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Original Research Article

Comparison of different doses of intrathecal buprenorphine with 0.75% hyperbaric ropivacaine in caesarean section patients

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ABSTRACT

Background: Spinal anesthesia (SA) is widely considered the preferred technique for performing Cesarean sections (CS) due to its safety and effectiveness. The present study aimed to evaluate the benefits of combining Buprenorphine with hyperbaric Ropivacaine for SA in CS and to identify the optimal dose of Buprenorphine that provides the best balance between enhanced analgesia and minimal side effects.

Materials and Methods: This prospective, randomized, single-blind study included 150 patients undergoing elective Cesarean section. Participants were randomly assigned into three groups (n=50 each). Group A received 1.9 ml (14.25 mg) of 0.75% hyperbaric Ropivacaine combined with 30 μg of Buprenorphine. Group B received 1.8 ml (13.5 mg) of 0.75% hyperbaric Ropivacaine with 60 μg of Buprenorphine, while Group C (control group) received 2 ml (15 mg) of 0.75% hyperbaric Ropivacaine without Buprenorphine. The primary outcomes measured were the onset time and duration of sensory and motor blocks. Secondary outcomes included the duration of postoperative analgesia and neonatal safety, which was assessed using the APGAR scoring method. Statistical analysis was performed using the chi-square test and the t-test to compare the efficacy and safety across groups.

Results: The addition of Buprenorphine significantly accelerated the onset of sensory block in both Group A (1.49 ± 0.40 minutes) and Group B (1.92 ± 0.63 minutes), compared to the control Group C (4.94 ± 0.90 minutes). The duration of sensory block was also prolonged in Groups A (4.34 ± 0.24 hours) and B (4.55 ± 0.38 hours) compared to Group C (2.10 ± 0.18 hours). Group B, which received the higher dose of Buprenorphine (60 μg), exhibited the longest duration of analgesia with no observed neonatal side effects according to the APGAR scores.

Conclusion: The addition of Buprenorphine to hyperbaric Ropivacaine for spinal anesthesia in Cesarean sections enhances anesthetic efficacy by accelerating the onset and extending the duration of sensory and motor blocks. The use of 60 μg Buprenorphine provided the greatest duration of postoperative analgesia without compromising neonatal outcomes. These findings support the use of Buprenorphine as an effective adjuvant in spinal anesthesia for Cesarean deliveries.

1. Introduction

The Caesarean section (CS) is one of the most regularly done surgical operations globally, with spinal anaesthesia being the preferred method due to its advantages over general anaesthesia, including a lesser risk of aspiration, difficult intubation, and deleterious effects on the foetus.[1] However, spinal anaesthesia is not without its complications, such as hypotension, which can compromise uterine blood flow and foetal circulation, leading to foetal hypoxia and acidosis.[2]

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Ropivacaine is a pure S-type amide local anaesthetic known for its low central nervous system toxicity and cardiotoxicity.[3] It provides a good combination of sensory and motor block with stable intraoperative haemodynamic and a low incidence of postoperative problems, making it a suitable for spinal anaesthesia in CS patients.[4] Studies have demonstrated the safety and efficacy of Ropivacaine in various doses, highlighting its role in providing satisfactory analgesia while allowing for early postoperative ambulation.[5]

Opioids are often used as adjuvants to local anaesthetics in spinal anaesthesia to enhance anaesthesia; minimize side effects; prolong the duration of analgesia and reduce the requirement of post-operative analgesics.[6,7] Enhanced Recovery after Cesarean delivery (ERAC) mandates intraoperative initiation and postoperative continuation of a multimodal analgesia plan.[8]

Among the various opioids, Buprenorphine a mixed agonist-antagonist narcotic with high affinity at both μ and k opiate receptors stands out due to its high potency, lipid solubility, and long duration of action.[9,10] Buprenorphine acts as an agonist-antagonist at opioid receptors about thirty times more potent than morphine, providing effective analgesia with a ceiling effect on respiratory depression but not on analgesia.[11] It is a centrally acting lipid soluble analogue of the alkaloid thebaine with both spinal and supraspinal components of analgesia & a good choice as an adjuvant to intrathecal LA for managing moderate to severe postoperative pain. Buprenorphine is readily available as a preservative-free preparation which is compatible with the cerebrospinal fluid (CSF). Intrathecal doses (30 μg–150 μg) are much smaller than parenteral doses and are known to prolong analgesia. Being more lipophilic than morphine, buprenorphine has low medullary bioavailability after neuraxial administration so that the occurrence of side effects is lesser, making it an attractive adjuvant to intrathecal local anaesthetics like Ropivacaine for managing postoperative pain in CS patients.[12]

The combination of Bupivacaine and Buprenorphine has been explored in various studies to optimize postoperative analgesia and reduce adverse effects. Buprenorphine's high affinity for opioid receptors and its ability to prevent central sensitization through its antihyperalgesic properties contribute to its efficacy as an analgesic adjuvant.[13] Additionally, the intrathecal administration of buprenorphine in small doses results in minimal neonatal drug transfer compared to epidural or parenteral administration, making it a safer option for CS patients.[12]

To study the benefits of combining ropivacaine with buprenorphine and also to determine the optimal dose of buprenorphine that provides the best balance between analgesia and side effects this study was carried out. The purpose of this study was to examine the efficacy and safety of two different dosages of buprenorphine (30 μg and 60 μg) as an adjuvant to hyperbaric ropivacaine in spinal anaesthesia for CS patients. The objective was to assess the characteristics of sensory and motor blockage, duration of postoperative analgesia, and side effect profile in both the mother and the newborn in the early postoperative period.

2. Materials and Methods

This prospective, randomized, single-blind study was conducted in the Gynaecology and Obstetrics Operation Theatre of a tertiary healthcare center. Ethical approval was obtained from the Institutional Ethics Committee (IEC) (Approval No. IEC/Pharm/RP/79 Mar/2024). The trial was registered with the Clinical Trials Registry-India (CTRI No. CTRI/2024/04/065962).

The sample size was determined using the formula $Z^2(P)(1-P)/d^2$, based on the proportion of Cesarean sections reported in the NFHS-3 (8.5%) as per Roy et al. with a 95% confidence interval and a margin of error of 0.05.[14] A total of 150 patients were enrolled, with 50 participants assigned to each group. Group A received 1.9 ml (14.25 mg) of 0.75% hyperbaric Ropivacaine with 30 μg of Buprenorphine, Group B received 1.8 ml (13.5 mg) of 0.75% hyperbaric Ropivacaine with 60 μg of Buprenorphine, and Group C (control group) received 2 ml (15 mg) of 0.75% hyperbaric Ropivacaine without Buprenorphine.

The study included patients with American Society of Anesthesiologists (ASA) physical status I or II, aged 18-40 years, with a height of 145-160 cm, and pre-pregnancy weight between 45-80 kg, scheduled for elective Cesarean section. Exclusion criteria were patients with coagulopathy, severe pregnancy-induced hypertension, pre-eclampsia, eclampsia, pre-existing cardiac, hepatic, or neurological disorders, malignancy, infection at the injection site, or unwillingness to undergo spinal anesthesia. Written informed consent was obtained from all participants, ensuring compliance with ethical standards for human research.

The trial was single-blind, meaning that patients were unaware of their group assignment, while the anesthesiologists administering the medications and assessing outcomes were informed of the group allocation. This design could introduce observer bias; however, standardized procedures for drug administration and monitoring were implemented to minimize this risk. Preoperative evaluations included complete blood count, renal and liver function tests, and ECG. Patients were kept nil by mouth (NBM) for 6-8 hours prior to the surgery.

Intraoperatively, patients were monitored using ECG, non-invasive blood pressure (NIBP), and SpO2. Following intravenous line placement, patients were preloaded with 500 ml of Ringer's lactate solution before anesthesia induction. Spinal anesthesia was administered using a 23G or 25G Quincke's spinal needle at the L3-L4 interspace in a sitting position. After confirming free cerebrospinal

fluid flow, the study medication was injected intrathecally. Patients were then positioned supine. Hemodynamic parameters, including heart rate, systolic and diastolic blood pressure, mean arterial pressure, SpO2, and respiratory rate, were recorded every minute for the first 10 minutes, every 5 minutes for the next 30 minutes, and every 10 minutes for the following 90 minutes. Sensory block onset and duration were assessed at T12, T10, T8, and T6 dermatomes using the blunt-end needle pinprick method, while motor block was evaluated using the Modified Bromage Score. Hypotension, defined as systolic blood pressure <90 mm Hg or a reduction of more than 20% from baseline, was managed with ephedrine.

Postoperative monitoring of pulse rate, blood pressure, and respiratory status was performed every 15 minutes for the first 2 hours, then every 2 hours for the subsequent 24 hours. The APGAR scores of newborns were recorded at 1 and 5 minutes post-delivery. The regression of sensory and motor blocks was noted postoperatively, and pain scores were assessed using the Visual Analogue Scale (VAS). The timing of the first rescue analgesia dose and total analgesic doses required were documented. Patients were monitored throughout the study for adverse effects such as bradycardia, hypotension, nausea, vomiting, chills, sedation, and respiratory depression. The Ramsay Sedation Score was used to quantify the level of sedation.

Data analysis was conducted using the chi-square test for categorical variables, and the t-test was used to compare means between groups. The rigorous methodology employed ensured reliable and robust findings, contributing valuable insights into determining the optimal dose of Buprenorphine as an adjuvant to intrathecal Ropivacaine in Cesarean sections.

3. Results

The demographic parameters, including age, height, and weight, as well as the duration of surgery, are well-matched across the three groups, with slight variations. Group B patients had a slightly higher mean weight, while Group A had a lower mean weight with a higher standard deviation, indicating greater variability in this group. The duration of surgery was similar across all groups, which supports the comparability of the groups in terms of the procedural context. This uniformity in demographic and surgical parameters ensures that differences observed in other outcomes, such as sensory block onset and duration, can be attributed more confidently to the variations in anaesthesia rather than underlying demographic differences. (Table 1)

The consistent baseline values indicate that the groups were well-matched in terms of initial clinical conditions before the administration of anaesthesia, ensuring that any observed differences in outcomes are likely due to the differences in anaesthesia protocols rather than pre-existing differences in patient health. (Table 2)

The results show that adding buprenorphine to intrathecal ropivacaine considerably enhances the onset and duration of both sensory and motor blocks in caesarean section patients. Specifically, the greater dose of buprenorphine (Group B) caused a faster onset and longer duration of both sensory and motor blocks than the control group (Group C). Although the length of motor block, quality of block, and beginning of action were similar in the buprenorphine higher dose group (Group B) and the lower dose group (Group A), the duration of analgesia was longer in the buprenorphine higher dose group (Group B). (Table 3)

3.1. Total number of rescue analgesic doses

Group B required the fewest rescue analgesic doses (1.30 ± 0.46) within 24 hours, significantly fewer than Group C (3.06 ± 0.79) and slightly fewer than Group A (1.52 ± 0.50). Group B also required significantly fewer doses than Group C, though the difference between Group A and Group B was not statistically significant. (Table 4)

3.2. Requirement of first analgesic dose

Group B has the longest time (7.38 ± 0.87) before the first analgesic dose is required, followed by Group A (6.78 ± 0.48), with both significantly later than Group C (3.33 ± 0.42). The difference between Group A and Group B is statistically significant but smaller.(Table 4)

The mean APGAR scores at 1 minute are relatively consistent across the three groups, with Group A having a mean of 9.76, Group B at 9.68, and Group C at 9.72.

At 5 minutes, the APGAR scores show very little variation, with Group A and Group B both having a mean of 9.98, and Group C having a mean of 9.96. (Table 5)

4. Discussion

Postoperative pain is a major cause of fear and anxiety in hospitalized patients and so if patients remain pain-free during this period, they can cooperate with the circumstances well, leading to early recovery and mobilization thereby reducing untoward complications like thromboembolic phenomenon. According to the Enhanced Recovery after Cesarean delivery (ERAC) consensus statement of the Society of Obstetric Anesthesia and Perinatology (SOAP) mandates intraoperative initiation and postoperative continuation of a multimodal analgesia plan.[8] Optimal post-operative analgesia is a prerequisite to achieve the ERAC recommendations: Maternal-infant bonding, promotion of breast feeding, early oral intake. Pre-operatively placement of epidural catheter for combined spinal-epidural technique or oral paracetamol is beneficial according to procedure-specific postoperative pain management (PROSPECT) guidelines.[15] Intra-

Table 1: Demographic characteristics of patients

Parameters	Group A		Group B		Group C	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	27.04	3.69754	26.72	4.15535	25.52	3.25915
Height (cm)	152.18	4.77104	152.38	4.911	152.54	4.48676
Weight (kg)	66.58	12.49178	73.72	5.51821	69.98	5.56773
Duration of Surgery (min)	64.8	13.73807	66	15.017	64.7	13.64304

Table 2: Baseline clinical parameters across groups A, B, and C

Parameter	Group A (Mean ± SD)	Group B (Mean ± SD)	Group C (Mean ± SD)
PR Baseline (bpm)	84.00 ± 6.30	85.44 ± 7.38	85.08 ± 5.96
MAP Baseline (mmHg)	82.16 ± 6.92	82.22 ± 8.16	79.96 ± 6.27

Table 3: Sensory and motor blockade characteristics

Parameter	Groups	Mean ± SD	Mean Difference	p-value
Onset of Sensory Block (minutes)	Group C	4.94 ± 0.90	3.447 (C vs B)	< 0.001
	Group B	1.49 ± 0.40	3.017 (C vs A)	< 0.001
	Group A	1.92 ± 0.63	-0.430 (A vs B)	< 0.001
Duration of Sensory Block (hours)	Group C	2.10 ± 0.18	-2.446 (C vs B)	< 0.001
	Group B	4.55 ± 0.38	-2.232 (C vs A)	< 0.001
	Group A	4.34 ± 0.24	0.214 (A vs B)	0.002
Onset of Motor Block (minutes)	Group C	6.83 ± 1.06	5.344 (C vs B)	< 0.001
	Group B	1.48 ± 0.40	4.814 (C vs A)	< 0.001
	Group A	2.01 ± 0.74	-0.530 (A vs B)	< 0.001
Duration of Motor Block (hours)	Group C	1.63 ± 0.35	-2.408 (C vs B)	< 0.001
	Group B	4.04 ± 0.31	-2.279 (C vs A)	< 0.001
	Group A	3.91 ± 0.34	0.129 (A vs B)	0.014

Table 4: Analgesic dose characteristics

Parameter	Groups	Mean ± SD	Mean Difference	p-value
Total Number of Rescue Analgesic Doses (24 hrs)	Group C	3.06 ± 0.79	1.76 (C vs B)	< 0.001
	Group B	1.30 ± 0.46	1.540 (C vs A)	< 0.001
	Group A	1.52 ± 0.50	-0.220 (A vs B)	0.062
Requirement of First Analgesic Dose (hours)	Group C	3.33 ± 0.42	-4.055 (C vs B)	< 0.001
	Group B	6.78 ± 0.48	-3.454 (C vs A)	< 0.001
	Group A	7.38 ± 0.87	0.601 (A vs B)	< 0.001

Table 5: APGAR scores at 1 minute and 5 minutes across groups A, B, and C

Time	Group A (Mean ± SD)	Group B (Mean ± SD)	Group C (Mean ± SD)
1 Minute	9.76 ± 0.52	9.68 ± 0.65	9.72 ± 0.61
5 Minutes	9.98 ± 0.14	9.98 ± 0.14	9.96 ± 0.20

operative local anaesthetic (LA) wound infiltration; fascial plane blocks are recommended. Also, Intravenous Dexamethasone, Paracetamol, Non- steroidal anti-inflammatory drugs administered peri-operatively are very effective tools for pain management. Analgesic adjuvants transcutaneous electric nerve stimulation is used for pain control post-operative. Surgical techniques like Joel- Cohen incision, non- closure of peritoneum, abdominal binders contribute to pain relief.[15] Optimal postoperative analgesia is a prerequisite to achieve the ERAC recommendations. American Society of Anesthesiologists (ASA) recommends neuraxial opioids over intermittent administration of parenteral opioids for postoperative analgesia after neuraxial anesthesia for caesarean section.[7] To overcome disadvantages like spinal hypotension and shivering many kind of adjuvants have been used intrathecally like Morphine, fentanyl, sufentanil, dexmedetomidine, buprenorphine, Nalbuphine, clonidine etc. for spinal anaesthesia in LSCS patients. The most effective form of postoperative analgesia is through neuraxial morphine.[8] As

smaller doses are used intrathecally, neonatal drug transfer is negligible compared to epidural or parenteral opioids.[7] Different additives have been used to improve the efficacy of intrathecal Ropivacaine. However, these adjuvants are associated with undesired side effects.

To study the benefits of combining ropivacaine with buprenorphine and also to determine the optimal dose of buprenorphine that provides the best balance between analgesia and side effects this study was carried out. The demographic features in this study, such as age, height, weight, and operation duration, were similar across the three groups, with no statistically significant differences.(Table 1) This consistency in baseline features is required to ensure that the differences observed in the onset and duration of sensory and motor blocks, as well as analgesic requirements, are due to the anaesthesia procedure rather than human variability. Rawal et al. and Shah et al. found that preserving comparable demographic features across groups is crucial for assessing the efficacy of anaesthesia interventions.[16,17]

The findings revealed that adding buprenorphine to intrathecal ropivacaine greatly accelerates the onset and lengthens the duration of both sensory and motor blocks.(Table 3) Group B received a greater dose of buprenorphine, resulting in a faster start of sensory block (1.49 ± 0.40 minutes) than Group A (1.92 ± 0.63 minutes) and the control group, Group C (4.94 ± 0.90 minutes).(Table 3) In his study Mohat et al., noticed that the onset of sensory and motor block was slower in patients receiving ropivacaine. Furthermore, the duration of sensory as well as motor block was shorter in these patients.[18] Addition of Buprenorphine accelerates onset of action much required in surgeries like Caesarean Section. Similarly, the duration of sensory block was longest in Group B (4.55 ± 0.38 hours), compared to Group A (4.34 ± 0.24 hours) and Group C (2.10 ± 0.18 hours).(Table 3) Similar findings were reported by Borkotoky et al., where intrathecal buprenorphine provided longer sensory and motor blockade when combined with bupivacaine.[19] These dose-dependent effects of buprenorphine are well-documented in the literature Angadi et al., confirming its efficacy as an adjuvant to local anaesthetics.[20]

Our study demonstrated that Group B had the least requirement for rescue analgesics in the 24-hour postoperative period (1.30 ± 0.46 doses), which is significantly lower than Group C (3.06 ± 0.79 doses). (Table 4) The time to the first analgesic dose was also significantly prolonged in Group B (7.38 ± 0.87 hours) compared to Group A (6.78 ± 0.48 hours) and Group C (3.33 ± 0.42 hours).(Table 4) This observation is consistent with the findings of Kaushal et al., who reported prolonged analgesia with buprenorphine as an intrathecal adjuvant, significantly reducing the need for additional postoperative analgesics.[21]

The enhanced analgesic effect observed in Group B further supports the dose-dependent benefits of buprenorphine in managing postoperative pain in caesarean section patients. Dixit et al., also studied the beneficial effect of buprenorphine in managing postoperative pain in caesarean section patients.[22] In similar study Borse et al., found that Buprenorphine added to hyperbaric Bupivacaine had effective and considerably prolonged postoperative analgesia compared to Intrathecal Bupivacaine alone in Orthopedic Surgeries.[23]

Addition of Buprenorphine with 0.75% hyperbaric Ropivacaine accelerates onset of motor and sensory action; it prolongs the duration of sensory block and reduces post-operative analgesic requirement but it also prolonged the motor block which was less desirable in this study.

Shruthijayaram et al., in his study found that Intrathecal dexmeditomidine as adjuvant to isobaric ropivacaine had shorter sensory onset time and is associated with prolonged duration of sensory and motor block and prolonged the time for first analgesic demand when compared to buprenorphine with isobaric ropivacaine or plain isobaric ropivacaine with good hemodynamic stability and no significant side effects.[24] Arunkumar et al., found that the duration of the sensory and motor block with effective postoperative analgesia were more pronounced when buprenorphine was added to intrathecal Bupivacaine compared to nalbuphine added to intrathecal Bupivacaine in elective infraumbilical surgeries.[25]

APGAR scores at 1 and 5 minutes were similar across the three groups, with no significant differences, showing that the addition of buprenorphine had no deleterious impact on newborn outcomes. These APGAR scores suggest that the neonates across all groups had similarly strong outcomes immediately following birth, indicating that the different anaesthesia protocols did not negatively impact neonatal health as assessed by the APGAR scoring system. Previous studies Ravindran et al. and Ipe et al. have shown that intrathecal opioids, including buprenorphine, do not adversely affect neonatal APGAR scores.[12,26] This indicates that buprenorphine, even at greater doses, can be safely used as an adjuvant in spinal anaesthesia without jeopardising infant health.

This study had several limitations. It was single-blind, with only the patients unaware of their group allocation, which could introduce potential bias in anesthesia administration. The small sample size and single-center design limit the generalizability of the findings. The focus on short-term outcomes within 24 hours postoperatively does not account for potential long-term effects. Although demographic factors were comparable, confounding variables such as baseline pain tolerance, psychological factors, and prior exposure to anesthesia were not controlled. Pain relief was primarily assessed through analgesic requirements, without the use of comprehensive

pain assessment tools. Additionally, the study did not evaluate patient satisfaction or hemodynamic stability. The findings may not be applicable to patients with comorbid conditions, such as morbid obesity or chronic pain. Neonatal outcomes were only briefly assessed with APGAR scores, and no comparison was made with other intrathecal adjuvants. Future studies should address these limitations to offer more comprehensive insights.

5. Conclusion

The addition of 60 μg buprenorphine to hyperbaric ropivacaine significantly enhances anesthetic efficacy by accelerating the onset and prolonging the duration of both sensory and motor blocks. This combination also reduces postoperative analgesic requirements compared to ropivacaine alone, without adversely affecting neonatal outcomes, as demonstrated by stable APGAR scores. This approach provides an extended duration of postoperative analgesia while maintaining a favorable balance between efficacy and safety.

6. Source of Funding

Nil.

7. Conflicts of Interest

There are no conflicts of interest.

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