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External Validation of a Prediction Model to Assess the Risk of Severe Hemorrhage After Mini Percutaneous Nephrolithotomy: A Retrospective Cohort Study

Mini Perkütan Nefrolitotomi Sonrası Ciddi Kanama Riskini Değerlendiren Bir Tahmin Modelinin Eksternal Validasyonu: Retrospektif Kohort Çalışma

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ABSTRACT Objective: It is critical to predict the risk of bleeding after mini percutaneous nephrolithothomy (mini-PCNL). We aimed to perform external validation of the prediction model, which is used to predict the risk of severe hemorrhage after mini-PCNL. **Material and Methods:** Data on mini-PCNL performed between 2013 and 2023 were obtained retrospectively. Demographic data, renal anatomy, renal stone characteristics, and operative, success, and complications data were noted. Severe hemorrhage was defined as decrease in hemoglobin of more than 34.5 g/L or bleeding that required transfusion or angioembolization. Patients were grouped according to hemorrhage status, and data were compared between the groups. The risk of hemorrhage was calculated for each patient according to the prediction model. The success of the prediction model was evaluated using receiver operating characteristic (ROC) analysis and a calibration curve. **Results:** Postoperative hemorrhage developed in 87 (10.5%) of the 826 patients. The mean stone size was calculated to be higher in the hemorrhage group (p=0.036). The urinary tract infection rate was 59.8% in the hemorrhage group and 47.5% in the nonhemorrhage group (p=0.030). The rate of hydronephrosis was statistically higher in the nonhemorrhage group than in the hemorrhage group (29.0% and 18.4%, respectively, p=0.038). The mean operation time was 125.6±41.5 in the hemorrhage group and 104.3±41.6 in the nonhemorrhage group (p=0.001). The mean number of accesses was 1.3±0.5 in the hemorrhage group and was statistically higher here than in the nonhemorrhage group (p=0.003). In the ROC analysis, the estimated area under the curve was 0.703 (p=0.001, 95% CI=0.645-0.762). **Conclusion:** This study externally validates the success of the current prediction model in calculating the risk of hemorrhage after mini-PCNL in the treatment of kidney stones.

Keywords: Complications; hemorrhage; kidney calculi; percutaneous nephrolithotomy; validation study

ÖZET Amaç: Mini perkütan nefrolitotomi [mini percutaneous nephrolithotomy (mini-PCNL)] sonrası kanama riskinin öngörülmesi büyük önem taşımaktadır. Bu çalışma, mini-PCNL sonrası ciddi kanama riskini değerlendirmeyi amaçlayan bir tahmin modelinin harici doğrulamasını yapmayı hedeflemiştir. **Gereç ve Yöntemler:** 2013-2023 yılları arasında mini-PCNL uygulanan hastalara ait veriler retrospektif olarak incelendi. Demografik özellikler, renal anatomi, taş özellikleri, operatif sonuçlar ve komplikasyonlar kaydedildi. Ciddi kanama, hemoglobin düzeyinde >34,5 g/L düşüş veya transfüzyon ya da anjioembolizasyon gerektiren kanama olarak tanımlandı. Hastalar kanama durumuna göre gruplandırılarak karşılaştırıldı. Her hasta için kanama riski tahmin modeliyle hesaplandı ve modelin başarısı alıcı operatör karakteristiği analizi ve kalibrasyon eğrileri ile değerlendirildi. **Bulgular:** Toplam 826 hastanın 87'sinde (%10,5) postoperatif kanama gelişti. Kanama gelişen grupta taş boyutu daha büyük bulundu (p=0,036). İdrar yolu enfeksiyonu oranı bu grupta daha yüksekti (%59,8'e karşı %47,5; p=0,030). Hidronefroz, kanama olmayan grupta daha sık görüldü (%29,0'a karşı %18,4; p=0,038). Ortalama operasyon süresi kanama grubunda anlamlı şekilde daha uzundu (125,6±41,5 dk vs. 104,3±41,6 dk; p=0,001) ve giriş sayısı da daha yüksekti (1,3±0,5; p=0,003). Tahmin modelinin öngörü gücü kabul edilebilir düzeydeydi (eğri altı alan=0,703; p=0,001; %95 GA=0,645-0,762). **Sonuç:** Bu çalışma, mini-PCNL sonrası ciddi kanama riskinin hesaplanmasında mevcut tahmin modelinin başarısını eksternal olarak doğrulamaktadır ve modelin klinik kullanıma uygunluğunu desteklemektedir.

Anahtar Kelimeler: Komplikasyonlar; kanama; böbrek taşı; perkütan nefrolitotomi; validasyon çalışması

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Percutaneous nephrolithotomy (PCNL) is the established method for managing large and complex renal calculi.[1] Mini-PCNL, which uses miniaturized instruments, has been developed to reduce complication rates while achieving similar success rates.[2] Even though PCNL is considered a less invasive intervention, it can lead to complications of varying severity. The most common complications of PCNL are fever and hemorrhage requiring blood transfusions.[3] Severe hemorrhage can cause kidney damage, a prolonged hospital stay, the need for blood transfusion, and even kidney loss. For this reason, it is critical to predict and prevent the development of hemorrhage.

Nomograms defined for many surgical techniques are used to predict success and complications. Using nomograms is important for predicting the problems that a surgeon may encounter in the postoperative period, informing patients correctly, and standardizing treatment methods. Commonly used nomograms for outcomes after PCNL are Guy's, CROES, and S.T.O.N.E nomograms.[4-6]

For the purpose of determining the chance of severe bleeding after undergoing mini-PCNL, Zheng and colleagues designed a predictive nomogram.[7] The number of accesses, degree of hydronephrosis, congenital disorders affecting the urinary tract and urinary infections, operation time, and hounsfield unit (HU) of the renal calculi were linked with the risk of hemorrhage. In this study, we aimed to perform external validation of the prediction model, seeking to forecast the risk of major bleeding post mini-PCNL.

MATERIAL AND METHODS

Following approval from the Local Ethical Committee of Haseki Training and Research Hospital (dated 06/12/2023, reference number: 207-2023), the study was conducted in line with the ethical standards outlined in the Declaration of Helsinki. Data on mini-PCNL performed between 2013 and 2023 were obtained from the database of tertiary healthcare institutions. Demographic data, renal anatomy, renal stone characteristics, and operative, success, and complications data were noted. Stone size was calculated as the longest diameter length observed using computed tomography, and patients with calculi measuring more than 2 cm were enrolled in the study. HU was noted as the highest value of the stone. Severe hemorrhage was defined as decrease in hemoglobin of more than 34.5 g/L or bleeding that required transfusion or angioembolization. Urinary tract infection was indicated by urine culture positivity or leukocyte positivity in urinalysis.

Patients were grouped according to hemorrhage status, and all data were compared between the groups. The risk of hemorrhage was calculated for each patient according to the prediction model.[7] Patients below 18 years old or those lacking complete data, patients who used anticoagulant or antiplatelet medications, 2nd-stage PCNL, and patients with preoperative hemoglobin ≤90 g/L were excluded. Informed consent for mini-PCNL was obtained from all patients.

PREDICTION MODEL

The risk of serious hemorrhage was calculated using the following formula: $e^p/(1+e^p)$, $p=-6.7068+0.7829\times$ the number of accesses$+1.1620\times$hydronephrosis$+1.1334\times$congenital anomalies$+0.3915\times$urinary tract infection$+0.0101\times$duration of operation$+0.0008\times$ HU.[7]

MINI-PCNL TECHNIQUE

An 8 Fr semirigid ureterorenoscope was used to guide a guidewire to the ureter, a 5f ureteral catheter was placed over the guidewire, and the patient was placed in the prone position. The pelvicalyceal system was visualized using fluoroscopy, and an 18-gauge percutaneous access needle was inserted into the appropriate calyx using the triangulation technique. After the guidewire was sent to the pelvicalyceal system, serial dilatation was performed using amplatz dilators. A 21 Fr metallic sheath (Karl Storz, Tuttlingen, Germany) was placed under fluoroscopic guidance. A 19.5 Fr nephroscope (Karl Storz, Tuttlingen, Germany) was inserted into the pelvicalyceal system, and the stones were fragmented using a holmium YAG laser lithotripter (Sphinx, Lisa Laser, USA). The operation was terminated by placing a total tubeless or JJ stent, nephrostomy catheter, or both.

STATISTICAL ANALYSIS

Statistical evaluations were performed using SPSS version 27. To assess the normality of variable distributions, both the Shapiro-Wilk test and Q-Q plots were employed. Continuous variables were compared using either Student's t-test or the Mann-Whitney U test. Group differences in categorical variables were analyzed with the chi-square test. Receiver operating characteristic (ROC) analysis was conducted to assess the performance of the predictive model. A linear regression approach was utilized to develop a calibration curve, comparing predicted complication rates with the actual observed rates. Statistical significance was set at p value≤0.05.

RESULTS

Postoperative hemorrhage developed in 87 (10.5%) of the 826 patients included in the study. The mean age of the hemorrhage group was 46.8±12.8, and that of the nonhemorrhage group was 47.4±12.8 (p=0.670). Forty-five (51.7%) patients in the hemorrhage group and 317 (42.9%) patients in the nonhemorrhage group were male. The rates of diabetes mellitus, hypertension, and mean body mass index were similar between the groups (p=0.872, p=0.595, and p=0.274, respectively). Congenital urinary anomalies were present in 4 (4.6%) patients in the hemorrhage group and 17 (2.3%) patients in the nonhemorrhage group (p=0.198). The mean stone size was found to be higher in the hemorrhage group (p=0.036). The mean HU of the stones was 1089.7±373.6 in the hemorrhage group and 1044.1±320.8 in the nonhemorrhage group (p=0.218). The urinary tract infection rate was 59.8% in the hemorrhage group and 47.5% in the nonhemorrhage group (p=0.030). The rate of hydronephrosis presence was statistically higher in the nonhemorrhage group than in the hemorrhage group (29.0% and 18.4%, respectively, p=0.038) (Table 1).

TABLE 1: Comparison of patient demographic data, preoperative findings and stone properties by groups

	Hemorrhage (n=87)	No hemorrhage (n=739)	p value
Age (years)*	46.8±12.8	47.4±12.8	0.670
Gender			
Male	45 (51.7%)	317 (42.9%)	0.116
Female	42 (48.3%)	422 (57.1%)	
Diabetes mellitus	11 (12.6%)	98 (13.3%)	0.872
Hypertension	25 (28.7%)	233 (31.5%)	0.595
BMI (kg/m^2)*	25.8±4.7	26.4±4.7	0.274
Congenital anomalous	4 (4.6%)	17 (2.3%)	0.198
Previous stone surgery	39 (44.8%)	339 (45.9%)	0.853
Stone burden (mm^2)*	755.8±602.4	634.2±500.8	**0.036**
Hounsfield unit*	1089.7±373.6	1044.1±320.8	0.218
Urinary tract infection	52 (59.8%)	351 (47.5%)	**0.030**
Hydronephrosis			
None or mild	71 (81.6%)	525 (71.0%)	**0.038**
Moderate or severe	16 (18.4%)	214 (29.0%)	
Preoperative creatine (mg/dl)*	0.9±0.3	1.0±0.3	0.238

*mean±standart deviation; ASA: American Society of Anesthesiologists; BMI: Body mass index; CCI: Charlson comorbidity index

The average duration of the procedure was 125.6±41.5 in the hemorrhage group and 104.3±41.6 in the nonhemorrhage group (p=0.001). There was no difference between the groups in terms of the sides of the operation (p=0.198). When the access localizations were evaluated, the rate of patients with upper calyx and multiple tracts was higher in the hemorrhage group than in the nonhemorrhage group (p=0.001 and p=0.004, respectively). The mean number of accesses was 1.3±0.5 in the hemorrhage group and was statistically higher than in the nonhemorrhage group (p=0.003). The duration of hospitalization was statistically higher in the hemorrhage group (p=0.001). The mean hemoglobin decrease was 25.0±13.7 g/L in the hemorrhage group and 12.4±11.9 g/L in the nonhemorrhage group (p=0.001) (Table 2).

ROC analysis was utilized to assess the model's predictive performance (Figure 1). The estimated

TABLE 2: Comparison of operation data and postoperative follow-up results

	Hemorrhage (n=87)	No hemorrhage (n=739)	p value
Duration of operation (minimum)*	125.6±41.5	104.3±41.6	**0.001**
Side of operation			
Right	46 (52.9%)	337 (45.6%)	0.198
Left	41 (47.1%)	402 (54.4%)	
Access localization			
Lower calyx	52 (59.8%)	443 (59.9%)	0.975
Middle calyx	22 (25.3%)	208 (28.1%)	0.574
Upper calyx	35 (40.2%)	178 (24.1%)	**0.001**
Multiple	17 (19.5%)	81 (10.9%)	**0.004**
Number of accesses	1.3±0.5	1.1±0.4	**0.003**
Hospitalization time (hours)*	53.5±38.6	41.7±29.5	**0.001**
Hemoglobin drop (g/l)*	25.0±13.7	12.4±11.9	**0.001**

*mean±standart deviation

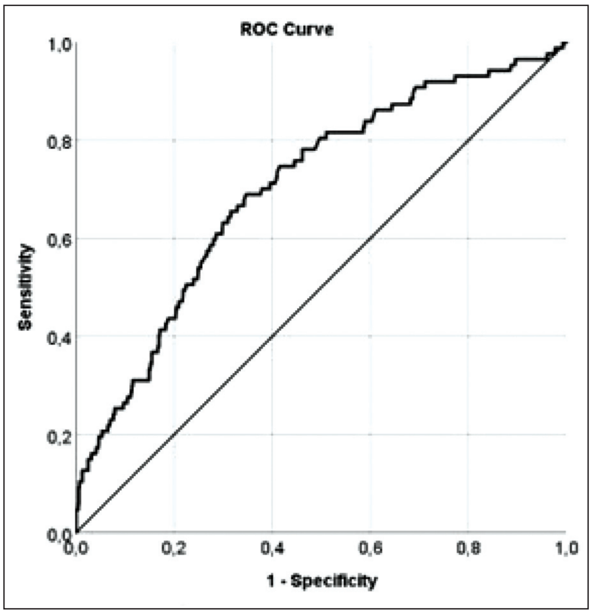

FIGURE 1: ROC analysis of the predictive model's ability to predict severe hemorrhage after mini-PCNL
The predictive ability of the model was analyzed using ROC analysis.

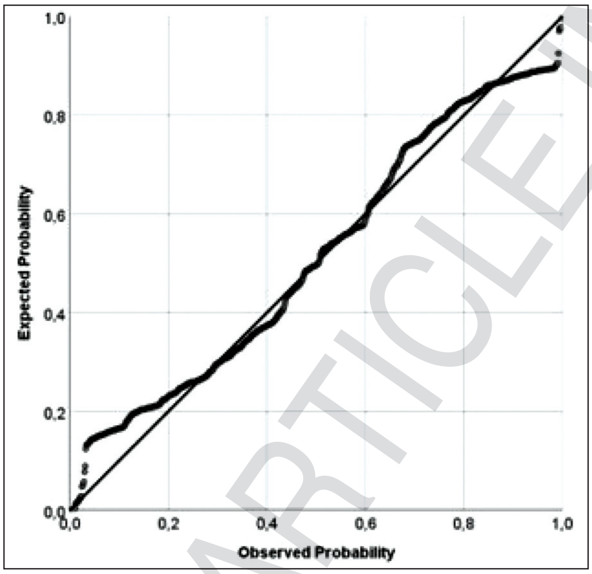

FIGURE 2: The calibration plot of the model

area under the curve was 0.703 (p=0.001, 95% CI=0.645-0.762), demonstrating high predictive accuracy for the risk of postoperative hemorrhage. The calibration plot of the model is shown in Figure 2, and the calibration curve shows that the prediction model is in strong agreement with the results of our study.

DISCUSSION

As a minimally invasive procedure, mini-PCNL offers high success rates in the treatment of renal calculi. Postoperative stone-free rates vary between 70% and 96%.[8] Although it is an effective treatment, the possibility of complications is almost inevitable. Perioperative or postoperative complication rates can reach up to 83%.[3] The most common serious complication, at a rate of 4-23%, is renal hemorrhage.[7] The findings of this study are in agreement with previously published literature, and the rate of severe hemorrhage was found to be 10.5%.

Factors associated with the probability of major hemorrhagic complications post-PCNL have been investigated in many studies.[9-11] Many factors, such as patient demographics, kidney stone characteristics, surgical technique, surgical experience, and operation data, have been associated with the risk of postoperative hemorrhage. However, the first prediction model on this subject was developed by Zheng et al.[7] The current study is the first external validation study to evaluate this prediction model.

The number of tracts has been associated with the risk of hemorrhage in the postoperative period. Hegarty et al. compared the results of single-tract and multiple-tract PCNL and reported a higher transfusion rate and higher hemoglobin reduction in patients who underwent multiple-tract PCNL.[12] Similarly, El-Nahas et al. reported hemorrhage rates of 0.8% in single-tract PCNL and 2.9% in multiple-tract PCNL.[13] In our study, we observed that an increase in the number of tracts increased the risk of hemorrhage, which is parallel to the literature.

Hemorrhage may occur during the stages of puncture, dilatation, instrument manipulation, or stone fragmentation.[14] A difficult puncture is a common cause of intraoperative and postoperative hemorrhage. Dilation of the pelvicalyceal system is a factor that facilitates puncture. There are some studies on the increased risk of bleeding after PCNL in cases without hydronephrosis.[15,16] In patients with urinary system anomalies, difficulties in the puncture and dilatation stages or the abnormal vascularization line may result in hemorrhage. Arora et al. found a relationship between the need for angioembolization after PCNL and in cases involving kidney anomalies.[17] In contrast, Osther et al. compared individuals with renal anomalies to those with normal anatomy and reported no significant difference in bleeding outcomes.[18] In our study, we found higher hemorrhage rates in patients without hydronephrosis, but there was no correlation between the presence of congenital anomalies and hemorrhage rates.

Apart from kidney anatomy, kidney stone features are also associated with the development of complications. Complex stones, large stones, and hard stones may make it more difficult to manipulate instruments or cause prolonged operation times and injuries to the pelvicalyceal system during fragmentation. Said et al. reported higher bleeding rates in cases of large and complex stones.[19] Gök et al. showed a correlation between a high HU and the risk of hemorrhage.[20] Prolongation of operation time has also been shown to cause an increased risk of bleeding.[13,21] Our results also showed that longer operation time increased the risk of hemorrhage.

Urinary tract infections are characterized by bacteriuria and inflammation. Inflammation of the pelvic-oral mucosa may pose a risk of bleeding during PCNL. Different results on this subject have been reported in the literature. Du et al. showed that preoperative urinary tract infection increase the possibility of bleeding.[22] Wang et al., on the other hand, found no relationship between the presence of leukocytes in urinalysis and postoperative bleeding.[23] Our analysis revealed a link between preoperative urinary tract infections and postoperative bleeding.

A prediction model with risk factors offers standardization in terms of complication management. The easy applicability of the prediction model developed by Zheng et al. is an important advantage.[7] Internal validation of the model has shown that it can make successful risk predictions. Our study has shown that this prediction model is applicable with high predictive success. Considering the data from the model study and the present study, tract localization was also associated with the risk of hemorrhage. Adding tract localization can improve the predictive power of the model. Considering the calibration curve, the prediction model showed higher expected complication rates than the actual complication rates observed in our study. This may be related to the fact that the number of patients who underwent multiple accessory procedures in the data constituting the prediction model was higher than in our study.

The first limitation of the current study is that it was a single-center study. Its retrospective nature might be considered another limitation. In addition, only 21 Fr mini-PCNL cases were evaluated in our study. Since the complication rates related to small stones are predicted to be low, the evaluation of kidney stones greater than 2 cm may cause bias by skewing the results toward higher complication rates.

CONCLUSION

This study externally validates the success of the current prediction model used to calculate the potential for severe bleeding after undergoing PCNL for the treatment of kidney stones. Using the prediction model before conducting the procedure may be instructive for planning postoperative follow-up and providing patients with accurate information.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Ufuk Çağlar, Arda Meriç;* ***Design:*** *Arda Meriç, Alı Ayrancı;* ***Control/Supervision:*** *Ömer Sarılar, Faruk Özgör;* ***Data Collection and/or Processing:*** *Alı Ayrancı, Çağlar Dizdaroğlu;* ***Analysis and/or Interpretation:*** *Ufuk Çağlar, Hüseyın Burak Yazılı;* ***Literature Review:*** *Çağlar Dizdaroğlu, Hüseyın Burak Yazılı;* ***Writing the Article:*** *Ufuk Çağlar, Arda Meriç;* ***Critical Review:*** *Faruk Özgör, Ömer Sarılar;* ***References and Fundings:*** *Çağlar Dizdaroğlu;* ***Materials:*** *Hüseyın Burak Yazılı.*

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