

Comparative evaluation of intrathecal isobaric levobupivacaine 0.5% and isobaric ropivacaine 0.5% in transurethral resection of prostate surgeries – a randomized control trial



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ABSTRACT

Background: Isobaric levobupivacaine and ropivacaine are newer long-acting local anesthetics that offer a favorable safety profile compared to bupivacaine, making them valuable alternatives for spinal anesthesia, particularly in elderly patients undergoing transurethral resection of the prostate (TURP). **Aims and Objectives:** This study aims to compare the efficacy, duration of anesthesia, hemodynamic stability, and safety of intrathecal 0.5% isobaric levobupivacaine versus 0.5% isobaric ropivacaine, each combined with fentanyl, in patients undergoing TURP. **Materials and Methods:** A total of 100 male patients (> 60 years) undergoing TURP were randomized into two groups (n=50 each). Group I received 2.5 mL of 0.5% isobaric ropivacaine with 0.5 mL fentanyl (25 µg), and Group II received 2.5 mL of 0.5% isobaric levobupivacaine with 0.5 mL fentanyl. Sensory and motor block onset, regression times, duration of analgesia, hemodynamic parameters, and adverse events were recorded and analyzed using the Statistical Package for the Social Sciences (P<0.05 was considered statistically significant). **Results:** Levobupivacaine (Group II) showed a significantly faster onset of sensory block (6.80 ± 1.92 min vs. 9.43 ± 4.66 min; $P=0.000$) and motor block (Grade 1: 3.68 ± 1.32 min vs. 5.12 ± 2.29 min; Grade 3: 5.15 ± 1.64 min vs. 8.19 ± 3.20 min; $P<0.01$) compared to ropivacaine (Group I). Group II also had a longer duration of sensory block (regression to S1: $P=0.001$), motor block ($P=0.034$), and delayed need for supplemental analgesia ($P=0.001$). Hemodynamic parameters remained stable in both groups, though transient differences were noted at 5 min post-injection. Bradycardia occurred more frequently in Group I (34% vs. 12%; $P=0.021$), while other side effects were comparable. **Conclusion:** Both agents provided effective spinal anesthesia with stable hemodynamic profiles in TURP patients. However, levobupivacaine demonstrated superior block characteristics and longer post-operative analgesia, making it more suitable for procedures requiring prolonged anesthesia. Ropivacaine may still be appropriate for short-duration or day-care surgeries.

Key words: Spinal anesthesia; Levobupivacaine; Ropivacaine; Transurethral resection of the prostate; Hemodynamic stability

INTRODUCTION

Although transurethral resection of the prostate (TURP) remains the standard surgical treatment of choice for

benign prostatic hyperplasia,¹ it is commonly associated with significant morbidity.² The procedure is associated with a perioperative morbidity of 18–26% and a mortality rate of 1%.³ Spinal anesthesia is a preferred choice given

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its advantages of being safe in respiratory disease, better reduction in post-operative pain, blunting of the stress response, and earlier detection of transurethral resection syndrome through preserved patient consciousness.^{3,4} However, concerns have been reported regarding the occurrence of hypotension as well as the risk in patients with ischemic heart disease with spinal anesthesia.³

Bupivacaine has a history of being the commonly used long-acting agent for spinal anesthesia;⁵ however, it is also associated with cardiac and central nervous system (CNS) toxicity.^{6,7} To address these concerns, newer agents such as levobupivacaine and ropivacaine have been introduced, with relatively lower cardiac and CNS side effects.⁷ Levobupivacaine is a long-acting agent with a slower onset of action, whereas ropivacaine has a short duration of action combined with a faster motor function recovery.⁷ Thus, the former is considered to be a preferred option for long surgeries, while ropivacaine is better for outpatient surgeries.⁷

Despite their increasing use, there is limited comparative data regarding the efficacy, safety, and hemodynamic impact of isobaric formulations of levobupivacaine and ropivacaine in the TURP population. Given the elderly age group, the need for hemodynamic stability, and the demand for reliable anesthesia with minimal side effects, a direct comparison of these two agents is clinically relevant.

This study was designed to compare intrathecal 0.5% isobaric levobupivacaine and 0.5% isobaric ropivacaine, each in combination with fentanyl TURP, in patients. The duration and onset of sensory and motor blocks were compared as the primary objective. The properties of sensory and motor blocks (onset and duration) were compared as the primary objective. The secondary objectives included assessment of block characteristics, hemodynamic changes, duration of post-operative analgesia, and the incidence of adverse events in both groups.

Aims and objectives

The study aimed to evaluate and compare the efficacy and safety of intrathecal isobaric 0.5% ropivacaine and 0.5% levobupivacaine in elderly patients undergoing transurethral resection of the prostate (TURP).

MATERIALS AND METHODS

Study design

This prospective, randomized controlled trial was conducted in the Department of Anaesthesiology and Critical Care at Sher-i-Kashmir Institute of Medical Sciences (SKIMS), Srinagar, over a period of 18 months, from 2017 to 2019.

The study aimed to evaluate and compare the efficacy and safety of intrathecal isobaric 0.5% ropivacaine and 0.5% levobupivacaine in elderly patients undergoing TURP.

Sample size and population

The required sample size was calculated based on previous studies comparing the onset and duration of spinal block between levobupivacaine and ropivacaine, using a power of 80% and a confidence level of 95%. A minimum of 45 patients per group was estimated to detect a clinically significant difference, and a total of 100 patients were included to account for potential dropouts. The reference for this calculation was derived from Mehta et al.,⁸ and similar clinical trials evaluating block characteristics in lower limb surgeries.

A total of 100 male patients, aged above 60 years, classified as the American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective TURP, were enrolled in the study. All patients submitted a written informed consent.

Group allocation and randomization

Patients were randomly allocated into two equal groups (n=50 each) using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes, which were opened just before the administration of anesthesia. The study was double-blinded. The study participants and the anesthesiologist responsible for recording intraoperative data were blinded to the group allocation.

- Group I (ropivacaine group): Received 2.5 mL (12.5 mg) of 0.5% isobaric ropivacaine combined with 0.5 mL (25 µg) fentanyl, totaling 3 mL.
- Group II (levobupivacaine group): Received 2.5 mL (12.5 mg) of 0.5% isobaric levobupivacaine combined with 0.5 mL (25 µg) fentanyl, totaling 3 mL.

Exclusion criteria

Patients with uncontrolled hypertension or diabetes, chronic obstructive pulmonary disease, infection at the injection site, coagulation disorders, ischemic heart disease, neurological disorders, or a known history of headache or hypersensitivity to amide local anesthetics or opioids were excluded from the study.

Procedure

No pre-medication was administered. After securing an 18-gauge intravenous cannula, patients were pre-loaded with Ringer's lactate at a dose of 20 mL/kg. Baseline hemodynamic parameters, including heart rate (HR), blood pressure, mean arterial pressure (MAP), and oxygen saturation, were recorded.

Spinal anesthesia was performed under aseptic precautions at the L3–L4 interspace using a 26-G Quincke needle in the sitting position. Upon confirmation of free cerebrospinal fluid flow, the allocated anesthetic solution was injected intrathecally over 15 s without barbotage or aspiration. Patients were then positioned supine.

Hemodynamic parameter monitoring was done every 2 min for the first 15 min, followed by every 5 min thereafter. Hypotension (systolic blood pressure <90 mmHg or a decrease >20% from baseline) was managed with 5 mg intravenous ephedrine. 0.5 mg atropine IV was used to treat bradycardia (<60 bpm).

Sensory block was assessed using the pinprick method to determine the time to reach the T10 dermatome, the highest level of block achieved, and regression to S1. Motor block was evaluated using the Modified Bromage Scale, noting time to onset, maximum grade, and regression to grade <3.

Time to the first request for analgesia was recorded, with 1 g of intravenous paracetamol administered for a Visual Analog Scale >3. Side effects included hypotension, bradycardia, nausea, vomiting, shivering, pruritus, sedation, or respiratory depression, which were recorded and treated.

Study endpoints

The primary endpoint compared the onset and duration of sensory and motor blocks between the two groups. Secondary endpoints included hemodynamic stability, time to first analgesic requirement, and the incidence of adverse effects in both groups.

Ethics

The study was approved by the Institutional Ethics Committee, Sher-i-Kashmir Institute of Medical Sciences, with reference number IEC-SKIMS/2019-51 dated November 25, 2019. Ethical conduct was maintained throughout, especially considering the inclusion of elderly patients.

Statistical analysis

The Statistical Package for the Social Sciences software version 23.0 (IBM Corp., Armonk, NY) was used for statistical analysis. The Student's t-test was used to compare continuous variables such as mean $\pm$ standard deviation, and compared using the Student's t-test. Categorical variables, as frequencies and percentages, were compared with the Chi-square test or Fisher's exact test as appropriate. A $P < 0.05$ was considered statistically significant.

RESULTS

This randomized controlled trial compared the intrathecal use of isobaric ropivacaine 0.5% with fentanyl (Group I)

and isobaric levobupivacaine 0.5% with fentanyl (Group II) in 100 patients undergoing TURP.

Baseline characteristics

The demographic and baseline characteristics of patients in the two groups are shown in Table 1. Both groups were comparable in terms of age and ASA physical status. The mean age in Group I (ropivacaine) was 69.0 ± 3.45 years, and in Group II (levobupivacaine) it was 69.44 ± 3.96 years ($P = 0.883$). ASA Grade I and II distributions were not significantly different between groups ($P = 0.384$).

Sensory and motor block characteristics

Group II (levobupivacaine) demonstrated a significantly faster time to achieve the highest sensory level, 6.80 ± 1.93 min, compared to Group I (ropivacaine). Group II (levobupivacaine) demonstrated a significantly faster time to achieve the highest sensory level, 6.80 ± 1.93 min, compared to Group I (ropivacaine), where the highest sensory level was achieved at 9.43 ± 4.66 min ($P = 0.000$). At 9.43 ± 4.66 min ($P = 0.000$). Similarly, motor block onset was faster in Group II (levobupivacaine), with Grade I achieved in 3.68 ± 1.32 min and Grade III in 5.15 ± 1.64 min, as compared to 5.12 ± 2.29 min and 8.19 ± 3.20 min, respectively, in Group I (ropivacaine). ($P = 0.000$ and $P = 0.002$, respectively).

Sensory regression to the S1 level was significantly prolonged in Group II (levobupivacaine) (383.14 ± 16.14 min) compared to Group I (ropivacaine). (286.56 ± 43.05 min; $P = 0.001$). Motor regression to Grade I also took longer in Group II (levobupivacaine) (331.92 ± 47.59 min vs. 224.32 ± 39.20 min; $P = 0.034$). Time to first supplemental analgesia was significantly delayed in Group II (levobupivacaine) (435.32 ± 27.60 min) compared to Group I (ropivacaine). (373.32 ± 29.37 min; $P = 0.001$), indicating longer post-operative analgesia (Table 2).

Furthermore, analysis of the sensory block distribution revealed that a significantly greater proportion of patients in Group II (levobupivacaine) achieved higher sensory levels compared to Group I (ropivacaine). In Group II, 28 patients (56%) reached the T8 level, and 15 patients (30%) attained a sensory level of T6. In contrast, the majority of patients in Group I, 27 patients (54%),

Table 1: ASA status and age distribution

Parameter	Group I (ropivacaine) (%)	Group II (levobupivacaine) (%)	P-value
ASA I	25 (53.19)	22 (46.81)	0.384
ASA II	25 (47.16)	28 (52.83)	0.384
Age (years)	69.0 ± 3.45	69.44 ± 3.96	0.883

ASA: American society of anesthesiologists

Table 2: Sensory and motor blockade characteristics

Parameter	Group I (ropivacaine)	Group II (levobupivacaine)	P-value
Time to highest sensory level (min)	9.43±4.66	6.80±1.93	0.000
Sensory regression to S1 (min)	286.56±43.05	383.14±16.14	0.001
Time to grade 1 motor block (min)	5.12±2.29	3.68±1.32	0.000
Time to grade 3 motor block (min)	8.19±3.20	5.15±1.64	0.002
Motor regression to grade 1 (min)	224.32±39.20	331.92±47.59	0.034
Time to first analgesia (min)	373.32±29.37	435.32±27.60	0.001

reached only the T10 level, with only seven and six patients achieving T8 and T6 levels, respectively. Statistical analysis showed significant differences in the distribution of sensory levels between the groups at T10 ($P=0.011$), T8 ($P=0.013$), and T6 ($P=0.044$). These findings indicate a more extensive cephalad spread of sensory blockade with levobupivacaine (Figure 1).

Hemodynamic parameters

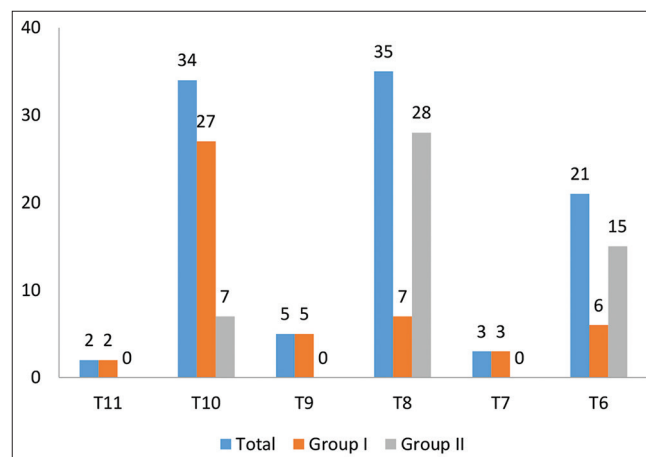
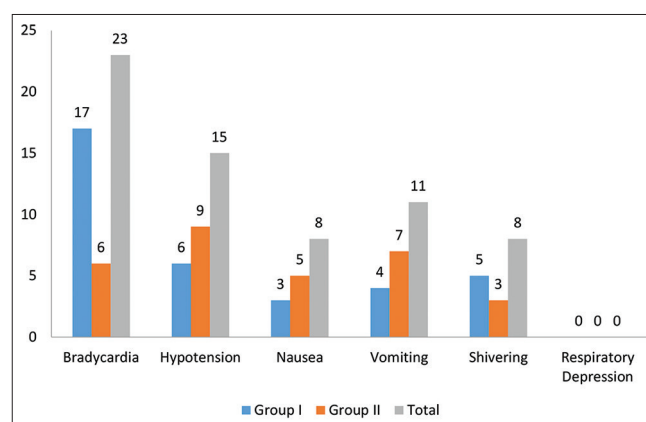
Although baseline hemodynamic values were similar between groups, transient statistically significant differences were noted at 5 and 10 min post-injection, favoring Group II. Beyond these intervals, both groups showed stable trends in HR, blood pressure, and MAP throughout surgery (Table 3).

Adverse effects

Bradycardia was significantly more common in Group I (ropivacaine), affecting 17 patients (34%) compared to 6 patients (12%) in Group II ($P=0.021$). Incidences of hypotension, nausea, vomiting, and shivering were slightly higher in Group II, but these differences were not statistically significant ($P>0.05$). No cases of respiratory depression or pruritus were observed in either group. These findings indicate both drugs were well-tolerated, with levobupivacaine associated with fewer cardiovascular adverse effects (Figure 2).

DISCUSSION

The present study provides a comprehensive comparison of isobaric levobupivacaine and isobaric ropivacaine for spinal anesthesia in patients undergoing TURP. By evaluating sensory and motor block characteristics, hemodynamic

**Figure 1:** Highest sensory levels achieved (n)**Figure 2:** Side effect comparison between Group I and Group II (n)

stability, and side effect profiles, we highlight the strengths and limitations of these commonly used local anesthetics.

Levobupivacaine demonstrated a faster onset of sensory block compared to ropivacaine, as indicated by the time to achieve the highest sensory level (6.80 ± 1.92 min in Group II vs. 9.43 ± 4.66 min in Group I; $P=0.000$). Our study was supported by similar findings of Mehta et al.⁸ The longer sensory block duration in the levobupivacaine group (383.14 ± 16.14 min vs. 286.56 ± 43.05 min in the ropivacaine group; $P=0.001$) further supports its efficacy. The findings of Mantouvalou et al.,⁹ and Cappelleri et al.,¹⁰ combined with our study results, highlight the pharmacokinetic advantage of levobupivacaine in achieving sustained sensory blockade.

The levobupivacaine group showed a higher sensory block (T8 or above in 56% of patients) as compared to the ropivacaine group (T10 in 54% of patients), which emphasizes the potency of levobupivacaine. Likewise, Athar et al.,⁷ also reported higher levels of sensory blockade with levobupivacaine in lower limb surgeries.

Table 3: Hemodynamic parameters at key intervals

Time point	HR (bpm)	Group II	P-value	SBP (mmHg)	Group I	Group II	P-value	DBP (mmHg)	Group I	Group II	P-value	MAP (mmHg)	Group I	Group II	P-value
Baseline	79.80±14.46	78.76±7.98	0.400	145.94±14.49	144.43±14.51	0.240	83.20±6.99	83.79±7.73	0.770	98.84±16.41	97.24±8.61	0.340			
5 min	79.06±14.14	73.52±8.51	0.020	141.62±9.93	132.90±11.17	0.002	76.64±9.38	77.70±8.33	0.550	89.18±12.34	84.46±6.93	0.020			
10 min	76.52±13.31	71.68±8.50	0.030	128.80±17.00	127.33±18.83	0.100	74.68±9.68	75.08±7.76	0.810	80.66±14.95	81.48±8.14	0.100			
End surgery	71.98±10.82	70.50±8.19	0.440	122.92±19.24	120.70±15.55	0.090	71.76±7.81	73.08±7.64	0.270	81.78±9.44	83.66±5.97	0.330			

HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, MAP: Mean arterial pressure

HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, MAP: Mean arterial pressure

In our study, levobupivacaine not only exhibited a faster onset of motor block but also maintained a longer duration compared to ropivacaine. The levobupivacaine group had a shorter mean time to Grade I motor block (3.68 ± 1.32 min) than in the ropivacaine group (5.12 ± 2.29 min; $P=0.000$), and the time to Grade III motor block showed a similar trend (5.15 ± 1.64 min vs. 8.19 ± 3.20 min; $P=0.002$).

The prolonged motor regression time to Grade I in the levobupivacaine group (331.92 ± 47.59 min vs. 224.32 ± 39.20 min in the ropivacaine group; $P=0.034$) aligns with observations by Mantouvalou et al.⁹ This extended duration of motor blockade may be advantageous in surgeries requiring prolonged immobilization but could be a limiting factor in ambulatory procedures.

Both groups demonstrated comparable baseline hemodynamics. However, significant differences were noted at 5 min post-spinal anesthesia, where the levobupivacaine group exhibited better HR and MAP stability. Similar findings were reported by Athar et al.,⁷ and Mehta et al.,⁸ supporting the theory that sympathetic blockade by levobupivacaine is less compared to ropivacaine, which reduces the risk of abrupt hemodynamic changes.

Despite transient differences, both anesthetic agents maintained overall hemodynamic stability throughout the procedure. These results suggest that no significant intergroup differences in systolic or diastolic blood pressures were noted at most time points.

The levobupivacaine group had a significantly longer time to first supplemental analgesia, compared to the ropivacaine group ($P=0.001$). This finding highlights the superior analgesic efficacy of levobupivacaine, consistent with studies by Cappelleri et al.,¹⁰ and Casati et al.¹¹ The prolonged duration of analgesia with levobupivacaine can enhance post-operative comfort and reduce the need for additional analgesic interventions.

Bradycardia was significantly more frequent in the ropivacaine group (34%) compared to the levobupivacaine group (12%; $P=0.021$). This may be due to the differential effects of these agents on sympathetic tone. Other side effects, including hypotension, nausea, vomiting, and shivering, were slightly more common in the levobupivacaine group, but the differences were not statistically significant, as observed in studies by Athar et al.⁷ Respiratory depression was not noted in either group, reflecting the safety profile of both agents.

While the majority of our findings are consistent with prior research, discrepancies exist. For instance, Gautier et al.¹² and Lim et al.¹³ reported no significant differences

in the duration of analgesia between ropivacaine and levobupivacaine. These variations may be attributed to differences in study design, patient populations, and drug dosages.

Similarly, Athar et al.⁷ observed faster onset of sensory and motor block with ropivacaine compared to levobupivacaine, in contrast to our study. This discrepancy could be due to their use of a higher concentration of ropivacaine (0.75%) and a younger study population (18–60 years) compared to our study, which used 0.5% concentrations in elderly patients (>60 years).

The results of this study suggest that levobupivacaine offers significant advantages over ropivacaine for spinal anesthesia in TURP patients, particularly in terms of sensory and motor block duration, prolonged analgesia, and reduced incidence of bradycardia. These benefits are particularly relevant in elderly patients with comorbid conditions, where hemodynamic stability and prolonged analgesia are crucial.

Overall, this study adds to the growing body of evidence supporting the use of levobupivacaine as a safe and effective alternative to ropivacaine for spinal anesthesia. Further research, particularly multicentric randomized controlled trials, is needed to validate these findings and explore their applicability in other surgical contexts.

Limitations of the study

Our study was powered adequately to detect differences in block characteristics, with the results being favorable. However, it is not devoid of limitations. The small sample size (n=100) may restrict the generalization of the study findings across a broader population. Thus, we believe that larger, multi-centric trials are warranted to validate the results in a diverse population base and clinical settings.

CONCLUSION

This study demonstrates that both 0.5% isobaric ropivacaine and 0.5% isobaric levobupivacaine, when combined with 25 µg fentanyl for spinal anesthesia, are effective in providing adequate anesthesia and maintaining hemodynamic stability during TURP, but levobupivacaine offers significant advantages. Patients receiving levobupivacaine experienced a faster onset and greater height of sensory and motor block, prolonged block duration, and delayed need for post-operative analgesia, all of which were statistically significant. In addition, levobupivacaine was associated with a lower incidence of bradycardia, indicating a more favorable cardiac safety profile.

Based on these findings, levobupivacaine is the more effective and safer agent for spinal anesthesia in elderly patients undergoing TURP, especially when a longer duration of anesthesia and analgesia is desired.

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Authors' Contributions:

SB- Literature survey, implementation of study protocol, collection and analysis of data, and prepared first manuscript draft; **VC**- Manuscript preparation and revisions, manuscript editing, data analysis and statistical analysis, and literature review; **PG**- Statistical analysis and interpretation, manuscript revision, and table preparation; **AV**- Manuscript review and editing, graphical preparation, and manuscript submission; **SS**- Manuscript review.

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