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Predictors of Clinically Significant Urinary Leakage Requiring Ureteral Stenting after Percutaneous Nephrolithotomy

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Abstract

BACKGROUND/AIMS: Urinary leakage after percutaneous nephrolithotomy (PNL) is a clinically relevant complication that may prolong hospitalization and necessitate additional interventions such as ureteral stenting. However, reliable predictors of clinically significant leakage remain insufficiently defined.

MATERIALS AND METHODS: This retrospective study included 305 patients who underwent PNL. The primary outcome was urinary leakage requiring double-J stent placement, defined as persistent drainage >24 hours after nephrostomy tube removal. Patients were divided into leakage (n=46) and non-leakage (n=259) groups. Clinical, radiological, and operative variables were analyzed. Univariate and multivariable analyses were performed using Firth penalized logistic regression. Model performance was evaluated using receiver operating characteristic analysis and calibration testing.

RESULTS: Urinary leakage occurred in 15.1% of patients. On multivariable analysis, multiple stones [odds ratio (OR)=55.66, p<0.001] and longer operative time (OR=1.017 per minute, p<0.001) were identified as independent risk factors; nephrostomy tube placement was strongly protective (OR=0.059, p<0.001). Lower calyceal stone involvement also remained significant (OR=0.255, p=0.044). The model demonstrated acceptable discrimination ((area under the curve=0.798, 95% confidence interval: 0.729-0.865) and good calibration (Hosmer-Lemeshow p=0.754).

CONCLUSION: Clinically significant urinary leakage after PNL is primarily associated with stone complexity and operative factors. Multiple stones and prolonged operative time increase the risk, whereas nephrostomy tube placement has a protective effect. The proposed model may assist in perioperative risk stratification and clinical assessment.

Keywords: Percutaneous nephrolithotomy, urinary leakage, double-J stent, nephrostomy tube, stone multiplicity

INTRODUCTION

Percutaneous nephrolithotomy (PNL) is currently one of the most effective and widely utilized surgical techniques for the management of renal stones, particularly those larger than 2 cm or with complex configurations.[1,2] Despite its high stone-free rates, PNL is inherently invasive and associated with a spectrum of complications. While bleeding and infectious events are more commonly emphasized, urinary leakage from the nephrostomy tract represents a frequently encountered yet relatively underrecognized clinical issue.[3,4]

Postoperative urinary leakage may lead to several adverse outcomes, including prolonged hospitalization, the need for additional

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interventions such as double-J (DJ) stent placement, impaired patient comfort, and an increased risk of infection. The reported incidence of this complication varies depending on the definition used, with most studies reporting rates of approximately 5-15%.[4-6] These findings suggest that post-PNL urinary leakage is a clinically relevant complication that may significantly affect patient management.

Previous studies investigating factors associated with urinary leakage after PNL have primarily focused on stone burden, degree of hydronephrosis, number of access tracts, operative time, and renal parenchymal thickness. However, the existing literature remains heterogeneous, with inconsistent findings across studies. In particular, it is still unclear which specific aspects of stone characteristics-such as volume, location, complexity, or multiplicity-play the most decisive role. Moreover, parameters like stone number and calyceal involvement have often not been sufficiently detailed or have been evaluated without considering their interactions with other variables.[4,7]

In this context, identifying reliable clinical predictors of urinary leakage after PNL is of considerable importance for optimizing perioperative management and developing preventive strategies in high-risk patients.

The aim of the present study was to determine the independent preoperative and intraoperative predictors of clinically significant urinary leakage requiring DJ stent placement following PNL. Furthermore, beyond identifying statistical associations, this study sought to translate these findings into a clinically applicable risk estimation approach. By integrating readily available perioperative variables into a predictive framework, we aimed to facilitate preoperative risk stratification and support individualized decision-making regarding postoperative drainage strategies.

MATERIALS AND METHODS

Study Design and Population

This retrospective cohort study initially screened 328 consecutive patients who underwent PNL at our institution between 2020 and 2025. Patients who underwent PNL and had complete clinical, laboratory, and imaging data, as well as clearly documented postoperative drainage status and urinary leakage outcomes, were included in the study. Patients with incomplete clinical data (n=12), concomitant major surgical procedures (n=2), urinary diversion (n=1), active malignancy (n=1), or early reoperation due to major complications (n=6) were excluded. Pregnant patient (n=1) was also excluded. After applying these inclusion and exclusion criteria, 305 patients were included in the final analysis. The study was approved by the Adıyaman University Non-Interventional Clinical Research Ethics Committee (approval no: 2026/3-1, date: 14.04.2026). Due to the retrospective nature of the study, informed consent was not required. Patients were categorized into the leakage group (n=46, 15.1%) and the non-leakage group (n=259, 84.9%).

Data Collection and Surgical Technique

Patient demographics (age, gender), stone-related factors (history of stone passage and surgery, laterality, staghorn status, stone number and location, stone dimensions, Hounsfield unit, surface area, volume), anatomical parameters (skin-to-stone distance, hydronephrosis grade), and operative details (operation time, access tract number, hospital stay, nephrostomy tube placement and duration, stone-free status) were collected from medical records and non-contrast computed tomography scans.

All PNL procedures were performed under general anesthesia in the prone position. Percutaneous renal access was obtained under fluoroscopic guidance, followed by tract dilation using amplatz dilators. Stone fragmentation was accomplished using pneumatic lithotripsy. The decision regarding nephrostomy tube placement (20-22 Fr) was made at the surgeon's discretion based on intraoperative findings. The primary outcome was urinary leakage requiring DJ stent placement, defined as persistent urinary drainage from the nephrostomy tract lasting more than 24 hours after nephrostomy tube removal. No quantitative threshold for the amount of leakage was used. The need for DJ stent insertion was determined by the treating urologist's clinical judgment. In all 46 patients who developed urinary leakage and required DJ stent placement, the leakage resolved completely following stent insertion.

Statistical Analysis

Continuous variables were assessed for normality using the Shapiro-Wilk test. Normally distributed variables were compared using an Independent Samples t-test (mean ± standard deviation), while non-normally distributed variables were compared using the Mann-Whitney U test (median, interquartile range). Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate.

Univariate logistic regression analyses were performed for each variable. Variables with $p<0.25$, as well as those considered clinically relevant, were included as candidates for multivariable analysis. Multicollinearity was assessed using variance inflation factors (VIFs). Due to the potential for sparse-data bias and quasi-complete separation, multivariable analysis was also performed using Firth penalized logistic regression to provide bias-reduced estimates. Model discrimination was evaluated using the area under the receiver operating characteristic curve (AUROC) with 95% confidence intervals obtained via 1000-iteration bootstrap resampling. Due to the potential for sparse-data bias and quasi-complete separation, multivariable analysis was additionally performed using Firth penalized logistic regression, providing bias-reduced estimates. The final multivariable model included four variables. The optimal cut-off value was determined using Youden's J index. Model calibration was assessed using the Hosmer-Lemeshow goodness-of-fit test. All analyses were conducted using Python version 3.10, NumPy version 1.26.4, and PyTorch version 2.5.1 with CUDA 12.1 support, together with the SciPy, scikit-learn, and statsmodels libraries. A two-sided p-value <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 305 patients were included. Urinary leakage occurred in 46 participants (15.1%). The demographic and clinical characteristics are presented in Table 1. Median age was comparable between groups (39.0 vs. 42.0 years, p=0.524). No significant difference between gender was observed (60.9% vs. 60.6% male, p=1.000).

Compared with the non-leakage group, patients with urinary leakage had significantly higher rates of multiple stones, involvement of the upper, middle, and lower calyces, prolonged operative time, and residual stones. In contrast, nephrostomy tube placement was significantly less frequent in the leakage group (Table 1).

Univariate Logistic Regression

Univariate analysis identified 12 variables with $p<0.25$ as candidates for multivariate modeling (Table 2). The strongest univariate predictors were multiple stones [odds ratio (OR)=9.312], lower calyx stone (OR=3.391), residual stones (OR=3.057), upper calyx stone (OR=2.836), and multiple access tracts (OR=2.819). Nephrostomy tube placement (OR=0.240) and non-staghorn status (OR=0.281) were protective.

Multivariate Logistic Regression

All candidate variables showed acceptable multicollinearity (VIF <10; range: 1.05-5.63). Given the potential for sparse-data bias and quasi-complete separation, the final multivariable analysis was performed using Firth penalized logistic regression (Table 3). Multiple stones remained the strongest independent predictors of urinary leakage (OR=55.66, $p<0.001$). Each additional minute of operation time was associated with a 1.7% increase in the odds of leakage (OR=1.017, $p=0.001$). Nephrostomy tube placement remained strongly protective (OR=0.059, $p=0.001$). Lower calyceal stone involvement remained statistically significant after penalization (OR=0.255, $p=0.044$). The direction and magnitude of associations were consistent with those observed in conventional logistic regression analysis, supporting the robustness of the findings.

Table 1. Comparison of baseline and operative characteristics between urinary leakage and non-leakage groups

Variable	No leakage (n=259)	Leakage (n=46)	p-value
Continuous variables			
Age (years)[a]	42.0 (29.0-54.0)	39.0 (28.3-53.0)	0.524
Stone height (mm)[a]	19.2 (16.1-24.1)	19.0 (15.1-24.9)	0.786
Stone width (mm)[a]	23.0 (18.7-28.8)	25.9 (19.4-33.9)	0.078
Stone length (mm)[a]	25.7 (21.2-33.4)	28.1 (21.3-36.4)	0.435
HU[a]	1111.5 (881.2-1308.5)	1146.6 (851.8-1333.3)	0.844
SSD (cm)[b]	7.86±2.21	7.68±2.03	0.603
Stone area (mm^2)[a]	453.7 (320.0-709.0)	581.7 (308.1-951.2)	0.227
Stone volume (mm^3)[a]	5749.9 (3438-11266)	7502.4 (3322-15186)	0.418
Op. time (min)[a]	110.0 (95.0-125.0)	122.5 (101.3-150.0)	**0.001**
Hospital stay (h)[a]	115.0 (80.0-150.0)	120.0 (94.3-162.0)	0.268
NT time (h)[a]	64.0 (40.0-72.0)	64.5 (44.3-71.5)	0.567
Categorical variables			
Male gender	157 (60.6)	28 (60.9)	1.000
Hx stone passage	49 (18.9)	13 (28.3)	0.211
Hx stone surgery	51 (19.7)	10 (21.7)	0.905
Left side	127 (49.0)	24 (52.2)	0.816
Non-staghorn	228 (88.0)	31 (67.4)	**0.001**
Multiple stones	157 (60.6)	43 (93.5)	**<0.001**
Pelvis stone	239 (92.3)	42 (91.3)	0.769
Upper calyx stone	41 (15.8)	16 (34.8)	**0.005**
Middle calyx stone	90 (34.7)	27 (58.7)	**0.004**
Lower calyx stone	161 (62.2)	39 (84.8)	**0.005**
Multiple access	18 (6.9)	8 (17.4)	**0.039**
Nephrostomy tube	250 (96.5)	40 (87.0)	**0.015**
Residual stones	45 (17.4)	18 (39.1)	**0.002**

Continuous variables were compared using Mann-Whitney U or Independent Samples t-test as appropriate, whereas categorical variables were compared using chi-square or Fisher's exact test. [a]Median(IQR); [b]Mean ± SD. Bold p-values indicate statistical significance ($p<0.05$).
NT: Nephrostomy tube, HU: Hounsfield unit, SSD: Skin-to-stone distance, Hx: History.

Model Performance

The Hosmer-Lemeshow test was not statistically significant ($\chi^2=5.032$, $p=0.754$), indicating adequate calibration. The AUC was 0.798 (bootstrap 95% CI: 0.729-0.865). Using Youden's J index (0.444), the optimal cut-off of 0.185 yielded 65.2% sensitivity, 79.2% specificity, 35.7% positive predictive value, 92.8% negative predictive value, and 77.0% accuracy (Table 4, Figures 1-3).

Effect Sizes

Operation time demonstrated a medium effect size (Cohen's d=0.649); all other continuous variables exhibited negligible effects. Among categorical variables, multiple stones (Cramér's V=0.238), staghorn stone (V=0.194), and residual stones (V=0.181) had the largest, though still small, effect sizes.

Descriptive Subgroup Comparisons

Leakage rates were consistent across genders (females 15.0% vs. males 15.1%). Staghorn patients had higher leakage (32.6% vs. 12.0%), as did those with multiple access (30.8% vs. 13.6%), no nephrostomy tube (40.0% vs. 13.8%), residual stones (28.6% vs. 11.6%), and severe hydronephrosis (20.4% vs. 9.2% for moderate). In subgroups with adequate sample sizes, the trends were consistent with those in the main analysis, particularly for multiple stones and operation time.

Table 2. Univariate logistic regression: variables with p<0.25

Variable	OR	95% CI	p-value
Staghorn (no)	0.281	0.137-0.578	**<0.001**
Multiple stones	9.312	2.814-30.814	**<0.001**
Upper calyx	2.836	1.419-5.667	**0.003**
Middle calyx	2.668	1.407-5.062	**0.003**
Lower calyx	3.391	1.460-7.878	**0.005**
Operation time	1.017	1.008-1.026	**<0.001**
Multiple access	2.819	1.146-6.935	**0.024**
Nephrostomy tube	0.240	0.081-0.711	**0.010**
Residual stones	3.057	1.559-5.997	**0.001**
Hydronephrosis	1.564	0.978-2.501	0.062
Stone width	1.027	0.996-1.058	0.085
Hx stone passage	1.688	0.827-3.445	0.150

Variables with $p<0.25$ were considered candidate variables for multivariable analysis. Bold p-values indicate significance ($p<0.05$).
OR: Odds ratio, CI: Confidence interval.

Table 3. Firth penalized multivariate logistic regression model

Variable	B	SE	OR	95% CI	p-value
Multiple stones	4.019	0.982	**55.66**	8.12-381.72	**<0.001**
Operation time (min)	0.016	0.005	**1.017**	1.007-1.027	**<0.001**
Nephrostomy tube	-2.825	0.811	**0.059**	0.012-0.296	**<0.001**
Lower calyx stone	-1.367	0.677	**0.255**	0.068-0.961	**0.044**

Pseudo $R^2=0.201$; AIC=216.6; LLR $p<0.001$. Firth penalized logistic regression was applied to address potential sparse-data bias and quasi-complete separation, providing bias-reduced estimates. Bold values indicate statistical significance ($p<0.05$).
B: Coefficient, SE: Standard error, OR: Odds ratio, CI: Confidence interval, AIC: Akaike information criterion.

Table 4. Model performance metrics

Metric	Value
AUC (95% CI)	0.798 (0.729-0.865)
Hosmer-Lemeshow χ^2 (p)	5.032 (0.754)
Youden's J index	0.444
Optimal cut-off	0.185
Sensitivity	65.2%
Specificity	79.2%
PPV	35.7%
NPV	92.8%
Accuracy	77.0%
McFadden R^2	0.201
AIC	216.6

AUC: Area under the curve, CI: Confidence interval, PPV: Positive predictive value, NPV: Negative predictive value, AIC: Akaike information criterion.

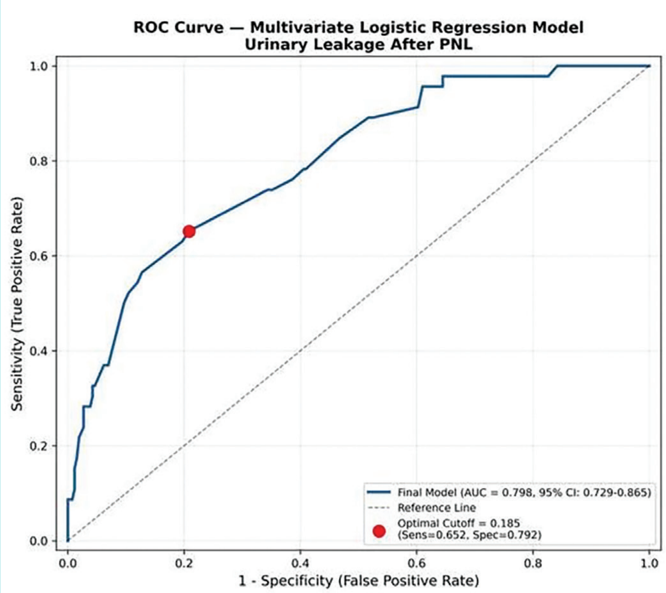

Figure 1. ROC curve of the final multivariate logistic regression model. AUC=0.798 (95% CI: 0.729-0.865). Red dot indicates the optimal cut-off (Youden's J =0.444).

ROC: Receiver operating characteristic, AUC: Area under the curve, CI: Confidence interval, PNL: Percutaneous nephrolithotomy.

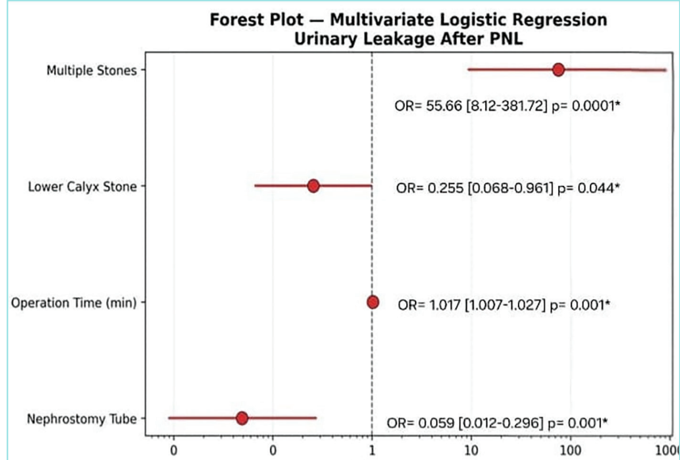

Figure 2. Forest plot of the final multivariate logistic regression model. Error bars represent 95% confidence intervals. Logarithmic scale; dashed line indicates OR=1 (null effect). *Statistically significant ($p<0.05$).

PNL: Percutaneous nephrolithotomy, OR: Odds ratio.

DISCUSSION

In this study, the main predictors associated with clinically significant urinary leakage requiring DJ stent placement after PNL were identified. The most notable finding was that the presence of multiple stones emerged as the strongest independent determinant of urinary leakage. In addition, prolonged operative time significantly increased the risk of leakage, whereas nephrostomy tube placement demonstrated a clear protective effect. Furthermore, the presence of lower calyceal stones remained an independent factor in the multivariable analysis. These findings indicate that both factors related to stone complexity and intraoperative parameters play a critical role in the development of postoperative urinary leakage. Moreover, the model developed in this study demonstrated acceptable discrimination and calibration, supporting its potential utility in perioperative risk assessment in clinical practice.

When the literature on urinary leakage after PNL is examined, factors frequently reported to be associated include stone complexity, degree of hydronephrosis, parenchymal thickness, presence of multiple access tracts, and residual stones. In particular, it has been reported that increased stone complexity and multiple access tracts may exacerbate renal parenchymal injury, delay tract healing, and consequently increase the risk of leakage. Similarly, several studies have demonstrated that the degree of hydronephrosis and parenchymal thickness are associated with the duration of urinary leakage. However, the existing literature is highly heterogeneous, and the predictors identified vary across studies, with no unified risk model currently established. This suggests that urinary leakage after PNL is a multifactorial complication and that both stone-related characteristics and intraoperative parameters should be evaluated together.[4,7-10]

The findings of the present study are generally consistent with those reported in the literature; however, several important differences should be emphasized. The presence of multiple stones was the strongest independent predictor of urinary leakage. Although previous studies have demonstrated an association between stone burden or complexity and leakage, data demonstrating such a pronounced effect size specifically for stone multiplicity remain limited. This suggests that the presence of multiple stones may not only increase overall stone burden but may also be associated with the involvement of multiple calyces, a broader dissection area, and a greater need for intrarenal manipulation.[10-15] However, the markedly asymmetric distribution of multiple stones between groups may also have contributed to inflation of the magnitude of the estimated OR despite the use of Firth penalization. Therefore, the reported effect size for stone multiplicity should be interpreted cautiously.

Similarly, prolonged operative time was identified as an independent risk factor, consistent with the literature, likely reflecting increased tissue trauma and sustained intrarenal pressure. The clear protective

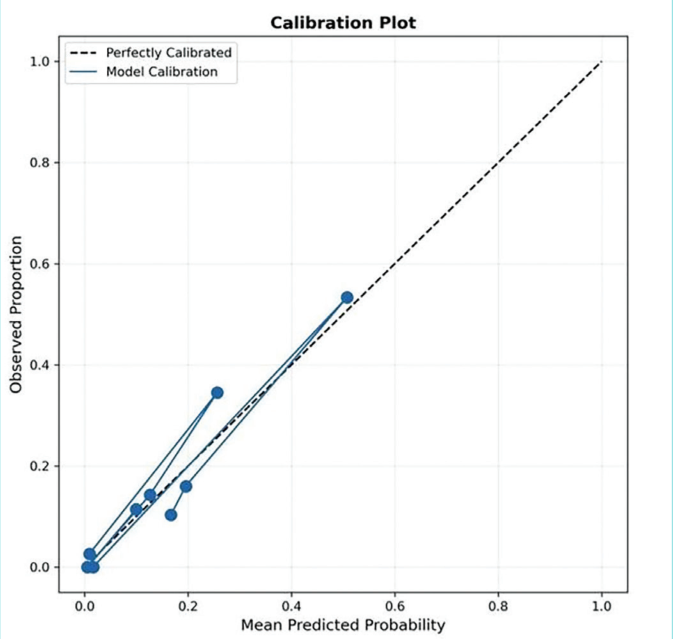

Figure 3. Calibration plot comparing predicted probabilities with observed proportions. Dashed diagonal represents perfect calibration.

effect of nephrostomy tube placement is noteworthy. While this finding is consistent with some previous reports, the role of nephrostomy placement remains controversial in the literature.[16-19] Therefore, it may be reasonable to reconsider nephrostomy use based on careful patient selection.

Interestingly, lower calyceal stone involvement showed a reversal in direction between the univariate and multivariable analyses. While lower calyx stones appeared to be associated with an increased risk of leakage in univariate analysis, the adjusted multivariable model demonstrated an inverse association after accounting for other covariates. This finding may reflect a suppression effect related to the strong co-occurrence between lower calyx involvement and the presence of multiple stones, where the presence of multiple stones was the dominant predictor in the final model. Therefore, the observed association for lower calyx stones should be interpreted cautiously and not necessarily as evidence of an isolated protective effect.

The development of urinary leakage after PNL is a multifactorial process, as emphasized in the literature, arising from the interplay among renal parenchymal injury, disruption of collecting-system integrity, and alterations in intrarenal pressure dynamics. Previous studies have reported that, particularly in cases with large stone burden and complex stone configurations, the need for manipulation of multiple calyces and prolonged intrarenal instrumentation may delay tract healing and increase the risk of leakage.[20]

In addition, increased irrigation pressure and prolonged operative time may contribute to microperforations within the collecting system and to the development of parenchymal edema, thereby facilitating postoperative urinary extravasation along the tract. Indeed, some studies have demonstrated that in cases with reduced parenchymal thickness and significant hydronephrosis, tract closure may be delayed and the duration of leakage prolonged.[10,21,22] Within this context, the identification in our study of the presence of multiple stones and of prolonged operative time as independent risk factors appears consistent with the current pathophysiological framework.

The clinical implications of these findings are particularly noteworthy. The preoperative identification of factors such as multiple stones and an anticipated prolonged operative time may enable the surgeon to plan the drainage strategy. In this context, individualized consideration of nephrostomy tube placement or early DJ stent use for selected high-risk patients may be reasonable.

Furthermore, the acceptable discriminative performance of the developed model suggests that patient-specific risk prediction may be feasible through the combined evaluation of these parameters. This approach may assist perioperative risk stratification and support more individualized clinical assessment in selected patients.

Another important strength of our study is that it not only identifies independent risk factors but also presents a predictive model in which these factors are evaluated collectively. The model's AUC of 0.79 indicates a clinically meaningful level of discrimination, while satisfactory calibration further supports its reliability. However, the model's moderate explanatory power suggests that urinary leakage after PNL is fully predictable and that unmeasured factors may contribute to its development. Therefore, prospective external validation is required before broader clinical implementation. This underscores the need for future studies to incorporate more detailed anatomical and intraoperative parameters to further improve predictive performance.

Study Limitations

This study has several limitations. First, due to its retrospective design, it is subject to selection bias and therefore limits the ability to establish causal relationships. Second, although the study includes a relatively large patient cohort, its single-center nature may restrict the generalizability of the findings. Third, some potentially important anatomical and physiological parameters-such as renal parenchymal thickness along the access tract and intrarenal pressure measurements-were not available and, therefore, could not be included in the analysis. Fourth, validated stone complexity scoring systems, such as CROES, S.T.O.N.E., Guy's, and S-ReSC, were not incorporated into the present analysis; therefore, a comparative evaluation against established nephrolithometric systems could not be performed. In addition, decisions regarding nephrostomy tube placement and DJ stent insertion were based on the intraoperative judgment of the surgeon, which may have introduced variability into clinical practice. Moreover, the observed protective association of nephrostomy tube placement may have been influenced by indication (protopathic) bias, since intraoperative decisions regarding drainage were likely guided by case complexity, bleeding severity, and anticipated postoperative complications. Therefore, the reported effect estimate for nephrostomy tube placement should not be interpreted as causal. Although Firth penalized regression analysis was used to mitigate the effects of rare events and separation bias, residual confounding cannot be entirely excluded. Finally, while the developed model demonstrated acceptable discrimination and calibration, it has not undergone external validation; therefore, its clinical applicability should be supported by prospective, multicenter studies.

CONCLUSION

Clinically significant urinary leakage requiring DJ stent placement after PNL is a multifactorial complication influenced by stone-related and intraoperative factors. In this study, the presence of multiple stones and a prolonged operative time were independently associated with urinary leakage, whereas nephrostomy tube placement was associated with a lower risk of leakage. The proposed predictive model showed acceptable discrimination and calibration, suggesting its potential utility in perioperative risk assessment. Identification of high-risk patients may assist in perioperative risk assessment and postoperative monitoring. Further prospective, multicenter studies are warranted to validate these findings and enhance their applicability in clinical practice.

MAIN POINTS

- Clinically significant urinary leakage requiring ureteral stenting occurred in 15.1% of patients after percutaneous nephrolithotomy.
- Stone multiplicity was the strongest independent predictor of postoperative urinary leakage.
- Prolonged operative time was significantly associated with an increased risk of leakage, likely reflecting cumulative intrarenal trauma and pressure.
- Nephrostomy tube placement demonstrated a strong protective effect against clinically significant leakage.
- The proposed predictive model showed acceptable discrimination (area under the curve: 0.798) and may support individualized perioperative drainage strategies.

ETHICS

Ethics Committee Approval: The study was approved by the Adıyaman University Non-Interventional Clinical Research Ethics Committee (approval no: 2026/3-1, date: 14.04.2026).

Informed Consent: Due to the retrospective nature of the study, informed consent was not required.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F.Ç., Concept: F.Ç., Design: H.K., Data Collection and/or Processing: F.Ç., H.K., Analysis and/or Interpretation: H.K., Literature Search: F.Ç., H.K., Writing: F.Ç., H.K.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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