ORIGINAL RESEARCH

Reporting Success Rate And Complications Of Percutaneous Nephrolithotomy Using Guy's Stone Score And Modified Clavien Grading System

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ABSTRACT

Introduction & Purpose: Percutaneous nephrolithotomy (PCNL) is a well-proven minimally invasive treatment modality for the management of renal calculi. However, PCNL is not without complications. This study aims to assess the complications after PCNL using the Modified Clavien grading system and the success rates of PCNL using Guy's Stone Score (GSS). **Methods**: 100 patients were enrolled in this study at Meenakshi Mission Hospital Madurai Tamilnadu, India, in duration April 2020 to March 2022. The stone burden and predictive difficulty were determined by radiographic studies and classified using the GSS. Patient underwent PCNL as per the standard protocol after ensuring sterile urine. The modified Clavien grading system was used for evaluating perioperative and postoperative complications of PCNL. **Results:** All renal units with GSS I were stone-free after one session of PCNL, GSS II needed one session in 83.3% and two sessions in 11.1% renal units, GSS III needed one session in 45.5% and two sessions in 36.4% renal units and GSS IV needed one session in 20% and two sessions in 40% renal units and remaining 40% renal units could not be made stone free in spite of multiple sessions. Total 87 complications occurred in 41 patients, grade 1 to 5 includes 28 (32.3%), 38 (43.7%), 7 (8%), 7 (8%), 3 (3.4%), 3 (3.4%), 1(1.1%). **Conclusion:** PCNL is standard care for large renal calculus. It is a safe, efficient, and feasible technique. Guy's score is a very simple and effective system to classify the complexity of various renal stones. It can guide urologists and, patients to make their decision and consent about different aspects of surgery. The Modified Clavien–Dindo system is easy to use and feasible tool to grade perioperative complications.

Keywords: Complications, Guy's Stone Score, Modified Clavien Grading, Stone Free Rate.

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is a well-established, minimally invasive treatment modality for the management of renal calculi. It is the first-line treatment option for large or multiple kidney stones and stones in the inferior calyx. However, PCNL is not without complications with recent multi-center studies showing that overall complication rate of 20.5%[1]. Complication rates as high as up to 83% have also been reported[2].

Earlier there was no consensus on how to define complications and stratify them by severity. This hampered comparison of outcome data and generated difficulties in informing patients about complications. The Modified Clavien system has been proposed to grade perioperative complications of general surgery[3]. The same classification system has recently been used by urologists to grade perioperative complications following radical prostatectomy[4], laparoscopic live donor nephrectomy[5], laparoscopic pyeloplasty[6], laparoscopic and open partial nephrectomy and Transurethral Resection of Prostate[7]. Results of this new classification to grade complications after PCNL have also been described [[8,9]].

Calculi are generally classified into simple or complex, or pelvic or calyceal based on location, or single or multiple. However, none of the systems could become a standard method due to the inherent fallacies of each system and also their inability to successfully predict outcome after PCNL. Thus to avoid the gray zones in the classification system and for predicting outcomes after PCNL, Guy's Stone Score (GSS) was conceived, validated and found to be an easy, reproducible and reliable method for describing the nature of calculi and predicting the stone-free rates[10] So, we analyzed perioperative complications of PCNL according to the modified Clavien system in which the stone complexity has been classified using the validated GSS and we have compared complications amongst various GSSs. We have also have compared GSSs with stone-free rates after PCNL.

GUY'S STONE SCORE

GRADE I

A solitary stone in the mid/lower pole with simple anatomy Or A solitary stone in the pelvis with simple anatomy.

GRADE II

A solitary stone in the upper pole with simple anatomy or Multiple stones in a patient with simple anatomy, any solitary stone in a patient with abnormal anatomy.

GRADE III

Multiple stones in a patient with abnormal anatomy Or Stones in a calyceal diverticulum Or Partial staghorn calculus.

GRADE IV

Staghorn calculus or any stone in a patient with Spina Bifida or Spinal Injury.

Thomas et al[10] validated Guy's stone score in 100 patients and found it to be an easy to use and reproducible and reliable method for describing the complexity of PCNLs when predicting the SFR. Johann et al studied 166 patients and inferred that The GSS is a straightforward grading system for the complexity of renal stones. When applied to preoperative CT scans, it offers good inter-rater concordance and is associated with rigorous endpoints of stone clearance.

Mandal et al[42] studied in 221 patients and correlated guy's stone score with clavien grading system concluded that low grade complications were self limiting and higher GSS associated with more complications and GSS effectively predicted stone free rates.

MODIFIED CLAVIEN SYSTEM

Grade 1: Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions. Allowed therapeutic regimens include drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy.

Grade 2: Complications requiring pharmacologic treatment with drugs other than allowed for Grade 1 complications. Blood transfusions and total parenteral nutrition are also included.

Grade 3: Complications requiring surgical, endoscopic, or radiologic intervention.

Grade 3a: Intervention not under general anesthesia

Grade 3b: Intervention under general anesthesia

Grade 4: Life-threatening complications (including central nervous system complications) requiring intensive care unit stay

Grade 4a: Single-organ dysfunction (including dialysis)

Grade 4b: Multiorgan dysfunction

Grade 5: Death of the patient

AIMS AND OBJECTIVES

- To assess the Prospective evaluation of complications after percutaneous nephrolithotomy using the Modified Clavien grading system.
- To assess success rates of percutaneous nephrolithotomy using Guy's Stone Score.

MATERIALS AND METHODS

STUDY DESIGN

A prospective study would be conducted in the Department of Urology, Meenakshi Mission Hospital & Research Centre (MMHRC), Madurai, Tamil Nadu

- Subjects admitted for percutaneous nephrolithotomy would be enrolled into the study from April 2020 to March 2022.

IEC Number- DNB/ CNS/CETSS/ 41159/ 13/ OTHERS/ 1127721/ 9478

INCLUSION CRITERIA

- Subjects who were admitted for percutaneous nephrolithotomy would be enrolled in the study.

EXCLUSION CRITERIA

- Co-morbidities such as renal insufficiency, diabetes, hypertension or cardiopulmonary diseases,
- Patients with coagulation disorders, hepatic disease, Cerebral vascular events.

METHODOLOGY

Preoperative complete blood count, serum creatinine, bleeding and coagulation profile and urine cultures were obtained from all patients. Radiologic evaluation included X-ray Kidney Ureter and Bladder (KUB), intravenous urography (IVU) and ultrasonography of KUB and CT urogram (CTU). The stone burden was determined by radiographic studies, and stones were classified using the GSS as Guy's I, II, III and IV.

OPERATIVE TECHNIQUE

Patient underwent PCNL as per the standard protocol after ensuring sterile urine. Cystoscopy and insertion of a ureteral catheter were the initial step. Patients were then placed prone and percutaneous access was obtained using C-armed fluoroscopy. Tract was dilated with Alken's serial dilator (Karl Storz) and a 28/30 F or 30/34 F Amplatz sheath was placed. Nephroscopy was performed with a rigid, 26F rigid nephroscope (Karl Storz). Calculi were identified and fragmented with pneumatic Swiss lithoclast. Stone clearance was confirmed intra-operatively by fluoroscopy. If needed, another puncture was made to achieve stone clearance. A double-J stent was placed using the antegrade approach at the end of the procedure. An external ureteral catheter was left in situ if the patient was planned for relook PCNL. A 20F nephrostomy tube was placed into the renal pelvis or the punctured calyx at the end of the procedure. The PCNL procedure was performed by experienced urologist.

Antibiotic prophylaxis was given to all the patients. Fever of >100° F was considered significant. Serum creatinine levels and blood counts were obtained in all patients postoperatively. On postoperative Day 1, plain film of the kidneys, ureters, and bladder was obtained. If complete stone clearance was documented and there was not significant hematuria, the nephrostomy tube was removed. After 12 h, if there was no urine leak from the nephrostomy site the urethral Foley and ureteral catheters were removed. If urine leak persisted for more than 24 h than DJ stent placement was done. DJ stent was removed after three to four weeks. If residual fragments were seen on postoperative X-ray, then re-look PCNL using either the same tract or new tract was done after two to four days. Although all patients needing intervention under general anesthesia is considered a Grade 3b complication, it was not considered a complication in the present study and has been mentioned separately. All patients were then followed up at one week and at one month after discharge from the hospital. In patients with bilateral renal stones procedure was staged. The PCNL procedure was considered successful if the patient was either stone-free or had any clinically insignificant residual fragments (CIRFs), defined as <4 mm, non- obstructive, non-infectious, and asymptomatic residual fragments.

Data recorded included the age, sex, stone complexity score according to GSS, clearance after first and second session, mean number of punctures, site of punctures, and mean duration of surgery. The modified Clavien grading system was used for evaluating perioperative and postoperative complications of PCNL. Complications in the same patient undergoing re-look procedures were counted independently as separate complications. The data will be entered into an Excel ™ (Microsoft, Redmond, WA) database and analyzed with an EPI-Info statistical software package. Data were analysed and compared using SPSS version 20 (SPSS, Inc., Chicago, IL).

RESULTS

100 PCNL in 95 patients were included in the study. Out of these in 5 patients had bilateral renal stones present.

LOCATION OF RENAL STONE

Total 95 patients (100 procedures) were included in the study. In 48 patients stone was on the right side, in 42 patients on the left side, and in 5 patients bilateral in location.

Table 1: Location of renal stone

Side of stone	No of patients	Percentage
Right	42	44.2%
Left	48	50.5%
Bilateral	5	5.3%

AGE

Mean age of the patient was 35.2 ± 10.5 years with age range of 16-72 years.

Table 2: Age distribution

Age	No of patients	Percentage%
<20	5	5.3
21-30	18	19
31-40	25	26.3
41-50	20	21
51-60	17	17.9
61-70	8	8.4
>70	2	2.1

SEX

Out of 95 patients 57 were males and 38 were females.

Table 3: Sex distribution

Sex	No of patients	Percentage%

Male	57	60
Female	38	40

BODY MASS INDEX (BMI)

The mean BMI was 25.8±10.4. Most of the patients had BMI between18-30.

Table 4: Body mass index

BMI	No of patients	Percentage%
<18	5	5.3
18-25	38	40
26-30	37	39
>30	15	15.7

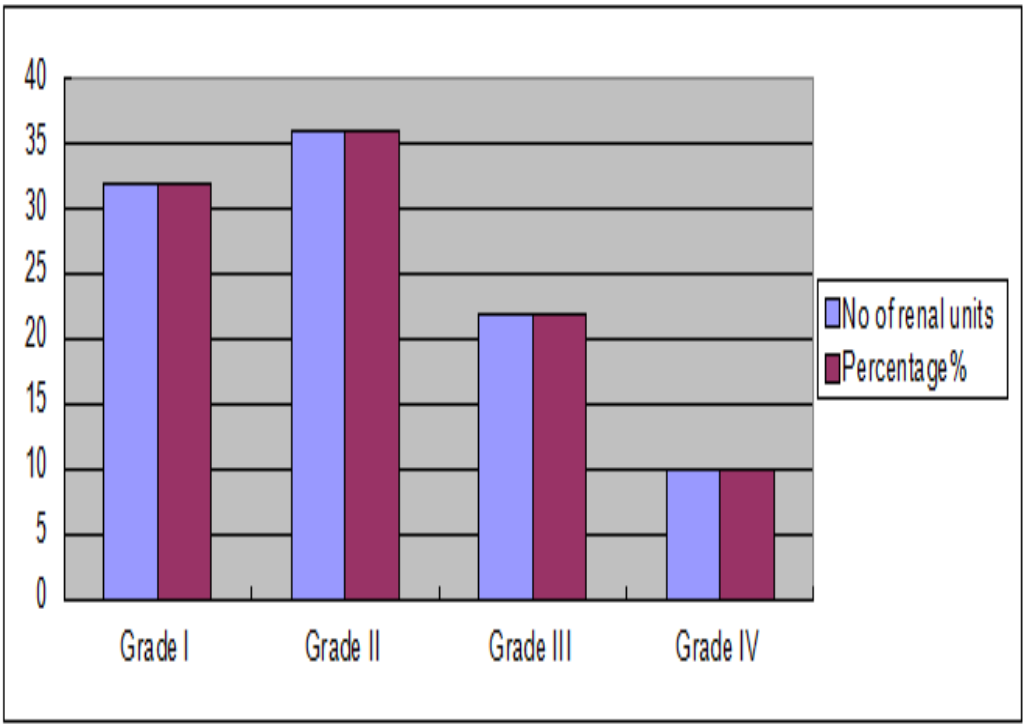
GUY'S STONE SCORE

Total number of renal units were 100 which had, GSS I in 32, GSS II in 36, GSS III in 22 and GSS IV in 10 patients. Most of the patients had GSS II renal stones followed by GSS I.

Table 5: Renal units according to Guy's stone score

Score	No of renal units	Percentage%
Grade I	32	32
Grade II	36	36
Grade III	22	22
Grade IV	10	10

Chart 1: Renal units according to Guy's stone score



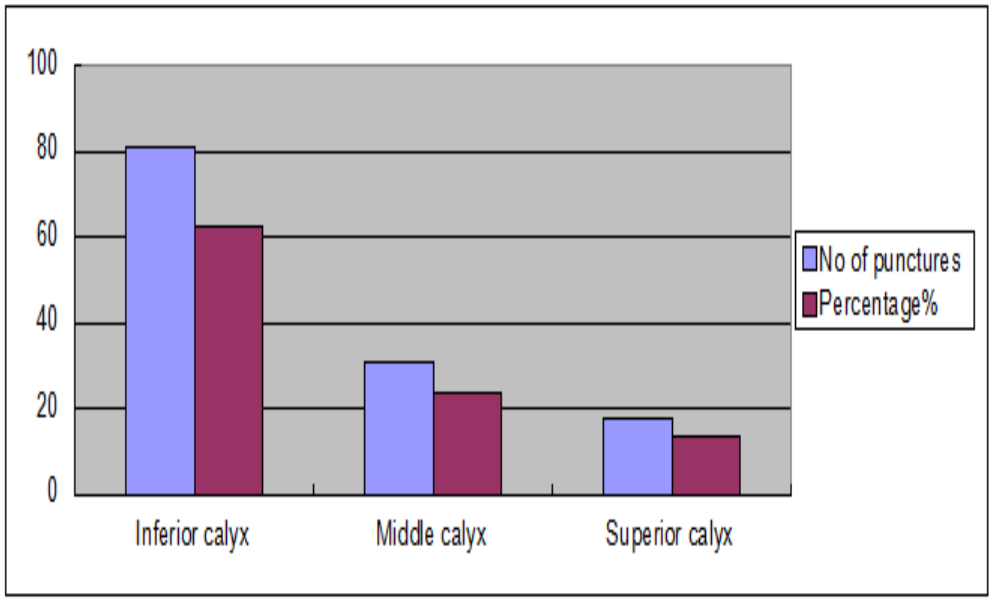
SITE OF RENAL PUNCTURE

Total number of punctures were 130 which includes inferior calyx punctures 81, middle calyx punctures 31 and superior calyx punctures 18.

Table 6: Site of Renal Puncture

Puncture	No of punctures	Percentage%
Inferior calyx	81	62.3
Middle calyx	31	23.8
Superior calyx	18	13.9

Chart 2: Site of Renal Puncture



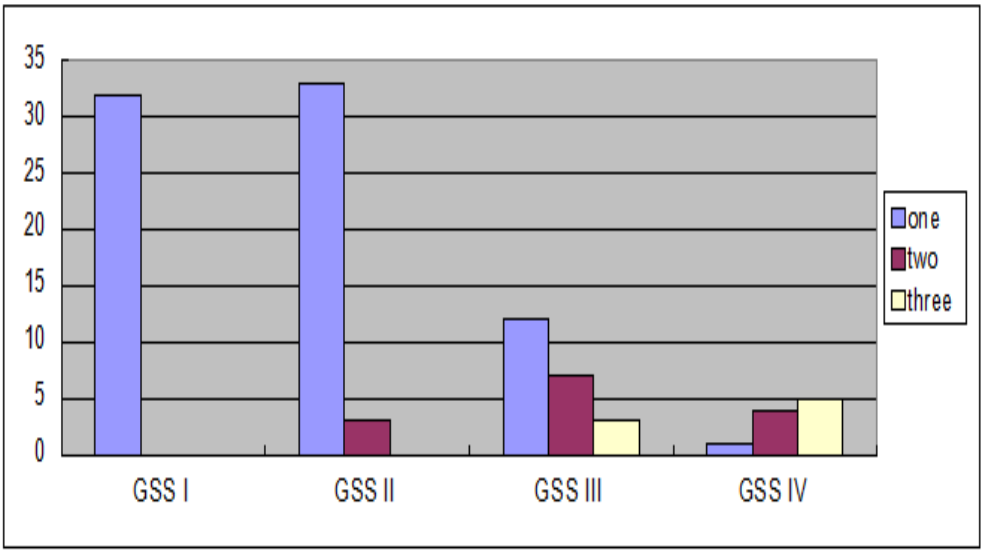
NO OF PUNCTURES AND GSS

Most of GSS I and GSS II had single puncture, where as stones in GSS III and GSS IV needed multiple puncture.

Table 7: No of punctures and GSS

No of punctures	GSS I	GSS II	GSS III	GSS IV
1	32	33	12	1
2	0	3	7	4
3	0	0	3	5

Chart 3: No of punctures and GSS



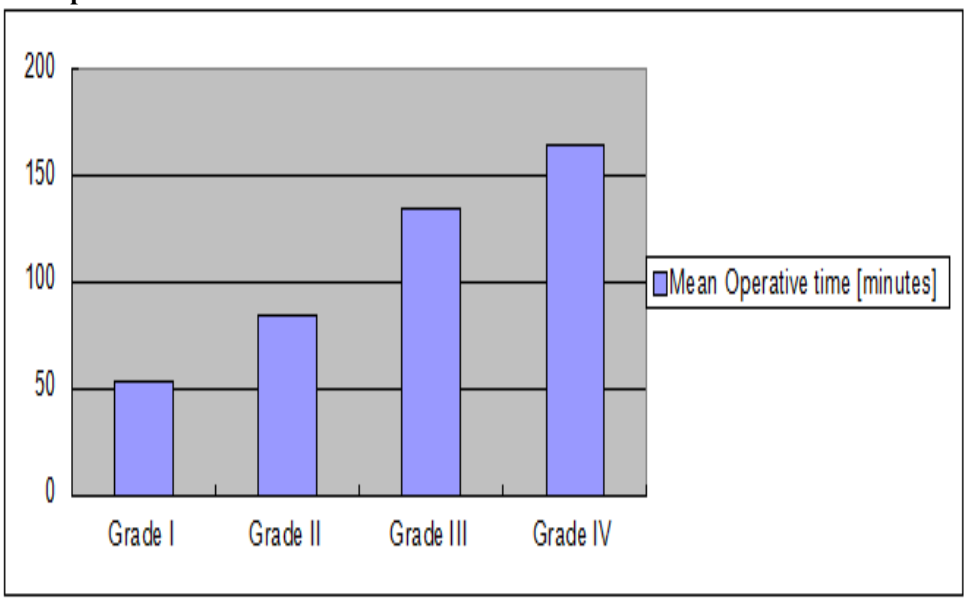
MEAN OPERATIVE TIME WITH GSS

Mean operative time in grade I to IV includes 53.2 min, 84.6 min, 135 min and 164.6 min.

Table 8: Mean operative time with GSS

GSS	Mean Operative time [minutes]
Grade I	53.2 ± 9.8 min
Grade II	84.6 ± 11.5 min
Grade III	135 ± 13.1 min
Grade IV	164.6 ± 15.2min

Chart 4: Mean operative time with GSS



MEAN HOSPITAL STAY

Mean hospital stay was more in patients with higher grades compared to grade I & II (I- 4.3±0.9, II- 5.2±1.1, III- 7.3±1.5, IV- 8.8±2.3).

Table 9: Mean Hospital stay and GSS

GSS Grade	Mean Hospital stay
I	4.3 ±0.9
II	5.2±1.1
III	7.3±1.5
IV	8.8± 2.3

MODIFIED CLAVIEN GRADING

Total complication rate was 41%. Total 87 complications occurred in 41 patients, grade 1 to 5 includes 28 (32.3%), 38 (43.7%), 7 (8%), 7 (8%), 3 (3.4%), 3 (3.4%), 1(1.1%). Most of the complications were grade 2 followed by grade 1.

Table 10: Modified clavien grading

Clavien grading	No of complications (Total - 87)	Percentage%
1	28	32.3
2	38	43.7
3a	7	8
3b	7	8
4a	3	3.4
4b	3	3.4
5	1	1.1

COMPLICATIONS ACCORDING TO MODIFIED CLAVIEN GRADING

Total number of complications include 87, with complication rate 41%. Grade 1 complications include fever (12.6%), transient elevation of serum creatinine (1.4%), pain, nausea and vomiting (9.3%).

Grade 2 complications include nephrostomy leak (11.5%), requirement for blood transfusion (25.3%), UTI, pneumonia and wound infection (6.9%).

Grade 3a complications include ureteral stent insertion (3.4%), Retention due to blood clots (1.1%), stent migration (3.4%).

Grade 3b complications include Arteriovenous fistula, Intra-operative bleeding requiring quitting the operation (3.4%), perirenal hematoma (2.3%), ureter bladder stone (2.3%).

Grade 4a complications include Bowel injury (2.3%), Myocardial infarction (1.1%). Grade 4b complication includes urosepsis (3.4%) and grade 5 includes death (1.1%).

The most common complication is blood transfusion (25.3%) followed by fever (12.6%). The death occurred in 1 patient.

Table 11: Complications according to Modified Clavien grading

Clavien Grade	Complications (87)	Percentage (41%)
1	Fever	11 (12.6%)
	Transient elevation of s.cr	9 (10.4%)
	Pain, Nausea and vomiting	8 (9.3%)
2	Nephrostomy leak	10 (11.5%)
	Blood transfusion	22 (25.3%)
	UTI, Pneumonia, Wound infection	6 (6.9%)
3a	Ureteral stent insertion	3 (3.4%)
	Retention due to blood clots	1 (1.1%)
	Stent migration	3 (3.4%)
3b	Perirenal hematoma	2 (2.3%)
	Arteriovenous fistula, Intra-operative bleeding requiring quitting the operation	3 (3.4%)
	Ureter-bladder stone	2 (2.3%)
4a	Bowel injury	2 (2.3%)
	Myocardial infarction	1 (1.1%)
4b	Urosepsis	3 (3.4%)
5	Death	1 (1.1%)

COMPARISON OF COMPLICATIONS ACCORDING TO MODIFIED CLAVIEN GRADING WITH CALCULI ACCORDING TO GSS

In patients with GSS I and II low grade complications were more common when compared with high grade complications. In patients with GSS III and IV higher grades were more common when compared with higher grades which was statistically significant. All grades of complications were seen in patients with GSS IV.

Table 12: Comparison of complications according to Modified clavien grading with calculi according to GSS

Clavien grade	Number	GSS I	GSS II	GSS III	GSS IV	P value
1	28	4	10	7	7	0.54
2	38	8	11	11	8	0.61
3a	7	0	2	3	2	0.034
3b	7	2	2	1	2	0.48
4a	3	0	1	1	1	0.023
4b	3	0	0	1	2	0.001
5	1	0	0	0	1	< 0.001

COMPARISON BETWEEN GSS AND STONE FREE RATES

In patients with GSS I all stones were cleared after 1st session. In patients with GSS II after 1st session 30, after 2nd session 4 were cleared, incomplete clearance seen in 2 cases. In patients with GSS III after 1st session 10, after 2nd session 8 were cleared, incomplete clearance seen in 4 cases. In patients with GSS IV after 1st session 2, after 2nd session 4 were cleared, incomplete clearance seen in 4 cases.

Table 13: Comparison between GSS and stone free rates

GSS	Clearance after 1st session	Clearance after 2nd session	Incomplete clearance	P value
GSS I	32	-	-	0.003
GSS II	30	4	2	0.025
GSS III	10	8	4	0.041
GSS IV	2	4	4	0.23

AUXILLARY PROCEDURES

Auxillary procedures needed in 10 patients. Stones were cleared in 6 cases and failure seen in 4 cases.

Table 14: Auxillary procedures for incomplete stones

Auxillary procedure	No of cases	Incomplete clearance
URSL	2	-
ESWL	4	3
PCNL	4	1

DISCUSSION

In spite of the high success rates, percutaneous renal surgery involves serious complications such as blood loss, adjacent organ injuries and life-threatening infections[46]. In Michel et al[2], retrospective analysis of complications in >1000 PCNL procedures was

performed and the complications were stratified into minor or major. Minor complications reported were extravasation (7.2%), transfusion (11.2-17.5%), and fever (21.0-32.1%), whereas major complications were septicemia (0.3-4.7%) and colonic (0.2-0.8%) or pleural injury (0.0-3.1%). However, terms such as minor and major are not standardized and therefore, an informative comparison of complications is difficult. Modified Clavien grading system, has been shown to be a reliable tool for more objective outcome comparisons after renal stone treatment[35]. Complications stratified as Clavien Grade 1 and 2 are considered as minor while Grades 3, 4, and 5 are considered major according to other classification systems[2].

Total 100 PCNL were performed during the study period with bilateral stones noted in 5 patients. Mean age of the patients was 35.2 ± 10.5 (16-72 years). Male to female ratio was 1:1.5. The mean BMI was 25.8±10.4. The total number of punctures made was 130 with a mean of 1.3 puncture per renal unit with inferior calyx puncture was common (62.3%).

The overall complication rate of 41% seen in our study is much higher than Labate eta al[1], in which out of 5724 PCNL procedures, 20.5% complication rate was reported. Reason for this difference could be prospective evaluation of the complications by a single observer as opposed to retrospective data in other studies

Complications of Grade II severity were most common in our patients. Bleeding, necessitating blood transfusion was the most common individual complication, observed in 25.3% (22 out of 87) of procedures and was much higher in comparison to the 5.7% reported by the CROES group[47]. However, an overall blood transfusion rate ranging from 5-18% has been reported in the literature[48]. This high rate of transfusion can be explained by the increased incidence of multiple calculus and staghorn calculi, necessitating multiple percutaneous accesses and also second look surgeries. Postoperative blood transfusion was done when hemoglobin dropped below 8 g/dl (because of low preoperative hemoglobin and also due to intra-operative blood loss). Blood transfusion rates also varied based on GSS as 6.3%, 11.1%, 36.4% and 80% of renal units with GSS I, II, III, and IV, respectively, required transfusion. High transfusion in GSS III and IV were probably due to the fact that most of these patients were managed by multiple punctures and also needed re-look procedures. In two (2.3%) patients the operation had to be terminated due to severe bleeding (Grade 3b complication) leading to hemodynamic instability and poor visualization. One patient (1.1%) needed angio-embolization for control of bleeding.

Fever in the postoperative period was the second most common complication (after blood transfusion) and was seen in 12.6% of procedures. The reported incidence of fever after PCNL has varied from as low as 2.8% to as high as 27.6%[35] (usually between 6.5-13%) and can be because of different patient populations and the policy regarding the use of antibiotics. Factors predisposing to fever after PCNL include preexisting untreated UTI, infected urinary stones, renal insufficiency, and duration of surgery (< 90 min), amount and pressure of irrigation fluid[49].

Wound infection occurred in six renal units. Wound infection was referred to as the skin and subcutaneous tissue infection at the nephrostomy site. All cases responded to proper cleaning, applying povidine iodine, and removing the nephrostomy tube after PCNL.

Pleural injury was seen in 3 (3.4%) renal units. These patients had a supra-costal puncture and constituted 8% of all supra-costal punctures. This is in concordance with the literature that reports 3-7% risk of pleural injury in supra-costal punctures[50].

Major or significant complications were generally uncommon. Skolarikos and de la Rosette in a current review with a systematic search for manuscripts on classification and grading of PCNL-related complications have reported that the frequency of major complications after PCNL was 0.9-4.7% for septicemia, 0.6-1.4% for renal hemorrhage necessitating intervention, 2.3-3.1% for pleural injury, and 0.2-0.8% for colonic injury[33]. In our series frequency of urosepsis / septicemia, pleural effusion and renal hemorrhage necessitating intervention were reported in 3.4%, 1.1%, 2.3% and 2.3% respectively. Septicemia can occur as a result of infection introduced via the access to the kidney or if the stones are infected. Mean operating time, blood transfusion rates and Mean hospital stay were more in patients with higher grades.

We excluded patients with co-morbidities because co-morbidity acts as a confounding factor leading to higher complications rates. Unsal et al[51] showed that preoperative co-morbidities increase the risk of postoperative complication after PCNL. More severe Complications were seen in patients with higher grades which is statistically significant. More severe Complications were seen in patients with higher grades which is statistically significant.

As in a previous study by Thomas et al[8], the GSS accurately predicted the SFR after PCNL in our study also. It was an easy-to-use, reproducible, objective and reliable method for describing the complexity of stones and predicting the SFR after PCNL. All renal units with GSS I were stone-free after one session of PCNL, GSS II needed one session in 83.3% and two session in 11.1% renal units, GSS III needed one session in 45.5% and two session in 36.4% renal units and GSS IV needed one session in 20% and two session in 40% renal units and remaining 40% renal units could not be made stone free inspite of multiple sessions. Therefore increasing stone complexity led to decreasing stone clearance rates. Auxiliary procedures needed in 10 cases. URSL in 2 patients, in 4 and PCNL in 4 cases. Failure rate was 4%.

The prospective nature of this study is the biggest strength of the present study as most studies

documenting the post-PCNL complications according to modified Clavien grading are retrospective in nature. In the present study we also compared complications of PCNL using the modified Clavien grading system with GSS. GSS and stone-free rates were also compared. The limitations of the present study are the small sample size and the non-blinded study protocol.

CONCLUSION

The Guy's stones score is accurate to assess stone-free rates correctly. Higher Guy's stones score needing ancillary procedures for complete stone clearance. Guy's stones score correlated well with the Modified Clavien Grading System for grading perioperative complications. The Guy's stone score is easy to use and reproducible.

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