

# COMPARATIVE STUDY ON SAFETY AND EFFICACY OF PCNL WITH OPEN SURGERY IN THE TREATMENT OF PATIENTS HAVING LARGE KIDNEY STONES

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## **Abstract:**

**Objective :** To compare the safety and efficacy of percutaneous nephrolithotomy (PCNL) and open surgery in the treatment of patients having large kidney stone (>2 cm ).

**Materials & Methods:** This comparative study included 80 patients diagnosed with kidney stone disease admitted in the NIKDU during the period of Jan' to Dec'2009 were divided conveniently into two groups. Intervention was done in the form PCNL(40) and open surgery (40). Clinical outcome like, perioperative complications, duration of surgery, mean hospital stay, convalescence period, amount of analgesia required to relief pain, stone clearance rate were reviewed and compared between the groups. There was no significant difference in preoperative variables such as age, sex, stone size in cm, stone number- single/multiple and stag horn Stone.

**Results:** There were statistically significant difference in the parameters between the groups, ( PCNL vs opensurgery[mean  $\pm$  SD]): duration of operation (min),  $97.90 \pm 24.89$  vs  $136.62 \pm 23.54$ , postoperative hospital stay (days),  $4.77 \pm 3.98$  vs  $9.55 \pm 3.65$ , mean time return to work (days),  $3.09 \pm 1.21$  vs  $6.25 \pm 1.53$ , ( p value is  $<0.001$ ). Intraoperative complications like bleeding requiring blood transfusion are significantly lower in PCNL (11 cases 34.1%) than in open surgery( 18 cases 45.0%), (Chi-square = 4.82;  $p=0.049$ ). The amount of analgesia required to relief pain was significantly reduced in PCNL vs open procedure (no patient required > 2 doses vs 27 patient required 3 or >3 doses ), p value is  $<0.001$ . The rate of stone clearance in percutaneous procedure, (25 cases, 80%) is approaching to that of open procedure, (34 cases 85%), ( $p>0.05$ ).

**Conclusion:** PCNL is relatively safe & better treatment option than open surgery in the treatment of large renal calculi, It has almost similar stone free rate at discharge home but has definite advantages of lower morbidity, shorter convalescence and more rapid return to work.

**Keywords:** PCNL (Percutaneous nephrolithotomy), RCT (Randomised controlled clinical trial).

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## Introduction

Kidney stone disease is existing among mankind since the earliest record of civilization. Hippocrates described the renal stone as first disease of the kidney<sup>1</sup>. High incidence of renal stone disease is found in U.S.A, U.K, Scandinavian countries, Mediterranean countries, portion of the Malayan peninsula and China. Low incidence is found in central and south America, most of Africa and part of Australia<sup>2</sup>. (stoller et al. 2000).

Now four minimally invasive treatment modalities are available for the treatment of kidney stones such as ESWL (Extra corporeal shock wave lithotripsy). Percutaneous nephrolithotomy (PCNL), retrograde ureteroscopic intra renal surgery and laparoscopic stone surgery<sup>3</sup>. (Lingeman et al. 2002). Now a days all uncomplicated and most of the complicated renal stones are treated by percutaneous method as a routine procedure in the western set up, although the technique is still evolving in the developing country like ours<sup>4</sup>.

Open stone surgery is an old and established procedure. In Bangladesh larger kidney stones are mostly treated by open surgery because of poor socioeconomic context<sup>5</sup>.

PCNL was not available in Bangladesh till January 2000. In National Institute of Kidney Diseases & Urology, this technique has been regularly undertaken since 2004. The present study is the first prospective randomized work conducted in NIKDU, Dhaka to compare the outcome like efficacy, morbidity and convalescence among PCNL & open surgery. An increasing awareness of this technique by both patients & referring physicians has raised important questions regarding the safety and efficacy of the percutaneous methods Vs standard renal surgery.

If any superiority of treatment by PCNL can be provided or shown that this is relatively safe than the method can further be popularized among the Urologist of our country and this study may be the basis of further research in this field.

## Materials & Methods

This comparative study, initially includes all the patient with kidney stone disease that were admitted In urology

department of NIKDU during the period of Jan'2009 to Dec'2009. Total 80 Patients were divided conveniently into two groups PCNL(40) and open surgery (40). Randomization was done by taking consecutive samples. Intervention was done in the form of PCNL and open surgery.

The cases were selected with the Inclusion criteria having stone size more than 2 cm, functioning kidney with sterile urine and the exclusion criteria is renal failure, pregnancy, uncontrolled bleeding disorder, congenital / acquired skeletal abnormalities and Infected urine

All patients were evaluated by history, clinical examination and Investigations having similar protocol. Before operation, each patient of two groups were evaluated and compared for age and sex of the patients, size, number, location of the stones and pelvicalyceal dilatation.

Open surgery was performed through standered flank incision with or without rib resection. A standered PCNL was performed with subcostal single puncture in 29 units and double puncture in 2 units. Initially pneumatic, later on ultrasonic lithotripsy was used. 18 Fr nephrostomy tube was left in each puncture and D-J stent (6Fr) was kept in ureter. Radiological evaluation was done postoperatively. Patient who were completely cleared of stones were considered stone free.

Patients were followed monthly for 3 months where, 9 patients were missed in percutaneous nephrolithotomy (PCNL) group resulting in 31 patients. Again history, clinical examination and Investigations like urine routine and culture, plain X-ray KUB were done and post PCNL data were recorded. All patients were asked about the time required to return to normal activities.

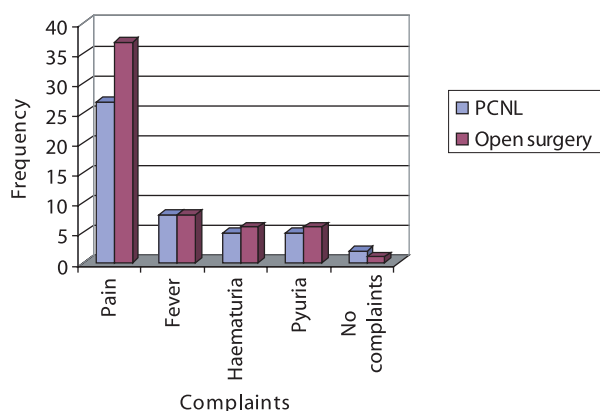
Statistical analysis was done meticulously by SPSS for windows-14 version program. Data was presented as mean  $\pm$  SD. probable value of less than 0.05 was considered significant. Test of significance was done by student t-test, z-test and chi-square test.

**Results**

Preoperative characteristics (mean ± SD) were as follows: (PCNL vs open surgery): age, 44.48 ± 10.31 vs 45.22 ± 15.53 yrs; sex, (male/female), 20/11vs 24/16; stone size in cm, 3.07±0.93vs3.44±1.09; stone number-single/multiple, 26(83.9%)/5(16.1%) vs 26(65.0%)/14(35.0%); stag horn Stone, 5(16.1%)vs 4(10.0%) . There were no significant difference between the two groups (p>0.05).

**Table-I**  
*Preoperative characteristics.*

Characteristics	Name of Operation	
	PCNL	Open surgery
No. of patients	31	40
Age in year (Mean ± SD)	44.48±10.31	45.22±15.53
Sex (male/female)	20/11	24/16
Stone size in cm (Mean ± SD)	3.07±0.93	3.44±1.09
Stone number- Single/ Multiple	26(83.9%)/ 5 (16.1%)	26(65.0%)/ 14(35.0%)
Stag horn Stone	5(16.1%)	4(10.0%)



**Fig. 1:** Chief complaints of the patients

**Table II**  
*Intra-operative complications.*

Type of complications	PCNL N= 31	Open surgery N=40
Bleeding	11	18
Colon Injury	1	0
Pleural Injury	0	3
RenalPelvis Injury	0	2
Total:	12(37.3%)	23(57.5%)

Chi-square = 4.82; p = 0.049

Intraoperative complications like bleeding requiring blood transfusion are significantly lower in PCNL (11cases 34.1%) than in open surgery(18 cases 45.0%), (Chi-square = 4.82; p = 0.049).

In open surgery, there was 3(7.5%) pleural injury and 2(5.0%) renal pelvis injury, where as 1(3.2%) colon injury was observed in PCNL group. Intraoperative complications are significantly lower in PCNL group than in open surgery group. In case of empty cells in a table Fisher’s exact test was done other wise chi-square test was done.

**Table-III**  
*Postoperative complications*

Type of complications	PCNL N= 31	Open surgery N=40
Wound infection	0	2
Wound dehiscence	0	1
Urinary leakage	1	2
Massive Hematuria	1	2
Septicemia	1	1
Total:	3 (9.6%)	8 (20%)

Chi-square = 0.563; p = >0.05

In PCNL group, septicemia developed in 1 case (3.2%), urinary fistula in 2 cases (6.4%), and , massive haematuria in 1 case (3.2%), but no patient developed wound infection or wound dehiscence. On the other hand in open surgery group, wound infection was recorded in 2(5.0%) cases, wound dehiscence in 1(2.5%), urinary fistula in 2 (5.0%) cases, massive haematuria in 2 case (5.0%) and septicemia in 1 (2.5%) cases. The overall post operative complications were compareable both in PCNL and open surgery group. In case of empty cells in a table Fisher’s exact test was done other wise chi-square test was done.

There were statistically significant difference in the parameters between the groups,( PCNL vs open surgery [mean ± SD]): duration of operation (min), 97.90 ± 24.89 vs 136.62 ± 23.54, postoperative hospital stay (days) , 4.77 ± 3.98 vs 9.55 ± 3.65, mean time return to work (days) , 3.09 ± 1.21vs 6.25 ± 1.53, ( p value is <0.001).

**Table-IV***Total operation time, post operative hospital stay and convalescence period*

Parameters	PCNL N= 31	Open surgery N=40	p value
Duration ofoperation(Min)(Mean ± SD)	97.90±24.89	136.62±23.54	<0.001
Hospitalstay(days)(Mean ± SD)	4.77±3.98	9.55±3.65	<0.001
ConvalescencePeriod(days) (Mean ± SD)	3.09±1.21	6.25±1.53	<0.001

**Table-V***Narcotic Analgesic Required*

Doses of analgesics	PCNL N= 31	Open surgery N=40
Single	25(80.6%)	8(20.0%)
Multiple	6(19.4%)	32(80.0%)

Chi-square = 25.82; p = &lt;0.00

The amount of analgesia required to relief pain was significantly reduced in PCNL vs open procedure ( no patient required > 2 doses vs 27 patient required 3 or >3 doses ), p value is <0.001.

**Table-VI***Stone clearance and Residual Stone*

Parameters	PCNL N= 31	Open surgery N= 40
Stone clearance	25(80.6%)	34(85.0%)
Residual Stone	6(19.4%)	6(15.0%)

Chi-square = 0.236; p = 0.627

The rate of stone clearance in percutaneous procedure,(25 cases,80%) is approaching to that of open procedure,(34 cases 85%), (p>0.05).

**Discussion:**

The present study has been designed to compare the outcome of PCNL and open surgery for the management of renal stone disease more than 2 cm in size. After counseling, taking consent and considering the inclusion and exclusion criteria finally 80 Patients were selected and divided into two groups, PCNL(40) and open surgery (40). In complete follow up 9 patients were missed in PCNL group resulting in 31 patients.

The mean age of the patients was 44.48 years (SD-10.31) in PCNL group and 45.22 years (SD-15.53) in open surgery. The age of the patient was statistically insignificant(>0.05). The age range of the present study is more or less comparable with the study done by Assimos et al. [6]. in 1991,( age:23 to 79 years) & by Brannen et al<sup>7</sup>. in 1985,(age:21 to 94 years). The highest age is higher in those countries is due to long life expectancy of that country and elderly people attending in the clinic .

The mean size of the stone in PCNL group was 3.07 cm ( SD-0.94 ) and in open surgery was 3.44 cm (SD-1.09). The size of the stone in both groups were analysed and found no significant difference (p>.05). In a study by Wong YC,<sup>8</sup>. in 1998,stone size was recorded between 2 to 7.5 cm which is almost similar to the size of stone of present study.

In PCNLvsopen surgery group ,11 (34.1%) casesvs 18 cases (45.0%) required blood transfusion. Regarding other injuries, there was 3 (7.5%) pleural injury and 2 (5.0%) renal pelvis injury resulted in open surgery group. Neither of this injuries occurred in PCNL group. 1 (3.2%) colon injury was happened in PCNL group, , which was not observed in open surgery group. However, intraoperative complications are significantly lower in PCNL group than in open surgery group.

In study of Al-kohlany et al.<sup>9</sup> in 2005, reported blood transfusion were required in 33% cases in open surgery and 14% cases in PCNL group. In this study intraoperative complications like bleeding, injuries to pleura, vessels or ureter were 7(16.3%) cases in PCNL vs 17 (37.8%) cases in open surgerywhich closely correlates with the other study.Rassweillier et al.<sup>10</sup> in 2000 showed, 37% vs 10% blood transfusion was required in open surgery and PCNL respectively.

However, in a recent study on PCNL Stephene R et al<sup>11</sup>. in 2013, reveals that much less no. of patients (3.8%) required blood transfusion, this may be due to



the fact that our study was very early experience of PCNL in this institute and the technique was performed on the large stone, (>2cm) .

Out of 31 renal units in PCNL, only 1 (3.2%) patients developed urinary fistula, which was managed by retrograde D-J stenting, 1 patient (3.2%) developed septicemia, that was treated by appropriate antibiotic and 1 patient (3.2%) developed massive haematuria which was managed conservatively by blood transfusion. Out of 40 renal units in open surgery, wound infection was recorded in 2(5.0%) cases, wound dehiscence in 1(2.5%) cases, urinary fistula in 2 (5.0%) cases, massive haematuria in 2 case (5.0%) and septicemia in 1 (2.5%) cases. Wound infection was significantly lower in PCNL than in open surgery group.

Very few post operative complications were encountered after PCNL in this series. Overall number of complications occurred in 3 cases (9.6%) in PCNL and 8 cases(20%) in open surgery group. A study on complication of PCNL by Lee et al. in 1987 in a series of 542 patients reported 4% overall complication.

In a study by Brannen et al<sup>7</sup>. in 1985 , no fistula recorded after PCNL but 9 cases (7.96%) urinary fistula was observed in open surgery. Slightly higher rate of infection in open surgery group was observed in our series than the above studies, may be due to better aseptic hospital environment of those centers than ours.

In present study, the mean operation time was noted 97.90 min (SD=24.89) in PCNL and 136.62 min (SD=23.55) in open surgery, which was very significantly lower in PCNL (  $t = -6.704$ ;  $p$  value is  $<0.001$ ). Al-kohlany et al<sup>9</sup>. showed that the mean operation time was 127vs 204 min in PCNL vs open surgery. Snyder<sup>12</sup>. also showed lower time ( 155 vs 266 min ) required in PCNL than open procedure. The overall time mentioned were longer as because the above studies were conducted on the staghorn calculi absolutely.

Mean hospital stay was 4.77 days for PCNL and 9.55 days for open surgery. In a comparative study between PCNL and open surgery Preminger [13] reported mean hospital stay for PCNL is 4 days and for open surgery is 10 days. Brannen et al.<sup>7</sup> in 1985, reported similar result of 5.5±0.3 days hospital stay after PCNL and 8.4±0.5 days after open surgery. The present study is almost similar to the above studies. Time return to work, in PCNL was significantly faster (mean 3.09 weeks) than in open surgery ( mean 6.25 weeks) (  $p$  value is  $<0.001$ ). Brannen and associates in 1985<sup>8</sup> (within 2 weeks vs

more than 3 weeks) & Al-kohlany et al<sup>9</sup>. reported the earlier (2.5 weeks vs 4.1 weeks) return to work in PCNL group than open surgery group.

In this study in PCNL group, 25 cases required 1 dose and 6 cases required 2 dose of narcotic analgesics. In open surgery group, 8 cases required 1 dose and 9 cases required 2 dose, 20 cases required 3 dose and 3 cases required >3 dose of narcotic analgesics. So dose of narcotic analgesia were very significantly reduced in PCNL group. ( Chi-square=25.82 ;  $p$  value is  $<0.001$ ).

Likewise, Snyder and Smith in 1986<sup>12</sup> found reduced dose (16 vs 33 doses) of narcotics needed in PCNL group than open operations. The result of the present study was compatible with the above study.

Here the rate of stone clearance and residual stone in percutaneous procedure, (25 cases, 80%) is approaching to that of open procedure, (34 cases 85%). In this series no significant difference were observed for clearance of residual stone by adjuvant procedure ( $p > 0.05$ ).

Brannen and associates<sup>7</sup> reported 97% and 96% stone free rate for PCNL and open surgery respectively. Al-kohlany et al<sup>9</sup> also showed 74% and 82% stone free rate for PCNL and open surgery respectively. Sagura JW et al.<sup>14</sup> in 1985 reported 3% and 10.4% residual stone in different series following PCNL approach. Assimos et al in 1991<sup>6</sup> in a retrospective study of 36 cases of staghorn calculi showed equal success rate in PCNL and anatomic nephrolithotomy.

Stone clearance and residual stone primarily depend upon the stone size, stone burden and composition. For this reason there is difference in stone clearance and residual stone rate which we have observed in the above studies.<sup>15</sup>

### Conclusion:

PCNL is relatively safe method & better treatment option over open surgery in treating large renal stone. PCNL has almost similar stone free rate at discharge home but has definite advantages of lower morbidity, shorter convalescence and more rapid return to work, in spite of some limitations like small sample size, purposive sampling & stone composition was not considered here. Further research should be conducted on two well matched comparative groups of large sample size to establish the findings of the present study.

**Conflict of Interest :** None Declared

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**Abbreviations:**

- ESWL: Extracorporeal Shortwave lithotripsy  
 ICPL : Percutaneous Nephrolithotripsy