ORIGINAL RESEARCH PAPER
Volume - 10 | Issue - 07 | July - 2021 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

EVALUATION OF COMPLICATIONS AND SUCCESS RATES OF PCNL,USING MODIFIED CLAVIEN GRADING SYSTEM: A SINGLE-CENTER EXPERIENCE.

Urology

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ABSTRACT

OBJECTIVE: The purpose of this retrospective study is to document the perioperative complications of percutaneous nephrolithotomy (PCNL) using the modified Clavien grading system at a tertiary care centre.

MATERIAL & METHODS: A retrospective study of 133 patients who underwent standard PCNL in the department of Urology and Renal Transplant,during the period January 2019 to March 2020 at Sri Aurobindo Institute of Medical Sciences,Indore, India. A structured questionnaire was used to get relevant information,while peri-operative complications were recorded using the modified Clavien grading system.

RESULTS: The mean age of patients was 38.2years,male: female ratio was 1.18:1. Stones were categorized as simple in 48.9% and complex in 51.1%. The lower calyx was the commonest site of stone location (45.5%) and puncture site (76.7%). The mean operative time was about 58 minutes and the mean haemoglobin drop was 1.5g/dl. The blood transfusion rate was 3% and the stone free rate after the procedure was 93.2%. The mean length of hospital stay was 3.4 days.

CONCLUSION: PCNL is an effective treatment with good clearance rate and acceptable morbidity in experienced hands.

KEYWORDS

Percutaneous nephrolithotomy, Renal Calculus, Clavien Grading, Complications,PCNL

1. INTRODUCTION

Urinary tract stone is a worldwide problem with an increasing incidence, prevalence and frequency of recurrence[1].

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. Greater surgeon experience and improvements in instrumentsas well as lithotripsy technology have increased the efficacy of PCNL, yielding stone-free rates of >90%.

PCNL is a treatment of choice for renal and upper ureteric stones. It is a minimally invasive procedure which involves creation of an appropriate percutaneous renal access, dilation of this tract and subsequent fragmentation/removal of the stone. In 1976, Fernstorm and Johansson[2] first reported the removal of renal calculus through a nephrostomy tract. The American Urological Association and European Association of Urology have suggested that percutaneous stone removal should be the first line treatment option for the management of staghorn calculi[3,4]. The technique of PCNL has developed over several years especially the miniaturisation of instruments and optics with aim of achieving lower morbidity[5]. It has long been proven to be safe and effective due to its minimal invasiveness, wide range of indications, lower morbidity, shorter operative time, lower postoperative complications and shorter hospital stay. The Modified Clavein System has been used by urologists to grade perioperative complications following radical prostatectomy, laparoscopic live donor nephrectomy,pyeloplasty, laparoscopic/open partial nephrectomy and most recently Transurethral Resection of Prostate.This new classification is used to grade complications after PCNL.

We report our perioperative complications of PCNL according to the modified Clavien system from our tertiary care hospital for a period of 1-1-2019 to 20-3-2020.

2. MATERIALS & METHODS

This study was conducted in the department of Urology,Sri Aurobindo Institute of Medical Sciences Indore,India between January 2019 to March 2020 after an approval from the ethical committee of the hospital. All patients undergoing PCNL for renal or upper ureteric calculi were included in the study. A written informed consent was taken from patients before enrolling them for the study. Those with coagulopathy were excluded from the study. All patients had a pre-operative assessment in the form of clinical evaluation, height, weight, complete blood count, creatinine ,coagulation profile, urine analysis and urine culture. Multi slice Contrast Computed Tomography (CT) scan was done in all patients and the longest diameter as seen in the CT imaging was taken as the stone size. Procedure was done under general anaesthesia.

Patient underwent PCNL as per the standard protocol after ensuring sterile urine.[6]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 and air pyelogram.[7]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, 20F rigid nephroscope (Karl Storz). Calculi were identified and fragmented with pneumatic lithoclast. Stone clearance was confirmed intra-operatively by fluoroscopy. If needed, another puncture was made or the method of intra-operative percutaneous caliceal irrigation(IPCI) was used to achieve stone clearance. Double-J stent was placed using the antegrade approach at the end of the procedure.The PCNL procedure was performed by a single urologist in the Unit.

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 KUB was obtained and complete stone clearance was documented.On Postoperative Day -2 Foley's catheter was removed. DJ stent placed, was removed after four to six weeks. If residual fragments were seen on postoperative X-ray or NCCT KUB(for radiolucent calculus), then re-look PCNL using either the same tract or new tract was done after two to four days. Few patients with no affordability issues were advised ESWL for residual stones.All patients were then followed up at one week and at one month after discharge from the hospital. 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.[22]

The modified Clavien grading system [Table 1] was used for evaluating perioperative and postoperative complications of PCNL. The data was collected through a structured proforma and analysed .

Table-1

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

3. RESULTS

A total of one hundred and thirty three (133) patients were included in the study during the period of 1-1-2019 to 20-03-2020. The mean age was 38.2 years with male to female ratio of 1.18:1. The mean BMI of the patients was 24.5kg/m2 TABLE-2 .

TABLE-2

VARIABLE	MEAN(S.D)
Age	38.2 (19.5)
M:F Ratio	1.18:1
B.M.I (kg/m2)	24.5 (5.8)
Stone Size (mm)	26 mm(10.6)
Operative Time (min)	58 min(29.5)
Hospital Stay (days)	3.4 days(1.5)

Stones were categorized as simple in 65 (48.9%) and complex (multiple, staghorn) in 68(51.1%) table-3

Table-3

Stones	Number	Percentage(%)
Simple	65	49.9
Complex	68	51.1

Majority of the stones were at the lower calyx and pelvis as shown in table-4 below.

Table-4

Stone Location	Percentage(%)
Upper Calyx	4.4
Middle Calyx	4.6
Lower Calyx	45.5
Pelvis	40.6
Upper Ureter	5.9

Out of the total 133 patients 102 patients (76.7%) had lower calyceal puncture, 21 (15.8%) and 10 (7.5%) had middle and upper calyceal site puncture respectively.

Complications noted following PCNL in the study group in table-5

Table-5

	COMPLICATION	FREQUENCY (n = 133)	PERCENTAGE(%)	CLAVIEN-DINDO GRADING
1.	Fever	5	3.8	I
2.	Transient raised creatinine	2	1.5	I
3.	Blood Transfusion	4	3	II
4.	Wound infection	2	1.5	II
5.	U.T.I	1	0.8	I
6.	Pleural Injury	2	1.5	IIIA
7.	Urosepsis	1	0.8	IVB
8.	DJ Stent Migration	1	0.8	IIIA

The mean operative time was 58 minutes. The mean haemoglobin concentration drop was 1.5g/dl. Stone free rate was 93.2%. The most frequent complication was fever (3.8%) 4 patients (3%) had haemorrhage that required transfusion. Only two patient (1.5%) had pleural injury following a supracostal approach as shown in table 5. There was no mortality recorded, with only 1 patient(0.8%) having urosepsis leading to ICU hospitalisation. The average length of hospital stay was 3.4 days.

4. DISCUSSION

The modified Clavien system is more objective and reproducible, representing a compelling tool for quality assessment and allows comparison of results between various studies.

The purpose of this study is to present an experience gained at a tertiary centre on PCNL and its outcome managed by a single urologist. This present study showed a mean age of 38.2 years, comparable to other studies Mousair-Balur et al[8] and Shohab et al[9] reported 40.7 and 45.0 years respectively. The literature is replete with reports that male has higher incidence of stone disease. This was seen in this study where male female ratio was 1.18:1. Agrawal et al[10] reported 1.8:1 as the male female ratio in their study Majority of the stones (51.8%) were complex (multiple, staghorn) in nature. This is similar to the finding reported by Sharma et al. In this study, 98.2% of the punctures were done via infracostal approach. The lower calyx (76.7%) was the commonest site of puncture. This is comparable to other studies where lower calyx is the commonest site of puncture[10,11] . This study showed a stone free rate of 93.2% which is similar to various studies with report of stone free rate > 90%[11,12] .

Although PCNL is an effective treatment option for renal stone, it is not without complications. In this study, Fever in the postoperative period was the most common complication 3.8% of procedures. The reported incidence of fever after PCNL has varied from as low as 2.8%[13] to as high as 27.6%[19] (usually between 6.5--13%[17,19]) and can be because of different patient populations and the policy regarding the use of antibiotics. Furthermore, fever due to other complications such as urinary tract infection (UTI), wound infection, urinoma, perinephritic abscess and urosepsis, as well as a side-effect of blood transfusion were not included in this group (they are classified separately into other categories, see Table 5). Factors predisposing to fever after PCNL include preexisting untreated UTI, infected urinary stones[14]renal insufficiency,[15]duration of surgery (< 90 min),[16]amount and pressure of irrigation fluid.[14]

Bleeding, necessitating blood transfusion was the second common individual complication, observed in 3% of procedures.However, an overall blood transfusion rate ranging from 5–18% has been reported in the literature.(19-20)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)[20]

Two patients (1.5%) had pleural injury following a supracostal approach. Mousai-Balur and colleagues[8] reported 0.7% as pleural injury in their study.This is in concordance with the literature that reports 3-7% risk of pleural injury in supra-costal punctures.[23] Access to the pelvicalyceal system is key for a successful PCNL therefore proper tract selection and appropriate equipment in experienced hands are essential for a good outcome.

Surgical complications can be reported in a variety of ways, and the means through which data are obtained and reported probably have as much impact on the "complication rate" as the procedure[24] One might be surprised by the high incidence of complications reported; however, the knowledge of Clavien system will tell us that the vast majority of complications are minor in severity and would not have been reported if a non-standardized reporting system had been used.[24]

5. CONCLUSION

In this study involving a relatively lesser number of cases from a tertiary care centre, the complication rate following PCNL was 13.5%. Grade 1, 2 and 3 complications, which were managed conservatively or by minimally invasive procedures constituted the main bulk of complications (>94%) while Grade 4 complications(<6%) were less common ,with no incidence of Grade 5 complication (mortality). This suggests that, PCNL is a safe and effective procedure with an acceptable complications.

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