

## RESEARCH PAPER

# Efficacy and Safety of Percutaneous Nephrolithotomy in Treating Lower Calyceal Renal Stone of 1-2 centimeter in Favorable Lower Pole Calyceal Anatomy: Comparison with Extracorporeal Shock Wave Lithotripsy

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## Abstract

**Background:** Renal stones commonly occur in the lower pole calyx, making treatment challenging due to anatomical factors. The main treatment options for lower calyceal stones are extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL). ESWL is preferred for stone <1cm, while PCNL is preferred for stone >2cm. However, for 1-2 cm stone with favorable lower pole calyceal anatomy, both treatments are practiced. ESWL is non-invasive with fewer complications but has lower stone clearance requiring multiple sessions.

**Objective:** To evaluate efficacy and safety of PCNL compared to ESWL in treating lower calyceal renal stone of 1-2 cm in favorable lower pole calyceal anatomy.

**Methods:** This was a single center quasi-experimental study on 44 patients, divided into two groups: group A (experimental group) and group B (control group), from January 2023 to August 2024 in the Department of Urology, Bangladesh Medical University (BMU), Shahbag, Dhaka. The unilateral, single, radiopaque, 1-2 cm sized lower calyceal renal stone in favorable lower pole calyx anatomy was included in the study. The computed tomography urogram (CTU) was carried out to assess the favorable infundibular characteristics, stone size, Hounsfield unit and skin to stone distance. Experimental group underwent PCNL and control group, ESWL. Operation duration, post operative complications determined by modified Clavien Dindo, duration of hospital stay and stone clearance were evaluated between the groups. Continuous variables were analyzed by t-test and categorical variables by chi-square test and fisher's exact test. *P*-value <0.05 was considered statistically significant.

**Results:** Experimental group (65±13.54 minutes) had shorter operation time compared to control group (70.23±23.73 minutes); but the difference was not statistically significant (*p*=0.374). Grade-1 complication was more in control group than experimental group. While grade-2 complication was more in experimental group than control group but overall complication rate was identical (*p*=0.763) between two groups. Duration of hospital stay was significantly shorter (*p*<0.01) in control group (11.09±3.89 hours) than experimental group (77.45±22.13 hours). Stone clearance was significantly (*p*=0.012) higher in experimental group (81.1%) than control group (45%).

**Conclusion:** PCNL offers better stone clearance but require longer hospital stay than ESWL with identical operation time and complication rates between them.

**Keywords:** Lower calyx stone, 1-2 cm renal stone, Favorable lower pole anatomy, Percutaneous nephrolithotomy, Extracorporeal shock wave lithotripsy.

## Introduction

Renal stone is one of the most common urological diseases. Its lifetime prevalence in adult is 10% across the world.<sup>1</sup> It predominantly occurs in the lower calyx with an incidence of 35-44%.<sup>1,2</sup> About

23% of lower calyceal stones are found to be measured between 1-2 cm.<sup>2</sup>

Bangladesh has a high prevalence of renal stone disease, although exact data is unavailable. People from northern part of the country suffers more commonly from this disease. Male gender is commonly affected with male to female ratio of 3:1.<sup>3</sup>

Treatment of lower calyceal stone is very challenging due to its gravity dependent position and infundibular characteristics like lower infundibulopelvic angle,

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infundibular length and infundibular width.<sup>4,5</sup> The decision for treatment of lower calyceal stone depends on stone growth, de novo obstruction, associated infection, stone composition and acute or chronic pain.<sup>6</sup>

The present treatment options of lower calyx stone include extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL) with its various modifications.<sup>4,7</sup> The choice of treatment relies on several factors like- patient's symptom, body habitus, stone size, number, location, hardness, anatomy of affected pelvicalyceal system, skin to stone distance, preference of both clinician and patient, availability of equipment and surgeon's expertise.<sup>1,5,6</sup> The main aim of treating this disease is to gain maximum stone clearance with minimum morbidity.<sup>8</sup>

According to EAU guideline 2024, ESWL is the preferred treatment option for <1cm and PCNL is preferred for >2cm lower calyceal renal stone. But for stone sized 1-2 cm, the treatment option depends on lower pole infundibular characteristics. In unfavorable lower pole calyceal anatomy with acute infundibulopelvic angle (<90°), narrow infundibular width (≤4mm) and long infundibulum (≥3cm), PCNL or RIRS is preferred over ESWL. Whereas, in favorable lower pole calyceal anatomy with 1-2 cm sized stone, ESWL or RIRS or PCNL either modality can be chosen.<sup>7</sup> So, there is still dilemma and optimal option remains in a grey zone for treating lower calyceal stone of 1-2 cm in favorable lower pole calyceal anatomy.<sup>6</sup>

Factors to be considered in defining the best outcome includes- stone clearance, operation duration, duration of hospital stay, post-operative complications and need of auxiliary procedures<sup>9</sup>.

PCNL and ESWL both are sophisticated and effective procedures for treating lower calyceal stone<sup>9,10</sup>. PCNL has high efficacy regarding stone clearance but highly invasive with more chance of post-operative complications and longer operative time and hospital stay<sup>1,4,11</sup>. Whereas, ESWL has the advantage of non-invasive procedure and as a result less complication along with shorter operating time and hospital stay. But it has lower stone free rate and the need for auxiliary procedure is high<sup>1,11,12</sup>.

This study aims to compare the outcome of PCNL and ESWL in treating lower calyceal renal stone of 1-2 cm in favorable lower pole anatomy in terms of stone

clearance, post-procedure complications according to modified Clavien Dindo grading, duration of operation, and hospital stay.

There are many studies comparing the outcome of PCNL and ESWL in treating lower pole renal stones in different parts of the world. However, no such study has undertaken in Bangladesh till now comparing the outcome of PCNL and ESWL in 1-2 cm lower calyceal renal stone in favorable lower pole anatomy. So, considering the geographic and genetic situation, food habit and body stature of Bangladeshi people, this study is important in the sense of proposing a preferred treatment option in these group of patients.

### Materials and Methods

This quasi-experimental study was conducted in the Department of Urology, Bangladesh Medical University (BMU) from January 2023 to August 2024. Patients of either gender, age 18-70 years, normal renal function with 1-2 cm unilateral, single, radiopaque, lower calyceal renal stone in favorable lower calyx anatomy were selected by purposive sampling after fulfilling inclusion and exclusion criteria; from outpatient department of BMU.

Patients with solitary kidney, horseshoe kidney, skeletal abnormality, obesity, recurrent renal stone disease, skin to stone distance >10 cm and stone > 1000 Hounsfield unit were excluded. CT urogram was carried out to evaluate lower pole calyceal anatomy, stone size, Hounsfield unit of stone and skin to stone distance.

Characteristics for favorable lower pole calyceal anatomy includes obtuse lower infundibulopelvic angle (>90°), wide lower pole infundibulum (≥4mm) and shorter infundibular length (≤3cm).<sup>13</sup>

Sample size was calculated and found to be 22 in each group. Patients were allocated by alternate assignment into two groups. Experimental group underwent PCNL and control group underwent ESWL.

Efficacy of both the procedures in this study was determined by operation duration, stone clearance and duration of hospital stay. Similarly, safety of both the procedures in this study was assessed by post-operative complications determined according to modified Clavien Dindo grading system<sup>18,19</sup>. Efficacy and safety were compared between two groups.

Follow up for stone clearance was done after one month and three months and evaluated by plain X-ray and ultrasonography of KUB region. Post-procedure complications were evaluated according to modified

Clavien Dindo grading system addressing pain (assessed by visual analogue scale score), fever, hemoglobin assessment on first post-operative day, necessity of blood transfusion, presence of hematuria and urinary tract infection.<sup>18,19</sup>

All the participants were counselled in details about the study and consent were taken. Experimental group patients underwent PCNL after admission. On scheduled day, PCNL was done using 24Fr nephroscope as per protocol. Whereas, control group patients underwent ESWL using new generation lithotripter, STORZ MODULITH SLK as day care procedure. Patients were given 1500-2000 shockwaves at 1-1.5 Hz frequency with 60 SMLI (STORZ Medical Lithotripsy Index) energy. Ramping was used as per protocol. Patients requiring multiple sessions were scheduled at two weeks interval.

Stone clearance was considered if there was no stone fragment or clinically insignificant residual fragment of  $\leq 3\text{mm}$  without any symptoms or obstruction evaluated by follow up radiography after three month.

All relevant data were collected in data collection sheet and analysis done using SPSS version 26.0. Data were expressed as mean and standard deviations for continuous variables and as frequency, and percentage for categorical variables. For statistical analysis, Chi-square test and Fisher's exact test were used for categorical data; independent sample t-test was used for continuous data. *P* value  $<0.05$  was considered statistically significant.

Prior to commencement of this study, the research protocol was approved by Institutional Review Board (IRB) of Bangladesh Medical University.

## Results

A total 44 participants divided into two groups were enrolled after fulfilling inclusion and exclusion criteria. In experimental group, 22 patients underwent PCNL whereas, in control group, 22 patients underwent ESWL. All the patients were followed up to three months post procedure.

Both groups had higher proportion of male patients, experimental group (59%) and control group (77.3%) but gender distribution in two groups found identical with *p* value of 0.195. The mean ages were,  $39.27 \pm 9.77$  years for experimental group and  $35.77 \pm 8.39$  years for control group, with no significant difference (*p*=0.609). The mean stone size in experimental group was  $1.54 \pm 0.19$  cm and  $1.43 \pm 0.22$  cm in control group which was not statistically significant (*p*=0.08). Stone location on the basis of laterality varied between the groups but without statistical significance (*p*=0.069) (table I).

Hounsfield unit of stone, lower pole calyceal infundibulopelvic angle, infundibular length and infundibular width in experimental group were  $876 \pm 76.15$  HU,  $109.95 \pm 8.99^\circ$ ,  $1.78 \pm 0.46$  cm, and  $8.40 \pm 1.22$  mm respectively. While in control group, these measurements were  $814.5 \pm 110.9$  HU,  $108.5 \pm 9.72^\circ$ ,  $2.07 \pm 0.41$  cm, and  $7.03 \pm 1.36$  mm respectively. The Hounsfield unit analysis showed significant difference between the groups (*p*=0.039), while infundibular characteristics did not differ significantly (table II).

**Table I:** Baseline characteristics of the patients in experimental group and control group (N=44)

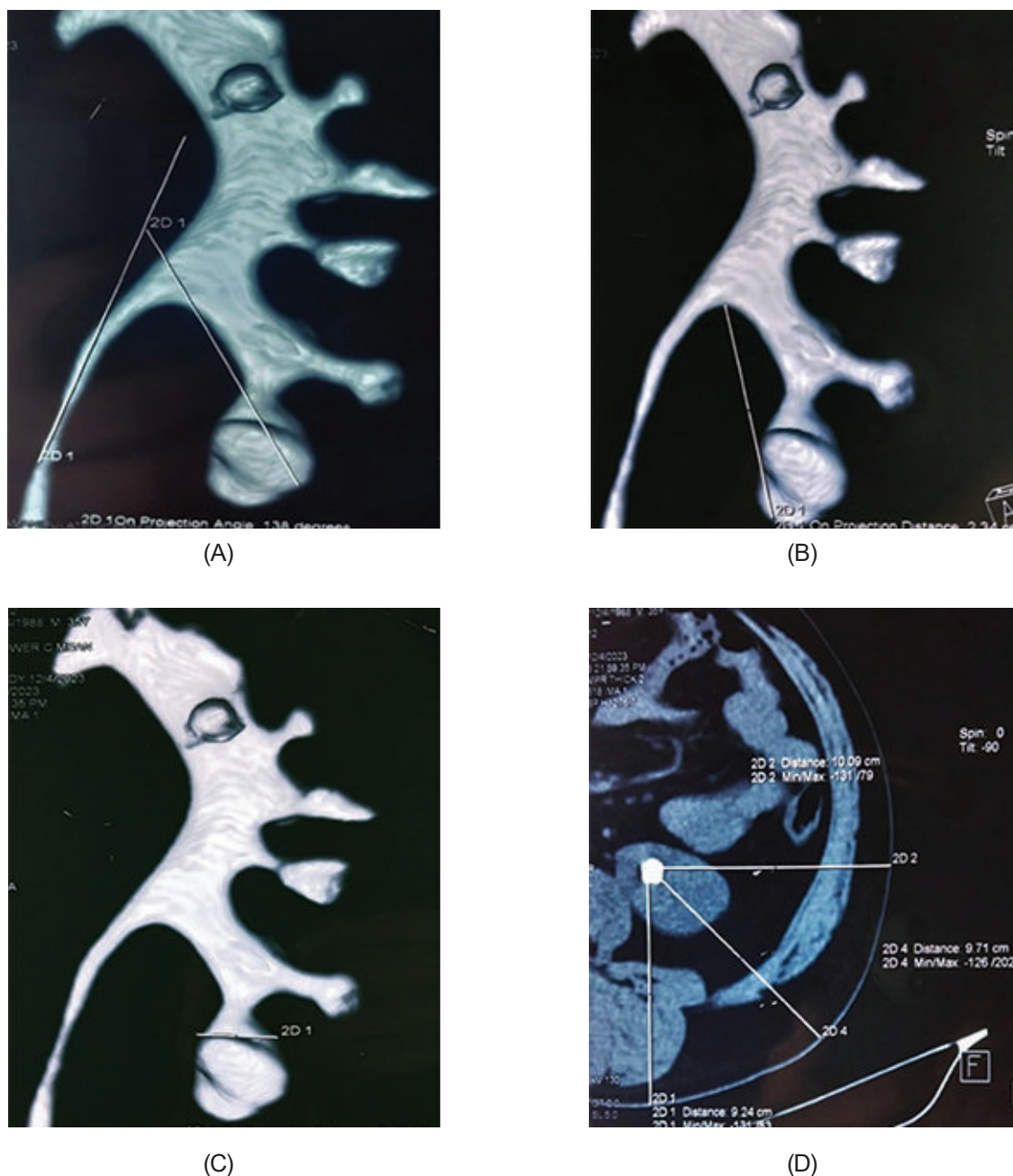
Variables	Experimental Group (n=22)	Control Group (n=22)	<i>p</i> -value
Gender (male: female) (%)	59: 41	77.3: 22.7	0.195 <sup>a</sup>
Age (years)	$39.27 \pm 9.77$	$35.77 \pm 8.39$	0.609 <sup>b</sup>
Stone size (cm)	$1.54 \pm 0.19$	$1.43 \pm 0.22$	0.08 <sup>b</sup>
Stone laterality (Right: Left) (%)	31.8: 68.2	59.1: 40.9	0.069 <sup>a</sup>

n= observed number of patients, a= Chi-square test, b= Independent sample t-test

**Table II:** Stone containing lower pole calyceal anatomy and Hounsfield unit of stone in CT Urogram in experimental group and control group (N=44)

CT Urogram findings	Experimental Group (n=22)	Control Group (n=22)	<i>p</i> -value
Infundibulopelvic angle ( $^\circ$ )	$109.95 \pm 8.99$	$108.5 \pm 9.72$	0.283 <sup>a</sup>
Infundibular length (cm)	$1.78 \pm 0.46$	$2.07 \pm 0.41$	0.713 <sup>a</sup>
Infundibular width (mm)	$8.40 \pm 1.22$	$7.03 \pm 1.36$	0.483 <sup>a</sup>
Hounsfield unit (HU) of stone	$876.5 \pm 76.5$	$814.5 \pm 110.9$	0.039 <sup>a</sup>

a= Independent sample t-test



**Figure 1:** Factors for favorable lower pole calyceal anatomy shown in A, B, C in CT Urogram film and skin to stone distance shown in D in non-contrast film. A) Infundibulopelvic angle, B) Infundibular length, C) Infundibular width, D) Skin to stone distance.

Mean duration of operation in experimental group was  $65 \pm 13.54$  minutes and  $70.23 \pm 23.73$  minutes in control group with  $p$  value of 0.374. Duration of hospital stay was significantly ( $p < 0.001$ ) shorter in control group ( $11.09 \pm 3.89$  hours) than experimental group ( $77.45 \pm 22.13$  hours). Stone clearance was notably higher in experimental group (81.8%) than in control group (45.5%) after three months ( $P = 0.012$ ) (table III).

According to modified Clavien Dindo grading system, lower grade (grade-1) complication was higher in control group (40.9%) than experimental group (9.1%). Experimental group had more (40.9%) grade-2 complications than control group (13.6%). Overall complication rate in experimental group was 50% and in control group, was 54.5% with  $p$  value of 0.763 depicting overall complication rate to be comparable between the study groups (table IV).



**Table III:** Comparison of mean operation duration, hospital stay and stone clearance rate between Experimental Group (PCNL) and Control Group (ESWL)

Variables	Experimental Group (n=22)	Control Group (n=22)	p-value
Operation time (minutes)	65±13.54	70.23±23.73	0.374 <sup>a</sup>
Hospital stay (Hours)	77.45±22.13	11.09±3.89	<0.001 <sup>a</sup>
Stone clearance, n (%)	18 (81.8)	10 (45.5)	0.012 <sup>b</sup>

a= Independent sample t-test, b=Chi-square test

**Table IV:** Pattern of complications according to modified Clavien Dindo grading system in Experimental Group (PCNL) and Control Group (ESWL)

Variables	Experimental Group (n=22) n (%)	Control Group (n=22) n (%)
Grade 1	2 (9.1%)	9 (40.9%)
Grade 2	9 (40.9)	3 (13.6%)

**Table V:** Comparison of overall complications between Experimental Group (PCNL) and Control Group (ESWL)

Variables	Experimental Group (n=22) (%)	Control Group (n=22) (%)	p-value
Complication	11 (50)	12 (54.5)	0.763 <sup>a</sup>
No Complication	11 (50)	10 (45.5)	

a= Chi-square test

## Discussion

Selecting the most appropriate treatment for lower calyceal stone of 1-2 cm remains a debated issue in urology. ESWL is a minimally invasive technique, with favorable patient tolerance and low complication rate but has lower stone clearance, and higher retreatment requirements. Whereas, PCNL and RIRS has better stone clearance with disadvantage of having more complications.<sup>13</sup>

In this study, the mean age of the patients in experimental group and control group was 39.27 (±9.77) years and 35.77 (±8.39) years which matched the research work of Kumar et al. (2015).<sup>14</sup> Renal stone is more prevalent in male gender.<sup>3</sup> In the present study, male patients are predominant in both the groups, 77.3% in experimental group, and 59% in control group. The mean stone size in experimental group was 1.54 (±0.19) cm and 1.43 (±0.22) cm in control group in this study. This is almost similar to previous study where stone size was 1.58 (±0.24) cm and 1.5 (±0.22) cm.<sup>2</sup> In this study, Hounsfield unit of stone, lower calyceal infundibular angle, infundibular length and infundibular width all were favorable for ESWL but varied between two groups.

Similar findings were seen in a study by Aboutaleb et al. (2012).<sup>15</sup>

Mean operative time in experimental group and control group were 65 (±13.54) minutes and 70.23 (±23.73) minutes respectively. Operative duration in ESWL was shorter (51.02±7.08 minutes) in a study by Mohammed et al. (2024).<sup>16</sup> The prolonged operative duration in this study might be explained by the higher number of ESWL sessions required for some patients. Maximum four ESWL sessions were given to the patients for stone clearance.

In this study, the complication rates between the two groups were compared according to modified Clavien Dindo grading system which are depicted in Table-IV, V.<sup>18,19</sup> Grade-1 complications were higher in control group (40.9%) than experimental group (9.1%), which were comparable by several studies.<sup>16,20</sup>

Experimental group (40.9%) showed higher grade-2 complication than control group (13.6%). Saxby et al. found grade-2 complications in 2.4% and 12.19% in ESWL and PCNL patients respectively.<sup>20</sup>

Overall complication rates in experimental group and control group were 50% and 54.5% respectively with

$p$  value of 0.763. This finding aligns with previous studies done by Aboutaleb et al. where 31.6% patients following PCNL and 41.7% patients following ESWL, experienced complications.<sup>15</sup>

The duration of hospital stay was significantly higher in experimental group ( $77.45 \pm 22.13$  hours) than control group ( $11.09 \pm 3.89$  hours). Bozzini et al. reported that patients undergoing PCNL had a longer hospital stay compared to those of ESWL, with an average of 3.7 days for PCNL and 0.12 days for ESWL.<sup>21</sup>

After one- and three-months follow-up, experimental group achieved significantly higher stone clearance (81.8%) compared to control group (45%) with  $p=0.012$ . Donaldson et al.'s meta-analysis compared ESWL and PCNL for medium sized lower calyceal stone found stone clearance for PCNL 96.3% and for ESWL 54.5%.<sup>22</sup> Albala et al. conducted a multicenter randomized trial comparing PCNL and ESWL for lower calyceal stone up to three cm which showed stone clearance of 95% in PCNL and 37% in ESWL.<sup>23</sup>

This study showed that; with respect to the mean operation time and overall post-operative complication, both PCNL and ESWL are identical. Whereas, with respect to the stone clearance, better performance was found in PCNL although mean hospital stay was more in PCNL compared to ESWL.

Stone clearance is the mainstay in the treatment of renal stone. So, for the interest of maximum stone clearance, a little bit longer hospital stay can be accommodated.

This study had few limitations like it was single center study and duration of follow up was short. The sample size was also very small.

## Conclusion

PCNL offers better stone clearance but require longer hospital stay than ESWL with identical operation time and complication rates between them. So, PCNL may be considered as a preferred treatment option for 1-2 cm lower calyceal stone with favorable lower pole calyceal anatomy.

## Recommendation

Further multi center study with larger sample size is required to draw a definite conclusion regarding choice of treatment between PCNL and ESWL for 1-2cm lower calyceal stone with favorable lower pole calyceal anatomy.

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