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Original Research Article

A Comparative Clinical Study of Efficacy of 0.75% Isobaric Ropivacaine versus 0.5% Hyperbaric Bupivacaine in Patients Undergoing Elective Caesarean Section under Spinal Anesthesia

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Abstract

Background: The use of neuraxial anesthesia, such as spinal anesthesia, has become increasingly popular for elective cesarean sections. Local anesthetics are crucial in providing effective pain relief during these procedures. Ropivacaine and bupivacaine are two commonly used local anesthetics with different properties. This study aimed to compare the efficacy of 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine in providing spinal anesthesia for elective cesarean sections. The current study aimed to compare the clinical effects of 2ml of 0.75% intrathecal isobaric Ropivacaine with 2ml of 0.5% hyperbaric Bupivacaine for elective cesarean section.

Methods: N=100 parturients belonging to ASA physical status I & II scheduled for elective cesarean section were randomly selected for the study and were divided into two groups of 30 each Group B patient received 2ml of 0.5% hyperbaric Bupivacaine intrathecally. Group R patients received 2ml of 0.75% isobaric Ropivacaine intrathecally Onset and duration of sensory block, onset and duration of motor block, maximum height of sensory block, quality of anesthesia, and time of request for analgesia, hemodynamic parameters and adverse effects if any were studied.

Results: There was no significant difference in the onset of sensory block at T8 between the two groups: 158.40±41.89 sec with Bupivacaine and 174.00±44.12 sec with Ropivacaine (P=0.073). Maximum sensory height was higher in group R (T_2-T_6) than in group B (T_4-T_6) (P<0.001). The duration of sensory block was similar between groups, while motor block onset was faster in group B (P<0.001). Motor block duration was longer in group B (P<0.001). Analgesia request time, hemodynamic parameters, and side effects were comparable.

Conclusion: Ropivacaine 15 mg (2 ml of 0.75% isobaric Ropivacaine) provides a comparable quality of sensory block but has a slower onset and significantly shorter duration of motor block compared to Bupivacaine.

Keywords: Ropivacaine, Bupivacaine, Intrathecal, Cesarean Section.

Introduction

Spinal anesthesia is one of the most popular anesthetic methods for elective Caesarean section because of its action that begins rapidly, its easy technique, and it provides anesthesia for surgical operation without causing many side effects. The local anesthetic administered in this surgery is therefore important for the intended anesthetic as well as side effects for instance hypotensive effect, prolonged motor block, and recovery period [1]. Classical hyperbaric bupivacaine has been widely used for spinal anesthesia in the context of Caesarean sections because of its profound sensory and motor blockade and the predictable spread in the CSF [2]. However, because of issues of cardiotoxicity and the long duration of motor blockade efforts have been made to seek other agents like ropivacaine [3]. Another group of local anesthetics is known as amides, of which ropivacaine is a relatively newer long-acting anesthetic agent under increasing consideration in spinal anesthesia particularly in obstetric surgery [4]. It has the same sort of molecular structure as bupivacaine but has a lower risk of cardiotoxicity and toxicity to the central nervous system. Moreover, ropivacaine is found to have a superior sensory-motor blocking profile, which may be most beneficial in procedures such as Caesarean section, in which early mobilization and Net rapid motor recovery are desired [5]. However, it is still being studied further especially when used in spinal anesthesia, more preferably in the isobaric form.

The baricity of a local anesthetic is a contributing factor in the dispersion of the anesthetic within the intrathecal space. Hyperbaric solutions, including hyperbaric bupivacaine, are heavier than CSF, and as a result, the position of the patient determines the concentration of anesthetic all through the advancement [6]. In contrast, isobaric solutions like isobaric ropivacaine are neutral concerning CSF, leading to a potentially more uniform spread but less predictability in terms of block height. Recent research works comparing hyperbaric bupivacaine to isobaric ropivacaine have indicated some differences in the onset of anesthesia time of sensory and motor blockade, patient as well as hemodynamics stability [5,7,8]. Although bupivacaine remains the preferred long-acting anesthetic opioid, ropivacaine may be advantageous since the patients reported faster motor recovery and fewer side effects especially in obstetric anesthesia [1]. Due to the implications that the two agents may have for the safety of mothers who are going through Caesarean sections, it is necessary to compare the two agents in this paper. The rationale of the present study is twofold: First, comparing the efficacy of 0.75% isobaric ropivacaine to that of 0.5% hyperbaric bupivacaine in patients undergoing elective Caesarean section under spinal anesthesia; second, establishing the optimal dose of isobaric ropivacaine for such patients. Emphasis will be made on comparing such characteristics as onset, duration, and quality of sensory-motor block, changes in hemodynamics, and safety indicators. This comparison shall offer the clinicians awareness of the strengths and weaknesses between the two anesthetic agents, and therefore assist in decision-making on the improvement of anesthesia in Caesarean sections.

Material and Methods

This prospective randomized observational study was conducted on 100 pregnant patients admitted at Sultan Bazar Maternity Hospital attached to Osmania Medical College, Hyderabad, undergoing elective cesarean section from 2020-2023. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study in vernacular language.

Inclusion Criteria

1. ASA physical status I for singleton pregnancy.
2. Full term parturient undergoing elective cesarean section.
3. Valid informed/explained consent.

Exclusion Criteria

1. Patients with cardiac disease,
2. hematologic disease, diabetes,
3. Eclampsia, bleeding or coagulation abnormalities,
4. fetal distress or known fetal anomalies were excluded from the study.

Preanesthetic Examination and Preparation: The study protocol was approved by the Hospital Ethics committee and Ethical clearance was obtained from the institution for the study. A pre-anesthetic check-up was done one day before the surgery. Patients were evaluated for any systemic diseases and laboratory investigations were recorded. The procedure of spinal anesthesia was explained to the patients and written consent was obtained. Patients were advised overnight fasting and premedicated with inj. 10mg Metaclopramide and 50mg Ranitidine in preoperative holding. The patient was preloaded with an i.v. Infusion of one liter of ringer lactate solution.

Randomization: N=100 patients were randomly divided into two groups of 50 each by computer-generated random numbers.

Group I: Fifty patients received 2ml of injection 0.5%hyperbaric bupivacaine intrathecally. *Group II*: Thirty patients received 2ml of 0.75% isobaric Ropivacaine intrathecally.

Preparation of Operation Room: Boyle's anesthesia machine was checked. Appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, bougie, and working suction apparatus were kept ready before the procedure. After shifting to the operating theatre, IV access was obtained on the forearm with 18 Gauge IV cannula and IV infusion started with Ringer Lactate. Patients were monitored for heart rate (HR), Non-Invasive Blood Pressure (NIBP) peripheral oxygen saturation (SpO_2). Spinal anesthesia was performed with the patient in the lateral position using a 25-gauge Quincke needle at the $L_{3–4}$ or $L_{4–5}$ interspaces. The study solution (2 ml) was administered over 30 sec. The patient was turned gently and placed supine with left uterine displacement. After the spinal block, HR, RR, SpO_2, and NIBP were measured every 5 min until delivery and then every 15 min in the postoperative period. Hypotension was defined as a 20% decrease in blood pressure from baseline values and was treated with incremental i.v. Boluses of ephedrine 5–10 mg. Bradycardia had a defined heart rate of less than 60 bpm and was treated with IV atropine 0.5mg. Supplementary oxygen was given through a facemask. The level of sensory anesthesia, defined as the loss of temperature sensation with an ice test tube at the midclavicular level, and was measured every minute until it reached the T8 dermatome level and then every 10 min during surgery. The following variables were recorded. Time for the onset of the block at T_8, maximum block height, time for regression to L_1, total duration of analgesia (at S_1), time to request for analgesia, time of onset of motor block, degree of motor block, total

duration of the block, quality of anesthesia, and analgesics supplements given if any.

Time to motor block was assessed every minute using the Bromage scale (0=no motor block, 3=complete motor block of lower limbs) until complete motor block and then every 30 min until the return of normal motor function. The time to complete the motor block and complete recovery was recorded. The time to first complaint of pain and request for rescue analgesia was recorded. The quality of anesthesia, the quality of muscle relaxation (judged by the surgeon), and the degree of intraoperative patient comfort (judged by the patient) were recorded as excellent, good, fair, or poor.

Statistical Methods: Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at a 5% level of significance. Student t-test (two-tailed, independent) has been used to find the significance of study parameters on a continuous scale between two groups (Intergroup analysis) Mann Whitney U test has been used to find the significance between two groups for parameters on the non-interval scale. The chi-square test was used to find the significance of study parameters on a categorical scale between two groups.

Results

Table 1 shows that the mean age of Group R is 26.3±5.8 years and the mean age in Group B is 25.2±4.5 years. The difference between the groups is not statistically significant (Independent t-test, p=0.31). The mean height of Group R is 152.9 ± 6cm and the mean age in Group B is 153.1 ± 6.5 years. The difference between the groups is not statistically significant (Independent t-test, p=0.91). The mean age of Group R is 63.3±7 years and the mean age in Group B is 63.2±9.3 years. The difference between the groups is not statistically significant (Independent t-test, p=0.93). Therefore, both groups were comparable as far as the demographic characteristics are concerned. This minimizes the potential confounding effects of these factors on the outcomes.

Table 1: Demographic profile of the cases included in the study

	Group R		Group B		p-value
	Mean	± SD	Mean	± SD	
Age in years	26.3	5.8	25.2	4.5	0.31
Height (cm)	152.9	6.0	153.1	6.5	0.91
Weight (Kg)	63.3	7.0	63.2	9.3	0.93

Table 2 shows the time taken for the onset of sensory and motor block in the two groups. There was no significant difference in the time to onset of sensory block between the two groups (p-value = 0.09). Group B (0.5% hyperbaric bupivacaine) had a significantly faster onset of motor block compared to Group R (0.75% isobaric ropivacaine) (p-value < 0.001). Hyperbaric bupivacaine was associated with a significantly faster onset of motor block compared to isobaric ropivacaine. This suggests that hyperbaric bupivacaine may be more effective in blocking motor function.

Table 2: Time taken for the onset of sensory and motor block

	Group R		Group B		p-value
	Mean	±SD	Mean	± SD	
Sensory Block					
Time (minutes)	1.6	0.4	1.5	0.3	0.09
Motor Block					
Time (minutes)	12.5	2.1	8.9	3.0	<0.001*

*Significant

Table 3 presents the mean duration of sensory and motor block in the two groups. The mean time taken for the sensory regression in Group R is 2 hours 15 min 54 secs ±37 min 48 secs and the meantime taken for the sensory regression in Group B is 2 hours 26 min 42 secs ±48 min 36 secs. The regression is earlier in Group B but the difference is not statistically significant. The mean time taken for the motor regression in Group R is 1 hour 44 min ±35 min 30 secs and the meantime taken for the sensory regression in Group B is 2 hours 47 min 6 secs ±33 min 42 secs. The regression is very early in group R and the difference is statistically significant.

Table 3: Regression of sensory block and motor block in both groups

	Group R		Group B		p-value
	Mean	±SD	Mean	± SD	
Sensory Block					
Time (minutes)	135.9	37.8	146.7	48.6	0.22
Motor Block					
Time (minutes)	104.0	35.5	167.1	33.7	<0.001*

*Significant

Table 4 presents the maximum sensory level achieved in the two groups. A significantly higher number of patients in Group B (hyperbaric bupivacaine) achieved higher sensory levels (T5, T4, T3) compared to Group R (isobaric ropivacaine). A significantly higher number of patients in Group R achieved lower sensory levels (T6, T5). Hyperbaric bupivacaine appears to provide a higher level of sensory block compared to isobaric ropivacaine. This could be attributed to the increased density of the hyperbaric solution, which allows for a deeper spread of the anesthetic.

Table 4: Maximum sensory level blockade achieved

Sensory level	Group R	Group B	p-value
T6	2	12	0.002*
T5	14	18	
T4	14	15	
T3	13	2	
T2	7	3	
Total	50	50	

*Significant

Figure 1 presents the mean heart rate measurements over time for two groups. Both groups exhibited minimal changes in heart rate throughout the observation period. There were no statistically significant differences in heart rate between the two groups at any time point (p-values ranged from 0.4 to 0.9). This shows that both 0.5% hyperbaric bupivacaine and 0.75% isobaric ropivacaine appear to be well-tolerated by the cardiovascular system, with minimal effects on heart rate.

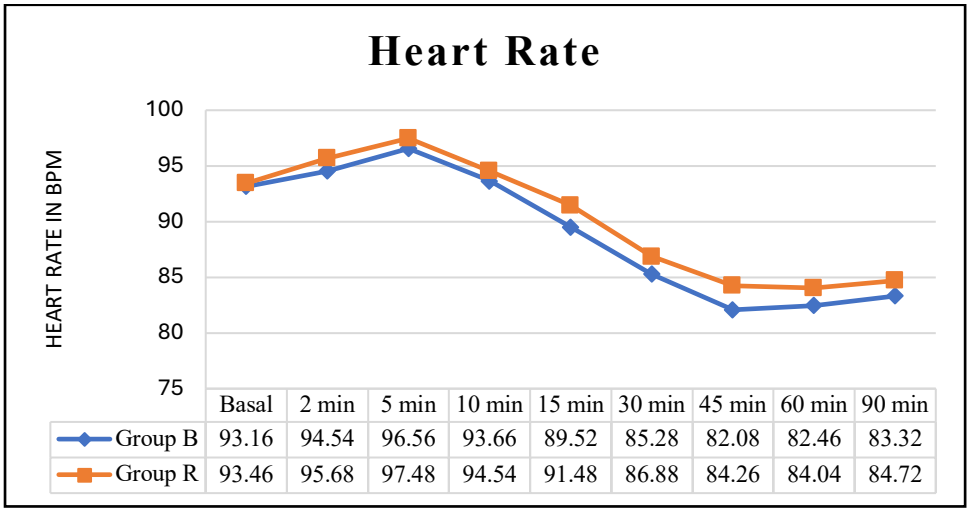
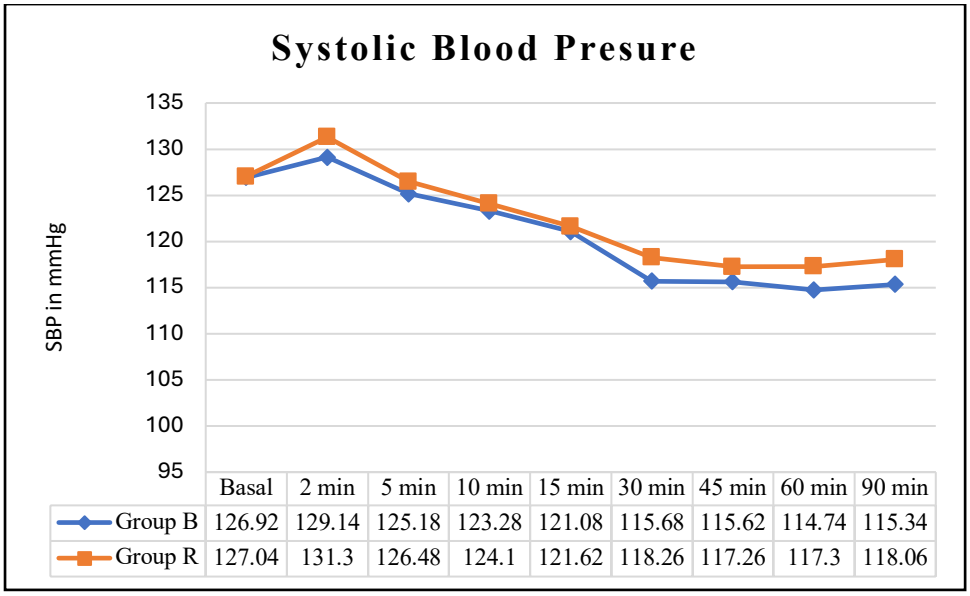


Figure 1: Showing the change in mean heart rate between the two intervention groups.

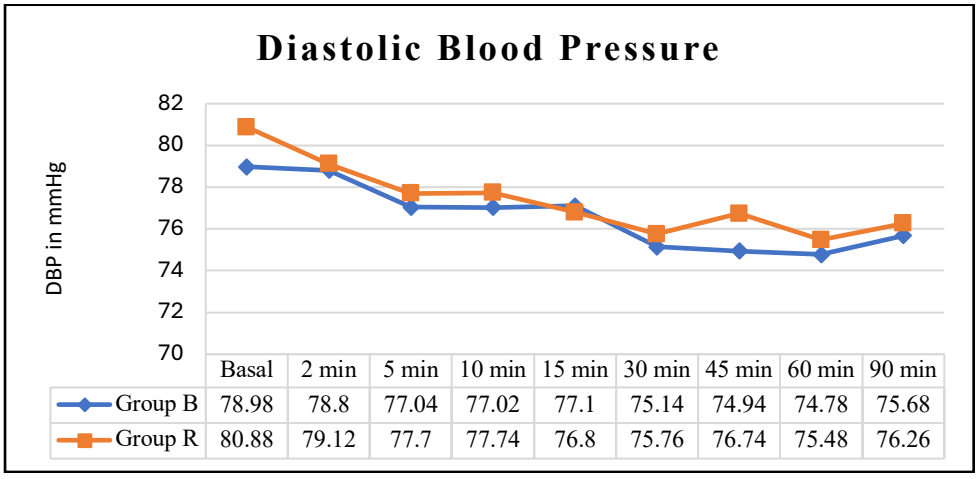
Figure 2 shows the mean systolic blood pressure (SBP) measurements over time for two groups. Both groups exhibited minimal changes in SBP throughout the observation period. There were no statistically significant differences in SBP between the two groups at any time point (p-values ranged from 0.3 to 1.0).



	Basal	2 min	5 min	10 min	15 min	30 min	45 min	60 min	90 min
Group B	126.92	129.14	125.18	123.28	121.08	115.68	115.62	114.74	115.34
Group R	127.04	131.3	126.48	124.1	121.62	118.26	117.26	117.3	118.06

Figure 2: Comparison of systolic blood pressure change between groups

Figure 3 shows the mean diastolic blood pressure (DBP) measurements over time for two groups: Group B (0.5% hyperbaric bupivacaine) and Group R (0.75% isobaric ropivacaine). Both groups exhibited minimal changes in DBP throughout the observation period. There were no statistically significant differences in DBP between the two groups at any time point (p-values ranged from 0.19 to 0.85).



	Basal	2 min	5 min	10 min	15 min	30 min	45 min	60 min	90 min
Group B	78.98	78.8	77.04	77.02	77.1	75.14	74.94	74.78	75.68
Group R	80.88	79.12	77.7	77.74	76.8	75.76	76.74	75.48	76.26

Figure 3: Comparison of diastolic blood pressure change between groups

Hypotension was noted in 20 (78%) of patients in group B and in 27(74%) of patients in group R. Bradycardia was noted in 6 (12%) of patients in group B, but no bradycardia was noted in group R. Nausea and vomiting was observed in 4 and 3 patients in group B and group R respectively. As all patients were catheterized urinary retention could not be monitored. There was no clinical or statistical significance in the incidence of side effectsin both groups given in (Table 5).

Table 5: Side effects in both groups of cases of the study

Side Effect	Group B	Group R
Hypotension	20(78%)	27(74%)
Bradycardia	6(12%)	0(0.0%)
Nausea & Vomiting	4(8%)	3(6%)
Urinary retention	0(0.0%)	0(0.0%)

Table 6 presents the APGAR scores of newborns in two groups. Both groups demonstrated high APGAR scores at both 1 and 5 minutes, indicating good neonatal condition. There were no significant differences in APGAR scores between the two groups at either time point. High APGAR scores

suggest that both ropivacaine and bupivacaine are associated with favorable neonatal outcomes. The absence of significant differences in APGAR scores indicates that the choice of anesthetic does not appear to have a substantial impact on neonatal well-being.

Table 6: APGAR scores of neonates born in two groups

APGAR score	1 min		5 min	
	Group B (No. of Pts)	Group R (No. of Pts)	Group B (No. of Pts)	Group R (No. of Pts)
< 4	0	0	0	0
5-7	2	1	0	0
8-10	48	49	50	50

Discussion

A prospective, randomized, controlled double-blind study was conducted at our hospital, involving 100 ASA I and II parturients undergoing Caesarean sections under subarachnoid block. The equipotent ratio between ropivacaine and bupivacaine is generally considered to be 3:2 or 2:1 [9]. In a dose-finding study, Khaw et al. [10] noted that the ED50 of isobaric ropivacaine for Caesarean section was 16.7 mg (14.1–18.8 mg) and the ED90 was 26.8 mg. Since hyperbaric bupivacaine 10 mg is commonly used at our institution, an equipotent dose of 15 mg ropivacaine was chosen for this study. All patients achieved an adequate level of anesthesia, except for one patient in each group who required intraoperative opioid supplementation. While some authors have considered sensory blockade onset at T10, we used T8, as it is more appropriate for Caesarean sections [11, 12]. Chung et al. [12] used 18 mg of hyperbaric ropivacaine for Caesarean deliveries and found that the onset time to T10 was 3.2 minutes. In our study, the mean onset time to T8 was 158 seconds with 15 mg ropivacaine, likely due to the use of an isobaric solution. McNamee et al. [13] using 17.5 mg of isobaric ropivacaine for hip arthroplasty, reported a median onset time of 2 minutes (2–5 minutes). Whiteside et al. [14] observed that the maximum level of sensory block was T7 with ropivacaine and T5 with bupivacaine when 15 mg of hyperbaric solutions were used for lower abdominal and lower limb surgeries. In our study, however, a higher sensory blockade was noted with ropivacaine (T2–T6) compared to bupivacaine (T4–T6), which may be attributed to the use of an isobaric ropivacaine solution.

Boztug et al. [15] found that the time for block regression to L1 was faster with ropivacaine (116 ± 31 min) compared to bupivacaine (152.2 ± 64.5 min) in outpatient arthroscopic surgeries. Similarly, in our study, regression to L1 was faster with ropivacaine. Chung et al. [12] reported that block regression to S1 was longer with bupivacaine (188.56 ± 28.2 min) than with ropivacaine (162.56 ± 20.2 min), though we observed no significant difference in regression to S1 between the groups, aligning with Khaw et al. [10] The time to first analgesic request was also comparable between groups, consistent with findings by Sanli et al. [16] and Gautier et al. [17]. A study comparing intrathecal bupivacaine (8 mg), levobupivacaine (8 mg), and ropivacaine (12 mg) for Caesarean sections by Gautier et al. [17], found the onset of Grade 3 Bromage motor block was 9 minutes with bupivacaine and 14 minutes with ropivacaine. Our study observed a faster onset: 4.5 minutes for bupivacaine and 9.25 minutes for ropivacaine, likely due to the higher doses used. This delayed onset with ropivacaine aligns with the findings of Ogun et al. [18]. Sanli et al. [16] noted a 118-minute duration of the motor block with 15 mg ropivacaine for Caesarean sections. Our study found a shorter duration of 95 minutes with ropivacaine, consistent with studies by Chung et al. [12] and Kallio et al. [19], which also reported shorter motor block durations with ropivacaine compared to bupivacaine. Chung et al. [12] observed complete motor block in all patients using either drug for Caesarean sections, which matches our findings. Similarly, Boztug et al. [15] reported complete motor block in 88% of ropivacaine patients and 100% of bupivacaine patients. In terms of hemodynamics, hypotension occurred in 38% of bupivacaine patients and 37% of ropivacaine patients, with no bradycardia in the ropivacaine group. Hemodynamics were well-managed, aligning with Ogun et al. [18]. All babies had APGAR scores above 7, and side effects were minimal.

Conclusion

Our study demonstrates that 15 mg of isobaric ropivacaine (2 ml of 0.75%) administered intrathecally provides effective anesthesia for Caesarean sections. The onset of sensory blockade is comparable to bupivacaine, though ropivacaine achieved a slightly higher sensory block. However, the duration of analgesia at L1 (L1 regression) was significantly shorter with ropivacaine. Additionally, ropivacaine had a delayed onset and shorter duration of motor block compared to bupivacaine. Therefore, ropivacaine is a suitable option for Caesarean sections, especially when early recovery is a priority for the mother.

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