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Original Research Article

Comparison of Hyperbaric Ropivacaine and Bupivacaine in Spinal Anaesthesia for Transurethral Resection of Prostate Surgery to Evaluate Effect on Safety Profile and Block Characteristics: a Randomised Double Blind Clinical Study

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Abstract

Background: Hyperbaric 0.75% ropivacaine has been widely used nowadays due to early recovery and better safety profile. We planned this study to compare the effect of intrathecal hyperbaric 0.75% ropivacaine and hyperbaric 0.5% bupivacaine in spinal anaesthesia for transurethral resection of prostate surgeries to evaluate effect on post spinal hypotension, sensory motor block characteristics and adverse effects.

Materials and Methods: 120 patients were randomly allocated into 2 groups of 60 patients each in Group B and R to receive spinal anaesthesia with 2.8 ml (14 mg) of 0.5% hyperbaric bupivacaine and 2.8 ml (21 mg) of 0.75% hyperbaric ropivacaine, respectively. The primary outcome measured was the incidence of hypotension. The secondary outcomes measured were vasopressor requirement, onset and duration of sensory-motor block, degree of motor block, haemodynamic profile and adverse effects. $P < 0.05$ was considered statistically significant.

Results: Group R patients had significantly lower incidence of hypotension (20 % vs 45%, P = 0.01) and bradycardia (3.3% vs 16%, p=0.03) compared to group B. The mean time for the onset of sensori-motor block was faster in Group B. The duration of sensory and motor block were lesser in ropivacaine group. The patients in ropivacaine group exhibited a lesser degree of motor block as compared to bupivacaine group. The duration of analgesia and haemodynamic parameters in both groups were statistically comparable.

Conclusion: Despite a slower onset time of block, intrathecal hyperbaric ropivacaine provides a better alternative to intrathecal hyperbaric bupivacaine for transurethral resection of prostate surgeries by providing a stable haemodynamic profile, shorter duration of sensorimotor block, a lesser degree of motor block, and thus allowing early ambulation.

Keywords: Bupivacaine, Ropivacaine, Spinal Anaesthesia.

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Introduction

Spinal anaesthesia (SA) is the most commonly used technique for transurethral resection of prostate (TURP), owing to various advantages over general anaesthesia (GA). Since benign prostate hyperplasia (BPH) is mostly seen in elderly people who also have multiple coexisting medical illnesses like hypertension, diabetes mellitus, coronary artery disease, chronic kidney disease, chronic obstructive pulmonary disease, etc. in which GA is more risky.

In addition, SA offers numerous advantages over GA such as the patient remains awake, less risk of deep venous thrombosis (DVT), less blood loss, early detection of bladder perforation and TURP syndrome and it is a cost effective technique too. Hence, SA remains the choice of anaesthesia in elderly patients undergoing TURP. [1]

Hyperbaric bupivacaine continues to be the gold standard in SA since long, but reports of cardiac toxicity and its long duration of motor block have always stimulated the researchers to find safer

agents with early motor recovery. [2] Ropivacaine is invented as pure levo-isomer, which is less lipophilic. Hence, it is 30-40% less potent and lesser cardio-neurotoxic compared to bupivacaine. [3] Ropivacaine causes less motor blockade, hence, tends to allow early motor recovery that can be helpful in reducing DVT in elderly patients. Initially, ropivacaine was available as isobaric preparations only and making it hyperbaric by adding dextrose in each and every case manually was found tedious, associated with risk of infection and unreliable baricity. Hence there was demand for hyperbaric ropivacaine that can be used in SA for more predictable block compared to isobaric ropivacaine. [4] Recently in 2021, commercial preparations of hyperbaric ropivacaine are introduced as 4 ml injection 0.75% and studies are being conducted to compare its efficacy and safety profile with conventionally used hyperbaric bupivacaine available as 4 ml injection 0.5%. [5] Ropivacaine and bupivacaine are considered equipotent when used in the ratio of 3:2. [6, 7] Therefore commercially hyperbaric ropivacaine is available as 0.75% so that it can be used in similar volumes as hyperbaric bupivacaine 0.5%.

Previous studies have shown that bupivacaine in SA may be associated with episodes of hypotension [spinal anaesthesia induced hypotension (SAIH)] with higher incidence in elderly wherein maintenance of mean arterial pressure (MAP) is crucial to prevent end organ damage. Hence, intrathecal agents with less adverse haemodynamic effects are always preferred. Intrathecal ropivacaine has been observed as a safer agent in SA owing to lesser cardio-neuro toxicity as well as reduced hypotensive episodes and early motor recovery as observed in various surgeries such as cesarean section, lower limb surgery, and lower abdominal surgery. [8,9,10,11]

However, there is paucity of studies comparing commercially available hyperbaric ropivacaine and bupivacaine in TURP that are powered enough to assess the effect of ropivacaine on reducing SAIH in elderly patients undergoing TURP which prompted us to conduct the present study.

We conducted a randomized, double blind study to compare 2.8 ml of 0.5% hyperbaric bupivacaine and 2.8 ml of 0.75% hyperbaric ropivacaine in spinal anaesthesia in elderly patients undergoing TURP regarding effect on incidence of hypotension as the primary objective. Secondary objectives are to compare the onset, peak level and duration of sensori-motor block, clinical efficacy in terms of need of supplementation, haemodynamic profile, and adverse effects.

Material and Methods

After taking institutional ethical committee approval, present study was undertaken in 120 patients undergoing TURP in SA in the urological operation theatre at a government medical college and teaching hospital. Written informed consent from the patients was taken. Helsinki codes of declaration and good clinical practice (GCP) guidelines were followed during the conduct of the study.

Inclusion criteria were elderly males 65-85 years age, ASA grade I-II, having BPH and undergoing TURP under SA. Exclusion criteria were patient refusal, allergy to study drugs, contraindications to SA, uncontrolled medical disease (ASA $\geq$ III), obesity (BMI $\geq$ 30), etc.

Based on previous study by Gupta S et al [10], the incidence of hypotension in TURP cases was 13.3% with hyperbaric ropivacaine and 36.6% with hyperbaric bupivacaine. To detect minimum difference in incidence of hypotension of 23% in two groups for present study, using 80% power (beta error 20%) and alpha error of 5%, we required 54 patients in each group. To compensate for 10% dropouts, we took 60 patients in each group.

One hundred twenty selected patients were randomized into two groups of 60 each using block randomization method and sealed envelope technique. To ensure double blindness to the study, one anaesthesiologist prepared anaesthetic drugs and was not involved further in the study. Another anaesthesiologist who was not aware of group allocation performed SA and recorded all the study data. Patient, surgeon and post-operative nurse were also not aware of group allocation.

The study groups were defined on basis of type of local anaesthetic received in SA as follows:

Group R (n = 60) - patients received 2.8 ml of 0.75% hyperbaric ropivacaine (ROPIN Heavy 4 ml injection, each ml contains ropivacaine hydrochloride 7.5 mg and dextrose monohydrate 80mg; by Neon Laboratory, India)

Group B (n = 60) - patients received 2.8 ml of 0.5% hyperbaric bupivacaine (Bupivacaine hydrochloride in Dextrose injection USP 4 ml, each ml contains bupivacaine hydrochloride 5 mg and dextrose 80 mg; by Health Biotech Ltd, Solan, India).

Preanaesthetic evaluation was done 1-2 days before the surgery and patients were advised to follow standard fasting guidelines and continue or omit the medicine for systemic illness as per disease protocol. On the day of surgery, a peripheral 18/20 G intravenous cannula was taken and balanced salt solution was started at 10 ml/kg/hour. Standard

monitoring using noninvasive blood pressure (NIBP), electrocardiography(ECG), and pulse oximetry was applied to the patient and baseline vital parameters as systolic, diastolic and mean arterial pressure (SBP, DBP, MAP), heart rate (HR), and peripheral oxygen saturation (SPO2) were recorded. After taking all aseptic precautions, SA was performed in sitting position at L3-4 interspace using 25 G Quincke's type spinal needle (PRICON, by ISCON surgical limited, Jodhpur) and after getting free flow of cerebrospinal fluid, intrathecal drug was injected as per group allocation. The end of intrathecal injection time was noted as time zero for all further data recording, and patient was turned supine. Sensory block was assessed every 3 min till 15 min using a spirit swab and loss of cold sensation was used to assess sensory block level. Time to T10 was defined as time of sensory onset.

Motor block level was assessed using Modified Bromage Score every 3 min defined as: 0 = able to flex hip, knee and ankle (no motor block), 1 = able to move knee and ankle but unable to flex hip, i.e. unable to raise extended leg (partial motor block), 2 = able to flex ankle, unable to flex hip and knee (almost complete motor block), and 3 = unable to move any part of the lower limb (complete motor block) [6]

The time taken to achieve maximum bromage score was defined as onset of motor block. A target sensory level of T10 and Maximum Bromage score of 2 or 3 were criteria to allow start of TURP surgery. If above level were not achieved in 15 min, case was declared as failed case and converted to GA and excluded from study.If above target block levels were achieved, surgery was started in SA but if intraoperative pain occurs, supplementation was given as fentanyl 50-100 mcg or ketamine 0.5-1 mg/kg or propofol 0.5-1 mg/kg and declared as partial success. If surgery could not be continued, case was converted to GA with intubation and declared as failed case and excluded. Clinical efficacy in each group was defined as proportion of cases in whom TURP was completed in SA without any supplementation.

SBP, DBP, MAP, HR, and SpO2 were noted at every 5 min till 30 min, then every 15 min till completion of surgery. A fall in MAP > 25% from baseline value or MAP < 65 mmHg was defined as hypotension and treated with mephentermine 6 mg at every 2 min till recovery of MAP within 25% baseline. If MAP falls again, it will be defined as next episode. Incidence of hypotension (defined as number of patients experiencing hypotension) and cumulative hypotension episodes were noted in each group. If hypotension is not corrected by 30 mg mephentermine, noradrenaline infusion 2-20mcg/min was started.

Bradycardia was defined as fall in HR > 25% from baseline or HR < 55/min and treated with atropine 0.4-0.6 mg. Nausea, vomiting was treated with ondansetron 4 mg, shivering with tramadol 50 mg intravenously (iv). Any other complication, if occurred, was noted and treated accordingly. Intraoperative fluid was given at 8-10 ml/kg/hour, blood/colloid were given as per losses and noted. The duration of surgery was noted as the time from the insertion of resectoscope into urethra till the procedure is complete and removal of all instruments after flushing out resected tissue and placing a urinary catheter.

Postoperatively, sensory and motor blocks were assessed every 30 minutes till sensory block regressed to S1 (sensory block duration) and motor block returned to Bromage Score 0 (motor block duration). The time of first pain postoperatively was defined as duration of analgesia and injection diclofenac 75mg iv was given as per hospital protocol. Patients were reviewed for 24 hours to note any adverse effects and treated accordingly.

Data were entered in MS Excel and analysed using SPSS version 20. At the outset normality of data was checked by Shapiro-Wilk Test. Categorical data were presented as number (proportion) and compared with Chi-square test or Fischer Exact test. Quantitative data were expressed as mean ± SD and compared with student t test. Ordinal data were expressed as median (interquartile range IQR) and compared with Mann Whitney U test. $P < 0.05$ was considered as statistically significant.

Results

Total 135 elderly patients were assessed for eligibility, 15 patients were excluded due to not fulfilling selection criteria and 120 selected patients were enrolled in the study and randomly divided in two equal groups of 60 each who received allocated intervention. All patients completed the study with no loss to follow ups or drop outs as shown in CONSORT flow diagram (Figure 1).

Both groups were found statistically comparable regarding age, weight, height, ASA grade, duration of surgery and fluid administered, $P > 0.05$ (Table 1).

Incidence of hypotension (primary outcome) was significantly lower in group R (20%), compared to group B (45%), P=0.01. Cumulative episodes of hypotension were also significantly less in group R (14) than in group B (36), P = 0.000. Mephentermine consumption was also significantly lower in group R (84 mg) as compared to group B (216 mg), P = 0.000. None of the patient in our study required noradrenaline. Incidence of bradycardia was also significantly lower in group R (3.3%) than in group B (16%), P = 0.03. But it was easily treated with atropine 0.4 mg in all patients.

Intraoperative MAP was significantly less in group B compared to group R at 10min (P = 0.000), 15min (P = 0.000), 20min (P = 0.000), after SA, thereafter it was comparable (P > 0.05) (Figure 2). Mean HR was comparable in two groups at all time intervals, P > 0.05 (Fig 3). Incidence of nausea was less in group R (1.6%) than in group B (5.0 %), P = 0.53 but it was statistically not significant.

All patients of group B and group R had achieved target sensory level of T10 and maximum Bromage score 3 in 15 min and TURP surgery was completed in SA without need of any supplementation, analgesia or conversion to GA showing clinical efficacy of 100% in both groups. Sensory onset was significantly slower in group R compared to group B (6.68 ±0.68 min vs 5.02 ±0.75 min, P = 0.000), motor onset was also significantly slower in group R compared to group B (7.67 ±0.91min vs 6.32 ±0.77 min, P = 0.000) but this difference was only 1-2 min, hence could not make much clinical impact as the surgery was elective surgery. Median value (IQR) of peak sensory level was T10 (T6-T10) in group B and T10 (T8-T10) in group R.

The duration of sensory block (170.97 ± 11.56 min vs 187.07± 11.83 min, P = 0.000), duration of motor block (142.45±15.95 min vs 169.15±8.80 min, P= 0.000) were significantly shorter in group R compared to group B respectively. Duration of analgesia in terms of time to first rescue analgesia were not significantly different in group R (195.60 ± 11.15 min) and group B (194.65 ± 12.51 min), P = 0.66. (Table 2)

Table 1: Demographic Characteristics, Duration of Surgery, Fluid Input and Urine Output

Variables	Group R (n=60)	Group B (n=60)	P-value[#]
Age (Years)	72.62 ± 4.32	72.31 ± 4.28	0.68
Weight (kg)	71.14 ± 9.21	72.22 ± 8.86	0.51
Height (cm)	157.15 ± 5.63	157.92 ± 6.15	0.48
ASA Grade (I/II)	35/25	38/22	-
Duration of Surgery (min)	40.52 ± 4.10	41.77 ± 4.21	0.102
Fluid Input (litre)	1440 ± 152.05	1433.33 ± 134.88	0.80

Values are the mean±SD or number as appropriate [#]Unpaired t test applied

Table 2: Comparison of Hypotension, Vasopressor Requirement and Other Complications in Two Groups

Variables	Group R (n=60)	Group B (n=60)	P-value
Incidence of Hypotension (Primary Outcome)	12 (20%)	27 (45%)	
1 Episode	10	20	
2 Episodes	2	5	
3 Episodes	-	2	0.01
Cumulative Episodes of Hypotension	14	36	0.000
Cumulative Number of Mephentermine Doses	14	36	0.000
Cumulative Amount of Mephentermine (mg)	84 mg	216 mg	0.000
Incidence of Bradycardia	2 (3.3%)	10 (16%)	0.03
Nausea	1 (1.6%)	3 (5%)	0.62

Values are number (percentage), Chi square test applied

Table 3: Sensory-Motor Block Characteristics

Variables	Group R (n=60)	Group B (n=60)	P-value
Onset of Sensory Block (Time to T10 in min)	6.68 ± 0.68	5.02 ± 0.75	0.000
Onset of Motor Block (Time to B3 in min)	7.67 ± 0.91	6.32 ± 0.77	0.000
Sensory block duration (min)	170.97 ± 11.56	187.07 ± 11.83	0.000
Motor block duration (min)	142.45 ± 15.95	169.15 ± 8.80	0.000
Time to first rescue analgesia (min)	195.60 ± 11.15	194.65 ± 12.51	0.66

Values are the mean±SD, Unpaired t test applied

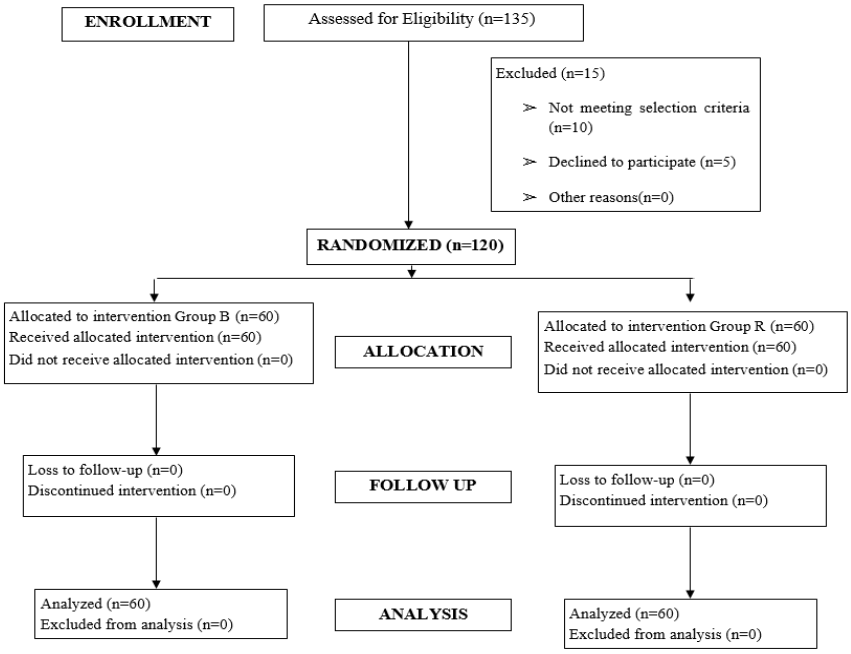

Figure 1: CONSORT Flow Diagram

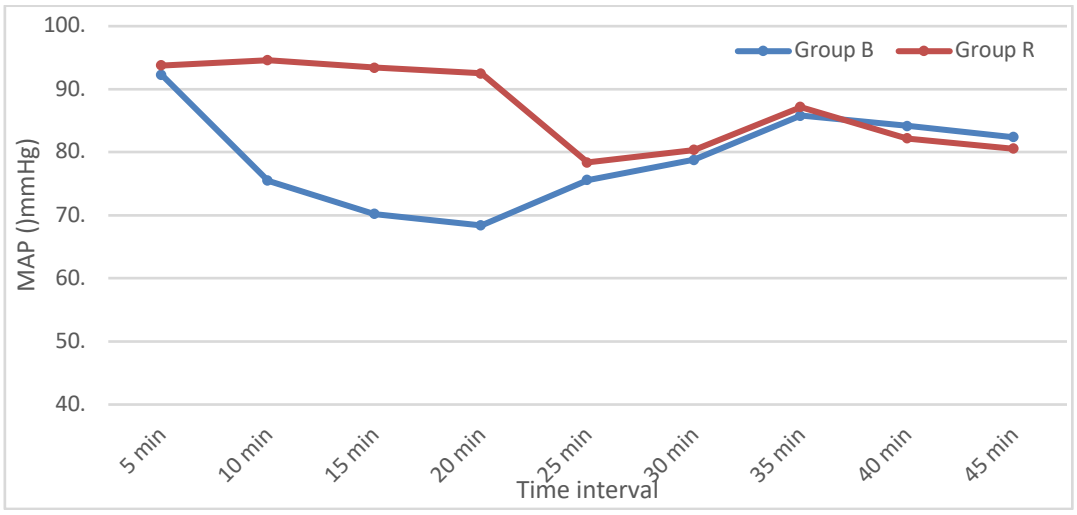

Figure 2: Comparison of Mean arterial pressure (MAP) in two groups

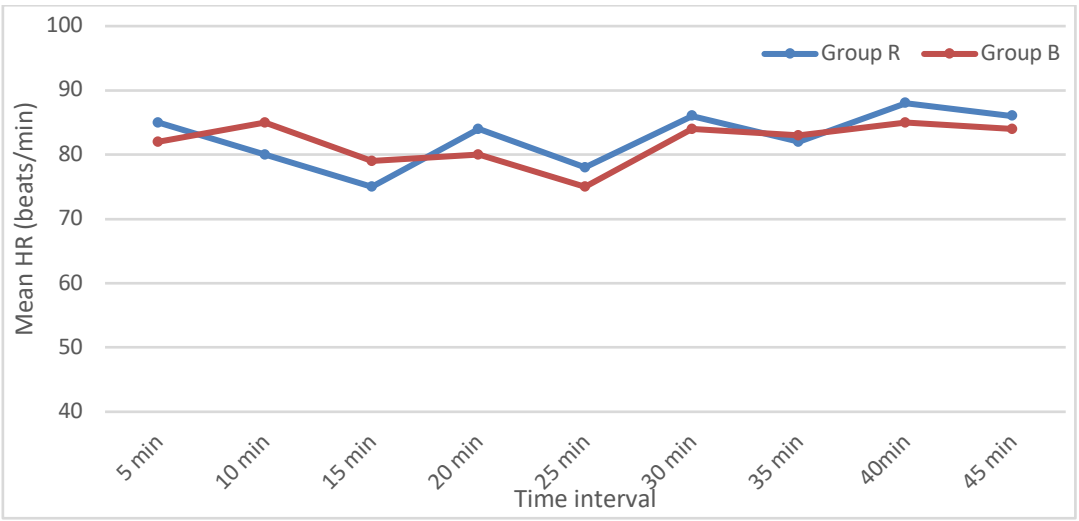

Figure 3: Comparison of Mean heart rate (HR) in two groups

Discussion

Present study compared the effects of equal volumes (2.8ml) of commercially available 0.75% hyperbaric ropivacaine (21mg) and 0.5% hyperbaric bupivacaine (14 mg) in spinal anaesthesia in elderly males (> 65 years) for TURP surgery. The use of ropivacaine was found to be associated with better haemodynamic stability in terms of significantly less incidence of hypotension, bradycardia and less requirement of vasopressors. Both drugs provided effective sensory motor blockade of sufficient duration for successful conduction of TURP in all cases without the need of supplementation and analgesia.

Similar findings were observed in previous study in TURP in elderly where use of hyperbaric ropivacaine in SA was found to be associated with better haemodynamic stability as evidenced by lower incidence of hypotension (13.3% vs 36.6%, P = 0.01) and bradycardia (6.6% vs 10%, P = 0.31) in ropivacaine group as compared to bupivacaine group. They also reported that fall in mean MAP in group B was significantly more compared to group R (P < 0.001) intraoperatively.[10]

Other recent studies in which commercial preparation of these two agents were compared, lower incidence of hypotension was reported with hyperbaric ropivacaine compared to bupivacaine in caesarean section (21.2% vs 45.4%, P = 0.04),[12] and lower limb orthopaedic surgeries (23.52% vs 49.41%, P = 0.000).[13] Another study also reported that incidence of hypotension in TURP was lower in ropivacaine group (6.6%) but the difference could not reach statistical significance, it could be because they made the ropivacaine hyperbaric by manual addition of dextrose so baricity may be unreliable.[14]

In our study, incidence of bradycardia was also significantly less in group R (3.3%) as compared to group B (16%), P = 0.03. It was in coherence to previous study in lower limb surgery (3.5% vs 11.76%, P = 0.043).[13] However, there was no significant difference in bradycardia reported in previous studies in TURP surgery. [10, 14]

Ropivacaine also produced significantly faster recovery from sensory motor block enhancing early ambulation as also reported in previous other studies in TURP and other surgeries.[4, 15] Ropivacaine is pure levo-isomer of bupivacaine which is a racemic mixture. Both are amide local anaesthetics and block the conduction of nerve impulse. Ropivacaine is less lipophilic, hence has 40% lower potency than bupivacaine, therefore higher doses of ropivacaine are needed to produce same effect as of bupivacaine.[4, 5, 15] Equipotent doses of ropivacaine and bupivacaine are considered to be in ratio of 3:2 in literature, therefore commercially hyperbaric ropivacaine comes as 0.75% and bupivacaine comes as 0.5%. [6,7] Hence when they are used in similar volumes in SA equipotent doses are achieved. In our study, we used 2.8 ml of 0.75% hyperbaric ropivacaine (21mg) and 0.5% hyperbaric bupivacaine (14 mg) in SA that came to be in ratio of 3:2. Lipophilicity is directly proportional to potency and inversely proportional to toxicity. This could be the reason that ropivacaine in SA resulted in less incidence of hypotension, bradycardia and faster motor block recovery that is useful for achievement of early recovery after surgery.

Ropivacaine also has one advantageous property i.e. sensory-motor block differentiation. Because of lesser hypophilicity ropivacaine is less likely to penetrate large myelinated motor fibres and has selective action on the pain transmitting A-delta and C fibres rather than A-beta fibres which are involved in motor function. [4, 15] This could be the reason that duration of analgesia was similar to bupivacaine but motor block duration was significantly reduced with ropivacaine compared to bupivacaine in present as well as in previous studies in TURP—as well as other surgeries. [10, 13, 14, 16] Onset of sensory-motor block was significantly slower with ropivacaine however this difference was only 1-3 min, which did not appear to have much clinically significant impact in operation theatre turnover time as these were elective surgeries. [10, 14, 16, 17] Though we should keep this difference in mind in emergency situations. There were some limitations of our study such as we conducted the study in elective cases with ASA grade I-II, so our results cannot be extrapolated to high risk emergency cases, and we suggest further studies need to be planned involving such patients. Secondly, we used NIBP monitoring in our study, however invasive BP monitoring could have shown changes in BP with further accuracy and beat to beat fluctuations.

Conclusion

We conclude that hyperbaric ropivacaine is superior to hyperbaric bupivacaine in SA in elderly males for TURP by producing significant reduction in incidence of hypotension and bradycardia and early motor block recovery.

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