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A Randomized Controlled Study to Analyze the Safety and Efficacy of Percutaneous Nephrolithotripsy and Retrograde Intrarenal Surgery in the Management of Renal Stones More Than 2 cm in Diameter

Piotr Bryniarski, Ph.D., Andrzej Paradysz, Ph.D., Marcin Zyczkowski, Ph.D., Andrzej Kupilas, Ph.D., Krzysztof Nowakowski, M.D., and Rafał Bogacki, M.D.

Abstract

Objective: The gold standard for removal of renal stones more than 2 cm in diameter is percutaneous nephrolithotripsy (PCNL). Retrograde intrarenal surgery (RIRS) has become more and more fashionable because of its high safety and repeatability, especially in smaller stones. Many retrospective studies have proved its efficacy and safety in larger calculi, however. We decided to compare prospectively both procedures in terms of safety and efficacy in renal pelvic stones more than 2 cm in diameter.

Patients and Methods: This was a randomized single tertiary care center trial with two arms (32 patients in each arm). The first group comprised patients who underwent PCNL, while in the second group, there were patients in whom RIRS with a semirigid ureteroscope was used. The primary end points were hematocrit and hemoglobin drop after surgery as equivalents of safety and stone disintegration rate in terms of efficacy. The secondary end points comprised operating room time, visual analogue scale of pain, pain treatment, and hospital stay.

Results: The mean hematocrit drop after the procedure was lower in the second group. Similarly, operating room time and hospital stay were significantly shorter after RIRS in comparison with PCNL. In the second group, patients had favorable features in terms of pain intensity and treatment after the procedure. PCNL showed higher efficacy (94%) in comparison with RIRS (75%). The power of 83% was calculated for the primary end point.

Conclusion: The efficacy of RIRS is acceptable and, emphasizing its high safety, it should be considered as a valuable alternative option for management of renal pelvic stones more than 2 cm in diameter.

Introduction

Nephrolithiasis is a very common illness affecting 5% of the population in the United States.[1] Untreated, it may lead to chronic kidney disease and finally end-stage renal disease. That is the reason that patients with kidney stones need prompt treatment and close monitoring.

Every year, the European Association of Urology (EAU) publishes its guidelines for stone disease treatment. For renal stones more than 20 mm, percutaneous nephrolithotripsy (PCNL) remains the treatment of choice independent of stone position within the kidney.[2]

New treatment methods, however, appear to be less invasive and safer but also less effective in retrospective studies. Retrograde intrarenal surgery (RIRS) is a procedure that has evolved since the advent of flexible laser fibers. Since its introduction in 1990, it has been used for small renal stones and after extracorporeal shockwave lithotripsy (SWL) failure.[3] With flexible ureteroscopes, urologists are now able to access even the lower calices of the kidney.[4] Unfortunately, these procedures have quite long learning curves and are burdened with high rates of fiber breakage. This may increase the complication rate and costs of the procedure. Therefore, RIRS with a flexible ureteroscope is used for smaller stones or, subsequently, after RIRS with a semirigid ureteroscope to disintegrate stone debris in the lower calix.

Because stones in the renal pelvis are quite easily accessible with rigid and semirigid ureteroscopes, we decided to test the efficacy and safety of these ureteroscopes in dealing with such stones and compare the results with the current gold standard—PCNL.

Department of Urology, Medical University of Silesia, Zabrze and Katowice, Silesia, Poland.

Patients and Methods

Ethics

The study was approved by the Silesian Medical University Ethics Committee and therefore has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All patients gave their informed consent before inclusion in the study.

Inclusion and exclusion criteria

The study was conducted prospectively between April 2008 and December 2010. Sixty-nine patients were enrolled in the study. Inclusion criteria consisted of:

a. Single stone located in the renal pelvis
b. Stone more than 2 cm in diameter

Exclusion criteria consisted of:

a. Previous stone treatment
b. Staghorn stone
c. Anatomic anomalies of the kidney

Three patients decided to undergo RIRS instead of PCNL during the randomization process and were disqualified from the study. Two patients did not undergo rediography in the 3 weeks after discharge and were excluded from the final analysis. Sixty-four patients completed the trial. The study was a per-protocol one, so only patients who completed the entire trial were the subjects of statistical analysis.

The patients received a diagnosis of renal pelvic stones in the outpatient clinic. Diagnosis was based on ultrasonography (US) of the abdomen and intravenous urography (IVU). During the day before endoscopic operation, radiography of the abdomen was performed in each patient and the position and size of the stone was confirmed.

Sample size estimation and randomization

Sample size was determined according to data in previous studies.[5] It was shown that hematocrit drop in the PCNL group is, on average, 5.5% and 1.5% in the RIRS group. It was calculated that analysis with 30 patients per arm will achieve 92% of power with 0.05 type I error. Finally, 32 patients were randomized and power analysis was conducted once more with current data to assess the reliability of the outcomes.

A simple randomization was performed at the day before the procedure using the random number function. Sixty-six patients who met our inclusion criteria were randomly assigned to two groups (PCNL and RIRS).

Endoscopic procedure

All patients are given prophylactic antibiotics (norfloxacin 400 mg twice a day) 1 day before the procedure, at the day of procedure, and 2 days afterward. At the day of surgery, patients are given 2500 mL of fluids intravenously, and the next day are given fluids orally. Paracetamol 1 g is given intravenously for each patient after surgery with 4 hour intervals up to the dosage of 4 g/d. In addition, pethidine hydrochloride 50 mg is injected intramuscularly on patient demand postoperatively. A hematocrit drop of more than 15%iss the single indication for blood transfusion.

The scheme of the PCNL and RIRS is described elsewhere. Briefly, before the PCNL procedure, a 5F ureteral catheter is inserted through a cystoscope. The percutaneous access to the renal pelvis is performed by the urologist. Retrograde pyelography is conducted at the beginning of the procedure. The telescopic dilation (classic prone position) with the PCNL set is used under fluoroscopic control through the lower calix. Finally, a 30F Amplatz sheath is positioned, and an ultrasonic lithotriptor with continuous irrigation is put in the sheath. After completion of PCNL, a 20F nephrostomy tube is inserted and clamped for 6 hours. Each procedure was performed by the same surgeon (A.K). Radiography of the abdomen is obtained the next day after the operation to evaluate the presence of residual stones.

Three weeks after the procedure, patient is advised to undergo a second radiographic evaluation of the abdomen to confirm that the stone was completely removed. If a residual stone is diagnosed, plans are made for the patient to undergo re-treatment. The kind of procedure depends on the size and localization of the stone.

For stones more than 2 cm, we use a standard semirigid ureteroscope 10/12F with tapered tip. The patient is in the dorsal lithotomy position. In addition, slight Trendelenburg position is obtained during insertion of instruments. First, a polytetrafluoroethylene guidewire is put in the ureter to allow safe passage of a 6/12 dilator. Second, the guidewire is evacuated, and a 5F stent is put in the ureter through the instrument's working channel. The ureteroscope is inserted in the ureter within the 5F stent, which now serves as a guide, until the kidney pelvis and stone are visualized. Rarely is such an insertion problematic with a 10/12F ureteroscope, and if occurs, the instrument is pulled back slightly. After that maneuver ureteroscope is gently pushed up while increasing the irrigation fluid pressure.

Occasionally, the proximal part of the ureter may be very narrow, which does not allow the safe passage of the instrument. In such situations, the procedure is aborted, the 5F stent is left in the ureter, and the patient is directed to the PCNL procedure. In each randomized patient in our group, however, we reached the enal pelvis with a semirigid ureteroscope. We did not perform fluoroscopy during RIRS.

The patient is then positioned in a light anti-Trendelenburg position, so larger fragments fall back directly on the laser tip. Disintegration of the stone is accomplished with a holmium laser (fiber 200 μ; energy 1.5 J; frequency 12 Hz; power 18 W; duration 150 μs; aiming beam 80%). Smaller stones are evacuated with baskets or graspers. If the debris located in the lower or middle calix is observed, the flexible ureteroscope is used for further disintegration. Routinely, a Double-J (DJ) catheter is placed after completion of the RIRS procedure, and radiography of the abdomen is obtained the next day after the operation to evaluate the position of the catheter and presence of residual stones. The day before discharge, the DJ stent is removed during cystoscopy. If the patient still has stone debris within the kidney, DJ catheter is left in the ureter, and the patient is discharged. Each procedure was performed by the same surgeon (M.Z). All patients after RIRS underwent ultrasonography (US) and IVU 3 months after the procedure to evaluate potential ureteral strictures.

Three weeks after the procedure, the patient is advised to undergo radiography of the abdomen to confirm that the stone was completely removed. If a residual stone $\geq$4 mm is

diagnosed, plans are made for the patient to undergo a second procedure with a flexible ureteroscope.

Statistical analysis

The study was designed as a randomized controlled trial to assess the safety and efficacy of two endoscopic procedures for renal pelvic stone disintegration (PCNL and RIRS). The primary end points were: hematocrit drop $\left(\frac{preoperative\ hematocrit - postoperative\ hematocrit}{preoperative\ hematocrit} \times 100\right)$, hemoglobin drop (computed similarly to hematocrit drop), and stone disintegration rate at the day after and 3 weeks after the procedure. The secondary end points comprised operating room time (min), pain (visual analogue scale) the day after the procedure, amount (mg) of pethidine hydrochloride administered for pain treatment, time of pain treatment (d), and hospital stay (d).

Univariate analysis was performed with the assistance of the *t* test for continuous variables with normal distribution and Mann-Whitney *U* test for variables without normal distribution. For categorical variables, the chi-square test was applied.

Multivariate analysis was performed to assess the primary end points (continuous variables) with the assistance of the generalized linear model. Adjusted means were computed with its 95% confidence intervals. Covariates comprised age, body mass index (BMI), and stone surface area (SA).

To assess and compare the disintegration rate between two aforementioned procedures, the discriminant analysis was performed. Covariates included in that model were age, sex, BMI, SA, side, and presence of urine stasis. Logarithmic transformation of variables without normal distribution in that model was conducted.

A P value of < 0.05 was considered significant. All analyses were conducted using Statistica Statsoft v. 8.0.

Results

Demographic and clinical characteristics are given in Table 1. The comparison of the outcomes between the groups is shown in Tables 2 and 3. The results were computed with univariate analysis. In both groups, there were no septic complications. All bleedings were treated conservatively and resolved spontaneously. We also did not observe the presence of abscesses within the wound after PCNL.

Multivariate analysis of primary and secondary end points confirmed the outcomes obtained in univariate analysis indicating that the RIRS procedure is more safe than PCNL (Table 4).

Finally, PCNL in discriminant analysis showed higher efficacy in the stone-free rate 3 weeks after endoscopy. We also observed such difference in stone-free rate assessed 1 day after endoscopy. As mentioned above, the type of procedure ($P = 0.005$) and SA ($P < 0.001$) in that analysis were statistically significant. Other variables such as age ($P = 0.3$), sex ($P = 0.3$), BMI ($P = 0.8$), side ($P = 0.5$) and concomitant stasis ($P = 0.9$) were not discriminative in terms of stone disintegration the day after the procedure. Similar results were obtained in terms of stone disintegration 3 weeks after endoscopy. Only type of procedure ($P = 0.01$) and SA ($P = 0.002$) were significantly discriminative.

In the PCNL group, two (6.25%) patients needed retreatment because of residual stones in the middle calix: 6 mm and 8 mm, respectively. They underwent single SWL with total stone disintegration. The efficiency quotient (EQ) for that group is 88%.

Similarly, in the RIRS group, four (12.5%) patients needed retreatment because of residual stones in the lower calix (two patients had a 4-mm stone, and other two, a 5-mm stone). They underwent RIRS with flexible instrument and holmium laser stone disintegration. The other four (12.5%) patients after primary procedure failure did not need secondary RIRS because the residual stones were less than 4 mm. The EQ for that group is 67%.

In none of the patients after RIRS were ureteral strictures diagnosed after 3 months with IVU. None of the patients had urine stasis or hydronephrosis in the US examination.

Given that the value of the hematocrit drop and corresponding standard deviation after both endoscopic procedures are as outlined in Table 3, we receive 83% power of test with 32 patients per arm.

Discussion

The EAU guidelines on urolithiasis state clearly that renal stones more than 2 cm in diameter should be managed with PCNL.[2] Authors emphasize the fact, however, that further studies are needed to evaluate RIRS as first-line treatment. It is obvious that not all renal stones are easily accessible with a rigid or semirigid ureteroscope. Only stones in the renal pelvis or upper calix may be an indication for RIRS. That is the reason PCNL is a more versatile option by which stones in calices and pelvis may be disintegrated.

The efficacy of PCNL in renal stones is high. In our study, the disintegration rates approach 82% and 94% 1 day after and

Table 1. Demographic and Clinical Characteristics of Analyzed Groups of Patients

	PCNL group (n = 32)	*RIRS group (n = 32)*	P *value*
Age, year, mean (SD)	51.8 (11.8)	53.4 (12.4)	0.2
Sex, no. (%)			
Female	16 (48.8)	17 (51.5)	0.8
Male	16 (51.6)	15 (48.3)	
Height, m, mean (SD)	1.67 (0.09)	1.7 (0.08)	0.21
Weight, kg, mean (SD)	78.03 (20.3)	81.3 (17.5)	0.22
BMI, kg/m^2, mean (SD)	27.35 (4.5)	27.76 (4.5)	0.44

PCNL = percutaneous nephrolithotripsy; RIRS = retrograde intrarenal surgery; SD = standard deviation; BMI = body mass index.

Table 2. Preoperative Characteristics of Analyzed Groups of Patients

	PCNL group (n = 32)	*RIRS group (n = 32)*	P *value*
Stone length, cm, mean (SD)*	2.4 (0.8)	2.2 (0.3)	0.77
Stone width, cm, mean (SD)*	1.8 (0,6)	2.4 (1.1)	0.09
SA, cm^2, mean (SD)	3.53 (1.7)	4.14 (1.5)	0.09
Side, no. (%)			
right	14 (43.7)	14 (43.7)	1.0
left	18 (56.2)	18 (56.2)	
Urine stasis, No. (%)			
yes	7 (21.8)	8 (25%)	0.76
no	25 (78.1)	24 (75%)	
Hemoglobin, g/dL, mean (SD)	13.99 (1.4)	14.47 (1.1)	0.38
Hematocrit, %, mean (SD)	40.4 (4.1)	40.33 (4.5)	0.74

*Estimated on abdominal radiography.
PCNL = percutaneous nephrolithotripsy; RIRS = retrograde intrarenal surgery; SD = standard deviation; SA = stone surface area (stone length × stone width × 3.14 × 0.25).

3 weeks after lithotripsy, respectively. The results from retrospective studies are similar.[6] PCNL, however, carries the significant risk of severe bleeding and need for blood transfusion in up to 30% of patients.[7–11] 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.[2] The other complication is fistula formation, which occurs in 7% of patients.[12] Finally, the mortality rate is estimated to be 0.5%.[13]

Usually, a hematocrit drop >2% (absolute value) after 6 to 12 hours may be considered significant.[14] Although we observed such a drop in both procedures, it was apparently higher after PCNL (Tables 3 and 4).

RIRS has good efficacy and a low complication rate with small renal stones.[15–18] 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 calpx is 47%, but increases up to 91% after an additional procedure.[19] In our study, the outcomes are similar, especially when assessed 1 day after surgery. Three

Table 3. Postoperative Characteristics of Analyzed Groups of Patients

	PCNL group (n = 32)	*RIRS group (n = 32)*	P *value*
OR time, min, mean (SD)	100.1 (29.9)	85 (17.6)	0.02
Hemoglobin, g/dL, mean (SD)[a]	12.3 (1.4)	13.5 (1.2)	0.002
Hematocrit, %, mean (SD)[a]	35.1 (4.1)	37.3 (4)	0.06
Hemoglobin drop, %, mean (SD)	11.8 (6.6)	6.4 (5.7)	< 0.001
Hematocrit drop, %, mean (SD)	12.7 (7.7)	7 (6.6)	< 0.001
Blood transfusion, No. (%)			
Yes	5 (15.6)	1 (3.1%)	0.08
No	27 (84.3)	31 (96.8%)	
Presence of stone at radiography, no. (%)[b]			
Yes	6 (18.75)	16 (50)	0.008
No	26 (81.25)	16 (50)	
VAS, points, mean (SD)[c]	3.5 (0.4)	2.5 (0.6)	0.002
Pethidine hydrochloride, mg, mean (SD)[d]	317.1 (192)	160.9 (101.3)	< 0.001
Pain treatment, d, mean (SD)	2.65 (1.4)	1.1 (0.4)	< 0.001
Fever >38°, no. (%)			
Yes	9 (28.1)	8 (25)	0.7
No	23 (71.8)	24 (75)	
Hospital stay, d, mean (SD)	11.3 (4.4)	6.8 (3.4)	< 0.001
Presence of stone at radiography, no. (%)[e]			
Yes	2 (6.25)	8 (25)	0.03
No	30 (93.75)	24 (75)	

[a]Blood sample collected 5 hours after procedure.
[b]Abdominal radiography the day after procedure, stone debris also included.
[c]Obtained 1 day after procedure.
[d]Throughout hospital stay.
[e]Abdominal radiography 3 weeks after discharge, stone debris also included.
PCNL = percutaneous nephrolithotripsy; RIRS = retrograde intrarenal surgery; SD = standard deviation; OR = operating room; VAS = visual pain analogue scale.

Table 4. Primary and Secondary Outcomes in Multivariate Analysis

	PCNL adjusted mean	*CI (±95%)*	*RIRS adjusted mean*	*CI (±95%)*	P *value*
Hemoglobin drop, %	11.8	14.1/9.6	6.3	8.6/4.1	<0.001
Hematocrit drop, %	12.6	15.3/10	7.1	9.7/4.5	<0.001
VAS, points	3.5	3.7/3.3	2.6	2.8/2.4	<0.001
Pethidine hydrochloride, mg	321.3	377.4/265.2	156.7	212.8/100.6	<0.001
Pain treatment, d	2.6	3/2.2	1.1	1.5/0.7	<0.001
Hospital stay, d	11	12.4/9.6	7.2	8.6/5.8	<0.001
OR time, min	102.7	111/94.5	82.3	90.5/74.1	<0.001

PCNL = percutaneous nephrolithotripsy; CI = confidence interval; RIRS = retrograde intrarenal surgery; VAS = visual pain analogue scale; OR = operating room.

weeks after endoscopy, however, the results are significantly better and approach the disintegration rate of 75%.

The main reason for the lower disintegration rate with RIRS in comparison with PCNL is that larger fragments fall back to the lower calix where they cannot be accessed with a semirigid ureteroscope. After that, urologists try to disintegrate them with a flexible ureteroscope; however, rarely with such equipment are urologists able to leave the kidneys without any stone debris. This is the main reason for failure of RIRS when assessed 1 day after the procedure. Interestingly, Smith and associates[20] described a technique to avoid such failure. At the beginning of the procedure, the authors were filling the lower calix with autologous blood, so stone debris did not fall back there during disintegration. Further studies are needed to evaluate whether that technique may increase the disintegration rate.

It is very important to understand that safe passage of the instrument through the proximal ureter is the first difficult step of that procedure. If apparent narrowing of the ureter is seen, it is better to abort the procedure and direct patients for PCNL. In our department, we have already conducted more than 100 RIRS with the semirigid ureteroscope and achieved more than 91% success in reaching the renal pelvis.

One may also be concerned about limited movements with with the semirigid ureteroscope during stone disintegration. Other maneuvers that facilitate the disintegration, however, include changing the position of the patient and filling/emptying the kidney pelvis. In addition, with limited maneuvers one may rotate the stone and make many holes in it. Finally, the stone will disintegrate into pieces. Then the situation is even more convenient, because smaller fragments fall back directly on the laser tip. The stone is usually disintegrated into smaller stones but most of it becomes very small "sand" that is evacuated with suction.

Not without significance are the results of secondary end points. The lower intensity of pain after RIRS makes it more convenient for the patient. Even burdened with lower efficacy, probably one would choose RIRS rather than PCNL if asked before the procedure. RIRS is obviously more cost-effective, especially when the amount of painkillers used, hospital stay, and operating room time are taken into consideration. These favorable features may be less prominent when the patient needs to be treated once more. Also, other techniques such as tubeless PCNL seem to have favorable characteristics in terms of pain intensity and treatment.[21]

One may be concerned about hospital stay in our study. In most Western countries, RIRS is considered an outpatient procedure in which the patient is discharged after 24 hours. Similarly, PCNL usually needs only 2 days of hospitalization. Our approach (from the procedural causes) is different, and therefore patients need a longer stay. We do not want to indicate the absolute amount of time needed for hospitalization (because it is sometimes country dependent), but we emphasize the relative difference in hospital stay between these two procedures.

Another reason for prolonged hospital stay is that we use a wide ureteroscope for RIRS. To avoid potential strictures, patients need a longer hospitalization, so ureters are able to recover with ureteral stents inserted. We emphasize that all patients after RIRS underwent IVU and US after 3 months of the procedure and in none of them were ureteral strictures diagnosed.

Our study has obvious limitations. The most important limitation is that we adopted a 15% hematocrit drop as a single indication for blood transfusion. Such a drop in the PCNL group was three times more frequent than we primarily expected. We decided to strictly follow this protocol to keep the study completely prospective, even though it meant that the transfusion rate was falsely increased. In the cohort of patients who were treated with PCNL in our department, the transfusion rate is 5.4%. Second, we emphasize that only a part of all renal stones may be managed with RIRS. Size and location are particularly crucial in selecting patients for that procedure. The largest stone that has been managed was 4 cm in diameter. There were no staghorn calculi in our group; however, even in such stones, RIRS was also described to be effective.[22] Third, the number of patients in each arm is small; however, the power analysis showed good reliability of the results. Finally, it was a single tertiary care center study.

Conclusions

Occasionally, bleeding after PCNL may be life threatening. The risk of significant hematocrit drop and need for blood transfusion make the procedure less safe than RIRS in which such complications are rare. On the other hand PCNL, remains more effective when evaluated 1 day after surgery as well as 3 weeks after. Nevertheless, the efficacy of RIRS is acceptable and, emphasizing its high safety, it should be considered a valuable option for management of renal pelvic stones more than 2 cm in diameter.

Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Piotr Bryniarski, Ph.D.
Department of Urology
Medical University of Silesia
3 Maja Street 13/15
41-800 Zabrze, Silesia
Poland

E-mail: piotr.bryniarski@hotmail.com

Abbreviations Used

BMI = body mass index
DJ = Double-J
EAU = European Association of Urology
EQ = efficiency quotient
IVU = intravenous urography
PCNL = percutaneous nephrolithotripsy
RIRS = retrograde intrarenal surgery
SA = stone surface area
SWL = shockwave lithotripsy
US = ultrasonography