IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 11 Ver. 8 (November. 2018), PP 31-37
www.iosrjournals.org

A Study on outcome of Percutaneous Nephrolithotomy

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Abstract
Background*:-The prevalence of urolithiasis is approximately 2 to 3 percent in the general population, and the estimated lifetime risk of developing a kidney stone is about 12%. Over time, renal stone management has undergone a dramatic change, beginning from the era of open pyelolithotomy, to the first percutaneous lithotomy (PCNL) in 1976.*
Material and methods*:- This study was conducted in the Department of Urology, Regional Institute of Medical sciences, a tertiary care center in Imphal, Manipur, during the period November 2015 to October 2017 after taking ethical committee approval. Fifty patients who attended the Urology Department and admitted for percutaneous nephrolithotomy during the study period were included in the study. The outcome and complications of these patients who underwent percutaneous nephrolithotomy were studied.*
Results*:- Our study showed that Guy's stone score grade 1 has stone clearance rate of 87.5%, grade2-87.5%, grade 3- 68.18% and grade 4- 25 (P-value being 0.04). This correlation between Guy's Stone score and stone free rate is statistically significant (P-value=0.04).In this study, patient with GSS 1 has 3% of Clavien-Dindo grade1, GSS 2(grade1-2%, grade2-6%), GSS 3(grade1-2%, grade2-14%, grade3a-2%), GSS 4(grade2-4%, grade 3a-2%).(P-value is 0.037).*
Conclusion*:- It may be concluded that as the Guy's stone score increases, the rate of stone clearance decreases, and also the grade of complications increases.*
Keywords*:- Percutaneous nephrolithotomy,PCNL complications, stone clearance .*

Date of Submission: 14-11-2018 Date of acceptance: 29-11-2018

I. Introduction

The prevalence of urolithiasis is approximately 2 to 3 percent in the general population, and the estimated lifetime risk of developing a kidney stone is about 12%.1 The lifetime risk of kidney stone formation is approximately 11% for men and 7% for women, which has a tendency to increase with changes in diet and climate. It is anticipated that other pre-existing medical conditions, such as diabetes and obesity, will further increase an individual's risk of developing nephrolithiasis.Besides a high prevalence, renal stone disease also has a tendency to recur if left untreated, with a reported recurrence rate as high as 50% at 5 years and 80–90% at 10 years, respectively.2

Over time, renal stone management has undergone a dramatic change, beginning from the era of open pyelolithotomy, to the first percutaneous lithotomy (PCNL) in 1976.1Percutaneous nephrolithotomy (PCNL), first reported by Fernstrom and Johansson in 1976.2Percutaneous nephrolithotomy (PCNL) is supported by the American Urological Association (AUA) and European Association of Urology (EAU) as first line treatment for large and complex upper urinary tract stones. This procedure can be challenging and carries a risk of significant morbidity. It has been estimated that complications after PCNL can be as high as 25%, nearly 5% of which are Clavien grade 3 or higher. Despite such challenges, PCNL remains a commonly performed procedure accounting for approximately 5% of all stone-related surgeries.3

The outcomes of PCNL can be interpreted in terms of success and complication rates. "Success" is often defined as the absence of residual stone fragments under conventional X-ray or computed tomography (CT) or when only clinically insignificant residual fragments (CIRF) are observed. CIRF was defined as residual fragments that were smaller than 4mm asymptomatic, non-obstructive, and non-infectious.4Numerous procedures are now available for the management of urinary stones. For the management of upper urinary calculi, the method of dilating the tract after percutaneous renal puncture to specifically remove urinary calculi was first established in 1976 by Fernström and Johansson. Today, PCNL plays an integral role in managing

renal stone disease and morbidity and mortality of the disease and also of the treatment itself, has been dramatically reduced.5

Presently, percutaneous nephrolithotomy (PCNL) is preferred as a safe and effective way to remove large or multiple upper urinary tract calculi.An increase in PCNL has been accompanied by variations in positions, techniques, and instruments, and these may have led to increased complications.

Following PCNL, 79.5% of patients may experience an uncomplicated postoperative period,although there are reports of an early complication rate of 50.8%. PCNL complications may occur during puncturing, access, or stone removal. A standardized classification allow us to compare complications among different instruments, techniques, and centers. In 2004, the modified Clavien system (MCC) was introduced and allowed us to classify complications based on life-threatening conditions, interventions required, and disability. In recent years, this classification has been used to report PCNL complications instead of using simply "minor" and "major" distinctions.6

Grade Description

Grade I Any deviation from the normal post-operative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions (allowed therapeutic regimens are antiemetics, antipyretics, analgesics, diuretics, electrolytes andphysiotherapy)

Grade	Description
Grade I	Any deviation from the normal post-operative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions (allowed therapeutic regimens are antiemetics, antipyretics, analgesics, diuretics, electrolytes andphysiotherapy)
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusion and total parenteral nutrition are also included.
Grade IIIa	Requiring surgical, endoscopic or radiological interventions not under general anesthesia
Grade IIIb	Requiring surgical, endoscopic or radiological interventions under general anesthesia
Grade IVa	Life-threatening complication requiring Intensive Care Unit management (single organ dysfunction).
Grade IVb	Life-threatening complication requiring Intensive Care Unit management (multiple organ dysfunction).
Grade V	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 indicated the need for a follow-up to fully evaluate the complication.

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Modified Clavien classification of surgical complications4,5

With numerous previous studies, pre- and peri-operative factors such as stone size and configuration, percutaneous access number and location, entry performed by radiologist or urologist, presence of hydronephrosis have been investigated as predictors of success rates and complications. Attempts to identify the associated variables showed variations among the results which has made it difficult to classify the patients so that the stone free rate (SFR) or complications can be predicted. Aiming for a quick, simple and reproducible method for the prediction of the outcomes of PCNL, the 'Guy's stone score' has been proposed by Thomas et al.They have found that the score correlates with stone free rates but not with complications. The grading system mainly takes into consideration the number of stones, stone location and whether the renal anatomy is simple or abnormal.5

Guy's stone score5

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 or 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

The score is based not just on the stones targeted for treatment in the particular procedure but on all of the stones and abnormal anatomy define asan abnormal renal anatomy, an abnormal collecting system or a patient with an ileal conduit (i.e. cases where the operating surgeon believes access may be difficult). The authors have concluded that the Guy's stone score can accurately predict the SFR status and have stated that the

insignificant correlation withcomplications may have resulted due to the small patient group of their study in which 100 patients were included.5So the aim and objects of our study was to evaluate the outcome of percutaneous nephrolithotomy(PCNL) in Regional Institute Medical Sciences,(RIMS) Imphal.

II. Materials And Methods

This cohort study was conducted in the Department of Urology, Regional Institute of Medical sciences, a tertiary care centre in Imphal, Manipur,during the period November 2015 to October 2017.The patients who attended the Urology Department and admitted for percutaneous nephrolithotomy during the study period were included in the study. Fifty patients who underwent percutaneous nephrolithotomy were studied.
INCLUSION CRITERIA:Patients who underwent percutaneous nephrolithotomy.

EXCLUSION CRITERIA:
1. Patients with high pre-operative serum creatinine and urea.
2. Non-opaque stones, patients with a double J stent, nephrostomy tube in situ.
3. Same session bilateral PCNL operations.

The study variables were age, gender, stone size, stone location, Guy's stone score, other concomitant disease, previous shock wave lithotripsy or renal surgery history, subcostal or intercostal entry, number of access tracts made during the operation, operation time, blood transfusion, complications, ClavienDindo classification, residual stone status, post-operative urine and blood culture results in post-operative fever patients. The detailed history and thorough physical examination was done for clinical diagnosis. Before surgery, patients was evaluated using blood cell count, coagulation tests, serum creatinine, urinalysis, urine culture, kidneys-ureters-bladder radiography, intravenous urography, ultrasonography, and computed tomography scan (in select cases). If patients were taking antiplatelet drugs, these drugs were discontinued for 10 to 14 days before surgery. Patients with UTI were treated by appropriate antibiotic therapy before the PCNL. Also appropriate prophylactic antibiotics were administered for all patients before and after the operation. The kidney stones were diagnosed by intravenous pyelography and/or computerized tomography (CT). Stones were classified according to the Guy's stone score.

PROCEDURES:

With the patient under suitable anesthesia, a 5 Frureteric catheter was inserted in the ipsilateral ureter, which later allowed for injection of contrast material for opacification and distension of the collecting system to aid in making an appropriate puncture. After ureteral catheterization, the patient's position was changed to the prone position on a C-arm compatible table. Once access was gained with a sheathed needle, the stylet was removed and a guidewire was inserted, through which tract dilatation was performed with either an Amplatz dilator. Using a rigid nephroscope, stone fragmentation by ballistic devices was done and the stone was removed byalligator forceps.

Intraoperative parameters like operation time, blood loss during surgery and post-operative parameters like wound infection, urinary leakage, time of convolution and length of hospital stay, analgesic requirement were recorded. X-ray KUB was taken on 3rd post-operative day and decision to subject the patient for relook PCNL, repeat surgery or any ancillary procedures were taken. The patients were followed up again at 1 month with X-ray KUB and any ancillary procedures like Extracorporeal Shock Wave Lithotripsy(ESWL) was provided. Stone clearance were decided from the X-ray KUB at 1 month, the X-ray KUB was read by an uninformed radiologist/urologist. All data were recorded in a proforma specially designed for the study.

STATISTICAL ANALYSIS:

Statistical analysis was done by using IBM SPSS Version 21 for windows. Descriptive statistics such as mean, proportion, percentage were used to present result. Chi square testwas used as a test of significance of the study for comparing the outcome variables.P-value <0.05 was taken as significant.The study was taken up after getting clearance from the Research Ethics Board, Regional Institute of Medical Sciences, Imphal. All the participants were informed about the nature of the study and those agreed to participate was asked to sign the informed consent form.

III. Results

A total of 50 patients with renal stones who were subjected to Percutaneous Nephrolithotomy (PCNL) were studied. Table 1 shows the age distribution of the patients . The youngest was 23 years and oldest was 67 years. The mean age of the patients was 42.14 ±11.28 years

Table 1: Age distribution of the patients (n = 50)

Age(years)	Number of patients	Percent (%)	Mean age(years)
20-40	23	46	42.14 ± 11.28
41-60	24	48	
61-80	3	6	
Total	50	100	

Table 2: Sex distribution of the patients

Sex	No. of patients	Percent(%)
Male	21	42
Female	29	58
Total	50	100

Table 2 shows the sex distribution of the patients. Study included 21 male and 29 female patients.

Table 3. Guy's stone score of the patients

Guy's stone score	No. of patients	Percent(%)
GSS 1	8	16
GSS 2	16	32
GSS 3	22	44
GSS 4	4	8
Total	50	100

Table 3 show Guy's Stone score of the patients in the study. Twenty-two patients have GSS 3, 16 patients have GSS 2, 8 patients have GSS 1 & 4 patients have GSS 4.

Table 4: Laterality of the renal stone

Laterality	No. of patients	Percent (%)
Right	22	44
Left	28	56
Total	50	100

Table 4 shows the laterality of the renal stone where the PCNL was done. In 28 patients, PCNL were done on left side, 22 were done on right side.

Table 5: Operating time of PCNL

Time(min)	No. of patients	Percent(%)	Mean operating time(min)
60-75	21	42	81.10 ± 13.53
76-90	20	40	
91-105	7	14	
106-120	2	4	
Total	50	100	

Table 5 shows the operating time of the patients in the study. The average operating time of the present study was 81.10±13.5 minutes.

Table 6: Hospital stay of the patients

Hospital stay (days)	No. of patients	Percent (%)	Mean(days)
5-10	46	92	7.96 ± 2.178
11-15	3	6	
>15	1	2	
Total	50	100	

Table 6 shows the hospital stay of the patients. Mean hospital stay of the patients in the present study was 7.96 ± 2.178 days.

Table 7: Stone free rate of the patients

Stone clearance	No. of patients	Percent (%)
Stone Free	26	52
CIRF	11	22
CSRF	13	26
Total	50	100

Table 7 shows the stone free rate of the patients the study. Seventy-four percent have stone free, 26% have clinically significant residual fragments.

Table 8: Complications of PCNL

Complications	No. of patients	Percent(%)
Atelectasis	3	6
Fever	8	16
Blood transfusion	7	14
Hydrothorax	2	4
Urine leak	3	6
Wound infection	2	4
Sepsis	2	4

Table 8 shows various complications of PCNL in the present study. Eight patients developed fever in the post-operative period, 7(14%) require blood transfusion.

Intercostal tube drainage was done in 2(4%) patients for hydrothorax. Urine leak and wound infection was seen in 3 and 2 patients respectively. Two patients developed sepsis. In our study, there was no patient with colon perforation ornephrocutaneous fistula.

Table 9: Clavien-Dindo Classification of the patients

Clavein-Dindo	No. of patients	Percent (%)
No complication	31	62
Clavein-Dindo 1	5	10
Clavein-Dindo 2	12	24
Clavein-Dindo 3a	2	4
Clavein-Dindo 3b-5	0	0
Total	50	100

Table 10: Correlation between Guy's Stone score and Clavien-Dindo classification

Guy's Stone score	Clavien-Dindo	P –value
1	1-6%	0.037
2	1-2% 2-6%	
3	1-2% 2-14% 3a-2%	
4	2-4% 3a-2%	

Table 10 shows correlation between Guy's Stone score and ClavienDindo classification of the study. As the grades of Guy's stone score increases, the number and severity of the complication increases. It was statistically significant (P-value = 0.037)

Table 11: Correlation between Guy's Stone score and stone clearance

Guy's Stone score	Stone clearance	P-value
1	87.5%	0.04
2	87.5%	
3	68.18%	
4	25%	

Table 11 shows correlation between Guy's stone score and stone clearance of the patients in the present study. Guy's Stone score 1 and 2 have stone clearance rate of 87.5% each, GSS 3 has 68.18% and GSS 4 has 25% stone clearance.

Table 12: Correlation between Guy's Stone score and operating time

GSS	TIME (MINS)				P-value
	60-75	76-90	91-105	106-120	
1	7(14%)	1(2%)	0	0	0.002
2	10(20%)	6(12%)	0	0	
3	4(8%)	12(24%)	5(10%)	1(2%)	
4	0	1(2%)	2(4%)	1(2%)	

Table 12 shows correlation between Guy's Stone score and operating time. Operating time GSS 1&2 ranges from 60-90 minutes, GSS 3 &4 ranges from 90-120 minutes. P-value is0.002

Table 13. Correlation of guy's stone score and stone clearance

GSS	Stone clearance			P-value
	SF	CIRF	CSRF	
1	7(14%)	0	1(2%)	0.04
2	10(20%)	4(8%)	2(4%)	
3	8(16%)	7(14%)	7(14%)	
S	1(2%)	0	3(6%)	

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Table 13 shows correlation of Guy's stone score and stone clearance. As the GSS increases, the rate of failure of stone clearance increases, which is significant (P-value is 0.04)

IV. Discussion

Urolithiasis affects about 2 million people every year in India. India comes under stones belt region and occupies parts of Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and north-east states. The prevalence of renal stone in India is approximately 7.6%.6

Surgery is the only prime treatment of renal stones. Extra-corporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), Open surgery, Laparoscopic pyelolithotomy is surgical interventions used in various conditions.

Guidelines on the management or renal stones recommends that PCNL is indicated for the treatment of renal stones >20 mm, including the treatment of staghorn calculi. PCNL is also an option for the treatment of renal stones between 10-20mm when located in a lower pole calyx as it has been shown to have higher degree of efficacy compared to SWL, with acceptable morbidity.

In the present study, age ranged from 23 years to 67 years with the mean age of 42.14 ±11.28 years.

In most of the studies males are more common than females.7 But studies from Italy8 and Greece9 showed that this ratio is reversed between 30-50 years age group. We also had the similar results females more common than males. The difference from the global data may be due to life style changes like working habits, fluid consumption and dietary habits.

In other studies, patient distribution according to Guy's stone score was similar for GSS 1, GSS 2 and GSS 3. In our study most of the patients has GSS2 and GSS 3(GSS 2-32%, GSS 3-44%).Laterality of renal stone was varied in the different studies. In the present studies, 28(56%) patients underwent PCNL on left side and 22(44%) on right side.

Sharma L etal10found that the mean operating time was 83 minutes. Our study has also similar operating time of 81.10±13.53 minutes. Other study has hospital stay ranged from 3 to 5 days, but our study has slightly longer hospital stay of 7.96±2.178 days.

EgimerzT etal5found that stone free rate was 80 %(SF-71%, CIRF-9%). Our present study has similar finding with stone free rate of 74%(SF- 52%, CIRF-22). Shin TS etal4 found that rate of complication was 40.2%. Our study showed complication rate 38%. As per ClavienDindo classification, 5(10%) patients have grade 1, 12(24%) have grade 2, 2(4%) have grade 3a. There was no patient with grade 3b to grade 5. In this study, 3 patients developed atelectasis which was managed by chest physiotherapy and nebulisation. Eight patients developed fever in the post-operative period. The causes of the fever were atelectasis, sepsis and urinary tract infection. Three patients developed post-operative urine leakage which was subsided after three days. Seven (14%) require blood transfusion. Those patients who had blood transfusion had GSS 3, 2 patients had multiple puncture and 1 patient had operating time of 110 minutes. Shin TS et al4found that rate of sepsis was 0.6%, in the present study, sepsis was found in 2(4%) patients. Sepsis was due to hydrothorax and urinary tract infection.

Intercostal tube drainage was done in 2(4%) patients for hydrothorax. Among them one patient had GSS 4, with upper calyceal puncture and operating time of 115 minutes. Other had GSS 3 with lower calyceal puncture and operating time of 95 minutes. There was no patient with nephrocutaneousfistulas or colon perforation.In our study, patient with GSS 1 has 3% of Clavien-Dindo grade1, GSS 2(grade1-2%, grade2-6%), GSS 3(grade1-2%, grade2-14%, grade3a-2%), GSS 4(grade2-4%, grade 3a-2%). As the Guy's Stone score increased, the number and severity of the complication also increased. This correlation between Guy's Stone score and Clavien-Dindo classification is statistically significant (P-value=0.037).

Thomas etal11 found that Guy's Stone score grade 1 had stone free rate of 81%, grade 2 of 72.4%, grade3-35%, grade 4-29%. Our study showed that grade 1-87.5%, grade2-87.5%, grade 3- 68.18% and grade 4-25%.This correlation between Guy's Stone score and stone free rate is statistically significant (P-value=0.04)

V. Conclusion

In order to establish PCNL as a feasible and reliable treatment modality and a good alternative to open surgery for renal calculi, there are several preceding conditions. First, the success rate of PCNL should be better or at least comparable to open surgery. Second, the complications of the procedures should be comparable or less.

Our study was conducted to find out the success as well as the complication of PCNL and also correlation between Guy's stone score and modified Clavien-Dindo classification.Our study showed that Guy's stone score grade 1 has stone clearance rate of 87.5%, grade2-87.5%, grade 3- 68.18% and grade 4- 25 (P-value being 0.04). This correlation between Guy's Stone score and stone free rate is statistically significant (P-value=0.04).In our study, patient with GSS 1 has 3% of Clavien-Dindo grade1, GSS 2(grade1-2%, grade2-6%), GSS 3(grade1-2%, grade2-14%, grade3a-2%), GSS 4(grade2-4%, grade 3a-2%).(P-value is 0.037). It may be concluded that as the Guy's stone score increases, the rate of stone clearance decreases, and also the grade of complications increases.

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Khumukcham Somarendra, "A Study On outcome Of Percutaneous Nephrolithotomy" IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 17, no. 11, 2018, pp 31-37.