A Comparison of Retrograde Intrarenal Surgery and Percutaneous Nephrolithotomy for Management of Renal Stones ≥ 2 CM

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Purpose: In this retrospective study, we aimed to compare the outcomes in patients who have been treated with percutaneous nephrolithotomy (PNL) and retrograde intrarenal surgery (RIRS) on renal stones ≥ 2 cm size.

Materials and Methods: We evaluated patients who underwent PNL or RIRS for renal stones ≥ 2 cm size between November 2011 and November 2014. Stone size, operation, fluoroscopy and hospitalization time, success rates, stone-free rates and complication rates were compared in both groups. Patients were followed for three months.

Results: 254 patients were in the PNL Group. 185 patients were in the RIRS Group. The mean age was 46.88 and 48.04 years in PNL and RIRS groups, respectively.
The patient and stone characteristics (age, gender, Body Mass Index, kidney anomaly, SWL history and stone radioopacity) were similar between two groups.
The mean stone size preoperatively was significantly larger in patients who were treated with PNL (26.33mm.vs 24.04 mm.; $P = .006$). In the RIRS group, the mean stone number was significantly higher than PNL group ($P < .001$).
The mean operative, fluoroscopy and hospitalization time were significantly higher in PNL group ($P < .001$). The stone-free rate was 93.3% for the PNL group and 73.5% for the RIRS group after first procedure ($P < .001$). No major complication (Clavien III–V) occurred in the RIRS group.

Conclusion: Although the primary treatment method for renal stones ≥ 2cm size is PNL, serious complications can be seen. Therefore, RIRS can be an alternative treatment option in the management of renal stones ≥ 2 cm size.

Keywords: percutaneous nephrolithotomy; retrograde intrarenal surgery; urolithiasis

INTRODUCTION

Currently, shock wave lithotripsy(SWL), retrograde intrarenal surgery(RIRS) and percutaneous nephrolithotomy(PNL) are the three main modalities for renal stone treatment. The European Association of Urology and American Urological Association guidelines for the treatment of renal stones >20mm recommend percutaneous nephrolithotomy as the first-line therapy, independent of stone location within the kidney[1,2]. PNL has an excellent success rate in clearing stone burden at reported rate up to 96,1%[3]. Despite its effectiveness, serious complications, such as blood loss, sepsis, adjacent organ injury and life-threatening medical complications are rare but still a source of concern[4]. Therefore, there have been efforts to modify the procedure to decrease potential complications (such as mini-PNL, ultra mini-PNL)[5-7].
The aim of all these efforts is to apply more effective treatment choices and less invasive methods to patients, to reduce complications and to return to ensure a normal life as soon as possible. RIRS has recently been a very impressive treatment option for the majority of renal stones, as a result of the technological advances and developments in flexible ureteroscope, it can minimize the risks associated with PNL as an outpatient procedure[1]. RIRS is approved as effective and minimally invasive procedure with achieving higher stone-free rates than SWL and lower morbidity than PNL[8]. However, RIRS may be a first-line option for larger stones (even ≥ 2 cm size) in patients where PNL is not an option or contraindicated[1]. Moreover, several groups have demonstrated excellent success rates with RIRS for large renal stones and it has already replaced PNL as a first choice treatment for renal stones requiring active treatment at some centers[9-11].
In this retrospective study, we aimed to compare the outcomes of patients who have been treated with standard PNL and RIRS on renal calculi ≥2 cm size. Recently, several authors have reported similar studies in a limited number of patients[3,12]. To the best of our knowledge, this study is the largest cohort that compares these methods directly in the management of large renal calculi (> 2cm size). We aimed to compare the effectiveness and safety of PNL and RIRS in the

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treatment of renal stones sized ≥ 2 cm.

MATERIALS AND METHODS

In this study, we retrospectively reviewed patients data who underwent standard PNL or RIRS for renal calculi sized ≥2 cm by the same surgical team at a single institution between November 2011 and November 2014. Treatment method was chosen according to the urologist and patients preference after assessing both potential risks and benefits (complication rates, stone-free rates, the passage of residual fragments, possible operative times and re-treatment rates, postoperative double-J stent placement, etc.) of each surgical option. Patients with an ureteropelvic junction obstruction, anomalous kidneys (except horseshoe kidney), a history of open or percutaneous interventions to the ipsilateral kidney, <18 years of age, or those having a solitary kidney were excluded. A total of 439 patients met these criteria and were divided into two groups according to the procedure performed; PNL Group n = 254, and RIRS Group n=185. The demographics of the patients and operative outcomes were compared.

Preoperative patient assessment included medical history, physical examination, complete blood count, serum biochemistry, urinalysis and urine cultures, coagulation profiles, and by the use of different imaging methods (kidney ureter bladder (KUB) graphy, ultrasonography (USG), intravenous urography and/or computed tomography). A preoperative negative urine culture was required before surgery, so any positive urine cultures were treated according to the antibiogram results. Stone size was defined as the maximum diameter of the stone on computed tomography. In cases of multiple stones, stone size was defined as the sum of the longest axis of each stone. Informed consent was taken from all patients preoperatively.

PNL technique

All PNL procedures were performed under general anesthesia.Patients were placed in the lithotomy position.Cystourethroscopy was made for open ended uretheral catheter insertion. After uretheral catheter insertion , percutaneous access was achieved by C-arm fluoroscopic guidance using an 18-gauge needle with the patient in a prone position. A 0.035-inch J-tipped guidewire was passed through the needle and into the collecting system under fluoroscopic guidance, and the nephrostomy tract was dilated up to 30 f with polyurethane serial Amplatz dilators(Microinvazive,Natick,-MA) or metal Alken dilators. A 30F Amplatz sheath was then placed over the dilators. All steps of tract dilation and sheath placement were done under fluoroscopic imaging. Stone fragmentation was accomplished with pneumatic lithotripter (Lithoclast; EMS, Nyon, Switzerland) and the stones fragments removed with forceps through a rigid nephroscope (26F, Karl Storz®). A nephrostomy tube was placed in all the patients at the end of the procedure(13). Time between entering the cystoscope and nephrostomy tube placement was defined as operation time.

RIRS technique

All RIRS procedures were applied under general anesthesia with the patient placed in the lithotomy position and semi-rigid ureteroscopy was routinely performed before flexible ureteroscopy to facilitate the ureter dilatation for insertion of access sheath.. A 0.035/0.038-inch hydrophilic safety guidewire was inserted into the renal pelvis under fluoroscopic guidance. Thereafter, a ureteral access sheath (9.5/11.5 F or 11/13 F) (Elit Flex, Ankara, Turkey) was placed over the hydrophilic guidewire in all patients. If the access sheath could not be placed easily, the stent was left approximately 1-2 weeks before repeating the procedure . The flexible ureterorenoscope (Karl Storz, Flex X2, GmbH, Tuttlingen, Germany) was inserted through the ureteral access. Stone fragmentation was achieved with a 200 µm holmium laser fibers (Dornier Med-Tech GmbH, Medilas H20, Wessling, Germany) until they were deemed small enough to be passed spontaneously. The small fragments were finally evacuated using a manual pump or tipless nitinol baskets (Zero Tip™; Boston Scientific Microvasive). In the majority of patients, a JJ stent was put into place at the end of the procedure and removed approximately 14-21 days postoperatively as an outpatient procedure[11]. The repeated session was achieved at intervals of 1–3 weeks in patients with incomplete fragmentation or residual stones which were checked on postoperative day 1 with KUB graphy and USG (if necessary). Time between starting endoscopy and JJ stent placement was defined as operation time.

Stone size, operation and fluoroscopy time, hospitalization time, postoperative JJ stent placement, success rates, stone-free rates and complication rates (using the modified Clavien grading system) were compared in both groups. Data was reported as the number and percent or median (range) as appropriate.

Stone clearance was assessed in the operation with fluoroscopic control and the day after surgery by KUB graphy or USG . All patients were evaluated with KUB graphy and USG after one month postoperatively in an outpatient clinic setting. Asymptomatic stones smaller than 3 mm were considered as clinically insignificant urolithiasis. Patients who were stone-free or with clinically insignificant urolithiasis one month after the last operation were considered to have been treated successfully. Patients were followed for three months.

Statistical Analysis

Analyse of data was made with Statistical Package for the Social Sciences for Windows packet programme (SPSS, Chicago). Distribution of numerical measurement values was tested with One-Sample Kolmogorov-Smirnov Test. If p value was < 0.05, distribution was not normal. Differences in terms of gender, renal abnormality, stone side and localization, bleeding, DJ usage, residual stone presence, opacity, success after the first session, complication, hydronephrosis, preoperative surgery and SWL history between two groups were searched with Pearson chi-Square test. Differences in terms of age, weight, preoperative hemoglobin value between two groups were evaluated with Student's t test. Differences in terms of height, American Society of Anesthesiologists (ASA) scores, stone number, stone size, operation time, hospital stay, preoperative urea and creatinine and body mass index (BMI) between two groups were evaluated with Mann-Whitney U test. In PNL and RIRS groups, whether changes in preoperative and postoperative hemoglobin, urea and creatinine were significant, were measured with Wilcoxon Signed Ranks Test. $P < 0.05$ was considered statistically significant.

Table 1: Demographic data and stone characteristics

	PNL Group (n=254)	RIRS Group (n=185)	*p* value
Age (mean ± SD) (years)	46.88 ± 14.35	48.04 ± 14.09	ns.
Gender; Male/Female (n)	155/99	111/74	ns.
Mean BMI (kg/m^2)	27 ± 3.78	25.71 ± 3.02	ns.
Anomalous kidney, n (%)	8 (3.1)	11 (5.9)	ns.
History of SWL, n (%)	70 (27.6)	57 (30.8)	ns.
	Radioopacity of stone, n (%)		
Non-opaque	26 (10.2)	20 (10.2)	ns.
Opaque	228 (89.8)	165 (89.8)	
Stone laterality; Right/left (n)	120/134	89/94	ns.
Stone number (mean ± SD)	1.5 ± 0.1	2.0 ± 0.1	< 0.001
Stone size (mean ± SD) (mm)	26.33 ± 0.44	24.04 ± 0.39	0.006
Stone location, n (%)			
Renal pelvis	102 (40.2)	62 (33.5)	
Lower calyx	66 (24.4)	52 (28.2)	
Middle calyx	12 (4.7)	25 (13.5)	< 0.001
Upper calyx	8 (3.1)	13 (7)	
Multicaliceal	70 (27.6)	33 (17.8)	

Abbreviations: SD, standard deviation; BMI,Body Mass Index; SWL, Shock Wave Lithotripsy; RIRS, Retrograde Intrarenal Surgery; PNL, Percutaneous Nephrolithotomy; ns, non significant

RESULTS

In our study 254 patients were in the PNL Group. 185 patients were in the RIRS Group. The mean age was 46.88 and 48.04 years in PNL and RIRS groups respectively. The patient and stone characteristics(age, gender, Body Mass Index(BMI), kidney anomaly, SWL history and stone radioopacity) were similar between two groups.

The mean stone size preoperatively was significantly larger in patients who were treated with PNL, with the average size for RIRS being 24.04 mm. and that for PNL being 26.33 mm. (P = 0.006). In the RIRS group, the mean stone number was significantly higher than PNL group (P < 0.001). The demographic data and stone characteristics are summarized in **Table 1**.

Eleven patients in the RIRS group and eight patients in the PNL group had horseshoe kidney. In the RIRS group, 57 patients and 70 patients in PNL group had previously undergone unsuccessful SWL applications. The mean operative time, fluoroscopy screening time and hospitalization time were significantly higher in PNL group (P < 0.001, for all of them). In one patient access sheath was not placed and JJ stent was placed 2 weeks before the second procedure. However, postoperative JJ stent placement was also significantly higher in the RIRS group (P < 0.001).

The stone-free rate was 93.3% for the PNL group and 73.5% for the RIRS group after a single procedure (P < 0.001). In the RIRS group, 23 patients had asymptomatic residual fragments < 10 mm in the lower pole of the kidney and were followed without any intervention; 22 required additional procedure (SWL in 1, second RIRS in 16, PNL in 5) and all of them were completely stone free, resulting in an overall success rate of 85.4%. Four patients were also lost the follow-up in RIRS group. In the PNL group, the success rate increased to 94.8% after a RIRS intervention (in 4 patients). Thirteen patients were followed without any intervention due to the asymptomatic residual fragments.

When we look at the complication (major and minor) rates, the difference was not statistically significant (P = .058). Five patients in the PNL group received blood transfusions, whereas none of the patients in RIRS group were transfused. No major complication (Clavien III–V) occurred in the RIRS group. However, there were four major complications (1.5%) in the PNL group. Three patients suffered from prolonged urine leakage (Clavien III) which was treated with a JJ stent. One patient died (Clavien V) due to cardiac arrest. Operative and postoperative data are summarized in Table 2.

DISCUSSION

PNL is recommended as a first line treatment option in the management of renal stones sized ≥ 2 cm[1,2]. However, life-threatening complications can be seen. Another treatment method is RIRS. Arising in 1990's, use of RIRS has increased by developing technology and extending experience[14]. Development in new flexible renoscopes and laser technology led to increase in area of use of this method[15-17].

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 pa-

Table 2: Per-operative and Postoperative data

	PNL Group (n=254)	RIRS Group (n=185)	*P* value
Operation time (min)	79.25 ± 35	54.29 ± 14.09	< 0.001
Fluoroscopy screening time (min)	6.5 ± 4.97	1.04 ± 1.32	< 0.001
Preferred Access, n (%)			
Lower calyx	244 (97)	-	
Middle calyx	10 (3)		
Hospitalization time (day) (mean ± SD)	3.94 ± 1.22	1.02 ± 0.23	< 0.001
Double-J placement, n (%)	76 (30)	155 (83.8)	< 0.001
Stone-free status, n (%)			
Stone free	229 (89.8)	151 (72.6)[a] /167 (80.3)[b] /168 (80.7)[c]	
CIRF [d]	9 (3.5)	5(2.4)a /0 (0)b /0 (0)c	
Rest	17 (6.7)	52 (25)[a]/ 41 (19.7)[b] /40 (19.3)[c]	
Success rates e, n (%)	237 (93.3)	136 (73.5)	< 0.001
Complication rates, n (%)	21 (8.3)	7 (3.8)	ns.
Minor (Clavien I-II) Complications			
Fever	12 (4.72)	7 (3.8)	
Blood transfusion	5 (1.96)	-	
Urinary tract infection	7 (2.75)	7 (3.8)	
Major (Clavien III-V) Complications			
JJ placement for urine leakage	3 (1.18)	-	
Death	1 (0.39)	-	
Auxiliary procedure, n (%)			
SWL	-	1 (0.005)	
RIRS	4 (1.57)	16 (8.67)	
PNL	-	5 (2.7)	
Observation	13 (5.11)	23 (12.7)	

Abbreviations: SD, standard deviation; BMI, Body Mass Index; SWL, Shock Wave Lithotripsy; RIRS, Retrograde Intrarenal Surgery; PNL, Percutaneous Nephrolithotomy; ns, non significant
a: 1st RIRS sessions, b: 2nd RIRS sessions, c: 3rd RIRS sessions
d: Clinically insignificant residual fragments
e: Success is defined as stone free + CIRF

tients with renal stones of 20-25 mm[10]. Mariani et al. reported a success rate of 92% in 15 patients with renal stones of 2-4 cm size[18]. Grasso et al. reported a success rate of 91% for 51 patients with renal stones sized ≥ 2 cm[19]. Palmero et al. applied RIRS to 106 patients with renal stones sized ≥ 2 cm[20]. 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[21].

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[22]. 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[23]. 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[24]. The stone size was between 2- 4 cm in only two of ten studies taken into consideration.

In our study, RIRS and PNL methods were compared in 439 patients with renal stones sized ≥ 2 cm. The following success rates were found: 93.3% and 73.5 for PNL and RIRS groups, respectively and 94.9% and 85.4% for the same groups in terms of total success rate. The results were similar to those found in studies in the literature.

In our study, the operation duration was found to be 79.2

± 34.9 and 54.29 ± 14.09 minutes for PNL and RIRS groups, respectively. The efforts for stone clearence are one reason for this result. Akman et al. indicated the operation durations of 38.7 ± 11.6 and 58.2 ± 13.4 minutes for PNL and RIRS groups, respectively[22]. In another study, Bryniarski et al. reported 100.1 and 85 minutes for the PNL and RIRS groups, respectively[23].

In our study, the scopy time was determined to be 6.5 ± 4.97 and 1.04 ± 1.32 minutes for PNL and RIRS groups, respectively. The results were similar to those found in studies in the literature. The difference was explained on the basis of taking scopy for entry to kidney via percutaneous access.

In terms of hospitalisation period, we determined the periods of 3.94 ± 1.22 and 1.02 ± 0.23 days for PNL and RIRS groups, respectively. The period passing for taking percutaneous nephrostomy led to increase in hospitalisation time in the PNL group. Applying tubeless PNL may shorten this period. The decision for tubeless PNL is made on the basis of existence or nonexistence of intraoperative bleeding, residual stones or perforation. Tubeless PNL was not applied to any patient in our research.

In terms of bleeding status, it was significantly higher in PNL group compared to RIRS group. It was associated with longer operation duration. In their research, Akman et al. concluded that the need for blood transfusion increases by 2.82 times in PNL operations longer than 58 minutes[25].

When complication rates are taken into consideration, although more complication was seen in PNL group, the difference was not statistically significant. No major complication was seen in RIRS group. In PNL group major complications were seen. In PNL group one patient died due to cardiac arrest. The number of minor complications were higher in PNL group but the difference was not statistically siginificant. When the literature is assessed, life-threatening complications may be seen in PNL operation. These are transfusion-requiring bleeding, septicaemia, colon injury, hemothorax, fever and urinary system infection. In our study, one of our patients died. Transfusion-requiring bleeding was detected at the rates of 0.8% to 45% in PNL operation in literatüre[26-28]. Significant complications are not observed in RIRS operation due to developing technology. Mini and ultra mini PNL can be applied to prevent the complications due to the sheath size.

In our study JJ stent usage was higher in the RIRS group. The major reason is access sheath usage .Another reason is residuel stones. The stone free rates were lower in the RIRS group .

If we look at limitations of our study, its being retrospective is a disadvantage. Due to retrospective nature, stone size was different between the groups. Another limitation is short patient follow up. Therefore an important complication related to access sheath usage in RIRS was not seen in our study.

When previous studies are taken into consideration, it is the largest study in the literature in terms of number of patients.

For treatment of renal stones sized < 2 cm RIRS can be used as first line treatment[29]. RIRS can be used for patients not requesting invasive treatment for stones of sized ≥2cm. Total cost level is a disadvantage to RIRS. Its shorter duration of hospital stay and operation as well as lower complication levels can compensate this disadvantage. Another disadvantage is that it may require multiple sessions. PNL can be taken into consideration for patients requesting treatment in single session.

As a conclusion, ≥ 2sized stone treatment is one of the controversial issues in urology. PNL is more effective than RIRS in treatment of these stones. And primary treatment method. Although the primary treatment method is PNL, significant complications can be seen. RIRS can be taken into consideration in cases not requiring invasive treatment. Comprehensive and prospective studies are needed.

CONFLICT OF INTEREST

No competing financial interests existed.

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