Predicting Surgical Outcome of Percutaneous Nephrolithotomy: Validation of the Guy’s Stone Score and Nephrolithometric Nomogram in Terms of Success and Complications

Perkütan Nefrolitotominin Cerrahi Sonuçlarının Öngörülmesi: Guy Taş Skoru ve Nefrolitometrik Nomogramın Başarı ve Komplikasyon Validasyonu

PCNL Sonucu ile Guy Taş Skoru ve Nomogram / PCNL Outcome with Guy Stone Score and Nomogram

Tulga Eğilmez, Mehmet Reşit Gören
Üroloji Kliniği, Başkent Üniversitesi Adana Uygulama ve Araştırma Hastanesi, Adana, Türkiye

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Özet
Amaç: Tek merkezden retrospektif olarak yapılan bu çalışmanın amacı, Guy taş skoru ve nefrolitometrik nomogram kabliliyeti ile PCNL başarı ön- görümesi ve gözlemlediğimiz komplikasyonların skorlaması sistemleri ile değerlendirilmesinin validasyonunun yapılmasıdır. Gereç ve Yöntem: PCNL ameliyatı uygulanmış 1646 yetişkin hastanın medikal kayıtları gözle yok edilmişdir. Gereklilik kuralları sağlayan 1325 hasta çalışmaya dahil edilmiştir. İstatistiksel analiz için gereklilik verileri hastaların medikal kayıtlarından edilmişdir. Bulgular: Gözlemlenen komplikasyonlarla ve başarı ile anlamlı korelasyonun bulunduğu tek preoperatif, operatif ve postoperatif değişken taş yüküdür (p<0,05). Guy taş skoru 1 ve 2, başarı ile ilişkilidir, skor 3 ve 4 komplikasyonlarla ilişkilidir (p<0,05). ASA skor 3 ve 4’ün komplikasyonlar ile ilişkili olduğu gözlemlenmiştir (p<0,05). Ameliatı süresi >120 dakika, staghorn taş varlığı, peroperatif ve postoperatif kan transfüzyonu, nefrostomi kateterin süresi, 2 gr/dl’den fazla ΔHg ve postoperatif kan/idrar kültüründe üreme olması gözlemlenen komplikasyonlar ile ilişkilidir (p<0,05). Nefrolitometrik nomogram verileri ile yapılan ROC eğrisi analizi, başarı eşik değeri %80,5 ile, nomogramın sensitivitesinin %71 ve spesitivitesinin %74 olduğu göstermiştir (ROC AUC=80%). Nomogramın gözlenen komplikasyon için daha iyi analizinde ise olası bir komplikasyonun önongörülemesi için veritane hızlıra ilişkili bulunmadığı göstermiştir (ROC AUC=67%). Tartışma: Bu çalışma, nefrolitometrik nomogramın başarı için iyi bir tahmin kabliliyeti olduğunu göstermiştir (ROC AUC=80%). Anahtar Kelimeler
Perkütan Nefrolitotomi; Guy Taş Skoru; Nefrolitometrik Nomogram

Abstract
Aim: This single institution retrospective study aims to validate the ability of Guy’s stone score and the nephrolithometric nomogram to predict the success of PCNL and to assess the correlation of the scoring systems with the complications encountered. Material and Method: Medical files of 1646 adult patients to whom a PCNL operation was performed were reviewed. A total of 1325 patients fulfilled the needed criteria and were included in the study. Study variables were recorded from the medical files for statistical analysis. Results. Stone burden was the only pre-operative, operative and post-operative variable that had a statistically significant correlation both with success and also with the complications encountered (p<0.05). Guy’s stone score grade 1 and 2 were associated with success and grade 3 and 4 were associated with complications (p<0.05). ASA score 3 and 4 were seen to be associated with complications (p<0.05). Operation time >120 minutes, presence of a staghorn stone, intra- and post-operative blood transfusion, duration of the nephrostomy catheter, ΔHg more than 2 g/dl and positive post-operative urine/blood culture were the other associated variables related to the complications encountered (p<0.05). ROC curve analysis performed to the nephrolithometric nomogram data showed that with a cut of value of 80.5% for success, the nomogram has a sensitivity of 71% and specificity of 74% (ROC AUC= 80%). The nomogram was further analyzed for an association between the complications encountered and showed that the association is not strong enough to predict a possible complication (ROC AUC= 67%). Discussion: This study shows that the nephrolithometric nomogram has a good predictive accuracy for success (AUC= 80%) and the Guy’s stone score has a good correlation both with success and with complications (p<0.05) and can be used for pre-operative counseling and decision making. Keywords
Percutaneous Nephrolithotomy; Guy’s Stone Score; Nephrolithometric Nomogram
Introduction

Percutaneous nephrolithotomy (PCNL) was first described in 1976 and since then, efforts have been made to make the procedure safer and more effective [1]. Today, PCNL plays an integral role in managing renal stone disease and morbidity and mortality of the disease and also of the treatment itself, has been dramatically reduced. On the other hand, although accepted as minimally invasive, it is an operation which still poses a significant risk of complications. Clavien system has been modified to grade these complications [2, 3] (Table 1).

Table 1. Modified Clavien classification system.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>Any deviation from the normal post-operative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions (allowed therapeutic regimens are antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy).</td>
</tr>
<tr>
<td>II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications.</td>
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<tr>
<td>IIIa</td>
<td>Requiring surgical, endoscopic or radiological interventions not under general anesthesia.</td>
</tr>
<tr>
<td>IIIb</td>
<td>Requiring surgical, endoscopic or radiological interventions under general anesthesia.</td>
</tr>
<tr>
<td>IVa</td>
<td>Life-threatening complication requiring Intensive Care Unit management (single organ dysfunction).</td>
</tr>
<tr>
<td>IVb</td>
<td>Life-threatening complication requiring Intensive Care Unit management (multiple organ dysfunction).</td>
</tr>
<tr>
<td>V</td>
<td>Death of a patient.</td>
</tr>
</tbody>
</table>

With numerous previous studies, pre- and peri-operative factors such as stone size and configuration, percutaneous access number and location, entry performed by radiologist or urologist, presence of hydronephrosis have been investigated as predictors of success rates and complications [4-10]. Attempts to identify the associated variables showed variations among the results which has made it difficult to classify the patients so that the stone free rate (SFR) or complications can be predicted. Aiming for a quick, simple and reproducible method for the prediction of the outcomes of PCNL, the ‘Guy’s stone score’ has been proposed by Thomas et al [11]. They have found that the score correlates with stone free rates but not with complications. The grading system mainly takes into consideration the number of stones, stone location and whether the renal anatomy is simple or abnormal. In this scoring system, calyceal diverticulum stones, staghorn stones and any stone in a patient with a spina bifida or spinal injury are the special circumstances that effect the grading of the stone (Table 2). The score is based not an abnormal renal anatomy, an abnormal collecting system or a patient with an ileal conduit (i.e. cases where the operating surgeon believes access may be difficult). The authors have concluded that the Guy’s stone score can accurately predict the SFR status and have stated that the insignificant correlation with complications may have resulted due to the small patient group of their study in which 100 patients were included.

On the other hand, Smith et al have recently developed a ‘nephrolithometric nomogram’ in order to predict the treatment success in PCNL in which they have used preclinical data and radiological information as the variables of the nomogram (Figure 1).

The results of this ‘The clinical research office of the Endourological Society (CROES)’ study showed that stone burden is the best predictor of SFR and case volume, prior stone treatment, presence of staghorn stone, stone location and stone count were the other associated factors [12]. Using these variables a nephrolithometric nomogram was developed which gives an estimated success rate in a range of 30-90% and was found to have a predictive accuracy.

This single institution retrospective study aims to validate the ability of Guy’s stone score and the nephrolithometric nomogram to predict the success of PCNL and to assess the correlation of the scoring systems with the complications encountered.

Material and Method

Medical files of 1646 adult patients to whom a PCNL operation was performed between 8/2002 and 5/2012 were reviewed. Exclusion criteria included non-opaque stones, patients with a stent, nephrostomy tube or indwelling catheter, patients with active UTI, operations in which the percutaneous access was made pre-operatively by a radiologist, contralateral renal or ureteric stone disease, second look PCNL and same session bilateral PCNL operations.

Data recorded from the medical files included: age, gender, stone size (burden), stone location, presence of hydronephrosis, other concomitant disease, previous shock wave lithotripsy or renal surgery history, American Society of Anesthesiologists (ASA) score, subcostal or intercostal entry, number of access tracts made during the operation, dilatation type (Amplatz dilators/ balloon dilatation), operation time, blood transfusion, complications, residual stone status, pre-operative and post-operative hemoglobin (Hb), post-operative renal and blood culture results. The kidney stones were diagnosed by intravenous pyelography
and/or computerized tomography (CT). Stones were classified according to the Guy’s stone score (Table 2). For the nephrolithometric nomogram, stone burden was calculated as the surface area calculated according to the EAU guidelines using the two greatest vertical and horizontal dimensional measures seen on a plain x-ray of the kidney-ureter-bladder (KUB) [13]. In patients without a KUB or intravenous pyelography but with a CT scan, the size of stones were calculated by the same way but by the dimensions obtained from the topogram of the non-contrast computed tomography images. Stones filling the renal pelvis and all of the calyces were defined as staghorn calculi and the area of each stone port located in the calyces and the pelvis was calculated separately and then added [13].

Operation time was derived from the anesthesia chart and defined as the time elapsed in minutes from the induction of anesthesia until the insertion of nephrostomy catheter. The patients were grouped into 4 groups (30-60 min, 61-90 min, 91-120 min, and >120 min). The difference of hemoglobin (ΔHb) was calculated by subtracting the hemoglobin value after surgery from the value obtained within a week before surgery. The patients were grouped into 5 groups (0-0.5, 0.6-1, 1.1-1.5, 1.6-2 and >2 gr/dl). Each surgeon’s annual case volume was counted for each year and the previous year value was used when calculating the nephrolithometric nomogram case/volume score. Nephrolithometric nomogram scores exceeding the upper limit of the nomogram (90%) were recorded as 90% for statistical analysis.

The patients were evaluated using a KUB performed on the morning after the procedure and a CT performed 1 month after the operation for the follow-up. Postoperative outcome was evaluated by this post-operative CT and patients lacking it were also excluded from the study. The residual stone status was evaluated in three categories; stone free (SF), clinically insignificant residual fragments (CIRF, residual fragments smaller than 4 mm) and clinically significant residual fragments (CSRF, residual fragments larger than 4 mm). Success rate was defined as the sum of SF and CIRF.

The type of complication encountered was noted and then classified according to the modified Clavien System [1]. For any patient, only the complication of highest grade was analyzed. According to the elective endoscopic operation preparation protocol of our clinic, all patients included in the study had a preoperative urine culture and were treated pre-operatively according to the antibiotic sensitivity tests. More than 105 organisms per milliliter detected on a urine culture was used to define an infection and the operations were performed only after achieving a negative urine culture. Again, according to the protocol, all patients received peri-operative prophylactic antibiotic treatment before surgery on arrival at the operation theatre with an intravenous administration of 1 g Cephazolin, a first-generation cephalosporin antibiotic and the antibiotic treatment was continued post-operatively with intravenous Ciprofloxacin 200 mg, bid, during the first post-operative day (POD). If post-operative fever >38°C was encountered, urine cultures from the nephrostomy catheter and two blood cultures were obtained and the intravenous antibiotic treatment was continued. The treatment was later changed according to the antibiotic sensitivity of the cultures. Otherwise, in the case of an uneventful post-operative period, this treatment was continued with per os Ciprofloxacin twice a day for 5 days starting from the post-operative day 2. Patients with known drug allergies, patients under age 18 or with renal insufficiency are exceptions for the above-mentioned peri-operative and post-operative antibiotic treatments and for the standardization of the treatment, these patients were not included in the study.

Patients that did not have medical data of the above mentioned study variables were excluded from the study. A total of 1325 patients fulfilled the needed criteria and were included in the study.

Operations: All of the operations were performed in a single center under general anesthesia. After ureteral catheter insertion in the lithotomy position, the patients were tilted to prone position. The pyelocalyceal system was approached with the insertion of an 18-gauge Chiba needle under fluoroscopic guidance. Tract dilation was achieved either via Amplatz or a high pressure balloon dilator NephroMaxTM (Boston scientific) after placement of a safety guide-wire in place. At the end of the dilation, a 30F renal sheath (Microvasive, Natick, Massachusetts) was placed and rigid nephroscopy was performed. A pneumatic lithotripter was used for stone fragmentation. The stone fragments were mechanically extracted and a nephrostomy catheter (14-20F) was placed at the end of the operation. The nephrostomy catheter was withdrawn following an antegrade pyelography which was performed after the gross hematuria cleared.

Statistical analysis: Statistical analysis of data was performed with Statistical Package for Social Sciences (SPSS) 15.0 for Windows and in addition to descriptive statistical methods (mean, standard deviation), Chi-square and Mann-Whitney tests were used for qualitative and numerical data, as appropriate. P values <0.05 were considered to be statistically significant. For the nephrolithometric nomogram validation, ROC curve analysis was performed to estimate the cut of values, sensitivity, specificity and area under the ROC curve (ROC AUC) values for evaluation of success and the complications encountered.

Results

Table 3 shows the demographic and clinical characteristics of the patients and stones. The mean age of the 1325 patients was 46.3±14.7 (range 18-86). Stone burden was the only pre-operative, operative and post-operative variable that had a statistically significant correlation both with success and also with the complications encountered (p<0.05). Guy’s stone score grade 1 and 2 were associated with success and grade 3 and 4 were associated with complications. The associations were statistically significant (p<0.05). Although neither presence of diabetes mellitus nor cardiovascular disease had a statistically significant association between success and complications, ASA score 3 and 4 were seen to be associated with complications (p<0.05). Operation time >120 minutes, presence of a staghorn stone, intra- and post-operative blood transfusion, duration of the nephrostomy catheter, ΔHb more than 2 gr/dl and and positive post-operative urine/blood culture were the other associated variables related to the complications encountered (p<0.05).

Presence and the degree of hydronephrosis had no statistical significant correlation with success or complications. The procedural information of the series is summarized in Table 4 and the post-operative data and outcomes are given in Table 5. The
ROC curve analysis showed that the association is not strong. With a 78.5% cut of value, it has a 65% sensitivity and 69% specificity (ROC AUC= 67%) to predict a possible complication.

The overall complication rate of this study was 24% and most of the complications encountered were Clavian grade 1 and 2. Clavian 3a, 3b, 4a, 4b and 5 were seen in 8% (3%, 3%, 1% and 1%, respectively). One of the three patients who died (Clavian 5) had a staghorn stone disease and an ASA score 4 (renal failure, diabetes mellitus and hypertension). The operation time was 140 min. and was stone free at the end of the operation. The operation was uneventful and was performed through lower and middle calyx entries. But massive bleeding occurred after the renal sheath was removed and was treated with embolization of the bleeding lower pole accessory artery. The other two patients also had large stones, operation times > 120 min. and Hb loss more than 2 gr/dl. But embolization was not performed and these patients were followed with blood transfusions. In all of the three patients, bleeding stopped but persistent fever was encountered in the post-operative period. They had all four of the systemic inflammatory response syndrome criteria (body temperature lower than 36°C or higher than 38°C, heart rate greater than 90 beats/min, respiratory rate greater than 20 breaths/min or PaCO2 less than 32 mmHg, white blood cell count greater than 12x10^9/L or less than 4x10^9/L, or >10% immature forms) but the nephrostomy and blood cultures showed no microorganism growth. Their conditions deteriorated in spite of the administered broad spectrum antibiotics and medical treatment. Eventually multiple organ failure (MOF) developed leading to death. Table 6 shows the complications and the complication rates encountered.
Both success rate and complication rate is important for determination of the surgical outcome of PCNL. Success rates can be easily assessed with a generally used < 4 mm cut off point to define CIRF and the sum of CIRF and stone free rates to define success rate. But complication rate determination shows variability among institutions which hampers comparison of outcome data between institutions and also in the same institution within time. Due to the variations among the reported complications which is mainly caused by classification of the complications as minor or major and with the need of a uniform grading system, the ‘Clavien classification system’ has been adopted and modified for the use in urology [3]. Tefekli et al. [14] were the first to report their peri-operative complications of PCNL using this system. They have also redesigned the complications of some of the previously reported large series in which the complications were categorized as minor and major and found that minor complications corresponded to grade 1 and 2, while major complications to grade ≥ 3 [15, 16]. They have concluded that the system is useful for grading the complications but still needs minor modifications especially concerning auxiliary procedures. Especially Clavian 1 and 2 complications have differences between institutions due to different antibiotic protocols. In an institution where antibiotics are administered post-operatively as a routine treatment, this antibiotic treatment is not accepted as a deviation from the normal pharmacological treatment. But in another institution where no post-operative antibiotics are routinely used, the same antibiotic treatment is graded as Clavien 1. Again, in an institution where radiological interventions are regularly and successfully performed, a complication might be treated by interventional radiology and general anesthesia might not be needed (Clavien 3a). But in another institution, the same complication may have to be treated by surgery under general anesthesia (Clavien 3b).

In the study of Smith et al. by which they have developed the nephrolithometric nomogram, stone burden was the best predictor of the stone-free rate. Other factors associated with the stone-free rate were case volume, prior stone treatment, stag-
horn stone, stone location and stone count. They have reported that the nephrolithometric nomogram has a predictive accuracy for success (AUC 0.76).

In this study when a cut of value of 80.5% for success is taken, the predictive accuracy for success has been found to be 80%. The nomogram has a sensitivity of 71% and specificity of 74%. Keeping in mind that the nomogram was not designed to predict complications, when the nomogram was further analysed for an association between the complications encountered, the ROC curve analysis showed that the association was not strong. With a 78.5% cut of value, it has a 65% sensitivity and 69% specificity (ROC AUC= 67%) to predict a possible complication. In this study, the total complication rate and also the severity of the complications are similar with the complications reported by Tefekli et al. [14] which was also a retrospective study. In their study, Clavien grade 1 complications were also seen less than grade 2 complications (4% vs. 16.3%, respectively). But in a prospective study of de la Rosetta et al., grade 1 complications were reported higher (11.1%) than grade 2 complications (5.3%) which supports the drawback of a retrospective study in means of the limited ability to identify some of the grade 1 complications [2].

**Conclusion**
A quick, simple and reproducible method which has a good correlation with the SFR and the complication rates of PCNL will improve accuracy of the preoperative counseling of the patient. This study shows that the nephrolithometric nomogram has a good predictive accuracy for success (AUC= 0.80) and the Guys’s stone score has a good correlation both with success and with complications (p< 0.05) and can be used for pre-operative counseling and decision making.

**Competing interests**
The authors declare that they have no competing interests.

**References**