ORIGINAL ARTICLE

Experience with resonance stent

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Abstract

The full metallic double-J ureteral stent (MS) represents a method for providing long-term drainage in malignant ureteral obstruction. The design and mechanical properties of the MS allowed higher efficacy in providing drainage in difficult cases in comparison to the standard polymeric double-J stents (experimental data). The clinical data showed controversial results. MS insertion was associated with variable patency rates. Careful patient selection resulted in efficient long-term management of malignant ureteral obstruction as well as in selected benign cases. The majority of the complications were reported to be minor while the major complications were scarce. The use of MS in pediatric patients is still very limited to draw conclusions. The cost-effectiveness of the MS was reported to be appropriate for the treatment of long-term cases. 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
metal stent; ureteral stent; Resonance stent; full metal ureteral stent; double-J metal stent

Citation
Kallidonis P, Goulimi E, Ntasiotis P, Panagopoulos V, Liatsikos E. Experience with resonance stent. *Hellenic Urology* 2016, 28 (2): 62-69

Introduction

Ureteral obstruction, either benign or malignant in etiology, is a common problem for the practicing urologists. The percutaneous nephrostomies (PN), the retrograde polymeric double - J ureteral stents (PS) and the metal mesh stents (MMS) are the three minimal invasive tools commonly used with variable success rates for the long term relief of ureteral obstruction. MMSs have been introduced in the urological clinical practice due to significant failure rates of PSs in the face of extrinsic malignant ureteral compression requiring long - term drainage[1,2]. Ureteral MMSs were associated with improvement of the patients' quality of life. Nevertheless, they were also associated with high rate of migration, stone encrustation and obstruction due to the urothelial hyperplasia. These complications resulted in limited efficacy for long - term ureteral drainage[3-5] and

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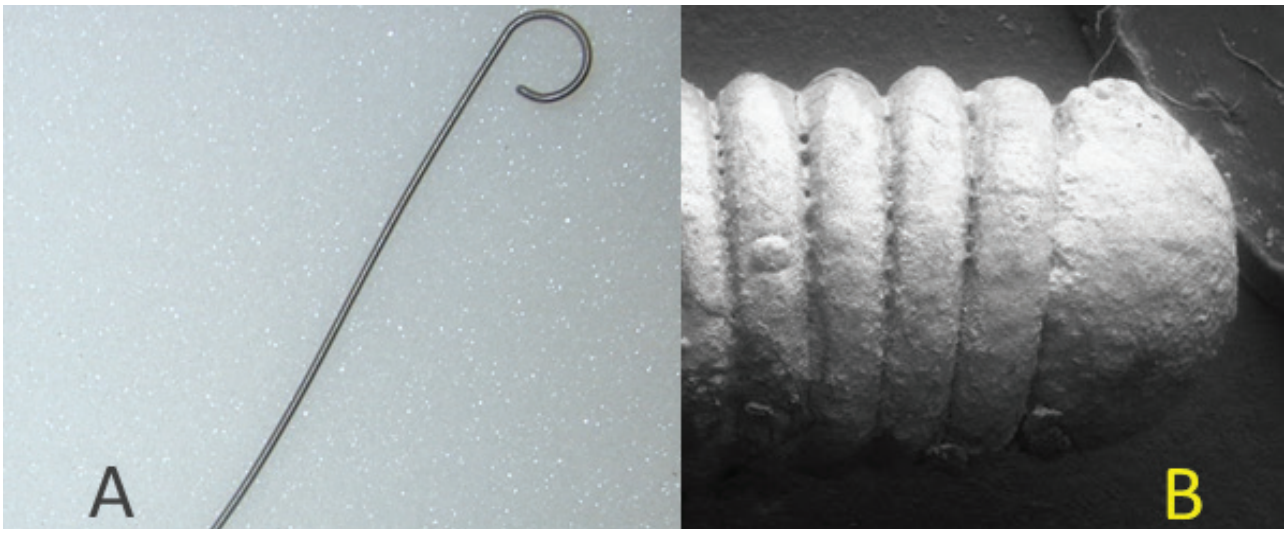

Figure 1A: *An Resonance stent after 12 months of indwelling. Notice that encrustation is not evident on the stent*
Figure 1B: *The same Resonance stent examined by the Electron Microscopy. The presence of encrustations on its surface is clear. Similar results were observed in all stents without macroscopically evident encrustation that were examined by the authors in Electron Microscopy (see Ref. 14)*

eventually limited the widespread application of the MMSs in the ureter.

An alternative treatment for extrinsic ureteral obstruction was introduced with the Resonance™ stent (Cook Medical, Ireland) (MS). The latter is an all metal, double pigtail stent. Cases of extrinsic tension sufficient enough to occlude the PSs are efficiently managed by the MS due to its incompressible metal structure. 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 MS is 6Fr. Its alloy is based on 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 such as occlusion by the external compression by tumor, the need for frequent stent changes and encrustation[6,7].

Experimental Data

Experimental settings have documented that the MS could provide efficient upper urinary tract drainage in cases that the PSs have failed. The MS provided less overall flow than a PS, continued to provide satisfactory drainage in cases of significant extrinsic ureteral compression resulting in occlusion of a PS[8]. When the mechanical properties of the MS were compared with the Silhouette coil - reinforced double - pigtail stent (Applied Medical, Rancho San Mirage, Calif) and PSs, the MS proved to have a higher tensile strength than the Silhouette stent while the latter stent was more resistant to extrinsic tension than the MS. Moreover, the PSs were less resistant than the above stent types[9]. The MS was also reported to be more resistant to extrinsic tension than the Silhoutte and the PSs. No permanent deformation of the MS was observed after the experimental evaluation while the Silhouette and PSs showed indentation[10]. The compatibility of the MS with radiotherapy has been evaluated in the porcine model. No significant histological differences were observed between the ureters containing the MSs and their controls after the performance of radiotherapy[11]. Another experimental study in a porcine model proved that Extracorporeal Shock Wave Lithotripsy (SWL) could be performed with safety in ureters having MSs. Thus, SWL could be used for managing encrustations formed on a MS in an attempt to postpone stent replacement[12]. The formation of encrustations on the MS was evaluated by Electron microscopy which showed the presence of biofilm lining and inorganic material on MSs after several months of indwelling[13,14]. In the study by Liatsikos et al., all stents without the macroscopic appearance of deposits had encrustations on their surface **(Figure 1A+B)**. Nevertheless, the presence of encrustations didn't result in occlusion of the MSs in the majority of the cases[14].

TABLE 1 *Urodynamic results*

Study	Number of stents/ Benign/ Malignant	Follow-up Benign/ Malignant	Patency rate	Complications x number of patients	Management of complications
Borin et al.[15]	2/-/2	-/4 months	100%	Urgency and frequency	Not reported
Nagele et al.[16]	18/5/13	11.6/7.3 months (mean)	Benign 75% Malignant 46%	Urinary tract infection x 6 Recurrent infections x 1 Persistent hematuria x 1 Encrustation x 2 Severe dysuria and pain x 2 Insufficient drainage x 4	Antibiotics Stent removal Stent removal Not reported Stent removal Stent removal
Wah et al.[17]	17/-/17	Up to 12 months	82.3%	Stent obstruction x 3	Nephrostomy placement
Liatsikos et al.[14]	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 x 10 Hematuria x 6 Encrustation x 1 Tissue ingrowth x 7* Insufficient drainage x 7 Bladder erythema x 2	Antibiotics Spontaneous resolution Stent removal Stent removal-Polymeric stent Stent removal Conservative
Li et al. [18]	23/10/13	5.1 (0.5-18.2) months (Mean)	82.6% (radiotherapy patients only 50%)	Acute pyelonephritis x 2 Stent obstruction x 4 Abdominal pain x 5 Flank pain x 3 Bladder pain x 3 Dysuria x 15	Stent removal Stent removal or observation Conservative Conservative Conservative Conservative
Wang et al.[19]	22/4/18	5 (1 day- 10.5) months (Mean)	Overall 77.3%, 6 months 81%, 9 months 27% (radiotherapy patients only 50%)	Migration x 1 Hematuria x 4 Urgency and bladder irritation x 2 Insufficient drainage x 5	Stent removal Spontaneous resolution Conservative Stent removal
Modi et al.[20]	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%	Encrustation x 3 Tissue ingrowth x 1 Obstructed stents x15 Migration x 1 Urinary tract infection x 8	Cystolithoapaxy or percutaneous nephrolithotomy Percutaneous stent removal Stent removal Stent removal Stent removal Stent removal when stent failure
Goldsmith et al.[21]	37/-/37	Up to 12 months	65%	Migration x 3 Progressive hydronephrosis x 9 Subcapsular renal hematoma x 3	Observation or stent exchange Stent removal or exchange Conservative
Potrezke et al. [26]	2/-/2 Pediatric case	3 years	100%	Not reported	N/A
Garg et al.[22]	10/8/2 Ureteroenteric	Up to 12 months	12.5%	Migration x 9	Stent removal and polymeric stent insertion

TABLE 1 *Urodynamic results*

Study	Number of stents/ Benign/ Malignant	Follow-up Benign/ Malignant	Patency rate	Complications x number of patients	Management of complications
Brown et al.[29]	8/-/8	Up to 7 months	20% within the first 4 months	Flank pain x 5 Hematuria x 2 Renal failure x 3 Renal obstruction x 4 Urinary tract infection x 4 Migration or malposition x 3	Not reported Not reported Stent removal and alternative drainage Stent removal and alternative drainage Not reported Repositioning or endoscopic intervention
Gayed et al. 2[5]	2/-/2 Pediatric population	3 weeks and 3 months	0%	Acute renal failure x 1 Flank, worsening hydronephrosis and pyelonephritis x 1	Dialysis, nephrostomy placement Stent removal, nphrostomy placement
Huertas et al.[27]	14/14/-	Up to 12 months	92%	Irritative bladder symptoms x2 Recurrent gross hematuria x 1 Recurrent urinary tract infection x 1	Alternative drainage Not reported Antibiotics and stent exchange
Taylor et al.[28]	26/17/9	Total 12 months, Benign 14 months, Malignant 10 months (Mean)	92%	Stent obstruction x 1	Stent removal and nephrestomy placement
Abbasi et al. [23]	27/0/27	Mean 7.4 months Subgroup of patients still living mean 11.4 months		Persistent azotemia x 2 obstructive symptoms x6	Conversion to percutaneous drainage Change to traditional stents x2 Removal of metallic stents x4

*N/A: non available *: Represents a special group of the study which includes patients with previous placement of permanent metal ureteral mesh stents. These stents had been occluded and were managed by MS insertion.*

Current Clinical Data

The clinical experience with the management chronic extrinsic ureteral obstruction by MS insertion is limited but continuously expanding. The first successful clinical case was reported by Borin et al. The MS insertion successfully drained for 4 months a ureteral obstruction due to retroperitoneal fibrosis associated with metastatic breast cancer[15]. Nagele et al. studied 14 patients with ureteral obstruction of both benign (5 ureters) and malignant etiologies (13 ureters). In this study, the MS managed to alleviate the obstruction for a mean follow - up time of 8.6 months. Complications were reported in half of the cases. Proper stent length selection was considered important by the authors for patient comfort[16]. Wah et al. inserted 17 MSs in 15 patients with malignant ureteral obstruction. Insufficient drainage was reported in 3 cases associated with bulky pelvic malignancy[21]. Brown et al. in a sample of 5 patients with malignant obstruction reported a failure rate up to 80% and a high fre-

quency (60%) of additional interventions for stent migration and malposition. In all MS failures, urinary tract infection was present and may have been responsible for the failures of the MSs[17].

A large series including 50 patients with both malignant (n= 25) and benign ureteral obstruction (n=25) was studied by Liatsikos et al. Malignant cases had a 100% patency rate during the mean follow - up period of 11 months (range 4 - 14 months), whereas the patency rate of the benign cases was only 44%. Only minor complications were reported such as transient hematuria, slight bladder irritation and positive urine cultures without symptomatic infection. MS failures were associated with benign cases. A higher efficiency of the MS was noted in malignant extrinsic obstructions in comparison to benign cases[14].

Li et al. inserted 23 MSs in 20 patients for both malignant and benign disease. They reported significantly lower patency rates for the patients who had undergone radiotherapy in comparison to the non - radiotherapy patients. The patency rate was 50% for the irradiated patients while the overall patency rate was 82.6%. Symptoms such as flank pain, abdominal pain, dysuria, pyelonephritis were associated with 65.2% of the cases. One case of pyelonephritis and another of persistent ureteral obstruction led to the removal of the stent[18]. Wang et al., in a series of 19 patients (26 MSs), reported similar results regarding the patency of patients who had previously undergone radiotherapy. A significantly higher patency rate was reported for the previously irradiated patients in comparison to those not treated by radiation therapy (50% vs 92.3%, respectively). For the total population, 5 stents failed over a mean follow - up period of 5 months and the patency rate was 77.3%. Complications, such as hematuria (n= 4) and urgency (n= 2) were observed in 6 patients[19]. The above evidence showed that patients who had undergone radiotherapy before MS insertion have a higher likehood for MS failure and should be carefully selected for MS.

Modi AP et al. reported multi - institutional experience including 59 obstructed renal units which were managed with 76 MSs. Both benign (n= 15) and malignant (n= 44) cases were treated. The median follow - up was 5 months (range 0 - 18). Hydronephrosis was stabilized in 47%, improved in 40% and worsened in 18% of the cases. Creatinine levels were improved in 28%, stable in 37% and worsened in 35% of the cases. MSs were placed in 41 malignant cases resistant to PS insertion. In 15 of these cases, the MSs failed to alleviate the obstructions. The obstruction of the MSs was noted within the first weeks after the placement with a median time of 1.5 months. Moreover, 43% of the stents were obstructed within the first 12 months[20]. Early stent failure within the first days to weeks has been also described by Liatsikos et al. [14]. Thus, a close follow - up of the patients with MS is necessary due to the risk of insufficient drainage.

Controversial results concerning the MS insertion were reported by Goldsmith et al. in a series of 25 patients (37 MSs) with malignant ureteral obstruction. Persistent obstruction after the insertion, progressive hydroureteronephrosis and increase in the creatinine values was observed in 12 patients (35%). Five failed stents had to be replaced by another MS resulting in successfully treatment of the obstruction. 3 cases of migration were reported. The risk of failure increased significantly when the prostate cancer invasion to the bladder was evident while placing the MS. In an attempt to define the possible risk factors of MS failure, the authors concluded that patients, who had undergone radiotherapy, had an ileal conduit and had a prior ureteral stent failure, presented a higher risk of MS failure. Subcapsular hematomas as a complication after MS insertion was described in 3 patients and these cases were treated conservatively. The failure rate was similar to PSs according to the conclusion of the authors[21].

Ten cases of ureteroenteric anastomotic strictures have been managed by MS insertion in the literature. Eight strictures were benign and two were related to tumor involvement. One stent remained in place for 10 months whereas nine of them migrated distally. When considering the above experience, ureteroenteric strictures should possibly be treated with other drainage approaches[22].

Abbasi et al. managed 20 patients (6 men and 14 women) with malignant ureteral obstruction in 27 renal units. 8 patients required further intervention (40%) of which 2 were managed by a percutaneous drainage and 6 patients by changing to traditional stents or removal of the MS. The failed cases had a mean follow

- up of 7.5 months (range 0 - 18). At the last follow - up, sixteen patients had died. 14 of these patients died with functioning MSs in place. One patient, who initially was managed by bilateral metallic stent placements, had a left stent removed due to migration. The authors concluded that though the failure rate for the MS is similar to that of traditional stents, the mean time to failure is longer. Thus, MSs could be considered for patients with malignant obstruction instead of PSs[23].

Benson et al. managed 23 patients by placing in total of 42 MSs with a median follow - up period of 13 months (range 2 - 32). 3 out of 42 MSs failed to provide drainage in patients with malignant obstruction. Failures were not reported for the benign cases. The failure cases were complicated by acute renal failure and hydronephrosis and were treated with PN placement. The authors concluded to the good tolerability, low complications rate and minimum failure rate of the Resonance MS[24].

The largest pediatric population treated by MSs includes 3 cases. In two of them, MSs did not succeed in managing the obstruction in both patients. The respective MS failure time periods were 3 weeks and 3 months[25]. One more pediatric case of malignant ureteral obstruction was successfully treated by the MS for 3 years. The stent was routinely exchanged every 12 months in order to avoid encrustation[26].

The **Table** summarizes current experience with the MS.

The Full Metallic Double - pigtail Ureteral Stent compared to standard Polymeric Double - pigtail Ureteral Stent and Metal Mesh stents

There are no comparative studies between the MSs and the PSs or MMSs in the current literature. MS insertion has been performed in cases of previous PSs and MMSs failure.

In the studies of previous PSs failure, the MS provided patency rates ranging between 37% and 100%[15, 16, 20, 26]. Case studies report similar patency rates (15, 26) while the respective rates of population studies range between 37 and 46%[16, 20]. Modi et al. revealed detailed data on the renal function and their population had a patency rate of 37%[20]. After MMS failure, the use of MSs showed disappointing results with failure of the MSs within a period of days[14].

The evaluation of cost for the Full Metallic Double - pigtail Ureteral Stent

Two studies are available in literature providing a cost comparison between the MSs and PSs. The cost - effectiveness of MS was higher than the PSs as the longer replacement periods of the MS replacement balanced the higher cost of the MS[27, 28].

Conclusion

Patient selection for MS insertion remains unclear since the experience with the stent is still controversial. Malignant ureteral obstruction cases could be managed efficiently in long - term[14 - 19, 23]. Previously irradiated patients seem not be good candidates for the MS[18, 19, 23]. It is not clear yet if patients with prostate cancer and bladder involvement as well as those with bulky pelvic disease should treated with MS[16, 21, 23]. All patients with MS should be under close follow - up especially during the first 8 weeks[14, 20]. Benign cases and pediatric patients require further investigation to establish criteria for the selection of these patients[14, 16, 18, 20]. MS is probably not appropriate for ureteroileal anastomotic strictures due to the high migration rates[21, 22]. Complications are usually minor and are limited with carefully selected[14, 16, 18]. Perioperative use of antibiotics is advised due to the high MS failures related to infection[20, 29]. Further investigation, especially comparative clinical trials, would document the outcome more extensively and would provide the proper indications for the MS.

Abbreviations

Polymeric ureteral stent (PS)
Percutaneous nephrostomy (PN)
Mesh stent (MMS)

Περίληψη

Η πλήρως μεταλλική αυτοσυγκρατούμενη ουρητηρική ενδοπρόθεση (ΜΕ) αρχικά παρουσιάστηκε σαν μια μέθοδος για τη μακροπρόθεσμη παροχέτευση σε κακοήθη απόφραξη του ουρητήρα. Η πειραματική αξιολόγηση της ΜΕ αποκάλυψε ότι οι μηχανικές ιδιότητες της επιτρέπουν την αποδοτική παροχέτευση σε δύσκολες περιπτώσεις που δεν μπορούν να αντιμετωπιστούν με την εισαγωγή μιας πολυμερικής ουρητηρικής ενδοπρόθεσης. Η κλινική εμπειρία με την ΜΕ έδειξε αμφιλεγόμενα αποτελέσματα. Οι κακοήθους αιτιολογίας αποφράξεις του ουρητήρα αντιμετωπίζονται με τοποθέτηση ΜΕ για μεγάλο χρονικό διάστημα. Ασθενείς που έχουν υποβληθεί σε ακτινοθεραπεία φαίνεται ότι δεν είναι καλοί υποψήφιοι για τοποθέτηση ΜΕ λόγω αυξημένης πιθανότητας για απόφραξη της και παρουσίαση επιπλοκών. Ασθενείς με ευμεγέθεις όγκους πυέλου και καρκίνου του προστάτη που διηθεί την ουροδόχο κύστη δεν είναι κατάλληλοι λόγω ελαττωμένων ποσοστών για επιτυχή παροχέτευση. Καλοήθεις περιπτώσεις και παιδιατρικοί ασθενείς απαιτούν περαιτέρω κλινική αξιολόγηση, ώστε να παρέχουν τις κατάλληλες ενδείξεις για τοποθέτηση ΜΕ. Τα στενώματα των ουρητηροεντερικών αναστομώσεων που αντιμετωπίζονται με ΜΕ έχουν αυξημένα ποσοστά αποτυχίας λόγω μετανάστευσης της ΜΕ περιφερικά με αποτέλεσμα την προεξοχή της μέσω του στομίου. Τα περιστατικά λιθίασης σχετίζονται με αυξημένο ποσοστό αποτυχίας λόγω ασβέστωσης της ΜΕ. Γενικά, το ποσοστό επιπλοκών παραμένει χαμηλό και οι σοβαρές επιπλοκές είναι σπάνιες και σχετίζονται με αιματουρία, δυσουρία, άλγος, ανεπαρκή παροχέτευση και ουρολοιμώξεις. Μονό μακροχρόνια περιστατικά φαίνεται ότι μπορούν να επιτύχουν μια αποδεκτή σχέση κόστους - αποτελέσματος όταν αντιμετωπιστούν με ΜΕ.

Λέξεις ευρετηριασμού

μεταλλική ενδοπρόθεση, ουρητηρική ενδοπρόθεση, μεταλλική ουρητηρική ενδοπρόθεση, αυτοσυγκρατούμενη ουρητηρική μεταλλική ενδοπρόθεση

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