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# Comparative evaluation of anesthetic efficacy and hemodynamic effects of intrathecal isobaric bupivacaine versus intrathecal isobaric levobupivacaine in the lower abdominal and lower limb surgeries

**Chinthavali Sujatha[1], Chandraleela Sundararajan[2], Arthi Asokan[3]**

*[1,2]Assistant Professor, [3]Associate Professor, Department of Anaesthesiology, Sri Venkateswaraa Medical College Hospital and Research Centre, Ariyur, Puducherry, India*

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## ABSTRACT

**Background:** The most frequently utilized approach in patients undergoing lower abdominal and lower limb procedures is spinal anesthesia with bupivacaine. **Aims and Objectives:** The aim of the study was to compare the anesthetic efficacy and hemodynamic effects of isobaric bupivacaine and isobaric levobupivacaine for spinal anesthesia. **Materials and Methods:** In our study, 80 patients (43 – male and 37 – female) between the ages of 18 and 70 years at Sri Venkateswaraa Medical College Hospital and Research Centre, Ariyur, Puducherry, were enrolled and split into Group I and Group II following approval by an ethical committee and written informed consent. Individuals in Group I were given 3 mL of preservative free 0.5% isobaric bupivacaine (Anawin™, bupivacaine hydrochloride, Neon laboratories, India), and Group II patients were given 3 mL of 0.5% isobaric levobupivacaine (Levoanawin™, levobupivacaine hydrochloride, Neon laboratories, India) for spinal anesthesia. A complete preanesthetic checkup was performed the day before surgery. **Results:** In this study, we observed no significant correlation between height, weight, and surgery duration. We discovered a statistically substantial distinction in motor and sensory blockade between the bupivacaine (Group I) and levobupivacaine (Group II) groups. In this study, Group I (50% of patients) had a lower occurrence of hypotension than Group II (20% of patients), indicating a statistically significant variation between the groups. **Conclusion:** When compared to levobupivacaine, individuals in the bupivacaine group required more administration of the vasoactive medicine ephedrine and the sympathomimetic drug atropine. Levobupivacaine is less cardiotoxic, neurotoxic, and equally potent local anesthetic compared to its racemate.

**Key words:** Spinal anesthesia; Bupivacaine; Levobupivacaine

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## INTRODUCTION

When compared to general anesthesia, spinal anesthesia is extensively utilized due to its quick onset and efficacious motor and sensory block. It is also simple to administer and has a strong muscle-relaxing effect, as well as additional benefits such as avoiding airway manipulations, pressor response to intubation, sore throat, emesis, nausea, excessive sedation, and polypharmacy. For lower abdominal and lower leg procedures, spinal anesthetic is preferred because it offers good motor and sensory impediment with quick action, reduced stress, and fewer thromboembolic episodes. The most prevalent approach in individuals undergoing lower abdominal and lower leg procedures is spinal anesthesia with bupivacaine.[1] Bupivacaine (1-butyl-N-[2,6-dimethylphenyl]piperidine-2-carboxamide) was initially produced in 1957 at Bofors Nebel Pharma facilities in Sweden and was characterized by Ekenstam et al.[2] It has

**Address for Correspondence:**
Dr. Chinthavali Sujatha, Assistant Professor, Department of Anaesthesiology, Sri Venkateswaraa Medical College Hospital and Research Centre, Ariyur - 605 107, Puducherry, India. **Mobile:** +91-8939012490. **E-mail:** sujathachinthavali@gmail.com

a protein-bound chemical structure containing a piperidine ring with a chiral center that results in two optically active stereoisomer (levorotatory [S-] and dextrorotatory [R+] configurations). When tested in humans and animals, levobupivacaine, racemic bupivacaine's S(-) enantiomer, has identical motor and sensory block properties but less cardiotoxic than intrathecal bupivacaine[3,4] and can be used for spinal anesthesia as an alternative to bupivacaine.[5] However, the most prevalent negative effects of this approach include bradycardia and systemic hypotension. Hypotension can be dangerous, especially in elderly people with a low cardiac reserve.[6] Levobupivacaine, the isolated S-enantiomer of racemic bupivacaine, belongs to the amide group of local anesthesia. It is the newest local anesthetic agent that lasts a long time, to be approved for clinical usage.[7] In case of an inadvertent intravascular injection, epidural levobupivacaine has the benefit of causing less cardiotoxic effects.[8,9] Levobupivacaine and racemic bupivacaine are now recognized to have equivalent pain-relieving strengths for epidural and spinal anesthesia; however, levobupivacaine is likely to elicit prolonged motor and sensory impediment.[10-12]

### Aims and objectives

The aim of the study was to compare the anesthetic efficacy and hemodynamic effects of isobaric bupivacaine and isobaric levobupivacaine for spinal anesthesia.

## MATERIALS AND METHODS

Eighty patients between the ages of 18 and 70 with American Society of Anesthesiologists (ASA) Class I and II were recruited in the trial after receiving ethical committee permission and provided informed consent. Patients who were to undergo elective lower abdomen and lower leg procedures under spinal anesthesia at Sri Venkateswaraa Medical College Hospital and Research Centre, Ariyur, Puducherry were chosen for the study. A random table generated by a computer (https://www.randomizer.org/) was used to choose 80 patients for the study population. Subjects who had a known intolerance to local amide anesthetics, had general contraindications to spinal anesthesia, or were severely obese (>130 kg or 150% the optimum weight) with an ASA Class of III or IV were not included in the study. Using sealed envelope procedure, individuals were allotted to either of the two study groups randomly. For spinal anesthesia, Group I was given 3 mL preservative-free 0.5% isobaric bupivacaine (Anawin™, bupivacaine hydrochloride, Neon laboratories, India), while Group II was given 3 mL of 0.5% isobaric levobupivacaine (Levoanawin™, levobupivacaine hydrochloride, Neon laboratories, India). A complete pre-anesthetic checkup was performed the day before operation. A general physical examination was performed, as well as a comprehensive evaluation, an inspection of the airway and a local examination of the lumbar spine. Investigations that were pertinent were evaluated. Individuals enrolled in the study were explained about the numerical rating scale (NRS) to measure their level of analgesia on a scale of 0–10 (absolutely no pain - the most pain conceivable) in the post-operative phase. Patients were instructed to limit oral intake of solids and fluids 8 h before surgery. On the night before the procedure, a 0.5 mg alprazolam oral premedication was provided. Subjects were moved to the operating room on the day of surgery, and a multipara monitor was attached. Continuous monitoring was initiated after recording the heart rate (HR), baseline respiratory rate, peripheral oxygen saturation ($SpO_2$), electrocardiography, and non-intrusive systolic and diastolic blood pressure. Patients were given 10 mL/kg body weight of ringer lactate solution through an intravenous (IV) line attached with 18-gauge Intracath™ for over 15–20 min. The study medication was delivered intrathecally in the midline of the L3–4 intervertebral area with a 25-gauge quincke needle under stringent aseptic circumstances and with the participants in a sitting position. An anesthesiologist prepared the drug in comparable syringes while keeping the drug volume constant, then the syringe was passed on to another anesthesiologist who conducted the spinal block while monitoring all of the patient variables.

The subjects were placed in a supine position immediately after receiving the medication. Numbness to the pinprick test in the midline using an 18 G blunt needle was used to assess sensory block. It was done initially for 10 min at 2-min intervals and at 5-min intervals until the level remained constant. The onset of sensory impediment (when the patient feels numb at the T-10 level), the maximum sensory block obtained, the time taken to attain maximum level of sensory block, and the total length of sensory block (regression to the T-10 dermatome) were all recorded. A modified Bromage scale was used to assess motor blockade (0=No paralysis, able to move hips/knees/ankles; 1=Able to move knees but unable to rise extended legs; 2=Able to flex ankles but unable to flex knees; 3=Unable to move any part of the lower limb).[13] After spinal anesthesia, these checks were repeated every 2 min for up to 10 min. Maximum motor impediment acquired, time taken to attain maximum motor block, and duration of total motor block (from the moment of drug delivery to motor restoration to Bromage 0) were all recorded. The surgery was started 10 min after the spinal anesthetic was initiated. The process was altered to general anesthesia if the amount of analgesia was insufficient. The hemodynamic parameters and oxygen saturation were monitored, before spinal anesthesia

was given and then at 5-min intervals till the surgery was completed. A drop in the mean arterial pressure to 60 mm Hg or more than 25% from baseline, also known as hypotension, was medicated with 6 mg of mephentermine bolus; a HR of 50 beats or less per min, defined as bradycardia, was medicated with 0.6 mg of atropine and hypoxia, defined as a drop in $SpO_2$ of <93% was managed with oxygen supplementation through a face mask. Hemodynamic parameters of the patients were monitored every 30 min in the post-operative unit until motor and sensory variables returned to normal. Individuals in both groups were requested to grade their pain on a VAS at every 15 min for 2 h, then every 30 min for 3 h, hourly for 12 h, and finally every 3 h until 24 h after the surgery. Both groups received tramadol hydrochloride (2 mg/kg) IV as a rescue analgesic through injection when they complained of pain (NRS >3). The total analgesia duration was calculated from the time; the medicine was administered subarachnoidally till the time; the patient requested the first dosage of rescue analgesic. Hypotension, bradycardia, sedation, vomiting, nausea, urine retention, headache, pruritus, backache, and neurological changes were all monitored over 24 h.

The study's main objective was to compare the time it takes for the onset of sensory blockade in the two groups. Motor blockade, highest motor/sensory level, time taken to attain peak motor/sensory block, and the degree to which it happens for both the groups were measured as a secondary result. The duration of analgesia and intraoperative hemodynamic impacts was also compared between the groups.

The size of the sample was calculated by substituting the values in standard deviation for the difference between two means (SD). For statistical calculations, the SPSS 20 software was employed. The analysis of variance and paired and unpaired *t* tests was used in the statistical evaluation. The data are provided as a mean minus standard deviation, the significance level of which was P< 0.05. The Chi-square test was used to assess the categorical data.

## RESULTS

In our study, we enrolled totally 80 patients and divided them equally into two groups. In Group I, 23 were male and 17 were female. In Group II, 20 were male and 20 were female. Most of patients affected were between the age group of 41–50 years (31 patients) followed by 51–60 years (21 patients), 31–40 years (13 patients), 61–70 years (10 patients), and 18–30 years (5 patients). Mean age of Group I=51.6±6.4 and Group II=53.84±5.8 (Table 1).

In our study, we observed various parameters such as height, weight, and duration of surgery were showed no significant differences (Table 2).

In our study, we compared the sensory and motor block activity about onset and duration showed significant difference between the two groups (P≤0.05) (Table 3).

The table shows the comparison of side effects between the two groups. Group II had less side effects compared to Group I (Table 4).

## DISCUSSION

The mainstay of spinal anesthesia currently is intrathecal opioids combined with local anesthetics. They preserve hemodynamic stability while enhancing the analgesia's

**Table 1: Age-wise distribution**

| Age (years) | Group I (n=40) | | Group II (n=40) | |
|---|---|---|---|---|
| | Male | Female | Male | Female |
| 18–30 | 1 | 1 | 2 | 1 |
| 31–40 | 2 | 3 | 3 | 5 |
| 41–50 | 8 | 6 | 9 | 8 |
| 51–60 | 7 | 5 | 4 | 5 |
| 61–70 | 5 | 2 | 2 | 1 |
| Total | 23 | 17 | 20 | 20 |

**Table 2: Height, weight, and duration of surgery**

| Parameter | Group I | Group II | P value |
|---|---|---|---|
| Height (cm) | 157.7±5.4 | 156.4±5.1 | 0.417 |
| Weight (kg) | 59.4±6.4 | 57.2±4.4 | 0.384 |
| Duration of surgery (mints) | 69.4±8.7 | 67.4±9.4 | 0.2164 |

**Table 3: Comparison of motor and sensory block between the two groups**

| Parameter | Group I | Group II | P value |
|---|---|---|---|
| Onset of sensory block (min) | 6.84±1.2 | 5.64±2.1 | 0.0347 |
| Onset of motor block (min) | 10.27±0.9 | 9.28±1.3 | 0.0465 |
| Duration of sensory block (min) | 207.8±9.4 | 187.1±7.8 | 0.00941 |
| Duration of motor block (min) | 240.21±10.8 | 194.3±9.9 | 0.002198 |

**Table 4: Comparison of side effects between the two groups**

| Side effects | Group I (n=40) | Group II (n=40) |
|---|---|---|
| Nausea | 5 (12.5%) | 2 (5%) |
| Vomiting | 1 (2.5%) | 0 |
| Hypotension | 20 (50%) | 8 (20%) |
| Bradycardia | 14 (35%) | 4 (10%) |

duration and quality by lowering the dose required of local anesthetics. Drowsiness, pruritus, vomiting, nausea, and, on rare occasions, ventilation depression are also common aftereffects of intrathecal opioids.[14] Fentanyl and Buprenorphine are both opioids that bind to the mu and kappa receptors. Fentanyl derived from phenylpiperidine that induces analgesia, euphoria, bradycardia, and sleepiness and Buprenorphine has approximately 30 times the analgesic efficacy of morphine. In spinal anesthesia, isobaric levobupivacaine is recently being used as a safe substitute for hyperbaric bupivacaine.[5] Intrathecal isobaric levobupivacaine combined with buprenorphine or fentanyl has also been effectively employed lately, though there is no direct comparison in the literature.[15-17] Racemic bupivacaine and levobupivacaine are said to be equivalent. 15–20 mg isobaric 0.5% levobupivacaine is considered to be the intrathecal dosage.[18] Bupivacaine is a local anesthesia that is commonly used as spinal anesthetic due to its great efficacy and lack of neurotoxicity. Because of its equivalent potency and lower neurotoxic and cardiotoxic effects, levobupivacaine is becoming more popular as an alternative for bupivacaine. It exhibits pharmacokinetic features that are extremely comparable to isobaric bupivacaine, and various studies have suggested that the higher rate of protein binding represents a lower level of toxicity.[19] Hence, the current investigation was carried out to compare the anesthetic efficacy and hemodynamic impacts of Bupivacaine and Levobupivacaine in individuals undergoing lower abdominal and lower leg procedures. A total of 80 patients (43 male and 37 female) were enrolled in this trial and separated into Group I and Group II. There was no substantial correlation between height, weight, and surgery duration in this investigation. We discovered a statistically significant distinction in the motor and sensory blockade between the bupivacaine (Group I) and levobupivacaine (Group II) groups in this investigation. The majority of clinical investigations comparing levobupivacaine and bupivacaine has found minimal differences between the two anesthetics and conclude that both perform similarly.[19-21] In 80 individuals who underwent elective hip replacements, Glaser et al.,[4] compared 0.5% isobaric solutions of levobupivacaine and bupivacaine (3.5mL) and found no clinical differences, hence, reaching the conclusion that the two drugs were equipotent and provided identical time of onset, durations, and degrees of sensory and motor blockade. Fattorini et al.,[22] observed no significant variations in spinal blockade features for hip surgery following a comparison of 3 mL 0.5% spinal bupivacaine with levobupivacaine. Sathitkarnmanee et al.,[23] compared the quality of sensory and motor block between 0.5% isobaric solutions of levobupivacaine and bupivacaine (3 mL) for elective lower abdominal and lower limb procedure with spinal anesthesia in 70 subjects and did not discover any notable variations between the two groups. In TUR surgery, Lee et al.,[24] evaluated the efficiency of 2.6 mL of 0.5% isobaric levobupivacaine to 0.5% racemic bupivacaine finding no substantial variations in the motor and sensory block quality or hemodynamic change. There was no statistically significant variation in motor and sensory block between the levobupivacaine and bupivacaine groups, according to Balasubramanian et al.[25]

In the present study, Group I (50% of patients) had a decreased occurrence of hypotension than Group II (20% of patients), indicating that both the groups have a statistically significant difference. Our results were similar to that observed by Mantouvalou et al.,[26] on 120 ASA Class I–III patients that there was a notable decrease in blood pressure in Bupivacaine group (42.5% subjects) compared to Levobupivacaine group (17.5% subjects). A similar study by Erdil et al., discovered that 30% subjects of Bupivacaine group had significant drop in blood pressure following spinal anesthesia compared to 10% patients of levobupivacaine group.[6] According to Balasubramanian et al.,[25] Group B had a higher rate of hypotension (52%) than Group L. (16%). Bradycardia was a prominent finding in our study, with 35% of subjects in Group I having it compared to 10% in Group II. In their study, Mantouvalou et al.,[26] found that bradycardia was experienced by 12.5% of individuals in the Bupivacaine group, while 10% of individuals had bradycardia in the levobupivacaine group. Fattorini et al.,[22] found that levobupivacaine has lower cardiotoxic and neurotoxic effects than bupivacaine, and a few other studies have provided evidence for the same.[27,28] According to a study by Balasubramanian et al.,[25] Group B had more bradycardia (30%) than Group L. (8%). However, according to del-Rio-Vellosillo et al.,[7] there were no variations in hemodynamics or the frequency of detrimental consequences between the two agents.

### Limitations of the study

There are no limitations to this study

## CONCLUSION

The results of this study indicate that 3 mL of 0.5% isobaric levobupivacaine and 3 mL of 0.5% isobaric bupivacaine have slightly different optimal strengths for spinal anesthesia, both in the aspect of onset time and motor and sensory block duration, as well as the regression time for two segment sensory block. When compared to levobupivacaine, individuals in the bupivacaine group needed more administration of the vasoactive medicine ephedrine and the sympathomimetic drug atropine. When

compared to its racemate, it is less cardiotoxic, neurotoxic, and has the same potency as a local anesthetic.

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**CS-** Concept and design of the study, review of literature, and original draft preparation; **SC-** Review of literature, preparation of manuscript, statistical analysis, and interpretation of results; and **AA-** Review, editing, interpretation of results, and revision of manuscript.

**Work attributed to:**
Department of Anaesthesiology, Sri Venkateswaraa Medical College Hospital and Research Centre, Ariyur - 605 107, Puducherry, India.

**Orcid ID:**
Dr. Chinthavali Sujatha - https://orcid.org/0000-0002-8003-3544
Dr. Arthi Asokan - https://orcid.org/0000-0002-8928-7065

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