

Predicting the failure of retrograde ureteral stent insertion for managing malignant ureteral obstruction in outpatients

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Abstract. Malignant ureteral obstruction (MUO) is an unpropitious sign that is commonly observed in patients with advanced incurable cancer. The present study aimed to evaluate predictive factors for the failure of retrograde ureteral stent insertion in the management of MUO in outpatients. A total of 164 patients with MUO were retrospectively assessed in this study. Clinical factors, including age, gender, type of malignancy, level of obstruction, cause of obstruction, pre-operative creatinine level, degree of hydronephrosis, condition of the contralateral ureter, prior radiotherapy, Eastern Cooperative Oncology Group performance status (ECOG PS), bladder wall invasion and technical failure, were recorded for each case. Univariate and multivariate logistic regression analyses were used to investigate the risk factors for predicting the failure of retrograde ureteral stent insertion. In total, 38 out of 164 patients experienced bilateral obstruction, therefore, a total of 202 ureteral units were available for data analysis. The rate of insertion failure in MUO was 34.65%. Multivariate analyses identified ECOG PS, degree of hydronephrosis and bladder wall invasion as independent predictors for insertion failure. Overall, the present study found that rate of retrograde ureteral stent insertion failure is high in outpatients with MUO, and that ECOG PS, degree of hydronephrosis and bladder invasion are potential independent predictors of insertion failure.

Introduction

Malignant ureteral obstruction (MUO) is an unpropitious sign that is commonly observed in patients with advanced incurable cancer. MUO may result from extrinsic compression by a pelvic or retroperitoneal primary lesion, a metastatic tumor from a distant primary lesion or peritonitis carcinomatosa of a gastrointestinal tract primary lesion. In addition, invasion of the ureter by cervical, ovarian, bladder, prostate or colorectal cancer can cause MUO. Once an obstruction occurs, it may progress to renal insufficiency with the appearance of an electrolyte imbalance, uremia or a life-threatening urinary tract infection, and effective management must be scheduled, particularly if further chemotherapy is planned or required (1,2).

In patients with MUO, retrograde ureteral stenting (RUS) under general anesthesia is usually considered as the first treatment choice, and if stent failure occurs, a percutaneous nephrostomy (PCN) is considered. In the majority of developing countries, such as China, due to a large population base and limited medical resources, cystoscopic RUS under local anesthesia is first attempted in such patients prior to other methods (1,2). The advantages of this procedure are its simplicity and convenience, with no requirement for hospitalization, and a cheaper cost. However, cystoscopic ureteral stent insertion is a challenging procedure even for the most experienced urologists, with a mean failure rate of 15.0-27.5% (3-12).

While the majority of previous studies have focused on the factors for stent functional failure in patients with MUO, such as baseline levels of serum creatinine (SCr), degree of hydronephrosis and being male in gender (4,5,8), studies on the predictive factors for the failure of retrograde ureteral stent placement under local anesthesia in outpatients have been rare (10).

Accurately predicting the possible failure of RUS insertion could significantly reduce the number of unnecessary procedures, as well as the associated pain. The present study retrospectively reviewed the experiences of our single institute in the treatment of MUO using RUS in outpatients and attempted to identify potential predictors for insertion failure. The present study subsequently attempted to develop and recommend appropriate future treatment strategies according to these factors.

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Abbreviations: MUO, malignant ureteral obstruction; RUS, retrograde ureteral stenting; PCN, percutaneous nephrostomy; ECOG PS, Eastern Cooperative Oncology Group performance status; SCr, serum creatinine

Key words: malignant ureteral obstruction, predictive factor, retrograde ureteral stenting

Materials and methods

Patient selection and data collection. All patients with MUO who required decompression by retrograde placement of an indwelling ureteral stent at Fudan University Shanghai Cancer Center (Shanghai, China) between January 2008 and April 2013 were retrospectively enrolled in this study under institutional review board approval.

Indwelling ureteral stent placement was indicated when MUO was strongly suspected from radiographic evidence without fever or sepsis. RUS exclusion criteria included ureteral obstruction induced by bladder cancer, iatrogenic damage to the ureter, previous cystectomy and urinary diversion procedures or renal transplants. Patients who had urological abnormalities or received previous urological surgeries were excluded.

Information on age and gender, type of malignancy, level of obstruction, cause of obstruction, pre-operative creatinine level, degree of hydronephrosis, condition of the contralateral ureter, prior radiotherapy, Eastern Cooperative Oncology Group performance status (ECOG PS), invasion into the bladder and technical failure were retrieved from the medical records. With the exception of age, pre-operative creatinine level and degree of hydronephrosis, other factors were coded as categorical variables. Computed tomography (CT), ultrasound or magnetic resonance imaging (MRI) results were reviewed to determine pre-operative gross tumor invasion into the bladder wall and the degree of hydronephrosis. Obstruction level was defined as the proximal or distal ureter based on the location of the obstruction above or below the sacroiliac joints. Obstruction was classified as extrinsic tumor compression or direct tumor invasion.

Surgery. At Fudan University Shanghai Cancer Center, all MUO patients without infection underwent RUS with a flexible cystoscope on an outpatient basis. If the first treatment failed, the patients were admitted to the hospital and treated with ureteroscopic RUS under general anesthesia. If the retrograde stent insertion failed, the patients were referred for placement of a unilateral PCN tube, or a stent was placed in the contralateral side for prophylactic purposes.

RUS failure was defined as an inability to place a ureteral stent using cystoscopy. Stent failure was defined as any ureteral unit (UU) in which stent insertion failed or any UU that continued to cause symptoms for the patient after stent placement (3-12). Stents were inserted by three experienced urological surgeons on an outpatient basis, using local anesthesia. Each patient provided informed consent prior to stent placement. All patients received 10 ml 2% lidocaine gel, which was retained in the urethra. A 6-F and 22-26 cm long ureteric stent (Endo-sof; Cook Urological, Spencer, IN, USA) was then passed over the hydrophilic guidewire under cystoscopic guidance. The wire was subsequently removed and coiling of the ends of the stent was confirmed with fluoroscopy. An abdominal X-ray was available in all cases to confirm correct stent position, and the stent was changed every 4 to 6 months on an outpatient basis.

Statistical analysis. Categorical variables were analyzed using contingency tests (Fisher's exact test and χ^2 test), while continuous data were analyzed using Student's t-test or non-parametric testing (Wilcoxon rank-sum test). Univariate and multivariate logistic regression analyses were performed

Table I. Clinical characteristics of 164 patients with retrograde ureteral stenting.

Variables	Value
Age, years	
Mean (median)	49.6 (49)
Range	22-79
Gender, n (%)	
Male	20 (12.2)
Female	144 (87.8)
Laterality, n (%)	
Unilateral	126 (76.8)
Bilateral	38 (23.2)
Type of malignancy, n (%)	
Cervical	103 (62.8)
Ovarian	19 (11.6)
Gastric	10 (6.1)
Rectal	11 (6.7)
Other ^a	21 (12.8)

^aSarcoma (n=6), endometrium (n=3), breast (n=3), lung (n=2), gallbladder (n=2), pancreas (n=2), prostate (n=2) and liver (n=1).

to determine the predictors of stent failure. Odds ratios (ORs) were computed together with 95% confidence intervals (CIs). $P < 0.05$ was considered to indicate a statistically significant difference. All statistical analyses were performed using SPSS software, version 19.0 (SPSS Inc., Chicago, IL, USA).

Results

Patient characteristics and stent placement results. In the current study, 164 patients underwent RUS, 144 cases (87.8%) were women and the median age of the group was 49.6 years, (range, 22-79 years). The distribution of the types of malignancies is shown in Table I; the most common primary malignancy causing MUO was cervical cancer (62.8%). Table II shows the clinical and radiographical parameters in the groups with successful and failed stent placement. Of the 164 patients, 38 experienced bilateral obstruction and 126 had unilateral involvement. Thus, a total of 202 UUs were available for analysis. The degree of pre-operative hydronephrosis ranged from 5 to 50 mm (median, 21.4 mm). RUS could not be performed in 70 (34.7%) UUs, and in 12 of these cases it was impossible to identify the ureteral orifice. The failure rate was 87.5% in patients with hydronephrosis >30 mm ($P=0.001$ vs. <30 mm), 66.7 vs. 28.4% in patients with ECOG PS >1 and ≤ 1 , respectively ($P=0.001$), and 87.5 vs. 32.5% in patients with and without bladder invasion, respectively ($P=0.005$).

Univariate analysis of stent failure. Table II lists the results of the univariate analysis, which evaluated the risk associated with failure. Univariate analysis of pre-operative clinical characteristics identified a total of six statistically significant predictors of insertion failure: ECOG PS (OR, 5.042; $P < 0.001$; 95% CI, 2.272-11.190), degree of hydronephrosis (OR, 5.733;

Table II. Clinical characteristics of UU and univariate analysis of variables associated with failure of stent insertion in 202 UUs.

Variable	Success	Failure	P-value	OR	95% CI
Mean age, years	50.48	48.20	0.133	0.978	0.950-1.007
Mean SCr, $\mu\text{mol/l}$	90.83	93.66	0.648	0.999	0.994-1.004
Gender, n (%)			0.380	0.688	0.297-1.591
Male	15 (57.7)	11 (42.3)			
Female	117 (66.5)	59 (33.5)			
ECOG, n (%)			0.001	5.042	2.272-11.190
≤ 1	121 (71.6)	48 (28.4)			
2-3	11 (33.3)	22 (66.7)			
Hydronephrosis degree, n (%)			<0.001	5.733	3.521-9.334
≤ 10	19 (95.0)	1 (5.0)			
≤ 20	76 (87.4)	11 (12.6)			
≤ 30	32 (58.2)	23 (41.8)			
≤ 40	5 (15.6)	27 (84.4)			
> 40	0 (0.0)	8 (100.0)			
Bladder invasion, n (%)			0.005	14.556	1.753-120.868
No	131 (67.5)	63 (32.5)			
Yes	1 (12.5)	7 (87.5)			
Cause of hydronephrosis, n (%)			0.006	3.695	1.383-9.871
Tumor compression	125 (68.3)	58 (31.7)			
Invasion of the ureter	7 (36.8)	12 (63.2)			
Prior radiotherapy, n (%)			0.004	2.403	11.325-4.357
No	90 (73.2)	33 (26.8)			
Yes	42 (53.2)	37 (46.8)			
Obstruction level, n (%)			0.253	1.414	0.782-2.545
Proximal ureter	62 (69.7)	27 (30.3)			
Distal ureter	70 (61.9)	43 (38.1)			
Primary disease, n (%)			0.233	-	-
Cervical	74 (61.2)	47 (38.8)			
Ovarian	22 (84.6)	4 (15.4)			
Gastric	11 (61.1)	7 (38.9)			
Rectal	10 (71.4)	4 (28.6)			
Other	15 (65.2)	8 (34.8)			
Side of stenting, n (%)			0.014	0.477	0.263-0.866
Left	41 (54.7)	34 (45.3)			
Right	91 (71.7)	36 (28.3)			
Laterality, n (%)			0.103	0.600	0.324-1.112
Unilateral	77 (61.1)	49 (38.9)			
Bilateral	55 (72.4)	21 (27.6)			

UU, ureteral units; OR, odds ratio; CI, confidence interval; SCr, serum creatinine.

$P < 0.001$; 95% CI, 3.521-9.334), bladder invasion (OR, 14.556; $P = 0.005$; 95% CI, 1.753-120.868), cause of hydronephrosis (OR, 3.695; $P = 0.006$; 95% CI, 1.383-9.871), prior radiotherapy (OR, 2.403; $P = 0.004$; 95% CI, 11.325-4.357) and side of stenting (OR, 0.477; $P = 0.014$; 95% CI, 0.263-0.866).

Multivariate analysis of stent failure. The results of multivariate Cox regression analysis for the prediction of failure in 202 UUs are summarized in Table III. ECOG PS ($P = 0.039$;

OR, 0.278; 95% CI, 0.083-0.945), degree of hydronephrosis ($P = 0.000$; OR, 6.459; 95% CI, 3.434-12.149) and bladder invasion ($P = 0.010$; OR, 77.340; 95% CI, 2.779-829.527) were statistically significant predictive factors for the failure of RUS.

Discussion

Malignant ureteral obstruction, whether unilateral or bilateral, is a frequent complication of advanced incurable pelvic or

Table III. Multivariate analysis between patient characteristics for prediction of failure of stent insertion.

Variable	P-value	OR	95% CI
ECOG PS (1 vs. 2-3)	0.039	0.278	0.083-0.945
Hydronephrosis degree (continuous)	0.000	6.459	3.434-12.149
Bladder invasion (yes vs. no)	0.010	77.340	2.779-829.527
Cause of hydronephrosis (ureter invasion vs. tumor compression)	0.758	1.253	0.299-5.249
Prior radiotherapy (yes vs. no)	0.123	2.174	0.811-5.828
Side (right vs. left)	0.113	0.628	0.220-1.790

OR, odds ratio; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status.

retroperitoneal malignancy and indicates a poor prognosis. To date, there is no consensus regarding the correct management of MUO (8,13,14). The use of ureteral stents to bypass the obstruction is common in clinical practice, and RUS is more advantageous than PCN, particularly in view of the limited life expectancy of patients with advanced malignancies (3,4,7). However, the incidence of insertion failure is markedly higher in cases of MUO, ranging from 15.0 to 27.5% (3-12). This high failure rate may be associated with extrinsic compression or invasion of the ureter by tumors, which may lead to the bending and deformation of the ureter, which then increases resistance during intubation in the majority of advanced malignancies (15). In a previous study of 61 advanced malignancies, the stent failed to indwell in 21.3% of patients and 17.9% of UUs (4). In addition, in a study reporting 14 years of experience in the management of extrinsic ureteral obstruction, 27.5% of UUs with MUO had insertion failure (11). By contrast, in one study published in 2008, only 12.2% of UUs with MUO had insertion failure (7). In the present cohort, the failure rate was 34.65% and this was higher than that in recent studies. The differences in the incidence of insertion failure may be due to various stent designs, or differences in patient demographics, sample size and the etiology of the malignancy. Another important difference is that stents were inserted on an outpatient basis using local anesthesia, but not under spinal or general anesthesia compared with previous studies. In the majority of areas in China, due to the large number of patients and the limited medical resources, the procedure is usually performed under local anesthesia in the outpatient operating room. The disadvantage of this method is that patients usually cooperate badly due to anxiety and pain during the surgery. Once the first step failed, the majority of the men were successfully treated with ureteroscopic RUS under general anesthesia in the Department of Urology, and this will be described in another future study.

Understanding the risk factors associated with the possible failure of RUS under local anesthesia may assist urologists in communicating better with patients, in selecting high-risk patients in whom to directly place stents under general anesthesia, and in avoiding unnecessary cystoscopic procedures and associated pain, infection risks and other complications. Previous studies reported several risk factors for stent failure (insertion failure and functional failure), which included baseline SCr, gross tumor invasion noted at cystoscopy, degree of hydronephrosis and the male gender (2,3,8,10). However, the majority of these studies were conducted over long periods, various

anesthesia styles and ureteric stents were used, and certain risk factors were obtained following cystoscopy. Furthermore, no study has been performed to predict the factors for RUS placement failure in a Chinese cohort. The present study analyzed the association between 11 factors and insertion failure, and demonstrated several independent pre-operative predictive variables, including degree of hydronephrosis, ECOG PS and bladder invasion diagnosed by imaging technology.

A previous study of 53 MUO patients indicated that the degree of renal pelvis separation was highly correlated with stent failure (3). Yossepowitch *et al* also suggested that in patients with extrinsic ureteral obstruction, a higher degree of hydronephrosis was associated with a greater likelihood of stent failure (2). As aforementioned, the present study also demonstrated that an increase in the degree of hydronephrosis was independently associated with insertion failure. Ureteral stenting often fails in those with a heavier renal pelvis separation, and the failure rate in the present study was 87.5% in patients with hydronephrosis >30 mm. Thus, a ureteral stent should be placed as early as possible; if stenting in the hydronephrosis side fails, prophylactic stenting in the contralateral side is highly recommended. In addition, in patients with renal pelvis separation of >30 mm, direct RUS under general anesthesia could be performed.

In the present study, ECOG PS ≥ 2 (OR, 3.597) predicted the failure of retrograde stenting, and the failure rate was 66.7%. These results were in agreement with those of the study by Kamiyama *et al* (3). Such patients have more advanced tumor staging and their general health is poorer (10). As found in the present study, many of them are unable to cooperate with their doctors, and cannot tolerate the pain associated with the procedure. Therefore, patients with worse ECOG PS are not candidates for stent insertion on an outpatient basis.

In the present study, 7 out of 8 patients diagnosed with bladder wall invasion on imaging failed to undergo stent placement, and multivariate analysis showed that bladder wall invasion was a significant predictive factor for stent failure (OR, 77.340). Jeong *et al* (14) retrospectively reviewed the use of ureteric stents placed for 86 patients with a non-urological MUO, and found that 13 (15%) experienced failure of retrograde stent insertion, and that the risk of failure for stent insertion significantly increased with the presence of bladder invasion (OR, 27.04; $P < 0.001$). Ganatra and Loughlin (11) analyzed 157 patients with MUO who underwent retrograde ureteral stent placement, and found that when invasion into the bladder was noted on cystoscopy, 55.9% (19/34; $P = 0.008$) developed stent failure. These patients usually

had large pelvic malignancies, which may directly invade the bladder or ureter and press on the renal duct (6,9). For these reasons, if a patient is found to have bladder invasion on CT or MRI, stent placement under local anesthesia is not suitable.

To the best of our knowledge, the relevant previous studies did not determine the predictive value of prior radiotherapy and the contralateral ureter in RUS (16,17). In clinical practice, urologists do not place a stent in patients with prior radiotherapy, as a number of these patients are diagnosed with radiation cystitis or retroperitoneal fibrosis after radiotherapy, and these diseases may interfere with the maintenance of urinary drainage. In the present study, bilateral hydronephrosis was not associated with insertion failure, and prior radiotherapy was shown to be associated with insertion failure on univariate analysis. However, multivariate analysis failed to confirm prior radiotherapy as an independent risk factor for MUO ($P=0.123$). This may be the result of the relatively small sample size, and the fact that, in the present study, the presence or absence of radiotherapy was predominantly listed as 'yes' or 'no', without any quantitation. The study found that the mean degree of hydronephrosis between patients treated with and without radiotherapy was significantly different, and the majority of patients who had received radiotherapy exhibited a higher degree of hydronephrosis. In addition, gender and baseline SCr levels were not associated with stent failure in the univariate analysis in the present study, and just one previous study found these two parameters to be risk factors for indwelling stent failure (18). Multivariate analysis did not confirm the side of stenting as an independent risk factor ($P=0.113$), which may have been due to possible selection bias.

The present study did have certain limitations. The study population was retrospectively enrolled from a single center in China. Although this is one of the largest series to date on RUS for malignant ureteral compression, ~74% of the patients presented with a pelvic gynecological malignancy and the subgroup analysis of cancer type was too small to reach significance. Thus, these cases are not representative of insertion failure in the general population of patients with these types of cancer. Secondly, the stents were inserted by three urologists, but the achievement ratio was not compared between the different urological surgeons. Thirdly, only one size of stent was used, and the pain score was not collected to analyze the association with insertion failure. Fourthly, due to a lack of follow-up, the outcome after stenting was not analyzed. Nevertheless, compared with previous studies, the present cohort was enrolled in a short period of time, and all the patients received the same anesthesia style and ureteric stents. Predictive factors were identified using only pre-operative variables, which are easily measured by standard assays in the majority of institutions. This facilitates the oncologist to determine the optimal treatment options for managing MUO and allows good communication with patients. In the future, a prospective study should enroll a larger number of patients and obtain more clinicopathological factors, with use of a good follow-up plan.

In conclusion, the rate of RUS insertion failure was high in outpatients with MUO. This retrospective analysis demonstrated that ECOG PS, degree of hydronephrosis and bladder invasion were independent predictive factors for the failure. These variables can be used to optimize the management of MUO. We suggest that a ureteral stent should be placed as

early as possible. Outpatient RUS surgery is not recommended for patients with hydronephrosis >30 mm, an ECOG PS ≥ 2 or for those with bladder invasion detected on CT or MRI.

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