

## Tekrarlayan üretral darlık hastalarında optik internal üretrotomi ve aralıklı self dilatasyonun etkinliği: Randomize kontrollü çalışma

*Efficacy of Optical Internal Urethrotomy with Intermittent Self Dilatation for Urethral Stricture: A Randomized Prospective Study*

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### Özet

**Amaç:** Üretra darlığı erişkin erkeklerde sıklıkla ikincil nedenlere bağlı gelişen yaygın görülen klinik bir durumdur. Üretral darlıkların tedavisinde optik internal üretrotomi (OIU), üretral dilatasyon ve açık üretroplasti gibi tedavi seçenekleri vardır. Aralıklı self-dilatasyon işleminin üretral darlık tedavisindeki yeri tartışmalıdır. Bu çalışmada tekrarlayan üretral darlıklarda self-dilatasyonun etkinliği araştırılmıştır.

**Gereç Yöntem:** Bu prospektif çalışmamızda hastalar iki gruba ayrılarak değerlendirildi. 67 hastadan oluşan çalışma grubuna OIU sonrası haftada iki kez self-dilatasyon uygulanırken, 63 hastadan oluşan kontrol grubuna ise OIU sonrası herhangi bir işlem yapılmadı. Hastalar primer olarak maksimum idrar akış hızı (Qmax) ile takip edildi. Sekonder olarak ise hastalar Uluslararası Eretil Fonksiyon indeksi, Uluslararası Prostat Semptom Skoru, rezidüel idrar hacmi, üriner sistem infeksiyonu ve Yaşam Kalite Skoru bakımından değerlendirildi.

**Bulgular:** Cerrahi sonrası birinci ay kontrolünde, kontrol grubu ve çalışma gruplarında sırasıyla ortalama Qmax 14,0±3,0 mL/s ve 14,3±2,4 idi (p = 0,44). Cerrahi sonrası üçüncü ayda ortalama Qmax değerleri sırasıyla 11,6±2,9 mL/s ve 13,3±2 mL/s bulundu (p=0,01) ve gruplar arasında IIEF skorları

### Abstract

**Objectives:** Urethral stricture is a commonly seen clinical entity in adult men that is mostly seen due to secondary causes. Optical internal urethrotomy (OIU), urethral dilatation and open urethroplasty are therapeutic options for strictures. It is still controversial whether intermittent self-dilatation is a good option for urethral stricture treatment.

**Aims:** We assessed the effectivity of self-dilatation on urethral stricture recurrence.

**Material and Methods:** The effectivity of self-dilatation was assessed prospectively in two groups of patients; 67 of these patients performed self dilatation twice a week after optical internal urethrotomy (study group), and 63 did not (control group). The primary outcome was to assess improvement in the maximum urine flow rate (Qmax), while the secondary outcome was to monitor the International Erectile Function Index, International Prostate Symptom Score, Quality of Life score, postvoiding residual urine volume, urinary infection, and other uroflowmetric parameters.

**Results:** In the first postoperative control, the mean Qmax were 14±3 mL/s and 14.3±2.4 mL/s in control group and study group, respectively (p=0.44). The third postoperative control revealed, the mean Qmax were

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benzerdi ( $p = 0,63$ ). Postoperatif altıncı ayda kontrol ve çalışma gruplarının ortalama Qmax değerleri sırasıyla  $9,2 \pm 2,4$  mL/s,  $12,2 \pm 1,8$  mL/s ( $p=0,34$ ) idi. Ortalama IIEF skorları bakımından gruplar arasında fark bulunmadı ( $p > 0,05$ ).

**Sonuç:** Optik internal üretrotomi sonrası self-dilatasyon kısa vadede minör yan etkileriyle kolay uygulanan bir yöntem olsa da üretra darlığını önlemede etkili bir yöntem değildir.

**Anahtar Kelimeler:** İnternal üretrotomi, Self dilatasyon, Üretral darlık

$11,6 \pm 2,9$  mL/s and  $9,2 \pm 1,8$  mL/s in control group and study group, respectively ( $p=0,01$ ) whereas IIEF scores were similar ( $p=0,63$ ). In the sixth month control revealed, the mean Qmax were  $9,2 \pm 2,4$  mL/s and  $12,2 \pm 1,8$  mL/s, respectively ( $p=0,34$ ). QoL, and IIEF values were not statistically different ( $p > 0,05$ ).

**Conclusion:** Although self dilatation after optical internal urethrotomy is an easily and commonly applied method with minor side effects, it does not help to prevent short-term urethral stricture and does not lengthen recurrence intervals.

**Keywords:** Internal Urethrotomy, Self-Dilatation, Urethral Stricture

## INTRODUCTION

Urethral stricture is seen in 0.6-1.4% of adult males (1). The aetiology of urethral strictures is 30% idiopathic and 70% due to secondary causes (sexually transmitted diseases, perineal trauma, and urological interventions) (2). Optical internal urethrotomy (OIU), urethral dilatation, intraurethral stents, and open urethroplasty are therapeutic options for strictures. Plasmakinetic energy can be used for treatment of urethral stricture (3). In daily practice, urethral dilatation following OIU is routinely used in urethral stricture disease. Our hypothesis was to show that whether self dilatation had positive impact on disease recurrence or not. In this study, we aimed to assess the efficacy of self dilatation after OIU.

## MATERIALS AND METHODS

A hundred and thirty male patients with urethral stricture were enrolled in the study from October 2011 to July 2015. Patients between ages of 26 and 89 with urethral strictures were randomized into a study group (SG) and control group (CG) (Figure 1). Patients older than 18 years with history of urethral stricture of mild to severe urinary symptoms were included for the study. Patients with prostate or bladder cancer, symptomatic benign prostatic hyperplasia, uncontrolled bleeding diathesis, mentally retarded disorders, neurogenic bladder dysfunction, impact calculus in the urethra and bladder neck were excluded to study.

After obtaining Local Ethic Committee approval from the Samsun Training and Research Hospital, patients were informed about the study, and consents were obtained. Cold knife optical internal urethrotomy (OIU) using a 21F urethrotome was applied under spinal anaes-

thesia with 12 o'clock incision of the stricture. Preoperative assessment included detailed medical history, uroflowmetry and urine culture. At the beginning, length of the stricture was determined using ultrasound, but lack of experience of the radiologist caused heterogeneity on diagnosis. All preoperative infections were treated with antibiotics. The length of the stenotic segment was measured with a 3 Fr urethral catheter. After the third postoperative day, self-dilatation was first performed and then taught to the patients in the SG with a 14 Fr catheter two times a week. Rod-shaped low-friction hydrophilic sterile disposable catheter tube was used at regular intervals to prevent the stricture recurrence. Data on patient age, aetiology, previous operations, anatomical site, International Erectile Function Index (IIEF), International Prostate Symptom Score (IPSS), Quality of Life (QoL), postvoiding residual urine volume (PVR), urinary infection, and uroflowmetric parameters were recorded (Table 1). Erectile function was evaluated using IIEF questionnaire, consisted of 1-15 questions. Domains of Erectile Function (questions 1-5, and 15), Orgasmic Function (questions 9 and 10), Sexual Desire (questions 11 and 12), Intercourse Satisfaction (questions 6, 7 and 8) and Overall Satisfaction (questions 13 and 14) were assessed. Each questions are scored 1 (Almost never or never) to 5 (Almost always or always) and total scores were recorded. Patients were classified as severe erectile dysfunction (ED) (score 0-6), moderate ED (score 7-12), mild to moderate ED (score 13-18), mild ED (score 19-24) and no ED (score 25-30). Lower urinary tract symptoms (LUTS) were assessed using IPSS questionnaire consisted of 7 questions. Patients were classified as mild LUTS (score 0-7), moderate LUTS (score 8-19), severe LUTS (score 20-35). Recurrence was defined as recurrent symptomatic stricture requiring fur-

**Table 1.** The preoperative characteristics of the patients

Characteristics	Control Group (N = 63)	Study Group (N = 67)	<i>p</i>
Age (Year)	73.9±13.1	68.4±13.4	0.896
PVR (mL)	85.6±57.6	79.5±55.8	0.690
IPSS	23.9±4.7	22.6±5.3	0.267
QoL	5.2±0.6	5.1±0.73	0.594
IIEF	6.2±8.4	8.3±8.7	0.66
Stenosis length (mm)	5.4±2.3	4.9±2.4	0.57
Stenosis Location			
Bulbomembranous	23 (36.5%)	29 (43.3%)	
Membranous	5 (7.9%)	8 (11.9%)	
Bulbous	24 (38.1%)	26 (38.8%)	
Distal penile	11 (17.5%)	4 (6.0%)	
Uroflowmetric values			
UF volume (mL)	181.5±53.8	199.7±39.2	0.28
UF Q maximum (mL/s)	7.9±2.7	7.5±2.4	0.56
UF average (mL/s)	3.9±1.9	3.8±1.6	0.51
UF time (s)	31.4±34.2	28.3±26.5	0.21
Urinary Infection (N, %)	13 (20.6%)	12 (17.9%)	0.69

PVR: Post-voiding residual urine volume; IPSS: International Prostate Symptom Score; QoL: Quality of Life; IIEF International Index of Erectile Function; UF: Uroflowmetry.

ther OIU proven with uroflowmetry ( $Q_{max} < 10$  mL, less than 150 mL of voided urine). The two groups were compared at the end of the first, third, and sixth months in terms of these parameters.

The Statistical Package of Social Science 15 (SPSS 15.0, Chicago, IL, USA) version 18 was used for Student's paired t-test for the assessment of demographic differences between the two groups and a chi-squared analysis was used to assess recurrence.  $P < 0.05$  was accepted statistically significant.

## RESULTS

Of the 220 patients, 120 were included in the SG, and 100 were in the CG. Thirty-seven patients (37%) in the SG, and 53 (44.2%) in the CG were excluded due to various reasons during the study. Study was completed with 63 patients in the CG (48.5%) and 67 in the SG (51.5%).

The mean ages of patients in the SG and CG were  $73.9 \pm 13.1$  and  $68.4 \pm 13.4$  years, respectively ( $p = 0.89$ ). Proximally located stricture rates in the SG and CG were 28 (44.4%) and 37 (55.2%), respectively, and distal stric-

ture recorded in the SG and CG were 37 (55.6%) and 30 (44.8%), respectively. When etiology was considered, 57 patients had postoperative stricture (90.5%), 5 had post-traumatic stricture (7.9%) and one patient had idiopathic stricture 1 (1.6%) in CG, while 59 patients had postoperative stricture (88%), 7 had posttraumatic stricture (10.4%) and one patient had idiopathic stricture (1.6%) in SG. There was no statistically significance between groups ( $p > 0.05$ ). In the preoperative period,  $Q_{max}$  were found to be  $7.9 \pm 2.7$  mL/s and  $7.5 \pm 2.4$  mL/s in CG and SG, respectively ( $p = 0.56$ ). Stricture length and location, urinary infection, IPSS, QoL, PVR, and IIEF were statistically non-significant ( $p > 0.05$ ) (Table 1). The most common anatomical site of stricture for both groups was the distal urethra, and there was no difference between two groups ( $p = 0.28$ ). The first and third postoperative months of controls revealed a significant improvement in PVR, IPSS, QoL (Table 2 and 3). In the first postoperative control, the mean  $Q_{max}$  were  $14 \pm 3$  mL/s and  $14.3 \pm 2.4$  in CG and SG, respectively ( $p = 0.44$ ). In the third postoperative control, the mean  $Q_{max}$  were  $11.6 \pm 2.9$  mL/s

**Table 2.** The treatment results of patients at 1<sup>st</sup> month control

Characteristics	Control Group (N = 63)	Study Group (N = 67)	p
PVR (mL)	28.1±27.3	14.7±21.5	0.002
IPSS	19.9±4.8	17.2±5.1	0.003
QoL	3.00±0.9	2.6±0.67	0.002
Uroflowmetric values			
UF volume (mL)	251.8±51.7	262.1±49.2	0.24
UF Q maximum (mL/s)	14±3	14.3±2.4	0.44
UF average (mL/s)	8.6±2.0	9.8±1.6	0.01
UF Time (s)	20.1±11.8	18±8.7	0.25
Urinary Infection (N, %)	7 (11.1%)	10 (14.9%)	0.56

PVR: Post-voiding residual urine volume; IPSS: International Prostate Symptom Score; QoL: Quality of Life; UF: Uroflowmetry.

and 13.3±2 mL/s in CG and SG, respectively (p=0.01). However, when data from the sixth month were considered, Qmax, QoL, and IIEF values were not statistically different (p>0.05) (Table 4). Thirty-two patients in the SG (47.8%) and 33 patients (52.4%) in the CG did experience no recurrence at the end of the sixth month (Table 5). There was no significant major or minor complications in both groups.

## DISCUSSION

On the basis of evidence-based medicine, this study has clearly demonstrated that self dilatation has no beneficial outcomes in long term. Urethral stricture is a common clinical problem in daily urological practice. Although a detailed medical history, physical examination, uroflowmetry (Qmax<10mL/s), endoscopy, and

urethrography are sufficient in urethral stricture diagnosis, additional tools, including the presence of obstructive lower urinary symptoms, assessment of QoL, sonourethrography, computed tomography (CT), and magnetic resonance imaging (MR) may aid in proper evaluation (4). Voiding or retrograde urethrography are useful tools for determination length of the stenotic segment (5). It was shown in the literature that the results of retrograde urethrography was not sufficient when was not combined with urethroscopy and it should not be a routine method in the diagnosis of urethral strictures (6). Sonourethrography is more likely to help in detecting the length of urethral spongiofibrosis. Sonourethrography have 86% sensitivity and 94% specificity for anterior strictures (7). The sensitivity of sonourethrography decreases when the stricture is located proximally (8). In our study, we

**Table 3.** The treatment results of patients at 3<sup>th</sup> month control

Characteristics	Control Group (N = 63)	Study Group (N = 67)	p
PVR (mL)	44.7±36.6	17.9±23.9	0.01
IPSS	21.6±4	18±4.8	0.01
QoL	3.76±0.7	2.7±0.7	0.01
Uroflowmetric values			
UF volume (mL/s)	224.5±38.8	237.7±41.9	0.06
UF Q maximum (mL/s)	11.6±2.9	13.3±2	0.01
UF average (mL/s)	6.8±1.8	9.2±1.8	0.01
UF Time (s)	22.5±14	17.1±7.2	0.01
Urinary Infection (N, %)	4 (6.3%)	2 (3%)	0.36

PVR: Post-voiding residual urine volume; IPSS: International Prostate Symptom Score; QoL: Quality of Life; UF: Uroflowmetry.

**Table 4.** The treatment results of patients at 6<sup>th</sup> month control

Characteristics	Control Group (N = 63)	Study Group (N = 67)	P
PVR (mL)	68.2±51.6	27.8±31.1	0.01
IPSS	23.3±4	18.6±5,1	0.02
QoL	4.6±0.7	3.1±0.8	0.49
IIEF	6.2±8.4	8.8±8.9	0.63
Uroflowmetric values			
UF volume (mL/s)	209.9±47.6	238.4±35.9	0.01
UF Q maximum (mL/s)	9.2±2.4	12.2±1.8	0.34
UF average (mL/s)	4.9±1.5	7.9±1.2	0.16
UF time (s)	28.4±21	20.1±9.7	0.01
Urinary Infection (N, %)	12 (19.1%)	5 (7.5%)	0.05

PVR: Post-voiding residual urine volume; IPSS: International Prostate Symptom Score; QoL: Quality of Life; IIEF International Index of Erectile Function; UF: Uroflowmetry.

**Table 5:** Relationship between stricture localization and recurrence at 6<sup>th</sup> month control

	Proximal	Distal	p
<b>Control Group</b> (N, %)	18 (60%)	12 (40%)	0.545
<b>Study Group</b> (N, %)	25 (71.4%)	10 (28.6%)	0.181

did not prefer the use of sonourethrography because its sensitivity depends on the radiologist's experience and sensitivity decreases in proximal strictures rather than in distal counterparts.

Optical Internal Urethrotomy, urethral dilatation, intra-urethral stent implantation, and open urethroplasty are the main therapeutic options for urethral stricture. Intralesional mitomycin C or triamcinolone injections may prolong the intervals between recurrences; however, these methods do not reduce the risk of recurrence, and, therefore, strong randomized controlled studies are necessary (9, 10).

Despite the 55% success rate of intra-urethral stents reported in most articles, stents are not widely preferred in first-line modality because they have serious side effects, such as incontinence, painful erections, dribbling, intractable pain, urinary infections, and stricture recurrence (11). Self dilatation after OIU provides a cure in approximately half of all patients, while the other half requires definitive open urethroplasty (12-14).

At the sixth month of control, 18 (28.6%) patients showed proximal, and 12 (19%) patients showed distal stricture recurrence in CG; whereas 25 (37.3%) patients showed proximal, and 10 (14.9%) patients showed distal

stricture recurrence in SG. Our results were consistent with the literature and revealed a lower recurrence rate in distal urethral stricture when compared to their proximal counterparts. Irrespective of stricture localization, overall recurrence rates were 47.6% and 52.2% in the CG and SG, respectively. In this study, we used 14 Fr catheter two times in a week for self dilatation. Although Lawrence and Lauritzen stated in their studies that using 16 or 18 Fr catheters revealed similar results in term of stricture recurrence, there is no consensus about catheter diameter, how long and how often to do self dilatation in literature (15-17). The short term success rates of OIU and urethral dilatation are limited. Steenkamp et al. reported that nearly half of the patients in their study sample were cured using OIU and the urethral dilatation technique (18). In our study, recurrence rates were 47.6% and 52.2% in the CG and SG in accordance with the literature, respectively. The urethral bougie dilatation method is no longer preferable because this procedure may cause numerous micro lesions in spongiofibrotic tissue, and, as a rule, scar tissue formation is observed four to six weeks after the procedure (18). We observed slightly greater proximal stricture recurrence in the SG than in the CG.

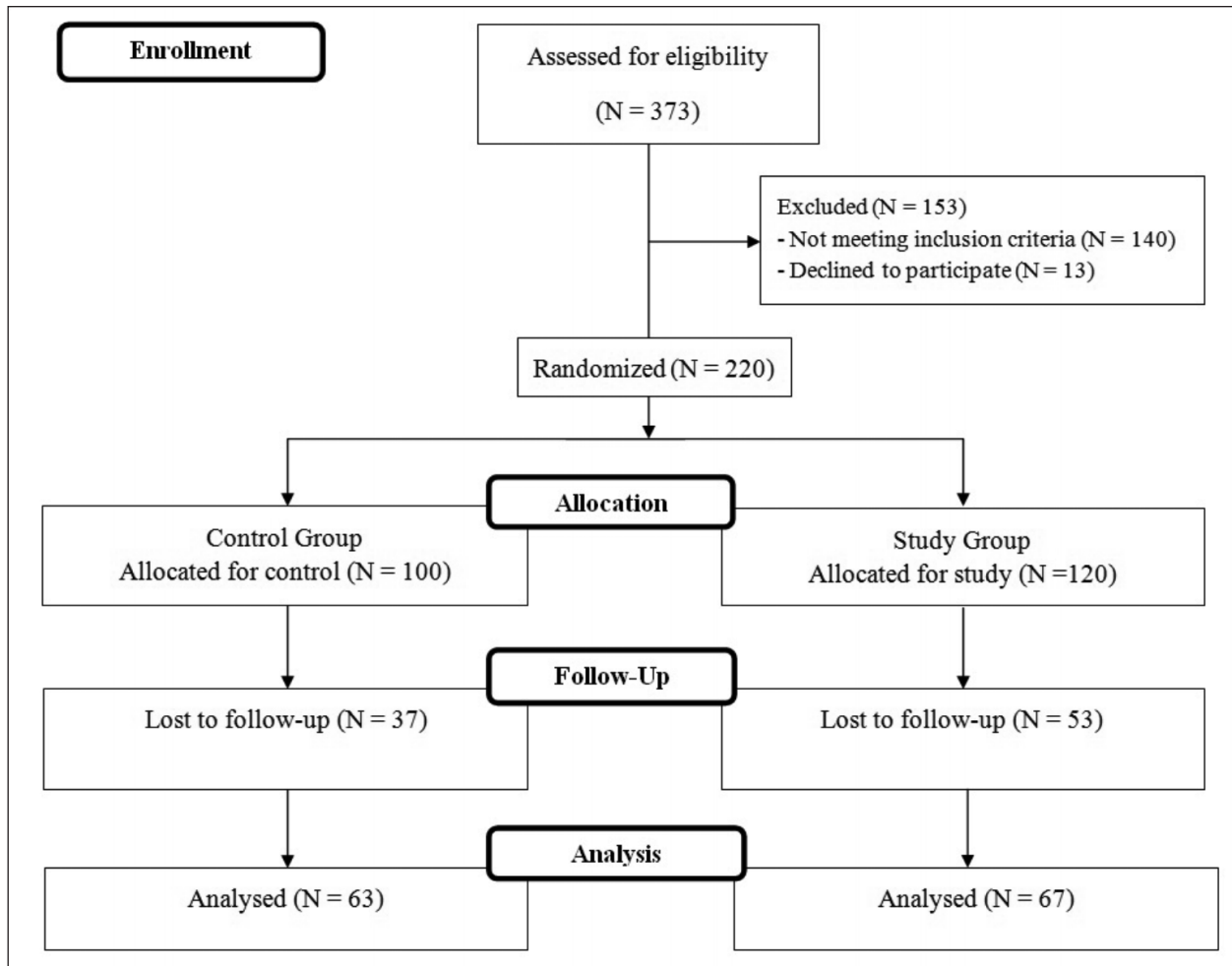


Figure 1. CONSORT Flow Chart of the study.

Self dilatation was first introduced as a technique by Lawrence and has mostly been used as the preferred modality by many urologists (15,19). The long-term success rate of OIU is dependent on the length of the stenotic segment, presence of urinary infection, localization of the stricture, time of the first recurrence, and a number of surgical interventions (20). Because self-urethral dilatation could frequently cause pain, we used 14 Fr catheter to reduce discomfort (19). The technique of combined OIU with self dilatation has been investigated in several trials. Although follow-up periods were shorter (up to 3 months), urethral stricture recurrence was as high as 78% (21, 22). It was reported that the outcomes of the OIU were poor in patients with strictures longer than 1 cm, multiple strictures, pendulous urethral strictures, bulbar strictures with significant spongiosfibrosis, and those re-

cur within the first 3 months. Tammela and Dubey reported that more than six months of self-dilatation had no benefit to patients (23, 24). Contrastingly, another study reported a 40% success rate with a group performing self dilatation over a period of 12-36 months compared to a group performing selfdilatation for only six months (14%) (25). Laser internal urethrotomy prevents recurrence at a rate of 77% and thus may be more likely to cause sepsis (13%). To obtain safer results, strong randomized controlled studies are necessary (26). Indeed, Jackson et al. stated in a Cochrane Database of Systematic Review that intermittent self dilatation following endoscopic treatment reduced risk of recurrent urethral stricture with very low level of evidence (27). Quality of life of the patients enrolled in a dilatation program is reported to be low due to moderate discomfort caused by the dif-

ficuity and pain associated with dilatation (28). In the six month control, even though PVR and IPSS were statistically different, progressive decrease in Qmax might have caused a decrease in QoL. Similar mean IIEF scores between two groups throughout the study can be explained by the fact preservation of the cavernosal nerve.

Open urethroplasty remains the gold standard technique due to its high success rate (29). This technique requires advanced experience and should be performed in reference hospitals. Nonetheless, open urethroplasty is accompanied by many complications, such as erectile and ejaculatory dysfunction, scrotal edema, curvature of the penile shaft, wound infections, perineal hematoma, fistula formation, rectal perforation, epididymal orchitis, meatal stricture, bacteremia, fever, urosepsis, and scrotal abscess. Rather than risking these medical problems, OIU is preferable rather simple technique that can be performed by even inexperienced surgeons at any urology clinic with a low rate of complication (30). Some authors advocate that OIU reduces the success rate of open urethroplasty, while others claim that there is no increase in recurrence rates with OIU (31). OIU is a safe and practical surgical method that has been used in the treatment of urethral stricture for over 40 years. In selected patients, the success rate reaches approximately 50-70% (32). Rouanet et al. observed that self-dilatation following OIU improved IPSS and disease-related QoL parameters. In agreement with their findings, the authors of our study revealed similar improvements at the end of the third and sixth months; moreover, they also reported a statistically significant improvement in PVR (33).

Short follow-up time is the limitations of this study.

Powerfull sides of this study are that it is evidence-based randomized controlled study and this area is poorly studied to date.

The weak side is short follow-up time.

## CONCLUSIONS

Optical internal urethrotomy is an easily applied surgical technique that does not require surgeons to possess special experience with tolerable side effects. However, its therapeutic effectivity is low in term of long-term results. Although OIU is widely performed by many urologists, open urethroplasty is the best therapeutic op-

tion for recurrent urethral strictures. In selected patients with distally located short strictures, the self-dilatation procedure is an acceptable first-line technique that prolongs recurrence time without increasing the complication rate. This study supports the hypothesis that self-dilatation performed twice a week after OIU following the initial endoscopic management of urethral stricture has no significant effect on the overall rate of stricture recurrence compared to the rate of recurrence following endoscopic treatment alone, but it may help to reduce the mean number of repeated interventions for stricture recurrence.

We declare no competing interests.

**Endnotes:** This study was presented as oral presentation during EAU 11<sup>th</sup> South Eastern European Meeting (SEEM), 6-8 Nov 2015, Antalya, Turkey. (Eur Urol Suppl 2015;14(8);e1415)

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