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POST-OPERATIVE URINARY RETENTION AFTER SPINAL ANESTHESIA IN HERNIA SURGERY:

A PROSPECTIVE, COMPARATIVE DOUBLE-BLIND STUDY BETWEEN ROPIVACAINE HEAVY 0.75% AND BUPIVACAINE HEAVY 0.5%

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ABSTRACT

Objective: The objective of this study was to evaluate and compare the effect of spinal anesthesia (SA) with bupivacaine and ropivacaine on recovery of bladder function and time of ambulation in healthy men who were scheduled for hernia surgery.

Methods: In this double-blind study, 60 patients of the American Society of Anesthesiologists I/II/III were assigned to Group B (bupivacaine)/Group R (ropivacaine). Before SA, ultrasonography-guided bladder volume was measured. After the operation, bladder volume was measured continuously every 2 hourly until the patient could void urine spontaneously or need of catheterization. Motor blockade and time of ambulation were recorded.

Results: Bromage scale at 4 h was significantly higher (p=0.0001) in ropivacaine showing intrathecal ropivacaine 3.5 mL produce shorter motor blockade then 3.5 mL bupivacaine. Both Group R and Group B were comparable in terms of ability to void urine (p>0.05), time to complete ambulation without support (p>0.05), and time to negative Romberg test (p>0.05). Negative correlation was found between the first spontaneous void urine and the modified Bromage scale.

Conclusions: After SA with bupivacaine, only two patients developed post-operative urinary retention and none in the ropivacaine. However, Group R required lesser time to void and early recovery of motor function. The time to first void urine was more than the time for complete ambulation (1–3.5 h after ambulation).

Keywords: Fixed-dose spinal anesthesia, Urinary retention, Ultrasound-guided bladder volume measurement, Modified Bromage scale, Romberg test, Time to first spontaneous voiding.

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INTRODUCTION

Ambulatory surgical interventions are occurring more frequently, as a consequence of mounting financial strain in the public health system. Spinal anesthesia (SA) is quick, cost-effective, and safe and seems to be ideal for below umbilical surgery and lower limbs surgery [1]. Although bupivacaine is used widely, hyperbaric ropivacaine 0.75% has gained popularity due to reduced potential for cardiotoxicity and neurotoxicity and is thus safer than bupivacaine. Ropivacaine has low lipid solubility, which is responsible for its lower penetration into myelinated motor fibers and thus lesser motor blockade with greater sensory–motor differentiation, and the effect of ropivacaine is of short duration, faster recovery of sensory and motor function.

Voiding capacity of urine is frequently seen as a crucial factor for early discharge following day care surgery [2]. Post-operative urinary retention (POUR) is the second most common complication seen after SA. Urinary retention that causes prolonged bladder distention can cause urinary tract infection and even harm the surgical repair made during pelvic and perineal surgery [3].

The present study used fixed doses of 3.5 mL 0.5% hyperbaric bupivacaine and 3.5 mL hyperbaric ropivacaine 0.75% to compare the time taken for first voiding of urine or need of catheterization in patients undergoing surgery for hernia after SA.

METHODS

This was a double-blinded study, and after obtaining institutional ethical committee approval and informed patient consent, a prospective,

single-center interventional study was conducted. Inclusion criteria for the study were patients aged 19–60 years, patients with American Society of Anesthesiologists (ASA) I, II, and III, patients undergoing elective surgery of hernia, surgeries lasting not more than 2 h, and patients willing to provide informed consent for SA. Exclusion criteria were patients with prostate hyperplasia, renal and liver disease, previous or current psychiatric illness, allergy to study drugs, and any contraindication to SA.

Patients were randomly allocated using sealed envelope into two groups of 30 patients in each Group R (ropivacaine) and Group B (bupivacaine). To achieve blinding in this study, an assistant prepared the drug syringes just before surgery in each case as well as coded them with the patient's number was the only one who knew the true 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.

The observer and patient were blinded about drugs given and group allocation. The anesthetic procedure and study procedure were explained to the patients. 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 or uncomfortable and cannot void.

All patients were asked to void just before surgery and bladder volume was measured with ultrasound just before giving SA. Patients with post-voiding residual volume exceeding 50 mL were excluded from the study.

Intravenous access was secured and IV fluids were started. Patients were monitored with electrocardiography, non-invasive blood pressure, and pulse oximetry measurement. Patients in both the groups received injection glycopyrrolate 4 $\mu g/kg$ and injection ondansetron 0.15 mg/kg as a premedication. Under all aseptic precautions, intrathecal injection was performed with 25 gauge Quincke needle at L3-L4 OR L4-L5 interspace. Group R received injection ropivacaine hyperbaric 0.75% 3.5 mL and Group B received injection bupivacaine hyperbaric 0.5% 3.5 mL. Patients were given oxygen through face mask (4 L/min). In the operating room, all vitals were monitored continuously. Any hypotension and bradycardia were treated with injection mephentermine and injection glycopyrrolate, respectively, if needed.

After surgery, ultrasound scans of the bladder were performed 2 hourly until spontaneous micturition or catheterization needed. Urinary retention was defined as a bladder volume >600 mL together with the inability to micturate. Patients were catheterized when these criteria were met. The commonly used modified Bromage scale was used to evaluate the patients' motor recovery process (Appendix 2). For motor function evaluation, Romberg test and ambulation test (assisted and unassisted) were performed when patients had attained a modified Bromage score of 0 and can perform a 90° leg raise. Assisted ambulation test was performed when helping someone in standing up and beginning to move with someone or something. Romberg test was interpreted negative if the entire motor activity was present; yet, it was interpreted positive if an anesthetic effect was present.

Demographic profiles such as age, ASA grade, body mass index, and surgical time were compared using mean and standard deviation. The discrete data were assessed by numbers and percentage. The difference

Table 1: Demographic distribution of patients

| Variable | Group R | Group B | p |
|------------------------------|----------|----------|------|
| Age (mean±SD) | 48±7.46 | 46±8.5 | 0.46 |
| ASA physical status I/II/III | 7/10/13 | 6/14/10 | 0.56 |
| BMI | 22.4±1.6 | 22.6±1.9 | 0.75 |
| Surgical time (min) | 84±17.4 | 82±14.5 | 0.77 |

^{*}Chi-square test. BMI: Body mass index, SD: Standard deviation, ASA: American Society of Anesthesiologists

in observations between the two groups was determined by the Chisquare test and t-test whenever it was applicable. After data tabulation in Microsoft Excel, descriptive and analytic statistics were performed for the two study groups using Epi Info software. p<0.05 was considered statistically significant.

alculation of sample size

We used data from a previous study to calculate the sample size [4]. Using Microsoft Office Excel-13 software, the mean±standard deviation time to void urine was 7±1.3 h for ropivacaine and 8±2.3 h for bupivacaine. The significance level was taken as 5%, and the power was taken as 90%. The required sample size came to 30 for each group and the total required sample size for both the groups.

Statistical analysis

Analysis of the data obtained was done by an independent investigator, which was not involved in the care of the patient. Analysis was done on 60 patients, with 30 in each group. The data were entered into Ms Excel and were tested with Student's t-test and Chi-square test as applicable. The p < 0.05 was considered statistically significant. Correlation coefficients were calculated between the time to void first urine after the procedure and the modified Bromage score.

RESULTS

This study group resembles the population as the difference between two groups of patients among their variables such as age, ASA status, BMI, and surgical time have no significant differences (p>0.05).

As described in Tables 2 and 3, there was a negative correlation between the time to void first urine and modified Bromage scale, as in our study value of the correlation coefficient lies between 0 and -0.3 which shows week negative correlation (a negative correlation coefficient of -0.8 indicate a strong correlation and correlation coefficient -0.3 indicates weak correlation).

There was no significant difference between the two groups for time to void first urine (p=0.098). When it comes to time to assisted and complete ambulation too, there was no significant difference between the two groups (p=0.101 and 0.108, respectively). Effect of the motor block was significantly denser in Group B than Group R (p=0.00011 at 4 h of postoperatively). Finally, there was no significant difference in Romberg test to be negative between the two Groups (p=0.13).

Table 2: Ropivacaine group: Correlation coefficients between time to void urine and modified Bromage scale

| Variable | Bromage scale at 1 h after spinal anesthesia | Bromage scale at 2 h after spinal anesthesia | Bromage scale at 3 h after spinal anesthesia | Bromage scale at 4 h after spinal anesthesia |
|-------------------------|---|--|--|--|
| Correlation coefficient | -0.166 | -0.07 | -0.15 | -0.44 |

Table 3: Bupivacaine group: Correlation coefficients between time to void urine and modified Bromage scale

| Variable | Bromage Scale at1 h | Bromage Scale at 2 h | Bromage Scale at 3 h | Bromage Scale at 4 h |
|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | after spinal anesthesia | after spinal anesthesia | after spinal anesthesia | after spinal anesthesia |
| Correlation coefficient | -0.007 | -0.14 | -0.04 | -0.06 |

Table 4: Effect of spinal anesthesia on motor function and urine voiding function in hours

| Characteristics | Group R (n=30) mean±SD in hour | Group B (n=30) mean±SD in hours | p |
|---------------------------------------|--------------------------------|---------------------------------|---------|
| Time to first void urine | 4±1.03 | 4.5±1.04 | 0.0 |
| | | | 98 |
| Time to assisted ambulation (with the | 3.2±0.56 | 4.0±0.7 | 0.101 |
| help of someone or aid of something) | | | |
| Time to complete ambulation | 4.3±0.9 | 7.4±1.1 | 0.108 |
| Bromage score (4 h post-anesthesia) | 4.9±0.66 | 4.1±0.79 | 0.00011 |
| Time to Romberg test to be negative | 6.7±0.57 | 7.5±0.63 | 0.13 |

^{*}Student's t-test

Table 5: Blader volume assessment

| Bladder volume | Group R (Mean±SD) | Group B (Mean±SD) | p (t-test) |
|-------------------|----------------------|----------------------|------------|
| Bladder volume | 19.5±03.69 | 20±05.0 | 0.39 |
| before surgery | | | |
| 2 h after surgery | 48±08.0 | 56.5±016.2 | 0.065 |
| 4 h | 89.66±010.5 | 98.16±032.73 | 0.18 |
| 6 h | 159±07.62 | 155.5±046.7 | 0.715 |
| 8 h | 215±026.66 | 236.16±065.9 | 0.125 |

^{*}Student's t-test

There was no significant difference in bladder volumes assessed by ultrasonography in both the groups at various hours (p<0.05).

DISCUSSION

POUR, a common phenomenon across surgical centers, has been variously defined as "the inability to void urine 8 h after the end of surgery with bladder being distended or patient being uncomfortable [5] or to "inability to void urine >12 h after induction of anesthesia with >500 mL urine drained on catheterization [6].

In our study, when bupivacaine and ropivacaine were used in the doses of 3.5 mL for SA, we found a statically significant difference in recovery of motor functions. Motor blockage was more prolonged in the bupivacaine group. However, Group R required more or less the same time to void urine as compared to Group B. No patient developed the POUR in the ropivacaine group, while two patients of the bupivacaine group developed retention and needed catheterization.

The incidence of urine retention after central neuraxial conduction blocking, which included SA, epidural anesthesia (EA), and combination spinal-EA, varied widely ranging from 0% by Mulroy *et al.* [7] to 76% by Gedney and Liu [8]. According to Gautier *et al.*, using ropivacaine for SA causes a lower incidence of POUR and enabled patients to move and urinate earlier than those receiving an equivalent dose of bupivacaine [9]. In our study, we could not find such a difference.

High-dose, long-acting local anesthetic usage was found to higher prevalence of POUR [6,10]. The time to void was shortened with short-acting and low-dose local anesthetics due to a quicker regression of sensory and motor block [11,12], which resulted in quick recovery of bladder function, which is necessary for daycare surgery. The observation that total normalization of detrusor strength occurs about 1–3.5 h after ambulation is comparable with the time to void urine, which was longer than the time required for complete ambulation [7,8].

Particularly, in the case of ropivacaine, there was a significant less dense motor block at 4 h. In a comparable manner, Axelsson *et al.* showed that bladder function restoration takes longer than motor function restoration for ambulation [13]. As detrusor strength recovers later than the recovery of patient's capacity to stand stably without swaying, that is, negative Romberg test, ability to void had a high positive relation between ambulation and ability to do the Romberg test.

In addition to other pre-operative risk, the meta-analysis by Baldini et al. revealed that the two main perioperative factors that cause POUR are a lengthy surgery procedure and SA or EA. To minimize POUR, the most suitable one spinal anesthetic drug, and dosage are still unknown [14].

Van Kleef *et al.* reported good-quality motor block for ropivacaine without any unanticipated adverse effects [15]. According to a study by Kulkarni *et al.*, intrathecal ropivacaine was linked, in comparison to bupivacaine, to delayed onset sensory block, rapid recovery of motor functions, and earlier function of voiding the urine [16]. Malhotra *et al.*'s meta-analysis, however, showed that ropivacaine and bupivacaine

had comparable sensory blockage qualities, whereas motor function recovery was quicker with ropivacaine [17].

CONCLUSIONS

Using 3.5 mL bupivacaine heavy or ropivacaine heavy for surgical anesthesia resulted in satisfactory anesthesia and recovery of urinary function within 6–10 h postoperatively. Time for micturition took longer than time for ambulation. Both study medicines showed a high positive association between time to void urine and time for complete ambulation with negative Romberg test. Both the drugs are comparable in terms of the occurrence of POUR.

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AUTHOR'S CONTRIBUTION

Dr. Hetal Kanabar: Concept and design of the study and prepared the first draft of the manuscript. Dr. Dipti Desai: Interpreted the results; reviewed the literature and manuscript preparation. Dr. Dinesh C. Babariya: Design of the study, literature search, and data acquisition. Dr Laxmi Yadav: Manuscript preparation and manuscript editing. Dr. Kanvee M. Vania: Editing of the manuscript.

CONFLICTS OF INTEREST

The author confirms no conflicts of interest.

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APPENDIX

Appendix Table

| Grade | Bromage score criteria |
|-------|---|
| 1 | Complete block |
| 2 | Almost complete block, able to move feet only |
| 3 | Partial block, able to move knee |
| 4 | Detectable weakness of hip flexion |
| 5 | No detectable weakness of hip flexion |
| 6 | Able to flex knee |