ORIGINAL ARTICLE

# STONE CLEARANCE AND COMPLICATION RATE OF MICRO PERCUTANEOUS NEPHROLITHOTOMY AND RETROGRADE INTRARENAL SURGERY FOR LOWER POLE RENAL STONE: A RANDOMIZED TRIAL

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**Background:** The use of unhealthy food and a sedentary lifestyle increases daily health problems. Renal stones are one among others. Endourology promises the minimum complications and the highest stone clearance rate. Indications of the two procedures overlap micro-PCNL and RIRS. The objective was to evaluate stone clearance and complication rate of micro-PCNL and RIRS for lower pole renal stones. M**ethods:** The research design of this study was a randomized trial and was done after approval of the ethical review committee. The sampling technique was consecutive sampling at the Urology department. Patients included in the study according to inclusion criteria were 96 in number. Randomization into two groups (RIRS vs micro-PCNL) was done by even odd method. All the procedure was done by a single senior urologist. **Results:** Their ratio among males and females was 2:1. Mean LOS in the RIRS group was 2.89±0.86 days and in the micro-PCNL group 2.58±0.65 days ($p$=0.047). The complication rate in the RIRS group was 6.2% and 8.3% in micro-PCNL ($p$=0.695). Mean post-operative haemoglobin was 12.30±1.07 g/dL among the RIRS group and among the micro-PCNL group it was 11.21±1.08 g/dL ($p$<0.001). There was an average haemoglobin drop in the micro-PCNL group of 1.09±0.01 g/dL. 75% clearance of stone after one session was achieved in the RIRS group while 79.2% was achieved in the micro-PCNL group ($p$=0.627). **Conclusion:** Length of hospital stay (LOS) and stone clearance rate (SFR) were similar in both groups with insignificant statistical differences. There is a need to conduct more studies with a large number of study participants and involving multi-centers.

**Keywords:** RIRS, PCNL; Stone-free rate; Length of stay; Kidney stone disease

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## INTRODUCTION

Global renal calculi burden is increasing with the timeline. Studies tried to determine the relationship between the progression of technology the renal calculi but still, there is no strong evidence of a relationship between both.[1] The suggested causes are more food consumption, decreased fluid intake and industrialization. Global prevalence of kidney stones varies from 6–15%.[2] Male to female ratio is 2:1 respectively with the peak age being second and third decade of life.[3,4]

The treatment choice depends upon the stone size, location and symptoms. Larger kidney stones (more than 2 cm) are treated by standard percutaneous nephrolithotomy (PCNL).[5,6] While moderate-sized stones (1–2 cm) are treated with retrograde intrarenal surgery (RIRS), electroshock wave lithotripsy (ESWL) or PCNL.[7] After the assessment of stone size and location, it provides enough information for decision-making in treatment options. URS is done for ureteric stones. RIRS is one of the modern procedures for renal stones in which a fibre optic endoscope moves retrograde via the urethra into the urinary bladder and then through the ureter into the pelvicalyceal system (within the Kidney).[8] It is better than the open surgical techniques with 10–12% complication rate and 85–88% stone-free rate.[1] The standard PCNL technique was introduced by Johansson and Fernstrom in 1976 for stones more than 2 cm.[9] In 1998, mini-PCNL was introduced to decrease the invasiveness.[6] The micro and ultra-mini PCNL were introduced by Mahesh Desai and Janak Desai in 2011 and 2013 respectively.[5]

Micro-PCNL first reported in 2011, used a 4.8Fr 'all-seeing needle to puncture a single-step procedure for fragmentation and tract formation under fluoroscopic or ultrasound guidance. The result of techniques, retrograde intrarenal surgery and micro-PCNL are competitive with one another.[10] However, researchers are in search to find the decision-making answer to the question of which technique is better. The efficacy (stone clearance rate) and safety

(complications rate) of both techniques require strong evidence to accept or reject them.[11]

The objective was to evaluate stone clearance and complication rate of micro-PCNL and RIRS for lower pole renal stones.

## MATERIAL AND METHODS

It is a randomized trial study conducted in the Department of Urology at Lahore General Hospital, Lahore from September 2021 to October 2022. A total of 96 patients were included in the study divided into two groups comprising 48 patients in each group. Group A, patients underwent RIRS while group B comprised of patients who underwent Micro PCNL. The sampling technique was consecutive sampling. Randomization of the sample was done by even odd method. Adult Patients more than 18 years old with renal calculi of 1-2 cm size in the lower pole of the kidney on either side were included in the study. Patient refusal, congenital diseases, pregnant women, bleeding diathesis (prolonged bleeding), skeletal dysmorphia, acute infection, and deranged renal functions were our exclusion criteria.

All patients who fulfilled the inclusion criteria were admitted from the outpatient department of Lahore General Hospital, Lahore and baseline investigations advised to get fitness from an anaesthetist.

All group A patients underwent RIRS in dorsal lithotomy position under general anaesthesia. To preserve the ureteral orifice and facilitate the process during operation, a ureteral access sheath (UAS) was used over a guide wire placed retrograde into the calyceal system under fluoroscope guidance.

In cases where ureteral narrowness was found, dilation of the ureteral orifice with mechanical dilation with a ureteroscope provided a solution during operation. D-J stent was placed for ureteral dilatation in a few patients for 2 weeks. UAS prevented from increase in intrarenal pelvic pressure (IPP) by providing anterograde fluid drainage. After reaching the calyceal system, the lower calyx is approached by a flexible ureteroscope. Holmium laser fragments the stone by a 200µm laser fibre in the lower calyx. A double Jj stent is placed in cases of complications such as residual stone, bleeding ureteral perforation etc. While in group B patients underwent micro-PCNL. It was performed in a supine position with 4.5 Fr micro-perc needle. Renal access was gained and stone fragmentation was done via a micro-perc needle. It was a single-step procedure. Lower calyx punctured under the fluoroscope guidance. Micro-perc inner needle was removed and a 3-way connecter was attached from where the telescope entered on one side and the other side connected with irrigation fluid. While the third and central port is used for 200 µm laser fibre. Stone fragmentation was done by using a holmium laser. A D- J stent was inserted in cases of complications such as residual stone and bleeding.

The record of the patients entered in performed *proforma* which is attached. Informed consent for study and surgery was taken from patients after a detailed explanation of the procedure along with complications. To minimize the risk of bias blinding technique was used in which the researcher did not know the allotment of groups to patients. On the first post-operative day, CBC ultrasound and X-ray KUB advised knowing the stone clearance and complications like pernepheric hematoma and urinoma. Dependent variables were the length of hospital stay stone-free rate and complications.

Data was entered and analyzed by using the SPSS 26.0 version. Quantitative variables such as age, BMI, stone size anatomical side and length of stay (LOS) in the hospital were described as Mean±S.D. for both groups. Qualitative variables like gender, stone clearance and post-operative complications in both groups are described as frequencies and percentages. A comparison of the frequency of stone clearance and postoperative complications was done by applying the post-stratification Chi-square test. A *p*-value of equal or less than 0.05 is considered significant.

## RESULTS

A total of 96 patients (48 in each group) were enrolled as per inclusion criteria. The mean size of stone among enrolled patients was 1.63±0.09 cm. The mean body mass index was 25.78±3.86 Kg $m^2$. The mean length of stay (LOS) was 2.74±0.77 days.

The mean stone size was 1.64±0.11 cm in the RIRS group while in the micro-PCNL group it was 1.62±0.09 cm; the mean body mass index was 26.18±4.31 Kg $m^2$ among retrograde intra renal surgery group and among micro percutaneous nephrolithotomy group it was 25.38±3.35 Kg $m^2$; the mean length of stay was 2.89±0.86 days among retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 2.58 ± 0.65 days; the mean preoperative haemoglobin level was 12.75±1.09 g dL among retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 12.48±1.02 g dL and the mean postoperative haemoglobin level was 12.30±1.07 g dL among retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 11.21±1.08 g dL.

There were 34 (70.8%) males and 14 (29.2%) females among retrograde intra renal surgery patients while the number of males among micro percutaneous nephrolithotomy were 32 (66.7%) and remaining 16 (33.4%) were females; regarding site involved by the stone showed that there were 22 (45.8%) patients having

right side involved and 26 (54.2%) had left side involved among retrograde intra renal surgery patients whereas there were 25 (52.1%) patients having right side involved and 23 (47.9%) had left side involved among micro percutaneous nephrolithotomy; regarding urinary tract infection 08 (16.7%) and 06 (12.5%) had the infection among retrograde intra renal surgery and micro percutaneous nephrolithotomy patients respectively; stone free rate showed that there were 36 (75%) patients among retrograde intra renal surgery and 38 (79.2%) had patients among micro percutaneous nephrolithotomy and complications after surgery showed that 3 (6.2%) patients had complications among retrograde intra renal surgery and 4 (8.3%) patients had complications among micro percutaneous nephrolithotomy surgery. Complications noted among retrograde intra renal surgery (RIRS) were Clavien-Dindo grade II (postoperative fever) among two patients and one patient had Clavien IIIa (peri-renal hematoma) whereas patients undergone micro percutaneous nephrolithotomy (micro-PCNL) showed that two had Clavien I (bleeding) and one had Clavien II (Post-operative fever) and Clavien IIIa (peri-renal hematoma) complications respectively. (Figure-1) The overall complications rate was 6.2% (03) in RIRS group while it was 8.3% (04) in micro-PCNL group. The difference between the two attributes was statistically insignificant ($p$=0.695).

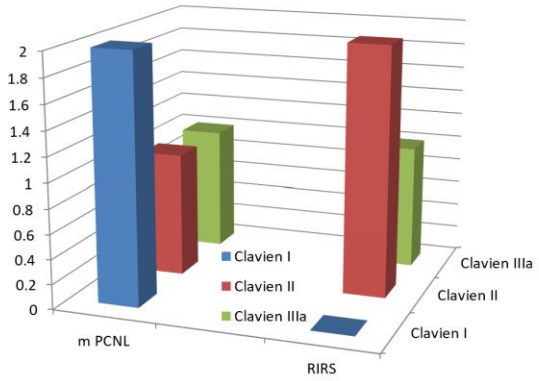


**Figure-1: Complications among m-PCNL and RIRS group**

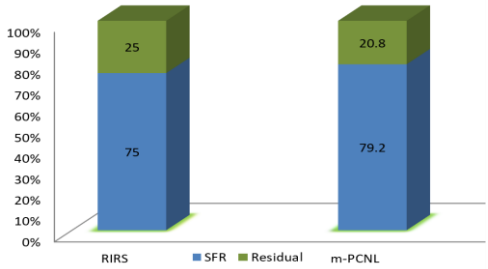


**Figure-2: Stone free rate in a single session after one month**

**Table-1: Association of gender and medical characteristics of the patients among studied groups**

| Variables | | RIRS | | Micro PCNL | | *p*-value |
|---|---|---|---|---|---|---|
| | | n. | % | n | % | |
| **Sex** | **Male** | 34 | 70.8 | 32 | 66.7 | 0.194 |
| | **Female** | 14 | 29.2 | 16 | 33.3 | 0.66 |
| **Site Involved** | **Right** | 22 | 45.8 | 25 | 52.1 | 0.375 |
| | **Left** | 26 | 54.2 | 23 | 47.9 | 0.54 |
| **UTI** | **Yes** | 08 | 16.7 | 06 | 12.5 | 0.334 |
| | **No** | 40 | 83.3 | 42 | 87.5 | 0.563 |
| **Stone free Rate** | **Yes** | 36 | 75 | 38 | 79.2 | 0.236 |
| | **No** | 12 | 25 | 10 | 20.8 | 0.627 |
| **Complication** | **Yes** | 03 | 6.2 | 04 | 8.3 | 0.154 |
| | **No** | 45 | 93.8 | 44 | 91.7 | 0.695 |
| **Total** | | **48** | **100** | **48** | **100** | |

**Table-2: Mean Comparison of Quantitative Variables among the Study Groups**

| Variables | RIRS, Mean ±SD | Micro PCNL Mean±SD | t-test, *p*-value |
|---|---|---|---|
| **Stone Size (cm)** | 1.64±0.11 | 1.62±0.09 | 1.02, 0.31 |
| **BMI (Kg m$^2$)** | 26.18±4.31 | 25.38±3.35 | 1.08, 0.31 |
| **Length of Stay (Days)** | 2.89±0.86 | 2.58±0.65 | 2.02, 0.047* |
| **Preoperative Haemoglobin (g dL)** | 12.75±1.09 | 12.48±1.02 | 1.23, 0.223 |
| **Postoperative Haemoglobin (g dL)** | 12.30±1.07 | 11.21±1.08 | 4.96 <0.001* |

*Significant *p*-value

There were 34 (70.8%) males and 14 (29.2%) females among retrograde intra renal surgery patients while the number of males among micro percutaneous nephrolithotomy was 32 (66.7%) and the remaining 16 (33.3%) were females. The difference was statistically insignificant ($p$=0.66); regarding site involved by the stone showed that there were 22 (45.8%) patients had the right side involved and 26 (54.2%) had the left side involved among retrograde intra-renal surgery patients whereas there were 25 (52.1%) patients having right side involved and 23 (47.9%) had left side involved among micro

percutaneous nephrolithotomy. The difference was statistically insignificant ($p$=0.54); regarding urinary tract infection 08 (16.7%) and 06 (12.5%) had the infection among retrograde intra renal surgery and micro percutaneous nephrolithotomy patients respectively. This difference was insignificant statistically ($p$=0.563); stone free rate showed that there were 36 (75%) patients among retrograde intra renal surgery and 38 (79.2%) had patients with micro percutaneous nephrolithotomy (Figure-2). The association between the two variables was insignificant statistically ($p$=0.627).

Among the two groups, the mean stone size was 1.64±0.11 cm among retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 1.62±0.09 cm. This mean difference was statistically insignificant ($p$=0.31); the mean body mass index was 26.18±4.31 Kg $m^2$ among the retrograde intra renal surgery group and among the micro percutaneous nephrolithotomy group it was 25.38±3.35 Kg $m^2$. This mean difference was also statistically insignificant ($p$=0.31); the mean length of stay was 2.89±0.86 days among the retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 2.58±0.65 days. This mean difference was statistically significant ($p$=0.047). In RIRS group, patients were admitted two times in hospital for ureteric stenting and second for RIRS. This is the reason of more LOS in this group.

The mean preoperative haemoglobin level was 12.75±1.09 g dL among the retrograde intra renal surgery group and among micro percutaneous nephrolithotomy group it was 12.48±1.02 g dL. This mean difference was statistically insignificant ($p$=0.223) and the mean postoperative haemoglobin level was 12.30±1.07 g dL among the retrograde intra renal surgery group and micro percutaneous nephrolithotomy group it was 11.21±1.08 g dL. This mean difference of postoperative blood haemoglobin was highly statistically significant ($p$<0.001). The mean difference of preoperative Hb and postoperative Hb in RIRS group is 0.45 which may be due to microscopic haematuria after instrumentation or lab error. (Table-4)

## DISCUSSION

The randomized trial included 96 patients with a male-to-female ratio of 2:1. Physical characteristics measured in the form of body mass index (BMI) of study participants were 25.78±3.86 Kg/$m^2$ which falls in the overweight category according to World Health Organization (WHO) BMI classification.[14]

The mean lower pole stone size of 1.63±0.09 cm and almost the same proportion of right and left kidney were involved. Stone size in both RIRS and micro-PCNL group was almost equal 1.64±0.11 cm and 1.62±0.09 cm respectively. It was according to the inclusion criteria of the study.

Hospital length of stay (LOS) in both groups was 3 days approximately. Patients were admitted before the day of surgery. Mean LOS in RIRS group was 2.89±0.86 days and in micro-PCNL group 2.58±0.65 days ($p$=0.047). All the patients' hospital stay was similar in our study which is not consistent with the results of Atis *et. al.*[15]

The complication rate in RIRS group was 6.2% and 8.3% in micro-PCNL ($p$=0.695). 16.7% study participants of RIRS group suffered from urinary tract infection (UTI) and 12.5% of micro- PCNL. Our study showed less complication rate than Bas *et. al*. and Michel *et. al.*[16,17]

Mean post-operative haemoglobin was 12.30±1.07 g/dL among the retrograde intra-renal surgery (RIRS) group and among micro percutaneous nephrolithotomy (micro-PCNL) group it was 11.21±1.08 g/dL ($p$<0.001). There was a mean haemoglobin drop in micro-PCNL group of 1.09±0.01 g/dL which is more than study of Bas *et. al*.[16] In our study 75% stone-free rate after one session was achieved in RIRS group while 79.2% achieved in the micro-PCNL group ($p$=0.627). Patients were treated with other auxiliary procedures. Statistically, there is no difference in both groups. Stone free rate in both groups for lower pole stone was almost similar. This is consistent with the study of Gao *et. al*. He *et. al* and Wang *et. al*.[18–20] While Tsai *et. al*. results showed better stone clearance in PCNL group.[21] Gu *et al*. study was in favour of RIRS in terms of stone free rate.[22]

Limited resources and the short duration of the study were major limitations. Results of this study will be useful for comparison with other centers.

## CONCLUSION

Study variables among RIRS group and micro-PCNL group showed more post-operative haemoglobin drop in micro PCNL group. Stone-free rate (SFR) was higher in micro-PCNL group with no statistical significance. Length of hospital stay (LOS) was slightly more in RIRS group because of pre-procedure stenting admission. There is a need to conduct more studies with a large number of study participants and involving multi-centers.

## AUTHORS' CONTRIBUTION

KS: Data collection, data analysis/interpretation. MAS: Write-up. MA: Literature search. KH: Study design. MN: Proofreading.

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