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Accuracy of CROES Stone Scoring System for Predicting Stone Free Status and Post Op Complications in PCNL: Finding the Truth.

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ABSTRACT

Background: To study and analyse demographics and correlation with clinical outcome in patients with Renal Calculus Disease & to assess the accuracy and usefulness of CROES Stone Scoring systems in predicting post PCNL Stone Free Status & Complication rates. **Methods:** 253 patients Diagnosed with renal calculus disease and were planned for PCNL at Institute of Nephro Urology, Bangalore from Jan 2017 to Nov 2018 were enrolled prospectively. Various demographic, Laboratory and Clinical Variables were collected & Statistical analysis done after deriving various Nephrolithometry scores. **Results:** Present study had 146 males & 107 females with mean age of 42.23 (IQR=19-84).CROES categories included <150,151-200,201-220,>220 & were noted to be 51,72,16,114 of sample size respectively.15 patients needed post op blood transfusion and Post PCNL SFR was noted in 216 patients with 37 patients needing auxillary procedures including Relook. Complications as graded by Clavian Dindo Classification 1,2,3a,3b,4 were seen in 32,25,5,0,1 respectively. **Conclusion:** Preoperative nomograms can prove as a valuable tool for proper patient counseling about the stone-free rate and complications associated with PCNL. CROES Stone Score was found to be very effective and accurate in predicting success rate of the PCNL procedure and predict Complications.

Keywords: PCNL, CROES Stone Scoring.

INTRODUCTION

The Prevalance of Urolithiasis is increasing day by day worldwide. Various modalities of Treatments are practiced worldwide which is individualised based on Stone features such as size, extent of calyceal involvement, pelvicaliceal anatomy, and anatomic malformations which dictate the feasibility of different treatment modalities and have significant impact on surgical outcomes. There is immense heterogeneity in methods for clinical and academic characterization of nephrolithiasis and for the evaluation of surgical outcomes.

Several key factors have been identified,that impact treatment outcomes and complication rates with PCNL, including indications for treatment, renal access, and available equipment. The Present day miniaturisation of PCNL accessories have created the trend to smaller or no nephrostomy tubes & thus contributed to increased efficacy of percutaneous stone disintegration and decreases in the overall morbidity rates for PCNL. Such improvements in techniques for percutaneous stone removal have resulted, for example, in significant decreases in transfusion rates, which were 25% in early reports and have decreased to 1% to 2% in more recent studies.[1,3,4]

PCNL has demonstrated safety and efficacy in the management of large, multiple, or complex renal stones. Other indications are the composition of the stone, the site of the stone, and the existence of obstruction distal to the stone, the certainty for the final result, the failure or the contraindication to SWL, and the presence of renal anatomic variation.[6]

With the increased incidence of surgical interventions comes the increased incidences of complications and morbidities. Thus Preoperatively various factors have to be assessed to curtail down the incidences of morbidities and complications and hence there is a need for implementation of predictive scoring systems to decide on the outcomes. Currently, there is no standardized method available that characterizes the complexity of renal stones and predicts surgical outcomes following percutaneous nephrolithotomy (PCNL). This can improve patient care by informing clinical decision making and patient counseling, in addition

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to improving academic reporting. An ideal scoring system should include variables that both influence surgical planning and are predictive of postoperative outcomes.[5,6]

Therefore various predictive models have been developed by various authors combining such different parameters. These include Guy's Stone Score (GSS), Clinical Research Office of the Endourological Society (CROES) nomogram, STONE score, and Seoul National University Renal Stone Complexity. Many studies have proven their value for predicting success rates of PCNL.[7,8]

CROES Nephrolithometric Nomogram includes.[7,8]

A. Stone Burden – calculated as follows:

1. Measure the maximum length of each stone in millimeters
2. Measure the maximum width of each stone in millimeters
3. Calculate the stone burden for each stone =0.785 X length X width
4. Add individual stone burdens if multiple stones

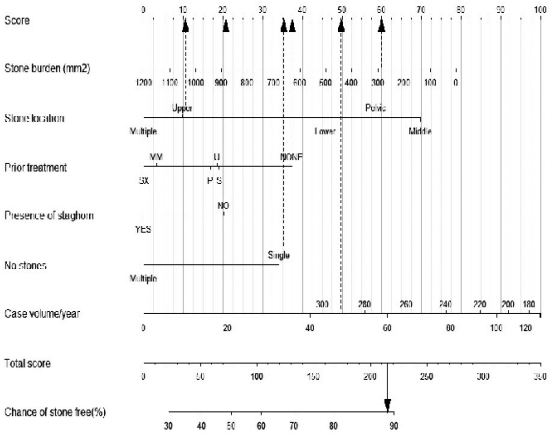
B. Calyceal location – position in renal pelvis or multiple calyces involved, including staghorn calculi

C. Stone count – single or multiple

D. Case volume

Each parameter is given a score of 0 to 100 & Later based on the nomogram(A+B+C+D) it is classified into <150, 151-200, 201-220,>220 based on various previous studies. Higher the score in CROES higher is the risk of non SFR and increased risk of complications.

The Nomogram for CROES stone scoring is given below



Complications of PCNL procedures were graded based on modified Clavian Dindo Classifications which is the most accurate and commonly followed system for Endourologic Procedures. Table Below explains the various grades of The Classification.[2]

This study discusses the CROES nephrolithometric scoring tool, its application for PCNL, and assesses the advantages and disadvantages of it. The stone-free status was defined as no visible stones or the presence of clinically insignificant residual fragments <4 mm on plain abdominal radiography or ultrasonography done 4 weeks after PCNL.

GRADES	DEFINITION
Grade 1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs such as antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade 2	Requiring pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade 3	Requiring surgical, endoscopic or radiological intervention
Grade 3A	Intervention not under general anaesthesia
Grade 3B	Intervention under general anaesthesia
Grade 4	Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management
Grade 4A	Single organ dysfunction (including dialysis)
Grade 4B	Multi-organ dysfunction
Grade 5	Death of a patient
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. This label indicates the need for a follow-up to evaluate the complication fully.

MATERIALS AND METHODS

We did a Prospective Observational study at the department of Urology, Institute of Nephro urology, Bangalore from January 2017 to November 2018.we collected data of Patients with renal calculus reporting to our department, who were further planned for PCNL procedure with diagnosis confirmed by preoperative non-contrast enhanced computed tomography (NCCT) were included in the study. Total of 253 patients were enrolled after Inclusion and Exclusion Criterias.

Inclusion criteria:

Patients above 18 years of age diagnosed to have Renal Calculus Disease by non-contrast CT by the clinician with stone size more than 1 cm, who are undergoing PCNL

Exclusion criteria:

Patients below 18 years age, with stone size less than 1 cm, with stone migrated from the upper ureter into the pelvis when URSL done as a primary procedure, with second stage PCNL, Patient with nephrostomy or ureteric stent in-situ preoperatively.

Methodology:

Patients with renal calculus presenting to the Departments of Urology, and diagnosis confirmed by preoperative NCCT KUB. The patients were informed about the study by providing them with "Participant information sheet". If they were willing to be part of the study, they were asked to give the consent. The details of imaging were collected for CROES nephrolithometry scoring as per "scoring protocol". Details of patient history, laboratory test values as advised by the treating physician, intraoperative PCNL details and postoperative patient recovery data including complications were collected in a proforma. These patients were then followed at 1month or during the time of Double J (DJ) stent removal. The routine post op imaging as decided by the treating doctor (X-ray KUB/ USG

scan) was collected at 4 weeks to look for stone clearance/ residual fragments. Patients with no residual fragment or residual fragment less 4 mm were grouped stone free and patients with fragments ≥4mm were grouped not stone free on X-ray KUB/ USG scan at 4 weeks follow up.

Study parameters collected include age, sex, Presenting complaints, Past history of stone disease and mode of management, Co-morbidities, Pre & post-op blood test values, Pre op NCCT image data for CROES nephrolithometry scoring. Also NCCT scoring data which is analyzed by another observer. PCNL procedure data, Post op recovery including complications data.

On follow up, at 4 weeks X-ray KUB/ USG image was done to look for stone free status.

Institutional Ethics Committee clearance was obtained for the study .The proceedings were followed according to the ethical principles of the Institutional Ethics Committee. Voluntary consent was acquired from each subject for collecting the data before starting the study.

Sample size was calculated using SAS 9.2 package. Data were analyzed using SPSS V15.0 (Statistical Package for Social Sciences, Version 15.0) package. ROC (Receiver Operating Curve) score for identifying cutoff for predicting the stone free status details were calculated with SPSS V15.0 and actual graphs were drawn with SAS9.2 package. Study data was analyzed as mean ± SD for continuous data, N for Number and Percentage for categorical data. Comparison of means of 2 groups were carried out by Studen's unpaired t test for numerical normal data. Chi square tests and Fisher Exact Probability tests were applied to compare percentages for categorical data between 2 and more than 2 groups. ANOVA (F test) was applied to compare means of more than 2 groups. Pearson Correlation Coefficient was used to find correlation between 2 variables. All statistical tests were two tailed. Alpha (α) Level of Significance was taken as P value ≤0.05.

RESULTS

A total of 253 patients with renal calculi diagnosed with preoperative non-contrast computed tomography were enrolled. Patients underwent PCNL procedure as planned by the treating urologist.

Only patients with age >18 years were included in the study. The youngest patient was 19 years age and the oldest patient was 84 years of age. The mean age at presentation was 42.23 years with a standard deviation of 13.10.

Out of 253 patients, 146(57.7%) patients were males and 107 (42.3%) patients were females.

115(45.5%) patients had left renal calculus and 138(54.5%) had right renal calculus.

146(57.7%) patients had 1-2 calyceal involvement, 58(22.92%) patients had 3 calyceal involvement and 49(19.36%) patients had complete staghorn calculus. In the stone free group, most of the patients i.e. 144(93.8%) patients had 1-2 calyceal involvement. In the not stone free group, 2 patients (5.4%) had 1-2 calyceal involvement. Of the remaining, 15 (40.5%) had all the 3 calyceal involvement and 20(54.1%) had staghorn calculus. There was a significant correlation (p=<0.001) between number of involved calyces and clearance rate.

Table 1: Comparison of Base line and Stone Characteristics of Study Patients.

Variable	Group, Calculate Mean(Standard Deviation)		P Value
	Stone Free(SFR)	Not Stone Free(nSFR)	
Outcome(N=253)	N=216	N=37	-
Age(yr)	42.41± 13.11	41.14± 13.20	t=0.5,NS,P=0.6
Gender Male (N=146) Female (N=107)	 127 (58.8%) 89 (41.2%)	 19 (51.4%) 18 (48.6%)	Fisher Exact Test F=0.47,NS,P=0.47
BMI(kg/m2)	25.30± 2.46	24.93± 2.50	t=0.8,NS,P=0.4
Side Right side (N=138) Left Side (N=115)	 121 (56.0%) 95 (44.0%)	 17 (45.9%) 20 (54.1%)	 Fisher Exact Test F=0.29,NS,P=0.29
Size(m2) 0-399 (N=157) 400-799 (N=63) 800-1599 (N=29) ≥1600 (N=4)	 141 (65.3%) 54 (25.0%) 21 (9.7%) 0 (0.0%)	 16 (43.2%) 9 (24.3%) 8 (21.6%) 4 (10.8%)	Chi sq.test value=29.7,DF=3,S,P<0.001
Obstruction None/mild (N=153) Moderate/severe (N=153)	 140 (64.8%) 76(35.2%)	 13 (35.1%) 24(64.9%)	 Fisher Exact Test F=0.001,S,P=0.001
Number of calyces involved 1-2 group (N=146) 3 Group (N=58) Staghorn (N=49)	 144 (66.7%) 43 (19.9%) 28 (13.4%)	 2 (5.4%) 15 (40.5%) 20(54.1%)	 Chi sq.test value=53.3,DF=2,S,P<0.001
Anatomy Simple (N=239) Complex(N= 14)	 205 10	 34 4	 Fischers Exact Test F=0.13,NS,P=0.13
Location of Stone Upper Pole (UP) (N=29)	 29	 0	Chi sq.test Value=75.0, DF=7,

Midpole(MP) (N=30) Lower pole (LP) (N=44) Renal Pelvis(RP) (N=56) Multiple (N=37) Partial Staghorn (N=30) Staghorn(N=20) Other (N=8)	30 44 55 24 21 8 5	0 0 1 13 9 11 3	Significant,P<0.001
Stone Number Single (N=161) Multiple (N=43) Staghorn (N=49)	 161(74.5%) 26(12.0%) 29(13.4%)	 0 (0.0%) 17(45.9%) 20(54.1%)	 Chi sq.test value=75.9,DF=2,S,P<0.001
Total CROES score	203.46± 41.16	139.27± 22.42	t=9.2,S,P<0.001
Length of stay (in days)	4.65 ± 1.43	7.19± 1.61	t=9.8,S,P<0.001
Procedure Duration (in min)	42.99± 9.99	71.49± 7.35	t=16.6,S,P<0.001
Amplatz Size(in Fr)	351.50± 232.14	722.78± 627.30	t=6.5,S,P<0.001

Table 2: Operative Time/Procedure Time

	Mean	**Median**	**Standard Deviation**	**Range**
Time in Minutes	47.15	45	13.95	30,90
	Group, Mean (Standard Deviation)		**P-Value**	
Time in Minutes	Stone Free (n=216)	Not Stone Free(n=37)		
	42.99± 9.99	71.49±7.35	t=16.6,S,P<0.001	

Student's unpaired t test
Conclusion: Significant difference

Table 3: CROES score and various PCNL outcomes

CROES score	**N=253**	**Mean Complication rates**	**P-value**	**Mean Hospital Stay**	**P-value**	**Mean Procedure time**	**P-value**
<150	51	0.20± 0.40	F=0.3	5.82± 2.17	F=10.2	59.71± 15.05	F=25.5
151-200	72	0.21± 0.41	Not Significant	5.40± 1.67	Significant	47.57± 14.92	Significant
200-220	16	0.25± 0.45	P=0.82	4.31± 0.87	P<0.001	42.81± 10.16	P<0.001
>220	114	0.25± 0.44		4.52± 1.37		41.89± 8.86	

Statistical Test: ANOVA (F test) one way.
Conclusion: Significant differences in Mean Hospital Stay and Mean Procedure time among CROES score categories.

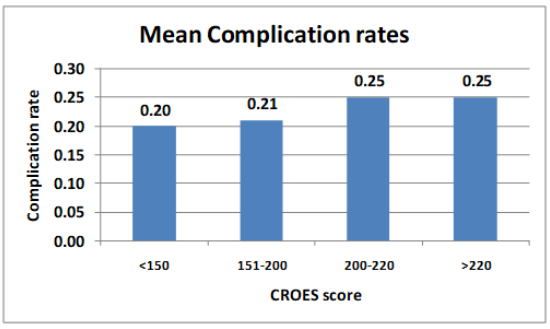


Figure 1: Mean Complication rates and CROES Score

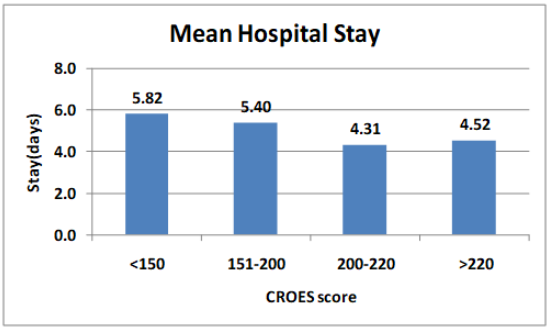


Figure 2: Mean Hospital Stay and CROES Score

Stone size in 157 (62.05%) patients was in the range of 0-399mm2 size, 63 (24.9%) patients in the range of 400-799mm2 size, 29(11.46%) patients in the size range of 800-1599mm2 and only 4 (1.58%) patient had size ≥1600mm2. 65.3% patients in the stone free group were in the 0-399mm2 size range. 43.2% of the not stone free group patients were in the size range of 0-399mm2, followed by 24.3% in the size range of 400-799mm2. There was significant correlation (p=<0.001) between larger stone size and lower SFR

The operative time of PCNL procedure was taken from the time of incision for puncture till the wound closure. Mean operative time was 47.15 minutes with a standard deviation of 13.95. Minimum operative time was 30 minutes and maximum time was 90 minutes. Mean operative time in the stone free group was 42.99±9.99 minutes and in not stone free group was 71.49±7.35 minutes. There was a statistically significant difference (p<0.001) between the duration of the procedure and stone clearance rate in all sub categories of CROES scores.

In our study, length of hospital stay was described as duration from the day of admission to day of discharge. In the stone free group, mean hospital stay was 4.65±1.43 days. In the not stone free group mean hospital stay was 7.19±1.61 days. Minimum length of stay was 2 days and maximum length of stay was 12 days. There was significant correlation (P<0.001) between nephrolithometry score for all Sub Categories of CROES score in the non-stone free group and the length of hospital stay.

The distribution of PCNL complications as per modified Clavein-Dindo classification in the study patients, 63 (24.9%) patients out of 253 had complications. Of these patients 25 (39.7%) had grade 1 complications, 5 (7.93%) patients had grade 3A complications, 32 (50.79%) patients had grade 2 complications and 1 (1.59%) patients had grade 4 complications. There was no statistical correlation between CROES nephrolithometry score and the PCNL complications.

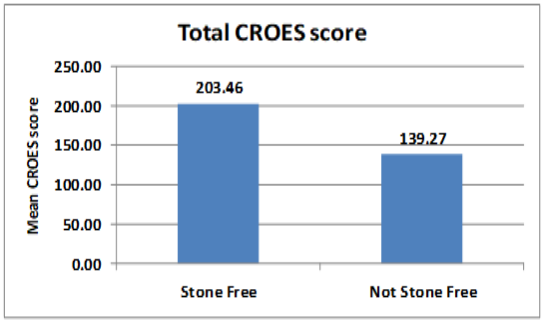


Figure 3: Mean Procedure Time and CROES score

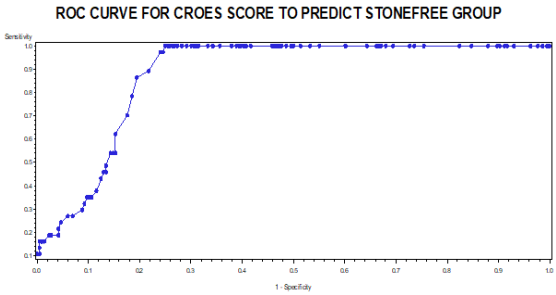


Figure 4: ROC for CROES score

Table 4: Area under the Curve

Test Result Variable(s):crscore				
Area	Std. Errora	Asymptotic Sig.b	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.878	.021	.000	.836	.920

Table 5: CROES Sub categorization and outcomes

	Stone free Group (n=216)	Stone Group (n=37)
CROES ≥160	169	4
CROES < 160	47	33
Total	216	37

Table 6: CROES Sensitivity and Specificity

Parameter	Value (%)	95% Confidence Intervals
Sensitivity	78.24	72.14,83.55
Specificity	89.19	74.58,96.97
PPV	97.69	94..35,99.07
NPV	41.25	34.74,48.08

DISCUSSION

Percutaneous nephrolithotomy has become a standard of care for management of renal calculi. The success of the procedure depends on many factors which affects access to the stones and its subsequent clearance. They include, stone burden, number, composition and location of calculi, BMI, HU and abnormal renal anatomy. But, a significant single predictor of success is not available. Therefore various predictive models have been developed by various authors combining such different parameters. These include Guy's Stone Score (GSS), Clinical Research Office of the Endourological Society (CROES) nomogram, STONE score, and Seoul National University Renal Stone Complexity.

NCCT KUB which is the Investigation of choice for any Urolithiasis evaluation & Management as per EAU and AUA Guidelines and is used in this study to derieve CROES Stone Score.

In the study CROES nephrolithometry score was analyzed for Percutaneous lithotomy outcomes, such as stone clearance rate, post-operative complications, length of stay, duration of procedure, including patients baseline characteristics in study sample.

253 patients with age ≥18 years having renal calculi of size ≥1cm were included in the study. Overall, 216 patients were rendered stone-free and 37 patients with residual fragments ≥4mm were not stone free. In the present study almost 57% of the patient were male and 43% female and there was no statistical difference & thus Age & gender didn't have any correlation with stone free outcome.

146(57.7%) patients had 1-2 calyceal involvement, 58(22.92%) patients had 3 calyceal involvement and 49(19.36%) patients had complete staghorn calculus. In the stone free group, most of the patients i.e. 75(93.8%) patients had 1-2 calyceal involvement. In the not stone free group, 2 patients (5.4%) had 1-2 calyceal involvement. Of the remaining, 15 (40.5%) had all the 3 calyceal involvement and 20(54.1%) had staghorn calculus. There was a significant correlation (p=<0.001) between number of involved calyces and clearance rate. This correlated with the study by okhunov et al with statistical significant correlation of p<0.001.[12]

Mean operative time in our study was 42.99 minutes in stone free group and 71.49 minutes in not stone free group. It indicated that there was correlation between procedure duration (p<0.001) with CROES score. It has been reported in the studies that greater CROES nephrolithometry scores were associated with statistical significant longer operative times. Similar Results were noted in CROES Global study group.[11]

In our study, length of hospital stay has been determined from the day of admission to the day of discharge. Mean hospital stay was 5.92 days with minimum was 2 days and maximum 12 days. Mean length of stay in stone free group and not stone free group was 4.65 days and 7.19 days respectively. There was correlation seen between CROES stone score and length of hospital stay (p<0.001). In most of the other studies there was significant difference

between the two groups. Similar Results were noted in CROES Global study group.[11]

Post-operative complications were documented as per modified clavein-dindo classification. Complications were documented in 63 patients from grade 1 to 4. 25 patients had grade 1 (pain, ileus, hydrothorax, bleeding), followed by 5 patients of grade 3A (clot evacuation under local anesthesia, intercostal drainage tube under local anaesthesia). 32 patients of grade 2 (Blood transfusion, prolonged antibiotics for urosepsis), and 1 patients of grade 4 complications(ICU Care), our study suggested that there was no correlation between CROES score and complications. okhunov et al also had a similar findings but they corroborated it for low sample size.[12]

Various similar studies were done which showed positive correlation of Guys stone Score with SFR and Predictions of Complications of PCNL which included:

Smith et al of CROES PCNL Group showed that with a sample size of 2806 with use of CROES Nephrolithometric Nomogram overall stone clearance rate was 82%, with overall no complications reported .post op stone free status(no fragments > 4mm) was documented by KUB radiograph.Odds Ratios and nomogram reported ROC AUC was 0.76. In this study Multivariate Logistic regression analysis was used.[9]

Bozkurt et al of Turkey showed that with a sample size of 437 with use of CROES Nephrolithometric Nomogram overall stone clearance rate was 75%, with overall 35% complications reported .pre operatively CT was used and post op stone free status(Asymptomatic residual stones <4mm) was documented by KUB radiograph(unless CT; which was reserved for symptomatic patients). Grade 1 had clearance of 48.5%, Grade 2 had clearance of 51.4%, Grade 3 had clearance rates of 69.1% and Grade 4 had clearance rates of 92.8%. In this study Linear and Logistic regression analysis were used.[11]

Labadie K et al of United states showed that with a sample size of 246 with use of CROES Nephrolithometric Nomogram overall stone clearance rate was 56%, with overall 17% complications reported .pre operatively CT was used. 80-129=22.7%, 130-169=46.4%, 170-219=45.5%, >220=72.7% clearance. In this study Logistic regression analysis was used.[10]

Strengths and limitations of the study:

The strength of our study: It was a prospective study. The limitation of the study: It was a single-centre study, Length of stay had some bias due to additional time required for clearance of insurance & Study population number was statistically significant, but was less in comparison to few other studies with large cohort.

CONCLUSION

Preoperative nephrolithometry scoring systems are a useful tool for the preoperative prediction of the success rate of Percutaneous Nephrolithotomy. The CROES nephrolithometry scoring system was evaluated as an option for applicability in the clinical setting. In the present study, CROES scoring system was found to be accurate in predicting the stone-free status after percutaneous nephrolithotomy. CROES score had significant correlation with the duration of the procedure & length of hospital stay , but failed to predict Post op complications .Thus The CROES score was a simple and easy to apply system for predicting the complexity of the stone for PCNL and stone clearance.

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