35.82±0.76	35.76±0.77	0.7547

Comparison of pulse rate between groups at various time intervals
There was no significant difference in mean pulse rate when compared between groups at baseline, 0th min, 5th min, 20th min, 30th min, 50th min, and 70th min intervals (P>0.05). A significant decrease in pulse rate was observed in group B subjects compared to group R subjects at 10th min (P=0.0035), 40th min (P=0.0235), and 60th min (P=0.0375) intervals. The detailed comparison pulse rate between the groups is shown in table 2.

Table 2. Comparison Of Pulse Rate Between Groups At Various Time Intervals

Time intervals (minutes)	Pulse rate (mean±SD)		P value
	Group B	Group R	
Baseline	81.2±6.25	80.26±4.31	0.5004
0	108.86±11.29	105.96±10.12	0.3130
5	75.63±3.16	76.36±3.22	0.3719
10	73.43±3.51	75.86±2.95	0.0035
20	73.66±3.04	72.6±3.57	0.2431
30	73.13±2.66	75.03±4.22	0.0503
40	72.36±2.07	74.33±3.95	0.0235
50	71.63±1.42	72.23±2.27	0.1902
60	70.66±0.88	71.73±2.41	0.0375
70	72.06±2.33	73.46±4.17	0.1306

Comparison of systolic blood pressure between groups at various time intervals
There was no significant difference in the systolic blood pressure when compared between the groups at baseline, 0th min, 5th min, 10th min, 20th min, 30th min, 40th min, 50th min, 60th min, and 70th min time intervals (P>0.05). A detailed comparison of systolic blood pressure according to time intervals is depicted in table 3.

Table 3. Comparison Of Systolic Blood Pressure Between Groups At Various Time Intervals

Time intervals (minutes)	Systolic blood pressure (mean±SD)		P value
	Group B	Group R	
Baseline	113.26±6.75	114.86±4.55	0.3793
0	119.46±15.65	119.1±11.22	0.9136
5	121.36±11.16	122.03±9.38	0.8056
10	116.86±10.21	118.8±7.29	0.3895
20	113.8±8.76	116.73±7.97	0.1730
30	110.6±8.86	113.96±7.86	0.1189
40	112.5±8.64	115.8±7.09	0.1012
50	119.1±5.79	118.6±6.38	0.7368
60	121.6±4.19	121±6.78	0.6605
70	124.63±3.71	123.66±6.70	0.4575

Comparison of diastolic blood pressure between groups at various time intervals
The diastolic blood pressure was comparable between groups at baseline, 0th min, 5th min, and 10th min intervals (P>0.05). A significant difference was observed in the 20th min (P=0.0019), 30th min (P=0.000794), 40th min (P=5.4e-09), 50th min (P=7.08e-10), 60th min (P=1.21e-07) and 70th min (P=4.13e-12) interval. A detailed comparison of diastolic blood pressure according to time intervals is depicted in figure 1.

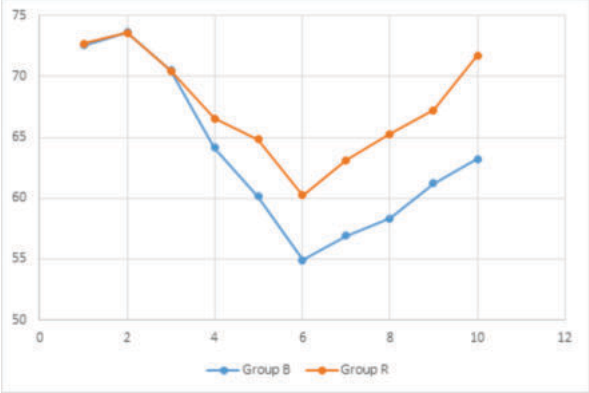

Figure 1. Comparison of diastolic blood pressure between groups at various time intervals

Assessment of sensory block.
The time required to reach the sensory block was significantly more in group R patients compared to group B patients (3.13±0.81 min vs 7.06±1.01 min, P=3.48e-23). Whereas, the time at which maximum sensory block was achieved was significantly more in group B patients than group R patients (17.96±2.34 min vs 16±2.69 min, P=0.0040) (fig.2)

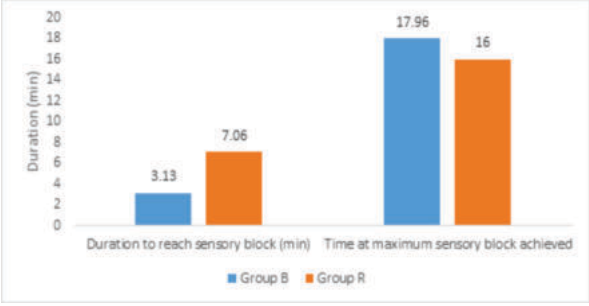

Figure 2. Assessment of sensory block

Time required to reach motor block-The time required to reach the motor block was significantly more in group R subjects compared to group B subjects (6.66±0.95 min vs 9.86±2.01 min, P=4.33e-11) (figure 3).

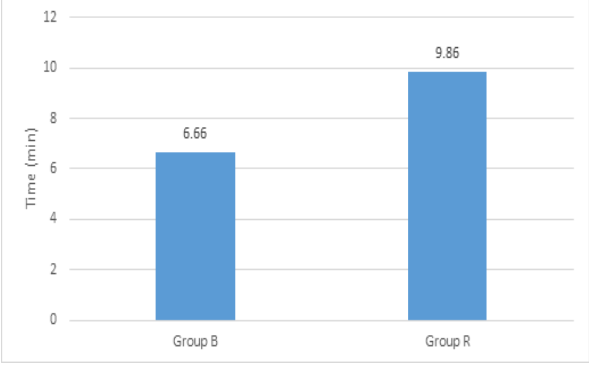

Figure 3. Comparison of time required to reach motor block

Time for two-segment regression-The time for two-segment regression was significantly more in group B patients (83.7±8.58 min) compared to group R patients (66.93±7.25 min) (P=1.53e-11) (table 4.)

Table 4. Comparison Of Time For Two-segment Regression Between Groups

Groups	Time for 2-segment regression (mean±SD)	P value
Group B	83.7±8.58	$1.53e^{-11}$
Group R	66.93±7.25	

Bromage scale score

The Bromage scale score was significantly high in group R subjects compared to group B subjects (2.26±0.98 vs 2.81±0.39, P=0.0024). A detailed comparison of the Bromage score is shown in table 5.

Table 5. Comparison Of Bromage Score Between Groups

Groups	Bromage scale score (mean±SD)	P value
Group B	2.26±0.98	0.0024
Group R	2.81±0.39	

Adverse effects

In groups B and R, a total of 46.66% and 30% of patients had adverse effects respectively. Hypotension was the most common adverse effect observed in 13.33% and 23.33% of group R and group B patients respectively. The detailed distribution of subjects according to adverse effects is depicted in figure 4.

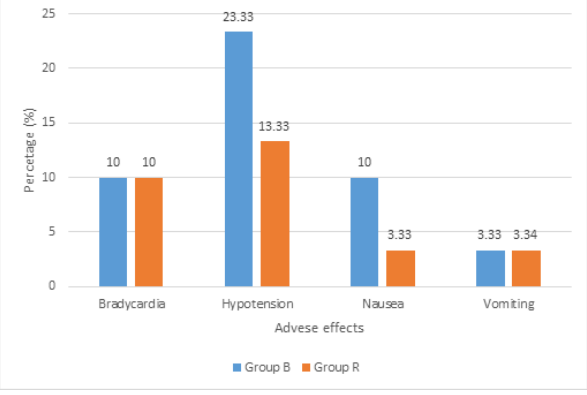

Figure 4. Distribution Of Subjects According To Adverse Effects

DISCUSSION-

The present study aimed to study the efficacy and safety profile between inj. ropivacaine 0.75% (H) and bupivacaine 0.5% (H) for lower abdominal and lower limb surgeries in spinal anesthesia. Every patient was monitored on different parameters as follows-

Age & Sex-The mean age of the group B and group R subjects was 38.46±17.97 years and 44±14.74 years respectively and were found to be similar when compared between both groups (P>0.05). In group B most of the patients (36.66%, n=11) were in the 12-28 years of age category followed by 29-44 years (26.66%, n=8), 46-60 years (23.34%, n=7), and 61-73 years (13.34%, n=4). Whereas, in group R majority of participants belonged to the 46-60 years of age category (40%, n=12) followed by 29-44 years (26.66%, n=8), 12-28 years (20%, n=6), and 61-73 years (13.34%, n=4). In both the groups, males were predominantly present compared to females (group B 63.34% and group R 76.66%). The male predominance in the studies may be due to lifestyle, occupation, and risk factors.

Body temperature- Hypothermia-associated shivering can cause physiological changes due to increased oxygen consumption and pain moreover, it also contributes to surgical site infection, myocardial ischemia, and perioperative coagulopathy. [24-26] Feng G. et al. in their study reported that group B patients had significantly higher shivering compared to group R patients. They witnessed decreased temperature but no hypothermia in ether groups. They concluded that in group R the intensity and incidence of shivering is less compared to group B patients. [27] In this study, there was no incidence of hypothermia in either group and the body temperature was comparable at all assessment time points. The difference in the results may be due to the type of surgery and inclusion criteria.

Pulse rate-The mean baseline pulse rate in group B and group R was 81.2±6.25bpm and 80.26±4.31bpm respectively. The average basal PR in both groups was comparable (P=0.5004). At various assessment points, the PR rate was found to be decreased from baseline. However, there was no significant difference observed in mean PR when compared between the groups at all-time intervals (P>0.05) except at the 10^{th} min (P=0.0035), 40^{th} min (P=0.0235), and 60^{th} min (P=0.0375) intervals. In the study of Tarkase AS. et al., no significant difference was reported at any time interval. [28] The difference in the results may be due to differences in inclusion criteria and type of surgery.

Systolic blood pressure-In this study, baseline SBP in groups B and R was 113.26±6.75 and 114.86±4.55 respectively. Post-induction spinal anaesthesia, when assessed at various time intervals, SBP was found to be decreased from baseline. However, when compared between the groups there was no significant difference in mean SBP at all- time intervals. These findings are similar to the study of Tarkase AS. et al. [28] Whereas, Shamili Y. et al. in their study suggested a significantly decreased SBP at 120^{th} min, 180^{th} min, 240^{th} min, 300^{th} min, and 360^{th} min. [23] The difference in the results may be due to the difference in the type of surgery, duration of surgery, and concentration of local anaesthetic drugs used.

Diastolic blood pressure- In both groups patient DBP was reduced from the baseline at different time intervals. Moreover, DBP was significantly reduced in group B patients compared to group R patients at 20min, 30min, 40min, 50min, 60min, and 70min time intervals.

Sensory block -The average onset of sensory block in group B patients was 3.13±0.81 min whereas, it was 7.06±1.01 min in the group R subjects. The onset of sensory block was rapid in group B patients compared to group R patients ($P=3.48e^{-23}$). The detailed comparison of the onset of the sensory block between studies is demonstrated in table 1. Furthermore, in this study mean time required to reach the maximum sensory block in group B and group R patients was 17.96±2.34 min and 16±2.69 min respectively. The time required to reach maximum sensory block was significantly less in group R than in group B patients. Previous studies have shown variable findings. [21, 22, 28, 29, 30] The differences in the results may be attributed due to the difference in the total volume of intrathecal solution, the difference in equipotent doses, baricity of drugs. Also, the definition of the onset of sensory block may vary in studies.

Table 1. Comparison Between Studies

Studies	The onset of sensory block			Maximum sensory block		
	Group B (min)	Group R (min)	P value	Group B (min)	Group R (min)	P value
Kulkarni KR. et al.[2]	3.2	4.3	0.033	15	13.5	P<0.05
Pandey M. [29]	1.45±0.53	2.61±0.58	<0.001	7.68±0.83	8.71±1.64	<0.001
Regmi G. et al [22]	7.50±1.67	10.10±1.76	0.000	-	-	-
Tarkase AS. et al.[28]	2.18±0.19	4.32±0.48	0.001	7.56±2.48	15.25±4.12	0.0060
Geetha C. et al.[30]	10.77±1.14	11.17±1.15	<0.05	24.37±2.28	25.1±2.11	<0.05
Khundongbam K. et al.[21]	-	-	-	9.17±1.51	9.10±1.97	0.884
Present study	3.13±0.81	7.06±1.01	$3.48e^{-23}$	17.96±2.34	16±2.69	0.0040

Motor Block-

The mean time required to reach the motor block in group B and group R was 6.66±0.95 min and 9.86±2.01 respectively. The time required to reach the motor block in group R was significantly more compared to group B patients. Various studies have shown similar findings. [2, 22, 28] The detailed comparison of time required to reach the motor block between studies is depicted in table 2. These findings suggested that ropivacaine is less potent towards motor nerves and the extent of sensory-motor separation is more as compared with bupivacaine however, it can produce reliable spinal anaesthesia. The reason for less potency of ropivacaine may be less lipid solubility leading to slow penetration in large myelinated A fiber.

Table 2. Comparison Between Studies

Studies	Group B (min)	Group R (min)	P value
Kulkarni KR. et al.[2]	11	14.5	>0.05
Tarkase AS. et al.[28]	6.28±1.64	10.32±4.20	0.0000
Regmi G. et al [22]	8.57±1.40	13.33±1.86	0.000
Present study	6.66±0.95	9.86±2.01	4.33e-11

Time for two-segment regression- In this study mean time of two segment regression in groups B and R was 83.7±8.58 min and 66.93±7.25 min respectively. Duration of regression was more rapid in group R subjects compared to group B patients ($P=1.53e^{-11}$).

Bromage score

The Bromage scale score was significantly high in group R subjects compared to group B subjects (2.26±0.98 vs 2.81±0.39, P=0.0024). Similarly, Kulkarni KR. et al. showed a lower incidence of Bromage score of grade III in ropivacaine-treated patients. [2] In the study of Geetha C. et al., the onset time to Bromage 3 was significantly shorter in the bupivacaine group (8.57 ± 1.406 min) than in the ropivacaine group (13.33 ± 1.86 min) with $P<0.001$. [30]

Adverse effects

In groups B and R, a total of 46.66% and 30% of patients had adverse effects respectively. Hypotension was the most common adverse effect observed in 13.33% and 23.33% of group R and group B patients respectively. Followed by bradycardia (10% vs 10%), nausea (10% vs 3.33%), and vomiting (3.33% vs 3.33%). In the study of Kulkarni KR. et al. hypotension was the most common adverse event observed in 20% and 27.5% of patients of group R and group B respectively followed by bradycardia (7.5% vs 10%). [2] Whereas, Regmi G. et al suggested hypotension (Group B=10%, Group R=6.6%), bradycardia (Group B=16.6%, Group R=3.3%), and nausea (Group B=13.3%, Group R=6.6%). [22] Takase AS. et al. in their study reported similar incidences of nausea and vomiting in both groups (4%). [28]

The other important limitations like adverse effects such as the non-availability of a standard densitometer in the operation theatre and the baricity of every freshly prepared hyperbaric ropivacaine solution were not checked. Also, hyperbaric ropivacaine is not available commercially; extreme antiseptic care is required to prepare the hyperbaric solutions.

CONCLUSION-

From the above study we conclude that, Ropivacaine can provide predictable and reliable spinal anaesthesia than commercially available hyperbaric bupivacaine. Ropivacaine produces a late sensory block, early regression, and a shorter total duration of the sensory blockade as compared to bupivacaine. It causes the late onset of motor blockade, with less degree and total duration of the motor blockade as compared to hyperbaric bupivacaine. Ropivacaine was more hemodynamically stable than bupivacaine. Recovery of motor and the sensory block was more rapid in ropivacaine than in bupivacaine. Incidences of adverse effects were comparable between ropivacaine and bupivacaine. Further studies are warranted to confirm the present study findings.

Conflict Of Interest- The authors declare no conflict of interest.

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