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ARTICLE

External validation of a simplified prognostic model for survival in patients with extrinsic malignant ureteral obstruction treated with tandem ureteral stents – a retrospective cohort study

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ABSTRACT

Introduction: Prognostic models of survival can identify patients with extrinsic malignant ureteral obstruction who will benefit from long-term drainage as offered by tandem ureteral stents. The study aims to validate a simplified prognostic model published by Cordeiro et al. and to identify additional prognostic predictors in a cohort of patients drained solely with tandem ureteral stents.

Methods: Medical records of consecutive patients who underwent drainage of malignant ureteral obstruction with tandem ureteral stents between 2007 and 2020 were reviewed retrospectively; patients with benign ureteral obstruction were excluded. Risk factors for survival included were: [1] the number of malignancy-related events (categorized as $\geq$4 and <4) and [2] the Eastern Cooperative Oncology Group Index (categorized as $\geq$2 and <2)]. Patients with $\geq$1 risk factor were grouped as intermediate-unfavorable risk and those without risk factors as favorable risk. The Kaplan–Meier and log-rank tests were used for survival analysis. Univariable and multivariable Cox regression analyses were used to identify predictors of outcome.

Results: The study cohort consisted of 65 patients; the median age was 60 years (IQR 51–72). The median follow-up time from diagnosis of hydronephrosis was 51 months (IQR 38–64). Estimated probabilities of survival at 1 month, 6 months 1 year, and 2 years were 100%, 87%, 75% and 57%, respectively in the favorable risk group ($n = 40$), and in the intermediate-unfavorable risk group ($n = 25$), 96%, 72%, 52%, and 20%, respectively, ($p = .003$). On multivariable analysis, the presence of $\geq$4 malignancy-related events (HR = 2.04, 95% CI [1.07–3.86], $p = .03$) and lung metastasis (HR = 2.37, 95% CI [1.0–5.6], $p = .05$) were associated with shorter survival.

Conclusions: Our findings validate the prognostic model published by Cordeiro et al. The model can be applied when counseling patients being considered for drainage with tandem ureteral stents.

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Introduction

Malignant ureteral obstruction (MUO) can be caused by locally advanced genitourinary malignancies or by metastatic disease to retroperitoneal lymph nodes, both of which compress and obstruct the ureter. If left untreated, the obstruction may lead to sepsis and/or renal unit failure [1]. Treatment options to relieve the obstruction include drainage with a percutaneous nephrostomy tube (PCN) or retrograde ureteral stent insertion using either a single stent or double (tandem) stents [2–4].

Tandem ureteral stents are efficacious in obstruction relief and provide long-term drainage with an indwelling time of up to one year [5,6], unlike PCN or a single stent which require replacement every 3–6 months. However, the presence of tandem stents may be associated with stent-related symptoms (e.g. increased urinary discomfort, pain during voiding) [5,7]. While no direct comparison was performed in such symptoms between single and tandem stents, these symptoms can be avoided when draining the kidney with a nephrostomy tube [8]. Treatment choice should aim to minimize the amount of replacement procedures.

Prognostic models can stratify patients according to their estimated survival time and identify those with long expected survival time that will most likely benefit from long-term drainage and less drain exchange procedures. Ishioka et al. found that several risk factors, including albumin <3 [g/dL], $\geq$3 malignancy-related events, and severity of hydronephrosis, were associated with decreased survival in a group of patients with MUO drained with nephrostomy tubes [9,10]. A simplified prognostic model published by Cordeiro et al. identified two main risk factors in patients drained with both single ureteral stent or PCN, including the number of malignancy-related events (categorized as $\geq$4 and <4), and the Eastern Cooperative Oncology Group (ECOG)

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index (categorized as $\geq$2 and $<$2) [11]; however, this risk stratification model has not been previously validated.

The current study aims to externally validate the model published by Cordeiro et al. in a cohort of patients with MUO drained solely by tandem ureteral stents and evaluate additional possible prognostic factors of survival.

Materials and methods

Study population

The study was approved by the Institutional Review Board committee (#0525-21-TLV). Medical records of 91 consecutive patients who underwent drainage of ureteral obstruction with tandem ureteral stents between January 2007 and January 2020 were reviewed. Twenty-six patients with benign ureteral obstruction were excluded, leaving 65 patients for further analyses.

Baseline clinical characteristics of the study cohort, including age, sex, ECOG index and underlying malignant disease were collected by the authors all of whom are board-certified urologists. Reports and images of axial imaging studies performed during the oncological follow-up which led to the diagnosis of hydronephrosis were reviewed for the severity and side of hydronephrosis, the presence of locally advanced disease, the presence, number and location of metastases, and the presence of pleural effusion and ascites. ECOG index (5-point scale) [12] was determined during patient admission before undergoing tandem ureteral stent insertion and retrospectively retrieved from the electronic medical records. Preoperative blood tests collected up to 14 d before the planned procedure were reviewed for hemoglobin levels [g/dL], neutrophil count [$10^3/\mu L$], lymphocyte count [$10^3/\mu L$], platelet count [$10^3/\mu L$], sodium [mmol/L], urea [mg/dL], creatinine [mg/dL] and albumin [g/dL] levels. The Neutrophil lymphocyte ratio (NLR) was calculated by dividing the absolute number of neutrophils and lymphocytes. Similarly, platelet lymphocyte ratio (PLR) was calculated by dividing the absolute platelet count and the absolute lymphocyte count. Glomerular filtration rate (GFR) was calculated using creatinine levels prior to kidney drainage based on the CKD-EPI equation [13].

Surgical Procedure

Patients underwent tandem ureteral stent insertion under general anesthesia. The obstructed segment was assessed with fluoroscopy after injecting contrast media in an antegrade and/or retrograde manner. A hydrophilic guidewire was introduced and passed across the obstruction, followed by the insertion of an 8/10 F co-axial dilator sheath. Subsequently, a second guidewire was passed across the obstructed segment. The ureteral narrowing was dilated as needed by a high-pressure balloon (UroMax Ultra^{TM}, Boston Scientific). Finally, two 7 F/26–28 cm hydrophilic low-friction, Percuflex Plus^{TM} stents (Boston Scientific) were placed [5].

Prognostic model

Patients were stratified into risk groups according to the Cordeiro et al. classification model based on the number of metastatic events related to malignancy (categorized as $\geq$4 and $<$4), and ECOG index (categorized as $\geq$2 and $<$2), Patients with $\geq$1 risk factors were categorized as intermediate-unfavorable risk and those without risk factors as a favorable risk group.

Statistical analysis and outcomes

Study findings were reported using descriptive statistics. Categorical variables were reported as frequency and percentage, and continuous variables were reported as the median and interquartile range. Baseline clinical characteristics were compared between the favorable and the intermediate-unfavorable risk groups using the Mann–Whitney *U*-test for continuous variables and the Fisher exact test for categorical variables.

The study outcome was overall survival. Time to death or last follow-up was calculated from the initial diagnosis of hydronephrosis. People who did not die during the study period were censored at the time of their last follow-up visit. The Kaplan-Meier method and log-rank test were used to evaluate the overall survival of risk groups. Time-dependent ROC curves were used to evaluate the predictive performance of the risk groups for overall survival.

In an attempt to find additional predictors of outcome, we performed univariable Cox proportional hazard regression analyses to evaluate the association between baseline characteristics and survival outcomes. NLR and PLR were previously associated with the aggressiveness and outcome of tumors and were therefore assessed as additional prognostic factors of survival [14–16]. *p*-values were adjusted due to multiple testing using the false discovery rate (FDR) method. A multivariable Cox proportional hazard regression model was build using variables who were found to be statistically significant on the univariable models. Patients with missing data were excluded from univariable and multivariable statistical analyses associated with this data.

All tests were two-sided. A *p*-value of $<$.05 was considered statistically significant. R programming language version 4.1.2 and RStudio^{TM} version 1.4.1717 were used for all statistical analyses.

Results

The study cohort consisted of 65 patients (52 females and 13 males) at a median age of 60 years (IQR 51–72). The baseline clinical characteristics of the study cohort are reported in Table 1. During the first procedure of tandem stent placement 30 patients (46%) required balloon dilatation. Stent failure and nephrostomy tube placement occurred in 8 patients (12%); 6 patients (9%) in whom the stents did not drain appropriately, and 2 patients (3%) who suffered from severe discomfort due to the presence of the stents. The median time to stent failure was 15 months (IQR 8–26).

Table 1. Baseline characteristics of patients ($n = 65$) with malignant ureteral obstruction who underwent drainage solely by tandem ureteral stents during 2007–2020.

Variable		Value, $n = 65$
Age in years (median [IQR])		60 [51, 72]
Time from hydronephrosis to tandem stent insertion in months (median [IQR])		2 [1, 2]
Sex (%)	Male	13 (20)
	Female	52 (80)
ECOG index (%)	<2	61 (94)
	≥2	4 (6)
Estimated GFR (median [IQR])		63 [37, 85]
Bilateral hydronephrosis (%)	No	52 (80)
	Yes	13 (20)
Hydronephrosis severity (%)	Grade 1–2	29 (45)
	Grade 3–4	36 (55)
Malignancy origin (%)	Gastrointestinal	31 (48)
	Genitourinary	20 (31)
	Retroperitoneal Sarcoma	6 (9)
	Other	8 (12)
Locally advanced disease (%)	No	20 (31)
	Yes	45 (70)
Metastatic disease (%)	No	13 (20)
	Yes	52 (80)
Malignancy-related events (%)	<4	42 (65)
	≥4	23 (35)
Lung metastases (%)	No	57 (88)
	Yes	8 (12)
Bone metastases (%)	No	59 (91)
	Yes	6 (9)
Liver metastases (%)	No	53 (82)
	Yes	12 (19)
Retroperitoneal metastases (%)	No	22 (34)
	Yes	43 (66)
Pelvic metastases (%)	No	43 (66)
	Yes	22 (34)
Peritoneal metastases (%)	No	47 (72)
	Yes	18 (28)
Pleural effusion (%)	No	63 (97)
	Yes	2 (3)
Ascites (%)	No	61 (94)
	Yes	4 (6)
NLR (median [IQR])		4 [2.7, 6.8]
PLR (median [IQR])		242 [155, 350]
Risk groups (%)	Intermediate-unfavorable	25 (39)
	Favorable	40 (62)

IQR: interquartile range; ECOG: Eastern Cooperative Oncology Group; GFR: glomerular filtration rate; NLR: neutrophil-lymphocyte ratio; PLR: platelet lymphocyte ratio.

The most common underlying malignancy was colorectal carcinoma ($n = 21$, 32%), followed by ovarian cancer ($n = 11$, 17%). Twenty-three patients (35%) had ≥4 malignancy-related events, and 4 (6%) had an ECOG ≥2. Therefore, 40 (62%) patients were included in the favorable risk groups, and 25 (38%) were included in the intermediate-unfavorable risk group. The median NLR value was 4 (IQR 2.7–6.8), and the median PLR value was 242 (IQR 155–350). Baseline clinical characteristics stratified according to risk groups are reported in Supplementary Table 1. After adjusting for multiple testing, patients within the intermediate-unfavorable risk group had a significantly higher rate of metastatic disease, ≥4 metastatic-related events, retroperitoneal metastases, pelvic metastases, and peritoneal metastases.

The median duration of follow-up for survivors was 51 months (IQR 38–64). A total of 52 patients died during the follow-up period at a median time of 16 months (IQR 9–25). The median time from diagnosis of hydronephrosis to insertion of tandem ureteral stents was 2 months (IQR 1–2). When stratified by risk groups, the median overall survival time was 26 months (IQR 10–49) for the favorable risk group compared to 13 months (IQR 5–24) for the intermediate-unfavorable risk group. Estimated survival probabilities at 1 month, 6 months, 1 year, and 2 years were 98%, 81%, 66% and 42% for the whole cohort, 100%, 87%, 75% and 57% for the favorable risk group and 96%, 72%, 52% and 20% for the intermediate-unfavorable risk group, respectively. Overall survival times differed significantly between the risk groups ($p = .0029$, log-rank test, Figure 1). Time-dependent ROC curves for overall survival based on the risk groups showed an AUC of 0.7 in the first 30 days and 0.538 after 180 days (Figure 2).

On exploratory univariable Cox proportional hazards regression analyses including baseline characteristics of the study cohort, after adjusting for multiple testing, ≥4 malignancy-related events (HR 2.45, 95% CI 1.36–4.4, adjusted p-value = .03) and presence of lung metastases (HR 3.5, 95% CI 1.58–7.92, adjusted p-value = .03) were associated with worse overall survival (Table 2). On multivariate analysis of adjusted significant variables, which included the two significant findings on univariable analysis the presence of both was associated with adverse outcomes, however only ≥4 malignancy-related events remained significant based on standard definitions. When performing a sensitivity analysis which included non-adjusted significant variables, we found an association between lung

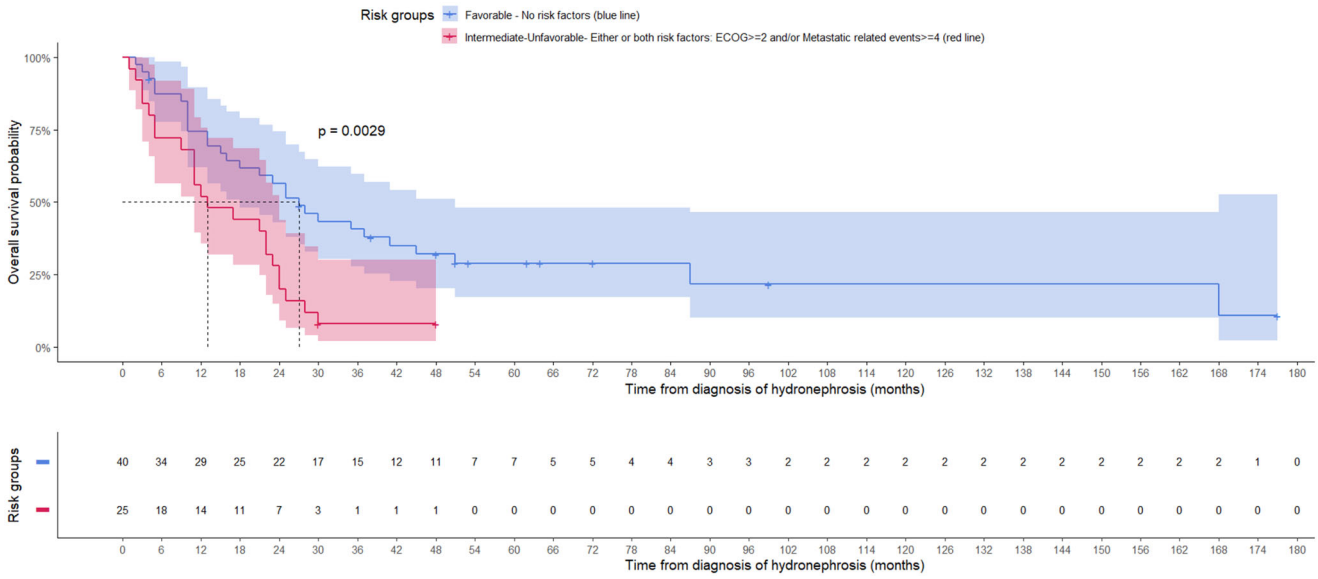

Figure 1. Kaplan–Meier curves of survival probability from diagnosis of hydronephrosis for patients with malignant ureteral obstruction who underwent drainage solely by tandem ureteral stents between 2007 and 2020 stratified according to Cordeiro et al. risk groups.

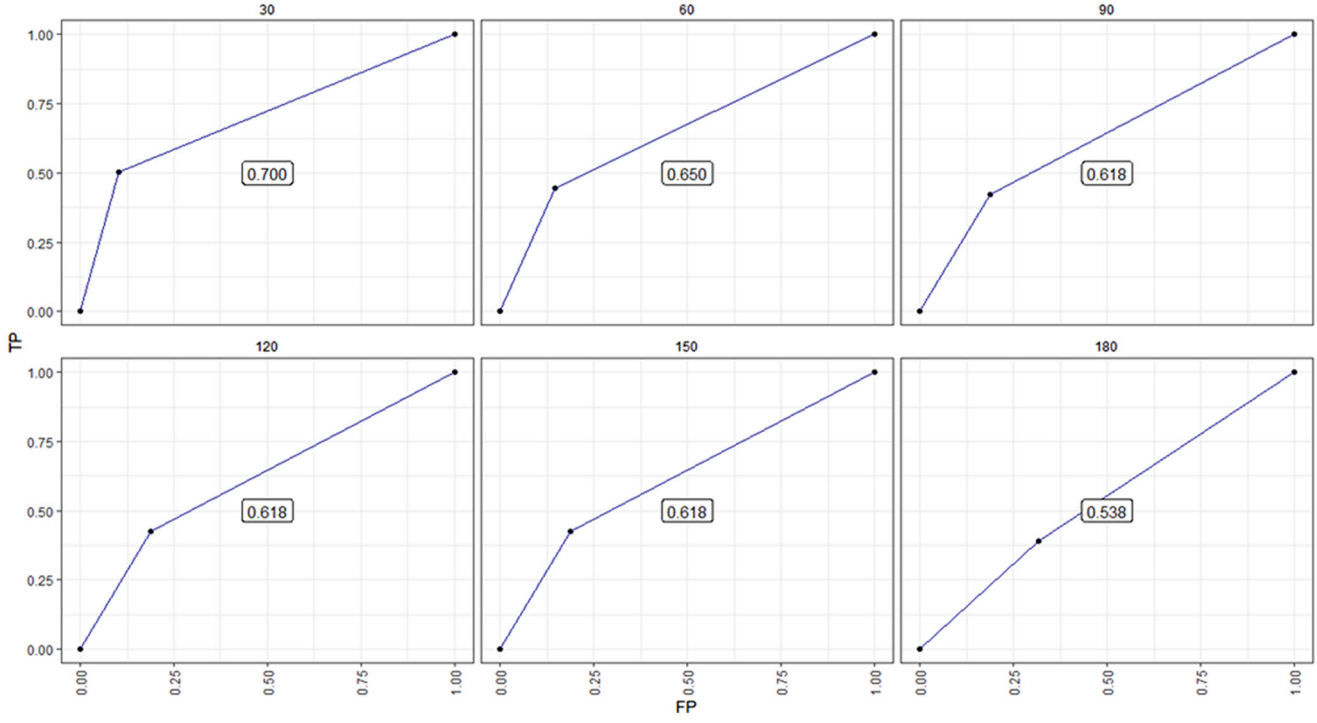

Figure 2. Time-dependent Receiver Operating Characteristic (ROC) curves evaluating the predictive performance of risk groups for overall survival within 30 d intervals (starting from 30 days until 180 days), in patients with malignant ureteral obstruction who underwent drainage solely by tandem ureteral stents between 2007 and 2020. The area under the curve (AUC) is reported; TP: True Positives; FP: False Positives.

metastasis and outcome that did not reach standard statistical significance (Supplementary Table 2); however, Pearson correlation analyses showed significant correlations between the variables. Notably, NLR and PLR, both of which were previously associated with outcomes of various malignancies, were not identified as significant predictors of outcome.

Discussion

In the current study, a simplified prognostic model for survival as suggested by Cordeiro et al. [11] was evaluated in a group of 65 patients with extrinsic MUO who underwent drainage solely with tandem ureteral stents. Patients classified into the favorable risk group (no risk factors) had a better outcome compared to patients in the intermediate-unfavorable risk group (one or two risk factors including the number of metastatic events $\geq$4 and ECOG index $\geq$2) with median survivals of 26 months and 13 months, respectively ($p = .0029$, log-rank test). Additionally, on Cox proportional hazard analyses aimed at identifying novel predictors of outcome in this patient population, the presence of $\geq$4 metastatic events and lung metastases were associated with shorter survival.

Table 2. Univariable and multivariable predictors of overall survival among patients with malignant ureteral obstruction drained solely by tandem ureteral stents during 2007–2020.

	Univariable					Multivariable analysis			
Variable	HR	2.5%	97.5%	*p*-value	Adjusted *p*-value	HR	2.5%	97.5%	*p*-value
Age (per 1 year)	1	0.98	1.02	.776	.88				
Female sex	0.96	0.49	1.87	.897	.94				
ECOG index ≥2	1.72	0.62	4.81	.301	.51				
Estimated GFR (per 1 mL/min/1.73 m^2)	0.99	0.98	1	.131	.32				
Bilateral hydronephrosis	1.09	0.57	2.08	.802	.88				
Grade 3–4 hydronephrosis	0.87	0.51	1.51	.627	.76				
Gastrointestinal malignancy	Ref.								
Genitourinary malignancy	0.78	0.41	1.49	.448	.616				
Retroperitoneal sarcoma	0.64	0.24	1.71	.376	.551				
Other malignancy	0.98	0.42	2.29	.97	.97				
Locally advanced disease	0.71	0.4	1.27	.251	.501				
Metastatic disease	2.32	1.07	5.01	.033	.104				
≥4 Malignancy-related events	2.45	1.36	4.4	.003	.03	2.04	1.07	3.86	.03
Lung metastases	3.53	1.58	7.92	.002	.03	2.37	0.99	5.64	.051
Bone metastases	2.1	0.88	5	.094	.259				
Liver metastases	1.37	0.68	2.75	.374	.551				
Retroperitoneal metastases	2.22	1.19	4.14	.012	.064				
Pelvic metastases	1.88	1.05	3.36	.033	.104				
Peritoneal metastases	2.18	1.17	4.04	.014	.064				
Pleural effusion	6.7	1.45	30.81	.015	.064				
Ascites	0.67	0.16	2.78	.585	.757				
NLR (per 1 unit)	1.03	0.98	1.08	.193	.425				
PLR (per 1 unit)	1	1	1	.273	.501				

HR: Hazards Ratio; ECOG: Eastern Cooperative Oncology Group; GFR: Glomerular Filtration Rate; NLR: Neutrophil Lymphocyte Ratio; PLR: Platelet Lymphocyte Ratio.

Malignances originating from the genitourinary system (prostate, bladder, cervix, ovary), the gastrointestinal system (colorectal cancer), and retroperitoneal malignancy (lymphoma, retroperitoneal sarcoma) are common causes of MUO [2,11]. Consistent with previous studies, most patients in our cohort had an obstruction due to gastrointestinal or genitourinary malignancies. MUO may be drained using PCN or a single ureteral stent. The reported success rates of single ureteral stents vary between 73% and 95%, and some studies reported failure rates of up to 40% [2]. In our institution, we drain MUO using tandem stents which allow a long-term indwelling time of up to 1 year with an acceptable failure rate of 18% [5]. However, the use of tandem ureteral stents may be associated with increased patient discomfort; thus, predictors of outcome may assist in deciding about the need and type of drainage that should be used based on the estimated life expectancy of patients.

Prognostic models were previously described in order to predict the estimated life expectancy of patients with external MUO [9–11,17]. Ishioka et al. identified on multivariate analysis that the number of events related to malignant dissemination (3 or more), low grade of hydronephrosis, and albumin blood concentration of ≤3 (g/dL) were associated with shorter survival in patients with MUO who were drained solely with PCN [9]. The factors identified by Ishioka et al. were later validated by Lienert et al. in a group of patients suffering from MUO mostly of urological origin who were drained with PCN. Lienert et al. identified albumin blood concentration of ≤3 (g/dL), the number of events related to malignant dissemination (3 or more), and sodium serum concertation of <135 (mmol/L) were associated with poor survival [10].

A prospective study performed by Cordeiro et al. suggested using a simplified risk stratification model for patients with MUO drained with PCN or a single ureteral stent. The authors identified the number of events related to malignant dissemination ≥4 and ECOG index ≥2 as significant prognostic factors. In their study, patients having 1 or 2 risk factors had a significantly shorter survival time than those without risk factors. We applied the model as suggested by Cordeiro et al. in a patient population drained solely by tandem ureteral stents categorizing patients into risk groups. Importantly, in the current study, the intermediate and unfavorable risk groups were grouped into one intermediate-unfavorable group (Table 3), with the favorable risk group having twice the median survival time than the intermediate-unfavorable risk group (26 months vs. 13 months, respectively, ($p = .0029$, log-rank test). The current cohort had a longer overall survival time than reported on Corderio's and Ishioka's cohorts, 21 months vs. ∼5 months and 3 months, respectively. We believe these differences may be attributed to the combination of 2 main factors. First, patients that were selected to undergo tandem ureteral stent insertion had a better prognosis than previous cohorts, this is evident from the better performance status of the patients (low occurrence of patients with ECOG index >2) and favorable laboratory results (median albumin of 3.9 g/dL). Second, as many of the patients in the cohort were treated in the last 10 years, their life expectancy might have been prolonged with novel treatments such as immunotherapy and targeted molecular therapies. Nevertheless, the approach of the study was not to examine whether a kidney unit should be drained or not, as suggested in the previous studies, but rather to predict who will benefit the most from long-term drainage and thus, which modality should be used to drain the obstruction. While drainage using tandem stent insertion comes with the price of undergoing a procedure under

Table 3. Risk group stratification of patients with malignant ureteral obstruction in the current study compared to the study by Cordeiro et al.

Risk factors: Number of malignancy-related events[a] ≥4 ECOG ≥2	Risk group stratification by Cordeiro et al.	Risk group stratification in the current study
No risk factors	Favorable	Favorable
1 risk factor (either risk factor)	Intermediate	Intermediate – Unfavorable
2 risk factors	Unfavorable	

ECOG: Eastern Cooperative Oncology Group index.
[a]Malignancy related events included – metastasis to any solid organ, bone or soft tissue.

anesthesia and experiencing stent-related symptoms associated with this form of drainage, this modality should be strongly considered in the favorable risk group. Nevertheless, in the intermediate-unfavorable risk group, drainage with PCN should be considered due to the shorter overall survival period and the ability to achieve this form of drainage without general anesthesia. In this risk group drainage with tandem ureteral stent remains an option for selected patients.

On exploratory analyses, evaluating multiple preoperative predictors of outcome in our cohort, we identified an association between the presence of lung metastases and worse outcomes. Previous studies have assessed the role of the site of metastases in predicting the outcome of patients suggesting different associations between metastatic sites and outcomes in different malignancies [18–20]. Bilen et al. evaluated the association between the site of metastasis and treatment outcome in advanced-stage cancer in patients treated with immunotherapy. Their cohort included mostly patients with melanoma (33%) and gastrointestinal malignancies (22%). They found no association between the presence of lung metastases and outcome [18]. In patients with stage IV colon cancer the site of metastasis was a significant predictor of outcome, as reported by Wang et al. Patients with lung metastases had a higher risk of death from any cause (HR: 1.39 CI: 1.34–1.43, $p < .001$) and cancer-related mortality (HR: 1.4 CI: 1.35–1.45, $p < .001$) when compared to patients without lung metastases. However, when using liver-only metastases as a reference, lung-only metastases were associated with better overall and disease-specific survivals. The authors also reported that the number of metastatic sites was an independent predictor of outcome [19]. In a study evaluating the association between metastatic site and outcome among patients with bladder cancer, patients with bone, brain, liver and lung metastases had worse overall and cancer-specific survivals compared to the patient without metastatic disease at corresponding sites (HR: 1.99, 95% 1.39–2.74, $p < .001$) for decreased overall survival among patients with lung metastases [20]. We did not find an association between liver and bone metastases and outcomes in our study possibly due to the inclusion of various types of malignancies in our cohort. Nevertheless, the association between the presence of lung metastases and adverse outcomes suggests this variable should be considered when building future models for predicting outcomes in patients with MUO.

The current study carries inherent limitations. First, unlike in the Cordeiro cohort who classified patients into 3 groups (favorable, intermediate, unfavorable), the current study stratified patients into 2 risk groups (favorable and intermediate- unfavorable) (Table 3), due to the low occurrence of patients with ECOG index ≥2 ($n = 4$). This can be attributed to the fact that the current cohort, chosen to undergo tandem ureteral stent insertion, had a better prognosis than the cohorts in previous studies, creating a selection bias, which restricts the generalization of the findings to other cohorts. Second, the study is limited by its retrospective nature and as a result the existence of information bias (lack or missing follow-up data), this was partially mitigated by the centralization of data in the electronic records found in our center, making both blood work results, axial imaging studies available even if they had been performed in other centers. Third, is the relatively small sample size studied. However, the long follow-up time partially mitigates this limitation. Future prospective studies with a larger cohort are required to validate these findings.

In Conclusion, prognostic models in patients with malignant ureteral obstruction can be used to stratify patients into risk groups identifying those who will benefit the most from long-term drainage. Our findings validate the model presented by Cordeiro et al.; the model can be applied to patients with malignant ureteral obstruction who undergo drainage with tandem ureteral stents. Patients in the favorable risk group will benefit the most from long-term drainage by tandem ureteral stents.

Ethics statement

The study protocol was approved by Tel Aviv medical center's ethics (Helsinki) committee (#0525-21-TLV).

Disclosure statement

The authors declare no conflict of interests.

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