Comparison of Saddle Block and Subarachnoid Block for Transurethral Resection of The Prostate in Elderly Cardiac Patients: A Randomized Clinical Trial

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ABSTRACT

Background: Transurethral resection of the prostate (TURP) commonly utilizes spinal anesthesia, but this method can pose risks, particularly hypotension. Saddle block, a variation of spinal anesthesia, targets the pelvic region and sacral nerve roots, potentially reducing hemodynamic disturbances.

Aim: To compare the hemodynamic effects and surgical adequacy of saddle block versus subarachnoid block for TURP in elderly cardiac cases. **Patients and Methods:** A total of sixty cases aged 60 and older with American Society of Anaesthesiologists III classification scheduled for TURP. They were randomly allocated into 2 groups of 30 patients each. Group I had subarachnoid block with 2 ml of levobupivacaine. Two millilitres of levobupivacaine were administered to Group II along with saddle block. Baseline and subsequent measurements for oxygen saturation, heart rate, diastolic, systolic, and mean arterial pressures have been recorded. Block levels were assessed, and ephedrine was administered as needed to manage hypotension. The total amount of vasopressors used was documented. Complications were monitored throughout.

Results: Group II (saddle block) exhibited a significantly lower incidence of hypotension compared to Group I (subarachnoid block) and required fewer vasopressors ($P < 0.05$). Both groups achieved adequate surgical conditions. No cases of volume overload, TURP syndrome, or bladder perforation were observed in either group.

Conclusion: Saddle block provides a safer alternative to subarachnoid block for TURP in elderly cardiac patients, offering reduced incidence of hypotension and decreased need for vasopressors, while maintaining adequate surgical conditions and avoiding major complications.

Keywords: Levobupivacaine, Transurethral Resection of Prostate, Spinal anesthesia.

INTRODUCTION

Transurethral prostate resection is a procedure used to treat individuals with benign prostatic hyperplasia, the most often performed surgical procedure [1,2].

Hemodynamic differences are greater with general anesthesia than with regional anesthesia [3]. Therefore, in TURP applications, regional anesthesia is generally preferred [4]. Prostate tissue is removed during transurethral resection by inserting a resectoscope via the urethra and utilizing an electrically powered cutting-coagulating metal loop or laser-22 vaporization energy. The prostatic capsule is typically retained while as much prostatic tissue as possible is removed using each approach. About 2.5 percent of TURP procedures result in bleeding that needs to be transfused [5]. There is a chance of circulatory overload because of the substantial absorption of irrigation fluid via the prostatic venous sinuses throughout the operation [6]. TURP cases are especially vulnerable to volume overload since most of them are older and have cardiovascular disease [7].

Spinal anesthetic promotes peripheral blood pooling, reduces the danger of circulatory overload, and makes it easier to identify issues such bladder perforation and TURP syndrome early on. In addition to reducing bleeding throughout operation and avoiding the necessity for tracheal intubation, which can irritate the airway and cause straining and coughing, the spinal approach also offers postoperative analgesia [8]. Elderly individuals get hypotension from spinal anesthesia more frequently than younger patients. Hypotension in older patients with heart disease is primarily caused by a reduction in systemic vascular resistance[9]. The chance of adverse effects is reduced by limiting the dosage to the required dermatomes[10].

A tiny local anesthetic bolus is directed onto the coccygeal nerve roots and the final four sacral spinal segments (S2–S5) in saddle anesthesia, a selective spinal anesthesia [11]. Sacral spinal segments (S2-S5) are specifically affected, and saddle block causes minimal vascular dilatation and infrequent hypotension. This block's advantageous action supports its status as the safest anesthesia [12].

The objective of this research was to compare the hemodynamic effects and surgical adequacy of saddle block versus subarachnoid block in elderly cardiac cases having TURP.

PATIENTS AND METHODS

Patients

Sixty male patients aged 60 and over were identified by the American Society of Anaesthesiologists (ASA) III as having ischemic heart disease (history of myocardial infarction, history of a positive treadmill test result, chronic stable angina

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lasting longer than 2 months, or an irregular Q wave on the ECG), TURP patients had prostate weighing between 100 and 150 gm with an ejection fraction (EF) of 35 to 50 percent were included. Patients under the age of 60, those with any conditions that raise intraabdominal pressure (or any intraabdominal mass), those with coagulation disorders, psychiatric illnesses, patients with spinal column abnormalities such as kyphosis or scoliosis, or those with any other contraindications for spinal anesthesia, recent decompensated heart failure, unstable angina, ventricular arrhythmias, severe aortic stenosis, severe mitral stenosis, and EF below 35% or above 50% were excluded. The study period will be specified as: "This study was conducted from January 2024 to December 2024.

Randomization: Cases have been randomly assigned into 2 equal groups (30 each) utilizing a computer-generated sequence before anesthesia. On the morning of surgery, a non-participating head nurse opened sealed envelopes, and a blinded assistant prepared anesthetic agents in equal volumes. Group allocation was concealed from patients, surgeons, and the researcher to ensure blinding.

Preoperative preparation

Each case's medical history, physical examination, and laboratory test orders were all part of the preoperative assessment process.

Premedication

An hour before anesthesia, each patient was given 4 mg of ondansetron.

Intraoperative management

The patients were fasted for eight hours before to the surgery. They stepped inside the operating room; an intravenous line was placed. An ECG, pulse oximetry, heart rate, non-invasive blood pressure, oxygen saturation, and a urinary catheter for urine output monitoring were all attached to a monitor for the patients.

Anesthetic technique

After confirming free CSF flow, 10 milligrams of 0.5% levobupivacaine (two millilitres) has been injected at L4-5 using a 25G Whitacre needle, with patients seated under aseptic conditions. Cases were then separated into 2 groups: Group I was placed supine immediately with a pillow under the head and shoulders; Group II remained seated for ten minutes prior to being situated supine similarly. Oxygen was given via nasal cannula at 3 L/min. Blood pressure was recorded every 3 minutes, and ephedrine was administered if it dropped ≥25% from baseline. All procedures were done by the same surgeon.

Surgical technique

Resection of the middle lobe's proximal region at six o'clock was the first step. The resectoscope was placed exactly in front of the verumontanum, and long incisions were made in its direction while controlling the termination of each cut. Extreme caution was exercised to prevent injury to the external sphincter, which could happen if the lower portion of the incision extends far or deeply past the verumontanum. If a median lobe was intravesical, it should be removed first using short swabs, being careful not to damage the ureteral orifices or cut down into the trigone. Each cut should be made adjacent to the one before it to create a smooth surface. The prostatic capsule is a fibrous structure that differs from the granular look of a prostatic adenoma. The lateral lobes were then the path taken for the resection. To speed up subsequent resection and manage hemostasis, each lateral lobe that was particularly big could be divided into halves at the nine and three o'clock positions. When the procedure was almost finished, an internal sphincter incision was done at the five and seven o'clock positions to reduce the risk of developing a bladder neck contracture.

Assessment parameters

- Age, weight, height, ASA class, and period of operation have been documented.
- Non-invasive systolic and diastolic blood pressure (NIBP), heart rate (HR), SpO_2, and mean arterial blood pressure (MAP) were measured at baseline (before block), immediately after block, at 5, 15, 20, 25, and 30 minutes, and after surgery. On the Post Anesthesia Care Unit (PACU), the same parameters were assessed at 0, 15, 30, 45, and 60 minutes after surgery; on the ward, they were measured at 2, 4, 6, 10, 15, 20, and 24 hours after surgery.
- The loss of acute feeling during a pinprick test has been utilized to assess the start and duration of sensory block, and it was observed at the midclavicular line on both sides. The research drug was administered, and the patient's sensory block level was monitored every minute for 10 minutes, 20 minutes, and the entire duration of the procedure. The duration of sensory blocking (regression to the S1 dermatome) and its time of onset were noted.
- Using the Modified Bromage Score (MBS), the degree of motor block has been assessed: 0 indicates no block, 1 indicates incapacity to elevate the extended leg, 2 indicates incapacity to bend the knee, and 3 indicates incapacity to flex the ankle joint or big toe. A sensory block and a motor block were evaluated simultaneously. The duration of the motor block, the time it took to get to MBS3, and the time it completely vanished were all noted. Additionally noted was the length of the block, or the time between the drug's intrathecal delivery and the MBS returning to zero.
- After arriving at the PACU (time 0), the cases in both groups have been observed for hemodynamic

parameters and pain using the Visual Analogue Scale (VAS) (which ranges from 0 = no pain to 10 = the worst pain imaginable). Thereafter, the patients were observed every 30 minutes for 120 minutes, then hourly for 8 hours postoperatively, then every 4 hours up to 24 hours postoperatively.

- Rescue analgesia was administered as an intravenous dose of 30 milligrams of ketorolac at the patient's request or when VAS not less than four. Time of the 1st dosage of rescue analgesia has been documented.
- For 24 hours following surgery, the cases were followed-up for adverse effects, involving headaches, bradycardia, vomiting, nausea, pruritus, neurologic abnormalities, bladder perforation, congestive heart failure, and TURP syndrome.
- Case satisfaction score has been determined at the conclusion of the research. The responses were noted as follows: 1 for "very dissatisfied," 2 for "dissatisfied," 3 for "neutral," 4 for "satisfied," and 5 for "very satisfied."

The outcomes

Mean arterial blood pressure was the primary outcome, and the incidence of postoperative coronary artery diseases (acute coronary syndrome clinical symptoms and ischemia ECG changes) as well as changes in heart rate, oxygen saturation, sensory block onset and period, and motor block onset and period were the secondary outcomes.

Sample size

The sample size calculation has been depended on the G Power 3.1.9.7 program. A power study showed that at a significance level of 0.05, a sample of 27 cases in each group would have 70% power to detect a 0.6 effect size difference between the two groups. To make up for those who dropped out, 30 participants were added to each group.

Ethical consideration:

New Valley University Medical Research Ethics Committee approved this prospective, randomized, double-blind comparison investigation (Approval no: 073920232). The Ethics Committee of Department of Anesthesia and Intensive Care approved the study protocol. This clinical trial was registered on ClinicalTrials.gov. The Helsinki Declaration's criteria were followed in the conduct of the research. All cases, or their legal representatives in accordance with the individual's conditions, gave written informed consent once the purpose of the trial was explained.

Statistical analysis

Data normality was assessed using the Shapiro-Wilk test. Normally distributed continuous variables were presented as means ± standard deviations and compared using independent t-tests. Non-normally distributed continuous variables were presented as medians (interquartile ranges) and compared using the Mann-Whitney U test. Categorical variables were presented as frequencies (percentages) and compared using the chi-square test or Fisher's exact test, as appropriate. Hemodynamic parameters were analyzed using repeated measures ANOVA for normally distributed data or Friedman test for non-normally distributed data. Post-hoc comparisons were performed using Bonferroni correction for multiple comparisons. Multivariate logistic regression analysis was performed to identify independent predictors of hypotension, with results presented as odds ratios (OR) with 95% confidence intervals (CI). All statistical analyses were conducted using SPSS version 20.0 (IBM Corporation, Armonk, New York, United States of America). A p-value of less than 0.05 was considered statistically significant.

RESULTS

After sixty-eight cases had their eligibility evaluated, three were disqualified and five declined to take part. The research included 60 individuals who were having endoscopic procedures to remove benign prostatic hypertrophy (Figure 1).

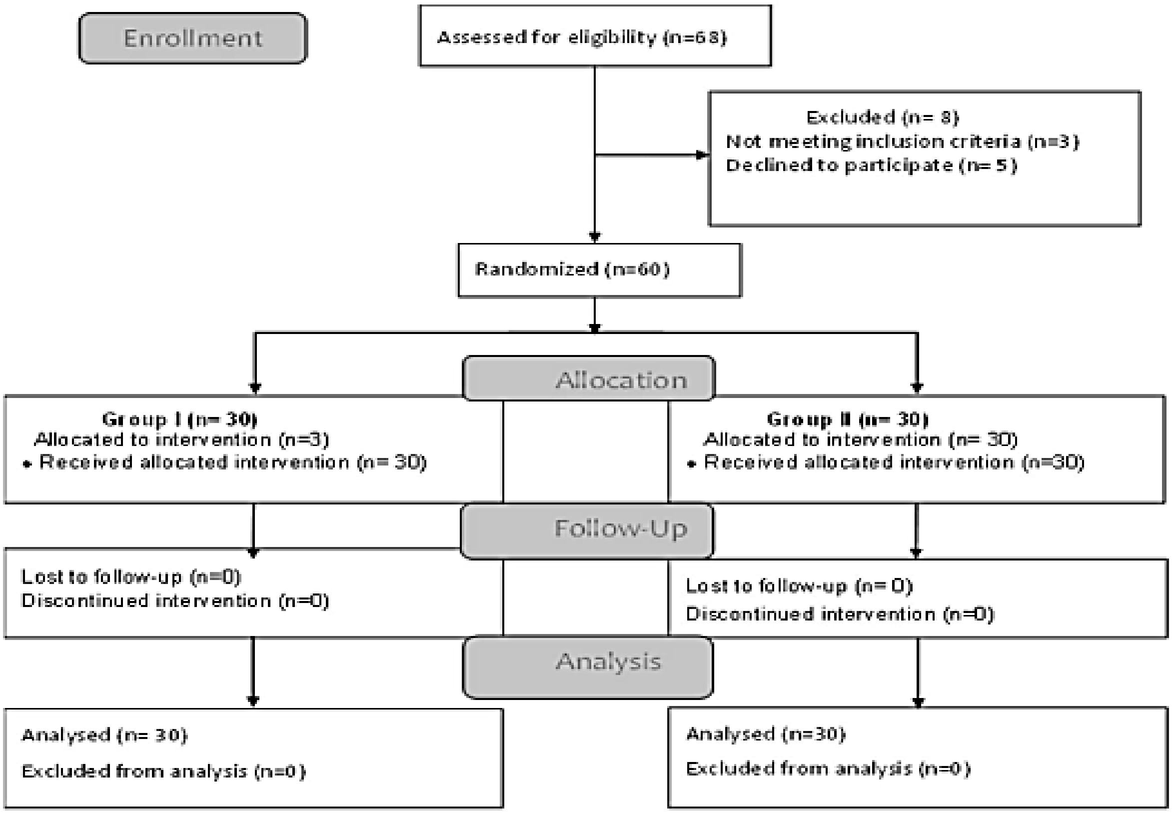

Figure 1. CONSORT flow chart.

- **Demographic data**

Age, weight, height, ASA, and length of surgery didn't differ statistically significantly (Table 1).

Table 1. Demographic data; age, height, weight, ASA, and period of operation

Variables	Group I (number=30)	Group II (number =30)	P-value
Age (years), mean±SD	66.6±5.7	67.5±5.6	0.199
Height (cm), mean±SD	170.3±3.3	171.9±3.4	0.072
Weight (kg), mean±SD	95.6±4.2	95.2±4.1	0.733
Duration of surgery (min), mean±SD	79.9±4.1	79.9±3.4	1.000
ASA score III/IV, n	27/3	28/2	1.000

Group I: spinal anesthesia; **Group II**: saddle block; **ASA**: American Society of Anaesthesiologists.

Statistical analysis: Independent t-test for continuous variables, Fisher's exact test for categorical variables.

- **Hemodynamic parameters**

All patients continued their usual cardiovascular medications, including beta-blockers, antihypertensives, and nitroglycerin for those with angina. These drugs may have affected hemodynamic parameters, but their use was evenly distributed between groups, minimizing bias. No other significant differences in medication use were noted.

The heart rate

Before spinal and saddle anesthesia, the baseline heart rates of the two groups were similar. There was only a statistically significant variance in the pulse rates of the 2 groups at 20 minutes intraoperatively and immediately following the block. At every time point, the PACU and ICU heart rates of the cases in the two groups under study didn't differ statistically significantly (Figure 2).

Among the two groups under study, there were a statistically insignificant variance in the changes in basal HR till the completion of the procedure.

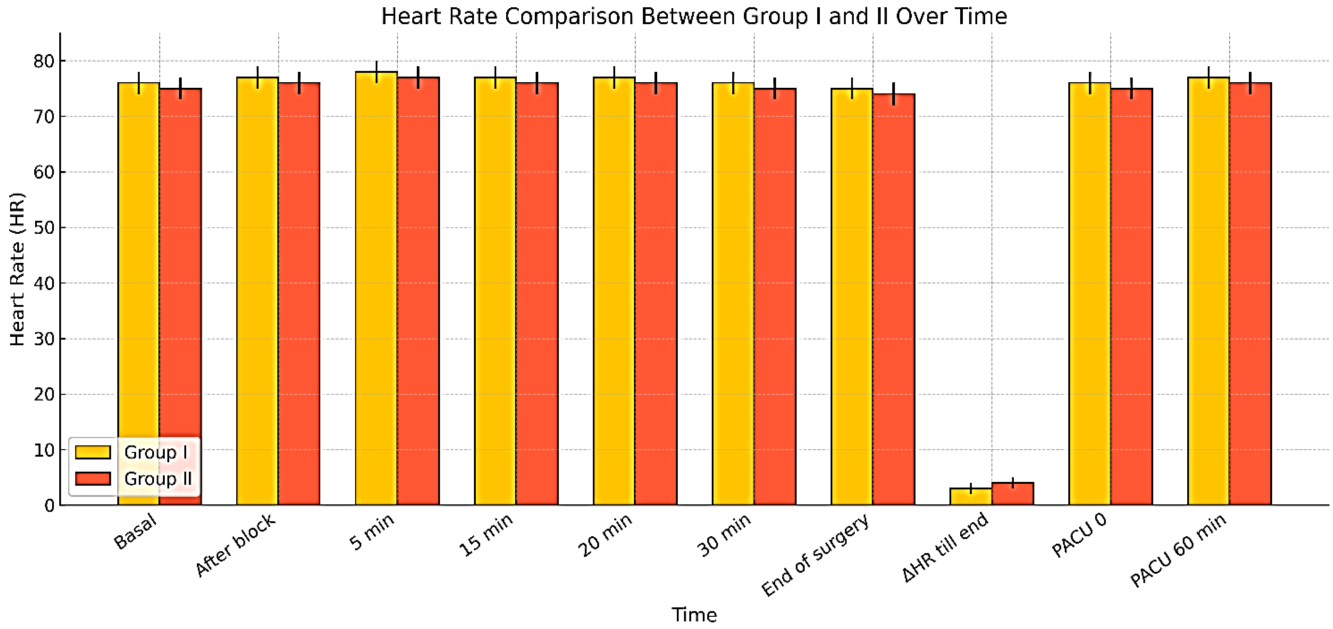

Figure 2. Heart rate differences between both groups.
Group I: spinal anesthesia; **Group II**: saddle block

Mean arterial blood pressure

A statistically insignificant variance has been observed in MAP among cases in the examined groups at baseline. Both groups had a statistically significant variance in MAP at all time points intraoperatively. Compared to the saddle group, the spinal group's MAP was lower. At all interval periods, there were a statistically insignificant variations in the PACU or ICU MAP between the two groups under study. Among the two groups under study, there were statistically significant variations in the changes in the basal MAP until the completion of the procedure (Figure 3).

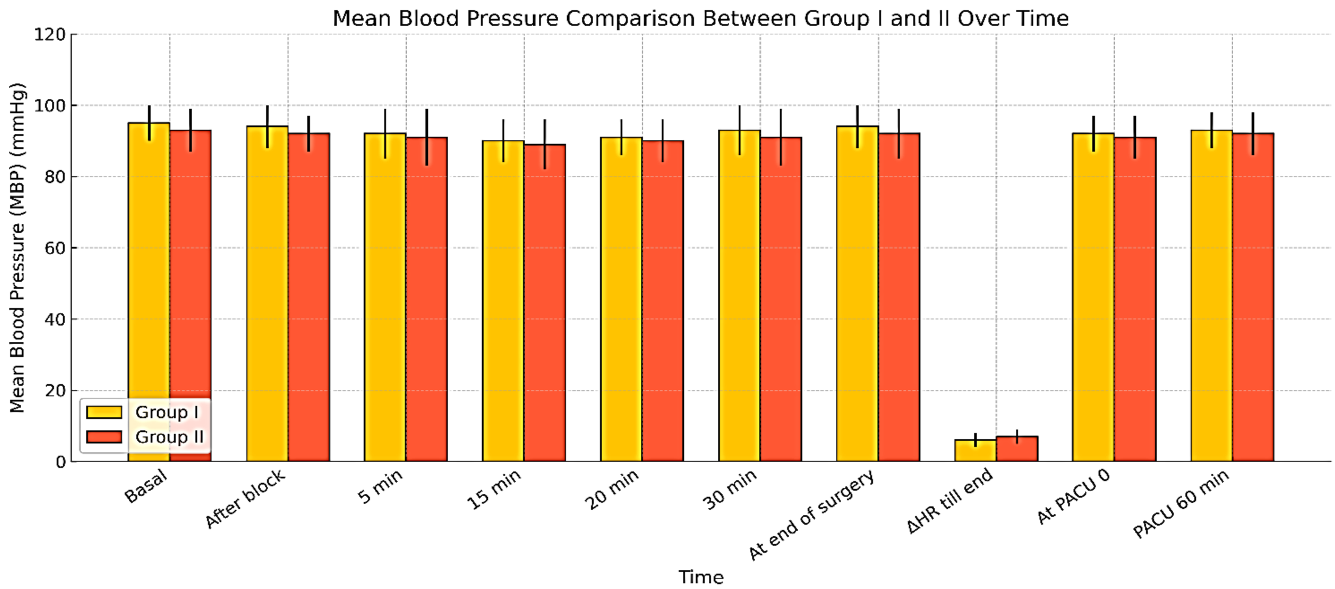

Figure 3. Blood pressure differences between both groups.
Group I: spinal anesthesia; **Group II**: saddle block.

Oxygen saturation (SPO_2)

Oxygen saturation (SPO_2) remained stable in both groups throughout the study period. Mean SPO_2 values ranged from 97.2% to 98.8% in Group I and 97.5% to 98.9% in Group II. No statistically significant differences were observed between groups at any time point (all $p > 0.05$). No patients experienced desaturation below 95% in either group. (No information is shown???????????????).

- **Sensory and motor block**
- Group I had motor and sensory block considerably earlier than Group II. Additionally, group I experienced the motor block for a considerably longer time of time (Table 2).

- **Ephedrine time and total doses as a rescue vasopressor**

There was a significant variance among the groups when comparing the need for ephedrine as a rescue vasopressor; the spinal group received the highest total doses of ephedrine as a vasopressor, while the saddle group received the lowest; additionally, the number of patients who required ephedrine differed significantly (Table 2).

Table 2. The onset of sensory and motor block, motor block period, number of patients who need ephedrine, and total dose of ephedrine

Variables	Group I (number =30)	Group II (number =30)	P-value
Onset of sensory block (min), mean±SD	4±1.5	5±1.9	0.027*
Onset of motor block (min), mean±SD	6.1±1.5	8.2±1.4	<0.001*
Duration of motor block (min), mean±SD	101±6.5	96±7.5	0.008*
Number of patients who need ephedrine, n (%)	15 (30%)	3 (10%)	0.001*
Total requirement of an intravenous ephedrine dose (mg), mean±SD	10.7±3.5	7.8±1.8	0.001*

*****: P value was significant . Statistical tests: Mann-Whitney U test for onset times and ephedrine dose; Chi-square test for categorical variables.

- **Postoperative side effects**

Side effects, like bradycardia and vomiting and nausea, didn't, however, differ significantly among the 2 groups. There were no further adverse effects, such as headache, arrhythmia, or heart failure, during the research (Table 3).

- **Patient satisfaction**

53.3% of cases in the spinal group and 96.6% of cases in the saddle group scored as sufficient (extremely satisfied, satisfied, or neutral) on the Likert scale; there was a significant variance among the groups (Table 3).

Table 3. Side effects and patient satisfaction

Variables	Group I (number =30)	Group II (number =30)	P-value
Side effects, n (%)			
PONV	6 (20%)	4 (13.3%)	0.488
Hypotension	15 (30%)	6 (20%)	0.015*
Bradycardia	2 (6.7%)	0	0.492
Patient satisfaction, n (%)			
Strongly unsatisfied	1 (3.3%)	0	<0.001*
Unsatisfied	13 (43.3%)	1 (3.3%)	
Neutral	5 (16.7%)	5 (16.7%)	
Satisfied	9 (30%)	12 (40%)	
Strongly satisfied	2 (6.7%)	12 (40%)	

PONV: postoperative nausea and vomiting, *****: P value was significant using Chi-square test or Fisher's exact test as appropriate.

- **Multivariate analysis**

Multivariate analysis identified saddle block as an independent protective factor versus hypotension (OR 0.35, ninety-five percent CI 0.18-0.67, p=0.002), while advanced age (>75 years), ASA IV status, coronary artery disease, and preoperative beta-blocker use were identified as significant risk factors for hemodynamic instability (Table 4).

Table 4: Multivariate Analysis of Factors Associated with Hypotension

Variable	Odds Ratio	95% CI	P-value
Saddle block technique	0.35	0.18-0.67	0.002*
Age >75 years	2.14	1.32-3.48	0.008*
ASA IV status	3.26	1.85-5.73	<0.001*
History of coronary artery disease	1.95	1.21-3.14	0.012*
Preoperative beta-blocker use	2.71	1.65-4.45	0.003*

CI: Confidence Interval; ASA: American Society of Anesthesiologists, *****: P value was significant.

DISCUSSION

According to the current study's findings, our institution performed TURP on sixty male patients with cardiac illness who were sixty-five years of age or older and under spinal or saddle anesthesia. We administered twenty-five μg of fentanyl along with ten milligrams of 0.5 percent levobupivacaine (2 ml) to achieve sufficient blocks of either saddle or spinal anesthesia. The saddle group had minor systemic adverse effects, such as hypotension, bradycardia, and desaturation, and considerably lessened the decline in the MAP, according to the study. Saddle anesthesia for TURP greatly reduced the need for vasopressors in patients with heart disease.

The inferior hypogastric plexus is the source of the nerve supply that travels from T11 to L2 in the sympathetic nervous system and from S2 to S4 in the parasympathetic nervous system to the prostate. Sacral nerves S2 to S4 are the source of pain fibers from the prostatic urethra, prostate, and bladder mucosa. Bladder distension sends a pain signal to L2 sympathetic fibers via T11 sympathetic fibers. The stretch feeling in the bladder is transmitted by the parasympathetic fibers of S2 to S4. The height of the regional block as much as T10 is enough for transurethral resection of the prostate surgery considering this innervation. The discomfort associated with a prostatic capsule perforation may be concealed by a higher amount of block [13].

Saddle block and spinal anesthesia are enough for the TURP surgery. The visceral pain feeling is transmitted from the prostate and bladder neck by variant parasympathetic nerve fibers, which are mostly generated from the 2nd and 3rd sacral nerve roots and travel with the pelvic splanchnic nerves [14].

The prostate sizes of patients in this study ranged from 100 to 150 grams. While larger prostates are associated with longer surgical times and potentially greater fluid absorption or bleeding risks [15], no significant differences in these factors were observed between groups. The anesthesia type had a more pronounced impact on hemodynamic parameters than the prostate size in this study, as both groups had comparable prostate sizes, minimizing variation from this factor.

Both groups I and II in the current trial got 10 mg of hyperbaric levobupivacaine (2 ml of 0.5%), however group I ling supine immediately following the injection, while group II sat for 10 minutes before lying supine. Patients in both groups had appropriate anesthesia; however, we observed that hemodynamic alterations in group I were more statistically significant (p below 0.05) than in group II, indicating a higher need for vasopressors in that group.

The present findings are corroborated by previous study, which discovered that patients who underwent saddle block had a lower frequency of hypotension and a lower requirement for vasopressors (P below 0.01) than cases who underwent spinal anesthesia, with both groups receiving ten milligrams of hyperbaric bupivacaine. In both groups, adequate surgical conditions were attained [13].

Additionally, other group of researchers discovered that saddle block, performed on patients undergoing tricuspid annuloplasty for TURP and mitral and aortic valve replacement, with 5 mg of hyperbaric bupivacaine and 1 ml of 0.5% and 50 mcg of fentanyl, did not have any negative cardiovascular effects, In this study, we used levobupivacaine, which has more hemodynamic stability than bupivacaine [16]. To assess the potential negative effects of hemodynamic changes on fifteen elderly patients with heart disease, an earlier study assessed the cardiovascular effects of spinal anesthesia. They found that five subjects experienced a 10% decrease in heart rate, while four subjects experienced a 10% increase in heart rate, but not a rise of more than 90 beats per minute [17].

Another study[8] observed that the fall of heart rate was more (twenty-one) following spinal anesthesia than epidural (seventeen percent) and general anesthesia (fourteen percent). In this investigation, we additionally discovered that the fall of HR was more in Group I (two patients) than in Group II where no patient had significant bradycardia (P>0.050).

LIMITATION

The current study has several limitations, such as the fact that we used higher doses of levobupivacaine in saddle blocks than is recommended, that we did not assess blood loss or irrigation fluid absorption, and that we did not quantify serum sodium.

CONCLUSION

In conclusion, saddle block can be used to safely execute transurethral resection of the prostate with a lower risk of hypotension and a lower need for vasopressors.

DECLARATIONS

- **Consent for publication:** I certify that each author has granted permission for the work to be submitted.
- **Funding:** No fund
- **Availability of data and material:** Available
- **Conflicts of interest:** None
- **Competing interests:** None.

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