A Single–Institution Experience with Metallic Ureteral Stents: A Cost–Effective Method of Managing Deficiencies in Ureteral Drainage

Adam S. Baumgarten, Tariq S. Hakky, Rafael E. Carrion, Jorge L. Lockhart, Philippe E. Spiess

Department of Urology, University of South Florida and Department of Genitourinary Oncology, Moffitt Cancer Center; Tampa, Fl, USA

ABSTRACT

Introduction: The limitations of traditional ureteral stents in patients with deficiencies in ureteral drainage have resulted in frequent stent exchanges. The implementation of metallic stents was introduced to improve the patency rates of patients with chronic upper urinary tract obstruction, obviating the need for frequent stent exchanges. We report our clinical experiences with the use of metallic ureteral stents in the management of poor ureteral drainage.

Materials and Methods: Fifty patients underwent metallic ureteral stent placement from 2009 to 2012. Stent failure was defined as an unplanned stent exchange, need for nephrostomy tube placement, increasing hydronephrosis with stent in place, or an elevation in serum creatinine. Stent life was analyzed using the Kaplan-Meier methodology, as this was a time dependent continuous variable. A cost analysis was similarly conducted.

Results: A total of 97 metallic stents were placed among our cohort of patients: 63 in cases of malignant obstruction, 33 in the setting of cutaneous ureterostomies, and 1 in an ileal conduit urinary diversion. Overall, stent failure occurred in 8.2% of the stents placed. Median stent life was 288.4 days (95% CI: 277.4-321.2 days). The estimated annual cost for traditional polymer stents (exchanged every 90 days) was $9,648-$13,128, while the estimated cost for metallic stents was $4,211-$5,313.

Conclusion: Our results indicate that metallic ureteral stent placement is a technically feasible procedure with minimal complications and is well tolerated among patients. Metallic stents can be left in situ for longer durations and provide a significant financial benefit when compared to traditional polymer stents.

ARTICLE INFO

INTRODUCTION

Long-term ureteral patency often presents a difficult therapeutic challenge in patients with chronic ureteral obstruction. Traditional polymer ureteral stents have been the mainstay of therapy; however, primary patency of polymer ureteral stents has been suboptimal due to tumor compression and encrustation (1,2). Additionally, standard of care recommends regular stent replacement at 3-month intervals to prevent failure (3,4).

Methods of managing poor ureteral drainage include percutaneous nephrostomy tube placement and internal drainage with double pigtail stent insertion. Many of these patients, however, experience recurrent urinary tract infections, tube

migration, bladder irritation, local urinary symptoms (e.g. frequency, urgency, dysuria, etc.), or require daily care of a nephrostomy tube site, causing reduced quality of life (5).

Metallic ureteral stents consist of spirally coiled metal constructed to optimize compressive and radial strengths. Their ability to resist encrustation allows them to remain in situ for up to 12 consecutive months (6). The implementation of metallic stents was introduced to improve technical feasibility and patency rates for management of patients with upper urinary tract obstruction, obviating the need for frequent stent exchanges.

Prior literature on metallic stents has reported equivocal results. Most retrospective studies have been somewhat limited by their small study populations, as metallic stenting is a relatively recent procedure. Failure rates anywhere from 7% - 66% have been reported in the few retrospective series currently available (5,7-11).

We report our clinical experience with the use of metallic ureteral stents in the management of poor ureteral drainage. We also present a comparative cost analysis of patients managed with such stents, as opposed to patients treated with traditional polymer ureteral stents.

MATERIALS AND METHODS

After institutional review board approval was obtained, 50 patients were retrospectively identified to have who had undergone metallic ureteral stent placements in the management of ureteral drainage deficiencies at two of our academic facilities in Tampa, Florida (Moffitt Cancer Center and Tampa General Hospital). A total of 97 metallic stents were placed between January 2009 and September 2012. The same two surgeons placed these stents at both hospitals. All stents had a diameter of 6 French and length, ranging from 20 to 30cm. All patients who had metallic ureteral stents placed, had chronic ureteral obstruction in the context of a malignancy or required chronic ureteral stenting in the setting of a cutaneous ureterostomy or ileal conduit. Exclusion criteria included patients that had a previous ureteral balloon dilation or retrograde/antegrade endopyelotomy. Covariates assessed in our Cox univariate/multivariate analysis of potential predictors of metallic ureteral stent failure included patient age at diagnosis, gender, body mass index, underlying malignancy, cancer stage, site of ureteral obstruction, prior radiation therapy, and serum creatinine/creatinine clearance (calculated by the Cockcroft-Gault formula).

The Resonance Metal Stent® (RMS; Cook Urological®, Bloomington, IN) was designed to provide long-term drainage of chronic upper urinary tract obstruction. All metallic ureteral stents were placed while the patient was under general anesthesia, in a retrograde manner, with both fluoroscopic and cystoscopic guidance in patients with an intact bladder. Patients undergoing a metallic ureteral stent placement, in the management of chronic ureteral obstruction, had an initial stenting using a polymer ureteral stent to ensure the ureteral obstruction was in fact chronic in etiology, and that patient tolerated internal ureteral stenting with minimal urinary symptoms, thus making this a feasible long-term treatment option. In the patients undergoing chronic ureteral stent placement in the context of a cystectomy and urinary diversion, consisting of either a cutaneous ureterostomy or ileal conduit, ureteral stents were placed under local, regional, or general anesthesia with the assistance of fluoroscopy. Once a retrograde pyelogram was performed, a guidewire was successfully placed into the collecting system, the cylindrical outer sheath was passed into the renal pelvis, and the wire was removed. The proximal stent was uncurled, and then advanced through the sheath using a pusher. Under fluoroscopy, a push-pull technique was used to overly advance the sheath while placing the stent. The proximal stent curl was noted in the renal pelvis, and the outer sheath was removed, causing the distal curl to uncurl. At the completion of the procedure, the final fluoroscopy image was shot and saved to confirm proper placement of the stent. Medical agents were not used to alleviate irritative or voiding symptoms unless symptoms were severe, in which case, oral anticholingeric medications were prescribed. Patients were seen at 6 months post--metallic stent placement to assess symptomatology, as well as a serum creatinine. If there were no issues at that visit, patients were scheduled for

metallic stent exchange between 9-12 months. If patients were symptomatic (i.e. flank pain, rising serum creatinine), a KUB and renal ultrasound were obtained to rule out stent migration, encrustation and non-functional stents, which would be suspected based on new or worsening hydronephrosis. If this was seen, patients then underwent an earlier stent exchange (within 1-2 weeks of that visit). In equivocal cases of a possible obstructed stent, a MAG-3 renal scan was obtained.

Stent failure was defined as: 1) an unplanned stent exchange, 2) the need for nephrostomy tube placement, 3) increasing hydronephrosis with metallic ureteral stent in place, or 4) a deteriorating renal function, as determined by serum creatinine or worsening creatinine clearance, suspected to be post-renal in nature. In patients tolerating the metallic ureteral stents, stent exchanges were scheduled at 9 to 12 months-time intervals to optimize stent function/drainage and decrease the likelihood of stent encrustation. Median stent life was calculated from date of stent placement to date of stent exchange using the Kaplan-Meier method. Stent exchanges were treated as separate, individual events in this statistical analysis. Predictors of stent failure were assessed using Cox regression univariate/multivariate modeling with a robust covariance matrix estimator.

The present cost analysis accounted for stent cost, mean operating room fees (billed 1 hour), mean anesthesia costs, and the annual stent exchange rate. The annual exchange rate for metallic stents was derived from data collected from this retrospective study, and the annual exchange rate from conventional polymer stents was extrapolated from previously published data (3,4). The cost analysis does not include any other direct or indirect cost, with the exception of assigning an economic loss to the patient for missed work. Economic loss was calculated based on Florida's Bureau of Labor Services mean daily wage of $157 US dollars.

RESULTS

A total of 97 metallic stents were placed in 50 patients (27 men, 23 women) during the 45-month accrual period. The mean patient age at diagnosis was 63.0 years (22-88 years). 37 patients (74%) had stents placed due to malignant ureteral obstruction, 12 patients (24%) had stents placed in the setting of cutaneous ureterostomies, and 1 patient (2%) had stent placement in the context of an ileal conduit. 14 patients (28%) had stents placed for genitourinary malignancies, 7 patients (14%) had stents placed for gastrointestinal malignancies, and 16 patients (32%) had stents placed for other malignancies, including lymphoma and sarcoma. A full breakdown of the indications for chronic ureteral stent placements is reported in Table-1. 13 patients (10 men, 3 women) had stents placed in the context of a cystectomy and urinary diversion. A total of 19 patients died with stents in situ. The patient characteristics of our study population are shown in Table-2.

At a mean patient follow-up of 303.2 days, stent failure occurred in 8 of the 97 stents placed among 16% (N = 8) of the total patients. The most common signs of stent failure were hydroureteronephrosis (N = 3, 37.5%) and recurrent urinary tract infection (N = 3, 37.5%). 1 stent failure (12.5%) was attributed to deteriorating renal function suspected to be post-renal in etiology, and 1 stent (12.5%) failed due to stent migration in a patient with a cutaneous ureterostomy diversion. Median time to stent failure was 68 days. Stent failures were managed by placing new metallic stents in 3 patients (37.5%), placement of a nephrostomy tube in 3 patients (37.5%), and exchange to a conventional polymer ureteral

Table 1 - Indications for Stent Placement.

Reason for Stent	Number of Patients
GU Malignancy	28%
GI Malignancy	14%
Ureteral Stricture	8%
Other Malignancy*	24%
Cutaneous Ureterostomy	24%
Ileal Conduit	2%

*Consists of sarcoma, lymphoma, small cell carcinoma, malignant breast cancer, primary peritoneal cancer, hemangiopericytoma

Table 2 - Patient Characteristics.

	Number of Patients			Age		BMI		Length of Follow-Up (days)	
	Total	Women	Men	Mean	Range	Mean	Range	Mean	Range
All Metallic Stents	50	23	27	62.96	22-88	27.86	18.04 - 47.12	273	19 - 1211
For Obstruction	37	20	17	61.41	22-88	27.79	18.04 - 47.12	297	19 - 1211
For Patients with No Bladder	13	3	10	67.38	45-75	28.04	20.62 - 39.17	203	41 - 659

stent in 2 patients, who appeared not tolerate the composition of the metallic stents (25%).

Eighteen of the 50 patients (36%) had stents exchanged during the study period of 45 months, with a median stent life of 288.4 days (95% CI: 277.4-321.2 days). Kaplan Meier analysis of stent life is shown in Figure-1. This analysis takes into account those stents that failed prematurely from the anticipated time of exchange.

The Cox univariate and multivariate analysis of potential predictors of metallic stent failure did not yield any endpoints of statistical significance including gender, age at diagnosis, body mass index, prior external radiation therapy, site of ureteral obstruction, and underlying malignancy (Table-3).

In our cost analysis, we determined that the mean cost for a single traditional polymer ureteral stent exchange is between $2,255 and $3,125 US dollars, while the mean cost for a single metallic ureteral stent exchange is between $3,170 and $4,040 US dollars, with their only difference being the cost of the actual stent being placed. The estimated annual cost for traditional polymer stents (exchanged every 90 days (3,4)) is between $9,648 and $13,128 US dollars, while the esti-

Figure 1 - Kaplan-Meir Analysis Median stent life calculated by Kaplan-Meier method: 288.4 days (95% CI= 277.4-321.2 days).
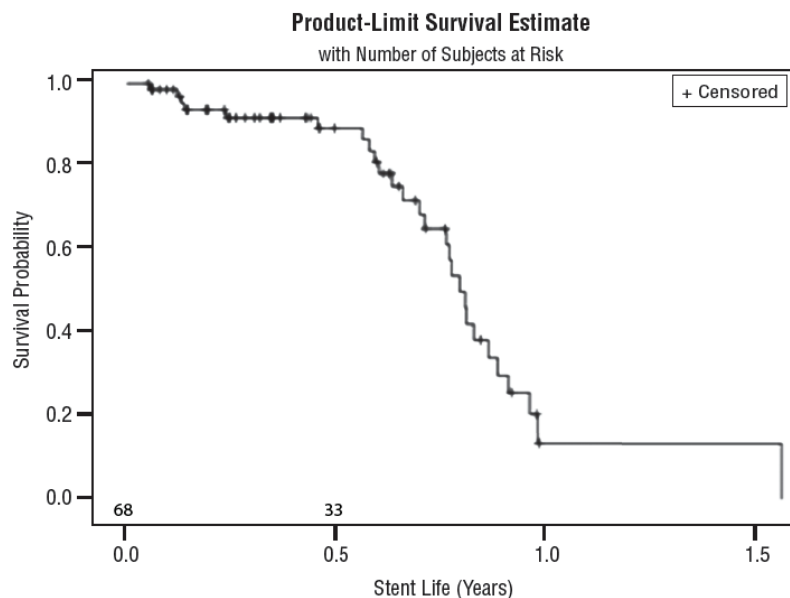
Table 3 - Predictive factors of metallic stent failure with p-values.

Variable	p value
Age at diagnosis	0.50
BMI	0.23
Malignancy Stage	0.38
Prior XRT	0.18
Sex	0.32
Site of Obstruction	0.94
Underlying malignancy	0.62

BMI = body mass index; **XRT =** radiotherapy

mated annual cost for metallic stents (exchanged every 288.4 days as noted in the present study) is between $4,211 and $5,313 US dollars. The Medicare cost of anesthesia for this procedure is estimated to be $130 US dollars, and the mean private health care insurance cost for anesthesia is $1,000 US dollars, which were used separately in these cost analysis calculations, hence the presented range of cost. Data used for the cost analysis is presented in Table-4. This results in between a 56.4% and 59.5% reduction in cost per patient--year, with the use of metallic ureteral stents in the management of poor ureteral drainage.

DISCUSSION

Deficiencies in upper tract drainage are a frequent problem encountered in routine urologic practice today. Conventional approaches in the management of chronic ureteral obstruction have been to place percutaneous nephrostomy drainage, which significantly decreases quality of life of the patient ailing from their malignancy (2). In addition, polymer ureteral stents have been used but have had disappointing results due to the frequency of stent exchanges (approximately every 3 months), stent encrustation, and pelvic tumor compression (1,2,12). Failure rates for traditional polymer stents in the setting of malignant ureteral obstruction are estimated to be between 40% and 60% (6,13). The use of metallic ureteral stents in the setting of deficient ureteral drainage obviates the need for an external urinary drainage bag, as well as decreasing the frequency of stent exchanges.

Metallic ureteral stents have been studied in a limited number of retrospective studies. Overall failure rates of metallic ureteral stents have ranged from 7% - 66% (5,7-11); however, most studies have been limited by low statistical power, with study populations as low as 14 patients. The present study is one of the largest single-institution studies, encompassing 50 patients, undergoing placement of 97 metallic ureteral stents. Our results show a failure rate of these stents of only 8.2%,

Table 4 - Cost Analysis.

	Metallic Stent	Polymer Stent
Stent Cost	$1,040	$125
Anesthesia Costs (Medicare)	$130	$130
Operating Room Fees	$2,000	$2,000
Average Lost Wages ($/day)[a]	$157	$157
Total Cost Per Stent Insertion	$3,327	$2,412
Stent Life (in years)	0.79	0.25[b]
Total Cost Per Year	$4,211	$9,648

[a] From Florida's Bureau of Labor Services
[b] From previously published literature (3,4)

exemplifying their clear benefit. Currently, metallic ureteral stents are indicated that they can be left in situ for up to 12 months (6). Our data shows a median stent life of 288.4 days before necessitating exchange. This is over three times longer than the average polymer stent life (3,4). In addition, although stents were elected to be exchanged between 9 to 12 months, we are now changing subsequent stents at 12 months with no additional sequelae (e.g. encrustation, decreased function, etc.). Longer stent in situ durations lead to less frequent trips to the operating room, decreased patient morbidity, decreased healthcare costs, and improved overall quality of life for the patient.

In addition, metallic ureteral stent placement procedures had minimal complications and were well tolerated by patients. Some patients complained of mild flank pain and/or dysuria directly after stent placement. This phenomenon was usually self-limiting, and probably due to expanding forces of the endoprosthesis (5). Goldsmith et al. described subcapsular hematoma formation following metallic stent placement in 12% of their study cohort. They argued that this was likely "related to the excessive length of the inner cannula relative to the outer sheath in the supplied introduced system" (8). In our larger single institution series, we did not experience any such complications and recommend gentle manipulation of the upper tracts during stent placement to avoid this issue.

To help predict treatment success or failure, we based our research on previously published peer reviewed scientific literature. As previously shown in Ganatra et al., the type of underlying malignancy did not predict stent success or failure in our series (13). Ganatra et al. also reported that gross tumor invasion noted at cystoscopy was a significant risk factor for stent failure and requirement of percutaneous nephrostomy (p = 0.008) (13). In addition, Goldsmith et al. reported that prostate cancer invading the bladder was a risk factor for stent failure (8). Bladder invasion was not specifically assessed as a risk factor for stent failure in our study. Wang et al. also showed that patients who had received previous radiation therapy had a significantly lower stent patency rate than those who did not receive previous radiation therapy. They hypothesized that radiation therapy causes ureteral fibrosis and impairs ureteral peristalsis, ultimately leading to more encrustation and a smaller ureteral lumen (11). Other studies nevertheless, have shown no difference in stent patency rates whether or not patients had received radiation therapy (8,10). Previous radiation therapy did not appear to predict stent outcome in our present series (p = 0.18).

We provide the first documented experience of metallic ureteral stents in the setting of cutaneous ureterostomies. Recent literature established that long term stenting (defined as greater than 3 months) of cutaneous ureterostomies improves their clinical outcome, decreasing stenosis in the left crossover ureter in the urinary diversion (14). 12 patients in our single institution series had metallic ureteral stents in the setting of cutaneous ureterostomies. The failure rate in this cohort was 16.7%, with a mean exchange rate of 220.3 days. The use of metallic ureteral stents in the setting of cutaneous ureterostomies appears to be a cost effective management for chronic stent placement in this population.

Metallic ureteral stents, when used in managing poor ureteral drainage, not only improved quality of life, but also is a cost-saving service. Despite the initial higher cost of the individual metallic stent versus traditional polymer ureteral stents ($1040 versus $125 US dollars, respectively), we report fewer surgical procedures (i.e. stent exchange) needed, which accounted for this cost difference. The overall cost reduction was estimated to be between 56.4% and 59.5% per patient-year, not taking into account other cost savings, including reduced post-operative office visits, fewer follow-up imaging studies, and any unforeseen operative complications.

We recognize several limitations to the present study, including the retrospective constitution of this single institution study design. Although larger (multicenter) studies have been conducted, our sample size of only 97 stent placements made our univariate and multivariate Cox regression analyses somewhat limited. Additionally, our study did not look at bladder tumor invasion as a risk factor for premature stent failure and also did not specifically characterize AUA symptom scores pre- and post-stent placement

within our study cohort. Furthermore, although our cost analysis examines the major variables of stent placement, it does not include data on failure and follow-up costs, such as repeat procedures, subsequent admissions, and necessary imaging. Cost analysis for patients with cutaneous ureterostomies and ileal conduits would differ slightly, however, these were not analyzed. Costs were calculated in patients with intact bladders. Lastly, the analysis took into account operating facility fees and anesthesia fees charged at our institutions, but these were not standardized across other institutions or regions.

CONCLUSIONS

In conclusion, this study highlights that metallic ureteral stents constitute a technically feasible solution for the management of deficiencies in ureteral drainage, while being well tolerated and imparting minimal complications to appropriately selected patients. Metallic ureteral stents can be left in situ for longer durations than traditional polymer ureteral stents and result in an estimated cost benefit of between 56.4% and 59.5%.

CONFLICT OF INTEREST

Dr. Philippe E. Spiess serves as a national lecturer for Cook Medical.

REFERENCES

1. Docimo SG, Dewolf WC: High failure rate of indwelling ureteral stents in patients with extrinsic obstruction: experience at 2 institutions. J Urol. 1989; 142: 277-9.
2. Wah TM, Irving HC, Cartledge J: Initial experience with the resonance metallic stent for antegrade ureteric stenting. Cardiovasc Intervent Radiol. 2007; 30: 705-10.
3. López-Huertas HL, Polcari AJ, Acosta-Miranda A, Turk TM: Metallic ureteral stents: a cost-effective method of managing benign upper tract obstruction. J Endourol. 2010; 24: 483-5.
4. Taylor ER, Benson AD, Schwartz BF: Cost analysis of metallic ureteral stents with 12 months of follow-up. J Endourol. 2012; 26: 917-21.
5. Liatsikos EN, Karnabatidis D, Katsanos K, Kallidonis P, Katsakiori P, Kagadis GC, et al.: Ureteral metal stents: 10-year experience with malignant ureteral obstruction treatment. J Urol. 2009; 182: 2613-7.
6. Borin JF, Melamud O, Clayman RV: Initial experience with full-length metal stent to relieve malignant ureteral obstruction. J Endourol. 2006; 20: 300-4.
7. Benson AD, Taylor ER, Schwartz BF: Metal ureteral stent for benign and malignant ureteral obstruction. J Urol. 201; 185: 2217-22.
8. Goldsmith ZG, Wang AJ, Bañez LL, Lipkin ME, Ferrandino MN, Preminger GM, et al.: Outcomes of metallic stents for malignant ureteral obstruction. J Urol. 2012; 188: 851-5.
9. Modi AP, Ritch CR, Arend D, Walsh RM, Ordonez M, Landman J, et al.: Multicenter experience with metallic ureteral stents for malignant and chronic benign ureteral obstruction. J Endourol. 2010; 24: 1189-93.
10. Nagele U, Kuczyk MA, Horstmann M, Hennenlotter J, Sievert KD, Schilling D, et al.: Initial clinical experience with full-length metal ureteral stents for obstructive ureteral stenosis. World J Urol. 2008; 26: 257-62.
11. Wang HJ, Lee TY, Luo HL, Chen CH, Shen YC, Chuang YC, et al.: Application of resonance metallic stents for ureteral obstruction. BJU Int. 2011; 108: 428-32.
12. Chitale SV, Scott-Barrett S, Ho ET, Burgess NA.: The management of ureteric obstruction secondary to malignant pelvic disease. Clin Radiol. 2002; 57: 1118-21.
13. Ganatra AM, Loughlin KR: The management of malignant ureteral obstruction treated with ureteral stents. J Urol. 2005; 174: 2125-8.
14. Rodríguez AR, Lockhart A, King J, Wiegand L, Carrion R, Ordorica R, et al.: Cutaneous ureterostomy technique for adults and effects of ureteral stenting: an alternative to the ileal conduit. J Urol. 2011; 186: 1939-43.

Correspondence address:
Philippe E. Spiess, MD
Associate Member,
Department of Genitourinary Oncology
Moffitt Cancer Center
12902 Magnolia Drive, Office 12538
Tampa, FL 33612, USA
Fax: + 1 813 745-8494
E-mail: philippe.spiess@moffitt.org