



Use of Temporary Membrane-Covered Self-Expandable Metallic Stent – UVENTA™ for Treatment of Recurrent Bulbar Urethral Stricture

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Introduction: Recurrent urethral stricture is a real challenge. Interestingly use of temporary double layered self-expanding nitinol urethral stent with polytetrafluoroethylene (PTFE) membrane coating (Uventa™, Taewoong Medical, South Korea) has been recently reported with promising short-term results in recurrent urethral stricture. However most of the reported studies are published as abstracts of either case reports or case series of miniscule numbers. The aim of our study is to evaluate the outcome of this temporary urethral stent in patients with recurrent urethral stricture after urethroplasty as well as after multiple visual internal urethrotomy.

Materials and Methods: In this retrospective study, 22 patients had placement of double-layered self-expanding stent with PTFE membrane coating (Uventa, Taewoong Medical) for recurrent bulbar strictures. The present study included cases between 2017 and 2020. The stricture in each patient were evaluated with Uroflowmetry and ascending urethrography. The data of demographic and clinical characteristics included age, aetiology, location and length of stricture, along with maximum urinary flow rate (Qmax), number of previous interventions, and stent-related complications.

Results: The overall clinical success was achieved in 13/22 (59.1%) of patients at a median follow-up of 17 months (range 2–44). The mean maximum urine flow rates were 7.07 ± 3.55 mL/sec, 23.50 ± 10.41 mL/sec, 21.41 ± 15.55 mL/sec, 14.88 ± 9.77 and 17.63 ± 12.28 mL/sec before, while stent in place, at 3 months, 6 months and 12 months after the procedure, respectively.

Conclusion: In our study, the success rate of temporary urethral stent placement has remained at 59.1% at a median follow-up of 17 months. We conclude that further randomized controlled studies with long-term follow up are required to fully evaluate the outcome.

Keywords: urethra, urethral stricture, recurrence, urethral stent

Introduction

Recurrent urethral stricture is a real challenge, especially after urethroplasty as well as after multiple visual internal urethrotomy. Treatment options for patients with recurrent urethral stricture depend on the primary management options including visual urethrotomy, urethral dilatation, or urethroplasty. The higher recurrent stricture rate denoting lower success rate has been reported in repetitive endoscopic interventions.^{1,2} Reported long-term success rate of 55% to 60% after the first internal urethrotomy which deteriorates after repeated urethrotomy to 0–40% at 48 months after the second urethrotomy and 0 at 24 months after the third urethrotomy.¹ Although urethroplasty has a better success rate for management of recurrent urethral stricture, it still has the failure rate ranging from 12%, to 58% depending on the type of surgery and the surgeon experience with reported complication rate of 7% to 33%.³ Endoscopic treatment for recurrent urethral stricture after urethroplasty has a recurrence rate from 10% to 50% depending on the type of previous surgery and prior endoscopic interventions.^{4,5}

The use of urethral metallic stents in the prevention of the recurrence and maintenance of patency of the urethra has been adopted by many surgeons because it is a minimally invasive technique. An ideal urethral stent should be self-expandable, non-migrating, easily inserted as well as removed and with no complications such as encrustation and mucosal ingrowth. The Stent designs varied in size, shape, and composition, number of layers and with incorporated special features of coating, anchors and thermodynamic function.

All literature available regarding metallic urethral stents show them to be made of nickel-titanium alloy (Nitinol) intended for temporary or permanent use were either single layer or double layers with PTFE membrane between the layers aimed to achieve successful long-term results.^{6–10}

Self-expanding permanent stent (UroLume, American Medical Systems) had promising early results but the long-term results have been discouraging with high complication rate due to tissue ingrowth through the stent leading to obstruction and the need for surgical removal of the stent.^{7,8} The temporary double-layered self-expanding nitinol stent with PTFE membrane coating (UventaTM, Taewoong Medical, South Korea) has recently been reported with promising short-term results in recurrent urethral stricture, but most of the studies were published as abstracts of either case reports or case series of small numbers.^{11–13} The special feature of UventaTM stent is its two nitinol layers, the outer provides a high friction coefficient which aimed to prevent stent migration, and the inner reinforces the overall radial force to maintain stent patency and interestingly there is the PTFE membrane layer between the layers to prevent tissue ingrowth. These unique features impressively help to maintain the patency of lumen and prevent mucosal ingrowth. It is manufactured in different length ranging from 4 to 10 cm.

The aim of our study is to evaluate the outcome of this temporary urethral stent in patients with recurrent urethral stricture after urethroplasty as well as after multiple visual internal urethrotomy or urethral dilatation.

Materials and Methods

Participants

In this retrospective study, 22 patients had placement of UventaTM stent (a double-layered self-expanding stent with PTFE membrane coating manufactured by Taewoong Medical, South Korea) for treating recurrent bulbar strictures. The present study included cases that were done between 2017 and 2020. All of the patients in this study had a history of undergoing numerous procedures. These procedures included dilations, internal urethrotomy, and / or urethroplasty.

The inclusion criteria in our study were: adult patients, recurrent bulbar urethral strictures, and a history of a minimum of two dilations/direct visual internal urethrotomy, or urethroplasty. On the other hand, the exclusion criteria were history of penile or posterior urethral stricture, history of pelvic malignancy or radiation, and history of hypospadias repair.

The patients were evaluated by Uroflowmetry and ascending urethrography.

In the present study, pre-operative demographics and clinical characteristics which were recorded are age of the patient, aetiology as well as location, and length, of stricture, maximum urinary flow rate (Qmax), number of previous direct visual internal urethrotomy/dilatations and previous urethroplasty, time to last stricture recurrence. The stent-related complications (stent migration, granulation tissue formation, stent encrustation, urine incontinence, pain, and infection) were documented as well. This study was approved by the surgical Research Committee, Hamad Medical Corporation (Ref: SR/RE/2021/008). This study was conducted in accordance with the Helsinki Declaration and the need for informed consent was waived given the retrospective nature of the study. However, the privacy of the participant's information regarding this study was maintained with confidentiality.

Surgical Technique

All patients received 2nd generation cephalosporins for prophylaxis. After induction of adequate spinal or general anaesthesia, the patient was placed in a lithotomy position either Direct-visual-internal urethrotomy at the 12 o'clock position, or urethral dilation was carried out. The epithelial cells from amniotic membrane (human amniotic epithelial cells) were injected in some patients. The procedure was then followed by the placement of the UventaTM stent in the

bulbar urethra. Sometimes a Nelaton urethral catheter was inserted temporarily for bladder drainage until full recovery from spinal anaesthesia.

All patients were evaluated with uroflowmetry and post voiding residual urine measurement in the postoperative third month. Stents were removed at 3 to 6 months' time after the procedure. Patients were followed up at 3, 6, and 12 months after stent removal and then yearly. Objective micturition outcome was evaluated by uroflowmetry. The post-procedure reoccurrence of stricture was suspected when their Qmax was <10 mL/s, and was verified by either combined ascending urethrogram and voiding cystography or flexible cystoscopy as Urology office procedures.

Statistical Analysis

Descriptive statistics of categorical variables focused on frequencies and proportions. Means and standard deviations, medians, and interquartile ranges (IQR) were reported for continuously coded variables. Chi-square and Kruskal–Wallis tests were used to compare the statistical significance of differences within categorical and continuous variables, respectively. The Kaplan–Meier method was used to assess the success rate of stricture-free duration. Statistical analyses were performed using SPSS with a two-sided significance level setup at $p < 0.05$.

Results

The mean age of the patients was 52.55 ± 11.36 (33–75). The mean stricture length was 1.964 (range 1.0–3.5) cm. The median number of previous failed direct visual internal urethrotomy or dilatation was 3 (range 1–11) and 14 (63.6%) patients had two or more urethral surgeries. Out of the total patients, 14 (63.6%) had previous failed urethroplasty. The aetiologies of the strictures were iatrogenic (63.6%), idiopathic 27.3%, infectious (4.5%) and traumatic (4.5%).

All stents were inserted successfully with no obvious intraoperative complications. The epithelial cells from amniotic membrane (human amniotic epithelial cells) were injected in 20 (90.1%) patients. Spontaneous voiding was achieved in all patients immediately after stent insertion. The overall clinical success was achieved in 13 (59.1%) of the 22 patients at a median follow-up of 17 (range 2–44) months. Encrustation was observed in one patient at the urethral stent implantation area who was late for his time of removal. Urine culture was positive for bacterial growth in 8 patients (36.4%) but there was no incidence of febrile urinary tract infection. There were no event of stent migration. Temporary urine incontinence happened in 8 patients (36.4%) and feeling of foreign body was reported in one patient (4.8%). The mean maximum urine flow rates were 7.07 ± 3.55 mL/sec, 23.50 ± 10.41 mL/sec, 21.41 ± 15.55 mL/sec, 14.88 ± 9.77 and 17.63 ± 12.28 mL/sec before, while stent in place, at 3 months, 6 months and 12 months after the procedure, respectively. The mean stricture-free survival from the date of the surgery was 27.1 months (CI 19.10–35.04) and the mean stricture-free duration from the date of stent removal was 20.5 months (CI 13.83–27.07).

Discussion

Failure of endoscopic surgery for recurrent urethral stricture is common. Stricture recurrence after intervention depends on various stricture characteristics such as location, length, caliber, number, and etiology in addition to the number of previous surgeries. Reported long-term success rate of 55% to 60% after the first internal urethrotomy which deteriorates after repeated urethrotomy to 0–40% at 48 months after the second urethrotomy and 0 at 24 months after the third urethrotomy.¹ Urethroplasty has a better success rate for recurrent urethral stricture with failure rate ranging from 12%, to 58% depending on the type of surgery and the surgeon experience³ The use of urethral stent has been adapted to overcome this challenge, especially in the patient with recurrence of urethral stricture after repeated dilation/internal urethrotomy or after failed urethroplasty.^{14,15} The basic concept of a temporary stent is intended to act as a scaffold during the healing and epithelization of the stricture region and to prevent contraction.^{14,16} Temporary stent insertion for bulbar strictures had significantly longer stricture-free duration in favor of dilation/DVIU followed by the stent.^{10,14,17} In our study, the overall clinical success was found to be 59.1% at a median follow-up of 17 months. Temeltas et al reported a success rate of 64.2% at a median follow-up of 29 months for the use of Allium[®] temporary urethral stent¹⁷ while Culha et al study showed a success rate of 81.4% at a median follow-up of 10.6-month.¹⁵ The low success rate of our study may due to the complexity of the cases because 63.6% of the case had two or more urethral surgeries and also 63.6% of our patients had a history of previously failed urethroplasty. Encrustation was observed in one patient who

refused to remove it in time because he felt happy with urination. The stent was found encrusted from the inside, so fragmentation of the encrustations using pneumatic lithotripsy and then removal of the stent was performed. There was no ingrowth of the urethral tissue inside the stent because of the double-layer coating of the stent as well as the presence of PTFE membrane between the layers. The short period of the presence of the stent makes the risk of encrustation rare. Temeltas et al reported stone formation with infection at the urethral stent implantation area only in one patient.¹⁷ Higher complication rate was reported with permanent Memotherm[®] urethral stent in recurrent bulbar urethral strictures (dribbling after micturition in 75%, discomfort in implantation area in 40%, stone formation in implantation area in 10% and partial stent migration in 10%).¹⁸

The current study is a retrospective study with its inherent limitations (eg, potentially missing patients and data may have some reporting bias). Large-scale studies could more precisely define the outcomes, with a large number of patients. Hence there is a need for prospective, randomized studies involving large number of patients with long-term results are necessary to support our findings. Despite such limitations, the current study is the only study with this number of patients that evaluates the use of UVENTA[™] stent for the treatment of bulbar urethral stricture.

Conclusion

The temporary urethral stent placement UVENTA[™] stent maintained urethral patency significantly longer than dilation or internal urethrotomy alone. The presence of a temporary urethral stent is likely to apply brakes to urethral stricture recurrence and controlled studies with a large number of patients in dedicated centers of high volume are still required to fully evaluate the outcome and safety profile.

Disclosure

The authors report no conflicts of interest in this work.

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