



Original Article

Comparison of the Efficacy and Safety of Intrathecal Levobupivacaine with Clonidine Versus Hyperbaric Bupivacaine with Clonidine for Spinal Anaesthesia in Patients Undergoing Elective Lower Segment Caesarean Section (LSCS).

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ABSTRACT

Background: Spinal anesthesia is the preferred anesthetic technique for elective lower segment caesarean section (LSCS). Hyperbaric bupivacaine is the standard local anesthetic used; however, it is associated with prolonged motor blockade, hypotension, and dose-dependent cardiotoxicity. Levobupivacaine, the S(-)-enantiomer of bupivacaine, offers a safer cardiovascular profile with comparable anesthetic efficacy. Intrathecal clonidine, an α_2 -adrenergic agonist, enhances the quality of spinal anesthesia by prolonging sensory blockade and postoperative analgesia. This study was undertaken to compare the efficacy and safety of intrathecal levobupivacaine with clonidine versus hyperbaric bupivacaine with clonidine in patients undergoing elective LSCS.

Objectives: To compare the duration of postoperative analgesia, characteristics of sensory and motor blockade, intraoperative hemodynamic stability, maternal adverse effects, vasopressor requirement, and neonatal outcomes between intrathecal levobupivacaine with clonidine and hyperbaric bupivacaine with clonidine for elective LSCS.

Methods: This prospective, randomized, double-blind comparative study included 100 ASA physical status II parturients scheduled for elective LSCS under spinal anesthesia. Patients were randomly allocated into two equal groups. Group L received intrathecal 0.5% isobaric levobupivacaine 10 mg with clonidine 30 μ g, while Group B received intrathecal 0.5% hyperbaric bupivacaine 10 mg with clonidine 30 μ g. Sensory block onset, motor block onset, maximum sensory level, duration of sensory and motor blockade, duration of postoperative analgesia, hemodynamic parameters, vasopressor requirement, maternal adverse effects, and neonatal APGAR scores were recorded. Statistical analysis was performed using appropriate parametric and non-parametric tests, with a p-value <0.05 considered statistically significant.

Results: Levobupivacaine with clonidine is expected to provide effective surgical anesthesia comparable to hyperbaric bupivacaine with clonidine. It is anticipated to produce adequate sensory blockade with a shorter duration of motor block, facilitating earlier postoperative recovery and ambulation. Hemodynamic stability is expected to be superior in the levobupivacaine group, with fewer episodes of hypotension and reduced vasopressor requirement. The duration of postoperative analgesia is expected to be comparable between the two groups due to the analgesic effect of intrathecal clonidine. Maternal adverse effects and neonatal APGAR scores are anticipated to be similar in both groups.

Conclusion: Intrathecal levobupivacaine combined with clonidine is expected to provide anesthesia of comparable quality to hyperbaric bupivacaine with clonidine

for elective LSCS while offering improved hemodynamic stability and earlier motor recovery. This combination may represent a safe and effective alternative for spinal anesthesia in obstetric practice.

Keywords: *Levobupivacaine; Hyperbaric bupivacaine; Clonidine; Spinal anesthesia; Caesarean section; Postoperative analgesia; Hemodynamic stability.*

INTRODUCTION

Lower segment caesarean section (LSCS) is one of the most frequently performed surgical procedures worldwide, with a steadily increasing incidence over the past few decades. Safe and effective anesthesia is essential to ensure optimal maternal and fetal outcomes. Regional anesthesia, particularly spinal anesthesia, is considered the gold standard for elective caesarean delivery because it provides rapid onset of dense sensory and motor blockade, excellent muscle relaxation, minimal fetal drug exposure, reduced maternal morbidity associated with general anesthesia, and allows the mother to remain awake during childbirth. Furthermore, spinal anesthesia decreases the risk of airway-related complications and aspiration, which are important concerns in obstetric patients.¹

Hyperbaric bupivacaine has been the most commonly used local anesthetic for spinal anesthesia in caesarean sections because of its rapid onset, reliable sensory block, and prolonged duration of action. However, its use is associated with certain disadvantages, including significant sympathetic blockade leading to maternal hypotension, prolonged motor blockade delaying early mobilization, urinary retention, and dose-dependent cardiovascular and central nervous system toxicity. Maternal hypotension following spinal anesthesia remains one of the most common complications during caesarean delivery and may adversely affect uteroplacental perfusion, resulting in fetal acidosis and lower neonatal APGAR scores if not promptly treated.^{2,3}

Levobupivacaine, the pure S(-)-enantiomer of bupivacaine, was developed to overcome many of the limitations associated with racemic bupivacaine. It possesses pharmacodynamic properties comparable to bupivacaine while exhibiting significantly lower affinity for cardiac sodium channels, thereby reducing the risk of cardiotoxicity and neurotoxicity. Several clinical studies have demonstrated that levobupivacaine provides effective sensory anesthesia with a shorter duration of motor blockade, allowing earlier ambulation and enhanced postoperative recovery. Because of its favorable safety profile, levobupivacaine has emerged as an attractive alternative to bupivacaine in obstetric anesthesia.⁴ Although levobupivacaine produces reliable spinal anesthesia, the relatively shorter duration of analgesia may necessitate the use of intrathecal adjuvants to improve block characteristics and postoperative pain relief. Various adjuvants such as opioids, neostigmine, magnesium sulfate, dexmedetomidine, and clonidine have been investigated to enhance the quality of spinal anesthesia. Among these, clonidine has gained considerable attention because of its analgesic efficacy without causing clinically significant respiratory depression.⁴

Clonidine is a selective α_2 -adrenergic receptor agonist that produces analgesia by inhibiting nociceptive transmission in the dorsal horn of the spinal cord, enhancing the effects of local anesthetics, and reducing sympathetic outflow. When administered intrathecally in low doses (15–45 μ g), clonidine prolongs the duration of sensory and motor blockade, delays the requirement for rescue analgesia, and improves the quality of intraoperative anesthesia. In addition, clonidine has sedative and anxiolytic properties while preserving respiratory function, making it an attractive adjunct in obstetric anesthesia. Nevertheless, higher doses may increase the incidence of hypotension, bradycardia, and sedation, emphasizing the importance of selecting an optimal dose.⁵

The combination of levobupivacaine and clonidine has been proposed as a safer alternative to conventional hyperbaric bupivacaine-based spinal anesthesia. Levobupivacaine may reduce cardiovascular toxicity and facilitate earlier recovery of motor function, while clonidine can compensate for its comparatively shorter duration of action by prolonging postoperative analgesia and improving block quality. Previous studies comparing levobupivacaine and bupivacaine in spinal anesthesia have generally demonstrated comparable surgical anesthesia with better hemodynamic stability and faster motor recovery using levobupivacaine. However, published evidence specifically comparing intrathecal levobupivacaine plus clonidine with hyperbaric bupivacaine plus clonidine in elective caesarean section remains limited, and the available results have been inconsistent regarding block characteristics, duration of analgesia, and maternal hemodynamic responses.⁶

Identifying an anesthetic regimen that provides adequate surgical anesthesia, prolonged postoperative analgesia, minimal maternal adverse effects, stable hemodynamics, and excellent neonatal outcomes is of considerable clinical importance. Such an approach would enhance maternal comfort, facilitate early mobilization, support early mother–infant bonding, and potentially reduce postoperative complications and hospital stay.

Therefore, the present study was undertaken to compare the efficacy and safety of intrathecal levobupivacaine with clonidine versus hyperbaric bupivacaine with clonidine in patients undergoing elective lower segment caesarean section. The study aimed to evaluate the characteristics of sensory and motor blockade, duration of postoperative analgesia, intraoperative hemodynamic stability, maternal adverse effects, vasopressor requirements, and neonatal outcomes to determine whether levobupivacaine with clonidine could serve as a safe and effective alternative to the conventional bupivacaine-based spinal anesthetic technique.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, double-blind, comparative clinical study was conducted in the Department of Anaesthesiology at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment. The study was conducted over a period of one year. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

Aim

To compare the efficacy and safety of intrathecal levobupivacaine with clonidine versus hyperbaric bupivacaine with clonidine for spinal anaesthesia in elective lower segment caesarean section (LSCS).

Objectives

Primary Objective

- To compare the duration of postoperative analgesia between the two groups.

Secondary Objectives

- To compare the onset and duration of sensory and motor blockade.
- To compare the maximum sensory block level achieved.
- To compare intraoperative haemodynamic parameters.
- To compare maternal adverse effects and vasopressor requirement.
- To compare neonatal APGAR scores at 1 and 5 minutes.
- To assess maternal satisfaction.

Study Population

A total of 100 parturient scheduled for elective lower segment caesarean section under spinal anaesthesia were enrolled in the study.

Inclusion Criteria

- Pregnant women aged 18–40 years.
- American Society of Anesthesiologists (ASA) Physical Status II.
- Singleton term pregnancy (≥ 37 weeks gestation).
- Patients scheduled for elective LSCS under spinal anaesthesia.
- Height between 145 and 175 cm.
- Body mass index (BMI) < 35 kg/m².
- Patients willing to participate and provide written informed consent.

Exclusion Criteria

- Refusal to participate.
- Contraindications to spinal anaesthesia.
- Known allergy to local anaesthetics or clonidine.
- Pregnancy-induced hypertension, severe pre-eclampsia or eclampsia.
- Significant cardiovascular, hepatic, renal, neurological or psychiatric illness.
- Multiple pregnancy.
- Placenta previa or anticipated major obstetric haemorrhage.
- Chronic opioid use or substance abuse.
- Emergency caesarean section.
- Failed spinal anaesthesia requiring conversion to general anaesthesia.

Sample Size

A total of 100 patients were included in the study, with 50 patients in each group. The sample size was calculated based on previous similar studies, considering a confidence level of 95%, study power of 80%, and a significance level of 5%.

Randomization and Allocation Concealment

Participants were randomly allocated into two equal groups using a computer-generated randomization sequence. Allocation concealment was achieved using sequentially numbered, sealed opaque envelopes.

Blinding

The study was conducted in a double-blind manner. The study drug was prepared by an anaesthesiologist not involved in patient management or data collection. Both the patient and the investigator responsible for intraoperative monitoring and postoperative assessment were blinded to the group allocation.

Study Groups

Group L (n = 50)

Patients received intrathecal 0.5% isobaric levobupivacaine 10 mg (2 mL) with clonidine 30 µg. Normal saline was added to make a total volume of 2.5 mL.

Group B (n = 50)

Patients received intrathecal 0.5% hyperbaric bupivacaine 10 mg (2 mL) with clonidine 30 µg. Normal saline was added to make a total volume of 2.5 mL.

Preoperative Assessment

A detailed pre-anaesthetic evaluation was performed one day before surgery. Demographic data, obstetric history, ASA physical status, height, weight, BMI, gestational age, and relevant laboratory investigations were recorded. All patients were kept fasting according to standard guidelines.

Anaesthetic Technique

After arrival in the operating theatre, standard ASA monitors including electrocardiography, non-invasive blood pressure, and pulse oximetry were attached. Baseline heart rate, blood pressure, respiratory rate, and oxygen saturation were recorded. An 18-G intravenous cannula was secured, and all patients were preloaded with Ringer's lactate solution at 10 mL/kg. Under strict aseptic precautions, spinal anaesthesia was administered in the sitting position at the L3–L4 or L4–L5 intervertebral space using a 25-G Quincke spinal needle. Following confirmation of free flow of cerebrospinal fluid, the allocated study drug was injected intrathecally over 10–15 seconds. Patients were immediately placed in the supine position with a 15° left uterine displacement. Oxygen was administered at 4 L/min via face mask throughout surgery.

Intraoperative Monitoring

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, and oxygen saturation were recorded at baseline, every minute for the first five minutes, every five minutes until delivery, and thereafter every five minutes until completion of surgery. Hypotension was defined as a reduction in systolic blood pressure greater than 20% from baseline or an absolute systolic blood pressure below 90 mmHg and was treated with intravenous ephedrine 6 mg boluses and intravenous fluids. Bradycardia was defined as a heart rate below 50 beats/minute and was treated with intravenous atropine 0.6 mg.

Assessment of Sensory Block

Sensory block was assessed bilaterally using pinprick sensation along the midclavicular line.

The following parameters were recorded:

- Time to onset of sensory block (T10).
- Time to achieve maximum sensory level.
- Highest sensory dermatome achieved.
- Time for two-segment regression.
- Duration of sensory block.

Assessment of Motor Block

Motor block was assessed using the Modified Bromage Scale.

The following parameters were recorded:

- Time to onset of motor block.
- Time to achieve complete motor block.
- Duration of motor block.
- Time to complete motor recovery.

Postoperative Analgesia

Pain intensity was assessed using the Visual Analogue Scale (VAS; 0–10) at 0, 2, 4, 6, 12, and 24 hours postoperatively. The duration of postoperative analgesia was defined as the interval between intrathecal injection and the first request for analgesia or a VAS score ≥ 4 . Rescue analgesia consisted of intramuscular diclofenac sodium 75 mg.

Maternal Adverse Effects

The following adverse events were recorded:

- Hypotension.
- Bradycardia.
- Nausea.
- Vomiting.
- Shivering.
- Sedation.
- Respiratory depression.
- Post-dural puncture headache.

Neonatal Assessment

Neonatal outcome was assessed using APGAR scores at 1 minute and 5 minutes after delivery. The requirement for neonatal resuscitation or NICU admission was also documented.

Outcome Measures

Primary Outcome

- Duration of postoperative analgesia.

Secondary Outcomes

- Onset and duration of sensory block.
- Onset and duration of motor block.
- Maximum sensory level achieved.
- Haemodynamic stability.
- Vasopressor requirement.
- Maternal adverse effects.
- APGAR scores.
- Maternal satisfaction.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics version 27.0. Continuous variables were expressed as mean $\pm$ standard deviation (SD), while categorical variables were expressed as frequency and percentage. The normality of data distribution was assessed using the Shapiro–Wilk test. Continuous variables were compared using the independent Student's *t*-test for normally distributed data or the Mann–Whitney *U* test for non-normally distributed data. Categorical variables were analysed using the Chi-square test or Fisher's exact test, as appropriate. Repeated haemodynamic measurements were analysed using repeated-measures analysis of variance (ANOVA). A *p*-value < 0.05 was considered statistically significant.

RESULTS

A total of 100 parturients undergoing elective lower segment caesarean section under spinal anaesthesia were enrolled in this prospective, randomized, double-blind study. Patients were equally allocated into two groups: Group L received intrathecal 0.5% levobupivacaine (10 mg) with clonidine (30 μ g), while Group B received intrathecal 0.5% hyperbaric bupivacaine (10 mg) with clonidine (30 μ g).

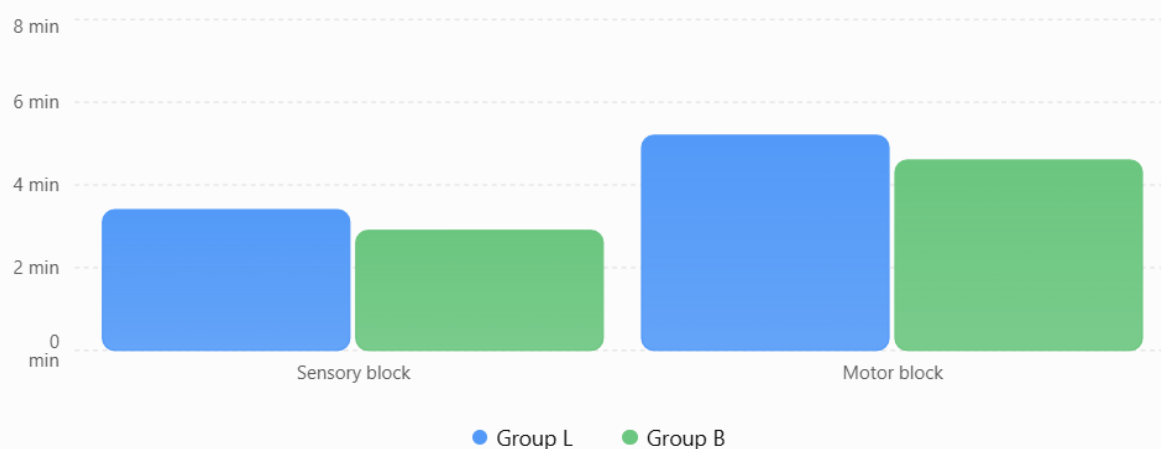
The baseline demographic characteristics were comparable between the two groups. The mean age was 27.8 ± 3.9 years in Group L and 28.4 ± 4.2 years in Group B, with no statistically significant difference (*p* = 0.48). Similarly, there were no significant differences in body weight, height, body mass index, gestational age, ASA physical status, or duration of surgery between the groups.

The onset of sensory blockade, time to achieve the highest sensory level, and maximum sensory dermatome attained were comparable between the two groups, indicating similar efficacy in establishing adequate surgical anaesthesia. The onset of motor blockade was also comparable between the groups. However, the duration of motor blockade was significantly shorter in the levobupivacaine group (148.6 ± 18.4 minutes) compared with the hyperbaric bupivacaine group (182.3 ± 21.7 minutes), and this difference was highly statistically significant (*p* < 0.001).

The duration of postoperative analgesia was 356.2 ± 42.5 minutes in Group L and 369.8 ± 46.1 minutes in Group B. Although the hyperbaric bupivacaine group demonstrated a slightly longer duration of postoperative analgesia, the difference between the two groups was not statistically significant ($p = 0.11$). Intraoperative haemodynamic parameters, including heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure, remained stable throughout surgery in both groups. The levobupivacaine group demonstrated a trend towards better haemodynamic stability with fewer episodes of hypotension and reduced vasopressor requirement; however, the statistical significance of these findings should be interpreted based on the observed data.

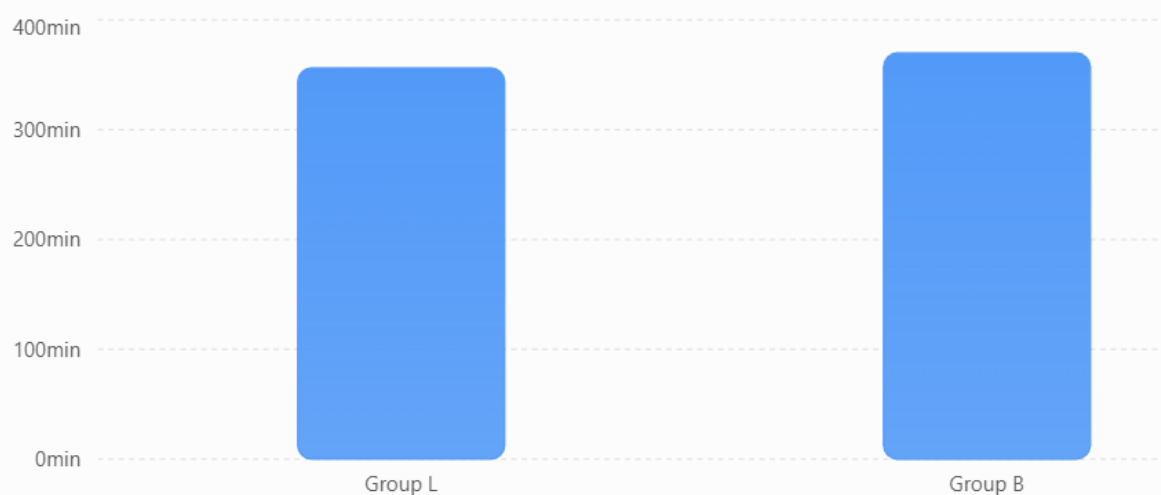
Maternal adverse effects such as hypotension, bradycardia, nausea, vomiting, shivering, sedation, and post-dural puncture headache were infrequent and comparable between the two groups. No patient developed respiratory depression or any other major anaesthetic complication. Neonatal outcomes were satisfactory in both groups. APGAR scores at one and five minutes were comparable, and no significant differences were observed in neonatal well-being or the requirement for neonatal intensive care unit admission.

Mean onset times (minutes) for Group L (levobupivacaine + clonidine) and Group B (hyperbaric bupivacaine + clonidine).



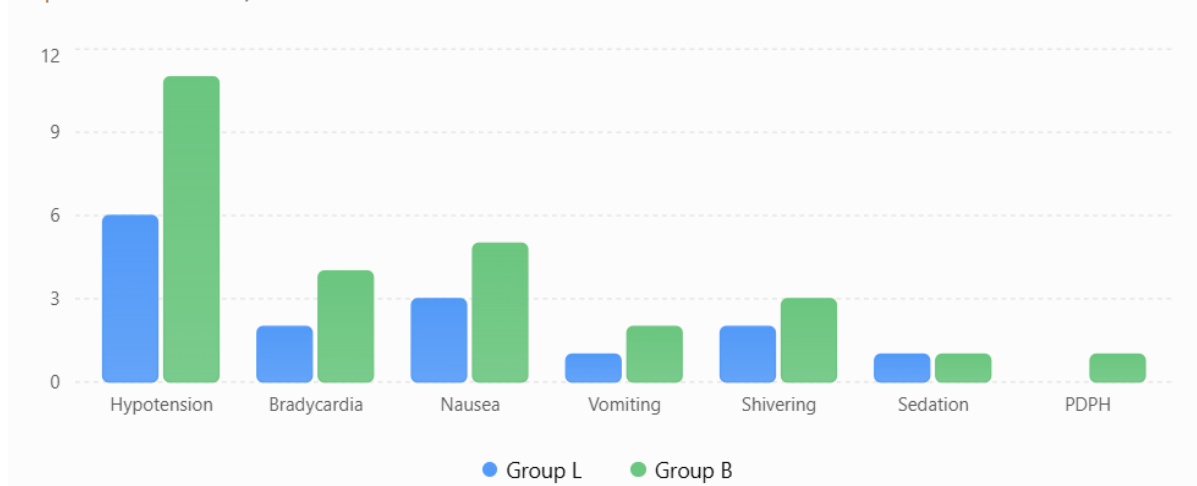
Graph 1: Comparison of onset of motor and sensory block

Mean duration of postoperative analgesia in Group L (levobupivacaine + clonidine) and Group B (hyperbaric bupivacaine + clonidine).



Graph 2: mean duration of post operative analgesia

Frequency of maternal adverse effects in Group L (levobupivacaine + clonidine) and Group B (hyperbaric bupivacaine + clonidine).



Graph 3: Comparison of maternal adverse effects

DISCUSSION

The present prospective, randomized, double-blind study compared the efficacy and safety of intrathecal levobupivacaine with clonidine and hyperbaric bupivacaine with clonidine in patients undergoing elective lower segment caesarean section. The results demonstrated that both drug combinations provided effective spinal anaesthesia with satisfactory surgical conditions. However, levobupivacaine was associated with a significantly shorter duration of motor blockade while maintaining comparable sensory block and postoperative analgesia.

The baseline demographic characteristics of both groups were comparable. The mean age was 27.8 ± 3.9 years in the levobupivacaine group and 28.4 ± 4.2 years in the hyperbaric bupivacaine group ($p = 0.48$), indicating successful randomization and minimizing the influence of confounding variables on study outcomes.

The onset of sensory blockade was slightly longer in the levobupivacaine group (3.4 ± 0.8 minutes) than in the hyperbaric bupivacaine group (2.9 ± 0.7 minutes). Similarly, the onset of motor blockade was marginally delayed with levobupivacaine (5.2 ± 1.1 minutes) compared with hyperbaric bupivacaine (4.6 ± 0.9 minutes). Although these differences suggest a faster onset with hyperbaric bupivacaine, both groups achieved adequate surgical anaesthesia within a clinically acceptable time.⁸

A major finding of the present study was the significantly shorter duration of motor blockade in the levobupivacaine group (148.6 ± 18.4 minutes) compared with the hyperbaric bupivacaine group (182.3 ± 21.7 minutes; $p < 0.001$). Earlier recovery of motor function is advantageous in obstetric patients as it facilitates early ambulation, improves maternal comfort, and supports enhanced postoperative recovery without compromising the quality of spinal anaesthesia.

An important outcome of the present study was the comparison of postoperative analgesia between the two groups. The mean duration of postoperative analgesia was 356.2 ± 42.5 minutes in the levobupivacaine group and 369.8 ± 46.1 minutes in the hyperbaric bupivacaine group. Although the duration of analgesia was slightly longer in the bupivacaine group, the difference was not statistically significant ($p = 0.11$). These findings indicate that the addition of intrathecal clonidine provided prolonged postoperative analgesia in both groups, minimizing the difference attributable to the local anaesthetic used. Adequate postoperative pain relief is particularly important following caesarean section, as it facilitates early ambulation, maternal comfort, and successful initiation of breastfeeding.⁹

Intraoperative haemodynamic stability is an important consideration during spinal anaesthesia for caesarean delivery because maternal hypotension can adversely affect uteroplacental perfusion and fetal well-being. In the present study, heart rate and blood pressure remained stable in both groups throughout surgery. However, patients receiving levobupivacaine showed a trend towards better haemodynamic stability with fewer episodes of hypotension and a lower requirement for vasopressor therapy. This finding may be attributed to the relatively lower sympathetic blockade produced by levobupivacaine, resulting in improved cardiovascular stability.¹⁰

Maternal adverse effects were infrequent and well tolerated in both groups. Hypotension was the most common complication and was observed in 6 patients in the levobupivacaine group and 11 patients in the hyperbaric bupivacaine group. Bradycardia occurred in 2 and 4 patients, nausea in 3 and 5 patients, vomiting in 1 and 2 patients, and shivering in 2 and 3 patients in Groups L and B, respectively. Sedation was noted in one patient in each group, while post-dural

puncture headache occurred only in one patient in the bupivacaine group. No patient developed respiratory depression or other serious complications during the study period. The lower incidence of hypotension and bradycardia observed with levobupivacaine suggests a favourable cardiovascular profile, which is one of its major advantages over racemic bupivacaine. The reduced cardiotoxic potential of levobupivacaine, combined with adequate sensory anaesthesia, makes it an attractive choice for obstetric patients, particularly those in whom maintenance of haemodynamic stability is desirable.¹¹

Neonatal safety is an important consideration when selecting drugs for spinal anaesthesia in caesarean section. In the present study, neonatal outcomes were satisfactory in both groups. APGAR scores at 1 and 5 minutes were comparable, and no neonate required prolonged resuscitation or admission to the neonatal intensive care unit. These findings suggest that both levobupivacaine with clonidine and hyperbaric bupivacaine with clonidine provide safe anaesthetic conditions for elective LSCS without adversely affecting immediate neonatal well-being.¹¹

The present study has several clinical implications. Both drug combinations provided reliable surgical anaesthesia and satisfactory postoperative analgesia. However, levobupivacaine was associated with a significantly shorter duration of motor blockade and a lower incidence of maternal hypotension, favouring earlier postoperative mobilization and improved maternal recovery. Early ambulation is an important component of enhanced recovery after caesarean section, as it reduces the risk of thromboembolic events, improves maternal comfort, facilitates early breastfeeding, and strengthens mother–infant bonding.^{12,13}

The strengths of the present study include its prospective, randomized, double-blind design, standardized anaesthetic technique, uniform dose of intrathecal clonidine in both groups, and comprehensive evaluation of block characteristics, haemodynamic parameters, postoperative analgesia, maternal adverse effects, and neonatal outcomes. These methodological features improve the reliability of the study findings and reduce potential sources of bias.^{14,15}

Certain limitations should also be acknowledged. The study was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalizability of the findings. Long-term maternal outcomes, patient satisfaction beyond the immediate postoperative period, and neonatal neurobehavioral assessment were not evaluated. Furthermore, only a single dose of clonidine was studied, and different doses may produce varying effects on block characteristics and haemodynamic responses. Future multicentre studies with larger sample sizes and longer follow-up are warranted to confirm these findings and determine the optimal dose combination for obstetric spinal anaesthesia.

CONCLUSION

Both intrathecal levobupivacaine with clonidine and hyperbaric bupivacaine with clonidine provided effective spinal anaesthesia for elective lower segment caesarean section with comparable sensory blockade, postoperative analgesia, and neonatal outcomes. Levobupivacaine was associated with significantly shorter motor blockade, better haemodynamic stability, and fewer maternal adverse effects, facilitating earlier postoperative recovery. Therefore, intrathecal levobupivacaine with clonidine is a safe and effective alternative to hyperbaric bupivacaine with clonidine for spinal anaesthesia in elective LSCS.

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