Original Article

Postoperative urinary retention: A controlled trial of fixed-dose spinal anesthesia using bupivacaine versus ropivacaine

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Abstract

Background and Aims: Following spinal anesthesia (SA), patient discharge is often delayed due to postoperative urinary retention (POUR), the incidence of which varies widely. The present study of bupivacaine versus ropivacaine in equianalgesic doses was taken to explore the correlation between time to void urine and time for complete functional recovery.

Material and Methods: In this double-blinded study fifty adult patients were assigned to two groups (bupivacaine/ropivacaine) according to alternate case allocation for receiving SA for lower abdominal, perineal, and lower limb surgeries, lasting less than 2 h. Statistical analysis was conducted using an intention-to-treat approach, using Mann–Whitney test for nonparametric data. Primary outcome data could not be obtained for 14 out of the 50 patients due to perioperative bladder catheterization. No patients were lost to follow-up.

Results: Both the bupivacaine and ropivacaine groups were comparable in terms of ability to void (8.0 ± 2.3 vs. 7.0 ± 1.2 h; $P > 0.05$), modified Bromage scale after 4 h of SA (1.8 ± 1.3 vs. 2.6 ± 0.9 grade; $P > 0.05$), time to complete ambulation (6.7 ± 1.4 vs. 6.1 ± 1.0 h; $P > 0.05$), and time to negative Romberg test (6.1 ± 1.4 vs. 5.6 ± 0.9 h; $P > 0.05$), respectively. Strong positive correlations ($r = 0.7–0.9$) were found between time to void urine and time for complete ambulation.

Conclusions: Time to void urine and recovery of motor functions were found comparable statistically when bupivacaine and ropivacaine were used in the doses of 12.5 and 18.75 mg, respectively, for SA. However, group ropivacaine required lesser time to void and no patient developed POUR. Time to void urine was more than the time for ambulation. This may indicate a need for "selective spinal anesthesia" or adjuvant combination technique to accelerate the resolution of a block for ambulatory surgery.

Keywords: Fixed-dose spinal anesthesia, postoperative urinary retention, postoperative urinary retention, time to void urine

Introduction

Ability to void urine is commonly considered as an important criterion for early discharge after day-case surgery.[1] Postoperative urinary retention (POUR) is one of the most common complications next to hemodynamic adverse effects following spinal anesthesia (SA), usually defined as "the inability to void 8 hours after end of surgery."[2-6] Prolonged bladder distention due to POUR can lead to urinary tract infection, detrusor dysfunction, and even damage the surgical repair following pelvic and perineal surgery.[7] Thus, for surgeons, early attainment of bladder function is a major concern, especially following short surgical procedures.[8]

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Despite many advantages of SA, there remains the problem of insufficient attainment of urinary bladder function, which significantly delays the discharge after day-case surgery.[9]

The present study used fixed doses of 2.5 ml of 0.5% of hyperbaric bupivacaine (12.5 mg) and 2.5 ml of 0.75% isobaric solution of ropivacaine (18.75 mg) to assess the time to void urine and time to achieve complete motor function recovery. The primary objective of the study was to compare POUR after SA with bupivacaine and ropivacaine. The secondary objective was to correlate the time of POUR to modified Bromage score, time to negative Romberg test, and time to ambulation.

Material and Methods

The present study was a double-blinded study, approved by the Institutional Ethics Committee, conducted during the period of September 2015–September 2018, in a tertiary care referral center in adult patients after written informed consent.

Fifty patients aged 18–60 years, with ASA grades I–II, Mallampati grades I and II, planned for elective or emergency surgery under SA for lower abdominal, perineal, and lower limb surgeries, lasting less than 2 h were enrolled in the study. After a thorough preanesthetic examination, clearance for surgery was taken and informed consent was obtained. Patients with a history of allergy to study medications, previous or current psychiatric illness, neurologic or vestibular disease, morbid obesity or any contraindication to SA were excluded from the study.

The patients allocated into one of the two groups of 25 patients each, Group A and Group B, on an alternate basis by an assistant independent from the study [Figure 1]. Allocation concealment was ensured with the assistant not being involved in the direct care of the patients and the group allocation only being revealed at the end of the study to the investigators. Blinding in this study was achieved by way of another assistant, who, under all aseptic precautions, prepared the drug syringes in the preoperative room just before the surgery in each case, as well as codified them with the patient number, and was the only person aware of the actual composition. The other investigator, blinded of actual drug composition, administered the drugs intrathecally and recorded the data. Randomization data were confidential until the time of unblinding at the completion of the study.

Procedure

Two different local anesthetics having different baricity, namely, Group B: hyperbaric (0.5%) bupivacaine (12.5 mg) and Group R: isobaric (0.75%) ropivacaine (18.75 mg),

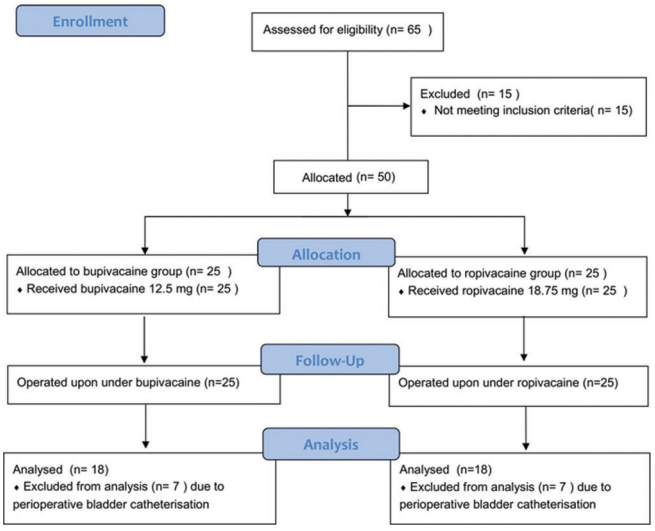

Figure 1: Clinical trial flowchart (as per CONSORT 2010)

were taken in an equal adjusted dose of 2.5 ml each for the conduct of SA.

Anesthetic protocol

No preoperative anxiolytic medication was administered, but patients were allowed to continue their routine medications. The anesthetic procedure was explained to the patient. The patients were also familiarized with the methods of assessment of the recovery process. They were told to inform the health care provider the time when they were able to void urine.

In the operating room, intravenous access was established and initial vital parameters were noted. They were placed in sitting position for administration of SA, the lumbar area was prepared aseptically and draped, and L2–L3 or L3–L4 intervertebral space was infiltrated with 2% lidocaine, using the midline approach. Under all aseptic precautions, 25-ga Quincke's spinal needle was inserted; on a free flow of cerebrospinal fluid, the study solution was injected intrathecally. The patient was placed supine immediately after injection, the time of which was recorded as "zero." The assessment of block characteristics, sensory–motor recovery process, and recording of data was done by an investigator who was blinded about the injected study solution.

The motor recovery process was assessed by the widely used modified Bromage scale [Appendix 1], tests of motor function evaluation in standing including Romberg test, assisted, and unassisted ambulation was not allowed to perform until they achieved the modified Bromage score of 0 and able to perform 90° leg raise.

The Romberg test was considered positive as long as the anesthetic effect was present, whilst the time taken for the test

to become a negative reflected complete motor activity, which was taken as the negative Romberg test.

Sample size calculation

A sample size of 25 in each group was calculated on the basis of time to void urine postspinal blockade. The underlying hypothesis was assumed to be a "continuous outcome superiority trial." The mean time to void urine was found to be 8–7 h in the bupivacaine and ropivacaine group, with a standard deviation of 1. The significance level was taken as 5%, and the power was taken as 90%. The required sample size per group was calculated to be 22 and the minimum total required sample size was calculated to be 44. Thus, in our study, a sample size of 25 was allocated to each group with a total number of 50 patients who received treatment in the form of bupivacaine and ropivacaine and underwent follow-up.

Statistical analysis

Analysis of the data obtained was done by an independent investigator, which was not involved in the care of the enrolled patients. An analysis was conducted using an intention-to-treat approach. The primary outcome could not be obtained for 14 patients, 7 in each group because they required perioperative bladder catheterization. Hence, an analysis was done on 36 patients, 18 in each group, using the freely available XL STAT add-on for Microsoft Excel 2013.

No patients were lost to follow-up, since patients were admitted to the same hospital postoperatively and discharged only after fulfilling the discharge criteria, which, among other things, included patient voiding urine.

The outcome data were not normally distributed (Shapiro–Wilk test); thus Mann–Whitney U test was applied. No, subgroup analyses for the primary outcomes were performed.

Correlation coefficients were calculated between the primary outcome and various secondary outcomes using the freely available Data Analysis Tool Pack add-on in Excel 2013. The correlation coefficient was interpreted by the Hinkle's rule of thumb[10] [Appendix 2].

Results

The demographic data are given in Table 1. Seven patients in each of the groups posted for caesarean sections that were catheterized perioperatively had to be excluded from the analysis. On analyzing the rest, using the primary outcome of time to void urine was comparable in the two groups. Two of 18 patients in the bupivacaine and none in the ropivacaine group had POUR.

Table 1: Demographic profile of patients

Variables	Group B (n=25)	Group R (n=25)
Age	40.8±13.0	37.2±13.6
Sex (male/female)	10/15	16/9
ASA grade I: II (%)	7:18 (28/72)	12:13 (48/52)
Weight (kg)	57.4±11.3	59.0±10.7

Data are presented as mean±SD; Group B: bupivacaine, Group R: ropivacaine; SD=Standard deviation; ASA=American Society of Anesthesiologist

Patients of both bupivacaine and ropivacaine groups took comparable time to become completely ambulatory and after 4 h of SA had comparable modified Bromage score grade and comparable time for Romberg test to become negative [Table 2].

Thus, for the primary and all secondary outcomes, with the Mann–Whitney *U* test, no statistically significant difference was observed between groups bupivacaine and ropivacaine.

Tables 3 and 4 show correlation coefficients, as per the secondary objective; highly positive correlations were found between the time to void urine and time to start unassisted complete ambulation which corresponds to the time to return of complete motor power (modified Bromage score – 0) and negative Romberg test.

Time to have a negative Romberg test had a low positive correlation with Bromage score till 2 hours but highly correlated after 4 h of SA. Time to negative Romberg test also had a highly positive correlation with unassisted ambulation and time to void urine in both the groups [Tables 3 and 4].

Discussion

The present study showed no statistically significant difference in time to void urine and recovery of motor functions statistically when bupivacaine and ropivacaine were used in the doses of 12.5 and 18.75 mg, respectively, for SA, though group ropivacaine required lesser time to void and no patient developed the POUR.

POUR, a common phenomenon across surgical centers, has been variously defined as "the inability to void 8 hours after end of surgery with bladder being distended or patient being uncomfortable"[3] or to "inability to void urine >12 hours after induction of anesthesia with >500 ml urine drained on catheterization."[4] Following SA, especially if a long-acting anesthetic agent or large doses of anesthetic agent being used, this causes prolonged blockage of transmission of action potentials in the sacral nerves innervating the bladder due to which the sensation of urgency to void on bladder distention disappears.[11,12] Thus,

Table 2: Effect of spinal anesthesia on motor functions and urine voiding function in hours

Characteristics (h)	Group B (*n*=25) Mean±SD	Group R (*n*=25) Mean±SD	*P* (Mann-Whitney)
Time to void urine (h)	8.0±2.3	7.0±1.3	0.294
Time to assisted ambulation (h)	4.9±2.0	4.9±0.8	0.838
Time to complete ambulation (h)	6.7±1.3	6.0±1.0	0.088
Bromage score (4-h postanesthesia)	1.8±1.3	3.0±0.9	0.110
Time to Romberg test to be negative (h)	6.0±1.4	5.6±0.9	0.126

Values are mean±SD; Group B: bupivacaine, Group R: ropivacaine; P value>0.0.5 indicates no statistically significant differences between two groups

Table 3: Bupivacaine group: correlation coefficients between the "time to void urine" and the modified Bromage scale, ambulation, and Romberg test

	Bromage scale at 60 min after SA	Bromage scale at 2 h after SA	Bromage scale at 4 h after SA	Time to assisted ambulation	Time to complete ambulation	Time to negative Romberg test
Correlation coefficient*	0.18	0.272	0.576	0.666	0.794	0.757
Significance	0.1-0.3	0.1-0.3	0.5-0.7	0.5-0.7	0.7-0.9	0.7-0.9
Interpretation	Negligible correlation	Negligible correlation	Moderate positive	Moderate positive	High positive	High positive

**Data analysis by tool Pak add-on in Microsoft Excel 2013*

Table 4: Ropivacaine group: correlation coefficients between the "time to void urine" and the modified Bromage scale, ambulation, and Romberg test

	Postspinal modified Bromage scale			Time to assisted ambulation	Time to complete ambulation	Time to negative Romberg test
	At 1 h	At 2 h	At 4 h			
Correlation coefficient*	0.239	0.296	0.581	0.685	0.839	0.791
Significance	0.1-0.3	0.1-0.3	0.5-0.7	0.5-0.7	0.7-0.9	0.7-0.9
Interpretation	Negligible correlation	Negligible correlation	Moderate positive	Moderate positive	High positive	High positive

**Data analysis by tool Pak add-on in Microsoft Excel 2013*

the normal urination process is not restored, even after emptying the bladder with a Foley catheter.[4,13] Such patients are said to have developed POUR.[12-14] With time, the level of analgesia regresses to lower segments to L5, reaching thereafter to S2–S4 and the strength of the detrusor muscle of the bladder start returning to normal, allowing the patient to void urine.[11-12,15] Thus, the ability to void is widely considered as one of the important criteria to discharge in-patients successfully.[1,2]

Following central neuraxial conduction blockade including SA, epidural anesthesia (EA), and combined spinal-epidural anesthesia, the reported incidence of urinary retention had wide variations from 0% by Mulroy *et al*.[16] ($n = 32$) to 76% by Gedney *et al*.[17] ($n = 160$). Gautier *et al*. showed that the use of ropivacaine for SA led to reduced incidence of POUR and allowed patients to walk and void urine earlier than the patients who were given bupivacaine in equivalent dose.[14]

Higher incidence of POUR was found with the use of long-acting and high-dose local anesthetics.[4,11] With short-acting and low-dose local anesthetics, the time to void was shorter because of faster regression of sensory and motor block leading to a rapid recovery of bladder function[18,19] which is the requirement for same day surgery.

It was seen that the time to void urine was more than the time for complete ambulation, consistent with the observation that complete normalization of detrusor strength occurs nearly 1–3.5 h after ambulation.[16,17]

A highly positive correlation between time to recovery from motor functions and time to void urine was seen especially in the case of ropivacaine [Table 4]. Similarly, Axelsson *et al*. have documented more time required for normalization of bladder functions than motor functions for the ability to walk.[12] Ability to void had a high positive correlation for ambulation and ability to perform negative Romberg test [Tables 3 and 4] as detrusor strength recovers late after the return of patient's ability to stand steadily without swaying, that is, negative Romberg test.

The meta-analysis by Baldini *et al*. showed that the major perioperative factors that contribute to POUR are a long duration of surgery, and spinal or EA, apart from other preoperative factors.[2] However, the preferred spinal anesthetic agent and dose for minimizing POUR are still unclear.[2]

The minimum effective anesthetic concentration of bupivacaine producing anesthesia at T12 level and complete motor

paralysis was 10 mg, that is, a dose which produces complete anesthesia within 20 min of administration in 50% of human subjects by blocking transmission of nerve action potential.[20,21] The doses less than 7.5 mg are associated with a high failure rate (25%).[18] The minimum analgesic concentration of local anesthetic for bupivacaine was found to be 0.16% in another study.[17] Therefore, the present study was conducted to compare the effect of SA on POUR using a fixed dose of 12.5. mg of bupivacaine and an adjusted dose of 18.75 mg of ropivacaine for surgical anesthesia for two reasons. First, only isobaric solution of ropivacaine and hyperbaric solution of bupivacaine are commercially available. Second, baricity of the local anesthetic agent (whether hyperbaric or isobaric solution) in equal doses has been found to have no significant effect on time to regression of the sensory blockade due to the distribution in cerebrospinal fluid.[3,11]

For ropivacaine, good-quality motor block without unexpected adverse events was documented by Van Kleef *et al*.[22] The study of Kulkarni *et al*. revealed that intrathecal ropivacaine was associated with delayed onset sensory block with rapid recovery of motor functions and sooner urine voiding function compared to bupivacaine.[23] However, the meta-analysis of Malhotra *et al*. documented similar sensory blockade properties of bupivacaine and ropivacaine, whereas the motor functions recovery was faster with ropivacaine.[24]

Limitations of the study

Our study had two limitations. First, the calculated sample size for the study came out to be 44 but only 36 patients were finally analyzed due to bladder catheterization intraoperatively. Thus, a larger study is required to validate the present observations. Second, motor function recovery was not assessed at zero score of the modified Bromage scale, and therefore, further study is warranted with extrapolation of observations till zero score of the modified Bromage scale to authenticate our findings and positive correlations.

Conclusion

Satisfactory surgical anesthesia was obtained and urinary voiding functions were achieved within 6–10 h postoperatively when either bupivacaine or ropivacaine was used in the dose of 2.5 ml for SA. Time to void urine required more time than the time for ambulation. Both the study drugs had high positive correlation ($r = 0.7–0.9$) between time to void urine and the time for complete ambulation and negative Romberg test. Delayed voiding, a cause of delayed discharge warrants for "selective spinal anesthesia" or adjuvant combination technique to accelerate resolution of the block for ambulatory surgery.

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Conflicts of interest

There are no conflicts of interest.

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Appendix 1: Modified Bromage scale

Grade	Criteria
0	(No motor block) full power
1	Inability to raise extended leg, able to move knees and feet
2	Inability to raise extended leg and move knee; able to move feet
3	Complete block of motor limb

Appendix 2: Hinkle's rule of thumb for interpreting the size of correlation coefficient[10]

Size of correlation	Interpretation
0.9-1.0 (−0.9-1)	Very high positive (negative) correlation
0.9-0.70 (−0.9-0.70)	High positive (negative) correlation
0.50-0.70 (−0.50-0.70)	Moderate high positive (negative) correlation
0.30-0.50 (−0.30-0.50)	Low positive (negative) correlation
0.00-0.30 (−0.00-0.30)	Negligible correlation