Preventive effects of tamsulosin for postoperative urinary retention after lower limb arthroplasty: A randomized controlled study

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Purpose: This prospective, randomized, controlled study investigated the use of tamsulosin, a selective alpha-blocker, as a prophylactic medication to prevent postoperative urinary retention (POUR) following lower limb arthroplasty.

Materials and Methods: The criterion for diagnosing POUR was the use of a postoperative bladder volume of over 400 mL with incomplete emptying. Patients who underwent primary total hip or knee arthroplasty were randomly assigned at a 1:1 ratio to tamsulosin treatment and non-treatment groups at a single center from September 2018 to November 2018. The treatment group received 0.2 mg of tamsulosin orally once at night for 3 days starting on postoperative day 1. During this 3-day period, an indwelling Foley catheter was maintained. The incidence of POUR according to tamsulosin treatment following lower limb arthroplasty was the primary outcome.

Results: In total, 100 patients were enrolled, of whom 5 discontinued participation. POUR was diagnosed in 20 of the remaining 95 patients (21.1%). The treatment group contained 48 patients, of whom 6 (12.5%) developed POUR, whereas POUR occurred in 14 of the 47 patients (29.8%) in the non-treatment group. Tamsulosin treatment reduced the risk of POUR by two-thirds (odds ratio [OR], 0.337; 95% confidence interval [CI], 0.117–0.971; p=0.044). The risk reduction associated with tamsulosin treatment remained robust post-adjustment for potential covariates (OR, 0.250; 95% CI, 0.069–0.905; p=0.038).

Conclusions: Tamsulosin administration immediately after lower limb arthroplasty reduced the incidence of urinary retention and diminished the need for long-term catheterization.

Keywords: Adrenergic alpha-antagonists; Aged; Arthroplasty; Urinary retention

INTRODUCTION

Lower limb arthroplasty is a common operation in elderly patients with degenerative arthritis, and one of the most frequent complications after total joint arthroplasty is postoperative urinary retention (POUR) [1]. POUR refers to a condition in which after surgery, a patient cannot urinate even when the bladder is completely filled [2]. This condition causes considerable distress in patients who undergo surgery, and sometimes it is not appropriately recognized. A failure to promptly detect and treat POUR can lead to bladder overdistention, which in turn increases the need for...
subsequent long-term catheterization after joint replacement surgery [3].

POUR has also been shown to prolong the length of hospital stay and to increase the risk of urinary tract infections (UTIs), which in turn result in a higher risk of infectious prosthetic joint complications. Indwelling catheter use can cause postoperative UTIs, and this risk increases with longer durations of catheter indwelling [4]. UTIs can cause hemotogenous bacteremia, which results in seeding of the prosthetic implants and ultimately leads to surgical infections after lower limb arthroplasty [5,6]. Therefore, perioperative pharmacological therapy using alpha-adrenergic antagonists has been considered as a way to reduce POUR [7,8].

Increased sympathetic activity contributes to POUR development after surgery, and treatment with alpha-adrenergic antagonists decreases the resistance of the proximal urethra and bladder neck and helps to restore postoperative urination. Tamsulosin treatment has recently been reported to be effective in preventing POUR after spine surgery, pelvic surgery, and herniorrhaphy [7,9,10].

In our previous study, we retrospectively explored predictive factors for POUR after lower limb arthroplasty and identified intraoperative volume overload and older age as independent risk factors for POUR [11]. This prospective randomized controlled study investigated tamsulosin, an alpha-adrenergic antagonist, as a prophylactic treatment for the prevention of POUR after lower limb arthroplasty.

MATERIALS AND METHODS

The Institutional Review Board of the Hallym University Dongtan Sacred Heart Hospital approved the protocol for the present study (approval number: HDT 20154009). This prospective, randomized, single-blind trial was carried out between September 2018 and November 2018. The study was conducted in a way that aligned with the Declaration of Helsinki. The study protocol adhered to the SPIRIT recommendations [12,13], and the study was reported in accordance with the CONSORT guidelines [13].

Of the patients hospitalized for lower limb arthroplasty, those who volunteered to participate in this trial and provided written informed consent were enrolled in this study. Patients over the age of 18 who underwent primary total hip or knee arthroplasty were included. Patients undergoing revision surgery were excluded. Patients taking medications for lower urinary tract symptoms or who had previously undergone prostatectomy were excluded from the study. Patients who preoperatively needed urinary diversions such as an indwelling urethral catheter or suprapubic cystostomy were also excluded, as were patients with a history of pelvic organ prolapse, urinary incontinence, or urinary retention. In addition, patients with orthostatic hypotension or dizziness were excluded.

1. Randomization

The research coordinator randomly assigned all eligible patients at a 1:1 ratio to either the tamsulosin treatment or non-treatment group using a computer-generated randomization table. The investigators were blinded to the treatment allocation until the trial was completed and the database was locked.

2. Intervention

Patients in the treatment group received 0.2 mg of tamsulosin administered orally once at night for 3 days, starting on postoperative day 1. A 16-Fr Foley catheter was inserted in the operating room immediately prior to surgery. According to our previous study, the indwelling Foley catheter was maintained for 3 days postoperatively [11]. The patient-controlled analgesia regimens were typically an established Intravenous set consisting of fentanyl citrate (2 mg) or an epidural set consisting of fentanyl citrate (0.5 mg) and ropivacaine hydrochloride monohydrate (0.2%).

3. Outcome assessment

The primary outcome was the incidence of POUR depending on whether patients received tamsulosin treatment following lower limb arthroplasty. The definition of POUR was clinical evidence of over 400 mL of residual urine volume by bladder ultrasound after a postoperative trial without a urethral catheter. The patients were checked using bladder ultrasound to determine whether they were unable to void or showed incomplete emptying in spite of a desire to void at least 4 hours after urinary catheter removal. In patients without a voiding sensation following removal of the Foley catheter, bladder ultrasound was used to check the residual urine volume at 6 hours later. If the residual urine volume exceeded 400 mL, urethral catheterization was performed. Those patients were classified as having POUR.

We collected data on parameters that could affect POUR, including patients’ demographic characteristics and perioperative findings, such as sex, body mass index, American Society of Anesthesiologists classification of physical status, type of surgery, volume of estimated blood loss, operative duration, anesthetic duration, volume of intraoperative intravenous fluid, volume of transfusion, and type of patient-controlled analgesia.
4. Statistics

As the primary outcome, the incidence of POUR after knee or hip arthroplasty was utilized for power analysis. The sample size was calculated using our published data and the pooled data from previous studies conducted with tamsulosin. The prior data from our institution indicated that the POUR rate after lower limb arthroplasty was 27.4% [11]. Previous studies reported the POUR rate after genitourinary surgery in tamsulosin-treated patients to be 5.3% [7,8,10]. The required sample size was calculated to be at least 45 for each group, with a type I error rate of 0.05 and an 80% power in a two-sided test, and an overall dropout rate of 10%. The Pearson chi-square test was performed to compare the difference in POUR incidence between the treatment and non-treatment groups. The associations of POUR with various clinical factors were analyzed using a multivariate backward stepwise logistic regression model to adjust for other related covariates. Backward elimination was conducted and variables with a p-value >0.2 were removed. The Hosmer–Lemeshow test was used to evaluate the regression model’s goodness of fit. Another comparative analysis between the two groups was performed using the Pearson chi-square or Student t-test for categorical and continuous variables, respectively. A two-tailed p-value <0.05 was considered to indicate statistical significance. The statistical analysis was performed using SPSS for Windows version 24.0 (IBM Corp., Armonk, NY, USA).

RESULTS

In total, 100 patients were enrolled, of whom 5 discontinued participation. One patient was treated in the intensive care unit for sepsis, including a UTI, and had an indwelling Foley catheter for a long time. Two patients requested an indwelling urethral catheter for another health problem, and the catheter was therefore not removed at 3 days postoperatively. One was later confirmed to have undergone previous prostatic surgery. There was one patient who did not receive any medication due to a mistake made by a research assistant. Data from 95 patients were analyzed. None of the patients discontinued the study due to medication-related adverse events (Fig. 1).

Patients’ baseline demographic characteristics and perioperative clinical data are summarized in Table 1. Sixty-five and 30 patients underwent hip and knee arthroplasty, respectively, and the two groups did not show any significant differences. The mean age of the participants in the two groups was similar. The two groups also showed no significant differences in sex, body mass index, comorbidities, operative duration, and intraoperative fluid administration.

Ninety-five patients underwent lower limb arthroplasty, of whom 20 (21.1%) developed POUR. The treatment group
contained 48 patients, of whom 6 (12.5%) were diagnosed with POUR, whereas POUR occurred in 14 of the 47 patients (29.8%) in the non-treatment group (Fig. 2). Tamsulosin treatment decreased the likelihood of developing POUR after lower limb arthroplasty by two-thirds (odds ratio [OR], 0.337; 95% confidence interval [CI], 0.117–0.971; p=0.044). The effect of tamsulosin remained consistent when the effects of potential covariates were adjusted (OR, 0.250; 95% CI, 0.069–0.905; p=0.038). Also, 38 patients (40%) were over 76 years, these patients could be associated with increased risk for POUR in multivariate analysis (OR, 3.667; 95% CI, 1.032–13.024; p=0.045) (Table 2).

**DISCUSSION**

Acute POUR is a frequently encountered complication, with an estimated incidence in general surgical patients of 21% to 36.6% [2,14,15]. POUR has a variety of adverse implications for patients and may affect surgical outcomes.

The pain or discomfort associated with POUR appears to be caused by bladder distention. Sympathetic stimulation in response to pain can give rise to hemodynamic changes such as...
as dysrhythmias and asystole [16]. Long-lasting ischemia of the bladder as a result of persistent over-distension can lead to longer-term bladder dysfunction and chronic kidney disease [17]. POUR may also have indirect sequelae, including delays in discharge from the hospital and iatrogenic UTIs, both of which can lead to increased hospital costs [18].

Because of differences in diagnostic criteria, few studies have reported post-void residual volume cut-off values, and there are currently no standard recommendations. Bladder volumes of 400 to 600 mL have been used as a criterion for the diagnosis of POUR [2,19-21]. We used a postoperative bladder volume over 400 mL with acute urinary retention symptoms as the criterion for diagnosing POUR. The reported incidence of POUR after lower limb arthroplasty ranges widely, from 10.7% to 77.8% [22]. The reported incidence of POUR after lower limb arthroplasty is up to 20 times greater than its incidence following any other procedure [23]. In our previous study, POUR occurred following lower limb arthroplasty in approximately 27% [11]. The present study found an incidence of POUR after lower limb arthroplasty of 21.1%. The incidence of POUR in the tamsulosin treatment group was 12.5%, while it was 29.8% in the non-treatment group. The OR for POUR in the treatment group was 0.337, reflecting a statistically significant difference. When the effects of potential covariates were adjusted, it was found that tamsulosin treatment lowered the risk of POUR to 0.25 times that of the untreated group, indicating that tamsulosin treatment for 3 days after lower limb arthroplasty was effective in reducing POUR.

Sympathetic, parasympathetic, and efferent somatic fibers supply the bladder. Visceral afferent fibers, also referred to as stretch receptors, arise from the bladder wall. Micturition, which is a physiologically intricate process, can be divided into the storage and voiding phases. Sympathetic innervation mediates the storage phase, whereas parasympathetic fibers are responsible for the voiding phase. Brainstem centers further govern micturition, which is a spinal reflex. Although the pathophysiology of POUR is not thoroughly understood, the greater length of time needed to recover bladder function after lower limb joint arthroplasty may be explained by the fact that lumbar spinal anesthesia involves a lower level of sensory and motor blockade than occurs with thoracic spine anesthesia [23]. Furthermore,

![Graph](image_url)

**Fig. 2.** Incidence of POUR among patients who underwent lower limb arthroplasty. Ninety-five patients underwent lower limb arthroplasty, of whom 20 (21.1%) had postoperative urinary retention (POUR). Of the 48 patients in the treatment group, 6 (12.5%) developed POUR after hip or knee arthroplasty, versus 14 of the 47 patients (29.8%) in the non-treatment group. *p<0.05.

**Table 2.** Significant predictive factors for acute postoperative urinary retention after lower limb arthroplasty by Cox univariate and multivariate analyses

| Variable                        | Univariate          | Multivariate         |
|---------------------------------|----------------------|----------------------|
|                                 | p-value | Odds ratio | 95% confidence interval | p-value | Odds ratio | 95% confidence interval |
| Tamsulosin                      | 0.044   | 0.337     | 0.117–0.971            | 0.038   | 0.250     | 0.069–0.905             |
| Age >76 y                       | 0.003   | 4.958     | 1.698–14.490           | 0.045   | 3.667     | 1.032–13.024            |
| Sex, male                       | 0.547   | 1.412     | 0.460–4.337            |         |           |                      |
| Body mass index >25 kg/m²       | 0.058   | 0.342     | 0.113–1.037            | 0.055   | 4.056     | 0.969–16.972            |
| Diabetes mellitus               | 0.016   | 3.879     | 1.291–11.650           |         |           |                      |
| Cerebrovascular accident        | 0.302   | 2.667     | 0.414–17.169           |         |           |                      |
| Hip lesion                      | 0.711   | 0.821     | 0.290–2.328            |         |           |                      |
| Emergency operation             | 0.008   | 0.125     | 0.027–0.581            | 0.062   | 5.697     | 0.914–35.504            |
| General anesthesia (vs. spinal) | 0.030   | 3.500     | 1.125–10.886           | 0.146   | 3.512     | 0.647–19.071            |
| EBL >500 mL                     | 0.057   | 0.280     | 0.075–1.040            |         |           |                      |
| Anesthetic time >215 min        | 0.695   | 0.808     | 0.278–2.350            |         |           |                      |
| Operative time >120 min         | 0.415   | 0.628     | 0.205–1.922            |         |           |                      |
| Intravenous PCA (vs. epidural)  | 0.009   | 4.000     | 1.409–11.354           | 0.717   | 1.327     | 0.288–6.104             |

ASA, American Society of Anesthesiologists; EBL, estimated blood loss; PCA, patient-controlled analgesia.
systemic opioid analgesia to manage pain can lead to a delayed perception of the need to void [23]. The capacity of the normal bladder is 400 to 600 mL. The physiology of micturition can be disrupted in the perioperative period due to anesthesia, the surgical procedure itself, and intraoperative physiological stressors. It is known that several drugs used in the perioperative period (e.g., anesthetic agents, analgesics, and sedatives) interfere with the micturition pathway [17,23]. Opioids, which are frequently used for analgesia both intraoperatively and postoperatively, trigger urinary retention as a result of parasympathetic inhibition, which blunts the sensation of bladder fullness, and increased sympathetic activity, which increases sphincter tone. It has been reported that neuraxial opioids lead to a higher incidence of urinary retention than intravenously administered opioids. Neuraxial local anesthetics augment the risk of POUR by interfering with both the efferent and afferent micturition pathways. General anesthetics also predispose patients to urinary retention by causing smooth muscle relaxation, thereby decreasing bladder contractility. They can also cause autonomic dysregulation of bladder tone. Longer-acting agents also pose a higher risk of causing bladder dysfunction due to prolonged over-distention [17,22,23].

The physiological response to surgical stress increases sympathetic tone, causing the detrusor muscle to relax and the internal urethral sphincter to close. Therefore, stimulation of the alpha receptor in the internal urethral sphincter increases the pressure in the bladder neck, leading to POUR [2]. Administration of tamsulosin could preserve the micturition reflex by inhibiting the increase in sympathetic nerve activity, thereby preventing POUR. Furthermore, tamsulosin is an α1-blocker with a particularly high affinity for α1A receptors, which predominate (from both numerical and functional standpoints) in the prostate and urethra, and the α1D receptors in the bladder [24]. The α1A adrenoceptor subtype in the smooth muscles of the prostate and urethra is responsible for the dynamic component of obstruction and related voiding symptoms [25]. Tamsulosin is an effective add-on treatment for acute urinary retention [24]. Men catheterized for acute urinary retention who are treated with tamsulosin are less likely to need re-catheterization and have more successful voiding post–catheter removal. The side-effect profile of tamsulosin was found to be similar to that of placebo, and consistent with known pharmacology [24,25]. Prior studies varied significantly regarding the length of tamsulosin administration [7,26,27]. We planned a 3-day treatment regimen of tamsulosin as a period during which steady therapeutic levels could be reached [27] there is little interference from postoperative stress and anesthesia-related effects [28,29], and the patient is immobilized postoperatively [30].

This study has limitations as a single-center, single-surgeon investigation and its relatively small sample size. Specific information about preoperative voiding function was unavailable. Despite the limitations of our study sample, we excluded patients with a history of urinary system disease before surgery and minimized selection bias by randomizing other preoperative factors. Further large-scale research, including placebo medication and measurements of preoperative urinary function, should be carried in the future.

CONCLUSIONS

Based on the findings of this study, short-term perioperative treatment with tamsulosin can reduce the incidence of urinary retention and the need for catheterization after lower limb arthroplasty. In particular, perioperative tamsulosin medication helps to prevent POUR and long-term catheterization after lower limb arthroplasty in patients over 76 years old.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS’ CONTRIBUTIONS

Research conception and design: Jun Hyun Han. Data acquisition: Chang Il Choi, Jong Keun Kim, Min Soo Choo, and Jun Hyun Han. Statistical analysis: Jong Keun Kim and Chang Il Choi. Data analysis and interpretation: Jong Keun Kim and Chang Il Choi. Drafting of the manuscript: Chang Il Choi, Jong Keun Kim, Min Soo Choo, and Jun Hyun Han. Critical revision of the manuscript: Seong Ho Lee, Jun-Dong Chang, and Jun Hyun Han. Obtaining funding: Jong Keun Kim and Jun Hyun Han. Administrative, technical, or material support: Jun Hyun Han. Supervision: Jun Hyun Han. Approval of the final manuscript: all authors.

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