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Original Research Article

A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE CLINICAL EFFICACY OF INTRATHECAL ROPIVACAINE AND BUPIVACAINE WITH FENTANYL IN SPINAL ANAESTHESIA FOR CESAREAN SECTION

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ABSTRACT

Background: Bupivacaine is the conventional local anaesthetic for spinal anaesthesia in cesarean section, whereas ropivacaine, a pure S (-)-enantiomer, may offer comparable efficacy with reduced cardiotoxicity and neurotoxicity. The aim and objective is to compare the efficacy, quality of anaesthesia, haemodynamic stability, side effect profile, and neonatal outcomes of 0.75% isobaric ropivacaine with fentanyl versus 0.5% hyperbaric bupivacaine with fentanyl in parturients undergoing elective cesarean section. **Materials and Methods:** In this double-blind randomised controlled trial, 120 ASA I–II parturients were allocated to receive either 2 mL of 0.75% isobaric ropivacaine + 25 µg fentanyl (Group R, n = 60) or 2 mL of 0.5% hyperbaric bupivacaine + 25 µg fentanyl (Group B, n = 60). Onset and duration of sensory and motor block, quality of anaesthesia, haemodynamic changes, side effects, and neonatal Apgar scores were recorded and analysed. **Result:** Sensory block onset to T10 was slower with ropivacaine (1.30 ± 0.46 min) than bupivacaine (1.13 ± 0.34 min; p = 0.026), and time to highest sensory level was longer (5.23 ± 2.17 min vs. 3.98 ± 1.16 min; p = 0.0001). The highest level achieved (T4) and sensory block duration were comparable (p = 0.657). Motor block onset was delayed (p = 0.02) and complete block occurred in fewer patients with ropivacaine (93.33% vs. 100%; p = 0.042). Motor block duration was significantly shorter with ropivacaine (165.08 ± 24.17 min) than bupivacaine (184.25 ± 17.70 min; p < 0.001). Haemodynamic parameters, side effects, and Apgar scores at 1 and 5 min were similar between groups. **Conclusion:** Both regimens provided effective and safe spinal anaesthesia for elective cesarean section. Ropivacaine resulted in a shorter motor block duration, facilitating earlier maternal mobilisation, but had a slightly delayed onset compared to bupivacaine. It may be considered a suitable alternative when early postoperative recovery is prioritised.

INTRODUCTION

Spinal or intrathecal anaesthesia has been a cornerstone technique in obstetric anaesthesia, particularly for cesarean section, owing to its reliability, rapid onset, and profound sensory and motor blockade. The single-shot spinal technique is widely employed, with hyperbaric bupivacaine being the conventional local anaesthetic of choice. Ropivacaine, introduced into clinical practice in 1996 and approved for intrathecal use by the European Union in February 2004, represents a more recent

alternative with a potentially improved safety profile compared to bupivacaine.[1]

Ropivacaine is a long-acting S-enantiomer amide local anaesthetic with lower lipid solubility and structural similarity to bupivacaine.[1] It preferentially produces sensory blockade over motor blockade and exhibits reduced cardiovascular and central nervous system toxicity, making it an attractive option for various surgical settings.[1] Its intrathecal application has been described in both obstetric and non-obstetric patients, and the addition of intrathecal opioids such as fentanyl or sufentanil has been shown to enhance the quality of anaesthesia while allowing lower local anaesthetic doses.[2] Kim HK demonstrated that 16 mg of 0.75% ropivacaine with 20 µg fentanyl provided satisfactory anaesthesia for elective cesarean section.[3]

In India, 0.5% hyperbaric bupivacaine with 25 µg fentanyl remains the standard intrathecal regimen for cesarean deliveries. However, given ropivacaine's potential advantages—particularly its shorter motor block duration and lower risk of haemodynamic instability—there is growing interest in evaluating its suitability as an alternative. While several international studies have compared ropivacaine and bupivacaine in obstetric anaesthesia, Indian data remain limited. Moreover, most studies have used different concentrations, baricity, and adjunct opioid doses, making direct comparisons difficult.

The present study was designed to compare the clinical efficacy and safety of equipotent intrathecal doses of 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine, each combined with 25 µg fentanyl, for elective cesarean section. The primary objective was to assess the quality of surgical anaesthesia, while secondary objectives included comparison of onset and duration of sensory and motor block, haemodynamic changes, requirement for vasoactive drugs, and neonatal outcomes.

MATERIALS AND METHODS

Study Design and Setting: This study was conducted as a double-blind, randomised controlled trial in the Department of Anaesthesiology, Lady Hardinge Medical College and Shrimati Sucheta Kriplani Hospital, New Delhi, over a period of 12 months from September 2012 to September 2013.

The study population comprised pregnant women scheduled for elective cesarean section under spinal anaesthesia who met the eligibility criteria. The inclusion criteria for the study comprised parturients with American Society of Anaesthesiologists (ASA) physical status I or II, aged between 18 and 40 years, with a height greater than 145 cm and a body weight less than 100 kg. The exclusion criteria included patients with any contraindication to regional anaesthesia, a known allergy to local anaesthetics, evidence of dysrhythmias on the preoperative electrocardiogram, severe psychiatric disorders, or a history of drug abuse.

Sample Size and Randomisation: A total of 120 patients were enrolled and randomised into two equal groups (n = 60 each). Randomisation was performed using a computer-generated random number table. Allocation concealment was maintained by an anaesthesiologist not involved in the clinical management or data collection, who prepared the study drug in identical syringes.

Blinding Both the patient and the investigator assessing the block characteristics were blinded to group allocation. The anaesthesiologist administering the intrathecal injection was also unaware of the study objectives.

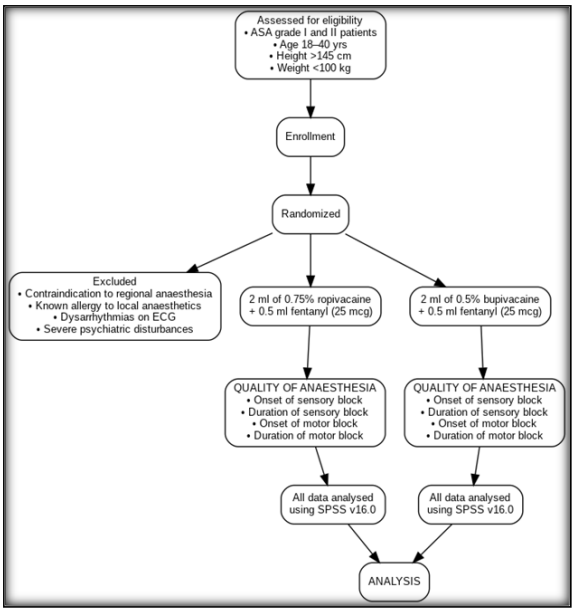

Figure 1: CONSORT Diagram

Preoperative Preparation: All participants underwent routine pre-anaesthetic evaluation, including history, physical examination, and relevant investigations. Patients were instructed to fast overnight after a light meal and were premedicated with tablet ranitidine 150 mg orally the night before and again 2 hours prior to surgery. Upon arrival in the operating room, standard monitors (ECG, non-invasive blood pressure [NIBP], and pulse oximetry) were applied and baseline haemodynamic parameters were recorded. Intravenous access was secured with an 18G cannula in the non-dominant forearm, and patients were preloaded with Ringer's lactate solution at 15 mL/kg over 15–20 minutes.

Anaesthetic Technique: Under strict aseptic precautions, subarachnoid block was performed at the L2–L3 or L3–L4 intervertebral space using a 25G Quincke spinal needle. After free flow of cerebrospinal fluid was confirmed, the study drug was injected slowly over 30 seconds. Patients were then placed supine with left lateral tilt to minimise aortocaval compression.

The two groups received:

- Group R (Ropivacaine group): 2 mL of 0.75% isobaric ropivacaine with 25 µg fentanyl (0.5 mL)

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- Group B (Bupivacaine group): 2 mL of 0.5% hyperbaric bupivacaine with 25 µg fentanyl (0.5 mL)

Surgery was allowed to commence once sensory block to the T6 dermatome and Bromage grade 1 motor block were achieved. Failure to achieve T5–T6 sensory block within 30 minutes was considered block failure, and such patients were excluded from further analysis.

Block Assessment: Sensory block was evaluated using the pinprick method at 1-minute intervals for the first 10 minutes and then every 2 minutes until the highest level was achieved. Onset time was defined as the time from injection to loss of sharp sensation at the T10 dermatome. The highest level attained and time to reach it were recorded.

Motor block was evaluated using the modified Bromage scale, where a score of 0 indicated full movement, 1 represented the inability to raise an extended leg, 2 denoted the inability to flex the knees but the ability to flex the feet, and 3 indicated the inability to flex the feet

Onset of motor block was defined as the time from injection to attainment of Bromage grade 1, and time to achieve grade 3 was also noted.

Intraoperative Monitoring and Management: Heart rate and blood pressure were recorded every minute for the first 5 minutes, every 5 minutes until 30 minutes, and every 15 minutes thereafter until the end of surgery. Continuous ECG and SpO_2 monitoring were maintained. Hypotension (systolic blood pressure < 90 mmHg or ≥ 20% fall from baseline) was treated with 250 mL Ringer's lactate bolus and incremental 3 mg doses of intravenous mephentermine. Bradycardia (heart rate < 60 bpm) was treated with 0.3 mg intravenous atropine.

The quality of surgical anaesthesia was graded as excellent when the patient had no complaints during surgery, good when the patient permitted the procedure but required intravenous ketamine at a dose of 0.2 mg/kg (up to a maximum of two doses), and poor when the block was inadequate and necessitated conversion to general anaesthesia.

Postoperatively, patients were monitored for haemodynamic stability, block regression, and any side effects. The duration of sensory block was defined as the time from intrathecal injection to regression of sensory level to the L1 dermatome, while the duration of effective analgesia was recorded as the time from injection to the patient's first request for rescue analgesia. The duration of motor block was measured from injection to the return of Bromage grade 0. Side effects, including nausea, vomiting, and electrocardiographic changes, were noted. Neonatal outcomes were assessed using Apgar scores at 1 and 5 minutes after delivery

Statistical Analysis: Data analysis was performed using SPSS version 27.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation (SD) and compared using the unpaired t-test. Categorical variables were compared using the Chi-square test. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 120 patients were enrolled and randomised equally into two groups: Group R (0.75% isobaric ropivacaine with 25 µg fentanyl) and Group B (0.5% hyperbaric bupivacaine with 25 µg fentanyl). All patients completed the study and were included in the analysis.

Demographic Profile: The groups were comparable with respect to age, weight, height, and duration of surgery, and no statistically significant differences were observed (p > 0.05) [Table 1].

Table 1: Demographic profile of patients

Parameter	Group R (Mean ± SD)	Group B (Mean ± SD)	t test value	p-value
Age (years)	25.916 ± 4.567	25.644 ± 4.748	0.32	0.749 (NS)
Weight (kg)	62.333 ± 6.141	61.117 ± 4.805	1.20	0.23 (NS)
Height (cm)	159.583 ± 4.056	158.742 ± 3.11	1.27	0.21 (NS)
Duration of surgery (min)	59.333 ± 14.186	56.750 ± 14.107	1.00	0.319 (NS)

Characteristics of Sensory Block: The onset time to achieve T10 sensory block was significantly slower in Group R (1.3 ± 0.462 min) compared to Group B (1.133 ± 0.343 min) (p = 0.026, t test value is 2.24). The time taken to reach the highest sensory level was also significantly longer in Group R (5.233 ± 2.166 min) than in Group B (3.983 ± 1.157 min) (p = 0.0001, t test value is 3.94). The highest level of sensory block achieved was T4 in the majority of patients in both groups, with no statistically significant difference [Table 2]. The duration of sensory block was comparable (p = 0.657) [Table 3].

Table 2: Highest level of sensory block achieved

Highest level	Group R n (%)	Group B n (%)	Chi square test statistic	p-value
T2	8 (13.33%)	7 (11.67%)	0.381	0.827 (NS)
T4	36 (60%)	34 (56.67%)		
T6	16 (26.67%)	19 (31.66%)		

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Table 3. Duration of sensory block

Parameter	Group R (Mean ± SD)	Group B (Mean ± SD)	t test value	p-value
Duration (min)	208.000 ± 19.424	209.500 ± 17.459	-0.444	0.657 (NS)

Characteristics of Motor Block: The onset of Bromage grade 1 block was significantly slower in Group R (1.4 ± 0.807 min) compared to Group B (1.133 ± 0.343 min) (p = 0.019, t test value is 2.35). The number of patients achieving Bromage grade 3 was slightly lower in Group R (93.33%) than Group B (100%) (p = 0.042). The onset of Bromage grade 3 was significantly delayed in Group R (8.857 ± 3.305 min) compared to Group B (5.633 ± 2.428 min) (p < 0.001, t test value is 6.08). The duration of motor block was significantly shorter in Group R (165.083 ± 24.173 min) than in Group B (184.250 ± 17.703 min) (p < 0.001) (Table 4).

Table 4: Comparing characteristics of motor block

Parameter	Group R (Mean ± SD) / n (%)	Group B (Mean ± SD) / n (%)	t test value/Chi square value	p-value
Onset of B1 (min)	1.4 ± 0.807	1.133 ± 0.343	2.35	0.02 (S)
Patients achieving B3	56 (93.33%)	60 (100%)	3.41	0.042 (S)
Onset of B3 (min)	8.857 ± 3.305	5.633 ± 2.428	6.08	<0.001 (HS)
Duration of motor block (min)	165.083 ± 24.173	184.250 ± 17.703	-4.95	<0.001 (HS)

Quality of Anaesthesia: The quality of anaesthesia was excellent in 96.66% (n=58) of patients in both groups, with no statistically significant difference (p = 0.513, chi square test value is 1.33) [Table 5].

Table 5: Comparing Quality of anaesthesia between groups

Grade	Group R n (%)	Group B n (%)	Chi square test value	p-value
Excellent	58 (96.66%)	58 (96.66%)	1.333	0.513 (NS)
Good	1 (1.67%)	2 (3.33%)		
Poor	1 (1.67%)	0 (0%)		

Duration of Effective Analgesia: The time to first rescue analgesia was comparable between groups (218.583 ± 20.463 min in Group R vs. 218.5 ± 32.013 min in Group B; p = 0.987, t test value is 0.01).

Intraoperative Hypotension and Bradycardia: The incidence of hypotension was 26.66% (n=16) in Group R and 38.33% (n=23) in Group B (p = 0.172). Bradycardia occurred in none of the patients in Group R and 5% (n=3) in Group B (p = 0.079). The mean mephentermine requirement was similar in both groups (3.375 ± 1.061 mg in Group R vs. 3.6 ± 1.265 mg in Group B; p = 0.293, t test value is -1.05).

Side Effects: The incidence of nausea was 8.33% (n=5) in Group R and 13.33% (n=8) in Group B (p = 0.865). Vomiting occurred in 1.67% (n=1) of Group R patients and 3.33% (n=2) of Group B patients. No ECG changes were noted in any patient.

Neonatal Outcomes: The Apgar scores at both 1 and 5 minutes were comparable between the two groups. At 1 minute, the mean score was 8.05 ± 0.219 in Group R and 8.067 ± 0.252 in Group B (p = 0.694, t test value is -0.394), while at 5 minutes, the scores were 8.9 ± 0.354 and 8.883 ± 0.372, respectively (p = 0.798, t test value is 0.25). These findings indicate that both groups achieved satisfactory neonatal outcomes, with no evidence of neonatal depression.

DISCUSSION

Ropivacaine is a long-acting amide local anaesthetic structurally similar to bupivacaine but formulated as the pure S(-)-enantiomer, which offers a reduced potential for cardiotoxicity and neurotoxicity.[1] The addition of intrathecal fentanyl enhances the quality of anaesthesia and prolongs postoperative analgesia without significantly increasing adverse effects.[2] While hyperbaric bupivacaine with fentanyl remains the standard intrathecal combination for cesarean delivery in India, ropivacaine has gained attention for its potentially shorter motor block duration and greater haemodynamic stability.

In the present study, equipotent doses of 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine, each combined with 25 µg fentanyl, were compared for elective cesarean section. Both regimens produced excellent surgical anaesthesia in over 96% of cases, with comparable sensory block duration, effective analgesia, haemodynamic profiles, and neonatal outcomes.

Sensory block onset to T10 was significantly slower in the ropivacaine group compared to the bupivacaine group, as was the time to achieve the highest sensory level. These results are consistent with findings from Eryilmaz et al,[4] and Singh et al,[5] who also reported delayed onset with ropivacaine. However, other studies, including those by Ogun et al,[6] Al-Abdulhadi et al,[7] and Danelli et al,[8] found no such difference, possibly due to variations in baricity, volume, dose, or definition of onset time. The most common highest sensory level achieved was T4 in both groups, similar to reports by Ogun et al,[6] Al-Abdulhadi et al,[7] and Eryilmaz et al.[4] The duration of sensory block did not differ significantly, which is in agreement with previous work by Ogun et al,[6] and Gautier et al.[9]

Motor block onset was slower with ropivacaine, and complete motor block (Bromage grade 3) was achieved in slightly fewer patients compared to

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bupivacaine. Importantly, the duration of motor block was significantly shorter in the ropivacaine group, a finding supported by Wahedi et al,[11] Singh et al,[5] and Kallio et al.[10] Clinically, this shorter duration is advantageous for promoting earlier ambulation, earlier micturition, and reduced risk of postoperative complications related to immobility.

Haemodynamic stability was comparable between the groups, though the incidence of hypotension and bradycardia was lower in the ropivacaine group, consistent with trends observed in prior studies.[7,5] The difference, however, was not statistically significant. Mean mephentermine requirements were also similar.

Side effects such as nausea and vomiting were infrequent and comparable between groups, and no ECG changes were observed in any patient. This aligns with earlier studies.[4-9] Neonatal outcomes, assessed by Apgar scores at 1 and 5 minutes, were similar in both groups, confirming that neither drug adversely affected immediate neonatal wellbeing. Recent meta-analyses,[13] and randomized controlled trials,[14] further corroborate that ropivacaine is as safe and effective as bupivacaine for spinal anaesthesia in cesarean section, with the added benefit of shorter motor block duration.

Overall, both agents proved to be effective and safe for spinal anaesthesia in cesarean delivery. Ropivacaine's key advantage lies in its shorter motor block duration, making it a valuable option where early postoperative mobility is desired. The slightly slower onset with ropivacaine may need to be considered when rapid block establishment is essential.

CONCLUSION

Both 0.75% isobaric ropivacaine and 0.5% hyperbaric bupivacaine, when combined with 25 µg fentanyl, provided effective and safe spinal anaesthesia for elective cesarean section, with comparable sensory block duration, quality of anaesthesia, haemodynamic stability, and neonatal outcomes. Ropivacaine demonstrated a shorter duration of motor block, which may facilitate earlier maternal mobilisation and recovery, aligning with enhanced recovery protocols. However, its slightly slower onset of sensory and motor block compared to bupivacaine should be considered in surgical planning. Given its favourable recovery profile, ropivacaine may be considered a suitable alternative to bupivacaine for spinal anaesthesia in obstetric practice, especially in cases where early postoperative mobility is desirable.

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