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Research Article

TO COMPARE THE OUTCOMES OF RETROGRADE INTRARENAL SURGERY (RIRS) WITH PERCUTANEOUS NEPHROLITHOTOMY FOR THE TREATMENT OF RENAL STONES ≥ 20 MM.

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Abstract:

Introduction: Retrograde intrarenal surgery (RIRS) performed using a flexible or semi rigid uretero renolescope marked the beginning of a new era in urology. Percutaneous nephrolithotomy is a standard treatment for larger stones with very good success rates but at the eve of high levels of patient's morbidity. It may be associated with Grade IV renal trauma. While RIRS is associated with minimal morbidity.

Objective: To compare the outcomes of retrograde intrarenal surgery (RIRS) with percutaneous nephrolithotomy for the treatment of renal stones ≥ 20 mm.

Study Design: Randomized Clinical Trial.

Setting: The study was conducted for 6 months at department of Urology, Sindh Institute of Urology and Transplantation (SIUT) Karachi since 1st-April-2017 to 30th-September-2017.

Materials and Methods: A total number of 136 patients with diagnosis of kidney stones (stone size ≥ 20 mm) were included in this analysis. Patients were randomly divided into two groups using lottery method. Group I: Patients underwent percutaneous nephrolithotomy and Group II patients underwent RIRS for the treatment of renal stones. Post-procedural X-ray KUB was done 2 weeks after the surgical procedure to determine the stone clearance in every patient. Mean hemoglobin drop and hospital stay time was noted for every patient.

Data analysis was carried out using SPSS v20.0. Independent sample t-test was used to compare the hospital stay and hemoglobin drop between the groups. While chi-square test was used to compare stone clearance rate between groups.

Results: The mean age of the patients in this study was 44.98 ± 10.68 years. There were 90 (66.18%) male patients and 46 (33.82%) female patients. Mean size of renal stones was 29.5 ± 6.3 mm. stone clearance was 64 (94.1%) in patients who underwent PCNL procedure while stone clearance rate was 59 (86.8%) in RIRS patients (p-value 0.14). Mean reduction in hemoglobin levels was 2.24 ± 0.52 g/dl in PCNL group and 1.92 ± 0.57 g/dl in RIRS group (p-value 0.001). Mean hospital stay was 1.55 ± 0.60 days in RIRS group versus 2.60 ± 0.71 days in PCNL patients (p-value < 0.001).

Conclusion: RIRS affords a comparable success rate, causes fewer complications than PNL, and seems to be a promising alternative to PCNL when larger stones are to be treated.

Keywords: Renal Stones, Retrograde Intrarenal Surgery, Percutaneous nephrolithotomy.

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INTRODUCTION:

Retrograde intrarenal surgery (RIRS) performed using a flexible or semi rigid uretero renolescope marked the beginning of a new era in urology. RIRS make smaller kidney stones more accessible and upper urinary tract tumors treatable, using minimally invasive methods.¹ RIRS was first used to treat small kidney stones.¹ But in recent years it was suggested that larger stones could also be treated via RIRS.²

Percutaneous nephrolithotomy is a standard treatment for larger stones with very good success rates but at the eve of high levels of patient's morbidity. It may be associated with Grade IV renal trauma.³ while RIRS is associated with minimal morbidity. So some urologists have suggested that RIRS, which is associated with fewer complications and less morbidity, should be used to treat large stones also.^{4,5}

Akman et al. concluded that RIRS is associated with less morbidity as compared to PCNL and can be used as an alternative to PCNL for the treatment of larger renal stones.⁶ Regarding safety of procedure, they found less hospital stay time (30.0 ± 37.4 hours) and mean drop in hemoglobin levels (0.29 ± 0.17 g/dl) in RIRS group as compared to 61.4 ± 34.0 hours and 1.65 ± 1.20 g/dl in PCNL group respectively. The mean stone clearance rate was 73.5% in RIRS group and 91.2% in PCNL group. Some other studies have concluded similar results.^{7,8} because region variation can happen as a result of experience of the operating surgeons or due to varying composition of renal stones among different regions.

So I have a plan to conduct this study to compare the outcomes of RIRS with PCNL in patients with renal stones ≥ 20 mm. This study will help to evaluate the outcomes of retrograde intrarenal surgery (RIRS) against PCNL in our patients. If results of RIRS will be comparable to that of PCNL, it will attract other urologists of Pakistan to use RIRS as a preferred technique to treat larger renal stones. Because this time PCNL is considered a treatment of choice in these patients in SIUT and perhaps in other institutes of

Pakistan. And hence this study will help to better treatment modality and to reduce patient morbidity associated with the use of PCNL as compared to RIRS.

MATERIAL AND METHODS:**STUDY DESIGN:** Randomized Clinical Trial.**SETTING:** The study was conducted at department of Urology, Sindh Institute of Urology and Transplantation (SIUT) Karachi.**DURATION OF STUDY:** 1-April-2017 to 30-September-2017**SAMPLE SIZE:**

The sample size for this study is calculated using the following formula;

$$n = (Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1 - p_2)^2$$

Stone clearance rate using PCNL procedure
(P₁) = 91.2 %⁶

Stone clearance rate using RIRS procedure
(P₂) = 73.5 %⁶

By taking level of significance 5% and power of the test 80%, the calculated sample size for this study is 68 patients in each group. So a total number of 136 patients were selected for this study.

SAMPLING TECHNAQUE: Non probability, Consecutive sampling**SAMPLE SELECTION:****Inclusion criteria:**

- All patients with diagnosis of renal stones larger than or equal to 20 mm
- Patients having age 15-60 years.
- Both genders male and female.
- Patients with any duration of kidney stone disease were included.

Exclusion criteria:

- Patients with untreated urinary tract infections (UTI) was excluded because these

conditions can affect stone clearance rate after the procedure.

DATA COLLECTION PROCEDURE:

Before starting the research work, approval was taken (after approval of synopsis) from the Institutional review board of the hospital. After approval, patients who presented in urology department of Sindh Institute of Urology and Transplantation fulfilling the inclusion criteria were included in this study until the required sample size of 136 patients was completed. An informed consent was taken from all patients before including them in this study. Patients were divided into two groups using lottery method. I made folded papers containing name of treatments and ask the patient to pick up one paper. Patients were divided into two equal groups depending upon the folded paper chosen by them. Group I: Patients underwent percutaneous nephrolithotomy and Group II patients underwent RIRS for the treatment of renal stones ≥ 20 mm.

Diagnosis of renal stones was made on the basis of ultrasound studies of the patients. Post-procedural X-ray KUB was done 2 weeks after the surgical procedure to determine the stone clearance in every patient. Mean hemoglobin drop and hospital stay time was noted for every patient according to the operational definitions. All the gathered information regarding outcomes of both procedures and other relevant information regarding patient was recorded on a pre-designed Proforma.

DATA ANALYSIS PROCEDURE:

Data analysis was carried out using SPSS v20.0. Mean and standard deviations were calculated for quantitative variables like age, size of renal stones, duration of renal stone disease, hospital stay, pre-op Hb, post-op Hb and hemoglobin drop. Categorical variables like gender, location of calculi and stone clearance rate was presented as frequency and percentage. Independent sample t-test was used to compare the hospital stay and hemoglobin drop between the groups. While chi-square test was used to compare stone clearance rate between groups. Stratification of confounder variables e.g. age, gender, size of renal stones, duration of renal stone disease, and location of renal stone was done. Post stratification Chi-square test was applied to determine the effect of these confounder variables on stone clearance rate and independent sample t-test was applied to determine the effect of confounder variables on hospital stay, hemoglobin drop) taking P-value ≤ 0.05 as significant difference.

RESULTS:

In this study, a total number of 136 patients were included, there were 68 patients who underwent percutaneous nephrolithotomy for the treatment of kidney stones and 68 patients underwent retrograde intra-renal surgery for the treatment of renal stones.

The mean age of the patients in this study was 44.98 ± 10.68 years. Minimum age of one patient was 16 years and maximum age was 60 years.

There was more males as compared to the females. There were 90 (66.18%) male patients and 46 (33.82%) female patients in this study.

The mean duration of renal stone disease was 5.06 ± 3.84 months. The minimum duration of disease 1 month and maximum duration of disease was 23 months (Table 1).

Mean size of renal stones was 29.5 ± 6.3 mm. Minimum size of renal stones was 2 cm and maximum size of renal stones was 40 mm (Table 2).

Re-op hemoglobin levels were 13.46 ± 1.24 g/dl of study patients. Post-op hemoglobin levels after 24 hours of surgery was 11.45 ± 1.08 g/dl. The mean reduction in hemoglobin levels after surgery were 2.08 ± 0.56 g/dl (Table 3).

Hospital stay period was 2.08 ± 0.85 days. Minimum duration of hospital stay was 1 months and maximum duration of hospital stay was 5 days (Table 4).

There were 108 (79.41%) patients who presented with unilateral renal stones and remaining 28 (20.59%) patients presented with bilateral renal stones (Fig. 8).

Successful stones clearance was achieved in 123 (90.44%) patients while failure rate was 13 (9.56%) patients. On comparison of stone clearance rate between the groups, stone clearance was 64 (94.1%) in patients who underwent PCNL procedure while stone clearance rate was 59 (86.8%) in RIRS patients (Table 7).

On comparison of mean reduction in Hb levels between the groups, the mean reduction in hemoglobin levels was more in PCNL group as compared to the RIRS group of patients. Mean reduction in hemoglobin levels was 2.24 ± 0.52 g/dl in PCNL group and 1.92 ± 0.57 g/dl in RIRS group with a p-value 0.001 (Table 5).

On comparison of mean hospital stay between the groups, mean hospital stay was significantly less in RIRS group as compared to the PCNL group. Mean

hospital stay was 1.55 ± 0.60 days in RIRS group versus 2.60 ± 0.71 days in PCNL patients. This difference was statistically significant (p -value < 0.001) (Table 6).

Stratification was done on the basis of age, gender, duration of renal stone disease, size of renal stones,

and location of renal stones to determine the effect of these confounder variables on hospital stay, mean reduction in hemoglobin and stone clearance rate. There was no significant effect of confounder variables on the outcomes of the study parameters.

Table 1. Descriptive Statistics of Duration of Renal Stone Disease.

Duration of Renal Stone Disease (Months)	
Mean	5.06
Standard Deviation	3.84
Minimum	1
Maximum	23

Table 2. Descriptive Statistics of Size of Renal Stones.

Size of Renal Stones (mm)	
Mean	29.5
Standard Deviation	6.3
Minimum	20
Maximum	40

Table 3. Descriptive Statistics of Mean Hemoglobin (Hb) Levels.

Mean Hemoglobin (Hb) Levels (g/dl)	Mean	Standard Deviation (S.D)	Minimum	Maximum
Pre-op Hb	13.46	1.24	10.60	16
Post-op Hb	11.45	1.08	8.0	14
Reduction in Hb levels	2.08	0.56	0.70	3.8

Table 4. Descriptive Statistics of Hospital Stay.

Hospital Stay (Days)	
Mean	2.08
Standard Deviation	0.85
Minimum	1
Maximum	5

Table 5. Comparison of Mean Hemoglobin Reduction between the Groups.

Hemoglobin Reduction (g/dl)	PCNL	RIRS	P-value
Mean	2.24	1.92	0.001
S.D	0.52	0.57	

Table 6. Comparison of Mean Hospital Stay between the Groups.

Hospital Stay (days)	PCNL	RIRS	P-value
Mean	2.60	1.55	< 0.001
S.D	0.71	0.60	

Table 7. Comparison of Stone Clearance Rate between the Groups.

Stone Clearance	PCNL	RIRS	P-value
Yes	64 (94.1%)	59 (86.8%)	0.14
No	4 (5.9%)	9 (13.2%)	

Table 8. Stratification of Age to Determine the Effect of Age on Mean Hemoglobin Reduction.

Age Groups	Hemoglobin Reduction (g/dl)	PCNL	RIRS	P-value
15-40 Years	Mean	2.35	2.00	0.02
	S.D	0.58	0.43	
41-50 Years	Mean	2.29	1.98	0.04
	S.D	0.31	0.45	
51-60 Years	Mean	2.26	1.80	0.01
	S.D	0.59	0.59	

DISCUSSION:

The EAU guidelines on urolithiasis state clearly that renal stones more than 2 cm in diameter should be managed with PCNL.⁹ PCNL, however, carries the significant risk of severe bleeding and need for blood transfusion in up to 30% of patients.^{10,11} This complication may be avoided by anatomically oriented access, but cannot be avoided completely. Usually when it occurs, the operation is terminated and a nephrostomy tube is inserted and clamped for 6 hours.¹² The other complication is fistula formation, which occurs in 7% of patients.¹² Finally, the mortality rate is estimated to be 0.5%.¹³

Arising in 1990's, use of RIRS has increased by developing technology and extending experience. Development in new flexible renoscopes and laser technology led to increase in area of use of this method. RIRS has good efficacy and a low complication rate with small renal stones. Severe bleeding or infection after intrarenal surgery is rare. Although a lower disintegration rate is obvious because of limited maneuvers with ureteroscopes and the inability to suck all debris, there is always the possibility to direct the patient to a secondary procedure. It was previously reported that the disintegration rate after one RIRS in cases with stones in the lower calyx is 47%, but increases up to 91% after an additional procedure.¹⁴⁻¹⁶

In the literature, there are studies about the usage of RIRS for the treatment of renal stones sized ≥ 2 cm. Breda et al. reported a success rate of 93.3% for 15 patients with renal stones of 20-25 mm. Mariani et al. reported a success rate of 92% in 15 patients with renal stones of 2-4 cm size. Grasso et al. reported a success rate of 91% for 51 patients with renal stones sized ≥ 2 cm. Palmero et al. applied RIRS to 106 patients with renal stones sized ≥ 2 cm. Hyams et al. stated a success rate of 85% for 120 patients with renal stones of 2-3 cm size for the study in which RIRS method was applied.¹⁷⁻¹⁹

There are few studies comparing RIRS and PNL methods for treatment of renal stones 2-4 cm in size. In their research in which 68 patients were included and RIRS

and PNL methods were compared, Akman et al. found the success rates of 91.2% and 73.5% for PNL and RIRS groups, respectively. In the follow-up conducted three months later, success rates of 97% and 94.1% were found for PNL and RIRS groups, respectively. Bryniarski et al. compared RIRS and PNL methods in 64 patients with pelvis stones of 2-4 cm size in a prospective study. Success rates of 81.25% and 50% were detected for PNL and RIRS groups, respectively and the success rates of 93.75% and 75% were reported after a follow-up study of 3 weeks. De et al. compared the RIRS and PNL methods in their review. The stone size was between 2- 4 cm in only two of ten studies taken into consideration.^{20,21}

In our study, we compared the outcomes of RIRS with PCNL, we evaluated the stone clearance rate, mean loss of blood in terms of reduction in hemoglobin levels and mean hospital stay of study patients.

In our study, stone clearance was 64 (94.1%) in patients who underwent PCNL procedure while stone clearance rate was 59 (86.8%) in RIRS patients. However, this difference in stone clearance rate was statistically insignificant. Palmero et al. found a stone clearance rate of 80.6% in patients of PCNL and 73.6% in RIRS patients, the success rate in their study like our study was little high in PCNL patients but this was not statistically significant.²² Zengin et al. found stone clearance in 95.5% patients who underwent PCNL and in 80.6% patients who underwent RIRS with insignificant p-value.⁵

In our study, mean reduction in hemoglobin levels was 2.24 ± 0.52 g/dl in PCNL group and 1.92 ± 0.57 g/dl in RIRS group of patients. Mean reduction in Hb levels in the study of Zengin et al. 1.4 g/dl in PCNL patients and 0.3 in RIRS patients.⁵

In our study, mean hospital stay was 1.55 ± 0.60 days in RIRS group versus 2.60 ± 0.71 days in PCNL patients. Mean hospital stay in the study of Zengin et al. was 2.3 days in PCNL patients and 1.1 days in RIRS patients.⁵ Palmero et al. found hospital stay of 16 hours in PCNL patients and 98 hours in RIRS patients.²² In most Western countries, RIRS is

considered an outpatient procedure in which the patient is discharged after 24 hours. Similarly, PCNL usually needs only 24 hour of hospitalization.

CONCLUSION:

RIRS affords a comparable success rate, causes fewer complications than PNL, and seems to be a promising alternative to PCNL when larger stones are to be treated.

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