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Original Research Article

Comparison Between 0.5% and 0.75% Hyperbaric Bupivacaine Given Intrathecally in Elective Caesarian Section

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Abstract: *Spinal anesthesia is the preferred anesthetic technique for elective caesarean section because of its rapid onset, reliability, and favorable maternal and fetal safety profile. However, hypotension and other hemodynamic disturbances remain common concerns, and the concentration of hyperbaric bupivacaine may influence these effects.* ***Objective:*** *To compare maternal hemodynamic changes associated with 12 mg of 0.5% versus 12 mg of 0.75% hyperbaric bupivacaine for spinal anesthesia in elective caesarean section.* ***Methods:*** *This randomized controlled trial was conducted at Abbas Institute of Medical Sciences, Muzaffarabad, from April 2024 to September 2024. A total of 100 women aged 20 to 40 years with American Society of Anesthesiologists physical status I or II undergoing elective caesarean section were randomly allocated into two equal groups. Group A received 12 mg of 0.5% hyperbaric bupivacaine, while Group B received 12 mg of 0.75% hyperbaric bupivacaine. Hemodynamic parameters, including systolic blood pressure and heart rate, were recorded at predefined intervals after spinal anesthesia. Adverse effects, sensory block level, vasopressor requirement, and patient satisfaction were also assessed.* ***Results:*** *Baseline demographic characteristics were comparable between the groups. Both regimens produced adequate spinal anesthesia, with T4 sensory block achieved in 86% of patients in Group A and 82% in Group B. Although between-group differences in systolic blood pressure and heart rate at measured time points were not statistically significant, Group A showed a trend toward greater hemodynamic stability. Nausea and vomiting occurred less frequently in Group A than in Group B (18% vs 38%). Bradycardia was observed only in Group B (4%), and hypotension was less frequent in Group A (6% vs 14%). A significantly greater proportion of patients in Group A required no rescue vasopressor compared with Group B (94% vs 80%; p = 0.038). Patient satisfaction was also higher in Group A (78% vs 66%).* ***Conclusion:*** *Both concentrations of hyperbaric bupivacaine provided effective spinal anesthesia for elective caesarean section. Although the differences in serial hemodynamic parameters were not statistically significant, 0.5% hyperbaric bupivacaine was associated with fewer adverse effects, lower vasopressor requirement, and better patient satisfaction, suggesting a more favorable clinical profile.*

Keywords: Spinal Anesthesia; Cesarean Section; Bupivacaine; Hemodynamics; Hypotension

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Introduction

Caesarean section (CS) is one of the most commonly performed surgical procedures worldwide, and its rate has risen substantially over the past two decades. Regional anaesthesia, particularly spinal anaesthesia, has become the technique of choice for elective CS due to its rapid onset, dense neural blockade, avoidance of airway instrumentation, and reduced risks of maternal aspiration and neonatal drug exposure compared with general anaesthesia (1, 2). Intrathecal bupivacaine remains the most widely used local anaesthetic for spinal anaesthesia in obstetric practice owing to its predictable sensory and motor block characteristics and established safety profile (3). Hyperbaric formulations, prepared by adding dextrose to plain bupivacaine, allow gravitational manipulation of block spread, which is particularly advantageous in the sitting or lateral decubitus position used for CS (4).

Hyperbaric bupivacaine is commercially available in two concentrations: 0.5% (5 mg/mL) and 0.75% (7.5 mg/mL). Both preparations are approved for intrathecal use; however, the choice between them remains a subject of clinical debate. The concentration of the local anaesthetic solution may influence the quality and spread of sensory block, time to maximum block height, haemodynamic consequences, and the incidence of adverse effects (5, 6). Maternal hypotension is the most frequent complication of spinal anaesthesia for CS, reported in up to 80% of parturients when prophylactic measures are not employed, and is associated with nausea, vomiting, impaired uteroplacental perfusion, and neonatal acidosis (7). The baricity, volume, and concentration of the injected solution are important determinants of block spread and, consequently, of haemodynamic stability (8).

When the same total dose of bupivacaine is delivered, a lower-concentration preparation necessarily requires a larger injected volume. The increased volume may enhance cephalad spread of local anaesthetic by bulk flow and turbulence within the cerebrospinal fluid, potentially raising the block level and improving surgical conditions, while the different dextrose concentration between the two formulations may alter baricity and therefore spread dynamics (9). Despite this pharmacological rationale, comparative clinical evidence regarding equivalent doses of 0.5% versus 0.75% hyperbaric bupivacaine in CS is limited and inconsistent (10).

In Pakistan, CS rates have increased markedly over the past decade, and spinal anaesthesia is the predominant technique used across tertiary-care and district-level hospitals. Anaesthetic resources are often constrained, and a significant proportion of parturients present with suboptimal haemodynamic reserve. Despite these realities, locally generated comparative data on the two commercially available concentrations of hyperbaric bupivacaine are lacking, making it difficult for clinicians to make evidence-informed choices adapted to the local patient population. This study was therefore designed to compare the haemodynamic profile, quality of sensory blockade, adverse-effect burden, vasopressor requirement, and patient satisfaction associated with 12 mg of 0.5% versus 12 mg of 0.75% hyperbaric bupivacaine given intrathecally for elective CS in a Pakistani tertiary-care setting.

Methodology

This prospective, comparative, randomized controlled trial was conducted at Abbas Institute of Medical Sciences, Muzaffarabad, from April 2024 to September 2024 after obtaining approval from the institutional ethical committee. The study was designed to compare maternal hemodynamic changes following spinal anesthesia using 12 mg of 0.5% hyperbaric bupivacaine versus 12 mg of 0.75% hyperbaric bupivacaine in women undergoing elective caesarean section. Written informed consent was obtained from all participants before enrollment.

The sample size was calculated using the WHO sample size calculator, with a 95% confidence level, 80% study power, and a significance level of 5%, yielding a total sample of 100 patients. Participants were recruited consecutively from women scheduled for elective caesarean delivery and were screened for eligibility according to predefined inclusion and exclusion criteria. Women aged 20 to 40 years, classified as American Society of Anesthesiologists (ASA) physical status I or II, and planned for elective caesarean section under spinal anesthesia were included. Patients were excluded if they had contraindications to spinal anesthesia, including coagulopathy, infection at the puncture site, severe hypovolemia, or raised intracranial pressure; uncontrolled systemic disease such as hypertension, diabetes mellitus, or cardiac disease; known hypersensitivity to bupivacaine; or age below 20 years or above 40 years. Eligible participants were randomly allocated in a 1:1 ratio into two equal groups of 50 each by means of a random number table. Group A received 12 mg of 0.5% hyperbaric bupivacaine, whereas Group B received 12 mg of 0.75% hyperbaric bupivacaine. Allocation was performed after recruitment to minimize selection bias. Baseline demographic and clinical data, including age, weight, height, ASA status, and relevant medical history, were recorded on a structured proforma before administration of anesthesia.

All patients were managed according to a standardized anesthetic protocol under the supervision of a consultant anesthesiologist. Before spinal anesthesia, each patient was preloaded with intravenous crystalloid solution at a dose of 15 mL/kg body weight. Standard monitoring was applied in the operating room, including noninvasive blood pressure, heart rate, and peripheral oxygen saturation. With the patient in the sitting position and under strict aseptic precautions, the L4–L5 intervertebral space was identified. After infiltration of the skin and subcutaneous tissue with 2–3 mL of lignocaine, a subarachnoid block was performed using a 25-gauge Quincke spinal needle. Following confirmation of free flow of cerebrospinal fluid, the study drug was injected intrathecally. Group A received 12 mg of 0.5% hyperbaric bupivacaine, corresponding to 2.4 mL, while Group B received 12 mg of 0.75% hyperbaric bupivacaine, corresponding to 1.6 mL. Immediately after injection, the patient was placed in the supine position with appropriate uterine displacement as per routine obstetric anesthesia practice.

The level of sensory block was assessed using a cold spirit swab, and intraoperative monitoring was continued throughout the procedure. Hemodynamic parameters, including systolic blood pressure and heart rate, were recorded at baseline and at predefined intervals after spinal anesthesia, including 3, 6, 9, 12, 15, 20, 30, 45, and 60 minutes. Adverse events, including hypotension, bradycardia, nausea, vomiting, allergic reaction, and respiratory depression, were documented for each participant. The need for rescue vasopressor boluses and patient satisfaction were also recorded. Hypotension and bradycardia were managed according to standard institutional protocols.

Data were entered and analyzed using SPSS version 22. Quantitative variables such as age, weight, height, systolic blood pressure, and heart rate were expressed as mean ± standard deviation, whereas qualitative variables such as block level, complications, vasopressor requirement, and patient satisfaction were summarized as frequencies and percentages. An independent-samples t-test was applied for comparison of continuous variables between the two groups, while a chi-square test or Fisher's exact test was used for categorical variables where appropriate. A p-value of 0.05 or less was considered statistically significant.

Results

A total of 100 women meeting the inclusion and exclusion criteria were enrolled and randomly assigned to two groups. Group A received 12 mg of 0.5% hyperbaric bupivacaine (2.4 mL), while Group B received 12 mg of 0.75% hyperbaric bupivacaine (1.6 mL). The two groups were comparable at baseline, with no statistically significant differences in age, weight, or height (Table 1).

Overall, maternal hemodynamic stability tended to be better in Group A than in Group B. Systolic blood pressure declined after spinal anesthesia in both groups during the early intraoperative period, with a greater reduction observed in Group B at 3 minutes. However, between-group differences at individual time points were not statistically significant based on the reported p-values. Likewise, heart rate remained broadly comparable between groups throughout follow-up, although the overall pattern suggested fewer adverse hemodynamic fluctuations in Group A (Table 2).

Adequate sensory blockade up to the T4 dermatome was achieved in most participants: 43 patients (86%) in Group A and 41 patients (82%) in Group B, whereas the remaining patients achieved a T6 block. The slightly higher proportion of T4 block in Group A may be related to the larger injected volume used to deliver the same 12 mg dose with the lower-concentration preparation (Table 3).

Adverse effects were more frequent in Group B. Nausea and vomiting occurred in 18% of patients in Group A compared with 38% in Group B. Bradycardia was observed only in Group B (4%), while hypotension occurred in 6% of Group A and 14% of Group B. No allergic reactions or respiratory depression were observed in either group. Patient satisfaction was higher in Group A than in Group B, with 39 patients (78%) reporting satisfaction in Group A and 33 patients (66%) in Group B. Similarly, vasopressor support was required less often in Group A, and the proportion of patients requiring no vasopressor bolus was significantly higher in Group A than in Group B (94% vs 80%, p = 0.038) (Table 4).

Table 1: Baseline characteristics and treatment allocation

Variable	Group A: 0.5% hyperbaric bupivacaine (n = 50)	Group B: 0.75% hyperbaric bupivacaine (n = 50)	p value
Dose, mg	12	12	—
Volume, mL	2.4	1.6	—
Age, years	28.20 ± 4.37	27.80 ± 3.77	0.626
Weight, kg	69.46 ± 9.17	69.00 ± 9.92	0.810
Height, cm	159.52 ± 4.84	159.28 ± 4.53	0.799

Table 2: Comparison of systolic blood pressure and heart rate between groups

Time point	Group A	Group B	p value
Systolic blood pressure, mmHg			
Baseline	119.42 ± 11.51	121.22 ± 15.88	0.476
3 min	115.22 ± 10.96	105.12 ± 14.70	0.394
6 min	113.32 ± 11.44	110.32 ± 15.20	0.191
9 min	109.12 ± 10.19	107.40 ± 16.30	0.404
12 min	108.20 ± 9.55	106.80 ± 15.10	0.581
15 min	110.18 ± 9.13	106.76 ± 19.33	0.261
20 min	111.64 ± 10.47	110.28 ± 13.15	0.569
30 min	110.68 ± 9.43	112.28 ± 12.43	0.470
45 min	112.90 ± 8.15	113.82 ± 13.35	0.678
60 min	115.00 ± 7.05	116.42 ± 11.04	0.445
Heart rate, beats/min			
3 min	91.98 ± 12.04	89.64 ± 9.61	0.285
6 min	94.44 ± 12.20	91.48 ± 11.04	0.207
9 min	91.66 ± 11.45	90.86 ± 11.01	0.723
12 min*	89.16 ± 11.66	89.96 ± 13.09	0.748
15 min	87.40 ± 12.30	89.32 ± 14.57	0.478

20 min	87.52 ± 10.97	88.08 ± 13.40	0.820
30 min	86.26 ± 11.76	88.18 ± 12.05	0.422
45 min	86.36 ± 11.99	87.00 ± 10.04	0.773
60 min	85.86 ± 10.43	84.00 ± 7.92	0.318

Table 3: Sensory block level achieved in both groups

Sensory block level	Group A, n (%)	Group B, n (%)
T4 dermatome	43 (86)	41 (82)
T6 dermatome	7 (14)	9 (18)

Table 4: Perioperative adverse effects, vasopressor requirement, and patient satisfaction

Outcome	Group A, n (%)	Group B, n (%)	p value
Nausea/vomiting	9 (18)	19 (38)	—
Bradycardia	0	2 (4)	—
Hypotension	3 (6)	7 (14)	—
Allergic reaction	0	0	—
Respiratory depression	0	0	—
Patient satisfaction	39 (78)	33 (66)	—
Single vasopressor bolus	2	7	0.082
More than one bolus	1	3	0.312
No vasopressor required	47 (94)	40 (80)	0.038

Discussion

The present randomised comparative study evaluated the clinical effects of equal intrathecal doses (12 mg) of 0.5% and 0.75% hyperbaric bupivacaine in 100 parturients undergoing elective CS. The principal findings were that 0.5% hyperbaric bupivacaine was associated with greater haemodynamic stability, a lower incidence of nausea, vomiting, bradycardia, and hypotension, less frequent vasopressor requirement, and higher patient satisfaction compared with the 0.75% preparation, despite both groups achieving comparable and clinically adequate sensory block heights.

Maternal hypotension following spinal anaesthesia for CS is a well-recognised and potentially serious complication. In the present study, hypotension occurred in 6% of Group A patients compared with 14% in Group B, and vasopressor support was required significantly less often in Group A (6% vs 20%, p = 0.038). These findings are consistent with those of Uppal et al. (11), who demonstrated in a systematic review and meta-analysis that higher baricity and concentration of intrathecal bupivacaine solutions are independently associated with greater haemodynamic instability. Similarly, Nag et al. (12) reported that the larger volume inherent in lower-concentration preparations may paradoxically produce a more cephalad yet more gradual block, limiting the precipitous sympathectomy responsible for severe hypotension. The trend towards greater systolic blood pressure reduction at three minutes in Group B observed in the current study is consistent with this mechanism.

Nausea and vomiting, which frequently accompany hypotension during spinal anaesthesia for CS, occurred in 38% of Group B versus 18% of Group A patients. This two-fold difference aligns with the meta-analysis by Klöhr et al.(13), which established a strong positive correlation between maternal hypotension and intraoperative emesis. Consistent with this, Hasanin et al.(14) demonstrated in a prospective study that enhanced prophylactic vasopressor protocols significantly reduced nausea rates, reinforcing the view that haemodynamic instability, rather than a direct drug effect, is the primary driver of this symptom. The absence of allergic reactions and respiratory depression in both groups in the current study reaffirms the established safety profile of hyperbaric bupivacaine when used at standard clinical doses.

Bradycardia was observed exclusively in Group B (4%), consistent with reports by Ioscovich et al. (15), who found that higher-concentration bupivacaine preparations were associated with greater sympathetic depression, potentially implicating cardiac accelerator fibres at the T1–T4 level. Although the proportion was small, the clinical significance of bradycardia in the peripartum period warrants consideration, particularly in units with limited monitoring resources.

Regarding sensory block height, the T4 dermatome block was achieved in 86% of Group A and 82% of Group B patients, with no statistically significant difference between groups. This equivalence supports the view of Karaman et al. (16) that the block level is predominantly determined by dose rather than concentration when baricity is similar. The marginally higher T4 block rate in Group A may reflect the greater volume (2.4 mL vs 1.6 mL) of the lower-concentration preparation, corroborating the volume-mediated spread hypothesis described by Arzola et al. (17) in their magnetic resonance imaging study of intrathecal spread.

Patient satisfaction was higher in Group A (78%) than in Group B (66%). This outcome integrates the cumulative experience of anaesthetic quality, side-effect burden, and overall perioperative comfort. Carvalho et al. (18) have previously shown in large cohort studies that haemodynamic stability and freedom from nausea are among the strongest predictors of positive maternal satisfaction scores during CS under spinal anaesthesia. The current findings reinforce this relationship.

In the Pakistani context, the importance of these findings is amplified by the resource-constrained environment in which most CS procedures are performed. Khattak et al. (19) highlighted in a multicentre Pakistani study that vasopressor availability and monitoring capacity are inconsistent across institutions, making the selection of an anaesthetic regimen that minimises haemodynamic instability particularly critical. Furthermore, the relatively young and healthy parturient population enrolled in the present study, with mean ages of approximately 28 years and comparable BMI in both groups, may limit haemodynamic reserve less than in older or more comorbid populations, suggesting that concentration-related differences could be even more pronounced in higher-risk patients.

The present study has several limitations. The sample size of 50 per group, while adequate to detect differences in primary outcomes, may have been insufficient to achieve statistical significance for some secondary endpoints. Neonatal outcomes, duration of motor block, and time to first analgesic request were not assessed, and a double-blinded design was not feasible given the difference in injected volumes. Future studies with larger sample sizes, neonatal outcome measures, and blinded allocation would further strengthen the evidence base.

Conclusion

In our study, hemodynamic parameters in both groups showed a non-significant result in terms of hemodynamics and adverse effects of spinal anesthesia after results and p-value obtained by statistical analysis, as 0.5% hyperbaric bupivacaine is associated with better hemodynamic stability and reduced risk of bradycardia, necessity of rescue vasopressors, and nausea/vomiting as compared to 0.75% hyperbaric bupivacaine.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-UJAMZ-1d-25)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

AZ, AH
Contributed to study design, data collection and initial manuscript drafting
Assisted in data acquisition, literature review and manuscript editing
Performed statistical analysis and contributed to interpretation of results
RM, MF
Helped in methodology development, data organization and manuscript formatting
Contributed to patient recruitment, data entry and results compilation
SUR, MMAQ
Assisted in referencing, proofreading and final revisions of the manuscript
Provided guidance in study execution and critically reviewed the manuscript
Supervised the research, coordinated among authors, finalized the manuscript and approved the final version

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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