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Effects of specific α-1A/1D blocker on lower urinary tract symptoms due to double-J stent: a prospectively randomized study

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Abstract The aim of our study was to evaluate the effect of tamsulosin in improving symptoms in patients with indwelling double-J ureteral stents. This prospective study lasted from April 2006 to March 2008. All the patients with symptomatic lower ureteral stones with <15 mm diameter were enrolled, and were prospectively randomized (random numbers table) into two groups. A total of 154 patients, with insertion of a double-J ureteral stent after ureteroscopic stone removal. In group 1, 75 patients were enrolled and received placebo for 2 weeks. Group 2 included 79 patients who received 0.4 mg of tamsulosin, once daily for 2 weeks. All patients completed the validated ureteral stent symptom questionnaire (USSQ) and quality of life of international prostate symptom scale (IPSS) for evaluating the symptoms of double-J stents and quality of life after double-J stent insertion and removal, respectively. The analysis of the questionnaire at W1 revealed a significant difference in the main score index of urinary symptoms, body pain and general health between groups 1 and 2. When comparing W1 evaluation with that of W4 after double-J removal, both groups showed significant worsening of urinary symptoms, body pain, general health and work performance, except sexual performance. The mean score of quality of life in IPSS was 4.21 in group 1 and 1.6 in group 2. Tamsulosin can improve a subset of stent-related urinary symptoms and quality of life effectively and may be applied in routine clinical practice.

Keywords α-1A/1D blocker · Double-J stent

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Introduction

Placement of a ureteral stent is a common urological intervention. It has been more than three decades since the first description of a cystoscopically placed temporary ureteral stent by Zimskind et al. [1], and indications and use have continued to expand [2]. However, the side effects and patient morbidity associated with ureteral stents have been identified as a potential health problem [3]. The great variety of complications range from the commonly experienced "stent syndrome" to the medicolegal dilemma of the forgotten stent [4].

The assessment of stent-related urinary symptoms is not easy when using common clinical measures. Joshi et al. presented validated questionnaires for the assessment of stent-related symptoms and the evaluation of their impact on patients' daily life [5]. This questionnaire may have levels of precision that exceed those of clinical measures. Besides, most efforts have been aimed toward improving stent materials and design. Few papers mentioned the resolution of troublesome symptoms. Recently, Deliveliotis et al. reported that the administration of afluzosin improved stent-related urinary tract symptoms and pain [6]. They hypothesized that a selective alpha$_1$-blocker might influence the stent-related symptoms, because the latter mimics the lower urinary tract symptoms due to benign prostatic hyperplasia. Tamsulosin is an another potent selective α-1A/1D blocker and well tolerated and clinically effective in improving symptoms and urinary flow rate in patients with symptomatic BPH. Therefore, we conducted a randomized double-blinded controlled study to evaluate the effect of tamsulosin in improving symptoms and quality of life in patients with indwelling double-J ureteral stents using specific questionnaire.

Materials and methods

Our Institutional Review Board approved the study, and all patients signed an informed consent form before participating. To detect a 30% difference in the proportion of stent-related complications in the treatment groups, at a significance level of 0.05 and a power of 90% a sample size of 75 patients per group was calculated. A total of 154 patients (122 males and 32 females), with insertion of a double-J ureteral stent after ureteroscopic stone removal, were prospectively randomized (using random numbers table) into two groups.

From April 2006 to March 2008, all the patients with symptomatic lower ureteral stones with <15 mm diameter were enrolled in this prospective study. In group 1, 75 patients (59 males and 16 females) (mean age 51-year-old), were enrolled and they received placebo for 2 weeks. Group 2 included 79 patients (63 males and 16 females) (mean age 50-year-old), who received 0.4 mg of tamsulosin, once daily before sleeping for 2 weeks. All patients completed the validated ureteral stent symptom questionnaire (USSQ) and quality of life of international prostate symptom scale (IPSS) for evaluating the symptoms of double-J stents and quality of life after double-J stent insertion and removal, respectively. Since USSQ and IPSS were adapted and translated in Chinese, and administered 1 week later for their first evaluation, another questionnaire was administered again 2 weeks after stent removal. We expected that at 2 weeks after stent removal, symptoms would have completely subsided. Thus, the questionnaire administrated at that time would have been representative of the baseline urinary symptoms, having nothing to do with ureteral calculi and ureteroscopic manipulation itself. Statistical analysis was performed using the Chi-square and non-parametric Wilcoxon 2-sample *t* test, as appropriate.

The exclusion criteria included benign prostatic hyperplasia-related lower urinary symptoms (International Prostate Symptom Score greater than 7); a history of interstitial cystitis, chronic cystitis, chronic prostatitis, or stent insertion; and chronic medication with alpha-blockers or analgesics. During the stenting period, all patients were prescribed Pipemic acid trihydrate 250 mg twice per day to minimize urinary tract infections and allowed to use sublingual buprenorphine 0.2 mg on demand and overall dosage was documented and compared. The same double-J ureteral stent design, all silicone coated (Cliny, Japan), was inserted in all patients. The stent size was fixed (Fr 7) and length was adjusted by body height, applied to all patients after ureteroscopic stone removal under intravenous general anesthesia and its correct position was confirmed with a plain kidney-ureter-bladder X-ray. The double-J stents were removed by cystoscopy 2 weeks later. All consenting patients were fully informed regarding the potential side effects of tamsulosin; however, they were not aware whether they were receiving a placebo or tamsulosin. Also, the physician who administered the medication was unaware of the treatment arm of the patients.

Results

All patients completed the study. No significant statistical difference was observed in patients' age, gender distribution, body height, stone sizes, stone location and operative times. (Chi-square test) ($P > 0.005$) (Table 1) No complications occurred after double-J stent placement.

The overall results are detailed in Table 2. The analysis of the questionnaire at W1 revealed a significant difference in the main score index of urinary symptoms, general

Table 1 Patients characteristics

Characteristic	Placebo	Tamsulosin	*P* value
Patients (*n*)	75	79	NA
Age (year)			0.94[a]
mean	51.5 ± 11.0	50.1 ± 9.7	
range	32–79	28–78	
Gender (*n*)			0.72[c]
Male	58	63	
Female	17	16	
IPSS before trial	2.52 ± 1.70	2.54 ± 1.69	0.929[a]
Male < 50 y/o	1.35 ± 1.09	1.46 ± 1.17	0.699[a]
Male > 50 y/o	3.75 ± 1.30	3.62 ± 1.20	0.686[a]
Female < 50 y/o	1.1 ± 0.88	1.5 ± 0.84	0.346[b]
Female > 50 y/o	3.29 ± 1.70	4.4 ± 1.51	0.162[b]
Body height (cm)	164.5	163.8	0.89[b]
Male	166.4	165.3	0.71[b]
Female	158.0	156.6	0.77[b]
Stone sizes (mm)	9.4	9.0	0.68[c]
Stone location			
Upper	8	8	0.79[c]
Middle	24	25	0.98[c]
Lower	43	46	0.92[d]
Operative times (min)	23.5	22.6	0.84[c]
Employment status			
Full time	50 (66.7%)	47 (59.5%)	0.76[c]
Part time	13 (17.3%)	17 (17.9%)	0.91[c]
Retired	9 (12%)	10 (12.7%)	0.85[c]
Others	3 (4%)	5 (6.3%)	0.81[c]
Sexually active (%)	32 (42.6)	32 (40.5%)	0.58[c]

NA not applicable

[a] *t* Test

[b] Non-parametric wilcoxon two-sample test

[c] Chi-square test

[d] Anova

Table 2 Randomization study results

Varible	Placebo	Tamsulosin	*P* value
Urinary symptoms			
W1 mean index score	31.59 ± 4.69	20.96 ± 3.38	<0.0001
Male < 50 y/o	31.3 ± 4.08	21.1 ± 3.31	<0.001[c]
Male > 50 y/o	31.8 ± 4.41	20.9 ± 3.02	<0.001[c]
Female < 50 y/o	30.5 ± 6.29	20.5 ± 3.33	0.01[a]
Female > 50 y/o	33.0 ± 6.14	20.9 ± 4.82	0.001[a]
W4 mean index score	15.1 ± 2.01	15.4 ± (11–22)	039
Male < 50 y/o	14.8 ± 1.59	15.6 ± 2.05	0.124[c]
Male > 50 y/o	15.1 ± 2.17	15.2 ± 1.91	0.867[c]
Female < 50 y/o	15.1 ± 2.08	15.2 ± 1.6	0.69[a]
Female > 50 y/o	16.3 ± 2.56	15.1 ± 3.14	0.324[a]
Body pain (patients)	32	32	0.65[b]
W1 mean sum VAS	5.72 ± 1.19	3.91 ± 0.95	<0.0001
W1 mean index score	13.3 ± 13.3	9.94 ± 9.65	0.04
Male < 50 y/o	9.15 ± 12.1	9.24 ± 9.59	0.974[c]
Male > 50 y/o	16.5 ± 13.2	11.0 ± 9.4	0.06[c]
Female < 50 y/o	10.6 ± 13.9	12.7 ± 12.0	0.803[a]
Female > 50 y/o	17.7 ± 14.7	8.0 ± 9.94	0.09[a]
W4 mean index score	3.81 ± 3.72	3.94 ± 4.06	0.93
Male < 50 y/o	4.65 ± 4.14	4.2 ± 4.3	0.69[c]
Male > 50 y/o	3.44 ± 3.41	3.2 ± 3.3	0.749[c]
Female < 50 y/o	3.0 ± 3.16	5.5 ± 5.4	0.232[a]
Female > 50 y/o	3.57 ± 4.16	4.0 ± 4.2	0.826[a]
Gereral health			
W1 mean index score	12.2 ± 2.99	10.1 ± 2.31	<0.0001
Male < 50 y/o	12.0 ± 2.8	10.0 ± 2.3	0.002[c]
Male > 50 y/o	12.0 ± 2.30	9.8 ± 2.3	0.001[c]
Female < 50 y/o	12.0 ± 3.6	11.0 ± 1.7	0.781[a]
Female > 50 y/o	14.0 ± 5.1	11.0 ± 2.6	0.094[a]
W4 mean index score	9.59 ± 3.12	8.24 ± 1.47	0.0011
Male < 50 y/o	10.0 ± 2.86	8.3 ± 1.5	0.008[c]
Male > 50 y/o	9.25 ± 2.55	8.1 ± 1.7	0.047[c]
Female < 50 y/o	8.9 ± 3.5	8.3 ± 0.8	0.862[a]
Female > 50 y/o	10.6 ± 5.5	8.4 ± 1.1	0.552[a]
Work performance			
Mean days in bed	1.73 ± 0.95	1.45 ± 0.71	0.04
Mean of days with lost activity	1.53 ± 0.91	1.48 ± 0.81	0.70
W1 mean index score	5.57 ± 1.91	11 ± (6–17)	0.03
Male < 50 y/o	12.1 ± 2.1	11.1 ± 2.17	0.06[c]
Male > 50 y/o	12.0 ± 3.37	10.4 ± 2.21	0.041[c]
Female < 50 y/o	11.7 ± 2.45	10.5 ± 2.17	0.435[a]
Female > 50 y/o	12.6 ± 3.1	12.4 ± 2.37	0.806[a]
W4 mean index score	3.37 ± 0.63	3.35 ± 0.62	0.84
Male < 50 y/o	7.12 ± 1.63	7.2 ± 1.6	0.761[c]
Male > 50 y/o	7.03 ± 1.86	6.5 ± 1.20	0.217[c]
Female < 50 y/o	6.8 ± 1.4	7.3 ± 1.9	0.581[a]
Female > 50 y/o	6.71 ± 1.5	8.2 ± 1.9	0.122[a]
Sexual performance			
W1 mean index score	4.23 ± 1.56	3.65 ± 1.20	0.11
Male < 50 y/o	3.54 ± 2.8	4.0 ± 3.0	0.537[c]
Male > 50 y/o	5.0 ± 3.0	4.2 ± 2.6	0.246[c]
Female < 50 y/o	5.6 ± 4.2	4.2 ± 2.6	0.561[a]
Female > 50 y/o	4.7 ± 2.9	6.1 ± 4.4	0.647[a]
W4 mean index score	3.92 ± 1.37	3.64 ± 1.07	0.40
Male < 50 y/o	4.3 ± 2.3	4.6 ± 2.9	0.633[c]
Male > 50 y/o	4.7 ± 2.0	4.8 ± 2.4	0.877[c]
Female < 50 y/o	4.9 ± 3.5	4.7 ± 2.3	0.955[a]
Female > 50 y/o	5.3 ± 2.4	6.9 ± 3.9	0.456[a]
Additional Problems	12.9 (8–19)	10 (5–20)	<0.0001
Male < 50 y/o	12.7 ± 2.61	9.5 ± 4.5	0.001[c]
Male > 50 y/o	12.8 ± 2.8	11.0 ± 4.8	0.068[c]
Female < 50 y/o	13.3 ± 3.89	13.0 ± 5.2	0.662[a]
Female > 50 y/o	13.7 ± 3.64	10.0 ± 6.7	0.055[a]
Feeling of suffering from UTI	2.11 ± 0.97	2.04 ± 0.99	0.80
Need for antibiotic intake	1.93 ± 0.86	2.04 ± 0.99	0.48
Need for professional assistance	1.75 ± 0.76	2.04 ± 0.99	0.046
Need to visit hospital	1.53 ± 0.60	2.04 ± 0.99	0.0006
Future another stent	5.57 ± 1.05	2.04 ± 1.00	<0.0001
Quality of Life	4.21 ± 0.89	1.60 ± 0.74	<0.0001
Buprenorphine dosage	0.096 ± 0.16	0.01 ± 0.04	0.0002
Male < 50 y/o	0.05 ± 0.10	0.02 ± 0.06	0.185[c]
Male > 50 y/o	0.16 ± 0.20	0	<0.001[c]
Female < 50 y/o	0.04 ± 0.08	0.03 ± 0.08	0.873[a]
Female > 50 y/o	0.09 ± 0.11	0	0.027[a]

y/o years of old

[a] Non-parametric wilcoxon two-sample *t* test

[b] Chi-square test

[c] *t* test

health and quality of life in IPSS between groups 1 and 2. When performing the W4 evaluation, there was no significant difference in all domain score betweens group 1 and 2. In the analysis of different time periods, when comparing W1 evaluation with that of W4 after double-J removal, both groups showed significant worsening of urinary symptoms, body pain, general health and work performance, except sexual performance.

The mean urinary symptom index was significantly less ($P < 0.0001$) in group 2 patients. All the urinary symptoms were present significantly less ($P < 0.0001$) in group 2. Stent-related urinary symptoms were considered significantly more of a problem in patients not taking the alpha1-blocker.

Stent-related pain was similar in both groups, but the overall intensity identified on the visual analog scale was more severe in group 1 patients ($P < 0.0001$). At W1, pain developed in the flank region in 12 group 1 patients and 13 group 2 patients; pain was noted in the groin area in six both group patients; nine patients reported pain in bladder area in each group. However, the mean pain index was not significantly less in patients taking tamsulosin ($P = 0.04$, 9.94 vs. 13.3). General health scores were significantly greater in patients not receiving the alpha1-blocker, leading to significant ($P < 0.0001$) interference with their lives, related to the presence of the stent. However, patients taking the alpha1-blocker (group 2) had significantly less difficulty in performing heavy activities ($P = 0.004$), did not feel tired ($P < 0.0001$), were more calm ($P = 0.01$), and enjoyed their social life more ($P = 0.81$). They rarely required extra help from their family or friends ($P < 0.0001$).

The days "off work" were similar ($P = 0.04$; 1.73 vs. 1.45 days in groups 1 and 2, respectively), and the "quality of work" described by the number of "rests," job efficiency, and regular hours of work did not differ among the two study groups and was not severely impaired ($P = 0.70$). A similar percentage of patients were reported to be sexually active in both groups (42.6 and 40.5% for groups 1 and 2, respectively, $P = 0.75$). Among these patients, the difference in the mean sexual matters score was no statistically significant (4.23 vs. 3.65 in groups 1 and 2, respectively, $P = 0.11$), with patients receiving tamsulosin reporting less pain during intercourse and being more satisfied with their sex lives without statistical significance. Feelings toward future repeat stenting were better in patients receiving tamsulosin than in patients receiving placebo, this difference reached statistical significance (2.04 vs. 5.57 in groups 2 and 1, respectively, $P < 0.0001$).

The mean score of quality of life in IPSS was 4.21 in group 1 and 1.60 in group 2. Only three patients in tamsulosin group experienced adverse effects associated with the medical therapy (transient hypotension, asthenia, syncope and palpitations), whereas no patients suspended medical therapy and the adverse effects disappeared. The mean dosage of buprenorphine was 0.096 in group 1 and 0.01 in group 2. Only four patients in group 2 needed sublingual buprenorphine therapy, whereas 25 patients in group 1 required such regimens and nine patients suffering from adverse effects (dizziness, anorexia and vomiting) and a statistical significant difference was noted ($P = 0.0002$).

Discussion

Indwelling double-J ureteral stents has become routine in the management of a variety of urinary tract diseases. Stents prevent urinary tract obstruction, divert urine, allow for faster tissue healing, dilate the ureter, and assist in stone passage [2]. However, the ideal stent is not yet available [3, 4, 7]. Many patients will experience significant stent-related morbidity, and an additional procedure to remove the stent is usually needed [3, 8]. To minimize the above-mentioned problems [9], new double-J stents with tapered distal ends made from hydrophilic material have been developed, and stents created from new biodegradable or tissue-engineered materials may eliminate the need for stent removal in the future [10, 11]. Although most efforts have been directed toward improving stent material and design, few data are available regarding possible pharmacological management of stent-related morbidity.

We conduct the study to evaluate the role of selective alpha$_1$-blocker for the improvement of stent-related symptoms with double-J ureteral stents. This hypothesis was based on the similarity of stent-related symptoms to benign prostatic hyperplasia-related symptoms, which can now be reliably recorded by USSQ. In our study, the selected medication was extended-release tamsulosin hydrochloride, which is the most recently approved selective alpha$_1$-adrenergic-receptor antagonist [12].

Tamsulosin acts as a competitive antagonist of alpha$_1$-adrenoceptor-mediated contraction of prostatic, bladder, and proximal urethral smooth muscle [1, 2]. Consequently, urethral pressure and resistance, bladder outlet resistance, bladder instability, and relevant symptoms associated with benign prostatic hyperplasia are reduced [14]. Studies have suggested a beneficial effect of tamsulosin on the quality of life in patients with benign prostatic hyperplasia. The once-daily formulation of tamsulosin has been developed to improve the convenience of dosing and to provide optimal pharmacokinetic coverage during a 24-hour period.

Joshi et al. [5, 15, 16] were the first to develop and assess the USSQ, suggesting that it has satisfactory validity with good evaluative and discriminate properties. The authors reported bothersome urinary symptoms and stent-related pain in 80%, with storage symptoms and incontinence the symptoms mostly affecting quality of life. Also, in the same study, as much as 40% of patients experienced sexual dysfunction [16]. Our results regarding the controls are in accordance with their findings. In fact, 66% of the patients receiving placebo reported stent-related pain. In this group of patients, frequency, urgency, pain during voiding, impaired the sexual matters, and general health index scores apparently developed. Patients in group 1 (placebo) were less capable of performing heavy activities and had pain during intercourse, decreasing their overall satisfaction.

As shown in our study, the use of tamsulosin alleviated stent-related urinary symptoms. Stent-related pain and urinary symptoms could be related to lower ureteral spasm or local trigone sensitivity. The possible mechanisms of ben-

efit could be ureteral smooth muscle relaxation, affecting ureteral motility. Recent studies have demonstrated that alpha$_1$-blockers enhance lower ureteral stone clearance in both sexes, possibly by causing ureteral dilation/relaxation [17, 18]. Recently, Davenport et al. reported that tamsulosin significantly reduced ureteric pressure in a pilot study [19]. In the present study, tamsulosin significantly reduced the prevalence of urinary symptoms. Stent-related pain was significantly less in patients receiving tamsulosin, who required significantly fewer analgesics. Tamsulosin reduced not only the pain during voiding, but also loin pain, possibly by reducing urine reflux by better bladder neck relaxation.

Sexual dysfunction due to a decreased libido and self-confidence was demonstrated in patients with stents and was associated with the urinary symptoms and pain attributed to the presence of the double-J stent in the study by Joshi et al. [15]. The decrease in urinary symptoms and associated pain in patients with double-J stents receiving tamsulosin still cannot improve sexual performance status in such patients in our study. However, the general health index score was significantly better in patients receiving tamsulosin; thus, these patients were more active, calm, and happy with their life. Additional problems, such as urinary tract infections, leading to the need for medical assistance or even hospitalization, were similar in both groups, probably reflecting proper stent placement and explaining in part why days "off work" were similar in both groups. Feelings for future stent placement were greater in tamsulosin group. Stenting makes patient happy, may be due to the improvement of urinary tract symptoms and pain. Several studies have demonstrated the beneficial effects of alpha-blockers in the treatment of voiding symptoms in women [20, 21]. Urodynamic studies in women with frequency, urgency, and urge incontinence have shown a modulating effect of alpha-blockers on bladder smooth muscle [20].

We acknowledge the potential limitations of our study as reported by Deliveveliotis et al. Only a single stent, design, size, and material were evaluated; however, it has been demonstrated that the degree of stent-related symptoms is not associated with the stent characteristics (composition, style, length) or placement techniques or body height or gender [22–24]. Besides, utilization of single stent can minimize the trial variability. We performed ureteroscopic stone manipulation with routine insertion of ureteral stent for 2 weeks until they completed the questionnaires and terminated treatment (tamsulosin or placebo). Our primary objective was to evaluate whether the concept of using an alpha$_1$-blocker is justified. Future randomized prospective studies of a larger sample of consecutive patients with a longer follow-up might potentially overcome our limitations and compare the morbidity of stents with different characteristics and insertion indications.

Conclusions

The double-J stent has become an integral part of the urologic intervention; however, stent-related morbidity is a reality in the great majority of patients. The administration of a selective alpha$_1$-blocker, such as tamsulosin, improves stent-related urinary symptoms, pain and voiding flank pain. Future research is needed to refine the exact role and mechanisms of selective alpha$_1$-blockers in managing stent-related symptoms.

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