



## EFFECTIVENESS OF TAMSULOSIN IN PREVENTION OF POST-OPERATIVE URINARY RETENTION (POUR)

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### ABSTRACT

**Background-** The prophylactic effect of tamsulosin in reducing POUR has not been investigated in a large randomized double blind study. Therefore the present study was conducted to investigate the efficacy of tamsulosin compared with placebo in preventing POUR.

**Methods-** This prospective randomized double blind, placebo controlled was performed in General Surgery Department of S.P. Medical College and associated group of hospitals, Bikaner, Rajasthan.

**Results-** 14 patients had surgery duration more than 45 minutes, out of which 9 (64.28%) patients developed POUR, On other side in 86 patients had surgery time less than 45 minutes, out of which 36 patients (42.8%) developed POUR.

**Conclusion-** Based on our study, pre-operative and peri-operative tamsulosin administration reduces the incidence of postoperative urinary retention and the need for catheterization in males after surgeries under spinal anesthesia.

**KEYWORDS :** POUR, Surgery, tamsulosin.

### INTRODUCTION

Post-operative urinary retention (POUR) is defined as the inability to void after surgery when the bladder is full.<sup>1,2</sup> POUR is common and represents upto 70% of all surgeries,<sup>1</sup> especially after hernia surgery<sup>3,4</sup> and anorectal surgery<sup>5-7</sup>. Typically, this phenomenon is painful and can result in increased cost of hospitalization, prolonged length of hospital stay, and urinary tract infection (UTI) which can occur primarily or secondarily to catheterization<sup>1,8</sup>. Urethral catheterization, a mainstay of initial management for patients with POUR, is associated with some complications and increase in cost of care.<sup>1,2,8</sup> Therefore, pharmacological therapy is considered as an interesting approach for patients developing urinary retention following surgery.<sup>2</sup>

Spinal anesthesia will block the afferent and efferent neural transmission from and to spinal segments S<sub>2</sub>-S<sub>4</sub> after 30-60 sec of spinal anesthetic injection, sensation of urgency to void disappears after 2 to 5 minutes because the detrusor contraction is completely abolished and its recovery depends on the duration of sensory block above S<sub>2</sub> and S<sub>3</sub> sacral segments, which is 5 to 6 hours. Complete normalization of detrusor strength occurs in 8 to 10 hours.<sup>9,10</sup>

Therefore, inhibition of alpha-adrenergic receptors located on the bladder neck and proximal urethra may prevent POUR and improve voiding. Several drugs including alpha-blockers and parasympathomimetics had been under investigation for their effectiveness in preventing POUR. Recent evidence has shown that the use of alpha-blockers facilitate voiding by decreasing the resistance of the proximal urethra and bladder neck and improving the urine flow.

Tamsulosin is a safe selective alpha 1-adrenergic receptor blocker characterized by its favorable side effect profile. The prophylactic effect of tamsulosin in reducing POUR has not been investigated in a large randomized double blind study. Therefore the present study was conducted to investigate the efficacy of tamsulosin compared with placebo in preventing POUR.

### MATERIAL AND METHODS

This prospective randomized double blind, placebo controlled was performed in General Surgery Department of S.P. Medical College and associated group of hospitals, Bikaner, Rajasthan.

#### Subjects

Male patients below 60 years who will be admitted in our center for elective surgery of inguinal hernia, varicocele, hydrocoele or other scrotal surgeries, fissure in ano, fistula in ano, perianal abscess, hemorrhoids or other surgeries under spinal anesthesia will be included in our study.

**Study Period:** 1 March, 2019 to 30 November, 2020.

**Study design:** Observational prospective randomized double blinded placebo control study.

**Sample Size:** Total patients to be taken 100, 50 patients will be taken in case group and 50 patients in control group.

#### EXCLUSION CRITERIA

- 1) Patients who have urinary symptoms before surgery,
- 2) A known history of neurological, urological or significant systemic disease (such as diabetes mellitus),
- 3) Previous history of urinary retention,
- 4) Previous urological surgery,
- 5) History of using medications that could interfere with natural voiding function such as benzodiazepines, cholinergic drug prior to surgery, or current treatment with alpha or beta agonists,
- 6) Surgical procedures last more than 90 minutes.

#### Method

After obtaining written informed consent from all participants, patients will be randomized to receive either two doses of 0.4mg of tamsulosin or placebo. Dose modifications will not be made in this study. If a subject has an intolerable adverse event or side effects related to the study treatment, the drug will be discontinued and the subject will be removed from the protocol.

All patients had undergone a clinical examination and blood

and urine analysis before surgery. Then, eligible patients included into the study based on clinical, laboratory, exclusion and inclusion criteria. After receiving the demographic data, the patients were randomly assigned (ratio 1:1) into two groups of intervention (50 subjects, administered 0.4 mg tamsulosin) and control (50 subjects received placebo at similar times in the intervention group). Duration of surgery was less than 90 minutes for both groups. For all patients, intravenous fluid less than 1500ml was prescribed in the operating room. Surgery was performed after short-term spinal anesthesia (lidocaine 5%). For postoperative pain control non steroidal anti-inflammatory drugs (NSAIDs) were used. Patients more than 60 years of age was not included in this study due to the higher prevalence of acute urinary retention in elderly people. It was considered to prevent bias from the high incidence of urinary retention in the elderly. Follow up outcome data will still be collected to allow for intent-to-treat analysis.

**Interventions**

Half-life of tamsulosin is 9-15 hours, so we will administer two doses with 12 hours intervals. The medications will be administered 14 and 2 hours before surgical operation. In case group patients were given oral tamsulosin tablet 0.4 mg and in control group patients were given placebo tablet in same schedule. These tablets were coded and given by investigator who was not involved in further study for ensuring double blinding. Patients will be asked to empty their bladder prior to surgery. Surgery will be performed under spinal anesthesia. Then the patients will be closely monitored by blinded research associates for the presence of urinary retention, any voiding difficulty and side effects during 12 hour after surgery, and the occurrence of POUR will be compared between both groups. Patients will be allowed to void once they felt they have a full bladder. NSAIDs prescribe for postoperative analgesia. Opioid analgesics will not administered to any patient postoperatively.

**Measurement**

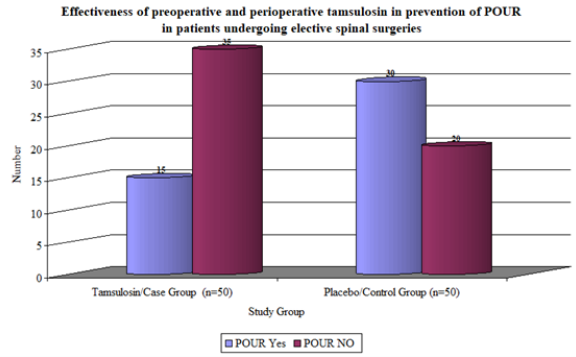
The diagnosis of urinary retention will be established when the patient had a painful and palpable mass in his suprapubic area, and was unable to void during the first 12 hours after surgery. The diagnosis will be confirmed by emptying of more than 400mL of urine by catheterization. A 14-French nelaton catheter will placed to decompress the bladder of patients who have palpable bladder or who did not urinate 12 hours after surgery. Catheter will be removed after 48 to 60 hours of chaterization and start voiding trial. If patient fails a voiding trial and develop urinary retention, outpatient urology consultation recommended. Patient will be discharged after a successful voiding trial without catheter.

**DATA ANALYSIS:**

Allobtained data weretabulated andimportantstatistical analysiswas done withthe help of SPSSsoftware (version 23). Microsoft excel and Microsoft word were usedto obtainvarious types of graphs such as bardigram. Chi-squared testand t test were used as test of significance for qualitative data. p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

**RESULTS**

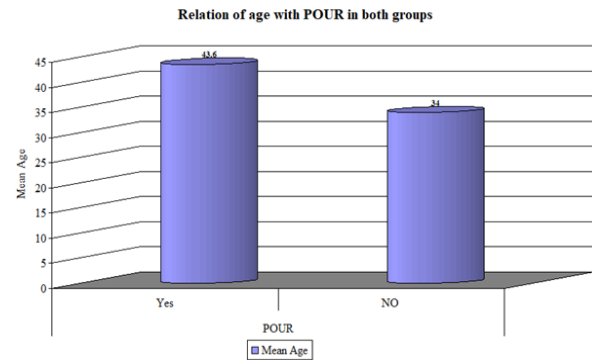
In this study, 50 patients included in tamsulosin group and 50 patients in control or placebo group. POUR in patients who received tamsulosin was significant lower than patients who received placebo, as 30% of patients treated with tamsulosin and 60% patients in placebo group reported urinary retention following surgery (p value =0.005).



**Relation of age with POUR in both groups**

|                        | All         | POUR      |           | P value |
|------------------------|-------------|-----------|-----------|---------|
|                        |             | Yes       | NO        |         |
| Mean age±SD (in years) | 38.38±13.10 | 43.6±12.5 | 34.0±12.2 | 0.0001  |

In this study, we found mean age of patients with POUR (43.6±12.5 years) was significantly higher than mean age of patients without POUR (34.0±12.2 years). (P value=0.0001)



**Distribution of patients according to duration of surgery with development POUR in all groups**

| Duration of surgery | Total         | POUR |
|---------------------|---------------|------|
| < 45min             | 86            | 36   |
| > 45min             | 14            | 9    |
| <b>Chi square</b>   | <b>12.776</b> |      |
| <b>p-value</b>      | <b>0.018*</b> |      |

\*p-value <0.05 is significant

14 patients had surgery duration more than 45 minutes, out of which 9(64.28%) patients developed POUR, On other side in 86 patients had surgery time less than 45 minutes, out of which 36 patients (42.8%) developed POUR.

**DISCUSSION**

Postoperative urinary retention is a well established and commonly encountered problem across all surgeries in patients undergoing spinal anaesthesia .Many factors associated with POUR like underlying disease, effects of anaesthetic agents, perioperative fluid therapy, surgical intervention, bladder outlet problems, postoperative immobilization, postoperative pain and use of narcotics for the same, duration of surgery, gender and age.

**Three methods have been used to diagnose POUR:**

- 1) History and physical examination (lower abdominal pain and discomfort and palpation or percussion of bladder in suprapubic area);
- 2) Bladder catheterization;
- 3) Ultrasonographic assessment of bladder postoperatively.

We used 1<sup>st</sup> criteria to confirm POUR in our study: patients

discomfort or palpable bladder or inability to void more than 12 hours after induction of anesthesia. We included patients upto 60 years old, because in older age there is a decrease in contractility of detrusor and increase in incidence of some diseases such as benign hyperplasia of prostate that present with urinary symptoms and may interfere with study results (development of urinary retention).

Present study is prospective randomized double blind, placebo controlled and was performed in General Surgery, Department of S.P Medical College and associated group of hospitals, Bikaner to determine if tamsulosin administered preoperatively and perioperatively is more effective than placebo in preventing postoperative urinary retention in patients undergoing elective spinal surgery.

In this study, 100 male patients below 60 years who were admitted in our center for elective surgery of inguinal hernia, varicocele, hydrocoele or other scrotal surgeries, fissure in ano, fistula in ano, perianal abscess, hemorrhoids or other surgeries under spinal anesthesia were included. After obtaining written informed consent from all participants, patients were randomized to receive either two doses of 0.4mg of tamsulosin or placebo. Dose modifications will not be made in this study.

The key finding of this study was, Patients who received tamsulosin preoperative less likely developed POUR. In case group 50 patient given tamsulosin out of which 15(30%) developed POUR and in control group how received placebo 30 patient (60%) develop POUR. This observation was statically significant (P value < 0.05).

Similar findings were obtained in a study by Madani et al. where they studied effectiveness of tamsulosin in prevention of postoperative urinary retention. They found that POUR in patients who received tamsulosin was significantly lower than placebo, as 5.9% of the patients treated with tamsulosin and 21.1% placebo group, reported urinary retention following surgery (p = 0.001).<sup>11</sup>

In a study among 626 patients, undertaken by Ahmad et al. to assess preventive effects of tamsulosin on POUR post anorectal surgeries under spinal anaesthesia, they found that use of tamsulosin (0.4 mg oral tamsulosin 6 hours preoperatively and 6-8 hours postoperatively) led to reduction in incidence of post operative urinary retention. Similar to findings of our study.<sup>12</sup>

Mohammadfallah et al. also found that perioperative tamsulosin represents effective strategy to reduce the risk of POUR in patients undergoing inguinal herniorrhaphy.<sup>13</sup>

Another study was undertaken by Akkoc et al. where they studied prophylactic effects of alpha blockers on postoperative urinary retention in 180 patients undergoing surgery under spinal anaesthesia. They also found that incidence of urinary retention (defined in their study as painful suprapubic bulge, confirmed by 500ml of urinary evacuation post catheterization) was significantly lower in tamsulosin group, being 5%, compared to 25% in control group. They also thus suggested as in our own study that preoperativetamsulosin reduces incidence of POUR and also need for urinary catheterization after surgeries under spinal anaesthesia.<sup>14</sup>

Petros and colleagues reviewed 295 inguinal herniorrhaphies in spinal anesthesia, age less than 53 years, and perioperative fluid less than 1200ml significantly reduced the incidence of POUR.<sup>15</sup> Lee and colleagues declared that POUR increases with age, with the risk increasing by 2.4 to 2.8 times in patients over 50 years of age.<sup>16</sup> MohammadFallah et al. no

statistically significant differences were found between the two groups in terms of age (p=0.18).<sup>13</sup> In our study we observed POUR is more common in older age group. 58.33% patients developed POUR in 51 to 60 years age group compare to 38.8% in 20 to 30 years age group.

Prolonged duration of surgery can cause POUR. Pavlin et al. found a significant correlation between bladder volume and the duration of surgery but failed to show a relationship between the bladder volume and the total amount of fluids administered.<sup>17</sup> In contrast, Peterson did not find any causal relationship between the duration of surgery and the risk of POUR.<sup>18</sup>

In our study we found that patient who have longer duration of surgery have more chances of developing POUR, 14 patients have surgery duration more than 45 minutes out of which 9(64.28%) patient developed POUR. On other side in 86 patients have surgery time less than 45 minutes 36 patients (42.8%) developed POUR.

In our study, only men were included and the other limitation of our study was that we did not record preoperative and postoperative fluid intakes of the patients.

## CONCLUSION

Based on our study, preoperative and perioperativetamsulosin administration reduces the incidence of postoperative urinary retention and the need for catheterization in males after surgeries under spinal anesthesia.

However, we recommend that this study be carried out more extensively on larger samples on different populations to arrive at final conclusion regarding validity of preoperative tamsulosin drug usage.

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