RESEARCH PAPER

# COMPARATIVE EVALUATION OF INTRATHECAL ISOBARIC AND HYPERBARIC LEVOBUPIVACAINE COMBINED WITH CLONIDINE FOR SPINAL ANESTHESIA: EFFECTS ON BLOCK CHARACTERISTICS, HEMODYNAMICS, AND POSTOPERATIVE ANALGESIA

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**ABSTRACT**

**Background:** Levobupivacaine is widely used for spinal anesthesia because of its favorable safety profile and lower cardiotoxicity compared with racemic bupivacaine. The addition of intrathecal clonidine enhances the quality and duration of spinal anesthesia. However, limited data are available comparing the clinical efficacy of isobaric and hyperbaric levobupivacaine when used with clonidine.

**Objectives:** To compare the efficacy, block characteristics, postoperative analgesia, and hemodynamic effects of isobaric levobupivacaine with clonidine and hyperbaric levobupivacaine with clonidine in patients undergoing elective lower abdominal and lower limb surgeries.

**Methods:** A prospective, randomized, comparative study was conducted in 60 adult patients of ASA physical status I and II scheduled for elective lower abdominal and lower limb surgeries under spinal anesthesia. Patients were randomly allocated into two groups of 30 each. Group I received intrathecal isobaric levobupivacaine with clonidine, whereas Group H received intrathecal hyperbaric levobupivacaine with clonidine. Sensory and motor block characteristics, duration of analgesia, postoperative Visual Analogue Scale (VAS) scores, hemodynamic parameters including heart rate and mean arterial pressure, and adverse effects were assessed and compared between the groups.

**Results:** Hyperbaric levobupivacaine with clonidine produced a significantly faster onset of sensory and motor blockade and achieved a higher sensory block level compared with isobaric levobupivacaine with clonidine ($p < 0.05$). The duration of sensory block, motor block, and postoperative analgesia was significantly prolonged in Group H ($p < 0.001$). Postoperative VAS scores were significantly lower in the hyperbaric group, with delayed requirement for rescue analgesia. Heart rate and mean arterial pressure remained comparable between the groups throughout the intraoperative and postoperative periods ($p > 0.05$). The incidence of adverse effects was low and similar in both groups.

**Conclusion:** Hyperbaric levobupivacaine combined with clonidine provides superior block characteristics and prolonged postoperative analgesia compared with isobaric levobupivacaine combined with clonidine while maintaining comparable hemodynamic stability and safety. It may be considered a preferable intrathecal anesthetic option for elective lower abdominal and lower limb surgeries.

**Keywords:** Levobupivacaine; Clonidine; Spinal anesthesia; Hyperbaric; Isobaric; Postoperative analgesia; Subarachnoid block.

**How to cite this article:** Sowmya NM, Manasa G, Darshan MS. Comparative Evaluation of Intrathecal Isobaric and Hyperbaric Levobupivacaine Combined with Clonidine for Spinal Anesthesia: Effects on Block Characteristics, Hemodynamics, and Postoperative Analgesia. Int J Drug Deliv Technol. 2026;16(64s):1351-1360. DOI: 10.25258/ijddt.16.64s.141

**Source of support:** Nil

**Conflict of interest:** None

## INTRODUCTION:

Spinal anaesthesia is a widely used regional anaesthetic technique for lower abdominal, pelvic, perineal, and lower limb surgeries because of its rapid onset, reliable sensory and motor blockade, excellent postoperative analgesia, and reduced

perioperative morbidity compared with general anaesthesia.[1]

Bupivacaine has traditionally been the most commonly used local anaesthetic for spinal anaesthesia. However, concerns regarding its cardiotoxic and neurotoxic effects have led to the development of safer alternatives. Levobupivacaine, the pure S(-)-enantiomer of bupivacaine, provides effective anaesthesia with a lower risk of cardiovascular and central nervous system toxicity while maintaining comparable clinical efficacy.[2,3]

The characteristics of spinal blockade are influenced by the baricity of the local anaesthetic solution. Isobaric levobupivacaine has a density similar to cerebrospinal fluid, resulting in a relatively predictable spread. Hyperbaric levobupivacaine, prepared by adding dextrose, is denser than cerebrospinal fluid and may provide faster onset, greater cephalad spread, and prolonged duration of blockade.[4,5]

Various intrathecal adjuvants have been used to enhance the quality and duration of spinal anaesthesia. Clonidine, an $\alpha_2$-adrenergic agonist, prolongs sensory and motor blockade by acting on spinal $\alpha_2$ receptors and enhances postoperative analgesia without significant respiratory depression.[6,7] Previous studies have demonstrated that the addition of clonidine to intrathecal local anaesthetics improves block characteristics and extends the duration of analgesia.[8]

Although levobupivacaine and clonidine have been extensively studied individually, limited data are available comparing isobaric and hyperbaric levobupivacaine when combined with clonidine. Therefore, the present study was undertaken to compare the onset and duration of sensory and motor blockade, duration of postoperative analgesia, hemodynamic effects, and adverse effect profile of isobaric levobupivacaine with clonidine and hyperbaric levobupivacaine with clonidine in patients undergoing elective lower abdominal and lower limb surgeries under spinal anaesthesia.

## METHODOLOGY:

This prospective observational 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 in the study.

A total of 60 patients scheduled for elective lower abdominal and lower limb surgeries under spinal anaesthesia were included in the study.

**Inclusion Criteria**

- Patients aged 18–65 years.

- American Society of Anesthesiologists (ASA) physical status I and II.

- Patients undergoing elective lower abdominal and lower limb surgeries under spinal anaesthesia.

- Patients willing to participate and provide written informed consent.

**Exclusion Criteria**

- Patient refusal.

- Known allergy to local anaesthetics or clonidine.

- Coagulation disorders or anticoagulant therapy.

- Infection at the site of spinal puncture.

- Severe cardiac, hepatic, renal, or neurological disease.

- Pregnancy.

- Contraindications to spinal anaesthesia.

**Study Groups**

The enrolled patients were divided into two groups of 30 patients each based on the intrathecal drug administered.

**Group I (n = 30)**

Received 3 mL of 0.5% Isobaric Levobupivacaine with Clonidine 30 µg intrathecally.

**Group H (n = 30)**

Received 3 mL of 0.5% Hyperbaric Levobupivacaine with Clonidine 30 µg intrathecally.

All patients underwent a detailed pre-anaesthetic evaluation one day before surgery. Patients were kept nil per oral for 6 hours before surgery. On arrival in the operating room, standard monitors including electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry ($SpO_2$), and heart rate monitoring were attached.

Baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded. Intravenous access was secured using an 18G cannula, and patients were preloaded with Ringer's lactate solution (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 25G Quincke spinal needle. After confirmation of free flow of cerebrospinal fluid, the study drug was injected

intrathecally. Patients were immediately placed in the supine position.

**Data Collection**

Sensory Block Assessment

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

The following parameters were recorded:

- Onset time of sensory block.
- Highest sensory level achieved.
- Time to attain maximum sensory block.
- Time for two-segment regression.
- Duration of sensory block.

Motor Block Assessment

Motor blockade was assessed using the Modified Bromage Scale.

The following parameters were recorded:

- Onset time of motor block.
- Maximum motor block achieved.
- Duration of motor block.

Hemodynamic Parameters

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded at baseline, every 2 minutes for the first 10 minutes, every 5 minutes up to 30 minutes, every 15 minutes intraoperatively, and postoperatively at 1, 2, 3, 6, 12, and 24 hours.

Duration of Analgesia

Duration of analgesia was defined as the time interval between intrathecal injection and the first request for rescue analgesia or when the Visual Analogue Scale (VAS) score was ≥4.

Adverse Events

The incidence of hypotension, bradycardia, nausea, vomiting, shivering, sedation, respiratory depression, and any other complications was recorded.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) software version 25.0.

Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were expressed as frequency and percentage.

A p-value <0.05 was considered statistically significant.

**RESULTS :**

A total of 60 patients undergoing elective lower abdominal and lower limb surgeries under spinal anesthesia were enrolled in the study. Patients were randomly allocated into two groups of 30 each.

**Table 1 :Demographic Characteristics**

The demographic variables were comparable between the two groups. There was no statistically significant difference regarding age, weight, height, gender distribution, or ASA physical status ($p > 0.05$).

| Variable | Group I (n=30) | Group H (n=30) | p-value |
|---|---|---|---|
| Age (years) | 38.6 ± 10.2 | 39.8 ± 9.7 | 0.64 |
| Weight (kg) | 62.4 ± 8.3 | 63.7 ± 7.9 | 0.52 |
| Height (cm) | 164.2 ± 5.8 | 165.1 ± 6.2 | 0.58 |
| Male/Female | 18/12 | 17/13 | 0.79 |

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|---|---|---|---|
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**Table 2: Sensory Block Characteristics**

| Parameter | Group I | Group H | p-value |
|---|---|---|---|
| Onset of sensory block (min) | 5.8 ± 1.2 | 3.9 ± 0.9 | <0.001 |
| Maximum sensory level | T6 | T5 | 0.04 |
| Time to peak sensory level (min) | 11.4 ± 2.3 | 8.7 ± 1.8 | <0.001 |
| Two-segment regression (min) | 118.6 ± 12.8 | 136.9 ± 15.1 | <0.001 |

The onset of sensory blockade was significantly faster in Group H than in Group I. Hyperbaric levobupivacaine produced a more rapid spread within the cerebrospinal fluid, resulting in earlier onset and higher sensory blockade. The duration of sensory block was also significantly prolonged.

**Table 3: Motor Block Characteristics**

| Parameter | Group I | Group H | p-value |
|---|---|---|---|
| Onset of motor block (min) | 7.2 ± 1.4 | 5.1 ± 1.0 | <0.001 |
| Duration of motor block (min) | 185.4 ± 21.6 | 228.7 ± 24.3 | <0.001 |

**Group H demonstrated significantly faster onset and prolonged duration of motor blockade compared to Group I.**

**Table 4: Comparison of Heart Rate (beats/min) Between Groups**

| Time Interval | Group I (Isobaric + Clonidine) Mean ± SD | Group H (Hyperbaric + Clonidine) Mean ± SD | p-value |
|---|---|---|---|
| Baseline | 82.1 ± 8.4 | 81.5 ± 7.9 | 0.81 |
| 5 min | 78.4 ± 7.2 | 76.9 ± 6.8 | 0.42 |

| | | | |
|---|---|---|---|
| 10 min | 74.8 ± 6.9 | 72.1 ± 6.4 | 0.11 |
| 15 min | 71.6 ± 6.5 | 69.4 ± 6.2 | 0.18 |
| 30 min | 70.2 ± 6.1 | 68.1 ± 5.8 | 0.17 |
| 45 min | 71.5 ± 5.9 | 69.8 ± 5.7 | 0.25 |
| 60 min | 73.4 ± 6.0 | 71.7 ± 5.9 | 0.28 |
| 1 h Post-op | 75.8 ± 6.4 | 74.2 ± 6.1 | 0.31 |
| 2 h Post-op | 76.4 ± 6.5 | 74.9 ± 6.2 | 0.35 |
| 4 h Post-op | 77.6 ± 6.8 | 76.1 ± 6.4 | 0.39 |
| 6 h Post-op | 78.5 ± 6.9 | 77.2 ± 6.5 | 0.46 |
| 12 h Post-op | 80.1 ± 7.1 | 79.3 ± 6.8 | 0.65 |
| 24 h Post-op | 81.2 ± 7.3 | 80.5 ± 7.0 | 0.71 |

Heart rate decreased following spinal anesthesia in both groups and gradually returned toward baseline values postoperatively. No statistically significant intergroup differences were observed at any time point.

**Table 5: Comparison of Mean Arterial Pressure (mmHg) Between Groups**

| Time Interval | Group I (Isobaric + Clonidine) Mean ± SD | Group H (Hyperbaric + Clonidine) Mean ± SD | p-value |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Baseline | 93.4 ± 6.8 | 94.2 ± 7.1 | 0.67 |
| 5 min | 88.2 ± 6.4 | 86.8 ± 6.2 | 0.39 |
| 10 min | 83.9 ± 5.8 | 81.7 ± 5.6 | 0.14 |
| 15 min | 79.8 ± 5.6 | 77.6 ± 5.3 | 0.12 |
| 30 min | 78.6 ± 5.9 | 76.4 ± 6.1 | 0.14 |
| 45 min | 80.5 ± 5.7 | 78.8 ± 5.8 | 0.25 |
| 60 min | 82.1 ± 5.8 | 80.4 ± 5.7 | 0.26 |
| 1 h Post-op | 84.5 ± 5.9 | 83.1 ± 5.8 | 0.35 |
| 2 h Post-op | 86.2 ± 6.1 | 84.8 ± 5.9 | 0.37 |
| 4 h Post-op | 87.4 ± 6.3 | 86.1 ± 6.0 | 0.42 |
| 6 h Post-op | 88.5 ± 6.5 | 87.2 ± 6.1 | 0.44 |
| 12 h Post-op | 90.6 ± 6.7 | 89.4 ± 6.4 | 0.48 |
| 24 h Post-op | 92.1 ± 6.8 | 91.2 ± 6.5 | 0.60 |

MAP decreased during the initial period following spinal anesthesia due to sympathetic blockade and gradually returned toward baseline values. No significant differences were observed between the two groups throughout the study period.

**Table 6: Incidence of Hemodynamic Complications**

| Complication | Group I n (%) | Group H n (%) | p-value |
|---|---|---|---|
| Bradycardia | 1 (3.3%) | 2 (6.7%) | 0.55 |
| Hypotension | 2 (6.7%) | 4 (13.3%) | 0.39 |
| Vasopressor Requirement | 1 (3.3%) | 3 (10.0%) | 0.30 |
| Shivering | 3 (10.0%) | 2 (6.7%) | 0.64 |

**Hemodynamic adverse events were infrequent and comparable between the two groups.**

**Table 7: Comparison of Postoperative VAS Scores**

| Time after Surgery | Group I (Isobaric + Clonidine) Mean ± SD | Group H (Hyperbaric + Clonidine) Mean ± SD | p-value |
|---|---|---|---|
| 1 hour | 0.3 ± 0.5 | 0.1 ± 0.3 | 0.08 |
| 2 hours | 0.8 ± 0.7 | 0.4 ± 0.5 | 0.02* |
| 4 hours | 1.8 ± 0.9 | 1.1 ± 0.7 | 0.001* |
| 6 hours | 2.9 ± 1.1 | 1.7 ± 0.8 | <0.001* |
| 8 hours | 3.8 ± 1.2 | 2.4 ± 0.9 | <0.001* |
| 12 hours | 4.7 ± 1.1 | 3.2 ± 1.0 | <0.001* |
| 18 hours | 3.9 ± 1.0 | 2.8 ± 0.8 | <0.001* |
| 24 hours | 3.2 ± 0.9 | 2.5 ± 0.8 | 0.003* |

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***Statistically significant ($p < 0.05$)**

Postoperative pain assessment using the Visual Analogue Scale demonstrated lower pain scores in the Hyperbaric Levobupivacaine with Clonidine group throughout the postoperative observation period. During the first postoperative hour, both groups exhibited excellent analgesia with minimal pain scores. However, as the sensory block regressed, VAS scores increased progressively in both groups.

Consequently, patients in the hyperbaric group experienced delayed onset of postoperative pain and reduced analgesic requirements.

**Table 8: Rescue Analgesic Requirement**

| Parameter | Group I | Group H | p-value |
|---|---|---|---|
| Time to First Rescue Analgesic (min) | 312.5 ± 34.6 | 402.8 ± 42.7 | <0.001* |
| Total Rescue Analgesic Doses in 24 h | 2.1 ± 0.6 | 1.3 ± 0.5 | <0.001* |

Patients in the Hyperbaric Levobupivacaine with Clonidine group required rescue analgesia significantly later and consumed fewer analgesic doses during the first 24 postoperative hours. This finding further supports the superior analgesic efficacy of the hyperbaric formulation.

**DISCUSSION:**

The present study compared the clinical efficacy and safety of isobaric levobupivacaine with clonidine and hyperbaric levobupivacaine with clonidine for spinal anesthesia in patients undergoing elective lower abdominal and lower limb surgeries. The primary findings of this study demonstrated that hyperbaric levobupivacaine combined with clonidine produced a faster onset of sensory and motor blockade, achieved a higher sensory level, prolonged the duration of sensory and motor block, and provided longer postoperative analgesia compared to isobaric levobupivacaine with clonidine. Hemodynamic stability and incidence of adverse effects were comparable between the two groups.

In the present study, the onset of sensory block was significantly faster in the hyperbaric levobupivacaine group. Hyperbaric solutions contain dextrose, increasing their density relative to cerebrospinal fluid and facilitating predictable spread under gravitational influence. This enhanced distribution within the subarachnoid space may explain the rapid onset and higher sensory blockade observed in Group H. Similar findings were reported by Fattorini et al., who demonstrated a more predictable and rapid onset of spinal block with hyperbaric levobupivacaine compared with isobaric preparations.9

The maximum sensory block achieved was significantly higher in the hyperbaric group. The greater cephalad spread observed with hyperbaric levobupivacaine is likely due to increased baricity and better intrathecal distribution. These findings are in agreement with studies conducted by Alley et al. and Luck et al., who reported superior spread characteristics and greater reliability of sensory blockade with hyperbaric formulations.10,11

The onset of motor blockade was also significantly faster in the hyperbaric group. Rapid penetration of local anesthetic into nerve roots and enhanced distribution within cerebrospinal fluid may contribute to this observation. Similar results have been reported by Glaser et al., who found shorter onset times with hyperbaric levobupivacaine during lower limb orthopedic procedures.3

An important finding of the present study was the prolonged duration of sensory and motor blockade in the hyperbaric levobupivacaine group. The addition of clonidine likely contributed to this effect. Clonidine is an α2-adrenergic agonist that enhances neuraxial analgesia by inhibiting nociceptive neurotransmitter release and augmenting local

anesthetic action at the spinal cord level. The synergistic interaction between clonidine and levobupivacaine has been demonstrated in several previous studies.7,8

The duration of postoperative analgesia was significantly longer in patients receiving hyperbaric levobupivacaine with clonidine. This prolonged analgesic effect may be attributed to both the extended sensory blockade and the analgesic properties of intrathecal clonidine. Clonidine acts on presynaptic and postsynaptic α2 receptors in the dorsal horn of the spinal cord, suppressing pain transmission and prolonging postoperative comfort. Similar observations were reported by Kanazi et al. and Dobrydnjov et al., who demonstrated significantly prolonged analgesia following intrathecal clonidine administration.12,13

Hemodynamic parameters remained stable throughout the intraoperative period in both groups. Although mild reductions in heart rate and mean arterial pressure were observed following spinal anesthesia, the changes were clinically insignificant and did not require aggressive intervention. Levobupivacaine is known to possess a favorable cardiovascular safety profile compared with racemic bupivacaine because of its lower affinity for myocardial sodium channels. This characteristic likely contributed to the hemodynamic stability observed in both groups.2

The incidence of adverse effects including hypotension, bradycardia, nausea, vomiting, and shivering was low and comparable between groups. No serious complications were encountered. These findings are consistent with previous investigations demonstrating that intrathecal clonidine in low doses provides effective prolongation of anesthesia without significantly increasing adverse events.14

Overall, the results of the present study suggest that hyperbaric levobupivacaine combined with clonidine offers several clinical advantages over isobaric levobupivacaine with clonidine. These advantages include faster onset, improved block characteristics, prolonged postoperative analgesia, and comparable hemodynamic stability. Therefore, hyperbaric levobupivacaine with clonidine may be considered a superior intrathecal anesthetic option for lower abdominal and lower limb surgeries.

## CONCLUSION:

Hyperbaric levobupivacaine combined with clonidine provides superior block characteristics and prolonged postoperative analgesia compared with isobaric levobupivacaine combined with clonidine while maintaining comparable hemodynamic stability and safety. It may be considered a preferable intrathecal anesthetic option for elective lower abdominal and lower limb surgeries.

**Financial support and sponsorship:** Nil

**Conflicts of interest:** There are no conflicts of interest.

**Acknowledgements:** First and foremost I thank our institution for providing platform and opportunities for conducting this study and also for providing required equipment. I also thank our HOD and other seniors in our department for guiding me throughout the study and for constant support from topic selection, methods and methodology, proofreading and interpretation of results. I would like to thank statistical team for the analysis of the data. I thank the study subjects for taking part in the study and also thank our surgical colleagues for their support.

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