Original Article

Efficacy, Hemodynamic Stability and Safety of Hyperbaric Bupivacaine versus Hyperbaric Ropivacaine in Spinal Anaesthesia for Elective Caesarean Sections: A Randomised Controlled Trial

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ABSTRACT

Background: The use of regional anaesthesia, particularly spinal anaesthesia, has transformed obstetric analgesia, especially during caesarean sections. Bupivacaine and ropivacaine are commonly used agents, each with distinct efficacy and safety profiles.

Objective: This study aims to compare the efficacy and safety of hyperbaric bupivacaine versus hyperbaric ropivacaine in terms of hemodynamic changes, sensory and motor block onset, duration, and incidence of complications during elective caesarean sections.

Methods: A randomized double-blinded controlled trial was conducted with 100 patients undergoing elective caesarean sections. Participants were divided into two groups: Group Ro received hyperbaric ropivacaine, and Group Bu received hyperbaric bupivacaine. Key parameters such as sensory and motor block onset times, hemodynamic stability, and complications were monitored and analysed using appropriate statistical methods.

Results: The bupivacaine group exhibited a significantly quicker onset of sensory (13.2 minutes) and motor blocks (11.58 minutes) compared to the ropivacaine group (14.45 minutes and 14.25 minutes, respectively). However, the ropivacaine group had a lower incidence of hypotension (10% vs. 24% in the bupivacaine group, p=0.04), indicating better hemodynamic stability.

Conclusion: While bupivacaine provides faster sensory and motor block onset, ropivacaine demonstrates a more favourable safety profile with fewer complications, particularly regarding hemodynamic stability. This suggests that ropivacaine may be a safer alternative in obstetric anaesthesia, especially for patients at risk of hypotension.

Keywords: Regional anaesthesia, spinal anaesthesia, bupivacaine, ropivacaine, caesarean section, hemodynamic stability, obstetric analgesia.

INTRODUCTION

The advent of regional anaesthesia has substantially revolutionized the domain of obstetric analgesia and anaesthesia, especially in the context of caesarean section deliveries. [1] Among the various modalities employed, spinal anaesthesia is notably favoured due to its swift action, minimal remnants of residual effects, and the provision of adequate anaesthesia during surgical interventions. [2] Among the anaesthetic agents, bupivacaine and ropivacaine stand out owing to their efficacy and comparatively lower toxicity profiles in the management of intraoperative pain. [3] This study seeks to address critical concerns regarding the utilization of these two agents, specifically focusing on their hemodynamic effects, efficacy, and safety profiles during elective operative procedures.

In recent years, given the increasing rates of caesarean deliveries globally, optimizing anaesthetic techniques and agents has garnered substantial attention from medical practitioners and researchers alike. [4] Caesarean sections, while often necessary for maternal or foetal indications, are not devoid of risks associated with anaesthesia, necessitating a thorough understanding of the pharmacodynamics and hemodynamic implications of the agents employed. [5, 6] Anaesthetic choices can significantly influence intraoperative haemodynamic, maternal comfort, and ultimately, neonatal outcomes. Consequently, establishing a comparative framework to evaluate bupivacaine and ropivacaine, particularly in their hyperbaric formulations, is pivotal for enhancing anaesthetic practice in this domain. [7]

The efficacy of an anaesthetic agent is typically determined by its onset time, duration of action, and the quality of analgesia it provides. It is critical for anaesthesiologists to ensure not only that the birthing process is as painless as possible, but also that the mother's physiological responses are stable during this period [8]. Hemodynamic changes, including blood pressure and heart rate fluctuations, are integral to patient safety and must be vigilantly monitored. The appropriate selection of an anaesthetic agent that maintains hemodynamic stability while still delivering adequate analgesia is crucial for achieving optimal maternal-foetal outcomes. [9, 10]

Bupivacaine has historically been the agent of choice for spinal anaesthesia owing to its high-potency profile and a longer duration of action. However, its propensity for producing hypotension, particularly in the obstetric population, is notable and raises concerns regarding maternal and foetal well-being. [11] On the contrary, ropivacaine has been shown to possess analgesic

properties comparable to bupivacaine, but with a potentially improved safety margin concerning cardiovascular stability. [3]

Comprehending the nuances of how bupivacaine and ropivacaine influence haemodynamic can prove indispensable for enhancing anaesthetic protocols and patient-centred care[12]. Moreover, in light of the increasing body of research advocating for the multimodal approach to postoperative analgesia, elucidating the comparative effectiveness of these two agents could guide clinicians towards informed decision-making regarding perioperative pain management and overall anaesthetic strategy. [13]

It is incumbent upon researchers to not only delineate the efficacy of these anaesthetic agents in terms of anaesthetic depth and duration but also to closely scrutinize their impact on maternal haemodynamic.

The objective of this research article is to compare the efficacy and safety of hemodynamic changes induced by hyperbaric bupivacaine versus hyperbaric ropivacaine when used for spinal anaesthesia in patients undergoing elective caesarean sections. The study aims to evaluate and contrast the onset, duration, and quality of sensory and motor blockades, as well as the overall hemodynamic stability and incidence of adverse effects associated with each anaesthetic agent. By doing so, the research seeks to determine which anaesthetic provides a more favourable profile for use in caesarean section procedures, ensuring both effective anaesthesia and patient safety.

MATERIALS AND METHODS

This study was a randomized double-blinded controlled trial conducted at the Department of Anaesthesiology and Critical Care of tertiary care hospital of eastern India from March 2023 to February 2024. Informed consent was obtained from all participants, with a Participant Information Sheet provided in their local language.

Sample Size: A total of 100 patients undergoing caesarean sections with spinal anaesthesia were recruited, with 50 patients assigned to each intervention group.

Inclusion Criteria: The inclusion criteria for the study encompass patients classified as ASA Grade I and II, specifically targeting pregnant women aged between 20 and 35 years who are in their 37th to 42nd week of gestation. These participants must be scheduled for a caesarean section under spinal anaesthesia and have provided valid, informed written consent.

Exclusion Criteria: The exclusion criteria for the study include patients who refuse to participate, those with local site infections, coagulopathy, or spinal deformities. Additionally, individuals classified as ASA Grade III and IV, those with allergies to local anaesthetic drugs, a history of seizures or neurological deficits, and those suffering from severe renal, hepatic, respiratory, or cardiovascular diseases are excluded. Furthermore, patients with a height of less than 150 cm are also not eligible for the study.

Intervention: Patients were randomly assigned to one of two groups. Group Ro received 2.5 mL of 0.5% Hyperbaric Ropivacaine intrathecally whereas Group Bu received 2.5 mL of 0.5% Hyperbaric Bupivacaine intrathecally.

Methodology:

Preoperative assessment and preparation were conducted per departmental protocols. Baseline parameters (blood pressure and heart rate) were recorded after patient transfer to the operating theatre. An 18G cannula was used for intravenous access, and all patients were pre-loaded with 1000 mL of Ringer Lactate over 15-20 minutes before spinal anaesthesia. Vital parameters were monitored, and lumbar puncture was performed at the L3-4 interspace using a 26-gauge Quincke spinal needle. The study drug was administered at a rate of 0.2 mL/sec upon free cerebrospinal fluid flow. Patients were then positioned supine, and hemodynamic parameters were continuously monitored.[14]

Outcome Parameters:

Parameter	Details
Sensory Block	Time of onset, peak sensory block, and duration assessed using a 27-gauge needle and visual analogue scale.
Motor Block	Time to complete motor block and duration assessed using the modified Bromage scale.
Hemodynamic Parameters	Monitored at specified intervals post-block.
Complications	Hypotension (a fall in SBP or MAP below 20-30% of the baseline), bradycardia (HR <60/min), and respiratory depression (RR <8/min or SpO2 <85%).

Statistical Analysis

Data were analysed using SPSS version 24. Continuous variables were expressed as mean ± SD, while categorical data were reported as percentages and frequencies. Differences between groups were evaluated using unpaired t-tests for continuous data and chi-square or Fisher's exact tests for categorical data, with a significance threshold of $p < 0.05$.

RESULTS

The mean age, gestational age, BMI, and duration of surgery for both groups were statistically similar, with p-values indicating no significant differences. Specifically, the mean age and BMI had p-values of 0.872 and 0.593 respectively, suggesting minimal variation between groups. Similarly, gestational age (p=0.822) and surgery duration (p=0.109) were also comparable. The ASA status distribution (ASA I and II) was nearly identical between the groups, with a p-value greater than 0.99, further indicating no significant difference. Overall, both groups were well-

matched in terms of these baseline characteristics. [Table 1]

The time to onset of sensory block was 14.45 minutes for the Ro group and 13.2 minutes for the Bu group. The mean difference in onset times between the two groups was 1.25 minutes, with a 95% confidence interval ranging from 0.6089 to 1.8911. The p-value of 0.0002, obtained from the unpaired t-test, indicates a statistically significant difference in the time of onset of sensory block between the two groups, favoring the Bupivacaine group for a quicker onset. [Table 2]

Table 1: Comparison of Baseline Demographic and Clinical Characteristics between Group Ropivacaine (Ro) and Group Bupivacaine (Bu)

Parameters	Group Ro (n = 50)	Group Bu (n=50)	P-value
Age in Years, Mean ± SD	28.56 ± 4.89	28.72 ± 5.03	0.872209*
Gestational Age in Weeks,	37.94 ± 2.17	38.04 ± 2.25	0.821511*
BMI in kg/m^2,	23.34 ± 2.61	23.08 ± 2.23	0.593488*
Duration of Surgery,	63.80 ± 12.05	67.47 ± 10.62	0.109381*
ASA Status			>0.99**
ASA I	23	24	
ASA II	27	26	

*Unpaired t-test **Fisher's Exact Test

Table 2: Comparison of Time of Onset of Sensory Block (upto T4) between Group Ropivacaine (Ro) and Group Bupivacaine (Bu)

	Group R	Group B
Number of Patients (N)	50	50
Time to Onset of Sensory Block in Minutes	14.45	13.2
Standard Deviation (SD)	1.58	1.65
Difference in Mean	1.25	
95% CI of Mean Difference	0.6089 to 1.8911	
P-Value (Unpaired t test)	0.0002	

Table 3: Comparison of Time to Complete Motor Block between Group Ropivacaine (Ro) and Group Bupivacaine (Bu)

	Group R	Group B
Number of Patients (N)	50	50
Complete Motor Block in Minutes	14.25	11.58
Standard Deviation (SD)	3.75	3.72
Difference in Mean	2.67	
95% CI of Mean Difference	1.1876 to 4.1524	
P-Value (Unpaired t test)	0.0005	

Table 4: Comparison of Complications between Group Ropivacaine (Ro) and Group Bupivacaine (Bu)

Complications	Group R (N = 50)	Group B (N = 50)	P-Value (Fisher's Exact test)
Hypotension	5 (10.00%)	12 (24.00%)	0.04
Bradycardia	4 (8.00%)	6 (12.00%)	0.35
Respiratory Depression	0 (0.00%)	0 (0.00%)	NA

The complete motor block was achieved in 14.25 minutes for the Ro group and 11.58 minutes for the Bu group. The mean difference in time to complete motor block between the two groups was 2.67 minutes, with a 95% confidence interval ranging from 1.1876 to 4.1524. The p-value of 0.0005, derived from the unpaired t-test, indicates a statistically significant difference in the time to complete motor block between the two groups, with the Bupivacaine group achieving a quicker block. [Table 3]

In terms of hypotension, 10.00% (5 patients) in the Ro group and 24.00% (12 patients) in the Bu group experienced this complication, with a p-value of 0.04, indicating a statistically significant difference favouring the Ro group. For

bradycardia, 8.00% (4 patients) in the Ro group and 12.00% (6 patients) in the Bu group were affected, with a p-value of 0.35, showing no significant difference between the groups. There were no cases of respiratory depression in either group. Overall, the data suggests that the Ro group had fewer complications related to hypotension compared to the Bu group.

Initially, Group Bu starts with a higher mean heart rate compared to Group Ro. Throughout the 90 minutes, Group Bu's heart rate shows fluctuations but generally stays higher than Group Ro's heart rate, which remains relatively stable with slight increases. [Figure 1]

Figure 1: Comparison of Heart Rate

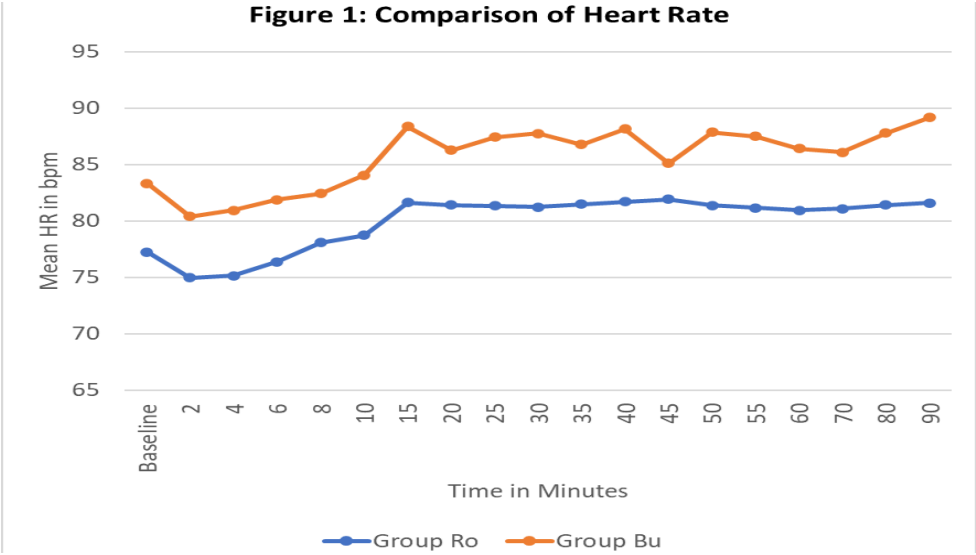
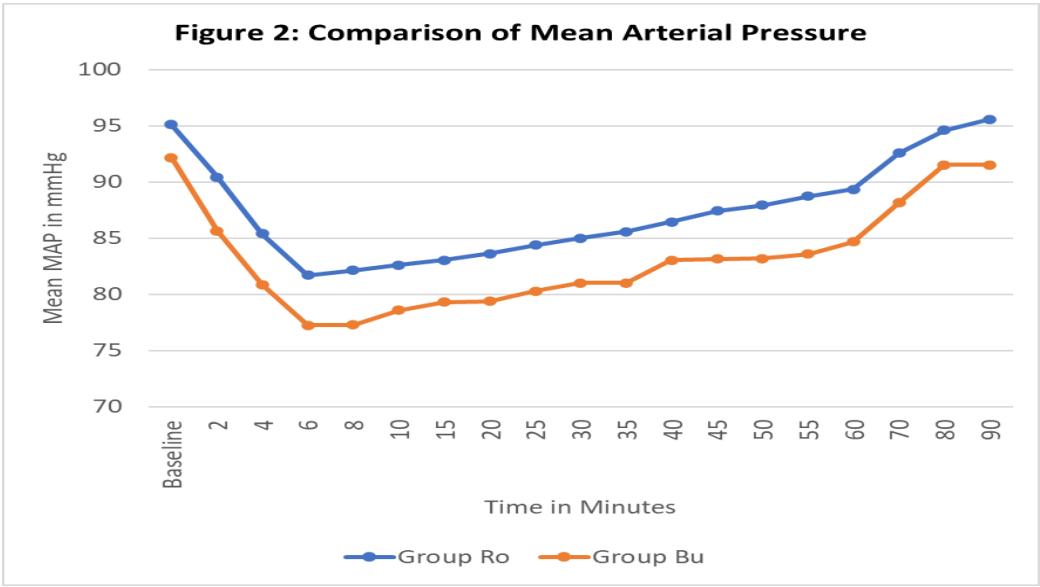


Figure 2: Comparison of Mean Arterial Pressure



Within the first 10 minutes, both groups experience a decrease in MAP, with Group Bu showing a more significant drop. Following this, both groups' MAPs begin to stabilize and gradually increase. Throughout the 90 minutes, Group Ro consistently maintains a higher MAP compared to Group Bu.

DISCUSSION

Our study comparing the efficacy and safety of Ropivacaine (Ro) and Bupivacaine (Bu) for achieving sensory and motor blocks, as well as the incidence of complications, aligns with several findings in the existing literature. According to Kang et al. (2024), their systematic review and meta-analysis of epidural Ropivacaine versus Bupivacaine for cesarean sections found that Bupivacaine provided quicker onset times but was associated with higher complication rates, which is consistent with our findings.[14] Our study confirms that while Bupivacaine achieves sensory and motor blocks faster, it also shows a higher incidence of hypotension.

The findings of this study can be critically examined through the lens of pharmacodynamics and pharmacokinetics of Ropivacaine and Bupivacaine. Ropivacaine, being a relatively newer local anaesthetic, is known for its reduced cardiotoxicity and better sensory-motor differentiation compared to Bupivacaine. The quicker onset of sensory and motor blocks observed with Bupivacaine could be attributed to its higher lipid solubility and faster diffusion

through nerve membranes. However, this same property might also contribute to its higher incidence of hypotension, as rapid absorption into systemic circulation can affect cardiovascular stability more profoundly. Ropivacaine, with its slower onset, provides a more gradual absorption, allowing the body to maintain hemodynamic stability better, thus explaining the fewer incidences of hypotension and better-maintained arterial pressures. [12, 13]

Moreover, the molecular structure of Ropivacaine, being a pure enantiomer, is designed to minimize central nervous system and cardiovascular toxicity, which likely contributes to the observed lower rates of adverse events in the study. Bupivacaine, despite its effective anaesthetic properties, poses a higher risk due to its racemic mixture, which includes both active and potentially more toxic enantiomers. This difference in molecular composition also aligns with the literature findings, where Ropivacaine consistently shows better safety profiles. Thus, the scientific rationale behind these findings hinges on the intrinsic pharmacological differences between these two local anaesthetics, underscoring Ropivacaine's edge in safety without significantly compromising efficacy.[14]

Amingad et al. (2024) conducted a double-blind study comparing 0.75% heavy Ropivacaine with 0.5% heavy Bupivacaine in cesarean sections and concluded that Bupivacaine had a faster onset of action. This aligns with our data showing shorter times to complete motor and sensory block in the Bu group. However, they did not report a significant difference in complication rates, whereas our study found a higher incidence of hypotension in the Bu group, suggesting a potential area for further research.[15]

Similarly, Hashemian et al. (2024) explored the effects of spinal-induced hypotension in preeclampsia patients and found Ropivacaine to be associated with better hemodynamic stability. This is corroborated by our findings that Ropivacaine resulted in fewer hypotensive episodes compared to Bupivacaine, reinforcing the idea that Ropivacaine may offer a safer profile in terms of hemodynamic stability.[16]

Patil et al. (2023) compared isobaric forms of Ropivacaine and Bupivacaine in lower abdominal surgeries and noted that while both agents were effective, Bupivacaine had a faster onset of action but also a higher incidence of adverse events. Our results align closely with these findings, showing a significant difference in the speed of onset of motor and sensory blocks favoring Bupivacaine, alongside a higher rate of hypotension.[17]

HABIBZADEH et al. (2022) compared intrathecal Bupivacaine and Ropivacaine regarding hemodynamic stability during elective cesarean sections. Their study reported that patients receiving Ropivacaine had fewer hemodynamic fluctuations, which is consistent with our observation of better-maintained mean arterial pressure in the Ro group. This further supports the utility of Ropivacaine in maintaining stable hemodynamic parameters.[18]

Anant et al. (2022) evaluated the hemodynamic effects of regional Ropivacaine versus Bupivacaine in infra-umbilical surgeries. They found that Ropivacaine offered comparable efficacy with fewer hemodynamic disturbances, mirroring our results where Ropivacaine showed a lower incidence of hypotension and more stable mean arterial pressures compared to Bupivacaine.[19]

Olapour et al. (2020) compared the effects of Bupivacaine and Ropivacaine in cesarean deliveries with spinal anesthesia and found similar patterns in onset times and hemodynamic stability. Our study adds to this body of evidence by providing detailed statistical analysis, confirming that while Bupivacaine's onset is quicker, Ropivacaine offers safer hemodynamic profiles, making it a preferred choice for patients with higher risks of hypotension.[20]

Kumar et al. (2020) and Wang et al. (2019) also highlighted the benefits of Ropivacaine in maintaining hemodynamic stability during infra-umbilical surgeries and cesarean sections, respectively. These studies, along with ours, suggest a consistent trend where Ropivacaine provides a balance between efficacy and safety, particularly in terms of hemodynamic parameters, despite Bupivacaine's faster onset of action.[21, 22]

Overall, our study supports the findings of previous research, demonstrating that while Bupivacaine achieves a faster sensory and motor block onset, Ropivacaine provides a more stable hemodynamic profile and fewer complications, making it a safer alternative in specific clinical scenarios. Further research could focus on optimizing dosing strategies to balance these benefits effectively.

CONCLUSION

The onset of sensory block was significantly quicker in the Bupivacaine group compared to the Ropivacaine group. Similarly, the time to complete motor block was also faster in the Bupivacaine group. Regarding complications, the Ropivacaine group exhibited fewer incidences of hypotension compared to the Bupivacaine group. The figures further supported these findings by illustrating a higher mean arterial pressure in the Ro group throughout the observation period, potentially indicating better hemodynamic stability. Overall, Bupivacaine demonstrated faster sensory and motor block onset, while Ropivacaine showed a lower incidence of certain complications and better-maintained arterial pressure, suggesting a nuanced balance between efficacy and safety for these anaesthetic agents.

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