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요관 내시경 수술에서 탐스로신의 요관 확장 및 요관 부목 관련 증상 완화에 미치는 영향: 이중 맹검, 무작위 배정, 위약 대조군 연구

Effect of Perioperative Tamsulosin on Successful Ureteral Access Sheath Placement and Stent-Related Symptom Relief: A Double-Blinded, Randomized, Placebo-Controlled Study

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이 논문을 의학석사 학위 논문으로 제출함

2024 년 2 월

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남경현의 의학석사학위 논문을 인준함

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Abstract

Purpose

This study aimed to investigate the effect of taking tamsulosin prior to surgery on the successful insertion of a 14 French (F) ureteral access sheath (UAS) during the procedure, as well as the impact of pre- and post-operative tamsulosin use on symptoms related to the ureteral stent.

Materials and Methods

This study was a randomized, single-center, double-blinded, placebo-controlled trial of 200 patients undergoing retrograde intrarenal surgery. Patients received either tamsulosin (0.4 mg) or placebo from 1 week before the surgery until stent removal. The patients were randomly assigned to one of four groups: Group 1 received tamsulosin throughout the entire study period, Group 2 received tamsulosin before surgery and placebo after surgery, Group 3 received placebo before surgery and tamsulosin after surgery, and group 4 took placebo before and after surgery. The Ureteral Stent Symptoms Questionnaire was completed between postoperative days 7 and 14 just before the stent removal.

Results

In total, 160 patients were included in the analysis. Their mean age was 55.0 ± 11.0 years, and 48 (30.0%) were female. In the group receiving pre-operative tamsulosin, the success rate of 12/14F UAS deployment was significantly higher

compared to the pre-operative placebo group (88.0 vs. 75.3%, p=0.038). Pre- and post-operative tamsulosin use did not significantly alleviate symptoms related to the ureteral stent.

Conclusions

These results revealed that pre-operative administration of tamsulosin improved the success of larger-sized UAS, while pre- and post-operative tamsulosin use did not significantly alleviate symptoms related to ureteral stents.

Keywords: adrenergic alpha-antagonists; tamsulosin; ureteroscopy; lower urinary tract symptoms

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Introduction

Ureteral access sheath (UAS), first introduced by Takayasu and Aso in 1974, has been widely used during ureteroscopic surgery [1]. UAS facilitates repeated access to the upper tract, reduces intrarenal pressure, and provides better vision, which is an essential part of surgery [2]. Also, it has been demonstrated that larger-sized UAS is associated with higher irrigation flow in vitro [3], and it proved to be more efficient in removing larger-sized stones in vivo [4].

However, the use of UAS can reduce the blood flow and cause ischemic damage to the ureter [5], and it can also lead to ureteral wall injury [6]. Also, the risk of high-grade ureteral wall injury is higher in patients with larger-sized UAS [7]. Recent retrospective studies have reported that preoperative administration of tamsulosin aids the deployment of larger-sized UAS [8, 9]. Tamsulosin is an alpha 1A and 1D receptor antagonist that causes the relaxation of ureteral smooth muscles, and this muscle relaxant effect might help the insertion of UAS [10]. However, prospective data on this matter are limited.

Alpha blockers are also frequently used after ureteroscopic surgery to alleviate symptoms related to ureteral stents; however, there is still an ongoing debate about their efficacy [11-14]. Although commonly used in the field of urolithiasis, ureteral stents have a negative impact on the quality of life.

This study aimed to investigate the effect of tamsulosin prior to surgery on the successful insertion of larger-sized UAS in a prospective manner, as well as pre- and post-operative tamsulosin use on the symptoms related to ureteral stents.

Materials and Methods

Study design

This study was designed as a randomized, single-center, double-blinded, placebo-controlled trial. This study was approved by the Institutional Review Board at Asan Medical Center, Seoul, Republic of Korea (No. 2019-1329) and registered at the Clinical Research Information Service (cris.nih.go.kr; KCT0004394).

Selection criteria

The predefined inclusion criteria were: 1) patients undergoing retrograde intrarenal surgery for unilateral renal stones, 2) between 20 and 80 years old, 3) the sum of the unilateral renal stones between 5 mm and 4 cm, 4) those who voluntarily decided to participate in this clinical study and completed a written informed consent form.

The main predefined exclusion criteria were: 1) patients with a history of ureteral stenosis, 2) patients with a history of using tamsulosin, calcium channel blockers, or steroids within the last 4 weeks, 3) patients with a ureteral stent inserted before surgery. More detailed information about the trial inclusion and exclusion criteria is provided in Supplementary Appendix 1.

Randomization and patient grouping

The participants were randomly assigned to groups 1 to 4 in a 1:1:1:1 ratio. A computer program based on a random number generator was used for randomization. The

patients, investigators, and treating clinicians were unaware of the group assignments until the time of the primary analysis.

Based on the group, the patients received either tamsulosin 0.4 mg or placebo (which were identical in appearance) 1 week before the surgery. After the surgery, the patients took tamsulosin 0.4 mg or placebo until the removal of the ureteral stent, which was done between postoperative day 7 and 14. Group 1 (G1) received tamsulosin pre- and post-operatively. Group 2 (G2) took tamsulosin before the surgery and placebo after the surgery. Group 3 (G3) took placebo before the surgery and tamsulosin after the surgery. Group 4 (G4) received placebo during the whole study period. After the surgery, all participants were given a prescription for 350mg of morniflumate and exclusively used morniflumate along with test drugs for pain control, refraining from any other medications such as anticholinergics.

Assessments and Follow-up

On the day of enrollment, baseline patient characteristics, including age, sex, laboratory data, urinalysis, urine culture, plain radiography (kidney-ureter-bladder), and CT scans were obtained. The Korean version of the validated Ureteral Symptoms Score Questionnaire (USSQ) was used to measure the symptoms due to ureteral stents. All patients were asked to fill out the urinary domain of the USSQ at baseline before the placement of the ureteral stent.

Follow-up visits were made between 7 to 14 days after the surgery. On that day, USSQ scores were measured, and then the ureteral stent was removed. The second follow-up visit took place between one to two months after the surgery, and radiographic assessment was conducted using CT scans and plain radiography (Figure 1).

Outcomes

The primary outcome was the rate of successful deployment of the 12/14 French (F) UAS. Need for balloon dilation, UAS size less than 12/14F, or ureteral stenting alone were considered as failures. Other outcomes included ureteral injury during the surgery, operative time, stone-free rate, adverse events related to tamsulosin, and symptoms related to ureteral stents assessed by the patient-reported USSQ score.

The success rate of 12/14F UAS insertion, ureteral injury, operative time, and stone-free rate were compared between groups who took tamsulosin before the surgery (pre-operative tamsulosin group; group 1 and group 2) and groups who took placebo before the surgery (pre-operative placebo group; group 3 and group 4). The ureteral injury was classified with regard to the post-ureteroscopic lesion scale (PULS) [15]. Stone-free status was defined as either absence of stones or clinically insignificant residual fragments (diameters less than 4mm) on follow-up CT scans.

Surgical technique

The surgery was performed by a single experienced surgeon. Patients were placed in the lithotomy position and underwent general anesthesia. A retrograde pyelogram was performed to identify the presence of ureteric strictures and the location of the stone. 12/14F UAS insertion was first tried on all patients. If it failed, the size of the UAS was stepped down to 11/13F, and then 10/12F. If the placement of a 10/12F UAS failed, either balloon dilation or ureteral stenting alone was performed based on the decision of the surgeon. Once the UAS was inserted, flexible ureteroscopy was conducted. Stone fragmentation was performed with a holmium laser, and stone retrieval was conducted with a basket. At the end

of the surgery, the presence of any ureteral injury was carefully checked, and the ureteral stent was inserted.

Statistical analysis

Continuous variables are expressed in mean and standard deviation. Baseline patient characteristics were compared using analysis of variance for continuous variables and chi-square tests for categorical variables.

The success rate of 12/14F UAS, ureteral injury, operative time, and stone-free rate were compared between the pre-operative tamsulosin groups (G1+G2) and the pre-operative placebo groups (G3+G4). Chi-squared tests were used to compare these variables. As for the USSQ score, analysis of variance was used to compare the groups (G1 vs. G2 vs. G3 vs. G4). Tukey's method was used for post hoc analysis. All tests were 2-sided with statistical significance considered at $p<0.05$. All data analyses were performed using IBM SPSS Statistics for Windows, version 21.0 (IBM Corp., Armonk, NY, USA).

Results

Patients

This study was conducted between April 2020 and September 2022, and 200 patients were enrolled. During the study period, 40 patients were dropped from the study, leaving 160 patients to the analysis. The CONSORT diagram of patient enrollment is shown in Figure 2.

The patients were balanced in terms of baseline characteristics (Table 1) except for the urine culture. In Group 2, seven patients exhibited positive urine culture, whereas in the other groups, only one patient per group exhibited a positive urine culture. All patients with positive urine cultures received appropriate antibiotic treatment and were confirmed to have negative results before proceeding to the surgery.

Outcomes

Perioperative parameters and surgical outcomes are described in Table 2. For 15 patients (9.4%), the surgical procedure was finished with the placement of a ureteral stent only, as no UAS of any size could be inserted. Additionally, balloon dilation was performed in 4 patients due to stricture in the distal ureter.

Due to the substantial size of the stone burden, 27 patients needed multiple surgical sessions. Additionally, there were 5 other patients who required extracorporeal shock wave lithotripsy following their initial surgery.

The primary outcome is shown in Table 3 as the success rate of 12/14F UAS insertion during the surgery. By that measure, the proportion of successful 12/14F UAS insertion was

higher in the pre-operative tamsulosin group compared to the pre-operative placebo group (88.0% vs. 75.3%, p=0.038).

As for ureteral injury, it tended to be more common in the pre-operative tamsulosin group, although it was not statistically significant (30.0% vs. 15.3%, p=0.098). No patient had ureteral injury grade 3 or higher. On follow-up CT scans, none of the patients exhibited complications such as ureteral stricture.

No significant difference was observed between the groups receiving pre-operative tamsulosin and placebo in terms of operative time (38.3 minutes vs. 41.8 minutes, p=0.260) and stone-free rate (67.1% vs. 56.0%, p=0.154). However, both outcomes exhibited a trend favoring the pre-operative tamsulosin group. Two patients reported adverse events related to tamsulosin use. One patient complained of nausea, and the other had orthostatic hypotension. Both were compliant with their medications.

The USSQ scores are summarized in Table 4. No significant intergroup differences were found in the domains of the urinary index, pain index, sexual matters, or additional problems. The analysis of variance for general health (p=0.047) and work (p=0.035) found statistically significant results; however, post-hoc analysis did not reveal statistical significance.

Discussion

The results of this prospective randomized controlled study revealed that pre-operative tamsulosin administration (0.4 mg daily for 1 week) increased the success rate of 12/14F UAS insertion during the surgery without significant differences with respect to ureteral injury, operative time, and stone-free rate. However, the effect of larger-sized UAS on stone-free rate may appear more evident in larger-sized stones.

The outcomes observed in this study support the use of tamsulosin before the surgery. It may enhance the success of large-sized UAS insertion. This notion finds alignment with Kaler et al.'s findings [8], who reported that pre-operative use of tamsulosin nearly doubled the 14/16F UAS insertion rate (87% vs. 43%). Erturhan et al. [9], on the other hand, set 9.5/11.5F UAS placement in the first attempt as their primary outcome. While the utilization of tamsulosin two weeks before surgery appeared advantageous (65.2% vs. 44%), statistical significance was not reached, possibly attributable to the limited sample size. This study focused on the accomplishment of 12/14F UAS insertion (not 16F) as the primary outcome, which might account for the relatively marginal variance in success rates.

Koo et al. reported that pre-operative tamsulosin 0.4 mg administration lowered the highest UAS insertion force during the surgery, using a homemade measurement device [16]. The authors used 12/14F UAS in their trial, and tamsulosin use lowered the UAS insertion force at the ureterovesical junction and proximal ureter in an Asian population. Although there is no study directly comparing ureter sizes between races, many endourologists may agree that Asian populations have relatively narrow ureters [17], in alignment with the narrow pelvic space in Asians compared to Mexicans or Caucasians [18]. In this study, none of the patients experienced severe ureteral injury (more than PULS grade 2). This result implies that

12/14F UAS insertion in an Asian population, regardless of pre-operative tamsulosin use, is relatively safe concerning ureteral injury. Also, pre-operative tamsulosin facilitated 12/14F UAS insertion without severe ureteral injury.

According to a recent literature review, two attempts are being made to facilitate UAS insertion: one is using an alpha-blocker, and the other is pre-stenting [19]. Although preoperative stenting is known to ease UAS placement, routine pre-stenting is controversial [20-22]. Pre-stenting requires additional procedures before the surgery. Also, ureteral stents are associated with bothersome urinary symptoms, including flank pain, discomfort, dysuria, urinary frequency, and hematuria [23, 24]. Instead, tamsulosin use before the surgery is relatively safe and without serious complications, as shown in the results.

In this study, USSQ scores were used to evaluate patient symptoms related to the ureteral stents in various domains, such as urinary function, pain, sexual matters, general health, and work. Stent-related symptoms were assessed on the day of stent removal, which was performed between postoperative day 7 and 14. And participants were divided into four groups to assess the effect of tamsulosin before and after the surgery and the possible effect of long-term tamsulosin use. However, the analysis of USSQ scores across the four groups did not reveal any statistically significant differences (Figure 3). This raises questions about the potential impact of tamsulosin on stent-related symptoms and patient well-being. Many studies have advocated the effect of alpha-blockers in relieving stent-related symptoms [11, 25], but in this study, the use of tamsulosin was not confirmed to improve these symptoms.

The discomfort caused by a ureteral stent is primarily known to be due to stimulation from the distal curl located within the bladder [26]. In the bladder, alpha-blockers primarily act on the bladder neck, reducing the contraction of the bladder outlet [27]. In this study, the use of alpha-blockers did not lead to a reduction of discomfort caused by ureteral stents,

possibly because they had limited impact on the symptoms induced by the distal curl of ureteral stents.

This study is not without limitations. First, this study was conducted at a single center, and the participants were all from an Asian population. Second, the Coronavirus Disease 2019 (COVID-19) pandemic had a negative impact on this study, delaying patient enrollment and causing dropouts. In the oncologic field, the COVID-19 pandemic had a negative impact on patient enrollment, and more than half of ongoing clinical trials reported that the pandemic had a ‘moderate’ to ‘high’ impact on patient visits [28]. In this study, the COVID-19 pandemic led to a dropout of 31 patients during the study, ultimately resulting in an analysis involving 160 patients. Despite these limitations, this study marks as the first randomized, placebo-controlled prospective trial to investigate the potential effect of pre- and post-operative use of tamsulosin on the perioperative outcomes of retrograde intrarenal surgery.

Conclusion

This study demonstrates that pre-operative administration of tamsulosin (0.4mg daily for a week) enhances the success rate of 12/14F UAS insertion during retrograde intrarenal surgery. However, no significant differences were found in ureteral injury, operative time, or overall stone-free rate between the groups. Pre- and post-operative tamsulosin use did not significantly impact stent-related symptoms or patient comfort. Tamsulosin can be used as an effective modality before retrograde intrarenal surgery to aid the surgical process without compromising patient safety.

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Table 1. Demographics and pre-operative parameters[a]

	Group 1 (n=40)	Group 2 (n=43)	Group 3 (n=36)	Group 4 (n=41)
Age (years)	56.5 ± 10.0	55.9 ± 10.9	54.3 ± 10.8	53.1 ± 12.1
Female (n, %)	13 (32.5)	14 (32.6)	9 (25.0)	12 (29.3)
BUN (mg/dL)	15.8 ± 4.1	14.6 ± 3.2	15.0 ± 4.3	15.4 ± 4.7
Serum creatinine (mg/dL)	0.9 ± 0.2	0.9 ± 0.2	0.9 ± 0.2	1.2 ± 1.9
Urine pH	6.2 ± 0.9	6.4 ± 0.8	5.7 ± 0.7	6.0 ± 0.8
Urine culture (n, %)				
No growth	31 (77.5)	30 (69.8)	32 (88.9)	40 (97.6)
Positive	1 (2.5)	7 (16.3)	1 (2.8)	1 (2.4)
Others	8 (20.0)	6 (14.0)	3 (8.3)	0 (0.0)
Stone laterality (n, %)				
Right	19 (47.5)	20 (46.5)	20 (55.6)	19 (46.3)
Left	21 (52.5)	23 (53.5)	16 (44.4)	22 (53.7)
Stone size (cm)	1.5 ± 0.9	1.6 ± 0.7	1.8 ± 1.0	1.9 ± 0.9
Baseline USSQ	15.3 ± 2.9	15.9 ± 2.9	15.0 ± 3.2	15.2 ± 4.1

[a]Plus-minus values are means ± standard deviation. BUN denotes blood urea nitrogen and USSQ Ureteral Stent Symptoms Questionnaire.

Table 2. Perioperative parameters and surgical outcomes[a]

	Group 1 (n=40)	Group 2 (n=43)	Group 3 (n=36)	Group 4 (n=41)
Operative time (min)	34.1 ± 18.4	39.3 ± 17.4	37.1 ± 16.7	43.7 ± 20.1
Total laser time (min)	14.5 ± 16.3	15.4 ± 13.7	17.1 ± 17.5	20.5 ± 17.3
UAS used (n, %)				
DJ stenting only	1 (2.5)	2 (4.7)	3 (8.3)	5 (12.2)
Balloon dilation	0 (0.0)	1 (2.3)	1 (2.8)	2 (4.9)
10/12F	2 (5.0)	1 (2.3)	2 (5.6)	0 (0.0)
11/13F	2 (5.0)	1 (2.3)	1 (2.8)	5 (12.2)
12/14F	35 (87.5)	38 (88.4)	29 (80.6)	29 (70.7)
Ureteral injury[b] (n, %)				
Grade 0	26 (68.4)	30 (73.2)	27 (84.4)	31 (86.1)
Grade 1	7 (18.4)	10 (24.4)	5 (15.6)	2 (5.6)
Grade 2	5 (13.2)	1 (2.4)	0 (0.0)	3 (8.3)
Grade 3,4,5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stone-free state[c] (n, %)	30 (76.9)	25 (58.1)	22 (62.9)	20 (50.0)
Length of stay (days)	2.0 ± 0.5	2.4 ± 1.2	2.2 ± 0.6	2.3 ± 1.1
Adjuvant treatment (n, %)				
Medication[d]	7 (17.5)	6 (14.0)	11 (30.6)	7 (17.1)
ESWL	1 (2.5)	1 (2.3)	2 (5.6)	1 (2.4)
Multisession surgery	5 (12.5)	6 (13.9)	7 (19.5)	9 (23.0)
Adverse events related to tamsulosin use[e] (n, %)	1 (2.5)	1 (2.3)	0 (0.0)	0 (0.0)

[a]Plus-minus values are means ± standard deviation. UAS denotes ureteral access sheath, DJ double J, F French, and ESWL extracorporeal shock wave lithotripsy.
[b]Grade 0 means no injury, 1 superficial mucosal lesion, 2 submucosal lesion, 3 transection less than 50%, 4 transection more than 50%, and 5 complete transection.
[c]Stone-free state means either the absence of stones or clinically insignificant residual fragments (diameters less than 4mm) on follow-up CT scans.
[d]Mostly urine alkalinizing agents such as potassium citrate.
[e]One patient complained of nausea, and the other orthostatic hypotension.

Table 3. Comparison of outcomes between pre-operative tamsulosin and placebo groups[a]

	Pre-operative tamsulosin (n=83)	**Pre-operative placebo (n=77)**	***p*-value**
UAS (n, %)			0.038
14F	73 (88.0)	58 (75.3)	
Failed[b]	10 (12.0)	19 (24.7)	
Ureteral injury[c] (n, %)			0.098
0	56 (70.0)	61 (84.7)	
1	18 (22.5)	8 (11.1)	
2	6 (7.5)	3 (4.2)	
Operative time (min)	36.8 ± 18.0	40.6 ± 18.7	0.242
Stone-free state[d] (n, %)	55 (67.1)	42 (56.0)	0.154

[a]Plus-minus values are means ± standard deviation. F denotes French and UAS ureteral access sheath.

[b]Involves double J stenting only, need for balloon dilation, and UAS size less than 14F.

[c]Grade 0 means no injury, 1 superficial mucosal lesion, 2 submucosal lesion, 3 transection less than 50%, 4 transection more than 50%, and 5 complete transection. No patients had ureteral injury 3 or greater.

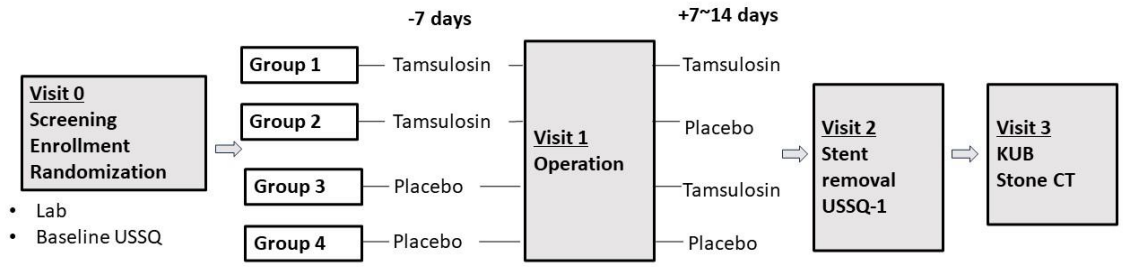
[d]Stone-free state means either the absence of stones or clinically insignificant residual fragments (diameters less than 4mm) on follow-up CT scans.

Table 4. USSQ score at the time of stent removal[a]

	Group 1 (n=40)	**Group 2 (n=43)**	**Group 3 (n=36)**	**Group 4 (n=41)**	***p*-value**
Urinary index	28.4 ± 6.3	26.0 ± 6.4	29.3 ± 6.8	26.5 ± 7.9	0.110
Pain index	20.5 ± 6.5	17.6 ± 6.2	20.9 ± 6.0	20.0 ± 6.1	0.185
General health	14.9 ± 5.1	13.0 ± 4.4	15.2 ± 5.5	12.6 ± 5.0	**0.047**
Work performance	8.0 ± 3.5	6.6 ± 2.8	8.4 ± 3.1	6.3 ± 2.6	**0.035**
Sexual matters	3.0 ± 0.0	3.3 ± 0.5	3.8 ± 0.8	3.3 ± 1.0	0.523
Additional problem	5.6 ± 2.3	5.1 ± 1.4	5.5 ± 1.7	5.2 ± 1.7	0.511

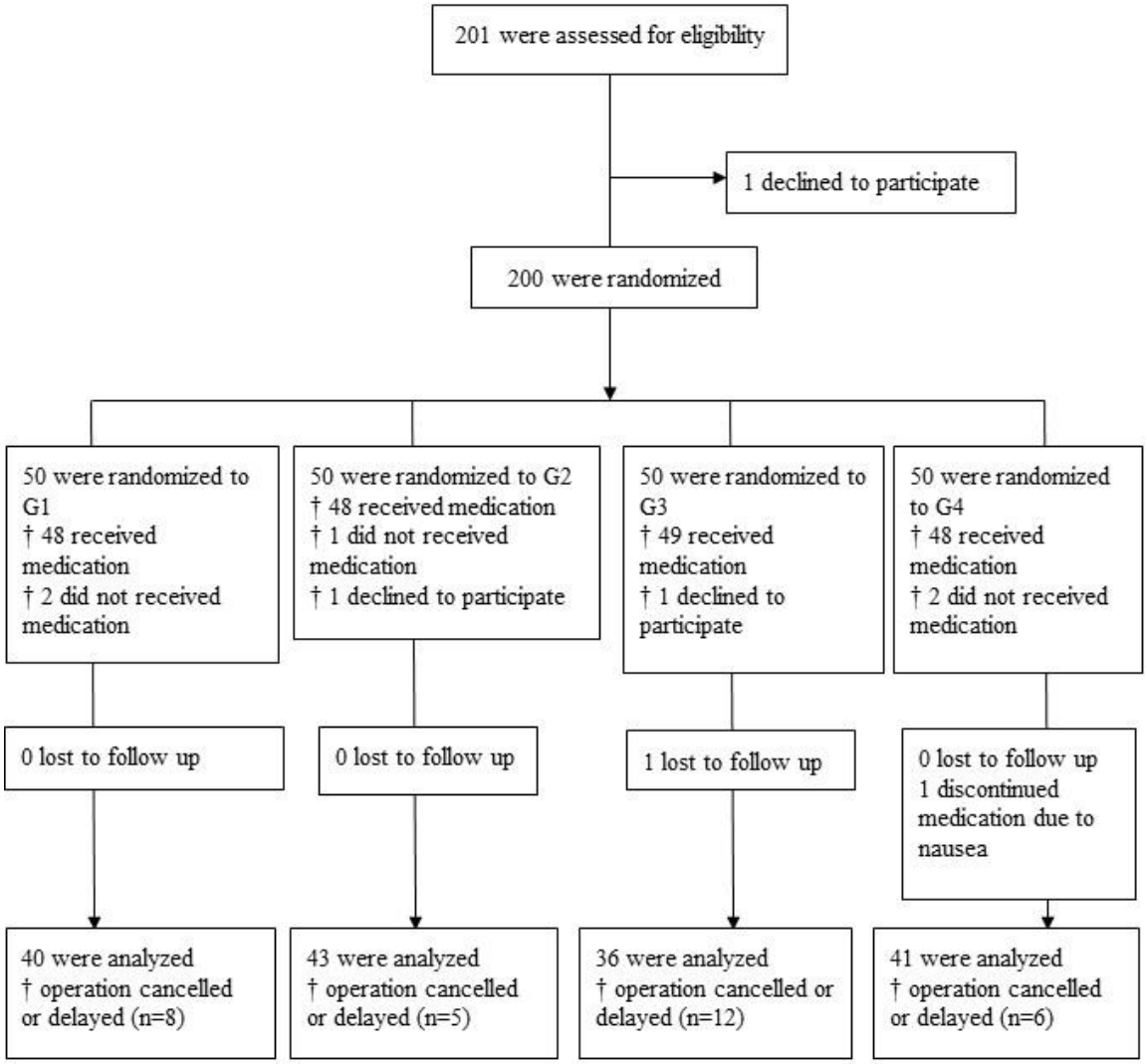
[a]Plus-minus values are means ± standard deviation. USSQ denotes Ureteral Stent Symptoms Questionnaire. Statistically significant results are presented in bold, but post-hoc analysis did not prove difference between each groups.

Figure 1. Study protocol



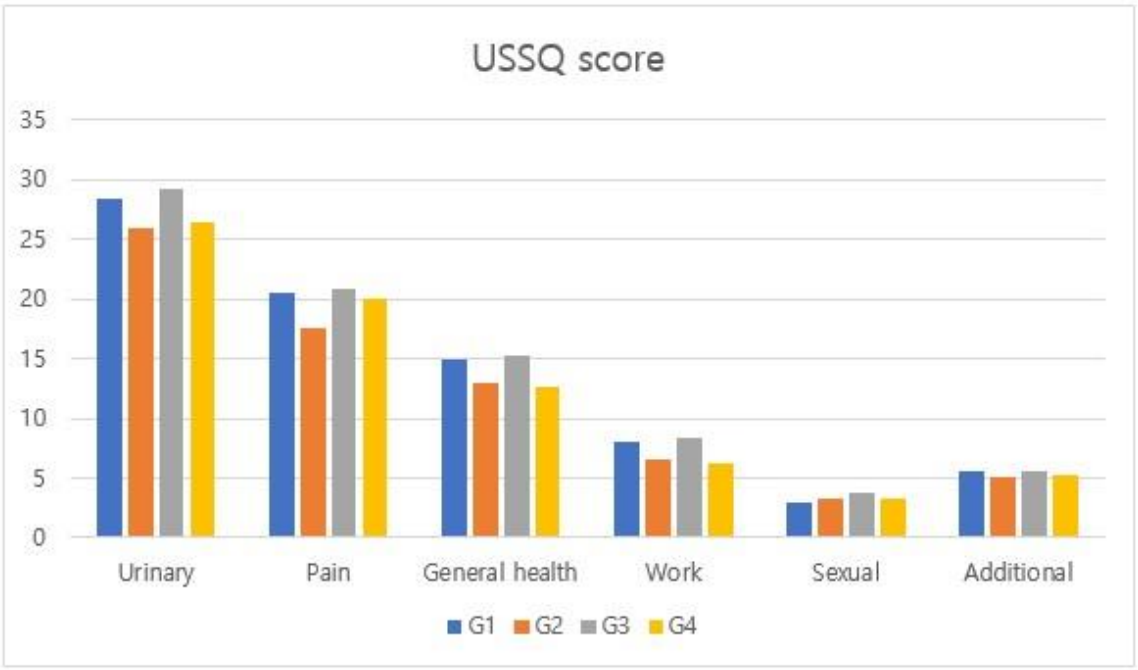
USSQ denotes Ureteral Stent Symptoms Questionnaire, KUB kidney-ureter-bladder, and CT computed tomography. USSQ scores were evaluated before the stent removal.

Figure 2. CONSORT diagram



G1~4 denotes group 1~4.

Figure 3. Comparison of USSQ scores among the four groups



USSQ denotes Ureteral Stent Symptoms Questionnaire and G1~4 denotes group 1~4.

Supplemental Appendix 1. Inclusion and exclusion criteria

Inclusion criteria

1. Patients between 20 and 80 years old who are planning to undergo ureteroscopic surgery due to unilateral renal or ureteric stones
2. Sum of all the stone sizes in unilateral renal or ureteric stones is between 5mm and 4cm
3. Patients who voluntarily decided to participate in this clinical study and signed a written informed consent form

Exclusion criteria

1. Patients with a history of allergic reactions to tamsulosin or its components
2. Patients diagnosed with orthostatic hypotension
3. Patients with a severe liver disorder
4. Patients with galactose intolerance, Lapp lactose deficiency, or glucose-galactose malabsorption
5. Patients with severe renal impairment (KDIGO CKD grade 3 or higher)
6. Patients with a history of renal ureter cancer or bladder cancer
7. Patients with a history of ureteral stenosis
8. Patients with febrile urinary tract infection (if there was evidence of fever above 38 degrees Celsius and urinary tract infection)
9. Patients who have a single kidney
10. Patients with a history of using tamsulosin, calcium channel blockers, or steroids

within the last 4 weeks

11. Patients with a history of previous intrapelvic surgery or radiation
12. Women who may be pregnant
13. Breastfeeding mothers
14. Patient with a ureteral stent inserted before surgery
15. Patients taking warfarin or H2 receptor blockers
16. Patients taking CYP3A4 or CYP2D6 inhibitors
17. Patients with an active disease judged by the researcher to be unsuitable for participation in the study

국문요약

서론

최근 Ureteral access sheath (UAS)는 요관경 하 결석 제거 수술에서 널리 사용되고 있다. UAS 는 상부 요로에 쉽게 접근할 수 있을 뿐만 아니라 신우 내 압력을 감소시키고 요관경 시야를 원활하게 확보할 수 있다. 본 연구는 수술 전 탐스로신의 복용이 14 French (F) UAS 삽입의 성공에 미치는 영향과 수술 전후 탐스로신이 요관 부목 관련 불편감에 미치는 영향을 조사하고자 하였다.

대상 및 방법

본 연구는 서울아산병원에서 요관경 하 신장 결석 수술을 시행받은 200 명의 환자를 대상으로 한 단일 기관, 무작위 대조, 이중맹검 시험으로 진행되었다. 환자들은 수술 1 주 전부터 요관 부목 제거 시점까지 탐스로신 0.4 밀리그램 혹은 위약을 복용하였다. 환자들은 총 4 개의 그룹으로 무작위 배정되었으며, 1 그룹은 연구 기간 내내 탐스로신을 복용하였으며, 2 그룹은 수술 전 탐스로신, 수술 후 위약을 복용하였고, 3 그룹은 수술 전 위약, 수술 후 탐스로신을 복용하였고, 4 그룹은 수술 전후로 위약을 복용하였다. 요관 부목 관련 증상의 평가는 설문 조사를 이용하여 수술 후 7 일에서 14 일 사이에 완료하였다.

결과

최종적으로 총 160 명의 환자가 분석 대상에 포함되었다. 평균 연령은 55.0 세였으며 남성 112 명, 여성 48 명이었다. 수술 전 탐스로신을 복용한 그룹에서 12/14F UAS 배치의 성공률이 수술 전 위약을 복용한 그룹에 비교하여 유의하게 높았다 (88.% vs. 75.3%, p=0.038). 수술 전후 탐스로신의 복용과 요관 부목과 관련된 증상 간의 유의한 차이는 없었다.

결론

본 연구는 탐스로신의 수술 전 투여가 큰 사이즈의 UAS 배치에 도움을 주는 것을 확인하였고, 수술 전후 탐스로신의 복용이 요관 부목과 관련된 불편감을 유의하게 완화시켜주지 않는 것을 확인하였다.