

# The full metallic double-pigtail ureteral stent: Review of the clinical outcome and current status

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## ABSTRACT

The full metallic double-J ureteral stent (MS) was introduced as a method for providing long-term drainage in malignant ureteral obstruction. Experimental evaluation of the MS revealed that its mechanical features allow efficient drainage in difficult cases, which could not be managed by the insertion of a standard polymeric double-J stent. Clinical experience with the MS showed controversial results. Careful patient selection results in efficient long-term management of malignant ureteral obstruction. The use of the MS should also be considered in selected benign cases. Major complications are uncommon and the minor complications should not hinder its use. Experience in pediatric patients is limited and warrants additional study. The cost-effectiveness of the MS seems to be appropriate for long-term treatment. Further investigation with comparative clinical trials would document the outcome more extensively and establish the indications as well as the selection criteria for the MS.

**Key words:** Double-J metal stent, double-pigtail metal stent, full metal ureteral stent, metal stent, resonance stent, ureteral stent

## INTRODUCTION

The management of ureteral obstruction is a common problem presenting to urologists. Currently, three minimal invasive techniques are used with variable success rates for long-term relief of upper urinary tract obstruction: these are percutaneous nephrostomy (PN), the retrograde polymeric ureteral stent (PS) and the metal mesh stent (MMS). Retrograde ureteral stenting has the advantages of easy insertion and its success rate ranges between 88% and 100% for intrinsic ureteral obstruction but declines to 56% for malignant extrinsic obstruction.<sup>[1,2]</sup> PSs require frequent changes and stent related symptoms result in a negative effect on the quality-of-life of the patients.<sup>[1,2]</sup> On the other hand, PN tubes are associated with the highest success

rate (98.7%), but significant morbidity.<sup>[3-6]</sup> In addition, PSs and PNs are associated with significant risk of infection, bacterial colonization, biofilm formation and eventually encrustation.<sup>[7-8]</sup> MMSs have been proposed as an alternative to the insertion of PNs or PSs in difficult cases where long-term drainage is necessary. MMSs are also associated with an improved quality-of-life in patients, but significant issues such as high rates of migration, stone encrustation and obstruction owing to urothelial hyperplasia reduce their widespread adoption.<sup>[6,9]</sup> Despite the initial promising results, ureteral drainage by the long-term use of MMSs resulted in limited clinical efficacy.<sup>[9,10]</sup>

Resonance™ (Cook Medical, Ireland) metallic double-J ureteral stent (MS) is an all metal, double pigtail stent that has been lately introduced as an alternative treatment for extrinsic ureteral obstruction. Its incompressible metal structure has been proven to provide drainage even in cases of extrinsic tension sufficient enough to occlude the PSs. The MS is shaped as a double-pigtail stent, but molded from a corrosion resistant alloy, which forms a tightly coiled spiral with no end-holes. The diameter of the MS is 6 Fr and its alloy consists of nickel, chromium, titanium and molybdenum. The design and material of the stent aim to overcome problems related to the use of MMSs such as encrustation, migration, tissue ingrowth and those related to PSs like occlusion by external tumor compression, the need for frequent stent changes and encrustation.<sup>[3,7]</sup>

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## INSERTION TECHNIQUE

The MS could be inserted by either antegrade (percutaneous) or retrograde (cystoscopic) approach. Patients with long strictures or strictures of the lower ureter should be considered for percutaneous approach while retrograde (cystoscopic) insertion could be performed in the remaining cases. General anesthesia is required for percutaneous insertion while retrograde insertion may take place under local or general anesthesia or sedation.

For the percutaneous approach, a standard PN technique is performed and a percutaneous tract is established. Then, a nephrostogram is performed in order to delineate ureteral anatomy and verify the exact length and position of the ureteral stricture. The stenosed ureteral segment is passed using a 0.035-inch guidewire and a balloon (8-10 mm diameter) is introduced to dilate any strictures not wide enough to accommodate the 9 Fr introducer sheaths of the MS. After dilator removal, a coaxial system including an inner 5 Fr ureteric catheter and an outer 9 Fr introducer sheath is introduced over the wire until the tip of the outer sheath protrudes into the bladder. The guidewire and inner ureteric catheter are removed and the MS is inserted through the introducer. A specially designed plastic pusher is used to push the proximal end of the MS inside the introducer sheath until the MS's distal pigtail curl is formed in the bladder. The introducer sheath is removed while holding the plastic pusher in place. The formation of a pigtail at the proximal portion of the MS inside the ipsilateral collecting system confirms the appropriate positioning and the sheath is completely removed.

Two points concerning the technique need emphasis. First, excessive pushing of the proximal end of the stent through the introducer sheath should be avoided as there is no retrieval system with the currently available MS deployment kit. Second, appropriate stent length depends upon the length of the ureter and may be approximated using the patient's height. Patients less than 1.75 m in height should be managed with the shorter versions of MS (22-26 cm) while patients with height over 1.75 cm should be managed with the 28 cm stent. Selection of proper stent length has been found to be necessary for patient comfort.<sup>[11]</sup>

Retrograde stent insertion under local or light anesthesia follows similar steps to the antegrade approach. In short, a guidewire is inserted in the ureteral orifice to bypass the stricture followed by dilation with a balloon. The coaxial system of the inner 5 Fr ureteric catheter and an outer 9 Fr introducer sheath is introduced over the wire and is advanced until the tip of the outer sheath protrudes into the renal pelvis. Then, the guidewire and the inner ureteric catheter are removed and the MS is inserted in the outer sheath (introducer) using a plastic pusher. When the MS reaches the renal pelvis, the proximal curl is formed and

the outer sheath is removed while keeping the pusher and stent in place, resulting in the formation of the distal curl of the MS in the bladder. Similar technique for MS insertion has been reported for the management of pediatric cases.<sup>[12]</sup>

## EXCHANGE TECHNIQUE

When MS exchange is deemed necessary, a hydrophilic guidewire is inserted in a retrograde fashion parallel to the stent and is advanced up to the kidney. Stent removal follows and a new stent is inserted over the guidewire as described above. Guidewire passage is not always possible, usually in cases of extensive epithelial hyperplasia at the level of stricture. In such cases, the MS is removed and a standard insertion technique is repeated. Perioperative antibiotic prophylaxis should be administered in both antegrade and retrograde approaches.

## EXPERIMENTAL DATA

MS has been evaluated in the laboratory setting in an attempt to document its efficacy in providing upper urinary tract drainage in difficult cases that are associated with PSs failure. In a porcine model, Blascko *et al.* showed that the MS had lower combined (intraluminal and extraluminal) flow in comparison to the standard PSs. However, the MS could not be occluded by the experimental suture ligation of the stented ureter under circumstances that would result in occlusion of the standard stent. In the latter setting, the MS provided adequate drainage.<sup>[13]</sup> Pedro *et al.* compared the MS to the Silhouette<sup>®</sup> coil-reinforced double-pigtail stent (Applied Medical, Rancho San Mirage, Calif) and a standard PS in a study investigating the mechanical properties such as tensile and compressive strengths. They demonstrated that both the MS and the Silhouette stents were more resistant to extrinsic tension in comparison to the PS. The MS proved to have a higher tensile strength while the Silhouette stent was documented to be more resistant to extrinsic tension.<sup>[14]</sup> Other investigators studied the resistance in extrinsic compression and exertion of radial force of the MS, the Silhouette stent and different types of PSs. The MS was observed to be the most resistant to extrinsic compression while the Silhouette followed (especially in the diameter of 8 Fr and 4.6 Fr). The PSs were less resistant than these stents and also had variations among them depending of their type. The MS did not appear to have any indentation on its structure after the compression study in contrast to the remaining stents, which all showed some permanent deformation. The authors attributed the latter phenomenon to the fact that the MS simply flexes or leans to one side upon tension and does not truly compress.<sup>[15]</sup>

The compatibility of the MS with radiotherapy was evaluated by Liatsikos *et al.* in the porcine model. Domestic pigs underwent a radiotherapy session including both ureters and the animals were followed-up to day 1, 7 and 15 after

treatment. One ureter carried a MS and the other carried a PS as control. No significant histological differences were observed between the ureters containing the MSs and their controls.<sup>[16]</sup> Another experimental study on domestic pigs provided data on the safety of managing encrustations on MS through extracorporeal shock wave lithotripsy (SWL). SWL could be used for the treatment of encrustations in an attempt to postpone stent replacement. It was demonstrated that SWL had the same effect on the ureter harboring the MS with its control (PS).<sup>[17]</sup>

Electron microscopy and elemental analysis (energy dispersive analysis by X-ray) were employed to evaluate the composition of the depositions on long-term indwelling MSs. The investigators observed the presence of biofilm lining and the limited presence of inorganic material on the removed MSs.<sup>[18]</sup> These results are similar to the results obtained using the same methods on MSs removed after long-term placement in a large clinical series by Liatsikos *et al.* In the latter study, the evaluated stents were selected for their characteristic macroscopic appearance. Thus, some of them were associated with high concentrations of inorganic material (stone formation) while others remained without visible deposits. Nevertheless, encrustation was observed by electron microscopy despite the macroscopically clean appearance of the examined MS [Figures 1a, b and 2a, b]. These encrustations did not result in occlusion of the majority of the MSs.<sup>[19]</sup>

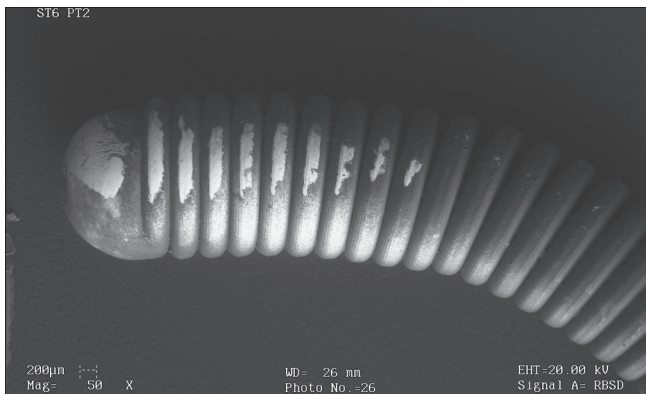
### CURRENT CLINICAL DATA

The requirement for long-term upper urinary tract drainage in cases of ureteral obstruction due to metastatic retroperitoneal or pelvic malignancy represents a significant urological challenge. The MS represents a promising minimal invasive alternative in the treatment of such cases. Clinical experience with the management of malignant ureteral obstruction by MS insertion is limited, but is continuously expanding. Borin *et al.* were the first to report the successful

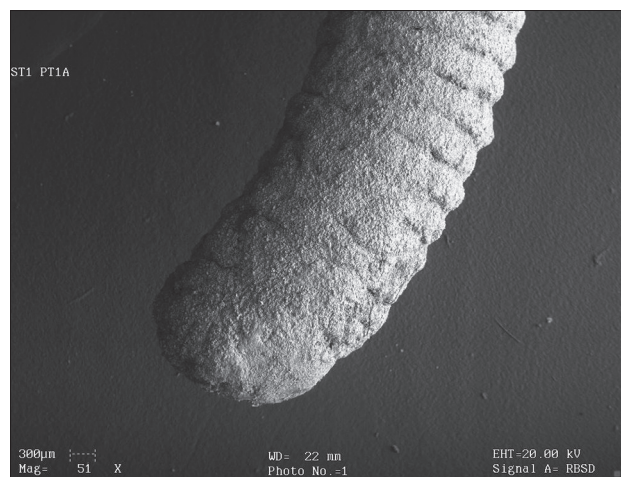
clinical use of a MS in a ureteral obstruction due to retroperitoneal fibrosis associated with metastatic breast cancer. The MS provided sufficient kidney drainage for 4 months.<sup>[20]</sup> Nagele *et al.* studied 14 patients (18 collecting systems) with ureteral obstruction of both benign (5 ureters) and malignant etiologies (13 ureters). In their study, the MS demonstrated promising results by ensuring kidney drainage for a mean follow-up time of 8.6 months. However, the incidence rate of stent related complications was reported to be high. Persistent hematuria, severe dysuria, pain and insufficient drainage were reported to occur in half ( $n = 7$ ) of the studied population. Inadequate drainage of the MS in bulky pelvic tumors was also reported. The investigators advised proper stent length selection for patient comfort.<sup>[11]</sup> Wah *et al.* reported their experience with 17 MSs inserted in 15 patients for the treatment of malignant ureteral obstruction. Failure of the MS to obtain sufficient drainage was reported in three cases.<sup>[21]</sup>

A small number of five patients with malignant ureteral obstruction showed a high MS failure rate up to 80% in a study of Brown *et al.* The investigators observed a high frequency (60%) of additional intervention for stent migration and malposition. In addition, concomitant urinary tract infection was present in all MS failures resulting in a possible relation of urinary infection and MS stent failure, which eventually requires additional investigation.<sup>[22]</sup>

Liatsikos *et al.* reported their experience with MS insertion in 50 patients for the management of both malignant and benign ureteral obstruction. Malignant disease was the cause of obstruction in 25 patients. The patency rate of the malignant cases was 100% during the mean follow-up period of 11 months (range 4-14 months). The benign cases including urinary lithiasis, iatrogenic and ureteroenteric strictures had a patency rate of 44%. Major complications were not observed while minor complications included



**Figure 1a:** A metal double-pigtail ureteral stent which has macroscopically clean appearance has been covered by a thin layer of encrustation when its surface is observed by electron microscopy. In fact, energy dispersive analysis by X-ray revealed that the deposits have high concentrations of calcium



**Figure 1b:** A metal double-pigtail ureteral stent which has macroscopically evident encrustation which is observed as a thick layer of encrustation in electron microscopy. High concentration of calcium and phosphate were detected by energy dispersive analysis



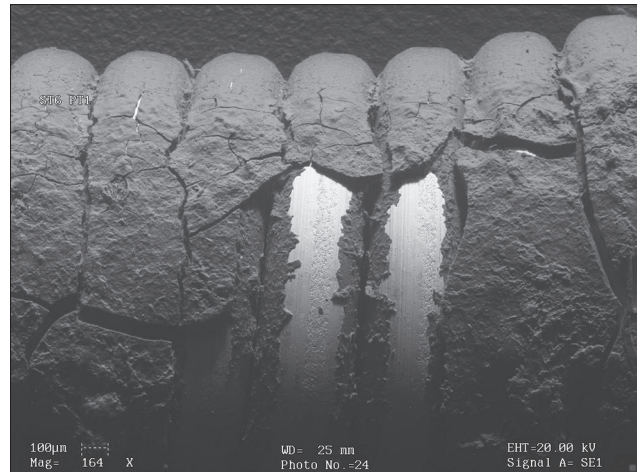


**Figure 2a:** Heavy encrustation on a stent which was indwelling for 13 months

transient hematuria, slight bladder irritation and positive urine cultures without symptomatic infection. The MS was noted to perform more efficiently in the case of malignant extrinsic obstruction in comparison to benign cases. In fact, the only cases of MS occlusion were associated with benign disease.<sup>[19]</sup>

Li *et al.* reported their experience with 20 patients (23 stents totally) inserted for malignant or benign disease. The authors subdivided their cases in patients who had or had not received radiotherapy. The overall patency rate was 82.6%. Patients who had undergone radiotherapy had a patency rate of 50% with MS insertion while those without previous radiotherapy did not experience MS occlusion. In fact, patients without previous radiotherapy were associated to 100% patency rate regardless of the nature of the obstruction (benign or malignant). Stent symptoms were observed in 65.2% of the cases (flank pain, abdominal pain, dysuria, and pyelonephritis). Nevertheless, no special consideration for stent length was taken to improve patient comfort during the study. Two stents were removed due to pyelonephritis and another two due to persistent ureteral obstruction.<sup>[23]</sup> Similar results of patency in patients previously treated by radiotherapy were reported by Wang *et al.* The investigators observed significantly higher patency rates in patients who had not received radiotherapy in comparison to those treated by radiation therapy (92.3% vs. 50%, respectively). It should be noted that these results were obtained from a series of 16 patients (26 MSs inserted). Complications were observed in 6 patients including hematuria ( $n = 4$ ) and urgency ( $n = 2$ ).<sup>[24]</sup> As a conclusion, radiotherapy was proven to be a factor negatively influencing the outcome of MS placement.

A multi-institutional experience reported 76 stents inserted in 59 obstructed renal units. Fifteen benign and 44 malignant ureteral obstructed cases were included. The median follow-up was 5 months (range 0-18 months).



**Figure 2b:** The appearance of same stent in electron microscopy

Hydronephrosis was stabilized in 47%, improved in 40% and worsened in 18% of the cases. Serum creatinine improved in 28%, was stable in 37% and worsened in 35% of the cases. MSs placed for the alleviation of PS-resistant obstruction remained obstructed in 15 out of 41 cases. All these cases had malignant etiology. It should be noted that the obstruction of the MS was observed early in the follow-up period with a median time of 1.5 months and stent obstruction was observed in 43% of the cases within the first 12 months. The phenomenon of early stent failure taking place within the 1<sup>st</sup> day to weeks has also been reported by Liatsikos *et al.*<sup>[19]</sup> As a result, the authors advised close follow-up of patients with MS as these patients are still susceptible to ureteral obstruction, infection and stent encrustation.<sup>[25]</sup>

Goldsmith *et al.* reported a series of 25 patients (37 stents) with malignant ureteral obstruction managed by MS insertion. The MS failed to alleviate obstruction in 12 patients (35%) and progressive hydronephrosis as well as creatinine increase were observed. Five failed stents were removed and replaced by another MS resulting in successful treatment of the obstruction without further failure. Although stent migration is rarely reported with MS, the authors observed three cases of migration. Moreover, an interesting phenomenon was a significantly increased risk of MS failure when the prostate cancer invasion of the bladder was evident during the stent placement procedure. The authors attempted to assess the presence of possible risk factors of MS failure and concluded that previous radiotherapy, the presence of ileal conduit and prior ureteral stent failure increased the risk for MS failure. A significant complication, which has never been reported by other investigators, was the formation of subcapsular hematoma after MS placement in three patients. Conservative management proved to be adequate. The authors concluded that the failure rate was similar to PSs. Nevertheless, a specially designed clinical trial would have been more appropriate for the documentation of the above conclusion.<sup>[26]</sup>

Gard *et al.* managed ureteroenteric anastomotic strictures by MS insertion. A total number of 10 ureteroenteric strictures were treated. Two strictures were associated with tumor involvement while the remaining strictures were benign in nature. Nine stents migrated distally resulting in the protrusion of the MS through the conduit stoma in eight cases. Only one stent remained in place for a period of 12 months. Ureteroenteric strictures may not be the ideal setting for the use of the MS and possibly other drainage approaches should be considered.<sup>[27]</sup>

In two pediatric patients, MS failed to alleviate the obstruction over a short time period (3 weeks and 3 months). Both patients presented with serious complications associated with obstructive uropathy (renal failure, pyelonephritis).<sup>[28]</sup> One case of tumor related ureteral obstruction was successfully addressed by the MS for 3 years by routinely exchanging the stent every 12 months to avoid encrustation.<sup>[12]</sup>

A summary of the clinical experience with MS is presented in the Table 1.

**Table 1: Summary of the clinical experience with the full metallic double-J ureteral stent**

Study	Number of stents/benign/malignant	Follow-up benign/malignant	Patency rate (%)	Complication×number of patient	Management of complications
Borin <i>et al.</i> <sup>[20]</sup>	2/-/2	-/4 months	100	Urgency and frequency	Not reported
Nagele <i>et al.</i> <sup>[11]</sup>	18/5/13	11.6/7.3 months (mean)	Benign 75, malignant 46	Urinary tract infection×6 Recurrent infections× 1 Persistent hematuria×1 Encrustation×2 Severe dysuria and pain×2 Insufficient drainage×4	Antibiotics Stent removal Stent removal Not reported Stent removal Stent removal
Wah <i>et al.</i> <sup>[21]</sup>	17/-/17	Up to 12 months	82.3	Stent obstruction×3	Nephrostomy placement
Liatsikos <i>et al.</i> <sup>[19]</sup>	54/18/25/7*	11 (4-14)/6.8 months/7 days* (mean), up to 16 months	Benign 44, malignant 100, benign*0	Dysuria and pain×10 Hematuria×6 Encrustation× 1 Tissue ingrowth×7* Insufficient drainage×7 Bladder erythema×2	Antibiotics Spontaneous resolution Stent removal Stent removal-polymeric stent Stent removal Conservative
Li <i>et al.</i> <sup>[23]</sup>	23/10/13	5.1 (0.5-18.2) months (mean)	82.6 (radiotherapy patients only 50)	Acute pyelonephritis×2 Stent obstruction×4 Abdominal pain×5 Flank pain×3 Bladder pain×3 Dysuria× 15	Stent removal Stent removal or observation Conservative Conservative Conservative Conservative
Wang <i>et al.</i> <sup>[24]</sup>	22/4/18	5 (1 day-10.5) months (mean)	Overall 77.3, 6 months 81, 9 months, 27 (radiotherapy patients only 50)	Migration×1 Hematuria×4 Urgency and bladder irritation×2 Insufficient drainage×5 Encrustation×3	Stent removal Spontaneous resolution Conservative Stent removal
Modi <i>et al.</i> <sup>[25]</sup>	69/19/50 (76 stents when including stent exchanges)	5 (0-18) months (mean)	Overall 57, >12 months indwelling 36, MSs for PSs replacement 37	Tissue ingrowth× 1 Obstructed stents× 15 Migration×1 Urinary tract infection×8 Stent related symptoms×10	Cystolithoapaxy or percutaneous nephrolithotomy Percutaneous stent removal Stent removal Stent removal Stent removal when stent failure
Goldsmith <i>et al.</i> <sup>[26]</sup>	37/-/37	Up to 12 months	65	Migration×3 Progressive hydronephrosis×9 Subcapsular renal hematoma×3	Observation or stent exchange Stent removal or exchange Conservative
Potrezke <i>et al.</i> <sup>[12]</sup>	2/-/2 pediatric case	3 years	100	Not reported	N/A

*Contd...*

Table 1: Contd...

Study	Number of stents/benign/malignant	Follow-up benign/malignant	Patency rate (%)	Complication×number of patient	Management of complications
Garg <i>et al.</i> <sup>[27]</sup>	10/8/2 ureteroenteric	Up to 12 months	12.5	Migration×9	Stent removal and polymeric stent insertion
Brown <i>et al.</i> <sup>[22]</sup>	8/-/8	Up to 7 months	20 within the first 4 months	Flank pain×5 Hematuria×2 Renal failure×3 Renal obstruction×4 Urinary tract infection×4 Migration or malposition×3	Not reported Not reported Stent removal and alternative drainage Stent removal and alternative drainage Not reported Repositioning or endoscopic intervention
Gayed <i>et al.</i> <sup>[28]</sup>	2/-/2 pediatric population	3 weeks and 3 months	0	Acute renal failure×1 Flank, worsening hydronephrosis and pyelonephritis×1	Dialysis, nephrostomy placement Stent removal, nephrostomy placement
Lopez-Huertas <i>et al.</i> <sup>[29]</sup>	14/14/-	Up to 12 months	92	Irritative bladder symptoms×2 Recurrent gross hematuria×1 Recurrent urinary tract infection×1	Alternative drainage Not reported Antibiotics and stent exchange
Taylor <i>et al.</i> <sup>[30]</sup>	26/17/9	Total 12 months, benign 14 months, malignant 10 months (mean)	92	Stent obstruction×1	Stent removal and nephrostomy placement

MSs=Metallic double-J ureteral stents, PS=Polymeric ureteral stent

## COMPARISON WITH STANDARD STENTS

Comparative data between the MSs and the PSs are not currently available. Several studies include cases of PSs failure, which were managed by MS insertion.

In these cases, the MS proved to provide patency rates ranging between 37% and 100%.<sup>[11,12,20,25]</sup> High patency rates have also been reported in case reports<sup>[12,20]</sup> while population studies reveal a patency rate ranging between 37% and 46%.<sup>[11,25]</sup> It should be noted that Modi *et al.* provided specific data on the above cases and reported a patency rate of 37%.<sup>[25]</sup> Liatsikos *et al.* reported disappointing outcome of MS insertion in patients with occluded MMSs. All MSs were occluded over a short period of days.<sup>[19]</sup>

## COST CONSIDERATIONS

Every novel treatment should be evaluated in terms of cost-effectiveness in comparison to the established standard treatment method. The MS has been proven to be more cost-effective in two available studies comparing MS to PS. Both studies showed that despite the higher cost of each MS placement/exchange procedure, the less frequent MS replacement result in a reduced financial burden.<sup>[29,30]</sup>

## CONCLUSIONS

The current experience with the MS lacks sufficient evidence for clear patient selection. Malignant ureteral obstruction is efficiently managed by MS placement in the long-term<sup>[11,19-21,23,24]</sup> Nevertheless, patients who have previously undergone radiotherapy do not seem to be good candidates since only half of their stents remain patent.<sup>[23,24]</sup> Patients with prostate cancer invading the bladder and those with bulky pelvic disease may also not be candidates.<sup>[11,26]</sup> The need for close follow-up of patients with MS insertion for malignancy should be emphasized especially during the first 8 weeks.<sup>[19,25]</sup> Outcomes in benign obstructions are equivocal.<sup>[11,19,23,25]</sup> Patients with stone disease are probably not appropriate for MS as are patients with ureteroenteric strictures.<sup>[19,26,27]</sup> The very limited experience with MSs in the pediatric population is unfavorable and warrants additional investigation.<sup>[12,28]</sup> Complication rate remains low if cases are carefully selected. Major complications are rare and the minor complications should not hinder the use of MS. In fact, discomfort, dysuria and mild hematuria have been reported by several investigators and should be managed conservatively without the need for stent removal.<sup>[11,19,23]</sup> The association of infection to occlusion of the MS suggests that perioperative antibiotics should be used.<sup>[22,25]</sup> The cost-effectiveness of the MS seems to be appropriate for the

long-term treatment.<sup>[29,30]</sup> Further investigation, especially comparative clinical trials, would document the outcome more extensively and would provide the proper indications for the MS.

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