

Evaluation of the STONE nephrolithometry score in predicting surgical outcomes of percutaneous nephrolithotomy: results of a prospective study at a university hospital

Evaluación de la escala de nefrolitometría STONE en la predicción de los resultados quirúrgicos de la nefrolitotomía percutánea: resultados de un estudio prospectivo en un hospital universitario

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Abstract

Objective: One of the popular advances in percutaneous nephrolithotomy (PCNL) includes nephrolithometry classification systems. It enables better patient counseling, surgery planning, outcome evaluation, and uniform academic reporting. The STONE nephrolithometry is a validated quantitative scoring system that is undervalued in clinical settings, and this study evaluates the scoring system's ability to predict the outcome of PCNL surgery.

Methodology: From January 2017 to June 2018, a total of 102 PCNL patients were studied prospectively. The STONE score was derived from a preoperative non-contrast computed tomography (NCCT) scan which was used to evaluate stone-free status at 4 weeks followup.

Results: The STONE nephrolithometry scoring system predicted stone-free rate (SFR) following PCNL surgery with an accuracy of 88%. The statistical cut off level of the STONE score of 8 was superior for predicting SFR. Individual variables such as stone size, degree of pelvicalyceal obstruction, number of calyceal involvement, and stone density were found to have a significant correlation with STONE score, although there was no statistically significant correlation between SFR and tract length (p=0.81). The score was divided into three categories: low complexity score 5-6 (SFR-58.7%), moderate complexity score 7-8 (SFR-40%), and high complexity score 9-13 (SFR- 1.2%). The STONE score had excellent inter-observer reliability and reproducibility (p=<0.001).

Conclusions: The STONE score was a simple and easy to apply tool for predicting the stone complexity and stone clearance after PCNL. The STONE score had no statistically significant correlation with postoperative complications. Furthermore, it demonstrated high inter-observer reliability and reproducibility.

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Keywords:

nephrolithometry

nephrolithotomy,

outcome, percutaneous

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STONE

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Resumen

Objetivo: Uno de los avances populares en nefrolitotomía percutánea (NLPC) incluye sistemas de clasificación de nefrolitometría. Permite una mejor orientación al paciente, planificación de cirugías, evaluación de resultados e informes académicos uniformes. La escala STONE es un sistema de puntuación cuantitativo validado que está infravalorado en entornos clínicos, y este estudio evalúa la capacidad del sistema de puntuación para predecir el resultado de la cirugía de NLPC. **Metodología:** Desde enero de 2017 hasta junio de 2018 se estudiaron prospectivamente un total de 102 pacientes con NLPC. La escala STONE se derivó de una tomografía computarizada sin contraste (NCCT) preoperatoria que se utilizó para evaluar el estado libre de cálculos a las 4 semanas de seguimiento.

Resultados: La escala de nefrolitometría STONE predijo la tasa libre de litos (TLL) después de la cirugía de NLPC con una precisión del 88 %. El nivel de corte estadístico de la escala STONE de 8 fue superior para predecir la TLL. Se encontró que las variables individuales como el tamaño del cálculo, el grado de obstrucción pielocalicial, el número de compromiso calicial y la densidad del cálculo tenían una correlación significativa con la puntuación STONE, aunque no hubo una correlación estadísticamente significativa entre la TLL y la longitud del tracto (p=0,81). La puntuación se dividió en tres categorías: puntuación de complejidad baja 5-6 (TLL -58,7%), puntuación de complejidad moderada 7-8 (TLL -40%) y puntuación de complejidad alta 9-13 (TLL -1,2%). La puntuación STONE tuvo una excelente fiabilidad y reproducibilidad entre observadores (p=<0,001).

Palabras clave:

Escala de nefrolitometría STONE, resultado quirúrgico, nefrolitotomía percutánea, complicaciones quirúrgicas, complicaciones

Conclusiones: El puntaje STONE fue una herramienta simple y fácil de aplicar para predecir la complejidad y la eliminación de los cálculos después de la NLPC. La escala STONE no tuvo una correlación estadísticamente significativa con las complicaciones postoperatorias. Además, demostró una alta fiabilidad y reproducibilidad entre observadores.

Background

Fernstrom and Johansson were the first to describe percutaneous nephrolithotomy (PCNL) technique in 1976.⁽¹⁾ One of the popular advances in PCNL over the past decade includes nephrolithometry classification systems. It enables better patient counseling, surgical planning, outcome evaluation, and uniform academic reporting. Many attempts have been made to develop a system to classify stones within the upper urinary tract and thereby to predict the PCNL outcomes. Guy's stone score (GSS), STONE score, Clinical Research Office of the Endourological Society (CROES) Nomogram, and Seoul Renal Stone Complexity Score (S-ReSC) are the four most notable scoring systems.⁽²⁾ Okhunov *et al.* in 2013 proposed a novel quantitative "STONE nephrolithometry score (SNS)" system that has been externally validated in several studies and can be readily applied in all clinical settings for PCNL procedures.^(2,3) This STONE acronym incorporates five components (Size, Tract length, Obstruction, Number of calyx involved, Essence) and are measured from preoperative non-contrast computerized tomography (NCCT) images.⁽¹⁾

Despite being a validated quantitative scoring system, STONE nephrolithometry is undervalued in clinical settings, and this study evaluates the scoring system's ability to predict the outcome of PCNL surgery. The objective of our study was to use the STONE score to predict the outcome of PCNL in terms of stone-free status. We also used the scoring system to stratify patients into risk groups based on a STONE score system, as well as to assess the inter-observer reliability and correlation with postoperative complications.

Materials & methods

We obtained ethical approval for this study from the 'Institutional Ethics Committee' (Kasturba Medical College; Reg no: ECR/146/inst/KA/2013/RR-16 and Study Reg no is IEC - 912/2016) and informed consent obtained from the study participants prior to study commencement. Our study complies with the Declaration of Helsinki. Adult patients (>18 years old) with renal stones >1cm found on NCCT and scheduled for elective PCNL surgery met the inclusion criteria. Patients under the age of 18, proximal ureteric stones, second stage PCNL, and patients with a prior nephrostomy or ureteric stent in-situ were excluded. Data from the InstaRISPACS imaging software were collected between January 2017 and June 2018, and 102 patients were included in the study.

The imaging data was gathered for STONE nephrolithometry scoring in accordance with the scoring protocol (Table 1).⁽¹⁾

Variables	Score					
vuriables	1	2	3	4		
Stone size (mm ²)	0-399	400-799	800-1599	≥1600		
Tract length (mm)	≤100	>100	-	-		
Obstruction	None/Mild	Moderate/Severe	-	-		
Calices (n)	0-2	3	Staghorn stone	-		
Essence (HU)	<950	>950	_	_		

Table 1. STONE Nephrolithometry scoring system

The stone size was calculated in square millimeters by using length and breadth obtained from the CT. The stone size was graded from 1 to 4 based on a calculated area of 0-399, 400-799, 800-1599, and 1600 mm2. The skinto-stone distance (track length) was defined as the mean vertical distance recorded on a supine NCCT film at 0, 45, and 90 degrees from the center of the stone to the skin. The distances estimated in patients with a body mass index (BMI) of 30 kg/m², which is the currently accepted threshold for obesity, were used to derive the cutoff of mean tract length of 100 mm. Urinary obstruction was determined by the degree of hydronephrosis and was scored according to the severity of collecting system dilation. When 1-2 calyces were involved, a score of 1 was assigned for the number of calyces involved, a score of 2 was assigned when three calyces were involved, and a maximum score of 3 was assigned when a complete staghorn calculus was present. The stone density score was assigned using a radiodensity threshold The imaging data was gathered for STONE nephrolithometry scoring in accordance with the scoring protocol (Table 1).⁽¹⁾ The stone size was calculated in square millimeters by using length and breadth obtained from the CT.

The stone size was graded from 1 to 4 based on a calculated area of 0-399, 400-799, 800-1599, and 1600 mm². The skin-to-stone distance (track length) was defined as the mean vertical distance recorded on a supine NCCT film at 0, 45, and 90 degrees from the center of the stone to the skin. The distances estimated in patients with a body mass index (BMI) of 30 kg/m², which is the currently accepted threshold for obesity, were used to derive the cutoff of mean tract length of 100mm. Urinary obstruction was determined by the degree of hydronephrosis and was scored according to the severity of collecting system dilation. When 1-2 calyces were involved, a score of 1 was assigned for the number of calyces involved, a score of 2 was assigned when three calyces were involved, and a maximum score of 3 was assigned when a complete staghorn calculus was present. The stone density score was assigned using a radiodensity threshold of Hounsfield units (HU) as \leq 950 units (score 1) or >950 (score 2).⁽¹⁾ The principal investigator's STONE nephrolithometry score was compared to that of the other two residents of widely different experience levels.

Postoperative complications were recorded according to Clavien-Dindo grading. Patients were followed up with an X-ray KUB or NCCT (for radiolucent calculus) scan four weeks later or at the time of their ureteric stent (Double J) removal to look for stone clearance or residual fragments. Patients with no residual fragment or a residual fragment <4 mm were classified as stone-free (SF) group, while patients with fragments \geq 4mm were classified as not stone free (NSF) group.

The SAS 9.2 programmer was used to calculate our sample size. SPSS V15.0 was used to analyze the data. The ROC curve was utilized to determine the cutoff score for predicting stone-free status. For numerical data, the Student's unpaired t-test was used to compare the means of two groups. To compare the means of more than two groups, ANOVA (F test) was used. To compare percentages for categorical data between two or more groups, Chi-square and Fisher Exact Probability tests were used. Pearson Correlation Coefficient was used to find a correlation between two variables. Cohen's Kappa was used to assess the level of agreement between two observers on the STONE score. STONE score outcome association with all individual variables was determined using multivariate regression analysis. The alpha (α) Level of Significance was taken as p-value ≤ 0.05 .

Results

A total of 102 patients were included in the study. The SF and NSF groups are compared in terms of age, BMI, stone size, tract length, degree of pelvicalyceal obstruction, number of calyceal involvement by stones, and stone essence (density of stone), as well as mean operating time, fluoroscopy time, and inpatient duration (Table 2).

	Group, mean (SD) or n (%)			
Variable	Stone free (n=80)	Not stone free (n=22)	p-value	
Outcome (N=102)	80	22		
Age (years)	49.14±14.21	45.32±11.25	p=0.2	
Gender				
Male	59(73.8%)	19(86.4%)	n-0.27	
Female	21(26.3%)	3(13.6%)	p=0.27	
BMI (kg/m ²)	26.76±5.07	27.51±5.47	p=0.6	
Side/Laterality				
Right	32(40.0%)	11(50.0%)	n=0.91	
Left	48(60.0%)	11(50.0%)	p=0.81	
Size (mm^2)				
0-399	66(82.5%)	4(18.2%)		
400-799	13(16.3%)	8(36.4%)	p<0.001	
800-1599	1(1.3%)	9(40.9%)		
21600	0(0.0%)	1(4.5%)		
Tract length (mm)				
≤100	53(66.3%)	14(63.6%)	n=0.81	
>100	27(33.8%)	8(36.4%)	p=0.01	

Table 2. Comparison of baseline and stone characteristics of study patients between stone-freeand not stone-free patients

Obstruction				
None/Mild	56(70.0%)	7(31.8%)	p=0.002	
Moderate/Severe	24(30.0%)	15(68.2%)		
No. of calvees involved				
1-2	75(93.8%)	11(50.0%)	p<0.001	
3	4(5.0%)	6(27.3%)		
Staghorn	1(1.3%)	5(22.7%)		
Essence (Hounsfield units)				
≤950	47(58.8%)	7(31.8%)	- 0.021	
>950	33(41.3%)	15(68.2%)	p=0.031	
Total STONE score	6.33±1.02	8.77±1.66	p<0.001	
Length of stay (days)	5.93 ± 2.40	6.05±2.10	p=0.8	
Procedure duration (min)	46.16±17.42	59.59±17.38	p=0.002	
Fluoroscopy Time (min/sec)	2.58±0.95	3.15±0.81	p=0.012	
Amplatz Size (Fr)	27.52±6.61	29.82±2.04	p=0.11	
Nephroscope (Fr)	21.72±5.55	24.11±2.56	p=0.054	

The SF group had a STONE score between 5 and 8, with one patient having a score of 9. The NSF group had a score between 7 and 11, with 1 patient each having a score of 5, 6, and 12 (Figure 1).

Figure 1. STONE Nephrolithometry total score distribution between SF & NSF groups



Figure 1. The bar diagram depicts the STONE total score in the X-axis and the number of SF and NSF patients in the Y-axis.

The STONE score was divided into three risk categories and compared between groups of SF and NSF patients (Figure 2).



Figure 2. The distribution of S.T.O.N.E. Nephrolithometry scores in the three risk groups

According to the modified Clavien-Dindo classification, 24 (23.5 %) patients experienced PCNL complications. It includes 11 (45.8%) grade 1 complications with a mean STONE score of 7.9, 4 (16.6%) grade 2 complications with a mean STONE score of 6.5, 4 (16.6%) grade 3a complications with a mean STONE score of 8.2, and 5 (20.8%) grade 3b complications with a mean STONE score of 6.6.

For the outcome, a ROC curve was drawn for Total STONE Score. Score has an accuracy or area under the curve (AUC) of 0.889 in predicting SFR, with a confidence interval of 0.794 to 0.985. We established three cutoff values for the total score (6, 7, and 8) and calculated the Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) with 95 % confidence intervals for each. The study found that for a cutoff level of total STONE score 8, sensitivity was 81.82 % and specificity was 86.25 %. The PPV was 62.07 %, with a NPV of 94.52 % (Figure 3).







Figure 2. The bar diagram depicts three risk groups in the X-axis, and the number of SF and NSF patients in the Y-axis.

Regression with all variables in the model for stone clearance after controlling for confounders for Stone Clearance, STONE score is significantly correlated with stone clearance. A lower STONE score predicts a greater chance of clearance. One unit increase in STONE score reduces the ODDS of stone clearance by 90% (Table 3).

Dependent: St	one Clearance	No	Yes	OR (univariable)	OR (multivariable)
STONE Score	Mean (SD)	8.8 (1.7)	6.3 (1.0)	0.23 (0.11-0.40, p<0.001)	0.10 (0.02-0.25, p<0.001)
BMI	WNL	7 (16.7)	35 (83.3)	-	-
	Overweight	7 (24.1)	22 (75.9)	0.63 (0.19-2.07, p=0.439)	9.21 (1.11-128.14, p=0.061)
	Obese	8 (25.8)	23 (74.2)	0.57 (0.18-1.81, p=0.343)	11.98 (1.55-144.47, p=0.028)
DJ Stent	Not Inserted	4 (36.4)	7 (63.6)	-	-
	Inserted	18 (19.8)	73 (80.2)	2.32 (0.56-8.57, p=0.216)	10.66 (0.84-185.62, p=0.072)
Fragmentation Time Minutes	Mean (SD)	12.0 (4.3)	10.4 (7.9)	0.97 (0.91-1.04, p=0.355)	1.23 (1.04-1.52, p=0.028)
Procedure Duration Minutes	Mean (SD)	59.6 (17.4)	46.2 (17.4)	0.96 (0.93-0.99, p=0.003)	0.99 (0.92-1.07, p=0.838)
Fluoroscopy Time Minutes	Mean (SD)	3.3 (0.8)	2.8 (0.9)	0.52 (0.30-0.88, p=0.017)	0.32 (0.07-1.29, p=0.113)

Table 3. Regression with all variables in the model

MODEL FIT: $\chi^2(7) = 61.88$, p = <0.001 Pseudo-R² = 0.58

Number in dataframe = 102, Number in model = 102, Missing = 0

AIC = 60.5, C-statistic = 0.937, H&L = Chi-sq(8) 34.07 (p<0.001)

Table 3. Summarizes the regression analysis for the dependent variable using all the predictor variables together in one go.

Discussion

Patients with a higher BMI and, as a result, a longer track length pose a greater technical challenge in PCNL procedures, which can have an adverse effect on perioperative outcomes. Because these obese patients have more fat distribution in the flank areas, BMI indirectly measures skin to stone distance.⁽¹⁾ Despite the fact that the majority of NSF patients had a higher BMI, this was not statistically significant (p=0.6). It is comparable to previous findings by Okhunov *et al.*, who did find that the average BMI was 29.5 ± 8.7 .⁽¹⁾ Even when exclusively obese patients were analyzed in a study, there was no effect of BMI on the scoring systems.⁽⁴⁾

As stone size increases, the patient's stone free rate (SFR) decreases. There was a statistically significant correlation (p<0.001) between the stone size and stone clearance rate. There was no discernible difference in the effect of tract length, which was \leq 100mm in 66.3% of SF patients and 63.6% of NSF patients (p= 0.81), which is consistent with previous research. ⁽¹⁾ These findings are consistent with the BMI data from the current study, as BMI indirectly measures skin to stone distance.

Stone free rate (SFR) was significantly lower in patients with a higher grade of pelvicalyceal obstruction, possibly because, while a dilated system was easy to puncture, stone fragments could migrate and scatter from the original sites to other remote areas of the collecting system. Similarly, Zhu *et al.* reported in a multivariate study that greater obstruction and subsequent hydronephrosis result in lower procedural success rates.⁽⁵⁾ Another study found that pelvicalyceal surface area and the presence of hydronephrosis were related to residual stone burden (26.6% vs 73.4%).⁽⁶⁾

In terms of calyceal involvement, the majority of the SF group had only one to two calyceal involvements (93.8 %). When all three calyces were involved by calculus or the presence of staghorn stone, SFR was only 50%. It suggests a significant correlation between SFR and the number of calyces involved by the calculi (p=0.001).

Stone fragility is determined by calculating stone density on CT in terms of Hounsfield units.⁽¹⁾ While 58.8 % of SF patients had a stone density of ≤950 HU, 68.2 percent of NSF patients had a stone density of >950HU (p=0.031). There have been studies that have generated contradictory findings regarding the relationship between stone density and SFR. The availability of different modes of intracorporeal lithotripters, such as pneumatic or Holmium: YAG laser, capable of fragmenting stones of varying densities, may also explain the lack of a strong association between stone density and stone-free status.⁽⁷⁾ In a larger CROES study, both extremely high and extremely low HU values of stones were linked to low SFRs and extended operative times. Stones with low Hounsfield units were likely to be uric acid or struvite in composition, which were difficult to identify during PCNL as they were poorly visible on fluoroscopy.⁽⁷⁾

There was no correlation seen between stone score and mean length of hospital stay (p=0.8). It could be because of a bias relating to the insurance scheme patients were on, as some government schemes took longer for approval and clearance prior to discharge. Furthermore, higher STONE nephrolithometry scores were linked to a longer operative time, longer fluoroscopy time, and the need for a nephrostomy tube.

In 24 patients, post-operative complications were documented (Clavien grade 1-3b).⁽⁸⁾ There were no Clavien grade 4 or 5 complications in any of the patients. Grade 1 complications (n=11) included pain, ileus, hydrothorax, and bleeding; grade 2 complications (n=4) included blood transfusion and prolonged antibiotics for urosepsis; grade 3a complications (n=4) included clot evacuation under local anesthesia and intercostal drainage tube under local anesthesia; and grade 3b complications (n=5) included patients who had angioembolization under sedation, DJ stent repositioning. Prior studies, including ours, found no association between the STONE nephrolithometry system and postoperative complications.^(9,10) Original study by Okhunov *et al.* found no significant correlation for postoperative complications, attributing this to a small sample size, which is consistent with our findings.⁽¹⁾

The STONE nephrolithometry scoring system was found to be a highly reliable tool for predicting PCNL outcomes, particularly in terms of SFR. The statistical cut off level of total STONE score of 8 was remarkably accurate in predicting stone-free status. The STONE nephrolithometry scoring system had an accuracy of 88% in predicting stone-free status with confidence interval 0.794 to 0.985. With an accuracy of 83.1 percent, this AUC outperformed the original study. A higher STONE nephrolithometry score was found to be associated with a lower SFR (p=0.001), which is statistically significant. Other previous studies, including Okhunov et al., found a correlation between nephrolithometry score and SFR, which is consistent with our findings. (1,9-17)

The principal investigator's STONE nephrolithometry score was compared to that of the other two residents of widely different experience levels. In terms of inter-observer reliability and reproducibility of the STONE score for renal calculi, there was statistically significant agreement (p=0.001) between two observers of widely different experience levels measuring the 5 variables and total STONE score. Srivastava et al. investigated interobserver reliability among surgeons and radiologists because both the Guy's score and the STONE nephrolithometry score are derived from CT scans alone without the need for clinical data. Both scores showed overall good agreement between surgeons and radiologists, albeit the

STONE score had a higher predictive value for the SFR than the GSS.⁽¹⁸⁾ Despite the fact that Vicentini *et al.* showed that Guy's score was the quickest to apply, a study by Al Adl AM *et al.* suggested that STONE score was easily adaptable in clinical settings.^(14,19)

If all scoring systems are good at predicting outcomes and are similar in their ability to do so, then why have we only studied the STONE nephrolithometry score? The ease with which a nomogram can be used in a clinical setting determines its applicability. Because the STO-NE nephrolithometry score is obtained from simply a CT scan without the clinical or patient data, it provides improved reproducibility among all medical fraternity, ease of generating the score, ease of expressing the complexity to the colleague practitioner even by the radiologist sitting at a distant location, and ease of counseling the patient with just a CT report containing the scoring values even in a primary care practice.

The strength of the study is that it is prospective, and the inter-observer variability has also been calculated. The study's limitation is that it was a single center study. Future research should focus on developing an unified scoring system for the entire interdepartmental medical fraternity, eventually leading to universal utilization.

Conclusions

The STONE score is a simple and easy-to-use tool for predicting the complexity of stones for PCNL and stone clearance in all clinical settings because it only requires data from a preoperative plain CT scan. Individual variables such as stone size, pelvicalyceal obstruction, number

of calyceal involvement, and density of stone were found to be as accurate as the total score in predicting stone-free status. The STONE score had no statistically significant correlation with postoperative complications. Furthermore, it demonstrated high inter-observer reliability and reproducibility.

CRediT Taxonomy

Anupam Choudhary: Writing–original draft Suraj Jayadeva Reddy: Writing–review & editing Suyog Shetty: Formal Analysis Bathi Sourabh Reddy: Data curation Anshuman Singh: Investigation Manjunath Irappa Wali: Investigation

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Conflict of interest

The authors declare no conflicts of interest.

Ethical approval

The study was conducted as an observational study after obtaining the institute ethical committee clearance (Kasturba Medical College; Reg no: ECR/146/inst/KA/2013/RR-16 and Study Reg no is IEC - 912/2016) in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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