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Predictors of time-to-nadir serum creatinine after drainage of bilaterally obstructed kidneys due to bladder cancer

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Abstract

Background: There are persistent controversies about the outcomes and benefits of drainage of malignant ureteral obstruction by percutaneous nephrostomy (PCN). This study aimed to assess the predictors of the time-to-nadir (TTN) of serum creatinine (SCr) levels after drainage of bilaterally obstructed kidneys (BOKs) due to bladder cancer (BC) by PCN.

Materials and methods: This prospective nonrandomized study included patients with BOKs due to BC treated by PCN between April 2019 and March 2022. The primary outcome measure was TTN.

Results: Of the 55 patients with a median age (range) of 66 years (47–86 years), 32 (58.2%) had a normal nadir SCr and 23 (41.8%) had a high nadir SCr within 21 days after drainage of BOKs due to BC. High nadir SCr was associated with a higher mean age ($p = 0.011$) and lower body mass index (BMI, $p = 0.043$). However, patients with normal nadir SCr had a significantly shorter TTN ($p = 0.023$) and an increased mean SCr trajectory ($p < 0.001$) during TTN. In multivariate analysis, low urine output at presentation ($p = 0.021$) and high BMI ($p = 0.006$) were associated with longer TTN. However, the mean parenchymal thickness ($p = 0.428$) and laterality of drainage ($p = 0.466$) were not associated with the mean TTN and SCr normalization rates. According to the modified Clavien-Dindo classification, 8 cases of hematuria were managed conservatively (grade 2), and 2 cases of PCN slippage were repositioned using local anesthesia (grade 3).

Conclusions: Despite the safety of PCN for drainage of BOKs due to BC, more than 41% of the patients failed to have a normal nadir SCr. Predrainage low urine output and high BMI were associated with longer TTN. Laterality of drainage had no significant effects on the TTN and SCr trajectory.

Keywords: Bladder cancer; Bilaterally obstructed kidneys; Malignant ureteral obstruction; Percutaneous nephrostomy; Time-to-nadir; Serum creatinine

1. Introduction

Bladder cancer (BC) is a common malignancy worldwide, with a specific burden in developing countries. A considerable proportion of patients with BC present with advanced disease due to poor sociocultural and health facility standards.[1] Muscle-invasive disease is one of the common causes of bilateral malignant ureteral obstruction.[2,3] Percutaneous nephrostomy (PCN) has been suggested as the initial management to relieve obstruction and acute kidney injury (AKI) in these cases. Although it has been studied with other types of malignancies,[3–6] BC has been solely targeted as a cause of bilaterally obstructed kidneys (BOKs) in some studies.[2,7] Hence, there is insufficient information or consensus regarding the laterality, benefits, and outcomes of BOKs drainage in these patients.[2,8] We aimed to define the predictors of time-to-nadir (TTN) as a prognostic tool for evaluating drainage of BOKs by PCN in patients with BC.

2. Materials and methods

This prospective study was performed at our hospital between April 2019 and March 2022. The target population was patients who underwent unilateral or bilateral PCN for the drainage of BOKs due to BC. This study included adult patients with a serum creatinine (SCr) level greater than 2 mg/dL and BC causing BOKs of grades 1–3 hydronephrosis according to Onen grading system of hydronephrosis.[9] The exclusion criteria were bleeding tendency, severe comorbidity preventing intervention, dialysis after drainage of BOKs, nonsimultaneous bilateral PCN, lost–to–follow-up patients, and refusal of participation in the study.

The sample size was calculated using EasyMedStat (version 3.17; EasyMedStat Co, Levallois-Perret, France) (http://www.easymedstat.com). With a power of 80%, margin of error of 10%, confidence level of 95%, and probability value of 0.5, a sample size of 54 patients was estimated. However, considering the percentage of patients who were lost to follow-up, we enrolled only 58 eligible patients. Fifty-five patients completed the follow-up (Fig. 1).

For all patients, the full medical history was obtained, including a history of loin pain; uremic manifestations, such as hiccough, vomiting, dyspepsia, anorexia, and urine output (UOP); comorbidities; and

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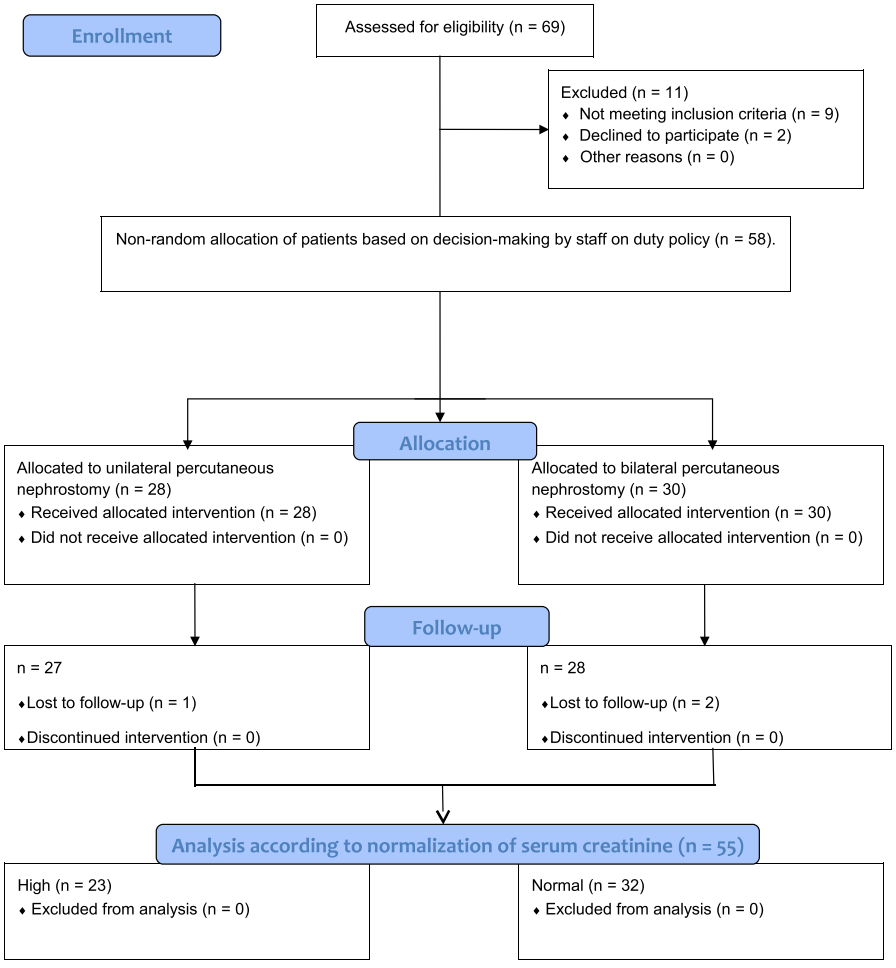

Figure 1. Flowchart of selection of patients who underwent drainage of BOKs due to BC by PCN: Steps from assessment for eligibility to follow-up and data analysis. Three patients were lost to follow-up. After drainage, 55 patients were differentiated into those with normalized SCr levels (32 patients) and those with non-normalized nadir SCr levels (23 patients). BC = bladder cancer; BOKs = bilaterally obstructed kidneys; PCN = percutaneous nephrostomy; SCr = serum creatinine.

surgical interventions. In addition, a systematic physical examination was performed to determine body temperature, body mass index (BMI), and loin tenderness. In all cases, laboratory workups included complete blood counts, SCr, blood urea nitrogen, blood gases, and random blood sugar. Imaging studies included ultrasonography for the detection of hydronephrosis and measurement of parenchymal thickness and computed tomography for defining the underlying cause of obstruction. Patients were counseled about the available options for management, and consent for participation in the current study was obtained from each participant. All predrainage workups and interventions, including drainage using PCN, were performed within a few hours of presentation of the patient to our emergency unit.

Unilateral or bilateral drainage of BOKs was performed using PCN according to standard techniques. Because of the emergency nature of the conditions, nonrandom allocation was performed according to the decision-making policy, which was mostly dependent on the staff member on duty or the operator. In our hospital, the decision is usually made individually in each case. The emergency (staff member or operator) urologist decides the laterality of drainage by considering many factors, such as the general condition or performance of the patient, anticipated effect on quality of life after patient counseling, and clinical and laboratory findings. Intraoperative and direct postoperative observations were performed for vital signs, consciousness level, and the color and amount of urine. Patients were discharged with instructions for healthcare within 3 days postoperatively.

The follow-up of patients was scheduled over 21 days. On postoperative days 1, 2, 3, 5, 10, 15, and 21, patients were evaluated for PCN patency, decompression of kidneys by ultrasonography, highest SCr level, and TTN. Time-to-nadir was defined as the number of days spent to reach the lowest value of SCr within 21 days, defined as reaching similar and consecutive values of SCr.

The primary outcome of this study was TTN after BOKs drainage. Nadir SCr was defined as the decrease in SCr to a normal level or the lowest value of SCr within 21 days, as for TTN described previously. The secondary outcome was the SCr normalization rate. The baseline SCr was considered to be the same as the nadir SCr identified within 21 days of drainage because the real baseline values were unknown. The normal SCr level was defined as 0.7–1.2 mg/dL, and UOP status was defined as normal if the UOP was greater than 400 mL/d. Low UOP included oliguria (100–400 mL/d) and anuria (<100 mL/d). Complications were graded using the modified Clavien-Dindo classification system.[10]

This study was conducted in accordance with the principles of the Declaration of Helsinki and its amendments. The study was approved by the local ethics committee at our university (institutional review board number: 17100860/2019). It was also registered at ClinicalTrials.gov (NCT04077008).

Statistical analysis was performed using EasyMedStat (http://www.easymedstat.com). Continuous variables are expressed as median (range; interquartile range) and categorical variables are expressed as frequency (percentage). We compared groups according to normalization of SCr levels (normalized vs. nonnormalized SCr groups). Normality and heteroskedasticity of continuous data were assessed using the Shapiro-Wilk test and Levene test, respectively. Continuous outcomes were compared using the Mann-Whitney U, analysis of variance, Welch analysis of variance, or Kruskal-Wallis tests according to the data distribution. Categorical outcomes were compared using the χ^2 test or Fisher exact tests. Spearman correlation was used to assess linear dependence between variables. Multivariate linear regression analysis was performed to assess the predictors of TTN. Data were checked for multicollinearity using Belsley-Kuh-Welsch technique. A p value less than 0.05 was considered statistically significant.

3. Results

After excluding 3 patients who were lost to follow-up, the study included 55 patients who underwent drainage of BOKs, including 47 men (85.5%) and 8 women (14.5%). The demographic and clinical characteristics are presented for all patients in Table 1.

In the comparison relative to the SCr normalization rate within 21 days after drainage (Table 2), 32 patients (58.2%) had normalized SCr levels and 23 patients (41.8%) had a nadir higher than the normal values of SCr. In the high nadir group, patients had a higher mean age (p = 0.011) and lower values of bilateral renal pain (p = 0.020). However, they had lower BMI (p = 0.043) and blood pH (p = 0.040) than the other group. The percentage of patients undergoing bilateral PCN (p = 0.079) and mean SCr at presentation (p = 0.290) in the normalized SCr group were not statistically significant compared with those in nonnormalized SCr group. The postoperative SCr level was significantly different between the groups only after postoperative day 5 (P < 0.001). In addition, there were significant differences between the groups in the mean SCr trajectory (SCr-Tr) during TTN (P < 0.001). Time to nadir was significantly shorter (p = 0.023) in the normalized SCr group than in the nonnormalized SCr group (Table 2).

In multivariate linear analysis, low UOP status at presentation (p = 0.021) and high BMI (p = 0.006) were associated with longer TTN after drainage of BOKs due to BC. Mean parenchymal thickness (p = 0.428) and laterality of drainage (p = 0.466) were not significantly associated with TTN (Table 3).

Regarding complications, 4 patients had postoperative hematuria in each group. All patients were treated conservatively without blood transfusion (grade 2). Percutaneous nephrostomy slippage occurred in only 2 patients in the normalized SCr group; in these patients, PCN was repositioned within 3–5 hours after slippage (grade 3).

Table 1

Demographic and clinical characteristics of all patients (n = 55).

Characteristics	Median (range, IQR) or frequency (percentage)
Age, yr	66 (47–86, 12)
Sex	
Men	47 (85.5%)
Women	8 (14.5%)
BMI, kg/m^2	23.1 (16.1–36.9, 7.6)
UOP at presentation	
Normal	32 (58.2%)
Low	
Oliguria	14 (25.5%)
Anuria	9 (16.4%)
Comorbidity	
None	39 (70.9%)
Yes	16 (29.1%)
Loin pain	
None	27 (49.1%)
Right	3 (5.4%)
Left	4 (7.3%)
Bilateral	21 (38.2%)
Temperature, °C	37 (36.5–38.8, 0.3)
Mean parenchymal thickness, mm	13 (8–16, 3)
SCr at presentation, mg/dL	6 (2.2–17, 3.6)
Predrainage emergency dialysis	9 (16.4%)
Tumor stage	
Stage 3	49 (89.1%)
Stage 4	6 (10.9%)
Laterality of drainage	
Unilateral	27 (49.1%)
Bilateral	28 (50.9%)
Nadir SCr	
Normal (0.7–1.2 mg/dL)	32 (58.2%)
High	
Mild-to-moderate (<2 mg/dL)	14 (25.5%)
Severe (≥ 2 mg/dL)	9 (16.4%)
TTN, d	15 (3–21, 5)
SCr-Tr during TTN, mg/dL/d	0.3 (0.03–3.1, 0.4)

BMI = body mass index; IQR = interquartile range; SCr = serum creatinine; SCr-Tr = serum creatinine trajectory; TTN = time to nadir; UOP = urine output.

4. Discussion

A nephrostomy tube for drainage of BOKs due to BC has been commonly used since the start of the era of formal nephrostomy tube insertion.[11] With the progression of technology, PCN is currently used widely for drainage of BOKs due to BC.[2,6,12,13] However, the benefits of bilateral PCN in BOKs are controversial due to many factors. First, patients with BOKs due to BC have major morbidity of malignancy, similar to patients with any other advanced pelvic malignancy. Therefore, there may be no oncological benefits of PCN.[6,12] Second, the SCr level in a large proportion of these patients does not improve to the normal level. This is attributable to the metabolic effects of malignancy.[6,7] Third, patients are usually older and may be unfit for surgery, expecting death from other causes. Fourth, considerable impacts of bilateral PCNs on the quality of life of these patients must be considered during decision making.[6] These controversies can be addressed through evaluation of the prognostic value of outcomes, such as the SCr normalization rate and TTN.

The SCr normalization rate has been commonly used as a tool for evaluating the success of BOKs drainage. Ekici et al.[7] reported an SCr improvement rate of 83%, with an improvement in the mean SCr level of 6 mg/dL (2.1–24.6 mg/dL). They did not identify any independent factors for the prognostic role of this rate. The current results showed a similar mean (range) SCr level, which improved from 6.4 mg/dL (2.2–17 mg/dL) to 1.3 mg/dL (0.4–2.5 mg/dL). However, the SCr normalization rate (58.2%) was lower than that reported by Ekici et al.[7] This difference might be attributed to the variable definitions of normal SCr level; Ekici et al.[7] defined it as 0.8–1.4 mg/dL, and we defined it as 0.7–1.2 mg/dL. In addition, our results showed that the SCr normalization rate was associated with older age and

Table 2

Comparison between the 2 groups of patients with normalized and non-normalized SCr within 21 days after drainage.

Variables	Patients with normalized SCr, median (range, IQR) or frequency (percentage) (n = 32)	Patients with nonnormalized SCr, median (range, IQR) or frequency (percentage) (n = 23)	*p*
Age, yr	65 (47 to 75, 9.5)	71 (59 to 86, 15)	0.011
Sex			
Men	28 (87.5%)	19 (82.61%)	0.707
Women	4 (12.5%)	4 (17.39%)	
BMI, kg/m^2	25.3 (17.3 to 35.9, 6.1)	21.3 (16.1 to 36.9, 3.7)	0.043
Comorbidity			
Yes	9 (28.3%)	7 (30.4%)	0.896
No	23 (71.7%)	20 (69.6%)	
Smoking			
Yes	11 (34.38%)	8 (34.78%)	>0.999
No	21 (65.62%)	15 (65.22%)	
Pain			
None	16 (50%)	11 (47.8%)	
Right	0 (0%)	3 (25%)	0.020
Left	1 (6.2%)	3 (25%)	
Bilateral	15 (93.8%)	6 (50%)	
Temperature, °C	37.1 (36.5 to 38.6, 0.4)	37 (36.6 to 38.8, 0.3)	0.105
UOP status at presentation			
Normal	18 (56.3%)	14 (60.9%)	0.948
Low	14 (43.7%)	9 (39.1%)	
Loin tenderness			
None	26 (81.3%)	22 (95.7%)	
Unilateral	1 (16.7%)	0 (0%)	>0.999
Bilateral	5 (83.3%)	1 (100%)	
Predrainage dialysis	5 (15.6%)	4 (17.4%)	0.775
Mean parenchymal thickness	13 (8 to 16, 2.5)	11.5 (9.5 to 16, 4)	0.154
Random blood sugar	111.5 (75 to 250, 23.5)	97 (45 to 330, 49)	0.103
pH	7.36 (7.15 to 7.47, 0.14)	7.40 (7.18 to 7.47, 0.07)	0.040
Acid-base deficit, mmol/L	–8 (–21 to 1, 8)	–7.8 (–15 to 1, 8.1)	0.537
HCO_3, mmol/L	17 (6.7 to 23, 9.8)	17 (11.2 to 23, 6.4)	0.531
Laterality of drainage			
Unilateral	12 (37.5%)	15 (65.2%)	0.079
Bilateral	20 (62.5%)	8 (34.8%)	
SCr at presentation, mg/dL	6.2 (2.2 to 17, 6)	6 (2.2 to 9.2, 2.7)	0.290
Postoperative SCr measures, mg/dL			
SCr on day 1	4.5 (1.9 to 14.8, 5.1)	5.1 (2.2 to 8.8, 2.7)	0.785
SCr on day 3	3.8 (1.2 to 13, 5.4)	4.5 (2 to 9.8, 2.7)	0.256
SCr on day 5	2.6 (0.7 to 9.1, 4)	3.8 (1.8 to 7.3, 2.5)	0.077
SCr on day 7	1.8 (0.5 to 10.6, 2.8)	3.2 (2 to 6.9, 2.1)	0.005
SCr on day 10	1.8 (0.3 to 4, 1.6)	2.9 (1.8 to 5.2, 1.6)	<0.001
SCr on day 15	1.1 (0.4 to 2.9, 0.4)	1.9 (1.4 to 3.9, 0.5)	<0.001
SCr on day 21	0.9 (0.4 to 1.2, 0.4)	1.9 (1.4 to 2.5, 0.5)	<0.001
Pyuria at 1 wk after drainage	15.5 (3 to 100, 10)	20 (8 to 100, 18)	0.699
TTN, d	15 (3 to 21, 9)	15 (10 to 21, 0)	0.023
SCr-Tr, mg/dL/d			
SCr-Tr during first 3 days	0.6 (–0.3 to 3.2, 0.9)	0.3 (–1 to 1.9, 0.4)	<0.001
SCr-Tr during week 1	0.6 (–0.5 to 1.7, 0.7)	0.3 (0.03 to 0.9, 0.2)	0.006
Mean SCr-Tr during TTN	0.6 (0.1 to 2.1, 0.6)	0.3 (0.03 to 0.5, 0.2)	<0.001

BMI = body mass index; IQR = interquartile range; SCr = serum creatinine; SCr-Tr = serum creatinine trajectory; TTN = time to nadir; UOP = urine output.

lower BMI. These factors are surrogates of reduced functioning nephron mass and higher risks of AKI development.[14]

The current results showed that there was no significant difference in the SCr normalization rate in unilateral versus bilateral drainage of BOKs caused by BC, consistent with the findings of a previous study.[7] In addition, this finding was parallel to the lack of significant effect of unilateral drainage on the length of TTN. These effects might be attributed to the burden of malignancy, which is the underlying cause of BOKs.[5]

The definition of TTN in patients with AKI is related to how much benefit could be provided by early recovery to the possibility of cure or better early management. This issue is controversial in patients with malignancy, including those with BC.[6,15,16] Our results showed that TTN was significantly shorter in patients with normalized SCr than in those with nonnormalized SCr. This might be because the factors that promote SCr normalization rate could be indirect causes of short TTN. However, no statistically significant factors affecting TTN were identified in the current study to support this hypothesis.

A mean SCr-Tr of 0.5 mg/dL/d with a wide range (0.03–3.1 mg/dL/d) was achieved among patients in the current study. This rate was significantly different according to improvement or nonimprovement

Table 3

Multivariate linear regression analysis of the predictors of the TTN of SCr.

Variables	Odds ratio	*p*
BMI, kg/m^2	–0.37 (–0.62 to –0.113)	0.006
Status of low UOP at presentation	3.3 (0.52 to 6.07)	0.021
Mean parenchymal thickness, mm	0.25 (–0.38 to 0.89)	0.428
Unilateral drainage	0.96 (–1.66 to 3.58)	0.466

BMI = body mass index; SCr = serum creatinine; TTN = time-to-nadir; UOP = urine output.

of SCr. This indicates that the process of SCr decline from its level at the time of presentation to the nadir level is complex and may be affected by numerous variables, as reported in other forms of AKI.[15–18]

To our knowledge, the current study is the only one to consider TTN and SCr-Tr outcomes after drainage of BOKs due to BC. It was one of the few studies that exclusively address BOKs in patients with BC. However, its limitations include the short-term follow-up and inability to judge the effect of TTN on the probability of patients being cured or obtaining better management of BC.

5. Conclusions

A large proportion of patients with BOKs due to BC failed to achieve normal SCr levels after drainage by PCN, regardless of the laterality, mode of drainage, or SCr levels at presentation. Serum creatinine level normalization was associated with patient age and BMI. The decline in SCr levels seems to be nonlinear, and TTN was significantly shorter in patients with normalized nadir SCr than in those with nonnormalized nadir SCr within 21 days after drainage. Unlike the mean parenchymal thickness and bilateral drainage, low UOP status at presentation and high BMI were associated with longer TTN after drainage of BOKs due to BC.

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Statement of ethics

The study was approved by the local ethics committee at our university (institutional review board number: 17100860/2019). It was also registered at ClinicalTrials.gov (NCT04077008). This study was conducted in accordance with the principles of the 1964 Declaration of Helsinki and its later amendments. Informed consent to participate was obtained from each participant in this study.

Conflict of interest statement

The authors declare that they have no conflicts of interest.

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Author contributions

RAG: Participated in practical work, concept design, data collection, statistical analysis, writing, revision, and approval;
AMA: Participated in concept design, practical work, data collection, writing, revision, and approval;
AIA: Participated in writing, revision, supervision, and approval;
AME: Participated in concept design, writing, revision, supervision, and approval;
HMB: Participated in statistical analysis, writing, and approval.

Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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