

# Alfuzosin vs. Silodosin in the Improvement of Ureteral Stent-Related Symptoms after Endoscopic Surgical Treatment of Urolithiasis: A Retrospective Comparison

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## Abstract

### Purpose

In this study, we aimed to compare the efficacy of two  $\alpha$ -blockers, alfuzosin and silodosin, which have different pharmacological properties despite being uroselective, in the treatment of double-J stent (DJS)-related symptoms.

### Methodology

Fifty-six male patients who underwent DJS implantation and for whom all data were available were included in the study. All patients were asked to complete the validated Turkish version of the Ureteral Stent Symptom Questionnaire (USSQ), international prostate symptom score (IPSS), and international index of erectile function-5 (IIEF-5) the day before stent removal and again one month after stent removal. Statistical analysis of these variables was performed in the groups, and a value of  $p < 0.05$  was considered statistically significant.

### Results

Significant decreases in IPSS, IPSS-quality of life, and USSQ scores were observed in both Group A and Group S one month after stent removal compared with before stent removal ( $p < 0.05$ ). Whereas no side effects were observed in the alfuzosin group (Group A), retrograde ejaculation was observed in 8 (25.2%) patients in the silodosin group (Group S) ( $p = 0.006$ ). Furthermore, a statistically significant increase in IIEF-5 score was observed in both groups after stent removal compared with IIEF-5 score with stenting ( $p < 0.05$ ).

### Conclusion

The DJS has a significant impact on patients' quality of life and should only be used when indicated, not routinely after every endoscopic stone procedure. Considering that silodosin may cause more ejaculation problems than alfuzosin, we believe that both drugs can be used in male patients to resolve DJS-related symptoms.

**Keywords:** Alfuzosin, Silodosin, Double-j Stent, Urolithiasis

## 1. Introduction

Ureteral double-J stents (DJS) are an essential part of any urological procedure and help to reduce the risk of obstruction after surgery [1]. However, nearly 80% of patients experience at least one lower urinary tract symptom (LUTS) after DJS placement, including dysuria, incomplete voiding, urgency, hematuria, and

suprapubic discomfort [1-3]. Although there is no proven cause of these symptoms, it is highly probable to be caused by trigonal hypersensitivity, ureteral and bladder wall spasms [3]. The increase in pressure from the bladder to the renal pelvis during micturition can also be the cause of these symptoms [1]. All of these symptoms have a negative impact on patients' quality of life (QoL) and

increase the search for different treatment modalities [1, 3]. DJSs' texture, design, and length have been changed, or drug-coated stents have been used to reduce these symptoms, but none of these strategies has completely solved these problems [2-4].

In addition to the texture changes in DJSs, medical treatments are being investigated for the reduction of DJS-related symptoms [1-3]. According to the proposed pathophysiological mechanisms of LUTS due to DJSs,  $\alpha$ -receptor blockers, phosphodiesterase-5 (PDE5) inhibitors, anti-muscarinics, and beta-3 agonists have been investigated to improve DJS-related symptoms [1, 3, 5, 6]. To date, different  $\alpha$ -blockers, such as alfuzosin, silodosin, and tamsulosin have been used in clinical trials to standardize the management of symptoms associated with DJSs [4, 7, 8].

Alpha-blockers are divided into two groups:  $\alpha$ -1 selective (terazosin, doxazosin) and  $\alpha$ -1 subtype selective or uroselective (tamsulosin, alfuzosin, silodosin). Alpha-blockers, which have different pharmacological properties, also have different profiles of efficacy and side effects [9]. In this study, we aimed to compare the effects of two uroselective  $\alpha$ -blockers (alfuzosin vs. silodosin) with different pharmacological properties and side effect patterns on the resolution of DJS-related symptoms after endoscopic urolithiasis surgery.

## 2. Methodology

The study was approved by the Institutional Review Board of Ankara City Hospital (IRB number: E2-23-3480, date: 01/03/2023). This retrospective study was conducted between April 1, 2022, and January 1, 2023, on 56 patients who underwent double-J stenting (4.8 F, 26 cm standard stent, polyurethane) after ureterorenoscopy/retrograde intrarenal surgery (URS/RIRS) for ureteral and/or kidney stones by two surgeons. The URS procedures included in the study were performed under general anesthesia using an 8/9.8 F rigid ureteroscope (Richard Wolf, Germany), and RIRS procedures were performed under general anesthesia using a Karl Storz flex X2 renoscope (Karl Storz, Germany) and a 10 F ureteral sheath (Plastimed Co., Turkey). All patients received a 16 F Foley urethral catheter at the end of surgery, and these catheters were removed on the morning of postoperative day 1. All patients enrolled in this study provided written informed consent.

Male patients over 18 years of age who were sexually active, who were employed full time, whose stone is opaque, patients with a first stone episode, who had no contraindications to the medications used in this study, and for whom all data were available were included in the study. Patients with a history of lower urinary tract surgery, with non-opaque stones, previous prostate or bladder surgery, bladder/prostate pathology (prostatitis, interstitial cystitis, prostate cancer, overactive bladder, or neurogenic bladder), pelvic irradiation, diabetes, acute or chronic renal failure, solitary kidney, or congenital urinary anomaly; patients receiving medical treatment that could affect the outcome of the study ( $\alpha$ -blockers, beta-blockers, 5- $\alpha$  reductase inhibitors, PDE5 inhibitors, anticholinergics, or cholinergics); patients operated under spinal anesthesia;

patients with postoperative residual stones greater than 3 mm or bilateral stones; patients with a preoperative episode of pyelonephritis or urine culture growth in the perioperative period, patients with impacted stones in the urinary tract, patients with any urinary tract injury during surgery; patients with bilateral DJS; patients with long-term stent implantation (periodic replacement); retirees; students; and patients lost to follow-up were excluded.

All patients underwent preoperative investigations, such as plain radiography of the kidney, ureter, and bladder (KUB) and non-contrast computed tomography (nc-CT). In some patients, ultrasound was performed prior to nc-CT, but the diagnosis was not definitive, so the diagnosis was supported by nc-CT. Maximum stone size and prostate volume were measured by nc-CT imaging. Patients were discharged on the first postoperative day after removal of urethral catheters. Patients were randomized to receive either 10-mg alfuzosin tablets orally once daily (n=25) or 8-mg silodosin orally once daily (n=31) as an  $\alpha$ -blocker as part of the postoperative clinical routine until stent removal prior to discharge. Patients were also asked about their allergy status, and those with normal renal function tests were prescribed 25 mg diclofenac tablets postoperative in case of pain. All patients underwent KUB radiography for the exclusion of residual stone fragments and for evaluation of DJS status before stent removal. In our routine clinical practice, DJS removal is recommended one to four weeks postoperatively if there is no operation or patient-related requirement.

All patients were asked to complete the validated Turkish versions of the international prostate symptom score (IPSS), international prostate symptom score- quality of life (IPSS-QoL), and international index of erectile function-5 (IIEF-5). The Ureteral Stent Related Symptom Questionnaire (USSQ), validated in Turkish by Tanidir et al., was completed by patients one day before stent removal (i.e., with stent) and one month after stent removal (i.e., without stent) [10]. The USSQ includes a series of questions on urinary symptoms, body pain, sexual health, general health, work performance, and additional problems. When patients came in for stent removal, they were asked about their regular use of their prescribed medications, as well as whether they experienced any side effects while taking their medications, and if so, what these side effects were. Uroflowmetry (Qmax, Qmean, post-void residual, and voided volume) was performed, and data were recorded while the stent was in the patient; the stent was removed on the same day under local anesthesia with an 8/9.8 F rigid ureteroscope (Richard Wolf, Germany).

The demographic data and IPSS, IPSS-QoL, IIEF-5 and USSQ scores of patients were compared between Group A (alfuzosin) and Group S (silodosin) by univariate analysis. In addition, the IPSS, IPSS-QoL, IIEF-5, and USSQ results were compared between patients in Group A and Group S during stent implantation and after stent removal. The Statistical Package for Social Sciences (SPSS) version 22.0 (SPSS, Inc.) was used for statistical analysis. The Kolmogorov-Smirnov test was used to test the distribution of the data. Categorical variables were presented as numbers and

percentages. The chi-squared test was used to compare categorical variables between independent groups. Continuous data were expressed as median (range). Means of parameters that were not normally distributed were compared using the Mann–Whitney U test. The IPSS, IPSS-QoL, IIEF-5, and USSQ scores of patients with and without stents were compared within each group using the Wilcoxon test. A value of  $p < 0.05$  was considered statistically significant.

### 3. Results

A total of 56 male patients who underwent stent placement after stone surgery were included in the study. A comparison of the demographic and clinical characteristics of patients between Group A and Group S is shown in Table 1. The median age of Group A

and Group S was 38 (19–63) and 37 (25–63) years, respectively ( $p > 0.05$ ). No statistically significant differences were observed between the groups in terms of patients' body mass index, height, stone size, stent indwelling time, operation side (R/L), procedure performed (RIRS/URS), prostate volume, Qmax, Qmean, and post void residue. All patients enrolled in the study took their prescribed medication regularly and did not discontinue treatment. Whereas no side effects were observed in the alfuzosin group, retrograde ejaculation was observed in 8 (25.2%) patients in the silodosin group ( $p = 0.006$ ). The median age of patients who experienced retrograde ejaculation was 34 (25–44 years). The need for analgesia was found to be statistically significantly lower in Group S than in Group A ( $p = 0.002$ ).

	Group A(n:25)	Group S(n:31)	p
Age, yr	38 (19 - 63)	37 (25 - 63)	0,82
Height, cm	175(164 - 185)	173(167 - 190)	0,84
BMI, kg/m2	28,4 (20,8 - 37,6)	27,7 (21,7 - 35,9)	0,62
Stone size, mm	9 (0 - 27)	8 (5 - 22)	0,08
Stent indwelling time, day	23 (7 - 53)	22 (7 - 35)	0,12
Operation side, R/L	10/15	15/16	0,63
Procedures, RIRS/URS	7/18	6/25	0,45
Prostate volume, cc	19 (10 - 37)	21 (12 - 60)	0,75
Qmax	18,5 (7,7 - 52,9)	16,9 (3,2 - 166)	0,17
Qmean	10,1 (3,3 - 19,6)	8 (1,6 - 48)	0,08
PVR	20 (0 - 100)	20 (0 - 200)	0,29
Side effect, n (%)			
Retrograde ejaculation	0	8(25,8)	0,006
Fatigue	0	0	
Dizziness	0	0	
Orthostatic hypotension	0	0	
Total Analgesic used (Diclofenac mg)	625(0-2650)	525(0-1200)	0,002
BMI; body mass index, R; right, L; left, RIRS; retrograde intrarenal surgery, URS; ureterorenoscopy, PVR; post-void residue			

**Table 1: Comparison of Demographic and Clinical Data of Patients between Groups**

A comparison of IPSS, IPSS-QoL, IIEF-5 and USSQ variables before stent removal (i.e., with stent) and one month after stent removal (i.e., without stent) is shown in Table 2. The work performance without a stent was statistically significantly lower in Group S compared with Group A ( $p = 0.03$ ). There was no statistically significant difference between the other variables ( $p > 0.05$ ).

	Group A(n:25)		Group S(n:31)		p*
	Median(range)	p**	Median(range)	p**	
IIEF with stent	16,5 (5 - 25)	<0,001	15 (0 - 25)	<0,001	0,3
IIEF without stent	20,5 (13 - 25)		24 (5 - 25)		0,2
IPSS with stent	7 (1 - 26)	<0,001	9 (0 - 28)	<0,001	0,4
IPSS without stent	1 (0 - 6)		1 (0 - 6)		0,81

IPSS-QoL with stent	2,5 (0 - 5)	<0,001	3 (0 - 6)	<0,001	0,22
IPSS-QoL without stent	0 (0 - 1)		0 (0 - 2)		0,79
Urinary symptoms with stent	30 (17 - 38)	<0,001	29 (18,3 - 41)	<0,001	0,63
Urinary symptoms without stent	21,3 (11 - 31,3)		18,5 (11 - 32,5)		0,07
Body pain with stent	15 (6 - 25)	<0,001	14 (6 - 22)	<0,001	0,3
Body pain without stent	8 (6 - 17)		8 (8 - 15)		0,86
General health with stent	15 (6 - 28)	<0,001	16 (7 - 26)	<0,001	0,67
General health without stent	8 (6 - 24)		7 (6 - 18)		0,46
Work performance with stent	6 (3 - 15)	0,001	6 (3 - 15)	<0,001	0,97
Work performance without stent	3 (3 - 6)		3 (3 - 7)		0,03
Sexual health with stent	6 (5 - 19)	<0,001	8 (5 - 17)	<0,001	0,59
Sexual health without stent	5 (5 - 7)		5 (5 - 12)		0,13
Lost workday, day	5 (0 - 45)		5 (0 - 25)		0,87

IIEF; International Index of Erectile Function, IPSS; International Prostate Symptom Score, QoL; quality of life,

\*: Man-Whitney U test, \*\*: Wilcoxon test

**Table 2: Ureteral Stent Symptom Score, IIEF-5, IPSS and IPSS QoL with Stent and Without Stent in Two Groups**

Significant decreases in IPSS, IPSS-QoL, urinary symptoms, body pain, general health, work performance, and sexual health scores were observed in both Group A and Group S one month after stent removal (i.e., without stent) compared with before stent removal (i.e., with stent) ( $p < 0.05$ ). Furthermore, a statistically significant increase in IIEF-5 score was observed in both groups after stent removal compared to with stenting ( $p < 0.05$ ) (Table 2).

#### 4. Discussion

Following the tremendous development of fiber optics, flexible surgical instruments, and laser technology in recent years, endoscopic methods are increasingly being used in urinary stone surgery. In endoscopic urinary stone surgery, which includes procedures such as URS and RIRS, a DJS is often used due to residual stone fragments, mucosal damage, or the desire to dilate the ureter. Despite their excellent benefits, DJSs have been shown to cause problems in many areas, including patients' QoL, work performance, and sexual life during the time they are implanted [3, 5, 11]. Male patients in particular are more adversely affected by DJS due to the presence of the prostate and increased intravesical pressure, so we focused on this group in our study. Alpha-blockers, which reduce intravesical pressure by decreasing the tone of the ureter, trigone, bladder neck, and prostate, are an important group of drugs. In particular, tamsulosin, alfuzosin, and silodosin, which are selective for the  $\alpha$ -1a subtype, are expected to be a step forward in the treatment of DJS-related symptoms due to their uroselective effects [3, 12, 13].

Although both alfuzosin and silodosin are uroselective, the efficacy and side effect profile of silodosin may differ from that of alfuzosin due to its higher  $\alpha$ -1a affinity [9, 14]. To our knowledge, this is the first study to compare alfuzosin and silodosin in the treatment of DJS-related symptoms. In the present study, patients in both groups were able to complete treatment without discontinua-

tion; no side effects were observed in the alfuzosin group, whereas 8 (25.2%) patients in the silodosin group experienced retrograde ejaculation. Obviously, these results of our side effect profile need to be supported by larger case series to conclude that these drugs are safe because our sample size was relatively small. Although these retrograde ejaculation rates seen in the silodosin group are compatible with the literature, it should be kept in mind that this situation can be very troublesome for patients, considering that the median age of patients with retrograde ejaculation in our study was 34 years [15].

In the resolution of symptoms associated with DJS, Rane et al. suggested that the proportion of DJS in the bladder should not exceed the midline [16]. The fact that the height of the patients in our current study was similar between the two groups makes the results of the current study comparable. Medical treatments have an important place in the resolution of stent-related symptoms. Alfuzosin was shown to have a positive effect on pain, QoL, and sexual function in DJS-related symptoms [10]. In a prospective randomized trial comparing alfuzosin with a placebo by Syed M. Nazim et al., alfuzosin was also found to be superior to the placebo in resolving DJS-related symptoms [3]. In a study comparing the efficacy of two uroselective  $\alpha$ -blockers, tamsulosin and alfuzosin, and a placebo in the treatment of DJS-related symptoms, tamsulosin and alfuzosin were found to be similarly effective [17]. Studies with silodosin have also shown the superiority of silodosin over a placebo in the resolution of DJS-related symptoms [8, 18]. In addition, in these studies, the selective affinity of silodosin for the  $\alpha$ -1a receptor was higher than for the  $\alpha$ -1b and  $\alpha$ -1d subtype receptors, which indicates that it may have fewer cardiovascular side than those of other  $\alpha$ -blockers [14]. Studies comparing  $\alpha$ -blockers alone or in combination with antimuscarinics have shown that combination therapy is more effective in treating DJS-related symptoms [19, 20]. The combination of silodosin and solifen-

cin was shown to be more effective than silodosin alone in the treatment of stent-related symptoms [8]. In their study comparing tamsulosin, tadalafil, and a placebo, Aggarwal et al. showed that tadalafil was as effective as tamsulosin for urinary symptoms, pain, QoL, and work performance and was more effective than tamsulosin for sexual function[5].

Age, body mass index, stone size, stent indwelling time, side of surgery, type of procedure, and other characteristics of the patients included in our study were similar. Prostate volume, Qmax, Qmean, and post void residue values, which may influence the efficacy of  $\alpha$ -blockers, were also similar. The fact that these parameters were similar means that we had two homogeneous groups that were similar in terms of evaluating the effect of the drugs, which allowed us to make clearer comparisons. The need for analgesia during stent implantation was only statistically significantly higher in the alfuzosin group than in the silodosin group (Table 1).

Although the median duration of stent implantation was similar, the fact that one patient in the alfuzosin group remained stented for 53 days (due to the patient arriving late for stent removal without medical justification) may have increased the cumulative need for analgesia, which reduces the reliability of this result. In the alfuzosin and silodosin groups, there was a statistically significant improvement in all subscales of the USSQ between the stented period and the period after stent removal in favor of the stent-free period (Table 2). From this result, it can be concluded that both drugs are effective in resolving DJS-related symptoms.

We also found that on questionnaires such as the IPSS and IIEF-5, which allow us to assess LUTS and sexual function, the period with the stent was statistically significantly worse than the period after stent removal. PDE5 inhibitors such as tadalafil should be considered as a treatment option in male patients with DJS, according to Aggarwal et al. [5] Regarding work loss, although the median five-day work loss was similar in the alfuzosin and silodosin groups, work performance after stent removal was statistically significantly worse in the silodosin group than in the alfuzosin group ( $p = 0.03$ ). We believe that this result may be due to the nature of the patients' work, which we did not analyze.

Our study has some limitations that should be mentioned and recognized. The major limitation of our study is its retrospective nature. Other limitations include the relatively small sample size, the lack of a placebo arm, the lack of an assessment of the type of work involved, the use of a single stent type and size, and the inclusion of only male patients in the study.

## 5. Conclusion

Despite the limitations of our study, we were able to show that the effects of alfuzosin and silodosin in relieving DJS-related symptoms were similar in male patients. This is the first study to compare these two drugs regarding DJS-related symptoms. DJS has a significant impact on patients' QoL and should only be used when indicated, not routinely after every endoscopic stone procedure. Considering that silodosin may cause more ejaculation problems

than alfuzosin, we believe that both drugs can be used in male patients to resolve DJS-related symptoms. We believe that prospective, randomized, controlled trials with a placebo arm and larger sample sizes are needed to clarify the effects of alfuzosin and silodosin on the resolution of DJS-related symptoms.

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The study was internally funded.

## Conflicts of interest

The authors have no conflicts of interest to declare.

## Availability of data and material

The raw data is with the corresponding author and can be provided on request.

## Code availability

Not applicable for this section.

## Authors' contributions

MES, EO and MY conceived the study concept and design. MES, MEP and MK collected data for the study. MES, EO performed the surgical procedures. MES, MK and MEP analyzed the data. MES, MK, EO, MEP and MY interpreted the data and wrote the manuscript. MK, EO and MY provided critical feedback and helped shape the research, analysis and manuscript. MES and MY supervised the project. All authors discussed the results and commented on the manuscript.

## Ethics approval

The study was approved by the Institutional Review Board of Ankara Bilkent City Hospital (IRB number: E2-23-3480, date: 01/03/2023).

## Consent to participate (include appropriate statements)

Not applicable for this section.

## Consent for publication

Not applicable for this section.

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