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Bulbar Urethral Stents for Bulbar Urethral Strictures: Long-Term Follow-Up after Stent Removal

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Keywords
Bulbar urethral stricture · Bulbar urethral stent · Clinical efficacy · Stent · Urethral obstruction

Abstract
Background/Aim: The aim of this study was to assess long-term clinical efficacy of temporary bulbar urethral stent (BUS) used for treatment of recurrent bulbar urethral stricture (US). ***Materials and Methods:*** A total of 168 patients with recurrent bulbar US who underwent BUS placement after internal urethrotomy between 2009 and 2019 were enrolled. An indwelling time of 12 months was planned for the stents. After stent removal, the criteria for success of BUS treatment were defined as follows: no evidence of stricture on urethrogram or endoscopy, more than 15 mL/s of urinary peak flow, and no recurrent urinary tract infections. Patients were divided into 2 groups based on clinical success and compared. ***Results:*** The mean age, US length, and indwelling time were 46.7 (±8.3) years, 2.32 (±0.4) cm, and 9.7 (±2.3) months, respectively. Median (range) follow-up was 71 (8–86) months. Clinical success was achieved in 77.9% patients. Longer indwelling time (8–18 [81.88%] vs. 3–7 [60%] months) and US length <2 cm (84.25% [<2 cm] vs. 58.5% [≥2 cm]) were significantly associated with clinical success ($p < 0.05$). ***Conclusion:*** This study is both the largest patient series and the longest follow-up for BUS in bulbar US. Our results suggest that BUS can be a safe and minimally invasive treatment alternative among bulbar US treatment options.

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Introduction

Urethral stricture (US) is one of the most challenging problems in urology and is a common cause of lower urinary tract symptoms. Etiology of strictures includes trauma, urethral catheterization, urologic endoscopic interventions, and sexually transmitted diseases [1]. In addition, there has been an increase in the incidence of US as a result of commonly administered transurethral procedures in the practice of urology. In general, US is caused by a mucosal laceration, depending on etiological factors, and consequently the formation of scar tissue occurs [2]. Treatment of US depends on the length, location, and type of the stricture [3]. Direct visual internal urethrotomy (DVIU), urethral dilatation, and urethroplasty are the main treatment choices for recurrent US. Although urethroplasty has an almost complete success rate [4], DVIU is associated with high recurrence rates and inadequate long-term efficacy, in particular, for strictures longer than 1 cm [5], and failure rates vary from 55 to 70% within the first

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year [6]. The high recurrence rate associated with DVIU has led urologists to search for minimally invasive, alternative treatment methods for US [7], for patients who are unable or unwilling to undergo urethroplasty. Recently, there have been reports of novel minimally invasive treatment approaches, notably temporary urethral stents [8, 9].

The urethral stent was first introduced in 1988 for the treatment of recurrent US and was indicated for use in bulbar US only. The objective was to use permanently indwelling urethral stents in order to prevent the recurrence of US [10]. However, the success rates achieved were not encouraging and highly challenging complications occurred, such as stent migration and stents becoming embedded in deeper tissues, so that permanent stents were withdrawn from the market.

In this study, we aimed to assess our long-time experience and results with temporary placement of bulbar urethral stent (BUS) in the management of recurrent US. To the best of our knowledge, this is both the largest cohort and the longest follow-up period, in which BUS was used for recurrent US.

Materials and Methods

During the period 2009–2019, a series of patients with recurrent bulbar US had endoscopic placement of Allium BUS (Allium; Allium Ltd., Caesarea, Israel). All patients who were willing to undergo a minimally invasive treatment approach instead of urethroplasty surgery were informed that urethroplasty was the gold standard treatment method for bulbar US. The exclusion criteria for this study, in which long-term results were evaluated, were any patient with penile or posterior US, failure to comply with the follow-up protocol, or a history of pelvic malignancy or radiation therapy.

All patients provided informed consent prior to urethral stent placement. Ethical approval was obtained from the local Ethical Committee of the Kocaeli University (approval number: GOKAEK-2020/10.35). The patients were evaluated with retrograde urethrogram and uroflowmetry. Residual urine volume was estimated with ultrasonography. The American Society of Anesthesiologist (ASA) score, stricture etiology, and prior treatments were also documented. DVIU was performed prior to stent placement. Stricture length and stricture distance from the external sphincter were estimated during urethroscopy. Allium™ stents were inserted successfully and positioned correctly, just beneath the external sphincter in all participants.

Allium BUS Stent

The anatomical, functional, and structural features of the Allium BUS and its detailed pictures are available in our previously published article [11]. The Allium BUS has 3 different lengths (50, 60, and 80 mm). The indwelling time for the stents was planned to be 12 months. Progressive decrease in urinary peak flow rate during this period, recurrent urinary tract infection, and stent migration were removal criteria. The success criteria after stent removal were urinary peak flow greater than 15 mL/s, no recurrent urinary tract infection, and no evidence of stricture on urethrogram or endoscopy at the sixth month. Clinical success was assessed by endoscopy and an urethral luminal circumference that allowed passage of a 15 Fr flexible cystoscope (Storz 11272 C; Karl Storz, Inc., Germany). Urinary peak flow rates were estimated at 3, 6, 9, and 12 months after stent removal. At each of these visits, urine cultures were taken. Telephone follow-up was performed every 6 months for periods 1 year after BUS removal.

Statistical Analysis

Correlation between the success rate of stent treatment, the indwelling period, and the length of the stricture was investigated. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 13.0 (IBM Inc., Armonk, NY, USA). The paired *t* test, Mann-Whitney *U* test, and Pearson χ^2 test were used to analyze and compare the groups.

Results

The cohort included 168 patients with a mean ± standard deviation (SD) age of 46.7 (±8.3) years. In this cohort, 11.90% (n = 20) were assigned an ASA score of I, 21.42% (n = 36) were assigned an ASA score of II, 45.83% (n = 77) were assigned an ASA score of III, and 20.83% (n = 35) were assigned an ASA score of IV on preoperative anesthetic assessment. The causes of the stricture included trauma in 79 (47.02%), previous endoscopic urethral surgery in 72 (42.86%), infection in 8 (4.76%), and unknown in the remaining 9 (5.36%) patients. All patients had a history of one or more DVIU. Patients' medical histories revealed that DVIU had been performed only once in 13, twice in 44, 3 times in 36, and 4 or more times in 75 patients (Table 1). The number of stents used by size is indicated in Table 1.

The mean ± SD length of the stricture was 2.32 (±0.4) cm. Patients were discharged after voiding satisfactorily. No adverse events related to the stent or the procedure were recorded. Three patients reported discomfort at the site of the stent in the first 2 weeks after stent insertion, but all of them completed the treatment period of nearly 10 months. Four patients complained of mild early urinary stress incontinence, which resolved between 2 or 3 weeks postoperatively.

Mean urinary peak flow rate for the cohort was 4.7 mL/s before the procedure, which had improved to 18 mL/s 1 week after stent placement. Five stents migrated distally, up to 3 weeks after stent placement. These 5 stents were replaced immediately after the removal of the incorrectly positioned stent. Stent migration was again observed after 3 months, in one of these patients, in whom

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Table 1. Patients' demographics and clinical characteristics

Patients, *n*	168	
Stents, *n*	175	
Age, years, mean ± SD	46.7±8.3	
ASA score, *n* (%)		
1	20 (11.90)	
2	36 (21.42)	
3	77 (45.83)	
4	35 (20.83)	
Length of US, mean ± SD	2.32±0.4	
Indwelling period, months, mean ± SD	9.7±2.3	
Follow-up, months, median (range)	71 (8–86)	
BUS size, *n* (%)		
5 cm	96 (54.9)	
6 cm	57 (32.6)	
8 cm	22 (12.6)	
Etiology, *n* (%)		
Trauma	79 (47.0)	
History of transurethral intervention	72 (42.9)	
Infection	8 (4.8)	
Unknown	9 (5.4)	
Number of DVIU per patient, *n* (%)		
Once	13 (7.7)	
Twice	44 (26.2)	
Thrice	36 (21.4)	
≥4 times	75 (44.6)	
Preoperative urinary peak flow, mL/s (mean, SD)	4.7*	
Postoperative urinary peak flow, mL/s (mean, SD)[a]	18*	$p = 0.001$

ASA, American Society of Anesthesiologist; US, urethral stricture; BUS, bulbar urethral stent; DVIU, direct visual internal urethrotomy. * Paired *t* test was used for comparison of dependent samples. A p level <0.05 was considered statistically significant. [a] The measurement of all patients' urinary peak flow at 1 week after BUS replacement.

we had seen this complication before, and eventually, it was extracted. Additionally, severe obstruction was observed in 2 stents after 4 and 6 months of implantation.

The stents were removed 3–18 months after implantation (mean, 9.7 months). This removal was performed easily under local anesthesia (Table 1). There was no postprocedure complication observed. Briefly, the causes for early stent removal, defined as 3–7 months after implantation, were migration in 16, chronic refractory urinary tract infection in 11, and progressive decrease in urinary peak flow in 3 patients. To examine the region of the US, urethrogram and endoscopy were used 6 months after stent removal in 53 (31.5%) and 115 (68.5%) patients, respectively.

Median (range) follow-up was 71 (8–86) months after stent removal. Successful treatment was achieved in 131 (77.9%) patients, while 37 (22.1%) patients did not have clinical success (see Table 2). Longer indwelling time of between 8 and 18 months (mean, 10.9 months) was statistically significantly ($p = 0.009$) related to higher clinical success rate, compared to a shorter period of between 3 and 7 months (mean 4.6 months). In the group with longer indwelling stent time, the success rate was 81.88%, while this fell to 60% in the patients with shorter indwelling BUS time. When investigating the relation between clinical success and stricture length, 127 patients with a stricture length <2 cm had a clinical success rate of 84.25% (107 of 127), while 41 patients with a stricture of more than 2 cm had a clinical success rate of 58.53% (24 of 41, $p = 0.001$; Table 2). The clinical success rates after stent removal of patients who had a history of 1, 2, 3, and more than 3 DVIU procedures were 92.30, 90.90, 80.55, and 66.66%, respectively. When the patients were stratified by the number of DVIU procedures, the success rates after stent removal in patients were significantly different, with success being more likely in patients having had fewer DVIU procedures ($p = 0.009$; Table 3).

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Table 2. The comparison of clinical success according to BUS indwelling time and length of US

	Success (n = 131)	Nonsuccess (n = 37)	p value
Length of US, n (%)			0.001*
<2 cm	107 (84.25)	20 (15.75)	
≥2 cm	24 (58.5)	17 (41.5)	
BUS indwelling time (months), n (%)			0.009*
3–7	18 (60)	12 (40)	
8–18	113 (81.9)	25 (18.1)	

BUS, bulbar urethral stent; US, urethral stricture. * The Mann-Whitney U test was used for comparison of independent samples. A p level <0.05 was considered statistically significant.

Discussion

For the treatment of US, the gold standard method is urethroplasty, especially after the failure of DVIU and urethral dilatation. However, some patients and urologists prefer minimally invasive alternatives [9]. The use of a stent for the treatment of obstructed urologic diseases has been revolutionary. The use of a stent to maintain the patency of a lumen was first described for vascular disease in 1969 [12]. After the use of vascular stents, Milroy and coworkers [13] described a new urethral stent and used it in 12 patients in 1989. Since then, a temporary urethral stent is suggested as an alternative approach for those patients who have suffered recurrent US. Furthermore, Wong et al. [14] hypothesized that a temporary urethral stent might aid in the management of recurrent US. The temporary stent could act as a scaffold to splint against the mechanical forces of scar tissue contraction during the healing period, and this action may ultimately stabilize the stricture site during epithelization [14]. Similarly, the use of a temporary urethral stent after endoscopic management of complete bulbar urethral rupture was also presented in a recent study [8]. The ideal urethral stent would be easily placed and removed and allow urine passage while maintaining the integrity of the urethral sphincters [9]. The Allium BUS is a self-expandable, large-caliber, round, metal urethral stent designed for the treatment of US. The stent is constructed of a coiled, super-elastic metal alloy (nitinol) and coated with a copolymer, which prevents mucosal hyperplasia and encrustation. The insertion procedure is simple and easy to perform endoscopically, under local or general anesthesia. When inserted, the body, which provides a high radial force, should face the stenotic segment of the urethra. The soft proximal segment prevents sphincteric dysfunction that may cause incontinence [15]. First-generation stents were designed for permanent insertion, with the aim of achieving an epithelized urethra, but they had poor long-term results with complications including encrustation, migration, stone formation, and difficulty of reversal. All of these problems have led to a reduction in the use of permanently indwelling stents. In addition, the technical difficulty of removing permanent stents after failure renders them a nonviable option [16]. In comparison to reports of clinical experience with permanent first-generation stents, our long-term results have shown that temporary BUS has no major complications, except for migration.

Table 3. The clinical success according to the number of the DVIU in patients' history

	Success (131/168), n (%)	p value
1	12 (92.30)	0.009*
2	40 (90.90)	
3	29 (80.55)	
>3	50 (66.66)	

DVIU, direct visual internal urethrotomy. * The Pearson χ^2 test was used. A $p < 0.05$ value is considered statistically significant.

In our previous multicentric study with a median follow-up of 8.3 months, we reported our short-term results with Allium BUS [11]. Initial data on 44 (81.4%) of the 54 patients showed significant improvement in symptoms and urinary peak flow rate with a relatively small number of complications. In the present study with a larger group and longer follow-up (median follow-up time, 71 months), the success rate after stent removal was 77.9%. Temeltas et al. [5] also treated 28 patients with bulbar US with the Allium BUS. They removed all stents between 3 and 6 months after placement and followed up the patients for

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29 months. These authors reported a 64.2% success rate [5]. In our present study, we removed the stents around 10 months after placement, and the success rate was higher in the group in whom the BUS was indwelling for between 8 and 18 months. Yachia and Beyar [17] also reported their experience with 20 patients with recurrent US. They used Urocoil™ as a temporary stent. Their mean indwelling time was 10 months, and they reported only 1 stricture had recurred after a 10-month follow-up period [17]. The present study has shown a correlation between the indwelling period and clinical success. Choi et al. [18] also reported their use of a covered nitinol stent in 33 patients. Their success rate was 55%, but they stated that leaving a stent for a minimum of 4 months resulted in less stricture recurrence [18]. We also hypothesized that the long-term use of the Allium BUS may provide sufficient scaffolding after dilatation or DVIU and allow for re-epithelialization and stabilization of urethral caliber at the stricture site. Similarly, there is an ongoing study of temporary urethral stents after internal urethrotomy for US and better maximal urinary flow rate was reported compared to internal urethrotomy alone [19]. Moreover, we found a significantly poorer clinical success in patients with a US of >2 cm in length compared to patients with a stricture length <2 cm. Thus, it appears that, in addition to the indwelling time of the BUS, clinical success is also associated with stricture length. Regarding our findings, if these results are confirmed in other centers, the Allium BUS has the potential for the management of refractory bulbar US in patients who are unable or unwilling to undergo urethroplasty. While long-term follow-up of BUS replacement has positive results on urinary flow for the US, the lack of data regarding quality of life, such as sexual dysfunction, may be a limitation of this study. In addition, after cessation of in-clinic follow-up, which continued for 1 year after BUS removal, much of the follow-up data were collected from patient self-reports.

In conclusion, to date, the new generation of urethral stents has been reported to lead to fewer complications and to have better short- and mid-term functional outcomes. Further advantages of BUS placement include the ease of placement and ease of reversal. Due to the long-term follow-up in the present study and encouraging results with a large group of patients, we are confident to state that temporary placement of Allium BUS for an extended duration is an effective, safe, and minimally invasive procedure in inducing resolution of refractory bulbar US.

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Statement of Ethics

Ethical approval was obtained from the local Ethical Committee of the Kocaeli University (approval number: GOKAEK-2020/10.35). All patients provided informed consent prior to urethral stent placement.

Conflict of Interest Statement

There are no conflicts of interest.

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Author Contributions

M.Ü.: writer and analysis; K.T.: writer, analysis, and supervision; E.B.: data collection; Ö.K.: writer and analysis; S.Ç.: data collection; and M.M.Ç.: data collection, design of this study, and analysis.

References

1 Byun JS, Song JM. Ten years experience of post-traumatic complete urethral stricture treated with endoscopic internal urethrotomy. Korean J Urol. 1996;37:1300–7.
2 Armagan A, Soyupek S, Hoscan MB, Perk H, Serel TA, Koşar A. Comparison of the efficacy of internal urethrotomy and Benique dilatations in the management of recurrent anterior and posterior urethral strictures. (Article in Turkish). Turkish J Urol. 2006;32:404–10.
3 Huh G, Jung GW, Yoon JH. Clinical assessment of visual internal urethrotomy as primary treatment of urethral stricture. Korean J Urol. 1996;37:797–803.
4 Furr JR, Wisenbaugh ES, Gelman J. Urinary and sexual outcomes following bulbar urethroplasty-an analysis of 2 common approaches. Urology. 2019;130:162–6.
5 Temeltas G, Ucer O, Yuksel MB, Gumus B, Tatli V, Muezzinoglu T. The long-term results of temporary urethral stent placement for the treatment of recurrent bulbar urethral stricture disease? Int Braz J Urol. 2016;42(2):351–5.
6 Jordan GH, Wessells H, Secrest C, Squadrito JF Jr, McAninch JW, Levine L, et al. Effect of a temporary thermo-expandable stent on urethral patency after dilatation or internal urethrotomy for recurrent bulbar urethral stricture: results from a 1-year randomized trial. J Urol. 2013;190(1):130–6.

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7 Ozcan L, Polat EC, Otunctemur A, Onen E, Cebeci OO, Memik O, et al. Internal urethrotomy versus plasmakinetic energy for surgical treatment of urethral stricture. Arch Ital Urol Androl. 2015 Jul 7;87(2):161–4.
8 Ahn ST, Lee DH, Kim JW, Moon DG. Novel treatment strategy for management of traumatic bulbar urethral rupture using temporary urethral stent after primary realignment; retrospective comparison between thermo-expandable urethral stent and self-expandable polymer-coated urethral stent. J Clin Med. 2020;9(5):1274.
9 Silagy A, Merrett C, Agarwal D. Initial experience with Allium™ stent in the management of bulbar urethral stricture. Transl Androl Urol. 2017 Jul;6(Suppl 2):S88–91.
10 Milroy EJ, Chapple CR, Cooper JE, Eldin A, Wallsten H, Seddon AM, et al. A new treatment for urethral strictures. Lancet. 1988; 1(8600):1424–7.
11 Culha M, Ozkuvanci U, Ciftci S, Saribacak A, Ustuner M, Yavuz U, et al. Management of recurrent bulbar urethral stricture: a 54 patients study with Allium bulbar urethral stent (BUS). Int J Clin Exp Med. 2014;7(10):3415–9.
12 Dotter CT. Transluminally-placed coilspring endarterial tube grafts. Long-term patency in canine popliteal artery. Invest Radiol. 1969; 4(5):329–32.
13 Milroy EJ, Chapple CR, Eldin A, Wallsten H. A new stent for the treatment of urethral strictures. Preliminary report. Br J Urol. 1989; 63(4):392–6.
14 Wong E, Tse V, Wong J. Durability of Memokath™ urethral stent for stabilisation of recurrent bulbar urethral strictures: medium-term results. BJU Int. 2014;113(Suppl 2):35–9.
15 Bahouth Z, Moskovitz B, Halachmi S, Nativ O. Allium stents: a novel solution for the management of upper and lower urinary tract strictures. Rambam Maimonides Med J. 2017; 8(4):e0043.
16 Bahouth Z, Meyer G, Yildiz G, Nativ O, Moskovitz B. Update in urethral stents. Arch Esp Urol. 2016;69(8):601–6.
17 Yachia D, Beyar M. New, self-expanding, self-retaining temporary coil stent for recurrent urethral strictures near the external sphincter. Br J Urol. 1993;71(3):317–21.
18 Choi EK, Song HY, Shin JH, Lim JO, Park H, Kim CS. Management of recurrent urethral strictures with covered retrievable expandable nitinol stents: long-term results. AJR Am J Roentgenol. 2007;189(6):1517–22.
19 Shin YS, Lee DS. Urethral stent insertion following internal urethrotomy in the management of urethral stricture. Urol Int. 2020; 104(7–8):665–6.

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