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UVENTA URETHRAL STENTS: ARE WE TAKING A STEP FORWARD? THE FIRST CLINICAL SERIES

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Summary.- *OBJECTIVES: To describe first clinical results in term of safety, complications and short term efficacy of temporary placement of UVENTA urethral stent in the treatment of urethral and bladder neck strictures.*

METHODS: UVENTA urethral stent (Taewoong Medical) is a temporary self expandable covered metallic stent. Anti-migration system and different radial force distribution are the two main innovations. This is a retrospective evaluation of UVENTA stent temporary placements for urethral diseases in two urological Centers.

RESULTS: 15 patients underwent UVENTA stent placement between 2016 and 2018. Stent placement was easy and quick in all cases. Considering indwelling period: one patient reported urethral pain related to the stent in the first month, three patients had urinary infection treated with antibiotics; temporary stress incontinence was noted in 21% of bulbar-membranous stents; stent migrations was noted in 3 out of 4 bladder neck cases whereas no bulbar-membranous stents migrated. At removal no significant incrustation, stone or tissue ingrowth were noted, as well as new proximal or distal strictures. Stent removal was uncomplicated in all cases. Median follow up is 9.5 months (6-24). Considering strictures overall success rate is 73% (11/15): 82% for bulbar urethra (9/11) and 50% for bladder neck (2/4).

CONCLUSIONS: UVENTA urethral stent showed a satisfying safety profile with few and low grade complications. Absence of migration and damage on healthy mucosa are main achievements. Further cases are needed to confirm these results and to really explore its efficacy.

Keywords: *Urethral stent. Complication. Safety.*

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Resumen.- *OBJETIVOS: Describir los primeros resultados clínicos en términos de seguridad, complicaciones y eficacia a corto plazo de la colocación temporal de stent uretral UVENTA en el tratamiento de estenosis de uretra y de cuello vesical.*

MÉTODOS: El stent uretral UVENTA (Taewoong Medical) es un stent metálico temporal autoexpandible. Las dos principales innovaciones son el sistema antimigra-

ción y la distribución de la fuerza radial. Esta es una evaluación retrospectiva de la colocación de UVENTA en enfermedades uretrales en dos centros urológicos.

RESULTADOS: 15 pacientes recibieron UVENTA entre 2016 y 2018. La colocación del stent fue fácil y rápida en todos los casos. Teniendo en cuenta el periodo de catéter: un paciente describió dolor uretral relacionado con el stent en el primer mes, 3 pacientes tuvieron infección urinaria tratada con antibióticos; incontinencia urinaria de estrés en el 21% de pacientes con stent en uretra bulbomembranosa; la migración de stents se demostró en 3 de 4 casos con estenosis de cuello vesical, mientras, ningún caso de uretra bulbomembranosa migro. Al quitar el stent, no se observó incrustación significativa, litiasis o tejido en crecimiento, así como nuevas estenosis distales o proximales. La retirada del stent no fue complicada en la mayoría de casos. La mediana de seguimiento fue de 9,5 meses (6-24). Considerando la tasa de éxito en global fue de 73% (11/15): 82% para uretra bulbar (9/11) y 50% para cuello vesical (2/4).

CONCLUSIONES: El stent uretral UVENTA demostró un perfil de seguridad satisfactorio con mínimas complicaciones. La ausencia de migración o daño de la mucosa sana son las principales virtudes. Son necesarios más casos para confirmar estos resultados y explorar su eficacia.

Palabras clave: *Stent uretral. Complicación. Seguridad.*

INTRODUCTION

Urethroplasty is the gold standard in the treatment of urethral strictures leading to best results, but requires significant surgical skills. Success rate is 85-90% in experienced hands even if can rise up to 99% for bulbar strictures (1,2). Results drop to 58-69% in case of redo urethroplasty for bulbar and posterior strictures (3). Success rate of internal visual urethrotomy moved from 50-60% of old series to 10% in more recent papers (4,5). For this reason is recommended only for short strictures without history of previous treatments

Results are dramatically poorer in case of repeated procedures (1). Urethral stents have been proposed many years ago looking for an easy solution for urethral strictures. In the last 30 years different kinds of stent have been developed with questions about efficacy and complications. The ideal urethral stent would be easily inserted and removed, without stent-related complications and without recurrence after removal. Once in place it should not migrate, calcify and cause discomfort, without any tissue ingrowth. New concepts and designs have been introduced with the last generation of fully covered urethral stents. In this study we describe the use of temporary placement of UVENTA urethral stent for recurrent strictures.

MATERIAL AND METHODS

UVENTA urethral Stent (Taewoong Medical) is a temporary self expandable covered metallic stent. A nickel-titanium coil is completely covered by a silicone coat in the inner and in the outer part. Diameter varies between 10 to 16 mm (30 to 48 Fr) and the available lengths ranges from 4 to 10 cm. Anti-migration system and different radial force distribution are the two main innovations. 4 anchors are located on the distal end of the stent aiming to reduce migration and the radial force is maximum in the center of the stent with progressive reduction on the tips. Retrieval string at the proximal tip allows to remove the stent (Figure 1). We performed a retrospective evaluation of UVENTA stent placements for recurrent strictures of the lower urinary tract in two urological Centers. All patients included in this series signed a specific informed consent. All cases were managed according to the principles of the Declaration of Helsinki. Data about implantation and removal were collected as wall as complications during indwelling time and after removal. Success was defined as the lack of any further procedures during follow up and urethral patency at flexible urethroscopy (16 Fr) at 6 months after stent removal. Complications were recorded according to Clavien-Dindo classification. Patients with at least 6 months of follow-up after stent removal were included. Main aim of our study was to evaluate the safety profile during stent placement procedure, indwelling period, removal procedure and follow up. Recurrence rate was also evaluated as a secondary outcome

RESULTS

15 patients underwent UVENTA stent placement by two surgeons between 2016 and 2018. Pre, intra- and post-operative data are reported in Table I. 11 patients had a single stricture of the bulbar or membranous urethra, 4 had an anastomotic stricture following radical prostatectomy. All strictures were recurrent after at least one previous treatment (mean 2.1, max 5). All patients were studied by urethrogram and/or flexible urethroscopy before the procedure. All cases were performed under spinal anesthesia. passing the delivery system through a 26 ch cystoscope. Cold knife urethrotomy or anastomosis in-

cision was performed as first step. Delivery system was then inserted in the working channel of a 26 Fr cystoscope. Stent was released placing the central portion with the higher radial force covering the stricture. In case of urethral strictures antimigration flaps were always properly anchored in the proximal urethra. In case of anastomotic stricture the proximal portion of the stent was free in the bladder as well as the anti migration system. No specific intraoperative events were recorded. Urinary drainage by SP tube was placed in 3 patients. Dealing with post-operative complications during the indwelling period, one patient reported urethral pain related to the stent in the first month, managed with Paracetamol and NSAIDs. Urinary tract infections required antibiotic therapy - on urine colture - in 3 patients. Patients with bladder neck stricture were already incontinent before the stent due to repeated urethrotomies. 3 of the other 11 patients (27%) experienced some stress incontinence (1-2 pads per day) during indwelling period and they returned dry after removal. None of these complications led to stent removal.

3 out of 4 stents placed on the bladder neck migrated in the bladder two, three and six months after implantation; none of the other stents migrated. These complications were classified as grade IIIa since stent was removed to avoid possible obstructive complications, even if all patients were able to void. Stent migration was noted by X-ray or ultrasound control that we performed periodically for stent on the bladder neck, considering the higher risk of proximal migration.

Median indwelling time was 6 months (2-12). Stent removals were performed under spinal anesthesia using 17 Fr rigid cystoscope in outpatient procedure. No stone or tissue ingrowth were noted. New proximal or distal strictures with stent in situ were never noted at stent removal. In patients with longer indwelling time (5,6, and 7) some incrustation on the inner part were noted but without significant lumen reduction and not affecting stent removal. Also migrated stents were removed without any problems in the same manner. All procedures were free from intraoperative complications and time of procedures ranged between 2 and 6 minutes. Median follow up after stent removal is currently 9,5 months (6-24). Considering urethral stricture 82% of patients are recurrence free (9/11). Two out of four patients treated for bladder neck experienced at least one recurrence. Dealing with failures, patient 1 is scheduled for ileal conduit in radiation cystitis, patient 4 underwent one further urethrotomy, patients 7 and 15 underwent bulbar urethroplasty with buccal mucosa; in this two cases we didn't note any abnormal findings during surgery.

DISCUSSION

Urethral stents have been proposed many years ago looking for an easy solution for urethral strictures. Metallic stents designed for permanent implant were described in the last eighties with initial encouraging results, but long term complications led to abandon them (6). Permanent use and the absence of a coating system for the metallic coil were responsible of encrustations, stone formation and tissue ingrowth (7).

In the last years stents moved from a permanent use to a temporary adjuvant treatment after urethrotomy for posterior and bulbar strictures. Hypothesis is that the stent could guide the healing process after urethrotomy contrasting the scar contraction (8). Series are not homogeneous about indwelling time and results are contrasting, with persisting side effects as the main concern. Dealing with non-covered stents Wong et al used Memokath TM for 3 months in 22 patients after urethrotomy for recurrent bulbar stricture obtaining 78% of success rate after a follow up of 23 months (8). At the opposite success rate was only 25% with many adverse events in another study by Barbagli et al, with a longer indwelling time (9).

Fully covered metallic stents are the last generation of urethral stent designed for a temporary use. As a technical innovation metallic coil is completely covered by an inner and an outer polymeric film, aiming to reduce the risk of incrustation and tissue ingrowth. Good results have been published with ALLIUM stent in an adjuvant setting for bulbar strictures. Success rate ranges form 64% to 81%, with better results for longer indwelling time (10,11,12). Classical stent related complications seems to be shrinking thanks to the polymeric coat: incrustation is rare and tissue ingrowth is never described, even for stents in place for 12 months, but migration can be a bothersome problem.

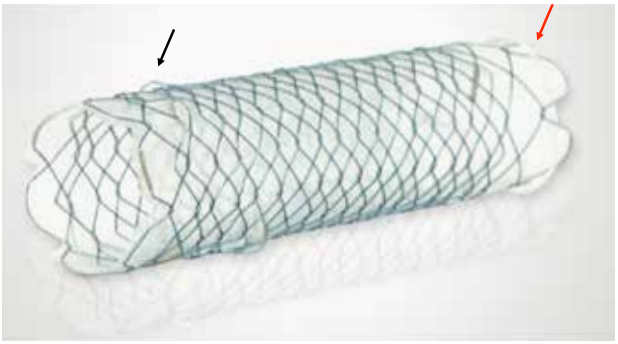

Figure 1. UVENTA urethral stent. Antimigration flaps in the proximal end (black arrow) and retrieval string in the distal one (red arrow).

Table I. pre, intra and post-operative results.

Pt	Urethral disease	Site of disease	Cause	Previous surgery (2)	Kind of stent (mm)	Bladder drainage	Complications (Clavien-Dindo)	Migration	Site of migration	Indwelling time (months)	Follow up (months)	Recurrence
1	Stricture	Bladder neck	RARP + RT	U-thomy (4)	60x14 (42 Fr)	SP tube	Migration (IIIa)	Yes	Bladder	3	9	Yes
2	Stricture	Bladder neck	RRP	U-thomy (3)	40x16 (48 Fr)	None	Migration (IIIa)	Yes	Bladder	6	6	No
3	Stricture	Bladder neck	RARP + RT	U-thomy (5)	40x16 (48 Fr)	SP tube	SP displacement (IIIa)	No	-	2	7	No
4	Stricture	Bladder neck	RRP	U-thomy (2)	40x14 (42 Fr)	SP tube	Migration (IIIa)	Yes	Bladder	2	7	Yes
5	Stricture	Membranous-Bul-bar	Trauma with incomplete fracture	U-thomy (3)	40x14 (42 Fr)	none	none	No	-	12	8	No
6	Stricture	Membranous-Bul-bar	Trauma with incomplete fracture	U-plasty (1)	40x14 (42 Fr)	none	UTI (II)	No	-	12	24	No
7	Stricture	Membranous.Bul-bar	Trauma with complete fracture	U-plasty (1)	40x14 (42 Fr)	none	none	No	-	12	11	Yes
8	Stricture	Membranous-bul-bar	TURP	U-thomy (1)	40x14 (42 Fr)	none	none	No	-	6	10	No
9	Stricture	Bulbar	TURP	U-thomy (1)	40x14 (42 Fr)	SP tube	Urethral pain (II)	No	-	6	9	No
10	Stricture	Bulbar	Exeresis of urethral diverticulum	U-plasty (1)	40x14 (42 Fr)	none	none	No	-	6	6	No
11	Stricture	Bulbar	Idiopatic*	U-thomy (1)	40x14 (42 Fr)	none	none	No	-	6	24	No
12	Stricture	Bulbar	Idiopatic*	U-thomy (2)	40x14 (42 Fr)	none	UTI (II)	No	-	6	21	No
13	Stricture	Membranous	Idiopatic*	U-plasty (1)	60x14 (42 Fr)	none	UTI (II)	No	-	6	20	No
14	Stricture	Bulbar	Catheter**	U-thomy (3)	40x14 (42 Fr)	none	none	No	-	6	7	No
15	Stricture	Bulbar	Idiopatic	U-plasty (1) U-thomy (1)	40x14 (42 Fr)	none	none	No	-	11	6	Yes

** after renal transplant. ** patient with kidney-pancreas transplant with pancreatic exocrine diversion to the bladder. Uthomy: urethrotomy. Uplasty: urethroplasty. SP tube: suprapubic tube. UTI: urinary tract infection. RARP: robot assisted radical prostatectomy, RT: radiation therapy. RRP: retropubic radical prostatectomy. TURP: transurethral resection of prostate*

Our series describes the use of UVENTA stent for recurrent strictures of bulbar, posterior urethra and bladder neck. Since the heterogeneity of our patients about site of the stenosis, ethiology and previous treatments detailed considerations about efficacy in term of recurrence free can't be assessed but we can focus on safety profile. Apart of stent migration in bladder neck group, results in term of safety and complication are excellent. Incrustation, calcification and tissue ingrowth were absent or minimal. Stents were well tolerated with discomfort responding to pain killers in only one patient. This has already been seen with the other covered stents, whereas it was a significant cause of early removal for non covered stents (9,13). Except for the bladder neck, our main evidence is the absence of stent migration and early new strictures at the ends of the stent. With other temporary stents the risk of migration is usually high, ranging from 11 to 22% (10,11,12). UVENTA stents introduce for the first time an anti migration system made by four small anchors in the distal part. Excluding bladder neck strictures we have not recorded stent migrations. Antimigration flaps are probably really effective in anchoring the stent at the mucosa without affecting stent removal or causing significant injury. 3 out of 4 stent placed on the bladder neck after radical prostatectomy migrated before the scheduled removal. Migration were always in the bladder without any complications. The reason could be that by retrograde placement antimigration flaps don't work since they are free in the bladder and not anchored in the mucosa (Figure 1). Antegrade placement through the bladder inverting the stent and anchoring the flaps to the urethral wall could be effective to avoid this complication.

The absence of new onset strictures at the extremity of the stent is the other remarkable finding.

This a frequent and serious complication that may arise. Proximal or distal stricture and narrowing were noted in 4 cases in the series by Silagy et al (11). The same complication was cause of early removal or further treatments also by Temeltas and Culha (10,12). We didn't experience such event. Distribution of radial force in UVENTA stent may be the reason. Radial force is higher in the central part with a progressive reduction towards the tips. Therefore highest force is focused only on the stricture with minimal compression on heathy mucosa, probably reducing the risk of edema and fibrosis. Except for bladder neck strictures we preferred to place 14 mm caliber stent not to risk ischemic injuries. This could be another technical tip to reduce trauma on healthy mucosa.

New onset stress urinary incontinence was observed in 21% of cases of bulbar-membranous stents. Patients need to be informed about this possible side effect and its temporariness since all cases were fixed after stent removal.

Considering bulbar and membranous strictures 82% of patients are free of recurrence after a mean follow up of 13.3 months and an indwelling time ranging from 6 to 12 months. Success rate of other covered stents were similar and seemed to improve after longer indwelling time (10,11,12). Considering the few side effects we can probably explore longer indwelling time (over 12 months), trying to reduce recurrence not affecting safety profile.

Bladder neck obstruction after radical prostatectomy is an other matter entirely. It represent a challenging scenario due to frequent recurrence and the progressive association with urinary incontinence. Repeated urethrotomies are usually the first line treatment. Re-do anastomosis by various approaches achieve better outcomes but is prerogative of few referral Centers (14). An easier solution would certainly be widely adopted. In our series 2 out of 4 patients are recurrence free after stent removal. Anastomotic stricture is a different scenario the can't be compared to urethral stricture. At the best of our knowledge this is the first experience with stents in this complex setting. In our series we maintained the stent for a shorter time (three stents were removed after migration, one after two months trying to avoid migration). The chance of a longer indwelling time by technical solutions as previously described could be crucial to improve success rate. Limit of this study is the retrospective design, the heterogeneity of the series, the lack of a pre and post-operative flowmetry and the short follow-up.

CONCLUSIONS

UVENTA urethral stent showed a satisfying safety profile with few and low grade complications. Compared to other covered stents the absence of migration when antimigration system works properly and of damage on healthy mucosa are significant achievements. Success rate seems similar to other covered temporary stents in the treatment of recurrent bulbar-membranous urethral strictures. Further cases with homogeneous indications are needed to confirm these results and to explore the effective role in the treatment of vescico-urethral strictures after some technical modifications.

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