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Assessing Functional Outcomes of Performing Per Cutaneous Nephrolithotomy in Chronic Kidney Disease Patients: A Prospective Study

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ABSTRACT
The Kidney Disease Outcomes Quality Initiative (K/DOQI) Advisory Board defines chronic kidney disease (CKD), a prevalent public health concern, as renal impairment that lasts longer than three months and results in a GFR below 60mL/min/1.73 m2. To assess PCNL's functional results for calculi in solitary functioning kidney with CKD/ bilateral renal calculi. And to determine the variables influencing renal replacement treatment in CKD patients after PCNL. The study is prospective in nature. A 4-variable MDRD equation was used to determine each patient's eGFR. One day prior to surgery, pre-PCNL serum creatinine and eGFR measurements were performed. For obstructed and contaminated systems, per cutaneous nephrostomy (PCN) or double--J (DJ) stenting was performed. After stabilization, prone PCNL was done on each patient. The measurements taken at the 6-month follow-up visit were compared to the preoperative CKD stage and eGFR. Based on changes in their CKD (eGFR) status, patients were split into two groups: Group 1 had improved or stable disease, while Group 2 had worsening disease. By contrasting the two groups, the impact of independent variables on kidney function following PCNL was assessed. The average preoperative eGFR (mean±s.d.) for patients in Group 1 was 32.48±7.52. Additionally, the patients' mean post-operative eGFR (mean±s.d.) was 40.66±7.13. Group 2 patients had mean preoperative eGFR (mean±s.d.) of 32.00±10.82 and postoperative eGFR (mean±s.d.) of 25.05±8.88. The mean post-operative eGFR distribution by group was statistically significant ($p<0.0001$). Following surgery, the CKD stage and eGFR status of 12 patients with stage 4 CKD improved. However, eGFR improved in 30, 4 and 1 individuals with CKD stages 3, 4 and 5, respectively, without causing CKD stage migration. Both eGFR and CKD stage worsened in two patients with CKD stages 3 and 4. We came to the conclusion that one practical way to treat kidney stones in individuals with chronic kidney disease (CKD) is to perform per cutaneous nephrolithotomy (PCNL). Additionally, our findings demonstrated that most patients' renal function improved or stabilized following stone removal. This improvement was observed more often in mild to moderate CKD. With the appropriate management of perioperative complications and comorbidities may further improve the outcome in such patients.

INTRODUCTION

Large kidney stones are removed surgically using a less invasive technique called per cutaneous nephrolithotomy (PCNL). usually suggested when less invasive techniques like ureteroscopy or extra corporeal shock wave lithotripsy fail. Chronic kidney disease (CKD) patients may pose particular difficulties for kidney stone management due to their compromised renal function, increased comorbidity burden, and the potential risk of worsening kidney function postoperatively. Assessing the functional outcomes of PCNL in CKD patients is essential, as understanding the procedure's impact on kidney function, quality of life and overall recovery can give insightful information about the advantages and disadvantages of PCNL in this susceptible group. The purpose of this study is to assess PCNL's safety and functional results in patients with CKD, contributing to evidence-based decision-making for surgical interventions in these patients. Current estimates of the prevalence of chronic renal illness in adult Americans range from 10-13%[1]. The age-adjusted incidence rate of end-stage renal disease (ESRD) in India is estimated to be 229 per million and more than 100,000 new patients enroll in renal replacement programs each year[2]. Chronic kidney disease (CKD) is defined by the National Renal Foundation's Kidney Disease Outcomes Quality Initiative (NFK/KDOQI) advisory council as renal impairment lasting more than three months and resulting in a glomerular filtration rate (GFR) of <60 ml/min/1.73 m2[3]. According to the findings of the SEEK (Screening and Early Evaluation of Kidney Diseases) study, 17.2% of people had chronic kidney disease (CKD). 7%, 4.3%, 4.3%, 0.8% and 0.8% of the population, respectively, had CKD in stages 1, 2, 3, 4 and 5[4]. Urolithiasis is one recognized risk factor for chronic kidney disease. Reports state that 3.2% of individuals with end-stage renal disease (ESRD) had urinary stone illness. Nephrolithiasis in individuals with chronic kidney disease (CKD) can be treated using a variety of techniques, such as laparoscopy, Per cutaneous nephrolithotomy (PCNL), extra corporeal shock wave lithotripsy (ESWL) and retrograde intra renal surgery (RIRS). PCNL provides the greatest stone-free rates in a single setting. it has become the gold standard treatment for complex renal stone disease with considerable burden. The process of PCNL has changed as a result of improved optics, fluoroscopic equipment and access sheath miniaturization. While mini-PCNL/Miniperc uses sheath sizes of 14-20 F, standard PCNL uses sheath sizes of 24 -30 F[5]. Numerous medical comorbidities, including diabetes, hypertension, anemia and bleeding problems, are common in individuals suffering from long-term kidney illness. Comorbid disorders can decrease the success rate, raise the danger of surgery and boost the potential for post-operative problems.

MATERIALS AND METHODS

This is prospective study conducted in the department of UROLOGY, RGKMCH and Kolkata from duration January 2022 to February 2024.

Study Design: A prospective study.

Place of Study: R. G. Kar Medical College and Hospital.

Period of Study: January 2022 to February 2024.

Study Population: department of UROLOGY, R. G. Kar Medical College and Hospital and Kolkata.

Sample Size: 50 patients.

Inclusion Criteria:

- Individuals with CKD with bilateral renal calculi or calculi in one kidney (eGFR<60/s.creatinine>2).
- [Eastern Cooperative Oncology Group (ECOG): 0-2] Good Performance Status.

Exclusion Criteria:

- [Eastern Cooperative Oncology Group (ECOG) >2] Poor performance status.
- The patient's refusal to consent to PCNL.
- Uncorrected diathesis of hemorrhage.
- Pregnant women.

In addition to the clinical history and examination, standard blood work up, urine analysis and other tests like KUB for nuclear medicine, ultrasonography and non-contrast computed tomography, were conducted. Guy's stone score[6] was used to calculate the stone complexity score. The eGFR of each patient was calculated using a 4-variable MDRD equation. CKD was categorized using the National Kidney Foundation Kidney Disease Outcome Quality Initiative approach. Pre-PCNL serum creatinine and eGFR values were taken the day before surgery. Utilizing the Eastern Cooperative Oncology Group (ECOG) Scale, performance status was assessed[7]. For obstructed and contaminated systems, per cutaneous nephrostomy (PCN) or double--J (DJ) setting was performed as a renal decompression measure. Patients only had surgery once their eGFR readings stabilized and post-decompression renal function was evaluated on a serial basis. Regarding preoperative renal replacement treatment and comorbidity optimization,

a nephrology consultation was obtained. When necessary and recommended by the nephrologist, renal replacement treatment was administered.

Surgical Technique: Every patient underwent prone PCNL using the bull's eye method or gradual descent. Swiss lithoclast pneumatic lithotripter and a 22 French stiff nephoscope (Richard Wolf, Germany) were utilized.

Following the operation, a DJ stent (6/26) was implanted in each patient. The operational time was recorded. Each patient's tract size, number of punctures, number of sessions and puncture site (infra costal vs. supra) were noted. Following a smooth surgery, the patient was released on POD 3 after the per urethral catheter was withdrawn. When there was no discernible radiopaque shadow in the C-arm's fluoroscopic image, the stone was considered completely cleared. The modified Clavien Dindo postoperative complication categorization was used to record the problems[8]. PCNL was done on the second side of individuals with bilateral calculi one month apart. Every patient had a follow-up X-ray KUB report at 3 weeks (for the removal of the DJ stent) and a urinalysis, serum creatinine, USG KUB and eGFR measurements at 6 months. Measurements taken at the 6-month follow-up visit were compared to the preoperative CKD stage and eGFR. Two groups of patients were created based on changes in their CKD (eGFR) status:

- **Group 1:** Improved or stable disease.
- **Group 2:** Worsened disease.

By contrasting the two groups, the impact of independent variables on kidney function following PCNL was assessed.

Statistical Analysis: For statistical analysis, data were initially entered into a Microsoft Excel spreadsheet and then analysed using SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Two-sample t-tests, which compare the means of independent or unpaired samples, were used to assess differences between groups. Paired t-tests, which account for the correlation between paired observations, offer greater power than unpaired tests. Chi-square tests (χ^2 tests) were employed to evaluate hypotheses where the sampling distribution of the test statistic follows a chi-squared distribution under the null hypothesis. P-values were determined from Student's t-distribution tables. A p-value ≤ 0.05 was considered statistically significant, leading to the rejection of the null hypothesis in favour of the alternative hypothesis.

RESULTS AND DISCUSSIONS

Table 1. Comparison of Different Variables Among Group 1 and group 2

Variable	Group1 (n=33)	Group 2(n=17)	p-value
Age (years)	47.45±6.14	47.64±6.43	0.918
Gender (male)	19	13	0.187
(female)	14	4	
Preoperative eGFR (mean) ml/min/1.73m2	32.48	32	0.853
Postoperative eGFR (mean)	40.66	25.05	<0.0001
History of open surgery	9	5	0.873
Diabetes Mellitus	4	5	0.131
Hypertension	5	7	0.041
Stone complexity score			
1	15	7	
2	11	6	
3	4	3	
4	3	4	0.930
Recurrent UTI	5	10	0.001
Operative duration (min)	74.87	69.64	0.364
Perioperative complication	5	6	0.103

Group 1=Improved or stable disease.
Group 2=worsened disease.

Patients in Group 1 had an average age of 47.4545±6.1496 (mean±s.d.). Patients in Group 2 had an average age of 47.6471±6.4318 (mean±s.d.). There was no statistically significant difference in the mean age distribution by group (p=0.9182). There were 14 (42.4%) female patients and 19 (57.6%) male patients in Group 1. Group 2 consisted of 4 (23.5%) female patients and 13 (76.5%) male patients. There was no statistically significant correlation between gender and group (p=0.1873). Nine patients (27.3%) in Group 1 had previously had open surgery. In Group 2, 5 patients (29.4%) had previously had open surgery. Between the group and the history of open surgery, there was no statistically significant relationship (p=0.8732). In Group 1, 4 patients (12.1%) had diabetes. In Group 2, five people (29.4%) had diabetes. There was no statistically significant correlation between Group and Diabetes Mellitus (p=0.1316). Five people (15.1%) in Group 1 had hypertension. In Group 2, 7 patients (41.1%) had hypertension. The group and hypertension were statistically significantly correlated (p=0.0412). In Group 1, there were 15 patients (45.5%) with a Stone Complexity score of 1, 11 patients (33.3%) with a Stone Complexity score of 2, 4 patients (12.1%) with a Stone Complexity score of 3 and 3 patients (9.1%) with a Stone Complexity score of 4. 7 (41.2%) patients in Group 2 had a Stone Complexity score of 1, 6 (35.3%) had a Stone Complexity score of 2, 3 (17.6%) had a Stone Complexity score of 3 and 1 (5.9%) had a Stone Complexity score of 4. There was no statistically significant correlation between the Stone complexity score and group (p=0.9301). 5 patients (15.1%) in Group 1 experienced recurrent UTIs. 10 patients (58.8%) in Group 2 experienced recurrent UTIs. There was a statistically significant correlation between the group and recurrent UTIs (p=0.00141). Patients in Group 1 had an mean operating time (min) of 74.8788±

18.9650 (mean±s.d.). Patients in Group 2 had an mean operating time (min) of 69.6471±19.4677 (mean±s.d.). There was no statistically significant difference in the mean operational duration (min) between groups (p=0.3643). The mean preoperative eGFR (mean±s.d.) for patients in Group 1 was 32.4848±7.5255. Additionally, the patients' mean post-operative eGFR (mean±s.d.) was 40.6667±7.1312. Group 2 patients had mean preoperative eGFR (mean±s.d.) of 32.0000± 10.8224 and postoperative eGFR (mean±s.d.) of 25.0588±8.8845. The mean post-operative eGFR distribution by group was statistically significant (p<0.0001). 12 patients of CKD stage 4 showed improvement in their CKD stage and eGFR status postoperatively. While 30, 4 and eGFR improved in 1 patient with CKD stages 3, 4 and 5, respectively, but did not result in CKD stage migration. 2 patients each of CKD stage 3 and 4 showed worsening of eGFR and CKD stage. This worsening might be due to their pre-existing comorbidities and somewhat perioperative complications, UTI.

Of the 50 individuals in our study, the majority were 41-50 years old [26 (52.0%)]. Adiga[10] revealed that the patients' average age was 52 years. We found that, mean Age was more in Group 2 [47.6471±6.4318] compared to Group 1 [47.4545±6.1496] nonetheless (p=0.9182), this was not statistically significant. Additionally, there were more men [32 (64.0%)] than women [18 (36.0%)]. Despite being 1.7:1, the male to female ratio was not statistically significant (p=0.1873). So, we did not find any significant correlation between age, gender with postoperative outcome. Also in others studies Watts[9] showed that According to multi variate analysis, renal function after surgery was not significantly predicted by comorbidities, African American ethnicity, age, gender, or pre-operative chronic kidney disease. And Kumar[11] showed that Of the 60 individuals who were examined, 80% were men and 20% were women. According to our research, Group 1 had a significantly greater percentage of patients with a history of open surgery [9 (27.3%)] than Group 2 [5 (29.4%)]. nonetheless (p=0.8732), this was not statistically significant. So this can be related to incidental findings and non-renal surgeries, as we did not have the patient of prior renal surgeries. He[12] showed that Guy's score was thought to be associated with grade 1 complications, while a history of diabetes mellitus was thought to be associated with grade 2 complications. In addition Kumar[11] showed that Of the 60 patients, 11.6% had coronary heart disease, 55% had hypertension and 36.7% had diabetes mellitus. In a similar way, we found that Group 2 had a greater percentage of individuals with diabetes mellitus [5 (29.4%)] than Group 1 [4 (12.1%)]. However, the results showed that this was not statistically significant (p=0.1316). Salasi[13] observed that a lower prevalence of stone-free condition and a higher frequency of minor and major complications of tubeless PCNL were linked to comorbidities such diabetes mellitus, hypertension, ischemic heart disease and chronic kidney disease. In a similar vein, our study revealed that Group 2 had a somewhat larger percentage of patients with hypertension [7 (41.1%)] than Group 1 [5 (15.1%)]. but p=0.0412 indicated that this was statistically significant. According to our research, Group 2 had a somewhat larger percentage of patients with perioperative complications [6 (35.2%)] than Group 1 [5 (15.1%)]. However (p=0.1033), this was not statistically significant. Patel[14] noted that proper management of comorbidities, perioperative UTIs, and complications might stop or slow the development of CKD status in these patients, however, we demonstrated that a greater proportion of patients in Group 2 had recurrent UTIs [10 (58.8%)] than in Group 1 [5 (15.1%)]. However, p=0.00141 indicated that this was statistically significant. So, recurrent UTI can be significant predictor of worsening of postoperative renal function. Darabi[15] showed that One of the most common medical emergencies is urinary tract stones, which can sometimes result in renal failure and other potentially fatal consequences like obstructive uropathy. We observed that, mean Stone complexity score was more in Group 2 [1.8824±.9275] compared to Group 1 [1.8485±.9722] but this was not statistically significant (p=0.9062). We found that, mean Operative duration (min) was more in Group 1 [74.8788± 18.9650] compared to Group 2 [69.6471±19.4677] but this was not statistically significant (p=0.3643). In our study, In Group 1, the mean Preoperative - eGFR of patients was 32.4848±7.5255. And the mean Post-op-eGFR of patients was 40.6667±7.1312. In Group 2, the mean Preoperative-eGFR of patients was 32.0000± 10.8224. and the mean Post-op-eGFR of patients was 25.0588±8.8845. And this improvement was statistically significant (p<0.0001). Also we found 12 patients of CKD stage 4 showed improvement in their CKD stage and eGFR status postoperatively. Although eGFR improved in 30, 4 and 1 patients with CKD stages 3, 4 and 5, respectively, they did not produce CKD stage migration. 2 patients each of CKD stage 3 and 4 showed worsening of eGFR and CKD stage. This worsening might be due to their pre-existing comorbidities and somewhat perioperative complications, UTI. Similar findings were also noted in Patel[14], Overall renal function improved in 45 (75%) of the patients, although postoperatively, it declined in 15

(25%) of the patients. Following management, eGFR improved in 14 (82.3%), 26 (64.28%) and 5 (62.5%) of the patients in stages 3, 4 and 5. And they found it statistical significant.

CONCLUSION

We came to the conclusion that one practical way to treat kidney stones among people suffering from chronic kidney disease (CKD) is to perform per cutaneous nephrolithotomy (PCNL). Additionally, our findings demonstrated that renal function had stabilized or improved. in most patients after stone removal. This improvement was observed more often in mild to moderate CKD. With the appropriate management of perioperative complications and comorbidities may further improve the outcome in such patients. PCNL can effectively reduce stone burden and improve kidney function, although careful patient selection and preoperative assessment are crucial to minimize potential complications.

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