

# Effect of Isobaric Levobupivacaine and Fentanyl versus Isobaric Ropivacaine and Fentanyl as an Adjuvant in Patients undergoing Transurethral Resection of the Prostate: A Randomised Clinical Study

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## ABSTRACT

**Introduction:** Ropivacaine is a newer local anaesthetic proven to have a lower systemic toxicity profile, particularly in terms of cardiac and Central Nervous System (CNS) toxicity, than the racemic and levorotatory isomers of bupivacaine, especially in elderly patients. Fentanyl, as an adjuvant, enhances analgesia and promotes early postoperative mobility.

**Aim:** To assess and compare the efficacy and safety of isobaric levobupivacaine and fentanyl versus isobaric ropivacaine and fentanyl in patients undergoing Transurethral Resection of the Prostate (TURP) under Spinal Anaesthesia (SA).

**Materials and Methods:** A randomised clinical study was conducted in the Department of Anaesthesia at SMS Medical College and Attached Hospitals, Jaipur, Rajasthan, India, from March 2021 to January 2023. A total of 60 patients ranging in age from 40 to 80 years, scheduled for elective TURP, were enrolled in the present study. The selected patients were randomly assigned into two groups, each consisting of 30 patients. Group A received a dosage of 2.6 cc of 0.75% isobaric ropivacaine (equivalent to 19.5 mg) along with 0.4 cc of fentanyl (equivalent to 20 micrograms). In contrast, group B received a dosage of 2.6 cc of 0.5% isobaric levobupivacaine (equivalent to 13 mg) and 0.4 cc of fentanyl (20 micrograms). The primary outcome measures were the onset of action, duration of sensory-motor block, and postoperative analgesia. Data were analysed using Epi Info version 7.2.1.0 statistical software. The quantitative data collected were summarised using the mean and Standard

Deviation (SD). A p-value of less than or equal to 0.05 was considered statistically significant.

**Results:** The majority of patients in the present study were elderly males in both groups. The mean age distribution in group A was 64.27±8.17, and in group B, it was 65.13±7.1. Both groups were comparable and not statistically significant (p=0.634). The mean weight of the two groups was similar, with group A at 64.9±7.49 kg and group B at 63.1±6.96 kg. Both groups were comparable and not statistically significant (p=0.334). The mean height of the patients was 165±4.85 cm in group A and 164±3.83 cm in group B, and it was comparable between the two groups without statistical significance (p=0.145). The duration of sensory block was 241.03±18.88 minutes in group A and 181.5±33.42 minutes in group B. The duration of motor block was 210.7±17.93 minutes in group A and 160±14.82 minutes in group B. Group A demonstrated a significant prolongation of sensory (p<0.001) and motor (p<0.001) block, as well as postoperative analgesia, when compared to 0.5% levobupivacaine with fentanyl.

**Conclusion:** The requirement for rescue analgesia occurred earlier in the levobupivacaine group. Therefore, the use of ropivacaine with fentanyl for spinal anaesthesia in TURP cases is a superior alternative compared to levobupivacaine with fentanyl, as it provides satisfactory quality and duration of block, as well as a longer duration of postoperative analgesia, as assessed by the Visual Analogue Scale (VAS) score and Modified Bromage score.

**Keywords:** Analgesia, Elderly, Transurethral resection of prostate

## INTRODUCTION

The TURP is a highly prevalent procedure performed for the treatment of Benign Prostatic Hyperplasia (BPH). The majority of patients who undergo these surgeries are elderly individuals. Spinal Anaesthesia (SA) is the most commonly utilised technique for TURP due to its ability to provide surgical anaesthesia, extended pain relief during the postoperative period, and effective management of acute operative pain, as well as the suppression of autonomic, somatic, and endocrine responses. Under SA, the patient remains awake, allowing for prompt recognition of signs and symptoms associated with water intoxication, fluid overload, TURP syndrome, and bladder perforation [1].

Historically, hyperbaric bupivacaine (0.5%) has been the preferred local anaesthetic for SA. However, the use of bupivacaine has been associated with an increased risk of fatal cardiac toxicity,

despite its long-acting properties. As a result, levobupivacaine, an S-enantiomer of bupivacaine, has emerged as a safer alternative. Levobupivacaine possesses similar pharmacodynamic characteristics to racemic bupivacaine, but it is less cardiotoxic and neurotoxic. However, it does offer a shorter duration of motor block compared to racemic bupivacaine. Another novel long-acting local anaesthetic, ropivacaine, has demonstrated similar efficacy to bupivacaine but with an improved safety profile, making it a valuable asset in regional anaesthesia [2-5]. Although levobupivacaine and ropivacaine exhibit prolonged durations of action, they do not provide sustained postoperative analgesia. The presence of uncontrolled postoperative pain can lead to various unfavourable acute and chronic consequences [4].

To address this issue, different adjuvants such as lipophilic opioids (e.g., fentanyl) are increasingly being administered intrathecally as supplements to local anaesthetics. This approach aimed to enhance

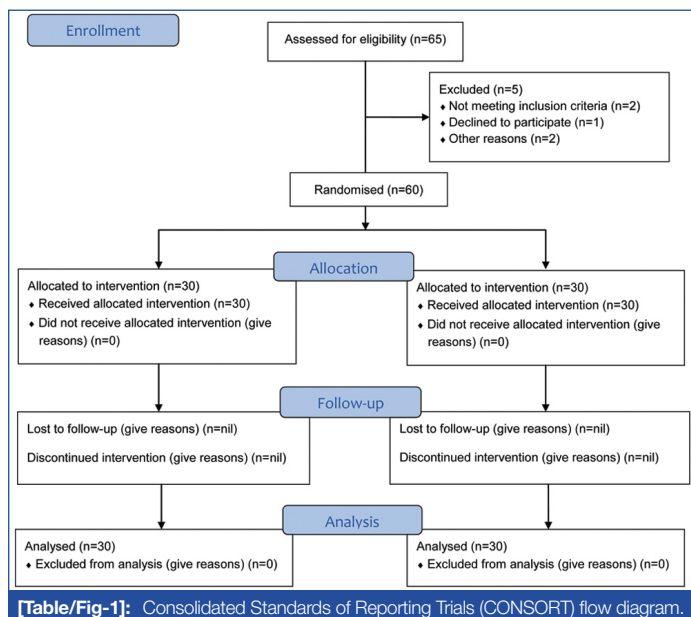
sensory blockade, thereby improving perioperative analgesia and intensifying sensory-motor blockade without exacerbating sympathetic blockade or prolonging motor recovery and discharge time. Additionally, it allows for the reduction of the local anaesthetic dose, particularly in high-risk patients and ambulatory procedures [6].

The objective of the present study was to evaluate and compare the effectiveness and safety of isobaric levobupivacaine with fentanyl versus isobaric ropivacaine with fentanyl in patients undergoing TURP under SA. The present study sought to compare the onset and duration of sensory and motor blockade provided by these two drugs, as well as the duration of analgesia, haemodynamic parameters, and side effects.

## MATERIALS AND METHODS

A randomised clinical study was conducted at SMS Medical College in Jaipur, India, from March 2021 to January 2023, following approval obtained from the Institutional Ethics Committee (IEC) (ref. no.: 1170/MC/EC/2021). Written consent was obtained from each patient, and the study enrolled a total of 60 individuals ranging in age from 40 to 80 years, with American Society of Anesthesiologists (ASA) physical status I-III, who were scheduled to undergo elective TURP. The study design was registered with the Clinical Trials Registry-India CTRI/2022/08/045107.

Selected patients were randomly allocated into two groups of 30 each using a computer-generated random number table, and the group allocations were kept in sequential brown envelopes. The Consolidated Standards of Reporting Trials (CONSORT) diagram is provided in [Table/Fig-1].



**Inclusion criteria:** Patients aged between 40-80 years with ASA physical status grade I-III, height  $\geq 150$  cm, weight 45-75 kg, and undergoing TURP surgery for a duration of 60-90 minutes were included in the study.

**Exclusion criteria:** Patients with negative consent, ASA physical status grade IV, contraindication to SA, local anaesthetic, drug allergy, or insufficient cognitive ability were excluded from the study.

**Sample size calculation:** A sample of 30 cases in each group is adequate at a 95% confidence interval and power of 80% to validate the expected difference of three in mean with a SD of 1.07 for the time of onset of sensory blockade (in minutes). This validation is required to compare the effects of isobaric levobupivacaine and fentanyl with isobaric ropivacaine and fentanyl in patients undergoing TURP [7].

### Study Procedure

After checking the written informed consent and fasting status, patients were taken to the operating theatre. An intravenous

infusion of normal saline at a rate of 4 mL/kg/hr was started using an 18 G cannula. Patients were monitored with standard anaesthetic monitors, including non invasive blood pressure, pulse oximetry, and Electrocardiogram (ECG). Baseline blood pressure, Mean Arterial Pressure (MAP), Heart Rate (HR), and Oxygen Saturation (SpO<sub>2</sub>) were noted.

With the patient in a sitting position, SA was performed under strict aseptic conditions. A 25 G Quincke's Babcock needle was used with a midline approach at the L4-L5/L3-L4 level. Patients received the study drugs according to their allocated group. Group A received a combination of 2.6 cc of isobaric ropivacaine with a concentration of 0.75% (containing 19.5 milligrams) and 0.4 cc of fentanyl with a dosage of 20 mg. Group B received 2.6 cc of 0.5% isobaric levobupivacaine (containing 13 mg) combined with 0.4 cc of fentanyl with a dosage of 20 micrograms [7].

Upon injection administration, the patient was immediately placed in a supine position with a neutral position. Once a sensory level beyond T10 was confirmed, the patient was positioned in the lithotomy position. Continuous electrocardiography, pulse oximetry, and intermittent Non Invasive Blood Pressure (NIBP) monitoring were conducted throughout the surgery. Hypotension, defined as a decrease in systolic blood pressure by more than 20% from the baseline value, was managed by administering intravenous fluids and incremental doses of mephentermine 5 mg intravenously. Bradycardia, defined as a heart rate below 60 beats per minute, was managed with incremental doses of atropine 0.4-0.6 mg intravenously. Any other immediate adverse effects experienced after intrathecal injection or during the perioperative period were observed and treated accordingly.

The level of sensory block was evaluated following the intrathecal injection of the study drug using a 20 G hypodermic needle (pinprick method) along the midclavicular line on both sides. The onset of sensory block was defined as the duration from the intrathecal injection of the study drug to the time required to achieve anaesthesia to pinprick at the T10 dermatomal level. The duration of sensory block was defined as the time taken for the sensory block to regress upto a 2-segment dermatome from the highest level achieved.

The onset of motor block was defined as the time taken for the motor block to reach a Bromage score of 3. Motor block was assessed using the Bromage scale. In the present study, authors recorded the onset and duration of motor block. The duration of motor block was evaluated by measuring the time from the highest to the lowest Bromage level.

Postoperatively, pain was assessed using a VAS, which involves the use of a 10 cm line divided into 10 equal parts. One end of the line represents the worst pain imaginable, while the other end represents no pain at all. The time of the first analgesic demand was noted, and intravenous tramadol 50 mg was administered as rescue analgesia.

## STATISTICAL ANALYSIS

The data were examined using the statistical software Epi Info version 7.2.1.0. All the data were recorded in an Excel spreadsheet. The quantitative data were presented as the mean and SD. The nominal or categorical variables were summarised as frequency (n) and percentage (%) and were analysed using the Chi-square test. The continuous variables were summarised as the mean and SD and were analysed using the independent sample t-test to compare between the two groups. A p-value  $\leq 0.05$  was considered statistically significant.

## RESULTS

The demographic data in both groups were comparable, with no significant differences in terms of age, weight, height, ASA

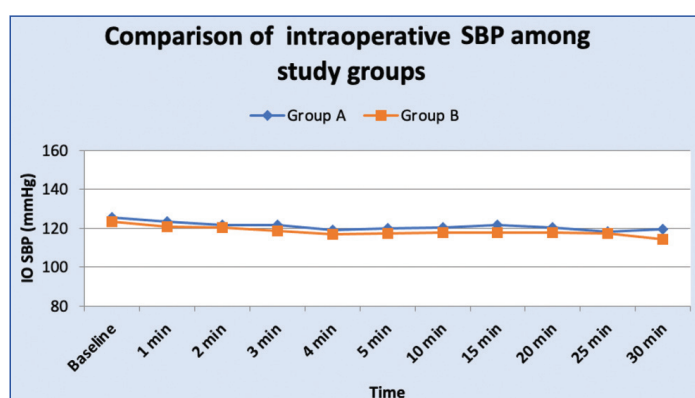
classification, and duration of surgery [Table/Fig-2]. The onset of block and the time required for complete sensory and motor block were observed to be earlier in group A compared to group B, as shown in [Table/Fig-3]. The differences between the two groups were found to be statistically highly significant, with a p-value of less than 0.001. The duration of sensory and motor blockade and the duration of analgesia were longer in group A compared to group B, and the differences were statistically significant ( $p < 0.001$ ) [Table/Fig-3]. Patients were haemodynamically stable in terms of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), MAP, HR and SpO<sub>2</sub> [Table/Fig-4-8]. No significant difference was observed between the two groups. None of the patients required supplemental oxygen, analgesia, or anxiolysis during the operation. There were no notable discrepancies between the two groups in terms of side effects [Table/Fig-9].

Variables	Group A (n=30) (Mean±SD)	Group B (n=30) (Mean±SD)	p-value
Age (in years)	64.27±8.17	65.13±7.1	0.634
Weight (kg)	64.9±7.49	63.1±6.96	0.334
Height (cm)	165.97±4.85	164.3±3.83	0.145
ASA grade (I/II/III)	11/17/2	14/13/3	0.579
Duration of surgery (in minutes)	50.83±11.30	52.±16.38	0.749

**[Table/Fig-2]:** Demographic profile of study groups. Values are in mean±SD ( $p > 0.05$  was considered statistically non significant); Test applied: Student's t-test

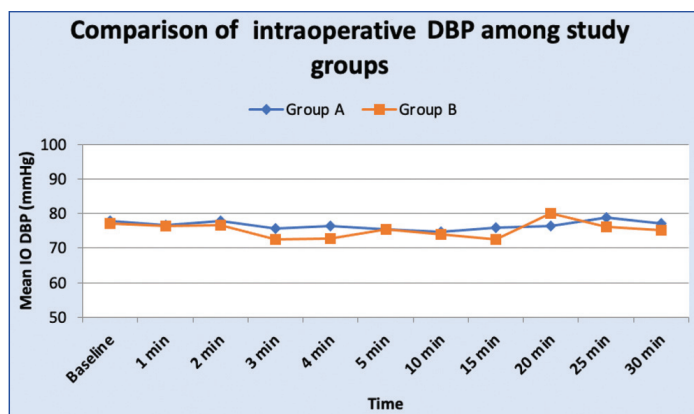
Variables	Group A (Mean±SD)	Group B (Mean±SD)	p-value
Time to reach T <sub>10</sub> sensory blockade level (min)	2.25±0.52	2.67±0.86	<0.001
Onset time of motor blockade (min)	4.23±0.97	5.54±0.82	<0.001
Duration of sensory blockade (min)	241.03±18.88	181.5±33.42	<0.001
Duration of motor blockade (min)	210.7±17.93	160±14.82	<0.001
Time to two segment regression (min)	122.53±10.06	106.27±10.72	<0.001
Time of first dose of rescue analgesia (in min)	304.47±78.72	157.53±11.22	<0.001

**[Table/Fig-3]:** Characteristics of Spinal Anaesthesia (SA) in two groups. Values are in mean±SD ( $p < 0.001$  was considered statistically highly significant); Test applied: Student's t-test; min: Minutes

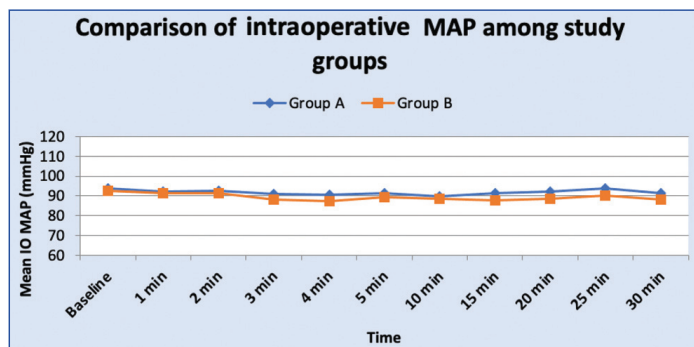


**[Table/Fig-4]:** Systolic Blood Pressure (SBP) among study groups (baseline and post spinal).

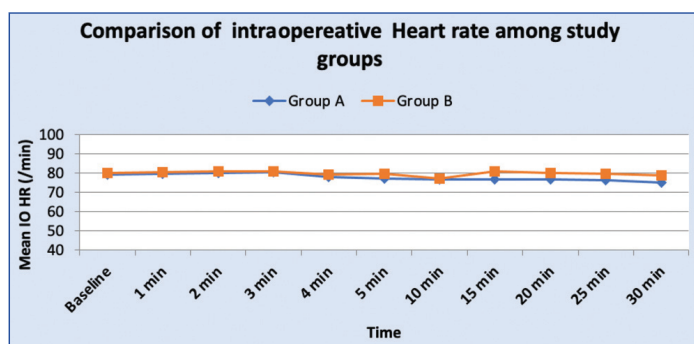
The mean Modified Bromage score at 1, 2, 3, and 4 hours postoperatively with SD was calculated. The t-test was applied between the groups and it was observed that the Modified Bromage score was significant at 2, 3, and 4 hours postoperatively among the two groups with a p-value <0.05 [Table/Fig-10]. Intraoperative pain was assessed by evaluating the VAS at five minutes after spinal anaesthesia. The mean VAS score was found to be comparable between the two study groups, with a p-value of 0.922, which is statistically not significant [Table/Fig-11].



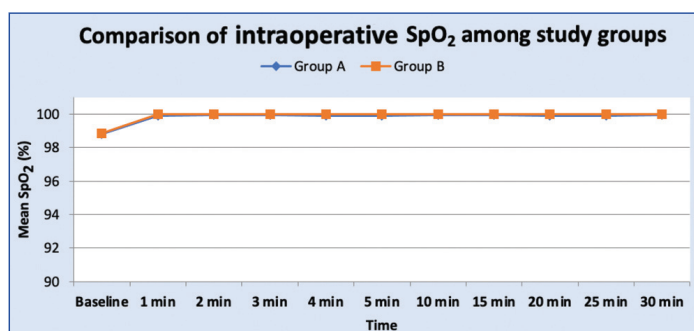
**[Table/Fig-5]:** Diastolic Blood Pressure (DBP) among study groups (baseline and post spinal).



**[Table/Fig-6]:** Mean Arterial Pressure (MAP) among study groups (baseline and postspinal).



**[Table/Fig-7]:** Heart Rate (HR) among study groups (baseline and post spinal).



**[Table/Fig-8]:** SpO<sub>2</sub> among study groups (baseline and post spinal).

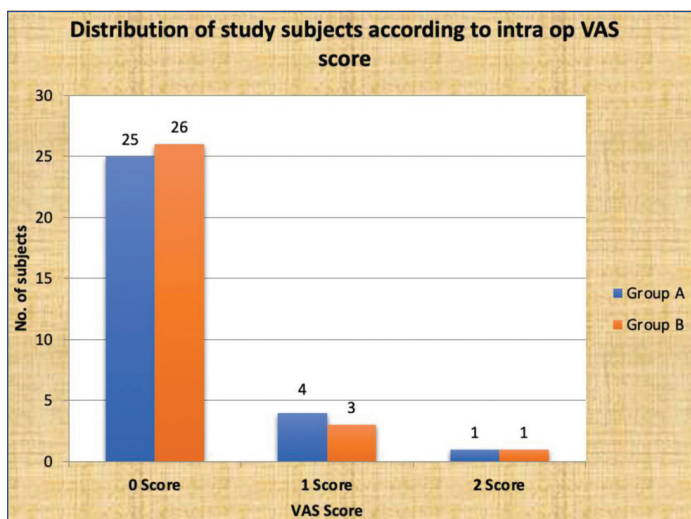
Variables	Group A n (%)	Group B n (%)	p-value
Hypotension	0	2 (6.7)	0.472
Bradycardia	0	2 (6.7)	0.472
Vomiting	0	2 (6.7)	0.472
Nausea	2 (6.7)	2 (6.7)	0.605

**[Table/Fig-9]:** Side-effects among study groups.

Time (in hours)	Group A (Mean±SD)	Group B (Mean±SD)	p-value
1	1.33±0.48	1.47±0.57	0.332
2	2.53±0.63	3.27±0.74	<0.001*

3	3.63±0.76	4.47±0.73	<0.001*
4	4.83±0.7	5.5±0.63	<0.001*

**[Table/Fig-10]:** Comparison of mean Modified Bromage score among study groups. p<0.001\* statistically highly significant



**[Table/Fig-11]:** Intraoperative Visual Analogue Scale (VAS) score among study subjects.

## DISCUSSION

Subarachnoid block is a commonly used anaesthetic technique for TURP. It is a safe, reliable, and cost-effective technique that provides adequate anaesthesia for surgery by relaxing the pelvic floor muscles and perineum. One advantage of using subarachnoid block is that the patient remains awake, allowing early recognition of signs and symptoms of TURP syndrome and bladder perforation [7]. Many patients undergoing TURP or Transurethral Resection of Bladder Tumour (TUR-BT) are elderly and may have co-existing pulmonary and cardiac diseases. By choosing levobupivacaine and ropivacaine, potential adverse effects can be avoided [8]. To address this concern, pre-emptive mixing of opioids with local anaesthetics for regional anaesthesia provides a better alternative. The addition of fentanyl in low doses to local anaesthetics enhances analgesia and intensifies motor and sensory blockade by acting on opioid receptors in the substantia gelatinosa of the dorsal horn of the spinal cord. Fentanyl, as an adjuvant, shortens the onset time and prolongs the duration of sensory block [9].

In the present study, it was observed that the mean onset time of sensory blockade at the T10 dermatome was achieved earlier in group A than in group B, and this difference was statistically significant (p-value <0.001). In a study by Chaudhary A et al., the time taken for onset of sensory blockade at the T10 level was reported to be 4.50±1.62 minutes in group A and 5.32±1.50 minutes in group B, which is longer than the time observed in the present study. This difference could be due to the smaller drug dose (1.8 mL ropivacaine 0.75%+fentanyl 10 µg) used in their study [10]. Esmaoğlu et al., reported in their study that the time taken for onset of sensory blockade in the levobupivacaine group was 2.2±0.7 minutes and the time to reach T10 was 7.5±2.7 minutes [11], which is much longer than the present study. However, this could be attributed to the synergistic effect of fentanyl that we used as an adjuvant to ropivacaine.

Both groups in the current study achieved a T10 sensory level, which is consistent with the findings of McNamee DA et al., In their study, reported a median onset time of sensory block at the T10 dermatome of two minutes (range 2-5 minutes) in group R and two minutes (range 2-9 minutes) in group B [12]. The mean onset time of motor block was higher in group B (5.54±0.82 minutes) compared to group A (4.23±0.97 minutes), and this difference was statistically significant with a p-value of <0.001. This finding is consistent with the study conducted by Seetharam KR and Bhat G, where

they reported a mean onset time of motor block in group RF of 5.2±1.1 minutes [13].

The mean duration of sensory block was statistically significant in both group A (241.03±18.88 minutes) and group B (181.5±33.42 minutes) with a p-value of <0.001. This result aligns with a study conducted by Bhati K et al., which also concluded that the sensory block duration in the ropivacaine with fentanyl group was 211.67±21.24 minutes, which is comparable to the present study [14]. Additionally, the results of the present study were similar to a study done by Akhtar N et al., in 2016, which showed that the duration of sensory block was longer in group RF than in group R (245.66±22.35 minutes vs 187.16±17.053 minutes; p<0.001) [15]. The duration of motor block was another crucial primary outcome to determine. The mean duration of motor block was statistically significant in both group A (210.7±17.93 minutes) and group B (160±14.82 minutes) with a p-value of <0.001. The present study's results were comparable to the study conducted by Akhtar N et al., in 2016, where they reported that group RF (289.33±23.11 minutes) produced a significantly longer duration of motor block compared to group R (232.33±18.65 minutes; p<0.001) [15]. However, the results of the present study differ from Mantouvalou M et al., who reported a duration of 269±20 minutes in group R but achieved with a smaller dose of 15 mg. This discrepancy could be attributed to the different definitions of motor study parameters used by Mantouvalou M et al., [16].

The mean time to two-segment sensory regression in the two study groups, group A (122.53±10.06 min) and group B (106.27±10.72 min), was statistically significant with a p-value of <0.001. This finding indicates that sensory blockade was longer in group A than in group B. Similar observations have been made in several other studies [5,11,12]. A report by Chaudhary A et al., indicated that there was no significant difference in the duration of two-segment regression and regression of sensory block to S1 between group A (105.35±12.30 min and 276.25±61.53 min, respectively) and group B (106.10±10.42 min and 287.22±65.10 min, respectively) [10]. The outcomes of these investigations exhibit similarities to the findings obtained from the current study.

Bhati K et al., conducted a research endeavor in which group A was administered isobaric levobupivacaine (0.5%, 0.3-0.4 mg/kg), while group B received isobaric ropivacaine (0.5%, 0.5 mg/kg) intrathecally. Both groups were administered fentanyl (0.2 µg/kg) as an adjuvant. The authors of the aforementioned study reported a shorter duration for the two-segment regression of sensory block in the levobupivacaine group (85.53±5.93 min) compared to the ropivacaine group (80.17±12.77 min). This difference could be attributed to the use of different age groups (pediatric) and lower drug doses in their study [14]. Layek A et al., observed in their study that the two dermatome regression time in sensory block was significantly shorter in their study (median 120 min vs 85 min; p<0.001). These findings are comparable to the present study [17]. Additionally, the mean time to the first dose of analgesia was longer in group A compared to group B (304.47±78.72 min vs. 157.53±11.22 min), and this difference was statistically significant with a p-value of less than 0.001. This indicates that the requirement of rescue analgesia was lower in group A compared to group B. Vampugalla PS et al., conducted an observation that indicated the comparability of the duration of analgesia between levobupivacaine and ropivacaine [18]. In contrast, Marron-Pena M and Rivera-Flores J concluded that the utilisation of hyperbaric Ropivacaine in their study resulted in longer-lasting residual analgesia and a quicker recovery of motor block [19].

In the present study, the difference in intraoperative Systemic Mean Systolic (SBP) and Diastolic Blood Pressure (DBP) (mmHg) among the groups was non significant. Intraoperative mean heart rate

was also found to be non significant. The findings of the present study are in accordance with the study done by Chaudhary A et al., which suggested that the addition of fentanyl to ropivacaine may offer the advantage of a shorter duration of complete motor block, haemodynamic stability, and without any increase in the frequency of major side effects [10]. In the current investigation, participants in group B exhibited a higher frequency of hypotension and nausea compared to group A. The incidence of hypotension and nausea in group B was determined to be 6.66%. However, these disparities were found to lack statistical significance. From a safety perspective, the administration of intrathecal ropivacaine demonstrates a heightened level of cardiovascular stability accompanied by a reduced occurrence of bradycardia. None of the patients in group A experienced bradycardia, while only 6.66% of those in group B did, which is comparable to the findings of Mantouvalou M et al., who reported a 5% incidence rate [16]. The present study's findings align with other studies conducted by Chaudhary A et al., and Koltka K et al., [10,20]. However, Athar M et al., discovered a higher incidence of hypotension in the levobupivacaine group compared to the ropivacaine group [4].

### Limitation(s)

In the present study, only patients who required TURP with ASA physical status I, II, III were included. The present study was limited to the elderly age group as BPH commonly occurs in this age group. Results may vary in other age groups and other types of surgeries. The results may also vary from investigations performed on other ethnic groups due to potential differences in body composition, height, and variations in subjective anaesthetic sensitivity.

### CONCLUSION(S)

The present study concluded that both drugs, ropivacaine and levobupivacaine with fentanyl, were well tolerated and provided effective anaesthesia. They can be safely used in TURP surgeries without significant haemodynamic changes. Ropivacaine, when combined with fentanyl, provides a faster onset and longer duration of sensory and motor blockade, as well as a prolonged duration of postoperative analgesia compared to 0.5% levobupivacaine with fentanyl. Therefore, for spinal anaesthesia during TURP, ropivacaine with fentanyl is a better option than levobupivacaine with fentanyl.

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#### AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

#### PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Apr 25, 2023
- Manual Googling: Jul 20, 2023
- iThenticate Software: Oct 05, 2023 (14%)

#### ETYMOLOGY: Author Origin

EMENDATIONS: 10

Date of Submission: **Apr 21, 2023**  
Date of Peer Review: **Jun 09, 2023**  
Date of Acceptance: **Oct 07, 2023**  
Date of Publishing: **Nov 01, 2023**