

Extracorporeal Shock Wave Lithotripsy and Retrograde Intrarenal Surgery for renal pelvis stone of 1-2 cm: a randomized clinical trial

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Submitted

August 3, 2022

Accepted

September 3, 2022

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Citation: Khan S, Ur-Rehman I,
Ullah A, Azam A, Bibi R, Khan
M, et al. Extracorporeal Shock
Wave Lithotripsy and Retrograde
Intrarenal Surgery for renal pelvis
stone of 1-2 cm: a randomized
clinical trial. J Rehman Med Inst.
2022 Oct-Dec;8(4):3-6.

ABSTRACT

Introduction: Urolithiasis is a common medical problem, having the probability to recur within 10 years. The choice of initial stone removal procedure has been established as a factor in recurrence of disease through enabling a stone-free period. There is a dearth of local studies on this topic to address the choice of initial stone removal procedure.

Objective: To compare the stone-free rate following Extracorporeal Shock Wave Lithotripsy (ESWL) and Retrograde Intra Renal Surgery (RIRS) for renal pelvic stone of 1-2 cm.

Materials & Methods: This randomized clinical trial was conducted in the Department of Urology, Lady Reading Hospital MTI, Peshawar, over a period of six months (July to December 2021) on 60 patients of renal pelvis stones, randomized equally into Group A (ESWL) and Group B (RIRS). In Group A parenteral analgesic was administered for pain relief. The ESWL was performed with patients in supine and lateral position while for Group B general anesthesia was administered. The RIRS was performed with patients in Supine Lithotomy position. All patients were investigated using Ultrasound and X-ray KUB (Kidney, Ureter, Bladder) done by senior sonologist of the hospital and CT KUB without contrast to confirm the presence of stones, their size and location. Ultrasound and X-ray KUB were obtained one month post-operative day of procedure to assess the clearance of stone in each group. Data were analyzed for descriptive and comparative statistics by SPSS 20.

Results: The mean age in Group A was 41 ± 10.67 years, and in Group B it was 42 ± 9.09 years. In Group A 20(67%) patients were male and 10(33%) patients were female; in Group B 21(70%) patients were male and 9(30%) patients were female. At one month postoperative follow-up, Group A had 10(33%) stone-free patients, and 20(67%) patients not stone-free. Group B had 22(73%) stone-free patients, and 8(27%) patients who were not stone-free. These differences of stone-free frequencies among the groups were statistically significant ($p < 0.05$).

Conclusion: The stone-free rate was significantly decreased in Extracorporeal Shock Wave Lithotripsy patients as compared to Retrograde Intrarenal Surgery patients for renal pelvic stone of 1-2 cm.

Keywords: Kidney Pelvis; Kidney Calculi; Lithotripsy; Nephrolithiasis.

The authors declared no conflict of interest. All authors contributed substantially to the planning of research, data collection, data analysis, and write-up of the article, and agreed to be accountable for all aspects of the work.

INTRODUCTION

Urolithiasis is a common medical problem. Studies show that patients with a history of kidney stones are likely to be diagnosed with kidney stone recurrence within 10 years. Patients with kidney stones may present with pain in right or left lumbar area, colicky in nature, sudden in onset, radiating to the back, along with hematuria, urinary tract infection, decreased kidney function, and even kidney failure.^{1,2} The estimated prevalence of urolithiasis is 10-15% in the population of developing countries but only 1-2% symptomatic patients come to the hospital for treatment. Renal stone disease is persistent in nature with a 50% return rate prospectively within 5 years. Similarly, the number of newly diagnosed cases and patients coming to the public sector hospitals for treatment has increased.³

There are varieties of treatment for kidney stones. One of them is a non-invasive technique which is known as Extracorporeal Shock Wave Lithotripsy (ESWL); it breaks the stones using shock waves. Other minimally invasive methods such as those of Percutaneous Nephrolithotomy (PCNL) and Retrograde Intrarenal Surgery (RIRS) are also extensively used to manage kidney stones due to a limited success rate of ESWL. Although ESWL is a non-invasive procedure easily done under local anesthesia, but still it has its own limitations related to patients with obesity and urinary tract infection.

ESWL is recommended to treat renal calculi smaller than 2 cm. The 20120 EAU guidelines on urolithiasis state clearly that ESWL remains the method of first choice for stones less than 2 cm within the renal pelvis and upper or middle calices.⁴ Moreover, ESWL has gained rapid global acceptance due to easy applicability, noninvasiveness, high efficacy in treating kidney and ureteral stones, and wide availability of lithotripters.⁵ Some of the research articles show that retrograde intra-renal surgeries were more effective than shock wave lithotripsy to treat 1 to 2 cm renal pelvic calculi in terms of a better stone-free rate, and lesser auxiliary procedure.⁶ Some studies demonstrated that ESWL and RIRS had stone-free rates of 71.4% and 84.2% respectively;

moreover, the mean procedure number was 1.18 in RIRS group.^{7,8} RIRS is considered superior to ESWL in terms of stones clearance.

However, both procedures are considered to be gold standards for kidney stone removal. The present study was conducted to compare both procedures for renal pelvic stone of 1-2 cm in size in terms of stone free rate. In this study, we compared the outcomes of ESWL and RIRS for 1–2 cm renal pelvic stone.

MATERIALS & METHODS

This randomized controlled trial study was conducted in the Department of Urology, Lady Reading Hospital MTI, Peshawar, Khyber Pakhtunkhwa, from July to December 2021 based on consecutive non-probability sampling of patients admitted for renal pelvis stones. The inclusion criteria were ages of 20-50 years, both genders, all patients with renal pelvis stones on non-contrast CT KUB (Kidney, Ureter and Bladder) of sizes 1-2 cm. To avoid bias, confounders, and to reduce the effect modifiers, selected exclusion criteria were pregnant women (based on history and ultrasound), active urinary tract infection (positive urine culture), ureteric stricture (based on CT evidence of previous KUB surgery), and a history of concomitant renal stones (based on ultrasound). All of these factors were assessed by taking detailed history of the patients including previous surgical history, drug history, and past medical records available with patients.

The purposes and benefits of the study were explained to included patients before written informed consents were obtained. All patients were investigated using Ultrasound KUB and X-ray KUB done by senior sonologist of the hospital and CT KUB without contrast to confirm the presence of stones, size and location. Other investigations included urine examination, including culture and sensitivity to confirm the presence or absence of urinary tract infection, renal functional tests (blood urea and serum creatinine) and complete blood picture.

Patients were randomized into two groups by random calculation through Microsoft Excel. Group A patient underwent ESWL and Group B patient underwent RIRS. In group A parenteral analgesic was administered for pain relief. The ESWL was performed with patients in supine and lateral position while for Group B general anesthesia was administered. The RIRS was performed with patients in Supine / Lithotomy position.

CT KUB was done 1 month postoperative day to assess the clearance of stone in each group; residual stones of less than 4mm were declared as stone-free rate. All the above mentioned information including name, age, duration of study and stone sizes were recorded in predesigned Performa.

Data were analyzed for all the independent and dependent variables through SPSS version 20. Mean and standard deviation was computed for all the quantitative variables, such as age, stone size, and duration of pelvis stone. Frequency and percentages in tabular form were calculated for categorical variables such as gender.

The Chi Square test was used for comparing the association of stone-free rate with the respective procedures. Stone-free rate

was also stratified by age, gender, and duration of pelvic stone to identify effect modifiers. Post stratification Chi Square test was applied with $p \leq 0.05$ considered significant.

RESULTS

The mean age of Group A patients was 41 ± 10.67 years, whereas in Group B the mean age was 42 ± 9.09 years. A significantly better outcome was seen in the RIRS group in the 31-50 years age group (Table 1).

Table 1: Stone free rate with age distribution (n=30 per group).

Age (years)	Stone Free Rate	Group A (ESWL)	Group B (RIRS)	p value
20-30	Yes	04	09	0.0618
	No	07	03	
Total		11	12	
31-50	Yes	06	13	0.0134
	No	13	05	
Total		19	18	

Gender distribution among the two groups was analyzed; in Group A 20(67%) patients were male and 10(33%) patients were female, whereas in Group B 21(70%) patients were male and 9(30%) patients were female. Both genders performed significantly better with RIRS in terms of the stone-free rate (Table 2).

Table 2: Stone free rate with gender distribution (n=30 per group).

Gender	Stone Free Rate	Group A (ESWL)	Group B (RIRS)	p value
Male	Yes	07	15	0.0193
	No	13	06	
Total		20	21	
Female	Yes	03	07	0.0372
	No	07	02	
Total		10	09	

The duration of pelvic stone among the two groups was analyzed. In Group A, 13 (43%) patients had duration of pelvic stone ≤ 1 year, and 17 (57%) patients had duration of pelvic stone > 1 year, with the mean duration of pelvic stone being 1 ± 1.31 year. In Group B, 14 (47%) patients had duration of pelvic stone ≤ 1 year and 16 (53%) patients had duration of pelvic stone > 1 year, with the mean duration of pelvic stone being 1 ± 1.37 year. Significant differences were observed in the RIRS group irrespective of duration of stone (Table 3).

Table 3: Stone free rate with duration of pelvic stone (n=30 per group).

Duration	Stone Free Rate	Group A (ESWL)	Group B (RIRS)	p value
≤ 1 Year	Yes	04	10	0.0346
	No	09	04	
Total		13	14	
> 1 Year	Yes	06	12	0.0220
	No	11	04	
Total		17	16	

The stone sizes among the two groups were analyzed, showing that Group A had 21 (70%) patients of stone sizes of 1 cm and 9 (30%) patients had stone sizes of 2 cm, with the mean size of 1.3 ± 0.57 cm. In Group B, 22 (73%) patients had stone sizes of 1 cm and 8 (27%) patients had stone sizes of 2 cm, with the mean size of 1.5 ± 0.61 cm. Stone-free rate among two groups was analyzed showing that in Group A, 10 (33%) patients were stone-free and 20 (67%) patients were not stone-free. In Group B, 22 (73%) patients were stone-free and 8 (27%) patients were not stone-free; additional sessions of ESWL and mini PCNL were required for the patients who were not stone-free. -RIRS was statistically superior to ESWL in stone size of 1 cm (Table 4).

Table 4: Stone free rate with stone size (n=30 per group).

Stone Size	Stone Free Rate	Group A (ESWL)	Group B (RIRS)	p value
1 Cm	Yes	07	16	0.0096
	No	14	06	
Total		21	22	
2 Cm	Yes	03	06	0.0858
	No	06	02	
Total		09	08	

DISCUSSION

According to a research study in China, by Pan J et al,⁹ Effective Quotients (EQ) for RIRS and mPCNL were 0.52 and 0.90, respectively. Initial stone-free rates (SFR) were 71.4 and 96.6%, respectively, for the RIRS group and the mPCNL group ($p=0.001$). In the RIRS group, the mean procedure number was 1.18, while in the mPCNL group, it was 1.03 ($p=0.035$). The mean hospital stay was shorter ($p=0.001$), although the operative time for RIRS was higher ($p=0.001$). Perioperative complications did not differ statistically across the groups. The RIRS group's first hospitalization, laboratory and radiology test costs were lower ($p=0.001$). The overall hospitalization cost, overall laboratory and radiology test cost, and post-operative out-patient department (OPD) visit costs were comparable across the two groups when the retreatment cost was considered. Thus, faster stone clearance and a reduced incidence of retreatment without significant side effects were obtained by mPCNL with equivalent total medical costs, suggesting that the procedure was more cost-effective for treating single renal stones having sizes of 2-3 cm. For patients who have contraindications to, or a preference against mPCNL, RIRS offers a further safe and preferred option.

In another study, Resorlu B et al¹⁰ had reported that the stone-free rate was 84.2% for the RIRS group and 85.8% for the mPCNL group after a single procedure ($p=0.745$). With supplementary therapy for RIRS and mPCNL, these percentages increased to 92.6% and 94.3%. In mPCNL and RIRS, minor problems categorized as Clavien I or II occurred in 17% and 8.4% of patients. No significant or major problems (Clavien III-V) occurred in either group. Although mPCNL had higher overall complication rates, these differences were not statistically significant ($p=0.07$). The mPCNL group had 7 patients who got blood transfusions, but none of the children in the RIRS group did ($p=0.015$). The mPCNL group's average hospital stay, fluoroscopy, and surgery periods were all much longer.

Among the first things to consider when choosing among different treatments for managing renal pelvic stones is a stone-free rate. In a pairwise meta-analysis of PCNL and RIRS reported in 2015,¹¹ the complication rate (OR 1.61; 95% CI 1.11–2.35; $p<0.01$), postoperative hemoglobin drop (weighted mean difference 0.87; 95% CI 0.51–1.22; $p<0.00001$), and hospital stay (weighted mean difference 1.28; 95% CI 0.79–1.77; $p<0.00001$) of RIRS showed better results than PCNL. However, the stone-free rate of PCNL was higher than that of RIRS (OR 2.19; 95% CI 1.53–3.13, $p<0.001$).

In another study, Zhang and colleagues performed pairwise meta-analysis of PCNL, ESWL, and RIRS for lower pole renal stones, showing better results of PCNL in terms of the stone-free rate compared to RIRS (OR, 0.41; 95% CI, 0.21–0.82; $p=0.012$) or ESWL (OR, 8.75; 95% CI, 3.29–23.26; $p<0.001$); no statistical difference was found between ESWL and RIRS (OR 1.97; 95% CI 0.98–3.95, $p=0.057$).¹²

In a research by Al-Zubi et al,¹³ 65.8% of the 155 patients showed overall success with their ESWL treatment, while in our study stone free rate was successful in 7 patients having stone size 1cm with $p=0.0096$, and in 3 patients having stones size 2 cm with $p=0.0858$. Ureteral stone passage rates were 35-70% in a USA 28-day trial, with stones passage in 4.6-20 days;¹⁴ in a Turkish study,¹⁵ stones passing rate was 53.57%, ESWL were more effective for stone of less 1cm or less and in distal ureter.¹⁶

CONCLUSION

The stone free rate was less in Extracorporeal Shock Wave Lithotripsy as compared to Retrograde Intrarenal Surgery for renal pelvic stone of 1-2 cm.

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