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Özgün araştırma / Original research

CROES nefrolitometri nomogramı perkütan nefrolitotomi sonuçlarını tahmin edebilir mi?

Can CROES nephrolithometric nomogram predict postoperative outcomes of percutaneous nephrolithotomy?

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Özet

Amaç: Çalışmamızda CROES nefrolitometri nomogramının perkütan nefrolitotomi sonuçlarını tahmin etmedeki değeri ve PNL komplikasyonlarımızın modifiye clavien sisteme göre değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntem: Merkezimizde opere edilen toplam 220 hasta çalışmaya alındı. Tüm hastaların klinik özellikleri, taş özellikleri (yeri, lokalizasyonu, alanı), geçirilmiş cerrahi operasyona ait özellikler (kan kaybı, operasyon süresi, diversiyon çeşidi) taşsızlık oranı ve komplikasyonlar değerlendirildi. Her bir hastanın verileri CROES nomogramı ile skorlandı ve hastaların öngürülen taşsızlık oranı belirlendi. Cerrahi sonuçlarımız ile standart CROES nomogramından elde edilen sonuçlar karşılaştırılarak CROES nomogramının etkinliği değerlendirildi. Bulgular: Body mass index Vücut kitle indeksi ortalaması 26.7±3.3 kg/m2 olan hastalarımızın yaş ortalaması 45.8±15.2 yıl idi ve erkek hasta sayımız daha fazlaydı (%60% vs %40%). Hastalarımızın %36.8'inde daha önce taşa yönelik geçirilmiş bir girişim öyküsü vardı. Staghorn taş oranı %12.7, ortalama taş alanı 452.8±213.4 mm2 olarak bulundu ve %57.3 hastada aynı böbrekte multiple taş vardı. Taşsızlık oranımız %78.2 olarak bulundu. CROES skoruna göre tahmini taşsızlık şansı oranımız %80 idi. Bu tahmini oran ile gerçek başarımız arasındaki fark ise sadece %1.8 idi.

Sonuç: CROES nomogramı ile PNL öncesinde taşsızlık oranı işlem öncesinde başarılı bir şekilde tahmin edilebilir. İlk başta kullanımı zor gibi olsa da kullandıkça basitleşen, anlaşılması kolay, parametleri objektif ve sonuçları akla yatkın olan bu nomogram klinisyenlere oldukça yol göstericidir.

Anahtar Kelimeler: CROES nomogramı, Perkütan nefrolitotomi, Skorlama sistemi

Abstract

Objectives: To assess the prediction of stone clearance of percutaneous nephrolithotomy using the 'CROES' nephrolithometric score, and analyze complications of using modified Clavien classification system.

Materials and Methods: A total of 220 operated patients were included in the study. Overall patient characteristics, stone localization, stone burden, prior stone surgery, urine analysis, blood loss, operative duration, postoperative JJ stent and/or nephrostomy tube, stone-free status, and complications were analyzed. Data from each patient were scored with CROES nomogram, and the predicted stone-free rate of patients was determined. The efficacy of CROES nomogram was evaluated by comparing our results with standard CROES nomogram. Results: The average age of our patients with the mean body mass index of 26.7±3.3 kg/m2 was 45.8±15.2, and the number of our male patients was higher (60% vs 40%). 36.8% of our patients had of previous stone surgery history. Staghorn stone rate was found 12.7%, the average stone area was 452.8±213.4 mm2, and multiple stones in the same kidney was 57.3%. Our stone-free rate was found as 78.2%, and estimated chance of stone free rate was 80% according to the CROES score. The difference between estimated rate and our real success was only 1.8%.

Conclusions: CROES nomogram has been considered as a simple and easy way for prediction of SF rate prior PNL. to reach more reliable outcomes, a greater number of randomized controlled trials are needed. However, it may still deserve to be use in the daily practice because it gives an idea for success after PNL. Even though this study is a retrospective setting, our results may help to guide for clinicians..

Key words: CROES nomogram, Percutaneous nephrolithotomy, Scoring system

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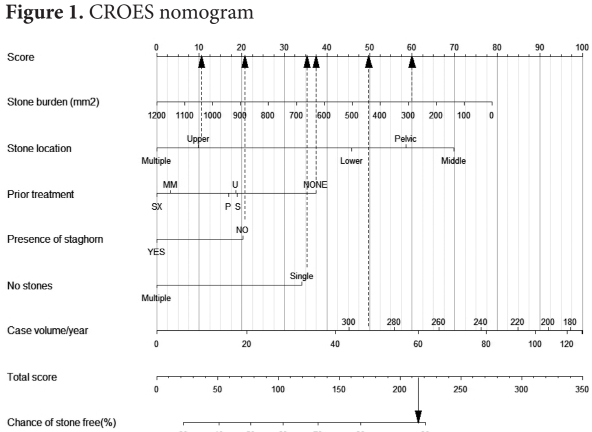
Introduction

Percutaneous nephrolithotomy (PNL) is one of the most widely used methods in the world for the surgical treatment of kidney stones (1). The aim by PNL is to ensure the succesful treatment (stone free or residual fragments less than 4 mm). The succesfull treatment depends on clinical and physical characteristics of the patients in addition to the stone features such as size, the extent of calyceal involvement, pelvicalyceal anatomy, and the anatomic malformations dictate the feasibility of different treatment modalities and have significant impact on surgical outcomes (2-6). Since the success rate depends on that many variables, In order to evaluate the surgical outcomes, academic nomograms are needed, but there was no standard method for prediction of success rate (1). However, in recent years new nomograms are being developed and adapted to daily practice.

Today the Clinical Research Office of the Endourological Society (CROES) nomogram, the Guy's Stone Score (GSS), Stone size, Tract length, Obstruction, Number of involved calyces, and Essence/stone density (S.T.O.N.E.) nephrolithometry, and Seoul National University Renal Stone Complexity (S-ReSC) score nomograms are the most commonly used methods in predicting the results of PNL (6). These nomograms provide an evaluation by considering not only stones and renal anatomy, but also the patient's clinical characteristics, e.g. body mass index (BMI), a history of pre-existing kidney surgery, and experience of the surgeon (7).

Figure 1. CROES nomogram



(Abbreviations: U, ureterorenoscopic stone treatment. SX, pyelolithotomy. P, percutaneous nephrolithotomy. S, extracorporeal shock wave lithotripsy.)

In this study, the efficacy of CROES nomogram and clinical applicability was analyzed by comparing post-treatment success rates of PNL using the standard CROES nomogram score of the same patients. We also evaluated our complications using the modified Clavien system (8).

Material and Methods

After obtaining the ethics committee approval, medical files of patients who were undergoing PNL between November 2010, and June 2016 were reviewed retrospectively. Indication for PNL was based on the type and size of the stone. Radiological, clinical and surgical characteristics of the patients were recorded. Patients with non-opaque stones were excluded from the study. Before the procedure, urine cultures were obtained, and 1 g single dose cefazolin prophylaxis were given one hour before surgery. Patients were received a single dose of prophylactic antibiotic, and the procedure was routinely performed under prone position using aAmplatz dilators up to 30 Fr. patient characteristics, stone localization, stone burden ($\Sigma = \Sigma = 0.785$ X $length_{max}$ X $width_{max}$, mm^2), prior stone surgery, urine analysis, operative duration, postoperative PNL stent and/or nephrostomy tube, stone-free status, and complications were analyzed. Blood loss was assessed using postoperative hematocrit drop. No residual fragments or residual fragments less than 4 mm were defined as stone-free (9). We assessed residual fragments using kidney, ureter, and bladder (KUB) film one month after PNL.

A patient with a history of shock wave lithotripsy and one renal pelvic stone (approximately 200 mm^2) with an average case volume of 48 patients per year. A total stone score of 191 in this patient predicts 85% chance of treatment success (Figure 1).

The patients' data were scored using CROES nomogram in order to predict stone-free rate (Figure 1). Three parameters are used in order to predict success rate in the CROES nomogram: patient (prior treatment status), surgeon (annual case volume of a surgeon), and stone parameters (burden, localization). Our average annual number of cases was 40 patients per year. The efficacy of CROES nomogram was assessed for comparison the surgical outcomes of the patients (8). The Clavien grading system is defined in four grades (Grade I: any deviation from the normal postoperative course without the need for phar-

Table 1. Demographic characteristics of the patients

	Overall	Stone free	Residual stone
Number of the patients (N, %)	220 (100%)	172 (78.2%)	48 (21.8%)
CROES score [mean (SD)] (min-max)	168.1±66.4 (57-263)	221.1±57.4 (80-263)	80.5±25.7 (57-220)
Chance of Stone-free (%)	80%	90%	51%
Age (years), [mean (SD)]	45.8±15.2	46.4±15.5	43.8±14.3
Gender, n/N, (%)			
Male	132/220 (60%)	106/172 (61.6%)	26/48 (54.2%)
Female	88/220 (40%)	66/172 (38.4%)	22/48 (45.8%)
BMI, kg/m^2 [mean (SD)]	26.7±3.3	26.6±3.5	26.7±2.4
Comorbidity, n/N, (%)			
Diabetes mellitus	21/220 (9.5%)	14/172 (8.4%)	7/48 (14.6%)
Cardiovascular diseases	40/220 (18.2%)	29/172 (17.5%)	11/48 (22.9%)
Neurological diseases	4/220 (1.8%)	2/172 (1.2%)	2/48 (4.2%)
Past surgery history n/N, (%)			
PNL	9/220 (4.1%)	2/172 (1.2%)	7/48 (14.6%)
ESWL	36/220 (16.4%)	22/172 (13.3%)	14/48 (29.2%)
Pyelolithotomy	10/220 (4.5%)	6/172 (3.6%)	4/48 (8.3%)
URS	23/220 (10.5%)	19/172 (11.4%)	4/48(8.3%)
Nephrostomy	3/220 (1.4%)	3/172 (1.8%)	0
Renal abnomalities, n/N, (%)			
None	217/220 (98.6%)	172/172 (100%)	45/48 (93.7%)
Horseshoe kidney	2/220 (0.9%)	0	2/48 (4.2%)
Ectopic kidney	1/220 (0.5%)	0	1/48 (2.1%)
Stone area, mm^2 [mean (SD)]	452.8±213.4	395.4±169.8	629.4±237.3
Number of stone n/N, (%)			
Solitary	94/220 (42.7%)	86/172 (50%)	8/48 (16.7%)
Multiple	126/220 (57.3%)	86/172 (50%)	40/48 (83.3%)
Stone localization, n/N, (%)			
Upper	5/220 (2.2%)	3/172 (1.7%)	2/48 (4.2%)
Middle	8/220 (3.7%)	6/172 (3.5%)	2/48 (4.2%)
Lower	26/220 (11.8%)	24/172 (14%)	2/48 (4.2%)
Pelvic	92/220 (41.8%)	85/172 (49.4%)	7/48 (14.5%)
Multiple	89/220 (40.5%)	54/172 (31.4%)	35/48 (72.9%)

macological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs such as antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy, and wound infections opened at the bedside; Grade II: Pharmacological treatment requirement with drugs, blood transfusions and total parenteral nutrition other than those allowed for grade I; Grade III-a Intervention not under general anaesthesia; Grade III-b: Intervention under general anaesthesia; Grade IV: Life-threatening complication (including central nervous system complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks) requiring intensive care management; Grade IV-a: Single organ dysfunction (including dialysis); Grade IV-b: Multi-organ dysfunction; Grade V: Death of a patient, and Suffix “d”: If the patient suffers from a complication at the time of discharge the suffix “d” (for disability) is added to the respective grade of complication indicates the need for a follow-up to evaluate the complication fully.

Statistical Analysis

For statistical evaluation, the Statistical Package for Social Sciences version 20 (IBM Corp., Armonk, NY, USA).15 (SPSS 15,0, Chicago, IL, USA) program was used. For the statistical analysis of data Kruskal-Wallis analysis of variance was employed. For pairwise comparisons of data, the Mann-Witney U test was used. Categorical variables were compared using Fisher’s exact test or Chi-square test. All values were expressed as mean±SD. P<0.05 was considered to be statistically significant.

Table 2. Outcome of the exit procedures

	Overall	Stone free	Residual stone
n	220	172	48
Operative time (min) [mean (SD)]	96.5±30.5	93.9±30.1	104.4±30.4
Hemoglobin decrease (g/dL) [mean (SD)]	1.98±1.4	1.96±1.5	2.03±1.3
Hematocrite decrease (%) [mean (SD)]	5.54±3.92	5.09±3.9	5.68±3.64
Postoperative hospital stay (days) [mean (SD)]	3.1±1.3	2.8±1.1	3.7±1.4
Clavien graded complications (n,%)			
Total	**77 (35%)**	**41 (23.9%)**	**36 (75%)**
Grade I	**49 (22.3%)**	**32 (18.6%)**	**17 (35.4%)**
Transient low-grade fever	18 (8.2%)	13 (7.6%)	5 (10.3%)
Transient elevation of creatinine	7 (3.2%)	2(1.2%)	4(8.3%)
Persistent pain	6 (2.7%)	4(2.4%)	2 (4.2%)
Nausea/vomiting	5 (2.3%)	2 (1.2%)	3(6.3%)
Tachycardia	4 (1.8%)	3(1.8%)	1 (2.1%)
Bradycardia	3 (1.3%)	3(1.8%)	1 (2.1%)
Transient confusion	2 (0.9%)	2 (1.2%)	0
Pulmonary edema	1 (0.4%)	1(0.6%)	0
Others	3 (1.3%)	2(1.2%)	1 (2.1%)
Grade II	**20 (9.1%)**	**7 (4.1%)**	**13 (27.1%)**
Blood transfusion	12 (5.6%)	5 (2.9%)	7 (14.5%)
Urinary leakage<24hour	4 (1.8%)	1 (0.6%)	3 (6.3%)
Fever (UTI) requiring change of antibiotic	3 (1.3%)	1 (0.6%)	2 (4.2%)
Pneumonia	1 (0.4%)	0	1 (2.1%)
Grade III a	**4 (1.8%)**	**1 (0.6%)**	**3 (6.3%)**
Hydrothorax	2 (0.9%)	1	1 (2.1%)
Urinary retention+colic (due to stone fragments)	2 (0.9%)	0	2 (4.2%)
Grade III b	**3 (1.3%)**	**1 (0.6%)**	**2 (4.2%)**
Urinary leakage requiring JJ stenting	2 (0.9%)	0	2 (4.2%)
Cystoscopic clot evacuation	1 (0.4%)	1 (0.6%)	0
Grade IVa	**1 (0.4%)**	**0**	**1 (2.1%)**
Nephrectomy	1 (0.4%)	0	1 (2.1%)
Grade IV b	0	0	0
Grade V	0	0	0

UTI: Urinary Tract Infection

Results

Two hundred twenty eligible patients met our inclusion criteria were included in this study. The average age was 45.8±15.2 years. Of the patients, 132 were male, and 88 were female (60% vs 40%). The mean body mass index (BMI) was 26.7±3.3 kg/m^2. Of the patients, 9.5% had diabetes mellitus, and 18.2% had cardiovascular disease. Previous stone surgery history was 36.8%. Preoperative culture positive urinary infection rate was 16.4%. Of the patients, 2 had horseshoe kidney (0.9%), one had ectopic kidney (0.5%), and all the three patients were stone free at first postoperative control. Staghorn stone rate was 12.7%, the mean stone burden was 452.8±213.4 mm^2, and 57.3% of patients had multiple stones in the kidney. The stones were mostly located in renal pelvis (41.8%) (Table 1).

The mean surgery time was 96.5±30.5 minutes, the mean hematocrit % decrease was 5.54±3.92, and the mean hospital stay was 3.1±1.3 days. The Overall complication rate was 35%. According to Clavien system, 22.3% of the patients had grade I, 9.1% had grade II, 1.8% had grade III a, 1.3% had grade III b, and 0.4% had grade IV a complications. None of the patients had grade IV b and

V complications. Two patients had hydrothorax due to upper pole access and managed with a thoracal chest tube insertion. was observed and nephrectomy was done in one patient with uncontrollable bleeding due to major vessel injury (Table 2).

We recorded 78.2% stone-free rate 1 month after surgery. The number of patients, previous stone treatment, stone burden and location, presence of staghorn stones and number of stones were put in the CROES nomogram, retrospectively. Our mean CROES score was 168.1±66.4 (57-263). The estimated stone-free rate was 80% based on CROES nomogram (Table 2).

Discussion

The main target in the stone surgery is to keep the stone-free rate as high as possible in patients, and for this purpose, several nomograms have been developed. Stone burden which is the most influential parameter, stone location, the number of stones, the presence of staghorn stones, case volume of the urologist and prior treatment history have been used in these nomograms. The success rate of PNL was reported 75.7% in the PNL Global study, which was done over a total of 5803 patients (10). Oner, et al. reported 84.8% SF rate (11). Nakamon, and Gökçe et al. reported the success rates 72.7% and 75.7%, respectively (12,13). In this study, we reported 78.2% stone free rate which was compatible with the literature.

There are several parameters effects the PNL outcomes, and these parameters are quite variable, and this variability can create problems for surgeons and patients. Patients have a tendency to learn the success rates prior to PNL. For this reason, there have been many nomograms developed in order to predict the success rate prior to PNL. The GSS nomogram determines a grade according to the number and localization of stones, staghorn stone status, and abnormal anatomical structure of the kidney. According to this nomogram, as the grade value increases, the success rate decreases (14). It has a total of 9 different scores between 5 and 13. The score 5–6 denotes a low complex stone, 7–8 is regarded moderate complex, and 9–13 indicates a high complex stone (15). The advantage of the GSS was reported significantly and independently to predict the stone-free rate but, GSS does not assess the calyceal involvement, size, density, and composition of the stone which are associated with technical difficulty of PNL. It was developed using variables the expert authors felt were significant rather than by data driven selection. Moreover, the simple four-grade compartmentalization of the GSS does not account for other clinical variabilities such as stone burden, surgeon experience, BMI, age, and comorbidities and these are the weak side of this nomogram. Although GSS is based on noncontrast CT, 62% overall SFS prediction rate limits the generalized use of this nomogram.. (16-18).

The CROES nomogram assesses the SF rate using stone characteristics, surgeon and patient. The greatest advantage of the CROES is the ability to evaluate the patient with a KUB film. Although CT is the best method in the evaluation of patients after PNL, it has been quite a controversial issue due to cost in particular (19). Sountoulides, et al. suggested in their study that using KUB film instead of CT for evaluation of the success rate after PNL in asymptomatic patients with radiopaque stones (20). Because residual fragments that may pass through the urinary tract spontaneously can be easily seen in KUB film in the early postoperative period and may cause false negative results (21). Thus we routinely evaluated our patients one month after PNL.

Another available parameter of CROES nomogram is the previous renal surgery. This parameter is not included in the GSS and S.T.O.N.E. nomograms. However, the studies have reported that CROES nomogram, in addition to GSS and S.T.O.N.E. nomograms estimate the SF chance at an equal rate in PNL (22). Previous stone surgery may carry a risk factor for future stone succesful management and may affect the clinician's decision for operation. For instance, these nomograms give a prompt and reliable chance for clinicians before the surgery.

S.T.O.N.E. nomogram has significant impact on postoperative outcomes using only a preoperative CT scan, making it ideal for building a retrospective database with limited clinical information. However, validation with a small cohort of this nomogram may limit its applicability to a wider patient population. A standardized method is needed to measure stone size and number of calices involved in order to improve predictive value, in addition to subjective assessment of degree of hydronephrosis.

The S-ReSC score is a simple, easily applicable and single variable based (stone location) tool using preoperative CT that predicts SFS. Creation and validation of the S-ReSC score with a cohort at a single center are the limitation.

There is undoubtedly a close relationship between the surgical experience and the success rate and complications. It is a fact that as the experience of the surgeon increases, complications decrease significantly (11). It is very important to bear the experience of the surgeon in mind during determination the SF chance. The CROES nomogram can be considered more reliable because it assesses the experience of the surgeon. In our study, the average CROES score was found as 168.1 in patients. The mean annual number of PNL surgery per one surgeon was 40, and our actual SF rate was 78.2%. The difference between SF rate of our study and literature was found only 1.8%. In this study, we reached satisfactory results compatible with the literature. The CROES nomogram is widely generalizable because it is based on data globally generated. Nevertheless, the CROES database was not created specifically for the development of a predictive model for SF rate. Lacking of radiologic data on hydronephrosis or other pelvicalyceal architecture may influence the surgical outcomes. Another limitation is the fact that many physicians consider that nomograms are not practical in the clinical setting. Nomograms are the suggestive applications for surgeons and patients prior to surgery. Although the nomograms do not have a high level of evidence and a greater number of randomized controlled trials are needed, they may provide guidance to clinicians (7). However, it is not clear that these nomograms are commonly used by endourologists. Elkoushy, et al. stated in their study, in which 162 endourologist joined via internet that 10% of participants did not know about nephrolithometric nomograms, and 8.5% did not practice it in the daily practice (7). We think that nephrolithometric nomograms could be considered in kidney stones with a high level of evidence in daily practice.

Even if the complications as part of surgery are quite annoying, it has to be considered by the surgeon. Reporting the complication rates in PNL may be instructive for inexperienced or moderately experienced other urologists. In this present study, we found a 35% complication rate. According to Clavien grading system, Clavien grade I, II III a, III b, and IV a complication rates were 22.3%, 9.1%, 1.8%, 1.3%, and 0.4%, respectively. The number of patients required anesthesia was 4 for the management of complications; two of these were JJ stenting due to prolonged urinary leakage, one was bladder irrigation due to massive hematoma, and one was nephrectomy due to uncontrolled bleeding. Grade IV b and grade V complication was not observed. In this regard, Rosette, et al. reported 4.2% Clavien I, 4.8% Clavien II, 2.2% Clavien III, 0.9% Clavien III b, 0.3% Clavien IV, 0.1% Clavien IV b and <0.1% Clavien V in a comprehensive study with 4230 patients (23). In an another study the complication rates were reported 12.7% Clavien I, 5.9% Clavien II in and 1%, but none of the patients were reported III b and a higher grade of Clavien (16). When compared to the other two studies, our Clavien I complication rate was significantly higher, probably due to temporary subfebrile fever, tachycardia and vomiting.

Retrospective nature and a low number of participants are the limitation of this study. In addition, all preoperative scores were calculated by a single author that may cause some biases.

In conclusion, CROES nomogram seems difficult to learn at the beginning, but as the urologists use this nomogram, its application becomes easier to use and, after a while it can be considered as a simple and easy way for prediction of stone free rate prior PNL. To reach more reliable outcomes, the greater number of randomized controlled trials are needed. However, it may still deserve to be used in the daily practice because it gives an idea for the success rate before PNL. Even though this study is a retrospective setting, our results may help to guide for clinicians.

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