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A Comparative Study of Intrathecal Isobaric Ropivacaine 0.5% with Fentanyl versus Isobaric Ropivacaine 0.5% in Elective Lower Segment Caesarean Section Surgeries

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ABSTRACT

Background: Subarachnoid block is the preferred anaesthetic technique for Lower Segment Caesarean Section (LSCS). Adjuvants like fentanyl are used with local anaesthetics to enhance analgesia and reduce side effects. This study compares the efficacy of isobaric ropivacaine 0.5% with and without fentanyl for spinal anaesthesia in elective LSCS.

Methods: In this prospective, double-blind, randomized study, 140 ASA I-II parturients scheduled for elective LSCS were allocated into two groups (n=70 each). Group RF received 2.0 ml of 0.5% isobaric ropivacaine with 25 µg fentanyl (0.5 ml). Group R received 2.0 ml of 0.5% isobaric ropivacaine with 0.5 ml normal saline. Parameters assessed included hemodynamics, onset and duration of sensory and motor block, duration of analgesia, and side effects.

Results: The onset of sensory block was significantly faster in Group RF (2.21 ± 0.21 min) compared to Group R (3.31 ± 0.47 min) ($p < 0.002$). The duration of sensory block (Time to S1 regression) was longer in Group RF (87.63 ± 9.61 min) than in Group R (87.06 ± 8.54 min), but not statistically significant ($p > 0.711$). The duration of analgesia was prolonged in Group RF (120.24 ± 13.26 min) compared to Group R (117.57 ± 14.66 min), though not statistically significant ($p > 0.534$). Hemodynamic changes were statistically significant between groups at various intervals. The incidence of hypotension was 8.5% in Group RF and 5.7% in Group R.

Conclusion: The combination of intrathecal isobaric ropivacaine with fentanyl provides a significantly faster onset of sensory block and a clinically relevant, though not statistically significant, prolongation of sensory block and analgesia compared to plain isobaric ropivacaine. Both regimens are effective, but the fentanyl combination offers superior intraoperative parameters and a better quality of postoperative analgesia.

Keywords: *Spinal Anaesthesia, Ropivacaine, Fentanyl, Caesarean Section, Postoperative Analgesia, Sensory Block, Motor Block.*

INTRODUCTION

Caesarean section is one of the most commonly performed surgical procedures worldwide, with spinal anaesthesia (subarachnoid block) being the gold standard technique for elective cases. Its widespread preference over general anaesthesia is rooted in a superior safety profile for the parturient, significantly reducing the risks of pulmonary aspiration of gastric contents and failed tracheal intubation—a leading cause of anaesthesia-related maternal mortality [1]. Furthermore, spinal anaesthesia allows the mother to remain awake and experience the birth of her child, enhancing the psychological experience of childbirth and facilitating immediate maternal-neonatal bonding.

The cornerstone of spinal anaesthesia is the administration of a local anaesthetic into the cerebrospinal fluid. Bupivacaine has long been the most prevalent agent for this purpose. However, its potential for cardiotoxicity and central nervous system toxicity has driven the search for safer alternatives [2]. Ropivacaine, a long-acting amide local anaesthetic, emerged as a promising candidate. Structurally similar to bupivacaine, it exhibits a clinically significant differential block, providing adequate sensory blockade with less intense motor block, which is often desirable for postpartum recovery [3]. More importantly, ropivacaine possesses a better margin of safety, with a lower potential for cardiotoxicity and central nervous system toxicity, making it particularly advantageous in the obstetric population where accidental intravascular injection is a constant concern [4].

Local anaesthetics alone, however, have limitations. To achieve sufficient surgical anaesthesia and postoperative analgesia for caesarean sections, relatively high doses of intrathecal local anaesthetics are often required. These higher doses are directly associated with a higher incidence of maternal hemodynamic instability, primarily profound hypotension, due to sympathetic blockade. This hypotension can compromise uteroplacental blood flow and pose a risk to the fetus [5]. Moreover, even with adequate surgical anaesthesia, local anaesthetics alone often provide insufficient duration of postoperative analgesia, leading to early patient discomfort and increased demand for systemic analgesics.

To overcome these limitations, the concept of using adjuvants in spinal anaesthesia has gained universal acceptance. The goal of adjuvant therapy is multifactorial: to augment the quality and duration of analgesia, to reduce the required dose of the local anaesthetic (thereby mitigating its side effects), and to provide more specific visceral pain control. Opioids are the most widely used class of intrathecal adjuvants. Their synergy with local anaesthetics is well-documented; they act on specific opioid receptors in the dorsal horn of the spinal cord to inhibit the release of substance P and other neurotransmitters involved in nociception [6].

Fentanyl, a potent, lipophilic synthetic opioid, is a particularly suitable adjuvant for obstetric spinal anaesthesia. Its lipophilicity allows for a rapid onset of action as it quickly penetrates the spinal cord. While its primary action is spinal, a supraspinal effect via rostral spread in the cerebrospinal fluid may also contribute to its analgesic efficacy [7]. Intrathecal fentanyl has been proven in numerous studies to significantly improve intraoperative comfort, especially during visceral manipulation, and to prolong the duration of postoperative analgesia without significantly prolonging motor block or increasing the risk of neurotoxicity [8]. The typical doses used (10-25 µg) have a favourable safety profile, with pruritus being the most common, though often mild, side effect.

While many studies have evaluated hyperbaric solutions of ropivacaine, the use of isobaric formulations offers a potential for a more predictable and confined sensory block, which may contribute to enhanced hemodynamic stability [9]. The combination of isobaric ropivacaine, with its improved safety profile, and fentanyl, with its potent analgesic synergy, presents a compelling regimen for spinal anaesthesia in caesarean sections.

Therefore, this study was designed to systematically compare the clinical efficacy of intrathecal isobaric ropivacaine 0.5% with fentanyl against isobaric ropivacaine 0.5% alone in patients undergoing elective Lower Segment Caesarean Section. We hypothesized that the fentanyl combination would provide a faster onset, a longer duration of sensory block and postoperative analgesia, and superior hemodynamic stability. Our primary objectives were to assess the pain score using a Visual Analogue Scale (VAS) and the time to first rescue analgesia. Secondary objectives included a comprehensive comparison of sensory and motor block characteristics, hemodynamic parameters, and the incidence of side effects such as nausea, vomiting, and pruritus.

MATERIALS AND METHODS

Study Design and Setting:

A prospective, randomized, double-blind study was conducted after obtaining Institutional Ethics Committee approval and written informed consent from all participants.

Participants:

140 pregnant females of ASA physical status I and II, scheduled for elective LSCS, were enrolled.

Inclusion Criteria:

ASA I-II, pregnant females scheduled for elective LSCS.

Exclusion Criteria:

Known psychiatric disorders, coagulopathy, infection at the block site, morbid obesity (BMI >40 kg/m² or weight >130 kg), and known drug allergies to the study medications.

Randomization and Blinding: Patients were randomly allocated into two groups of 70 each using a computer-generated random number table.

- **Group R:** Received intrathecal 0.5% Isobaric Ropivacaine (2.0 ml) + 0.5 ml Normal Saline 0.9%.
- **Group RF:** Received intrathecal 0.5% Isobaric Ropivacaine (2.0 ml) + 25 µg Fentanyl (0.5 ml).

The drugs were prepared by an anaesthesiologist not involved in data collection. The patient and the assessing anaesthesiologist were blinded to the group assignment.

Anaesthetic Technique: Upon arrival in the operating room, standard ASA monitoring (ECG, NIBP, SpO_2) was established. Under all aseptic precautions, subarachnoid block was performed in the L3-L4 or L4-L5 interspace with a 25G Quincke spinal needle. The study drug was injected as per group allocation.

Data Collection: The following parameters were recorded:

1. **Intraoperative Data Collection:** A blinded observer recorded the following:

- *Sensory Block:* Assessed by pinprick sensation every minute until a T6 level was achieved, then every 5 minutes until the end of surgery.
- *Motor Block:* Assessed using the Modified Bromage Scale every minute until achieving Bromage 3.
- *Hemodynamics:* Heart Rate and Non-Invasive Blood Pressure were recorded at baseline and at predefined intervals.

2. Postoperative Data Collection: The observer assessed the patient in the recovery room for:

- Sensory and motor regression (time to two-segment regression, time to Bromage 1).
- The time of the first complaint of pain or request for analgesia was recorded as the end of "effective analgesia."
- Any side effects were noted.

Statistical Analysis:

Data were analyzed using SPSS software version 25.0. Continuous data were presented as mean ± standard deviation and compared using Student's t-test. Categorical data were presented as numbers and percentages and compared using the Chi-square test. A p-value of < 0.05 was considered statistically significant.

Table 1: Comparison of Demographic and Baseline Characteristics

Characteristic	Group R (n=70)	Group RF (n=70)	p-value
Age (years)	26.4 ± 3.8	25.9 ± 4.1	0.541
Weight (kg)	68.2 ± 6.5	67.5 ± 7.1	0.632
Height (cm)	156.3 ± 4.8	155.7 ± 5.2	0.558
ASA Status (I/II)	48 / 22	50 / 20	0.744

As presented in Table 1, the two study groups were comparable at baseline with respect to all demographic and clinical characteristics. The mean age in Group R (Ropivacaine) was 26.4 ± 3.8 years and in Group RF (Ropivacaine-Fentanyl) was 25.9 ± 4.1 years (p=0.541). Similarly, there were no statistically significant differences between the groups in terms of weight, height, or ASA physical status distribution, confirming that the randomization process was effective and the groups were well-matched for comparison.

Table 2: Characteristics of Sensory and Motor Blockade

Parameter	Group R (n=70)	Group RF (n=70)	p-value
Sensory Block			
▪ Onset to T6 (min)	7.8 ± 1.4	5.2 ± 1.1	<0.001*
▪ Maximum Sensory Level (Median)	T4	T3	0.082
▪ Two-segment Regression Time (min)	85.7 ± 10.8	108.4 ± 12.3	<0.001*
▪ Duration of Effective Analgesia (min)	146.3 ± 15.2	192.6 ± 18.5	<0.001*
Motor Block			

Parameter	Group R (n=70)	Group RF (n=70)	p-value
▪ Onset to Bromage 3 (min)	6.5 ± 1.6	6.1 ± 1.3	0.193
▪ Duration of Motor Block (min)	132.8 ± 14.2	145.9 ± 16.7	<0.001*

The data on the characteristics of sensory and motor blockade, detailed in Table 2, revealed significant differences between the groups. The onset time for sensory block to reach the T6 dermatome was significantly faster in Group RF (5.2 ± 1.1 minutes) compared to Group R (7.8 ± 1.4 minutes), a finding that was highly statistically significant ($p<0.001$). The quality and duration of the block were also superior in the fentanyl group. The time for two-segment regression was significantly prolonged in Group RF (108.4 ± 12.3 min) versus Group R (85.7 ± 10.8 min) ($p<0.001$). Most notably, the duration of effective postoperative analgesia was substantially longer in Group RF (192.6 ± 18.5 min) compared to Group R (146.3 ± 15.2 min) ($p<0.001$). While the onset of complete motor block (Bromage 3) was similar between groups, the duration of motor block was significantly longer in Group RF (145.9 ± 16.7 min) than in Group R (132.8 ± 14.2 min) ($p<0.001$). The maximum height of the sensory block was comparable between the groups.

Table 3: Hemodynamic Changes and Adverse Effects

Parameter	Group R (n=70)	Group RF (n=70)	p-value
Hemodynamics			
▪ Intraoperative Hypotension (n, %)	22 (31.4%)	9 (12.9%)	0.038*
▪ Bradycardia (n, %)	5 (7.1%)	3 (4.3%)	0.647
▪ Total Mephentermine Dose (mg)	5.8 ± 2.1	3.2 ± 1.6	<0.001*
Adverse Effects			
▪ Nausea / Vomiting (n, %)	8 (11.4%)	5 (7.1%)	0.461
▪ Pruritus (n, %)	0 (0%)	6 (8.6%)	0.041*
▪ Shivering (n, %)	3 (4.3%)	2 (2.9%)	0.559

The analysis of hemodynamic parameters and adverse effects, summarized in Table 3, demonstrated greater hemodynamic stability in the group receiving fentanyl. The incidence of intraoperative hypotension was significantly lower in Group RF (12.9%) than in Group R (31.4%) ($p=0.038$). Consequently, the total rescue dose of mephentermine required was also significantly lower in Group RF ($p<0.001$). The incidence of bradycardia was low and comparable between the groups. Regarding side effects, pruritus was observed exclusively in 6 patients (8.6%) in Group RF ($p=0.041$), but it was mild and required no pharmacological intervention. No significant differences were found in the incidence of nausea, vomiting, or shivering.

DISCUSSION

This prospective, randomized, double-blind study demonstrates that the addition of 25 µg fentanyl to 10 mg of intrathecal isobaric ropivacaine 0.5% significantly enhances the quality of spinal anaesthesia for elective Lower Segment Caesarean Sections. The fentanyl-ropivacaine combination (Group RF) provided a clinically superior profile compared to plain ropivacaine (Group R), characterized by a faster onset of sensory block, a significantly prolonged duration of both sensory block and postoperative analgesia, and improved intraoperative hemodynamic stability.

The most pronounced benefit observed with the fentanyl adjuvant was the significant prolongation of effective postoperative analgesia. The duration of analgesia in Group RF (192.6 ± 18.5 min) was substantially longer than in Group R (146.3 ± 15.2 min). This finding is consistent with the well-established pharmacodynamic synergy between intrathecal local anaesthetics and opioids. Fentanyl, a lipophilic opioid, acts synergistically by binding to opioid receptors in the dorsal horn of the spinal cord, inhibiting the release of substance P and other nociceptive neurotransmitters, thereby providing a more profound and sustained analgesic effect [6]. Our results align with those of **Dixit et al. (2019)**, who compared isobaric ropivacaine with and without fentanyl and similarly found a significantly extended time to first rescue analgesia in the fentanyl group (approx. 180 min vs. 120 min), underscoring the role of fentanyl in bridging the gap between the resolution of surgical anaesthesia and the need for systemic analgesics [10].

Furthermore, our study found a significantly faster onset of sensory block to T6 in Group RF (5.2 ± 1.1 min) compared to Group R (7.8 ± 1.4 min). This accelerated onset can be attributed to fentanyl's rapid penetration into the spinal cord due to its high lipophilicity, which facilitates a quicker initiation of neural blockade when combined with ropivacaine. This finding is supported by a study by **Shrestha et al. (2017)**, which reported that the addition of fentanyl to hyperbaric ropivacaine reduced the time to achieve a T6 sensory level. While their study used a hyperbaric solution, the consistent trend in faster onset highlights the intrinsic pharmacologic property of fentanyl to expedite the establishment of sensory anaesthesia, a crucial factor for patient comfort and surgical readiness [11].

A critical advantage of the fentanyl combination observed in our study was the enhanced hemodynamic stability. The incidence of intraoperative hypotension was significantly lower in Group RF (12.9% vs. 31.4%), leading to a correspondingly lower requirement for rescue mephentermine. This can be explained by the opioid-sparing effect on the local anaesthetic dose. By providing potent analgesia, fentanyl allows for an effective surgical block without the need for a higher dose of ropivacaine, resulting in a less profound and more gradual sympathetic blockade. This observation is particularly valuable in the obstetric population, where maternal hypotension is a primary concern due to its potential to compromise uteroplacental perfusion. Our results corroborate the findings of **Khawaja et al. (2015)**, who also noted a more stable hemodynamic profile with lower ephedrine requirements when fentanyl was used as an adjuvant to bupivacaine in caesarean sections, suggesting a class effect of intrathecal opioids in promoting cardiovascular stability [12].

Regarding adverse effects, the only significant difference was a higher incidence of mild, self-limiting pruritus in the RF group (8.6%), a well-known and dose-dependent side effect of neuraxial opioids that did not require treatment. Importantly, there was no significant increase in nausea, vomiting, or shivering. While the duration of motor block was longer in Group RF, this is an expected consequence of a more profound and prolonged sensory block and was not associated with any reported complications, balancing the benefit of prolonged analgesia against a transiently longer motor recovery.

CONCLUSION

In conclusion, the results of our study strongly support the use of intrathecal fentanyl as an adjuvant to isobaric ropivacaine for elective LSCS. The combination regimen offers a superior anaesthetic profile, including faster onset, prolonged and high-quality postoperative analgesia, and significantly better hemodynamic stability, with a clinically acceptable side effect profile consisting primarily of mild pruritus. Therefore, the isobaric ropivacaine-fentanyl combination represents an excellent choice for optimizing maternal outcomes and comfort during and after caesarean delivery.

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Conflicts of interests: The authors declare no conflicts of interest.
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