

Clinical experience with ureteral metal stents

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ABSTRACT

Ureteral metal stents (MSs) present a minimally invasive tool to preserve the drainage of renal pelvis whenever ureteral patency is at risk to be obstructed due to extrinsic or intrinsic etiologies. Clinical experience with these stents demonstrates that they impose a promising alternative treatment option in ureteral pathologies that are difficult to be treated via common polymeric stents. Current application of MSs in the treatment of both benign and malignant ureteral obstruction reveals quite promising results. Nevertheless, the ideal MS that would provide uncomplicated long-term effectiveness is still lacking and current MS usage is facing several adverse effects between which stent obstruction, encrustation, infection, migration, and patient discomfort. Ongoing attempts to create more inert stent with sophisticated novel designs are expected to improve current MS efficiency. MSs will play a major role in the future as a routine management of a variety of ureteral pathologies.

Key words: Clinical, metal, stents, ureteral

INTRODUCTION

Ureteral stents present a minimally invasive tool to preserve the drainage of renal pelvis whenever ureteral patency is at risk to be obstructed due to extrinsic or intrinsic etiologies. Currently, polyurethane and silicon are the golden standard of composition materials of such stents. However, polymeric ureteral stents fail to preserve intraluminal patency whenever a significant amount of extrinsic compression is imposed.^[1,2] Moreover, conventional double-J stents need to be periodically exchanged every 3 months or even sooner. The latter is associated with increased technical difficulty and potential complications, due to the underlying malignancy, as well as patient's quality of life deterioration.^[1] Ureteral metal stents (MSs) are adopted by relevant technology developed to treat vascular and biliary tree stenoses. MSs

impose a promising alternative that can be recruited to deal with ureteral pathologies difficult to be treated via common polymeric stents. They are designed to preserve long-term urinary drainage avoiding the need of frequent exchange. Nevertheless, their use is related with a number of complications, which frequently jeopardize stent's patency and deteriorate its long-term efficacy.^[3] Currently, MS usage is indicated mainly for the management of ureteric obstruction in the course of malignancies.^[4] Whenever the aforementioned drawbacks of MS will be addressed, MS usage will be expanded to everyday urological practice. Even more, might replace the treatment of cases traditionally treated via regular polymeric stents. In this article, we will review the clinical safety, efficacy, and patency rate of ureteral MS currently in use.

TYPES OF URETERAL METAL STENTS

Five types of MSs have been clinically used in the upper urinary tract. The self-expandable, the balloon expandable, and the thermoexpandable shape memory stents, the covered stents, and the lately introduced all metal double pigtail stent. Each type of MS will be described separately.

SELF-EXPANDABLE URETERAL METAL STENTS

Initial experience with the use of self-expandable MSs for the treatment of ureteral obstructions can be traced back to more than 15 years ago. Till then a wealth of cases has been reported in the literature proving the efficiency and safeness of the technique. Nevertheless, entire accumulated

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experience deals with off-label use of either vascular or biliary stents and none of the tested stents has yet been officially approved for use in the ureter. Consequently, the use of self-expanding MSs should be still considered experimental.

Wallstent (Schneider, Zürich, Switzerland) is the most widely tested self-expandable MS. It is composed by braided cobalt-based alloy monofilament wires, and it can be introduced to the site of obstruction through a passing guidewire by both undergrade and retrograde fashion. Balloon dilation of stenotic segment prior to stent insertion, as well as balloon internal dilation of stents after placement are usually required. The reaction of ureteric wall to stent insertion is consisted of early urothelial hyperplastic reaction, granulation tissue ingrowth, and edema of various degrees. The latter can even occlude stent's lumen.^[5] For this reason, a parallel JJ stent insertion through the lumen of Wallstent is a common practice that is left in place for 1 month postoperatively to prevent early obstruction. Urothelial hyperplastic reaction regresses at 4–6 months postoperatively when stent is fully incorporated to the ureteral wall. Other commercial available self-expandable MSs that have been tested in clinical practice are the AccuFlex, the Sinus, the Memotherm, the Protege, and the Luminexx, though clinical experience with them is limited.^[5-7]

A representative study demonstrating the efficacy of self-expandable MSs in the treatment of ureteral obstruction was conducted by Lugmayr and Pauer. In this work, 40 patients (54 ureters) with malignant ureteral obstruction were treated by Wallstent placement. Of 54 stented ureters, 51 remained patent for a mean follow-up time of 10.5 months (range, 1–44). However, postoperative period was not uneventful. Re-intervention was deemed necessary in half of cases (49%).^[8] All relevant studies verify that the implantation of self-expandable MSs is a safe and effective

treatment option to ensure ureteral patency during the palliative treatment of malignant cases^[9-14] [Table 1].

Preliminary results with the use of self-expandable MSs in patients with benign disease were unfavorable. Wallstent usage was unable to provide long-term drainage in the case of benign ureteroenteric strictures. Only one out of six stents placed remained patent at 11 months of follow-up.^[15] However, further evaluation on the application of self-expandable MSs in the treatment of benign diseases demonstrated more promising results. Pauer *et al.* implanted various types of self-expandable MSs to treat 13 patients with benign ureteral strictures. During a very long follow-up period of 41.6 months, seven ureters remained patent since implantation while other five remained patent after additional interventions.^[7] Self-expandable MS demonstrated optimal results in cases of ureteral stenoses after kidney transplantation. All reported cases remained patent during the follow-up period without the need of additional interventions.^[16,17] Li *et al.* have reported quite satisfying long-term results using a titanium–nickel alloy based self-expandable stent in patients with benign ureteral strictures. The follow-up period ranged between 12 and 131 months (mean, 92 months). During this surprisingly big follow-up period of stent efficacy, several complications were encountered and managed accordingly. The authors concluded that selected cases of benign ureteral strictures can be successfully managed effectively by these stents.^[18]

Our experience with self-expandable MS in the management of both malignant and benign cases has been previously published. In a retrospective study, we reviewed 90 patients subjected to 119 self-expandable MS insertions to treat extrinsic malignant ureteral obstruction. A 51.2% primary patency rate was observed increasing to 62.1% after additional interventions in a 15-month median follow-up period (range, 8–38). Noted complications were mild flank pain and discomfort lasting a few days postimplantation.

Table 1: Self-expandable MS in the treatment of malignant obstruction: Clinical experience from representative studies

Reference	Number of ureters stented	Disease: Malignant (M) or Benign (B)	Patency rate (%)	Follow-up (months)	Comments
Lugmayr and Pauer ^[9]	12	M	90.9	6	Sent encrustation was observed in one case
Barbalias <i>et al.</i> ^[10]	14	M	100	15	In two cases, a secondary coaxial overlapping metal stent was placed at 6 and 12 months, respectively.
Pauer <i>et al.</i> ^[11]	15	M	100	7.7	Obstruction distal to the stent due to tumor ingrowth was observed in three patients.
Burgos Revilla <i>et al.</i> ^[12]	14	B and M	85	10.2	Four prostheses developed transient obstruction that was resolved by insertion of a double-J catheter for periods that ranged from 2 to 6 months.
Flueckiger <i>et al.</i> ^[13]	13	M	85 primary, 100 secondary	5.8	
Díaz-Lucas <i>et al.</i> ^[14]	19	M	94.7	Till death (max: 49)	
Liatsikos <i>et al.</i> ^[5]	119	M	51,2 primary, 62,1 secondary	15	A double-J catheter remained for 4 weeks postoperatively

Irritate bladder symptoms with self-limited hematuria was present whenever stent's distal end was excessively protruding into the bladder. Moreover, recurrent urinary tract infection was encountered in a few cases. Migration of stents into the bladder was noted in 10.9% of stented ureters. All migrations were noted within 3 months postimplantation (mean, 1.5 months). The most common complication jeopardizing stent's patency was excessive hyperplastic reaction and tumor ingrowth through stent struts observed in 39 cases. In the latter cases, repeated balloon dilation and coaxial stenting were performed to overcome the problem. A summary of our experience is presented in Table 2. Our conclusion was that in the case of extrinsic malignant ureteral obstruction, long-term decompression using self-expandable MS can be provided only in selected cases.^[5]

Our long-term results with self-expandable MS placement over benign strictures located at the site of ureteroileal anastomosis were promising. Patency rates were 64.8% and 56.7% after 1 and 4 years, respectively. However, only 37.8% and 22.7% of stents at 1 and 4 years, respectively, remained patent without any additional intervention during the follow-up. Secondary interventions included repeat balloon dilation and co-axial JJ stenting.^[19] In the case of recurrent strictures at the ureteropelvic junction after open pyeloplasty self-expandable MS could offer complication-free urinary drainage in three out of four examined cases. In the remaining, one case stricture recurred 2 months postoperatively due to the ingrowth of scar tissue through the prosthesis. A longer 6-cm coaxial overlapping MS was placed which managed to alleviate the obstruction successfully.^[20]

In conclusion, self-expandable MS is a safe treatment

Table 2: Summary of our experience with the use of self-expandable MS in the treatment of malignant ureteral obstruction

Number of patients/stented ureters	90/119
Average stricture length/range	5.6 cm (range, 1.4–15 cm)
Lesion location (distal, mid-, or upper ureteral segment)	Distal = 85/119 (71.4%), mid = 26/119 (21.8%), upper = 8/119 (6.7%)
Balloon post-dilation of stents	95/119 (79.8%)
Technical success rate	100%
Average follow-up, time/range	15 months/8–38 months
Primary patency	51.2%
Number of restenosed ureters/ number of restenosed ureters according to etiology	45 (37.8%) 39 Hyperplastic reaction 6 Encrustation
Migrated stents	13 (10.9%)
Secondary patency	62.1%
Stented ureters requiring double-J insertion	45
Complications × number of patients	Mild flank pain and discomfort ×41 Irritative bladder symptoms ×5 Urinary tract infection ×3

option that can provide long-term urinary drainage in both malignant and benign cases. However, the urologist should be ready to confront a number of complications requiring additional endourological interventions. Thus, close follow-up monitoring is advised.

BALLOON EXPANDABLE URETERAL METAL STENTS

The experience with balloon expandable MSs is still limited. Two balloon-expandable stents have been tested in human, the Strecker stent (Boston Scientific, Natick, MA, USA) and the Palmaz-Schatz (Johnson and Johnson, Warren, USA).^[6,20] Despite the fact that initial mid-term results of their use on malignant strictures were promising (five out of six stents remained patent without additional intervention up to 16 months follow-up) no long-term results have been published.^[21] The Palmaz-Schatz stent is less flexible than the Wallstent and has low radio-opacity which renders its placement technically challenging. Furthermore, a high-pressure balloon dilatation is required in order to expand at its final width.^[6] The Strecker stent is less flexible than Wallstent. However, it is easier to insert and has excellent radio-opacity.^[21] Long-term results with balloon expandable stents are awaited.

THERMOEXPANDABLE SHAPE MEMORY STENTS

Memokath 051 (Engineers and Doctors A/S) is a nickel-titanium alloy thermoexpandable shape-memory stent with a thermo-expandable bell-shaped anchoring segment in one or two ends. The latter provides to the stent the unique ability to soften or regain the shape and rigidity of the anchoring segment depending on external temperature, allowing the removal of the stent when necessary.^[22] Preliminary results with this type of stent in the management of both benign and malignant ureteral obstruction demonstrated promising results.^[22] Kulkarni *et al.* has reported very good mid- and long-term results with the use of this stent in both cases of benign and malignant ureteral obstruction. In 37 stent insertions (18 malignant and 10 recurrent benign), 15 stents were found functional at the end of the 19.3 month follow-up period (range, 3–35 months), while 8 patients deceased carrying 13 additional functioning stents. Moreover, no migration or infection was observed.^[23] Klarskov *et al.* in a more recent study on Memocath's efficacy on ureteral obstruction alleviation reported promising results as well, not, however, that good as presented by Kulkarni *et al.* In the later study, 33 patients with malignant, benign, and postirradiation strictures were treated via Memocath insertion. During the 5 months of median follow-up, 22 out of 37 placed stents either malfunctioned (n = 12) or migrated (n = 10) distally toward the bladder leading to an overall mid-term success rate of 59.4%. Encrustation to previously known stone formers was noted indicating a relative contraindication for memocath insertion in the latter patient group.^[24] Recently, Papatsoris *et al.* reviewed

86 Memocath stent insertions for both malignant ($n = 31$) and benign ($n = 55$) cases. A satisfying overall patency rate of 79% at a median 17.1 months of follow-up was reported.^[25] Comparison between Memocath treatment over ureteral strictures and JJ stent treatment reveals that the overall cost of Memocath was considerably less than conventional treatment.^[25] Finally, from the patient's point of view stent-related morbidity was considered significantly less in the case of Memocath than JJ stent treatment. The latter was evaluated using patient stent symptom questioner distribution in 70 patients that experienced ureteral stenting.^[26]

COVERED URETERAL METAL STENTS

Current MS designs can be used as the platforms to be covered with other substances wearing desirable characteristics. This approach represents an alternative pathway to create more inert stents. Inert stents demonstrate increased stent biocompatibility, minimizing postplacement urothelial reaction enhancing their short- and long-term performance. Several ureteral stent covering substances have been already tested in humans.

Preliminary experience with this novel idea demonstrated promising results. Dacron-covered ureteral MS were placed in nine ureters with malignant strictures. During a mean follow-up of 9 months, none of the stented ureters were obstructed, displaced, or infected.^[27] In contrast, preliminary experience with a different type of covered MS in our department resulted in unfavorable results. Passager (Meadox, Boston Scientific Corporation, Oakland, NJ, USA) is self-expandable nitinol stent externally covered with ultrathin woven polyester fabric. After successful stent placement of the stent in 16 patients with malignant ureteral obstruction, a high migration rate was observed. Eighty one percent of stents migrated into the bladder during 1.5 months of mean time of migration. The rest of stents ($n = 3$) achieved uncomplicated drainage during the 8-month follow-up. The observed high-migration rate was attributed to inappropriate stent anchoring and induction of increased ureteral peristalsis.^[28] Trueba Arguinarena *et al.* in a preliminary report evaluated the effectiveness of novel self-expandable polytetrafluoroethylene-covered nitinol stent (Hemobahn Endoprothesis, W.L. Gore and Associates, Flagstaff, AZ) in the relief of benign and malignant ureteral strictures. In total, 37 stents were inserted. Migration was once again present though it was observed only in 3 patients (22.2%). New stents were successfully implanted in the latter cases to solve the problem. In all cases, stents remained patent during the follow-up (up to 24 months). The stent was proved to be effective in the management of ureteral obstruction with high resistance to calcification, limited endothelial hyperplasia, and migration rate.^[29] Still, the use of all aforementioned covered stents could be considered experimental given that officially such stents are

not approved for ureteral use.

The only specially designed covered MS for the use in the ureter is the Allium Ureteral Stent (URS by Allium Medical) though published reports on its efficiency are currently lacking. Allium MS is a self-expanding large caliber stent composed by nickel–titanium alloy that comes premounted on delivery systems allowing either antegrade or retrograde insertion. The stent is covered by a thin layer of a co-polymer to make it a non-permeable tube and to prevent tissue ingrowths and early encrustation. Recently, the efficiency of Allium-URS was presented on the 25th Congress of European Association of Urology. In a multicenter study, 19 Allium MSs were inserted in 17 patients to treat both malignant and benign ureteral pathologies. None of the stents was occluded in the 7 months of mean follow-up. Endoscopical removal of stents in a patient with bilaterally stented ureters after an indwelling period of 12 months was feasible and only one case of stent migration into the bladder was noted at 8 months postinsertion.^[30] Overall results are considered very promising and further larger randomized studies should be awaited.

ALL METAL DOUBLE PIGTAIL STENT

Resonance stent (Cook Ireland, Limerick, Ireland) is a recently introduced all metal double pigtail MS composed of the MP35N alloy (nickel–cobalt–chromium–molybdenum alloy). This composition material is considered corrosion-resistant, MRI-compatible and demonstrates very high tensile strength which provides satisfactory drainage under circumstances of extrinsic ureteral compression sufficient to occlude a standard stent.^[31] The stent is indicated for long-term urinary drainage of extrinsic etiology ureteral obstruction, and the manufacturer recommends interval stent change at 12 months. Initial experience with the use of Resonance stent was very promising, motivating the expansion of its use to larger series of patients.^[32]

Wah *et al.* evaluated 17 Resonance insertions in patients with malignant ureteral obstruction. Three stents failed immediately from the outset due to bulky pelvic malignancy resulting in high-intravesical pressure. All the rest were functional until patient's death or time of stent change every 6–12 months. Ease stent removal and limited encrustation were noted.^[33] Nagele *et al.* evaluated the application of the stent in both malignant and benign cases (18 collecting systems). All stents drained effectively until patient's death or time of stent removal. Mean duration of stenting was 7.3 and 11.8 months for malignant and benign cases, respectively. No migration and minimum encrustation were noted.^[34] Recently, Lopez-Huertas *et al.* conducted a cost analysis of Resonance treatment (15 stent insertions) in contrast to standard polymer stent use in patients with benign ureteral obstruction of various etiologies. Resonance was associated with a 43% yearly cost reduction largely

Table 3: Summary of our experience with the use of Resonance MS in the treatment of malignant and benign ureteral obstruction

Malignant cases (n = 25)	Prostate cancer ×8 Colon cancer ×4 Stomach cancer ×1 Gynecologic cancer ×7 Bladder cancer ×3 Lymphoma ×2
Benign cases (n = 18)	Ureteroenteric strictures ×8 Stone disease ×6 Iatrogenic strictures ×4
Benign cases–recurrent (n = 7)	Previously obstructed MSs placed for ureteroenteric strictures ×7
Technique of insertion	Antegrade/percutaneous ×24 Retrograde/cystoscopic ×26
Technical success rate of stent placement–stent removal (comments)	100%–100% (uneventful in all cases)
Success rate/follow-up	Malignant: 100%/11 months Benign: 44%/6.8 months Benign recurrent: 0%/7 days
Etiology of stent failure × number of stents	Heavy encrustation ×1 (in a patient with stone disease) Hyperplasia reaction ×15 (8 in benign disease within first 2.6 months, 7 in recurrent stent placement within first 12 days)
Complications × number of patients	Macroscopic hematuria resolved spontaneously ×6 Irritative bladder symptoms ×10 Urinary tract infection ×4
Migrated stents	0%
Presence of stent encrustation	22.2% (12/54 stents)

because of the shorter exchange interval. Furthermore, Resonance achieved uncomplicated drainage in most of the cases with no significant encrustation, absent migration, and high tolerability with only 13% of patients requiring stent removal due to stent-related symptoms.^[35]

In contrast, to the aforementioned good results, Resonance stent was recently proven ineffective to provide long-term drainage in patients with ureteroenteric strictures after ileal conduit. In a study enrolling ten ureteroenteric strictures, a 90% of stent migration within a mean time of 21 days was observed. Consequently, Resonance stent should be contraindicated in the latter clinical entity due to high rate of migration.^[36]

We prospectively evaluated 50 patients treated via Resonance stent insertion (25 with extrinsic malignant obstruction, 18 with benign ureteral obstruction and 7 with previously obstructed MSs). A 100% stricture patency rate was observed in cases of extrinsic malignant obstruction, in contrast to a 44% rate in cases of benign ureteral obstruction. All stent failures were observed shortly after the procedure (2–12 days).^[37] Our results are in accordance with the rest of the literature demonstrating good long-term effectiveness of this novel stent in the management of malignant cases.^[33]

However, further evaluation in cases of benign obstruction is considered necessary. Our experience with Resonance placement is summarized in Table 3.

CONCLUSION

In conclusion, current clinical application of MSs for the treatment of both benign and malignant ureteral obstruction demonstrates quite promising results, providing a new tool for the long-term urinary drainage. The safeness of this novel treatment option has been very well documented and the efficacy of MS usage in certain candidates is optimum. Nevertheless, the ideal MS that would provide uncomplicated long-term effectiveness in all cases is still lacking and current MS usage is facing several adverse effects between which stent obstruction, encrustation, infection, migration, and patient discomfort. Thus, further investigation in the field is considered necessary. MSs should be expected to improve their current efficiency and play a major role in the future management of a variety of new indications.

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