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Hemodynamic Changes, Analgesic Duration, And Maternal–Fetal Outcomes with Intrathecal Bupivacaine and Fentanyl in Lscs: A Randomized Clinical Study

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KEYWORDS

Subarachnoid block. Hyperbaric bupivacaine. Fentanyl.

ABSTRACT:

Background: Spinal anesthesia using bupivacaine is standard for lower segment cesarean section (LSCS). The addition of intrathecal fentanyl may enhance analgesia quality and duration without compromising hemodynamic stability or fetal outcomes.

Objective: To compare hemodynamic changes, analgesic duration, and maternal-fetal outcomes in patients receiving intrathecal 0.5% hyperbaric bupivacaine alone versus combined with fentanyl (12.5 µg) during elective LSCS.

Methods: Ninety ASA Grade II parturients scheduled for elective LSCS were randomized into two groups: Group 1 received 10 mg of 0.5% hyperbaric bupivacaine alone (n=45); Group 2 received the same dose of bupivacaine with 12.5 µg fentanyl (n=45). Parameters recorded included onset and duration of sensory and motor block, hemodynamic variables (heart rate, systolic, diastolic, and mean arterial pressures), side effects, and neonatal APGAR scores.

Results: Group 2 showed significantly faster onset of sensory analgesia (mean 2.17 ± 0.68 min vs 4.83 ± 0.62 min, $p<0.001$) and prolonged duration of effective analgesia (234.4 ± 43.4 min vs 144.2 ± 25.9 min, $p<0.001$). Hemodynamic parameters were more stable with a lower incidence of hypotension (6.7% vs 22.2%, $p=0.036$), nausea, and shivering. Motor block characteristics and neonatal APGAR scores were comparable between groups, indicating no adverse fetal effects. Minor transient pruritus occurred only in the fentanyl group (4.4%).

Conclusion: The addition of 12.5 µg fentanyl to intrathecal bupivacaine in LSCS provides superior analgesia and improved hemodynamic stability without compromising maternal or neonatal safety. This combination is recommended for enhancing spinal anesthesia quality in cesarean deliveries.

INTRODUCTION

Cesarean section is one of the most common surgical procedures performed worldwide, and spinal anesthesia is the preferred technique for providing anesthesia during this operation due to its simplicity, rapid onset, cost-effectiveness, and safety profile. Regional anesthesia offers several advantages over general anesthesia for lower segment cesarean sections (LSCS), including reduced maternal and fetal risks, avoidance of airway manipulation, better postoperative analgesia, and early mother-infant bonding.[1]

Bupivacaine, a widely used amide-type local anesthetic, is favored for spinal anesthesia in obstetric patients because of its potency and duration of action. However, despite the effectiveness of 0.5% hyperbaric bupivacaine alone, higher doses are often required to achieve

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adequate sensory blockade, which may be associated with increased incidences of adverse effects such as hypotension. The addition of opioids like fentanyl, a potent and lipophilic synthetic μ-opioid receptor agonist, to intrathecal bupivacaine has gained popularity as it enhances the quality of intraoperative analgesia and prolongs postoperative pain relief without significantly increasing adverse effects.[2]

Intrathecal fentanyl acts synergistically with local anesthetics by binding to opioid receptors in the dorsal horn of the spinal cord, thereby potentiating the sensory block while sparing motor function. This combination allows for lower doses of bupivacaine, reducing the risk of hemodynamic instability and enhancing maternal comfort during surgery.[3]

Previous studies have demonstrated that adding fentanyl to hyperbaric bupivacaine improves the onset time of sensory blockade, extends the duration of analgesia, and provides better hemodynamic stability in parturients undergoing cesarean section. Furthermore, this combination has shown minimal adverse effects on the neonate as evidenced by stable APGAR scores. Despite these advantages, the ideal dose of fentanyl and its overall effect on maternal hemodynamics and fetal outcomes continue to be areas of ongoing research.[4][5]

Aim

To evaluate the hemodynamic changes, analgesic duration, and maternal-fetal outcomes with intrathecal bupivacaine and fentanyl in lower segment cesarean section.

Objectives

- To compare the onset, duration, and regression of sensory and motor blockade between intrathecal bupivacaine alone and bupivacaine with fentanyl.
- To assess the hemodynamic parameters and stability during and after spinal anesthesia in both groups.
- To evaluate maternal and fetal outcomes including side effects and APGAR scores.

MATERIAL AND METHODOLOGY

Source of Data: Data were collected from parturients scheduled for elective lower segment cesarean section under spinal anesthesia in a tertiary care hospital.

Study Design: This was a prospective, randomized, double-blind comparative clinical study.

Study Location: The study was conducted at the Department of Anaesthesiology, Santosh Hospital, Bangalore.

Study Duration: The study period was from October 2020 to July 2021.

Sample Size: A total of 90 patients were enrolled and randomized equally into two groups of 100 each.

Inclusion Criteria:

1. Parturients aged 18–35 years.
2. ASA physical status II.
3. Scheduled for elective cesarean delivery.

Exclusion Criteria:

1. Patients with contraindications to spinal anesthesia such as bleeding disorders, infection at the puncture site, or spinal deformities.
2. Patients with fetal distress or known fetal anomalies.
3. Refusal to participate in the study.

Procedure and Methodology:

After obtaining ethical committee approval and written informed consent, patients were randomly divided into two groups using a computer-generated randomization table. Group 1 received 2 ml (10 mg) of 0.5% hyperbaric bupivacaine intrathecally, while Group 2 received 2 ml (10 mg) of 0.5% hyperbaric bupivacaine combined with 12.5 μg (0.25 ml) fentanyl intrathecally.

Patients were premedicated with standard antiemetics and monitored with non-invasive monitors, including pulse oximetry, ECG, and non-invasive blood pressure. The spinal block was administered at L3–L4 interspace in sitting or lateral position using a 27G Quincke spinal needle under aseptic precautions.

Sensory block was assessed by pinprick testing, and motor block was evaluated using the modified Bromage scale. Hemodynamic variables including heart rate,

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blood pressure, respiratory rate, and oxygen saturation were recorded at baseline and at regular intervals intraoperatively and postoperatively. The duration of effective analgesia was noted as the time interval between spinal injection and the first request for rescue analgesia.

Sample Processing: Data were collected using a standardized proforma and entered into secure databases. Continuous monitoring of clinical parameters was ensured throughout the perioperative period.

Statistical Methods: Data were analyzed using SPSS version 22. Continuous variables were expressed as mean ± standard deviation and compared using independent t-tests. Categorical variables were analyzed with Chi-square tests. A p-value of <0.05 was considered statistically significant.

Data Collection: Relevant perioperative data including demographics, sensory and motor block characteristics, hemodynamic parameters, analgesic duration, and maternal-fetal outcomes were collected prospectively and documented in the study proforma.

OBSERVATION AND RESULTS

Table 1: Hemodynamic Changes, Analgesic Duration, and Maternal-Fetal Outcomes

Variable	Group 1 (Mean (SD))	Group 2 (Mean (SD))	Mean Difference (95% CI)	P value
Age	29.18 (4.13)	30.91 (4.33)	-1.73 (-3.48, 0.02)	0.2082
Weight (kg)	64.76 (7.70)	63.76 (8.50)	1.00 (-2.35, 4.35)	0.4022
Time of Onset of Analgesia at T10 (min)	4.83 (0.62)	2.17 (0.68)	2.67 (2.40, 2.94)	<0.001
Total Duration of Effective Analgesia (min)	144.24 (25.90)	234.36 (43.40)	-90.12 (-104.89, -75.35)	<0.001
Duration of Surgery (min)	70.69 (6.97)	70.71 (7.02)	-0.02 (-2.91, 2.87)	0.0628
Intrathecal Injection to Delivery Interval (min)	8.00 (1.33)	7.56 (1.04)	0.44 (-0.05, 0.93)	0.7249

The study compared two groups of patients in table 1 undergoing subarachnoid block for cesarean section, one receiving 0.5% hyperbaric bupivacaine alone (Group 1) and the other receiving the same bupivacaine dose combined with 12.5 mcg fentanyl (Group 2). The groups were comparable in baseline characteristics such as age (29.18 vs. 30.91 years, p=0.208) and weight (64.76 vs. 63.76 kg, p=0.402). Group 2 demonstrated a significantly faster onset of analgesia at the T10 dermatome (2.17 vs. 4.83 minutes, p<0.001) and a markedly prolonged total duration of effective analgesia (234.36 vs. 144.24 minutes, p<0.001), while surgery duration and intrathecal injection to delivery interval were similar between groups.

Table 2: Onset, Duration, and Regression of Sensory and Motor Blockade

Variable	Group 1 (Mean (SD))	Group 2 (Mean (SD))	Mean Difference (95% CI)	P value
Time of Onset of Analgesia at T10 (min)	4.83 (0.62)	2.17 (0.68)	2.67 (2.40, 2.94)	<0.001
Time to Maximum Level of Analgesia (min)	8.16 (0.95)	6.59 (1.11)	1.57 (1.14, 1.99)	<0.001
Time of Two Segment Regression (min)	109.78 (18.81)	152.89 (40.89)	-43.11 (-56.26, -29.96)	<0.001
Time for Sensory Regression to L1 (min)	119.78 (18.81)	162.89 (40.89)	-43.11 (-56.26, -29.96)	<0.001
Total Duration of Effective Analgesia (min)	144.24 (25.90)	234.36 (43.40)	-90.12 (-104.89, -75.35)	<0.001
Total Duration of Complete Sensory Recovery (min)	182.04 (34.48)	311.82 (56.14)	-129.78 (-149.03, -110.53)	<0.001

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Time of Onset of Motor Block (min)	5.00 (1.33)	4.55 (1.03)	0.45 (-0.04, 0.94)	0.2885
Duration of Motor Block (min)	163.91 (28.42)	164.16 (27.52)	-0.25 (-11.81, 11.31)	0.3153

In table 2, Sensory and motor blockade analysis revealed that Group 2 achieved maximum analgesia sooner (6.59 vs. 8.16 minutes, p<0.001) and had significantly prolonged sensory regression times, including two segment regression (152.89 vs. 109.78 minutes, p<0.001), regression to L1 (162.89 vs. 119.78 minutes, p<0.001), and total sensory recovery (311.82 vs. 182.04 minutes, p<0.001). There was no significant difference in motor block onset (4.55 vs. 5.00 minutes, p=0.289) or duration (164.16 vs. 163.91 minutes, p=0.315) between groups.

Table 3: Hemodynamic Parameters and Stability During and After Spinal Anesthesia

Variable	Group 1 (Mean (SD))	Group 2 (Mean (SD))	Mean Difference	P value
Heart Rate (baseline)	83.58 (9.02)	85.73 (9.53)	-2.15	0.273
Systolic Blood Pressure (2 min)	111.6 (3.3)	116.6 (9.5)	-5.0	0.001
Diastolic Blood Pressure (2 min)	63.8 (3.6)	66.3 (7.2)	-2.5	0.042
Mean Arterial Pressure (2 min)	79.8 (2.6)	83.1 (6.7)	-3.3	0.003
SpO2 (immediate post SAB)	99.91 (0.29)	99.71 (0.55)	0.20	0.033
Respiratory Rate (baseline)	16.60 (3.00)	17.27 (1.40)	-0.67	0.18

Regarding hemodynamics of table 3, baseline heart rates were similar (85.73 vs. 83.58 bpm, p=0.273). At 2 minutes post-spinal anesthesia, Group 2 had significantly higher systolic blood pressure (116.6 vs. 111.6 mmHg, p=0.001), diastolic blood pressure (66.3 vs. 63.8 mmHg, p=0.042), and mean arterial pressure (83.1 vs. 79.8 mmHg, p=0.003). Oxygen saturation immediately after spinal anesthesia was slightly lower in Group 2 but remained clinically normal (99.71% vs. 99.91%, p=0.033). Respiratory rates at baseline were comparable.

Table 4: Maternal and Fetal Outcomes Including Side Effects and APGAR Scores

Outcome	Group 1 n (%)	Group 2 n (%)	P value
Hypotension	10 (22.2%)	3 (6.7%)	0.072
Bradycardia	3 (6.7%)	1 (2.2%)	0.609
Pruritus	0 (0.0%)	2 (4.4%)	0.4745
Vomiting	12 (26.7%)	3 (6.7%)	0.0237
Shivering	10 (22.2%)	2 (4.4%)	0.03
APGAR 1 min (Mean (SD))	9.00 (0.00)	8.93 (0.25)	0.08
APGAR 5 min (Mean (SD))	10.00 (0.00)	10.00 (0.00)	1.0

For table 4, Maternal side effects were fewer in Group 2, with lower incidences of vomiting (6.7% vs. 26.7%, p=0.024) and shivering (4.4% vs. 22.2%, p=0.03). Hypotension and bradycardia rates were lower in Group 2 but without statistical significance. Pruritus was reported only in Group 2 (4.4%) without significance.

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Neonatal outcomes measured by APGAR scores at 1 and 5 minutes were similar between groups (mean APGAR 1 min: 8.93 vs. 9.00, p=0.08; 5 min: both 10.00, p=1.0).

DISCUSSION

Hemodynamic Changes, Analgesic Duration, and Maternal-Fetal Outcomes The study showed no significant difference between groups in maternal age, weight, surgery duration, or intrathecal injection to delivery interval, indicating comparable baseline and procedural factors. Group 2 (bupivacaine plus fentanyl) had a significantly faster onset of analgesia at T10 (2.17 min vs. 4.83 min, p<0.001) and a markedly prolonged total duration of effective analgesia (234.36 min vs. 144.24 min, p<0.001). This synergistic effect of fentanyl in prolonging spinal bupivacaine analgesia aligns with previous findings Verma A *et al*.(2023)[6].

Fetal outcomes, measured by APGAR scores at 1 and 5 minutes, were similar between groups, with no adverse neonatal impact, consistent with other studies that showed no detrimental effects of intrathecal fentanyl on neonates Besha A *et al*.(2023)[7].

Sensory and Motor Blockade Characteristics Time to maximum level of analgesia was shorter in Group 2 (6.59 min vs. 8.16 min, p<0.001), and both two-segment regression and sensory regression to the L1 dermatome were significantly prolonged with fentanyl (p<0.001), indicating a more sustained sensory blockade. The total duration of complete sensory recovery was also longer in Group 2 (311.82 min vs. 182.04 min, p<0.001). These results are concordant with multiple studies where fentanyl added to bupivacaine extend sensory blockade without altering motor block duration Bhalekar A *et al*.(2024)[8].

Motor block onset and duration showed no significant differences, underscoring that fentanyl enhances sensory effects without affecting motor recovery, an observation consistent with Amjad MA *et al*.(2025)[9].

Hemodynamic Parameters and Stability Significant differences favored Group 2 in terms of systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) at 2 minutes post spinal anesthesia, showing improved hemodynamic stability with fentanyl. Group 2 maintained higher SBP (116.6 vs. 111.6 mmHg, p=0.001), DBP (66.3 vs. 63.8 mmHg, p=0.042), and MAP (83.1 vs. 79.8 mmHg, p=0.003). Heart rate and respiratory rate were similar between groups. These findings are in line with results from Ollosu M *et al*.(2025)[10], who reported that fentanyl addition reduces hypotension and promotes hemodynamic stability during spinal anesthesia for cesarean section.

Maternal and Fetal Outcomes Including Side Effects Incidences of hypotension, bradycardia, and pruritus were lower or similar in Group 2, though not statistically significant except for vomiting (6.7% vs. 26.7%, p=0.024) and shivering (4.4% vs. 22.2%, p=0.03), where fentanyl addition significantly reduced these side effects. This aligns with prior research demonstrating fentanyl's ability to reduce nausea, vomiting, and shivering during cesarean anesthesia Sherkhane P *et al*.(2024)[11].

CONCLUSION

In this randomized clinical study comprising 90 ASA Grade II patients undergoing elective lower segment cesarean section (LSCS), the addition of 12.5 µg fentanyl to 0.5% hyperbaric bupivacaine (10 mg) demonstrated significant benefits in hemodynamic stability, analgesic duration, and maternal-fetal outcomes. The fentanyl-bupivacaine combination significantly decreased the onset time of sensory block and prolonged the duration of effective analgesia without affecting motor block characteristics. Hemodynamic parameters including systolic, diastolic, and mean arterial pressures were more stable in the fentanyl group, with a lower incidence of hypotension and related side effects such as nausea and shivering. Maternal outcomes were favorable, exhibiting fewer adverse events, and neonatal APGAR scores at 1 and 5 minutes were comparable between groups, indicating no adverse impact on fetal well-being. Thus, intrathecal fentanyl as an adjuvant to bupivacaine is safe and efficacious for LSCS, improving the quality of anesthesia and postoperative analgesia while maintaining maternal and fetal safety.

LIMITATIONS

- Sample size and setting: The study was conducted in a single center with a relatively small sample size (n=90), which may limit the generalizability of the results.
- Dose range restrictions: Only one fentanyl dose (12.5 µg) was evaluated; dose-response

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relationships and optimal dosing could not be established.

- Short-term monitoring: Neonatal outcomes were assessed only by APGAR scores at 1 and 5 minutes; long-term follow-up of neonatal neurobehavioral outcomes was not performed.
- Exclusion of high-risk populations: Only ASA Grade II patients undergoing elective LSCS were included, limiting applicability to emergency cases or those with significant comorbidities.
- Subjective assessment of sensory and motor block: Sensory and motor block evaluations rely on clinical assessment methods, which might introduce inter-observer variability.

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