

Original article:

## Percutaneous nephrolithotomy versus open surgery for renal stones- A prospective randomized study

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### ABSTRACT

**Background:** Nephrolithiasis is a common disease, with an increasing incidence and prevalence and has a significant economic impact associated with its treatment. PCNL is regarded as the most favoured modality for renal stones worldwide. But it is not without significant post-operative morbidity at times. There were very few randomised controlled studies available collating PCNL and open surgery for renal stones. Therefore, this study was planned to compare the outcomes of PCNL and open surgery for renal calculi.

**Material and Methods:** 116 patients of renal stones were studied, 60 in PCNL group and 56 in open surgery group. Standard PCNL was done and stones were fragmented with pneumatic lithotripter. Open surgery (Pyelolithotomy/Nephrolithotomy) was done as per standard technique. Demographic analysis, parameters like operation time, blood loss during surgery, urinary leakage, time of convalescence, length of hospital stay, stone clearance and complications were recorded. Stone-free status was evaluated at 3 months by Non contrast CT (NCCT) KUB.

**Results:** PCNL is superior to open surgery in terms of duration of operative time, hospital stay, convalescence and complications like wound infection. PCNL has a comparable outcome for stone clearance rate, need for ancillary procedures & other overall complications.

**Conclusion:** This study suggests that PCNL should be routinely performed as safe and effective alternative to open surgery for treatment of renal stones.

**Keywords:** Nephrolithotomy, Percutaneous nephrolithotomy, Pyelolithotomy, Renal calculus, Renal stones.

### Introduction

Nephrolithiasis is a common disease, with an increasing incidence and prevalence and associated with significant economic burden [1,2]. The life time prevalence of renal stone is 1%-15% but its probability varies according to age, gender, race and geographic location [3]. Stone diseases are more common in adult men [4]. The distribution of urolithiasis varies across the globe. In Asia, the stone belt has

been reported across Sudan, Saudi Arabia, UAE, Pakistan, India, Myanmar, Thailand, Indonesia and Philippines [5].

In India, the highest prevalence is from Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and states of north-east. The incidence of urolithiasis in Manipur is high, 11.6% of all cases in general surgery OPD were urolithiasis [6].

The advancement of minimally invasive management of stone disease over the past 2 decades has greatly facilitated the stones removal [7]. Now, percutaneous nephrolithotomy (PCNL) is the standard treatment modality for stones >20 mm, staghorn stones, calyceal diverticular stones, or stones in the lower pole. Although the stone-free rate following PCNL is between 78% and 95%, significant complications may be associated with this procedure, including sepsis, blood transfusion, and fever, colonic injury, and pleural injury [8]. The objective of the study is to compare the outcomes of percutaneous nephrolithotomy (PCNL) and open surgery for renal calculi attending urology department at the tertiary care hospital.

### **Material and Methods**

This was a prospective randomized study conducted in the Department of Urology, Regional Institute of Medical Sciences, Imphal, Manipur, India from February 2016 to January 2018 after obtaining approval from the Research Ethics board of the Institute [A/206/REB-Comm(SP)/RIMS/2015].

### **Inclusion criteria**

1. All patients of renal stones who underwent PCNL or Open Surgery.

### **Exclusion criteria**

1. Patients who refused to participate in the study.
2. Patients who underwent operation for renal stones and additional procedures in the same sitting, eg: pyeloplasty, Lower partial nephrectomy.
3. Patients with uncorrected coagulopathies, end stage renal diseases.

Total 122 patients were enrolled in the study out of which 6 patients left the study in between. So, 116 patients were studied, 60 in PCNL group and 56 in Open surgery group (Fig-1). After taking written and informed consent, patients were randomised into 2

groups based on computer generated random number table. All patients were assessed by physical examination, serum creatinine levels, urine culture and non-contrast CT (NCCT) KUB. All patients received prophylactic antibiotics before the surgery which were continued for 1 week post operatively.

### **PCNL Procedure**

Standard PCNL was performed under general anaesthesia. In lithotomy position, a ureteral catheter was placed with the aid of a cystoscope. In prone position, retrograde pyelography with puncture of calyceal system under fluoroscopic guidance. A 0.035-inch floppy tip radiopaque glide wire was inserted through the initial puncture needle. The needle was removed and the tract was dilated over the glide wire. The tract was first dilated with fascial dilators then guide rod was placed and step dilation was carried out with amplatz dilators. An amplatz sheath of 24 Fr was introduced over the dilator and stones were fragmented with pneumatic lithotripter in all patients. Access to the kidney was achieved through 1 puncture in 55 patients, 2 punctures in 5 patients. 6 Fr ureteral stent and 20 Fr nephrostomy tube was kept. The nephrostomy tube was removed on 1<sup>st</sup> post-operative day (POD) and foley catheter on 2<sup>nd</sup> POD. Ureteral stent was kept for 2 weeks. Operative time was defined as the time from entrance of the needle till the fixation of nephrostomy tube.

### **Open Procedure**

Open surgery was performed under general anaesthesia through a standard flank incision. After mobilization of the kidney, stones were retrieved through pyelolithotomy, extended pyelolithotomy or pyelo-nephrolithotomy. Abdominal drain was kept and pyelotomy was closed with catgut 3-0. Abdomen was closed in layers. Ureteral stent was kept for 2 weeks in all patients. Operation time was defined as time from skin incision to the end of the procedure.

### Post-Operative evaluation

Stone-free rate was defined as complete removal or stone fragments < 4 mm in diameter. Low-dose NCCT KUB was performed on 1<sup>st</sup> POD. Post-PCNL residual stones were managed by second-look PCNL, extra corporeal shock wave lithotripsy (ESWL) or Ureterorenoscopic lithotripsy (URSL) according to the residual stone size and location. ESWL was also used for residual stones after open surgery. Stone-free status was evaluated at 3 months by NCCT KUB.

Intraoperative parameters like operation time, blood loss during surgery and post-operative parameters like time of convalescence and length of hospital stay, complications like wound infection, urinary leakage, visceral injury were recorded.

### Statistical Analysis

Statistical analysis was done by using IBM SPSS Version 21 for windows. Chi square test and independent t test was used for analysing categorical variables and continuous variables respectively. A p-value <0.05 was considered as statistically significant.

### Results

Of 122 patients, 116 met the inclusion criteria, which were randomly assigned into 2 groups. There was a dropout of 2 patients in PCNL group and 4 patients in open surgery group, whereas remaining patients completed the study.

There was no statistically significant difference between the groups for patient's age, gender. The stone size ranged from 12-90 mm. The mean stone size was 24.4±10.4 mm and 32.9±15.2 mm in PCNL and open surgery group respectively. The difference of stone size between two groups was statistically significant (p = 0.004). Multiple stones were present in 16 patients and 27 patients in PCNL and open surgery group respectively. 21 patients in PCNL and 25 patients in open surgery group had staghorn calculus (Table-1).

Mean PCNL operation time was 91.45 min and operation time in open surgery group was 102.25 min. The difference between two groups is statistically significant (p = 0.001) (Table-2).

Patients treated with PCNL had a significantly shorter duration of hospitalisation (5.97±1.48 days) than patients treated with open surgery (9.04±1.78 days) (p value- 0.000) (Table-2).

Mean convalescence period was 10.4±2.31 days and 20.07±5.39 days in PCNL and open surgery group respectively. The difference was statistically significant (p value- 0.000) (Table-2).

Table 2 showed that stone free status at 3 month post-operative period. In PCNL group, stone free rate was seen in 43 (71.67 %) patients while in open surgery group, it was in 46 (82.14%) patients. The difference was not statistically significant (p = 0.332) (Table-2).

Wound infection was present in 2 patients in PCNL group and in open surgery group (10/56) and the difference was statistically significant (p = 0.003). Other complications like urine leak was found in 2 patients in PCNL group and in 4 patients in open surgery group (p = 0.710). Intra operative bleeding was found in 2 patients in either group (p = 0.972). Sepsis was found in 1 patient in either group (p = 0.149). Colon perforation, pneumothorax, hemothorax, Lung consolidation and calyceal rupture was seen in only 1 patient in PCNL group but was absent in open surgery group (p = 0.328) (Table-3).

### Discussion

PCNL is currently the preferred first line treatment for renal stones >20 mm, including staghorn calculi and stones of size 10-20 mm when located in a lower pole calyx [9]. However, open surgical procedures are only recommended for complete staghorn stones associated with infundibular stenosis or distortion of intrarenal anatomy [10]. The complications associated with PCNL are less than that of open surgery, with better stone

clearance rates. With increasing stone burden and complexity, an inherent fear exists of greater bleeding and complication rates [11].

The mean age of the patients in the open surgery group were  $40.54 \pm 10.7$  years and  $41.4 \pm 10.6$  years in PCNL group ( $p = 0.82$ ). Other study also showed the similar results [12].

As in most of the studies males are more common than females in both the group [12]. But studies from Italy and Greece showed that this ratio is reversed [13, 14]. We also had the similar results with females more common than males in both group but the difference was not statistically significant ( $p = 0.86$ ). The difference from the global data may be due to life style changes like working habits, fluid consumption, and dietary habits.

According to size of the stones, open surgery (78.57%) and PCNL (82.75%) was done for stone size  $> 20$  mm. The mean stone size was  $32.9 \pm 15.2$  mm and  $24.4 \pm 10.4$  mm in open surgery group and PCNL group respectively. The difference was statistically significant ( $p = 0.004$ ). Our results were similar to other study published [12].

In our study, PCNL group has mean operative time of  $91.45 \pm 19.9$  min. and open group has  $102.25 \pm 14.32$  min. The difference was statistically significant ( $p = 0.001$ ). Literature showed that mean operative time was  $170 \pm 32.9$  minutes for open group and for group including PCNL + ESWL was  $210.0 \pm 59.3$  minutes ( $p = <0.01$ ) [12]. Another study by Snyder showed operative time was shorter in PCNL, 155.1 minutes versus 266.5 minutes in anatomic nephrolithotomy [15]. This result may be because the number of staghorn or multiple stones were less in PCNL group.

In this study, the mean hospital stay and mean convalescence period is shorter in PCNL group as compared to open group. The difference is statistically significant ( $p = 0.000$ ). The result is similar to previous studies [15].

At three month post-operative period, 43 patients (71.67%) in PCNL group and 46 patients (82.14%) in open surgery group had no residual stones, but the difference is not statistically significant ( $p = 0.332$ ). Study done in Egypt showed the stone-free rate on follow up was 74% after PCNL and 82% after open surgery and the difference was not statistically significant [16].

In PCNL group, 12/60 patients had complications. 2 patients had urine leak after removing nephrostomy tube which was treated conservatively and subsided gradually over time. Two patients had intraoperative bleeding requiring blood transfusion. 1 patient had colon injury in which nephrostomy was kept as colostomy tube and 1 patient each had pneumothorax and hemothorax which was treated with intercostal drainage. 1 patient had sepsis and another patient had calyceal rupture that was treated conservatively. In open surgery group, 17/56 patients had complications. 4 patients had urine leak from incision site which was treated conservatively and subsided gradually over time. Ten patients had wound infection which was treated with appropriate antibiotics and secondary suturing was done later on. Two patients had intraoperative bleeding who required blood transfusion. 1 patient had sepsis that was treated with appropriate antibiotics and other supportive measures. The difference between complications of PCNL and open surgery was not statistically significant except wound infection ( $p = 0.001$ ) which was present only in open surgery group.

Charig CR compared the complications of PCNL and open surgery. In open surgery, 30.61% patients required more than 3 units of blood transfusion whereas in PCNL group, 0.5% required more than 3 units of blood transfusion. Sepsis was seen in 3.58% patients after open surgery and in 9.71% patients after PCNL. Urinary leakage was more after open surgery (6.84%) as compared to PCNL (1.42%). Wound infection was seen only after open surgery (8.46%) [17]. Complications in

our study were also comparable with the world literature. .

### Conclusion:

This study suggests that PCNL is a safe and effective modality in patients of renal stones. It is superior to open surgery in terms of duration of operative time though it is possible that cases of multiple stones in the open surgery group may have influenced the result. The hospital stay, convalescence and complications like wound infection is significantly less in PCNL group. PCNL has a comparable outcome for stone clearance rate, need for ancillary procedures & other overall complications. PCNL is less invasive than open surgery and complications were comparable as with other studies. Hence, this study suggests that PCNL can replace the open surgery in almost all the cases of renal stones.

### Recommendations:

There are very few studies available from North-Eastern part of India. So, further large scale study is required with large sample size as they have different geography, genetics.

### Limitations:

Our study has limitation, including relatively small sample size from single centre that may have jeopardized our statistical analysis. These limitations can be overcome in the future by conducting multicentre, randomized large sample size studies.

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Date of Publication: 30 December 2020

Author Declaration: Source of support: Nil , Conflict of interest: Nil

Plagiarism Checked: Urkund Software

Ethics Committee Approval obtained for this study? Yes

Was informed consent obtained from the subjects involved in the study? Yes

For any images presented appropriate consent has been obtained from the subjects: NA

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DOI: DOI: 10.36848/PMR/2020/12100.50410