ORIGINAL ARTICLE

EFFECTIVENESS OF SADDLE BLOCK VS SPINAL ANAESTHESIA IN TURP: AN OPEN LABEL RANDOMIZED CONTROL TRIAL

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Background: One of the most frequent diseases among male gender is benign prostatic hyperplasia. Transurethral resection of the prostate (TURP) is a minimally invasive procedure for resection of prostate through endoscopic technique. Recently there was a debate on role of saddle block in TURP. There we aimed to determine the effectiveness of spinal anaesthesia versus saddle block in terms of hemodynamic stability and vasoprbessor requirement in TURP. **Methods:** This open label randomized control trial was performed at Hamdard University Hospital, Karachi, Pakistan, during 1st October, 2021 to 31st March, 2022. Male patients of age 45–65 years requiring TURP, with well controlled diabetes and hypertension of ASA grade I-II were included into the study and randomly assigned into two study groups. Patients' parameters including blood pressure, heart rate, mean arterial pressure and oxygen saturation (SPO_2) were measured at baseline and intraoperative at every fifth minute interval till surgery completion. Patients' other parameters including age, surgery duration and comorbidity were also recorded. **Results:** Total 60 patients with 30 patients in each group were enrolled into the study. Maximum fall in systolic blood pressure, diastolic blood pressure, pulse rate and mean arterial pressure from baseline was significantly lower in patients receiving saddle block anaesthesia than spinal anaesthesia. Maximum fall in SPO_2 was not significantly different among two study groups. Maximum fall in all parameters excluding SPO_2 was significant between two groups for initial 20 minutes of the procedure. No statistically significant maximum fall was seen for all of the parameters beyond 20 minutes of the procedure. Vasopressor consumption was significantly lower in saddle block group than spinal anaesthesia. **Conclusion:** Application of saddle block anaesthesia is effective for TURP procedure with controlled hemodynamic status than spinal anaesthesia. Moreover, saddle block requires less vasopressor consumption than spinal anaesthesia technique.

Keywords: Hemodynamic stability; Spinal anaesthesia; Saddle block anaesthesia; TURP

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INTRODUCTION

One of the most frequent diseases among male gender is benign prostatic hyperplasia which is often associated with lower urinary tract symptoms and bladder obstruction. The incidence is 50% among age group 50–60 years in males which further increases with advanced age.[1] Transurethral resection of the prostate or TURP is a minimally invasive procedure for resection of prostate through endoscopic technique. This procedure is being used for many decades and yet thought to be as gold standard for bladder outlet obstruction due to prostatic hyperplasia.[2]

Various determinants are responsible for deciding the appropriate type of anaesthesia required including patients' age, underlying diseases, surgery type and duration, intraoperative body position, patient preference and pain management approaches.[3] However, spinal anaesthesia is the most preferred technique in TURP cases. Spinal block reaching to T10 dermatome for elimination of discomfort due to bladder distension, is essential.[4] Frequent complications of spinal anaesthesia are spinal headache, nausea, vomiting and hypotension.[5]

Saddle block anaesthesia is a kind of spinal anaesthesia which blocks the sacral nerve roots and give relaxation to pelvic muscles and is denser in lumbar, sacral and lower thoracic dermatomes. Likelihood of circulatory overload and hemodynamic instability is lower due to achievement of lower-level block.[6] It is a known fact that restricting the spread of spinal block propose many clinical benefits, one of which is reduction in hemodynamic impact of spinal anaesthesia.[7] Owing to this fact, comparison of spinal block versus saddle block in terms of hemodynamic status and vasopressor requirement has been studied by some researchers. However, these researchers are few.[6,8,9]

Intraoperative homodynamic stability is of high priority to assure patient safety. Furthermore, to the best of our knowledge locally no such investigation has been conducted yet in Pakistan. Thus, the present study was planned to explore the effectiveness of saddle block versus spinal anaesthesia in terms of hemodynamic stability and vasopressor requirement in TURP.

MATERIAL AND METHODS

The present open label randomization control trial was conducted at Department of Anaesthesia in Hamdard University Hospital, Karachi, Pakistan. Trial was registered at Clinical Trials.gov (NCT05285800). The study was performed during October, 2021 to March, 2022 with permission of institutional review board (Ethical#: ERC/MBBS/07/2021). Patients were recruited into the study with their written informed consent. Male patients of age 45–65 years American Society of Anaesthesiologists' (ASA) grade of I-II were included into the study. Patients who were diabetic and/or hypertensive were assessed to confirm having a well-controlled disease for their inclusion of such patients into the study. Patients with absolute contraindications of regional anaesthesia (such as allergy to local anaesthetics, coagulopathies, pre-existence neurologic deficit and inability to cooperate), deformity of vertebral column, thyroid disorder, psychiatric illness, neurological diseases, ischemic heart diseases and not willing to participate, were excluded. Previously conducted similar study showed that maximum fall in mean arterial blood pressure among spinal and saddle group was = 22.27±3.01 mmHg and 6.73±3.96 mmHg respectively.[8] Using a power of 80% and 5% level of significance, a sample of less than 30 patients per group was required as calculated by using online available calculator Open-Epi. However, we enrolled total 30 patients per group. Non-probability consecutive sampling technique was used to enrol study participants.

A thorough history was obtained, comprehensive physical examination and pre anaesthetic evaluation was done prior to the surgery. After receiving patient in operating room, an intravenous (IV) line was passed through 18-gauge venous cannula. Before 10 minutes of pre-load, systolic arterial pressure, diastolic arterial pressure, mean arterial blood pressure, pulse rate and peripheral oxygen saturation (SPO_2) were recorded as baseline parameters. Then patients were randomly allocated to either spinal anaesthesia or saddle block through sequentially numbered opaque sealed envelope protocol. In both the groups, 10 minutes before regional anaesthesia, patients were preloaded intravenously with injection Gelofusin 250 ml, thereafter co-loaded with injection Ringer lactate 5–10 ml/kg/hour. Patients in both the groups received 12 mg of 0.5% hyperbaric bupivacaine intrathecally by using 25-gauge pencil point tip needle through L3-L4 intervertebral space. However, in spinal group supine position was assumed immediately after injecting hyperbaric solution while in saddle block group, patients were instructed to sit for next 5 minutes of receiving hyperbaric solution and then a supine position was given.

After 10 minutes of giving the supine position in both of the groups, onset of sensory block and motor block was monitored through pin prick test and Bromage scale respectively. The range of Bromage scale was 0–4, where "0" shows no block, "1" shows failure to raise the extended leg against gravity but able to flex ankle joint, "2" shows incapability to flex the hip and knee joint but able to flex ankle joint, "3" shows incapability to flex the hip, knee and ankle joint but able to move toes and "4" means complete paralysis. Achievement of sensory block was again observed in next 15 and then 20 minutes of giving the supine position, if it was not achieved in initial 10 minutes. Patients not achieving the block within 20 minutes were excluded from the study. Procedure was started once desired sensory block was achieved. All procedures were carried out by a surgeon having at least 5 years of experience using a 24 Fr resectoscope.

The primary study outcome was effectiveness of the block in terms of comparison of hemodynamic parameters between the two blocks. The block showing lesser fall in hemodynamic parameter was considered as effective as compared to the other. The secondary outcome was incidence of any complication post-operatively. For recording primary outcomes after beginning of the surgery, patients' parameters including systolic and diastolic blood pressure (in mmHg), mean arterial pressure (MAP) (in mmHg), and peripheral oxygen saturation (SO_2) and pulse rate (in beats per minute) were monitored at every 5^{th} minute interval till the completion of surgery. Incidence of clinically significant hypotension (defined as >20% decrease in MAP from baseline) during the procedure was managed with vasopressor i.v ephedrine at a dose of 6 mg. For recording secondary outcomes, incidence of intra-operative complications during the procedure was also recorded. Figure 1 depicts the CONSORT diagram.

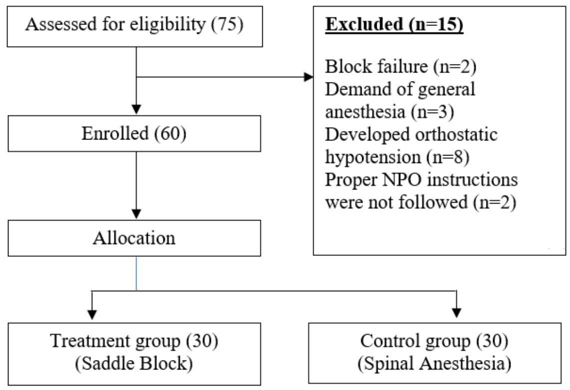

Figure-1: Consort diagram for the flow of patients involved in the study

Data was statistically analysed on SPSS version 21. Frequencies and percentages were computed for representing categorical variables. First normality assumption was assessed with Shapiro-Wilk test for summarizing numerical parameters. Gaussian distributed parameters were summarized as mean±standard deviation otherwise median with inter-quartile ranges were reported. Categorical variables were compared among two study groups with application of Chi-square or Fisher-exact test. Comparison was done for continuous variables among two groups using independent t-test if normality assumption was fulfilled; otherwise, Mann-Whitney U test was applied. Two tailed *p*-value ≤5% level of significance was defined as statistically significant.

RESULTS

Total 60 patients completed the study with equal allocation in each group. Overall mean age of patients was 55±5.4 years. Median body mass index was 30.8 (IQR=27.1–35.5) Kg/m^2. Quarter of the patients had ASA grade 1 (n=15, 25%). Median surgery duration was 38 (35–39) minutes. Pre-operatively median systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, heart rate and SPO_2 was 136 (IQR=134–140) mmHg, 84 (IQR=80–89) mmHg, 101.5 (IQR=98–106), 80.5 (IQR= 78–88) bpm, 98 (IQR=97–98)% respectively. Table-1 represents the comparison of patients' characteristics among the two study groups. Two study groups did not differ on the basis of any patients' features.

Table-2 depicts the comparison of maximum fall in patients' parameters from baseline. Maximum fall from baseline for systolic blood pressure (p<0.001), diastolic blood pressure (p=0.002), mean arterial pressure (p<0.001) and pulse rate (p=0.029) was significantly lower in patients receiving saddle block than patients underwent spinal block anaesthesia. Maximum fall from baseline for SPO_2 was not significantly different among the two study groups (p=0.856). Out of these 60, none of them developed intraoperative complications.

Table-3 represents the comparison of maximum fall in vitals within and after 20 minutes between the two study groups. Within 20 minutes, maximum fall from baseline for systolic blood pressure (p<0.001), diastolic blood pressure (p=0.045), mean arterial pressure (p<0.001) and pulse rate (p=0.025) was significantly different between spinal and saddle block groups. Maximum fall in vitals after 20 minutes was only significantly different for systolic parameter with higher fall in spinal group than saddle group (p=0.045). 6 (10%) of patients in spinal block were administered with ephedrine with mean dosage of 5±1.7 grams whereas none of the patient's required ephedrine in saddle group.

Table-1: Comparison of patients' characteristics among spinal and saddle block groups

Patients' features	Spinal block Median (Q1 – Q3) n=30	Saddle block Median (Q1 – Q3) n=30	*p*-value
Age (in years) #	55±5	55±5.8	Ɨ0.962
Body mass index (in Kg/m^2)	29.2 (26.6–34)	31.6 (27.6–37.6)	ǁ0.201
Duration of surgery (in minutes)	37 (35–39)	38.5 (34–39)	ǁ0.893
ASA gradeǂ			
I	9 (30)	6 (20)	ɩ0.371
II	21 (70)	24 (80)	
Comorbidsǂ			
Hypertension	19 (63.3)	14 (46.7)	ɩ0.194
Diabetes	11 (36.7)	18 (60)	ɩ0.071
Baseline clinical parameters			
Systolic blood pressure#	137±7	136.6±4.6	ǁ0.792
Diastolic blood pressure	84 (79–89)	84 (80–90)	ǁ0.427
Mean arterial blood pressure	101 (97.8–104.5)	103 (98.5–107)	ǁ0.202
Pulse rate	80 (76–87.3)	80.5 (78–90.3)	ǁ0.400
SPO_2	97 (97–98)	97 (97–98)	ǁ0.661

ASA: American Society of Anaesthesiologists, SPO2: oxygen saturation, Q1: First quartile, Q3: Third quartile, #: Normally distributed data is presented as mean ± standard deviation, Ɨ: Independent t-test was applied, ǁ: Mann-Whtineu U test was applied, ɩ: Pearson chi-square test was reported, ǂ: Data is presented as n(%)

Table-2: Comparison of maximum fall in parameters of hemodynamic status throughout the procedure among spinal and saddle block groups

Study parameters	Spinal block Median (Q1 – Q3) n=30	Saddle block Median (Q1 – Q3) n=30	*p*-value
Systolic blood pressure#	24.4±9	13.4±5	Ɨ**<0.001
Diastolic blood pressure	18 (14.7–21)	13 (8–17.3)	ǁ**0.002
Mean arterial pressure	18.5 (15–22.3)	12 (7–14)	ǁ**<0.001
Pulse rate	13 (8.5–18)	10.5 (3.8–12.3)	ǁ*0.029
SPO_2	0 (0–1)	1 (0–1)	ǁ0.856

SPO2: oxygen saturation, Q1: First quartile, Q3: Third quartile, #: Normally distributed data is presented as mean ± standard deviation, Ɨ: Independent t-test was applied, ǁ: Mann-Whtineu U test was applied, *: Significant at $p<0.05$, **: significant at $p<0.01$

Table-3: Comparison of maximum fall in parameters of hemodynamic status between two study groups during initial ≤20 minutes and later on >20 minutes throughout the procedure.

Study parameters	Spinal block Median (Q1 – Q3) n=30	Saddle block Median (Q1 – Q3) n=30	*p*-value
Systolic blood pressure			
Maximum fall ≤20 minutes#	23.8±9.3	11±5.6	Ɨ**<0.001
Maximum fall >20 minutes#	14.8±7	11.6±5.1	Ɨ*0.045
Diastolic blood pressure			
Maximum fall ≤20 minutes	18 (14.8–21)	10 (5.8–16)	ǁ**<0.001
Maximum fall >20 minutes	13 (8.8–15.3)	11 (8–15.3)	ǁ0.594
Mean arterial pressure			
Maximum fall ≤20 minutes	18.5 (15–21)	8.5 (7–14)	ǁ**<0.001
Maximum fall >20 minutes#	12.2±6.2	10.3±5.6	Ɨ0.211
Pulse rate			
Maximum fall ≤20 minutes	13 (7–15.8)	7.5 (2–12)	ǁ*0.025
Maximum fall >20 minutes	9 (2.8–12)	7 (1.8–12.3)	ǁ0.813
SPO2			
Maximum fall ≤20 minutes	0 (0–1)	1 (1–0)	ǁ0.072
Maximum fall >20 minutes	0 (0.3–0)	0 (0–1)	ǁ0.067

SPO2: oxygen saturation, Q1: First quartile, Q3: Third quartile, #: Normally distributed data is presented as mean ± standard deviation, Ɨ: Independent t-test was applied, ǁ: Mann-Whtineu U test was applied, *: Significant at $p<0.05$, **: significant at $p<0.01$

DISCUSSION

Perioperative morbidity in TURP procedures varies from 18–26% and the highest death rate could be 1%.[4] Peri-operative risk factors may be multifactorial depending on interaction of anaesthesia with patients' clinical status and particular surgical aspects.[10] Patients' safety is top most concern for anaesthesiologist. During previous decades, risk involved in anaesthetic care has been drastically lowered. However, still the anaesthesiologist holds the central role from patients' view in acute healthcare and the associated anaesthetic risks may not be considerably separated from peri-operative care and interventional risks.[11]

By the end of 20th century, minimally invasive surgical procedures and regional anaesthesia significantly appeared in medical world.[12] Regional anaesthesia (either epidural or spinal) is a choice predominantly in surgical procedures of lower abdomen and extremities for inducing only necessary sensory levels and leaving minimum impacts on sympathetic nervous system.[3] Thus, in TURP procedures regional anaesthesia is extensively applied instead of general anaesthesia. Regional anaesthesia has various benefits over general anaesthesia including reduced dosage, avoiding airway manipulation, rapid recovery, reduced side effects and ultimately reduced post-operative pain. However, type of anaesthesia applied exclusively bases on anaesthesiologist verdict.[13,14]

Globally technique of spinal anaesthesia is preferred because of the ease of monitoring of conscious patients. In TURP procedures, the height of spinal anaesthesia should not be beyond T10 level. Due to blockade of sympathetic nerves, vasodilation occurs which leads to diminishing of venous return which is a key factor for causing hypotension.[15] As a consequence; intraoperative the hemodynamic instability after spinal anaesthesia is common. Incidence of intraoperative hypotension is as low as 8% and as high as 33% relying on the number of parameters involved in defining it.[16]

Saddle block anaesthesia is a neuraxial approach involving intrathecal injection locally while sustaining the patient in a sitting position, with the purpose of particularly blocking the distal sacral dermatomes for anesthetizing the perineum.[17] In saddle block, the lowermost sacral spinal segments are involved and anaesthesia is limited solely to the saddle area. Hence the benefits include the preservation of lower extremity motor strength and a decrease in adverse effects like hypotension.[18] Since the cardiac issues during the TURP may leads to mortality and morbidity, thus using a firm anaesthesia approach with negligible haemodynamic alterations becomes very important.

In the present study maximum fall in systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and pulse rate from baseline, was significantly lower in patients received saddle block than patients receiving spinal block anaesthesia. A similar study from India reported that maximum fall for all the studied parameters was significantly lower in saddle block group than spinal block group.[8] Our findings are also in line to another Indian study reporting a significantly lower maximum fall for saddle block than spinal anaesthesia.[6] Again, a study from India comparing hemodynamic status for patients receiving regional anaesthesia through saddle block and subarachnoid block for TURP concluded that saddle block may be safely applied in TURP with lesser hemodynamic unevenness and vasopressor prerequisite.[19] The similar study conducted in Iraq with the intention to compare hemodynamic effects between the spinal anaesthesia and saddle block during TURP and it was concluded that under saddle block, the TURP may be safely performed with lower hypotension risk and lesser need of vasopressor.[9]

Fall in blood pressure is a matter of concern in spinal anaesthesia which has even the potential to cause death. The lowered point usually occurs within ten minutes of administering the injection and majority of the fatalities occur at this time point.[20] Thus in the present study, a maximum fall in parameters of hemodynamic status during initial 20 minutes and after 20 minutes was also compared among the two groups to further investigate hemodynamic changes with respect to time and it was seen that maximum fall in parameters of hemodynamic status between two groups was significantly different only for initial 20 minutes. Beyond 20 minutes, statistically no significant differences were observed in hemodynamic status of the two groups. Bejoy *et al.* also compared maximum fall in heart rate, systolic and diastolic blood pressure and mean arterial blood pressure among the two groups during first 20 minutes of receiving the block and later 20 minutes and did not find significant differences after 20 minutes for maximum fall in heart rate, systolic blood pressure and diastolic blood pressure. Only fall in mean arterial blood pressure was found to be significantly lower in saddle group than subarachnoid block group.[19]

In the present study, 10% of patients in spinal block were administered with ephedrine with mean dosage of 5±1.7 milligrams whereas none of the patients required ephedrine in saddle block group. Findings are consistent with other study that reported higher dosage of ephedrine was required in spinal block group than saddle block group.[8,19] Kshetrapal *et al* also observed that requirement of ephedrine was significantly higher in spinal anaesthesia group than saddle block group.[6]

This is to be noticed that in agreement to the previously available literature, this study also finds better results for saddle block than spinal block. Therefore, on the basis on this study we recommend to routinely use saddle block for TURP procedure in our local studies. However, the present study suffers with some serious limitations. The present study is of first kind in Pakistani settings from a single center private sector institute with a limited sample size which limits the generalizability of study results on entire Pakistani population. Moreover, this study does not evaluate the impact of intraoperative IV fluids on vitals. Hence, studies from Pakistan with larger sample size may be conducted in future to compare post-operative analgesic requirement and patient satisfaction associated between the two anaesthetic techniques.

CONCLUSION

Application of saddle block anaesthesia is effective for TURP procedure with controlled hemodynamic status than spinal anaesthesia. Moreover, saddle block requires less vasopressor consumption than spinal anaesthesia technique.

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Conflict of interest: We declare none of the conflict of interest

Research involving human participants/ethical approval:
The study was approved by Institutional Review Board of Hamdard University (Date: 30th September 2021, Approval #: ERC/MBBS/07/2021). The study was conducted after acquiring the approval letter from the chairman of Institutional Review Board. The trial was conducted according to the Declaration of Helinsinki.

Informed consent: All of the patients were recruited into the study with their written informed consent.

AUTHORS' CONTRIBUTION

NS did the introduction and manuscript writing and made final changes. MWI collected the data, did initial write up and analyzed the data. SNH helped in discussion writing and article review. AMR helped in initial write up and critically review article. SS collected the data and references.

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