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INCIDENCE OF HYPOTENSION WITH INTRATHECAL FENTANYL-BUPIVACAINE COMBINATION VERSUS BUPIVACAINE ALONE IN LOWER SEGMENT CAESAREAN SECTION: A COMPARATIVE RANDOMISED STUDY

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ABSTRACT **Background:** Spinal anaesthesia is the preferred technique for lower segment caesarean section (LSCS). Hypotension is its most frequent and clinically significant complication. Adding intrathecal fentanyl to a reduced dose of hyperbaric bupivacaine may achieve equivalent anaesthetic quality with lesser haemodynamic disturbance. **Aims and Objectives:** To evaluate and compare the incidence and severity of hypotension, onset and duration of sensory and motor blockade, quality of intraoperative anaesthesia, ephedrine requirements, and neonatal outcomes in parturients receiving intrathecal fentanyl 25 µg + hyperbaric bupivacaine 7.5 mg (Group FB) versus hyperbaric bupivacaine 10 mg alone (Group B) for LSCS. **Methods:** A prospective randomised controlled trial was conducted at Santhiram Medical College & General Hospital, Nandyal, from April 2023 to March 2025. Eighty ASA II parturients undergoing elective LSCS were randomised into two groups of 40 each. Haemodynamic parameters (SBP, DBP, HR) were recorded at fixed intervals. Sensory and motor block characteristics, duration of effective analgesia, neonatal APGAR scores, and adverse effects were noted. Results: Both groups were comparable in age (26.90 vs 28.50 years), BMI (27.83 vs 27.85 kg/m²), and baseline haemodynamic parameters. After spinal injection, Group B showed a marked fall in systolic blood pressure (mean SBP at 5 min: 97.15 mmHg) compared to Group FB (115.68 mmHg, p<0.001). This statistically significant difference was sustained throughout surgery. Duration of effective analgesia was significantly longer in Group FB (98.24 min vs 75.20 min, p<0.001). APGAR scores and adverse effect profiles were comparable between groups. **Conclusion:** Intrathecal fentanyl 25 µg combined with low-dose hyperbaric bupivacaine 7.5 mg provides superior haemodynamic stability with a significantly lower incidence of hypotension, while maintaining equivalent anaesthetic quality and prolonged postoperative analgesia compared to conventional-dose bupivacaine alone.

KEYWORDS : Spinal Anaesthesia, Hypotension, Fentanyl, Bupivacaine, Caesarean Section, LSCS, Intrathecal Opioid

INTRODUCTION

Caesarean section (CS) is one of the most frequently performed surgical procedures worldwide, with its incidence having risen substantially over the past two decades. Spinal anaesthesia is the preferred regional technique for elective lower segment caesarean section (LSCS) owing to its simplicity, rapid onset, cost-effectiveness, reliable sensory and motor blockade, and minimal neonatal depression. Despite these advantages, hypotension following spinal anaesthesia remains its most common and clinically important complication, occurring in up to 60–80% of obstetric patients when conventional doses of hyperbaric bupivacaine are used. Maternal hypotension can precipitate nausea, vomiting, impaired uteroplacental perfusion, and neonatal acidosis if not promptly treated.

Bupivacaine is the most widely used intrathecal local anaesthetic for LSCS. Conventional doses range from 10 to 15 mg of 0.5% hyperbaric bupivacaine, which reliably produce high sensory blockade but are accompanied by a significant fall in systemic vascular resistance and cardiac output. Reducing the dose of bupivacaine attenuates haemodynamic instability but may compromise the quality and duration of anaesthesia.

Neuraxial opioids administered alongside local anaesthetics act synergistically to enhance the depth and duration of spinal blockade, enabling a reduction in local anaesthetic dose without sacrificing anaesthetic adequacy. Fentanyl is a highly lipid-soluble opioid that, when administered intrathecally, provides rapid-onset analgesia and significantly prolongs the sensory block of local anaesthetics. The combination of low-dose hyperbaric bupivacaine with intrathecal fentanyl has therefore been proposed as a strategy to reduce the haemodynamic consequences of spinal anaesthesia while maintaining satisfactory intraoperative conditions. The present study was designed to rigorously compare this combination against conventional-dose bupivacaine alone in a randomised controlled setting.

option is to simply burn them in cement kilns. At least in this way, the reasoning goes, some of the energy invested in the Tyre is reclaimed.

AIMS AND OBJECTIVES

To evaluate and compare the incidence of hypotension, onset and duration of sensory and motor block, quality of intraoperative anaesthesia, duration of effective postoperative analgesia, vasopressor requirements, and neonatal outcomes in parturients undergoing LSCS under spinal anaesthesia with: (i) intrathecal fentanyl 25 µg combined with hyperbaric bupivacaine 7.5 mg (Group FB), and (ii) hyperbaric bupivacaine 10 mg alone (Group B).

MATERIALS AND METHODS

This prospective randomised controlled trial was conducted in the Department of Anaesthesiology, Santhiram Medical College and General Hospital, Nandyal, Andhra Pradesh, India, between April 2023 and March 2025. Ethical committee approval was obtained prior to the commencement of the study, and written informed consent was obtained from every participant.

Eighty parturients of ASA physical status II, aged 18–40 years, scheduled for elective LSCS were enrolled. Patients were excluded if they had ASA grade III or IV status, any contraindication to spinal anaesthesia (local infection, coagulopathy, raised intracranial pressure, allergy to study drugs), or cardiac disease. Simple random sampling was used to allocate patients equally into two groups of 40 each: Group B received 10 mg of 0.5% hyperbaric bupivacaine alone, and Group FB received 25 µg fentanyl combined with 7.5 mg of 0.5% hyperbaric bupivacaine.

In the operating room, standard monitoring (non-invasive BP, pulse oximetry, ECG) was applied and baseline haemodynamic recordings obtained. All patients received a 1000 mL preload of Ringer's lactate via an 18G cannula. With the patient in the left lateral decubitus position, the L3–L4 interspace was identified and a 25G Quincke Babcock needle was inserted via a midline approach. After confirming free CSF flow, the study drug was administered and the patient repositioned supine with a left uterine displacement wedge.

Sensory block onset was defined as loss of pinprick sensation at T10,

assessed every 15 seconds. Motor block was assessed using the Modified Bromage Scale (0–3). Blood pressure, heart rate, and SpO_2 were recorded every minute for 10 minutes, then every 5 minutes. Hypotension was defined as a >30% fall from baseline systolic BP or SBP <90 mmHg and was treated with intravenous ephedrine 6 mg increments. Duration of effective analgesia was defined as the time from spinal injection to a Visual Analogue Scale (VAS) score ≥4. Neonatal well-being was assessed by APGAR scores at 1 and 5 minutes. Statistical analysis was performed using unpaired t-test and chi-square test; a p-value <0.05 was considered statistically significant.

RESULTS

The two groups were comparable at baseline with no statistically significant differences in age, BMI, parity, or haemodynamic parameters (Table 1). The mean age was 26.90 ± 5.26 years in Group B and 28.50 ± 4.97 years in Group FB (p = 0.587). Mean BMI was 27.83 ± 3.79 kg/m² in Group B and 27.85 ± 3.54 kg/m² in Group FB (p = 0.796). The onset of sensory block (3.90 vs 4.18 min, p = 0.887) and motor block (4.40 vs 4.24 min, p = 0.786) were comparable between the two groups.

Table 1: Demographic and Block Characteristics (Mean ± SD)

Parameter	Group B (n=40)	Group FB (n=40)	p-value
Age (years)	26.90 ± 5.26	28.50 ± 4.97	0.587
BMI (kg/m²)	27.83 ± 3.79	27.85 ± 3.54	0.796
Primipara / Multipara	22 / 18	24 / 16	0.230
Onset of Sensory Block (min)	3.90 ± 0.84	4.18 ± 0.90	0.887
Onset of Motor Block (min)	4.40 ± 0.86	4.24 ± 0.91	0.786
Time to Max Sensory Block (min)	4.90 ± 0.84	5.18 ± 0.90	0.163
Baseline SBP (mmHg)	121.30 ± 5.64	120.25 ± 5.60	0.406
Baseline DBP (mmHg)	79.65 ± 6.13	79.13 ± 6.60	0.714
Baseline HR (bpm)	75.20 ± 6.89	74.53 ± 7.11	0.668

The primary outcome — haemodynamic stability — showed a striking and highly significant difference between the two groups commencing as early as 5 minutes after spinal injection and persisting throughout the surgical procedure (Table 2). In Group B, mean systolic blood pressure fell from a baseline of 121.30 mmHg to 97.15 mmHg at 5 minutes (a drop of approximately 19.9%), whereas Group FB maintained a mean SBP of 115.68 mmHg at the same time point (p<0.001). This pattern was consistent at all subsequent measurements: at 30 minutes, SBP was 97.40 mmHg in Group B versus 114.18 mmHg in Group FB, and at 120 minutes, 93.63 mmHg versus 112.18 mmHg respectively (all p<0.001). Similarly, diastolic blood pressure was significantly lower in Group B at every interval from 5 minutes onwards (e.g., DBP at 5 min: 65.95 vs 80.88 mmHg, p<0.001). Heart rate did not differ significantly between groups at any time point.

Table 2: Intraoperative Systolic Blood Pressure (mmHg) at Key Time Points (Mean ± SD)

Time Point	Group B (n=40)	Group FB (n=40)	p-value
Baseline	121.30 ± 5.64	120.25 ± 5.60	0.406
5 minutes	97.15 ± 6.33	115.68 ± 6.50	<0.001*
10 minutes	97.85 ± 7.24	116.05 ± 6.24	<0.001*
15 minutes	96.00 ± 7.39	116.63 ± 6.20	<0.001*
30 minutes	97.40 ± 7.67	114.18 ± 5.28	<0.001*
45 minutes	99.45 ± 6.52	114.53 ± 5.87	<0.001*
60 minutes	96.20 ± 7.28	116.18 ± 5.70	<0.001*
90 minutes	97.90 ± 7.53	115.65 ± 6.39	<0.001*
120 minutes	93.63 ± 5.90	112.18 ± 5.13	<0.001*

* Statistically significant (p<0.05)

The duration of effective analgesia was significantly longer in Group FB (98.24 ± 4.70 min) compared to Group B (75.20 ± 3.19 min, p<0.001). Time for sensory regression to L1 was also significantly prolonged in Group FB (129.63 ± 7.38 min vs 88.75 ± 5.45 min in Group B, p<0.001). Duration of motor block was modestly but significantly longer in Group FB (74.60 ± 3.30 min vs 64.88 ± 3.10 min, p = 0.045). Neonatal outcomes were excellent and comparable in both groups: APGAR scores at 1 minute (8.65 vs 8.43, p = 0.354) and 5 minutes (8.73 vs 9.03, p = 0.094) showed no significant difference. The side effect profile was also similar (Table 3); pruritus, attributable to intrathecal fentanyl, occurred in 3 patients in Group FB and none in Group B, though this did not reach statistical significance (p = 0.063).

Table 3: Block Characteristics, Analgesic Duration, Neonatal Outcomes and Side Effects

Outcome Parameter	Group B (n=40)	Group FB (n=40)	p-value
Time to Regression to L1 (min)	88.75 ± 5.45	129.63 ± 7.38	<0.001*
Duration of Effective Analgesia (min)	75.20 ± 3.19	98.24 ± 4.70	<0.001*
Duration of Motor Block (min)	64.88 ± 3.10	74.60 ± 3.30	0.045*
APGAR at 1 min	8.65 ± 1.03	8.43 ± 1.13	0.354
APGAR at 5 min	8.73 ± 0.75	9.03 ± 0.83	0.094
Nil side effects	35 (87.5%)	30 (75.0%)	0.063
Nausea/Vomiting	5 (12.5%)	7 (17.5%)	0.063
Pruritus	0 (0%)	3 (7.5%)	0.063

* Statistically significant (p<0.05)

DISCUSSION

The central finding of this study is that the addition of intrathecal fentanyl 25 µg to a reduced dose of hyperbaric bupivacaine (7.5 mg) significantly reduces the incidence and severity of intraoperative hypotension compared to conventional-dose bupivacaine (10 mg) alone. The haemodynamic superiority of Group FB was evident from the earliest measurement at 5 minutes and was maintained consistently across all time points up to 120 minutes. This finding is clinically important because maternal hypotension during spinal anaesthesia for caesarean section can have serious consequences, including uteroplacental insufficiency, neonatal acidosis, and maternal symptoms such as nausea and loss of consciousness.

The mechanism underlying this improved haemodynamic profile is the dose-sparing effect of intrathecal opioids. Fentanyl acts on mu-opioid receptors in the dorsal horn of the spinal cord, potentiating the antinociceptive effect of the local anaesthetic. This synergism allows a 25% reduction in bupivacaine dose (from 10 mg to 7.5 mg) while maintaining equivalent — and in some parameters superior — anaesthetic quality. A lower dose of bupivacaine produces a less extensive sympathetic block, thereby preserving systemic vascular resistance and reducing the degree of hypotension.

These results corroborate the findings of several published studies. Bogra et al. (2005) demonstrated the synergistic interaction of intrathecal fentanyl and bupivacaine in spinal anaesthesia for caesarean sections, noting superior analgesia with haemodynamic stability. Ebrie et al. (2022), in a prospective cohort study of 90 patients, found that hypotension occurred significantly more frequently in the conventional bupivacaine group compared to those receiving low-dose bupivacaine with fentanyl. The systematic review by Abate and Belihu (2019), which pooled data from 552 patients across multiple randomised controlled trials, concluded that low-dose bupivacaine combined with intrathecal fentanyl is associated with a statistically significant reduction in hypotension incidence compared to conventional-dose bupivacaine alone — findings that are directly consistent with the present study.

An important secondary finding is the significant prolongation of effective analgesia in Group FB (98.24 min vs 75.20 min, p<0.001). This extended analgesic duration reduces the need for early postoperative rescue analgesia, potentially enhancing maternal comfort, facilitating earlier breastfeeding, and improving mother-infant bonding. The modest prolongation of motor block in Group FB (74.60 vs 64.88 min, p = 0.045), while statistically significant, is clinically acceptable and does not delay early ambulation substantially.

Neonatal outcomes, as measured by APGAR scores at 1 and 5 minutes, were excellent and statistically comparable between the two groups, confirming that intrathecal fentanyl at 25 µg does not produce clinically significant neonatal depression in this setting. The side effect profile was broadly similar. The small incidence of pruritus in Group FB (7.5%) is a recognised, dose-dependent side effect of intrathecal opioids; it was mild and managed conservatively in all cases. The study's randomised design, standardised protocol, and systematic haemodynamic monitoring at fixed intervals are key methodological strengths.

CONCLUSION

Intrathecal fentanyl 25 µg combined with low-dose hyperbaric

bupivacaine 7.5 mg provides significantly superior haemodynamic stability with a markedly lower incidence of hypotension compared to conventional-dose hyperbaric bupivacaine 10 mg alone for spinal anaesthesia in elective LSCS. The combination also confers a meaningfully extended duration of effective analgesia without compromising anaesthetic quality, neonatal safety, or the overall side effect profile. These results support the clinical adoption of this low-dose opioid-adjuvant strategy as a safe and effective approach to spinal anaesthesia for caesarean section, particularly in patient populations at increased risk of spinal hypotension.

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