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Comparison of Stone Clearance in Extracorporeal Shock Wave Lithotripsy versus Micro-Percutaneous Nephrolithotomy in Patients with Small Renal Calculi

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ABSTRACT

Background: Renal calculi are a common urological problem, and the choice between minimally invasive options depends mainly on stone size and location. Extracorporeal shock wave lithotripsy (ESWL) and micro-percutaneous nephrolithotomy (Micro-PCNL) are standard treatments for small renal stones, but their comparative efficacy remains uncertain. **Objective:** To compare stone clearance outcomes of ESWL and Micro-PCNL in patients with small renal calculi. **Study Design:** Quasi-experimental study. **Settings:** Department of Urology, Sir Ganga Ram Hospital, in collaboration with Jinnah Hospital, Lahore, Pakistan. **Duration:** 16th July 2021 to 15th August 2022. **Methods:** Following ethical approval, 92 patients aged 18–65 years with renal stones <1.5 cm and normal renal anatomy were enrolled through non-probability consecutive sampling and divided equally into ESWL and Micro-PCNL groups (n = 46 each). Stone-free status was assessed by X-ray KUB. Data were analyzed using the Chi-square test, with $p < 0.05$ considered significant. **Results:** Mean stone size was 14.5 ± 0.50 mm in the Micro-PCNL group and 11.8 ± 2.64 mm in the ESWL group. Stone-free rates were 63% and 65.2%, respectively ($p = 0.82$). However, for stones >13 mm, Micro-PCNL achieved significantly higher clearance (63%) compared to ESWL (29.4%) ($p = 0.018$). **Conclusion:** Both ESWL and Micro-PCNL are effective for small renal stones, with no significant difference in overall clearance rates. Micro-PCNL, however, provides better outcomes for stones larger than 13 mm, making it a more suitable choice for slightly larger calculi within the small-stone category.

Keywords: *Stone free status, Micro-PCNL, ESWL, Small renal stones.*

INTRODUCTION

Nephrolithiasis is one of the serious conditions affecting human health to a great extent all around the world.[1] In South Asia including Pakistan about 1% - 19.1% of the population suffers from nephrolithiasis. The incidence of nephrolithiasis reaches its peak in population aged over 30 years. Males are more likely to suffer from urinary calculi with male to female ratio 1.9:1.[2] The kidney is the most common site for the development of urinary tract stones. Across the world, a rise in the prevalence of diseases related to nephrolithiasis has been observed, which is considered to be affected by diet, hot weather, lifestyle, hereditary factors, and comorbidities.[3] The rise in the incidence of renal stones creates the need for an effective and safe treatment choice.[4] Treatment options for nephrolithiasis are noninvasive and invasive. Noninvasive methods include watchful waiting, medical expulsive therapy, and Extracorporeal Shock Wave Lithotripsy (ESWL), and invasive methods include Uretrorenoscopy (URS), Percutaneous Nephrolithotomy (PCNL), Laparoscopic, Robotic, and open surgery.[5,6] Stone management depends on the stone and patient-dependent features such as stone size, location, patient habitus, and anatomy of the renal collecting system. Considering noninvasive procedures, watchful waiting and medical expulsive therapy are less common because many patients, due to worsening of their symptoms, derangement of renal function, and professional demand, require an active management but most of the patients also have fear of surgery, so ESWL can be the treatment of choice.

Many urologists and patients prefer extracorporeal Shock Wave Lithotripsy (ESWL) as it is a low-morbidity outpatient procedure.[7] ESWL is a non-invasive treatment of kidney stones with an acceptable success rate.[8] It is well recognized that the popularity of ESWL has been reduced during the past years, regardless of its non-invasive feature. This is somewhat elucidated by technological accomplishments acquired in the field of endo-urology. One more explanation is that numerous urologists have faced failure or have had insufficient success with ESWL in the removal of kidney stones. This effect may be because of the performance of the lithotripter used during the procedure of ESWL, but mostly, it is proved that the principles of the method of applying ESWL conducted before were poorly applied.[9]

Decision of invasive procedure (micro-PCNL) has to be made in patients with ESWL-resistant stones, stone location and patient habitus not suitable for ESWL, worsening of the symptoms, severe pain not responding to medication, stone causing recurrent Urinary tract infection (UTI), compromising renal function or obstructing the solitary functioning kidney. Sometimes patient opts for a single procedure, which can achieve complete stone clearance, and also some professions require complete stone clearance before the person can return to his/her job. Micro-PCNL provides a similar stone-free rate and a lower additional treatment rate for kidney stone disease.[4] Miniaturized PCNL procedures have gained increased popularity in recent years.[10] One study found that the success rate of micro-PCNL was 97.1% for the management of renal calculi of less than 1.5 cm.[11] Another study found 80% success rate of micro-PCNL for the management of renal calculi with average size of 1.6 cm.[12] However, a study has found stone-free status in 78.2% of cases.[12,13]

Literature showed that micro-PCNL, although invasive procedure but has more successful stone free rate than ESWL. One trial found that the stone free rate was 92.3% with micro PCNL while 75% with ESWL in patients with 1-2cm sized renal calculi. (P=0.017).[14] One more trial also showed similar findings, i.e., stone stone-free rate in 95.3% vs. 75% with micro PCNL versus ESWL in patients with 2-3 cm-sized renal calculi (p<0.001).[15]

There exist questions of which option to proceed with, though the literature shows that micro-PCNL may be superior in stone-free rate is a relatively newer procedure and has an invasive component, whereas ESWL has been used extensively and is less invasive despite lower stone-free rates. Addition to the current knowledge can enhance practitioners' evidence-based decision making for management options. The rationale to conduct this study is due to the limited evidence available comparing Micro-PCNL to ESWL, especially in the local population; the mounting evidence of greater stone-free rates with Micro-PCNL merits investigation especially in populations that are indigenous to the stone belt. The result of the current study will help to determine which procedure has a more successful stone clearance rate for management of small renal calculi. Thus, patient would undergo that procedure and avoid other procedures, which have a lower stone clearance rate for management of small renal calculi. The objective of this study is to compare the outcome of stone clearance with extracorporeal shock wave lithotripsy versus micro-percutaneous nephrolithotomy in patients with small renal calculi.

METHODS

This was a Quasi-Experimental study conducted at the Department of Urology, Sir Ganga Ram Hospital, Lahore, in collaboration with the Department of Urology, Jinnah Hospital, Lahore, for ESWL. While PCNL was done at Sir Ganga Ram Hospital, Lahore, during the time duration from 16th July 2021 to 15th August 2022. After approval from ERB vide letter No. 30 – Synopsis-MS-Urology/FJ/ERC on 16th July, 2021, the calculated sample size was 80 by using 80% power of the study, 5% level of significance, and percentage of stone-free status, i.e. 95.3% micro PCNL and 75% with ESWL. But after adding a 20% dropout rate the total sample size was 92 (46 in each group). Sample selection was done with the help of nonprobability, consecutive-sampling. Inclusion criteria for this study was patients aged between 18-65 years, both genders diagnosed with kidney stone, patients having kidneys in normal anatomical position with renal stone, patients with solitary kidney, either anatomical or functional, and renal stone size <1.5cm. The following patients were excluded from the study: ESWL resistant renal stones less than 1.5cm, Patients with multiple renal stones (assessed on CT scan) in different calyces (upper, middle, lower), Morbid obesity with a BMI >30, and bleeding diathesis (The coagulation profile was assessed, and patients with any abnormal results were excluded, even if they are on anticoagulants or have a medical history of bleeding issues.).

After obtaining the approval of the research project from the ethical board, 92 (46 in each group) patients fulfilling selection criteria were enrolled in the study at the Department of Urology, Sir Ganga Ram Hospital, Lahore, for Micro PCNL and Jinnah Hospital, Lahore, for ESWL. The feasibility and availability of both procedures were explained to the patient, and they decided on the type of procedure**.** Patients were consecutively selected until our sample size for each group was completed (Group A

=Micro-PCNL, Group B = ESWL). Informed consent was obtained from each patient. All patients had a detailed history and examination recorded and an ultrasound KUB done before any treatment. Demographic details (name, age, gender, location of stone, duration, and size of stone) were noted. The principal investigator collected all the data and filled out the proforma.

Micro-PCNL: Firstly, the patient was placed in the lithotomy position, cystoscopy was done, and the ureteric catheter was inserted and fixed to the transurethral Foley's catheter. The patient was repositioned to the prone position, and the pelvicalyceal system was demarcated by injecting the contrast medium. The 4.8 Fr PCNL access needle was inserted in the desired calyx under the fluoroscopic guidance, and a guide-wire was passed into the calyx. After the appropriate calyceal access, the three-way connector was attached to the needle. This would connect the saline irrigation tube, an adapter to allow 272μm laser fiber, and the 0.9mm flexible microperc telescope. Saline irrigation was done by using the mechanical pump with the foot pedal controls. Saline irrigation was kept to the lowest, which was just adequate for proper visualization. Normally, the intermittent saline irrigation with a flow rate of 100 ml/min offers good visualization without raising the intrarenal pressures. The ureteric catheter continuously drained the pelvicalyceal system. Intermittent manual suction via ureteric catheter further decreased the intrarenal pressure. The stone was completely marked with the laser. Then patients were shifted to the post-surgical ward and were followed up there. On 1st post-operative day, patients underwent X-ray KUB to confirm the stone clearance and ultrasound at 4 weeks. If there were no residual stone present inside the kidney at 4 weeks, then success was labeled. The researcher was the first assistant during all the procedures. All this information was recorded on a proforma (attached).

ESWL Procedure: The electromagnetic STORZ MEDICAL MODULITH SLX F2, Switzerland was used. Shockwaves were delivered at a rate of 90 shocks/min to a maximum of 3000 shocks per session. Stone disintegration was evaluated with a plain film and ultrasonography 4 weeks after 2 sessions, each session done 2 weeks apart. Evaluation for ESWL stone clearance was done only at completion of all sessions at 4 weeks.

Data Analysis: Data was entered and analyzed by SPSS v. 22.0. Mean and standard deviation were calculated for quantitative variables like age, duration since onset of diagnosis of renal stones and size of stone. The qualitative variables, i.e., gender, location of stone, stone-free status were presented as frequency and percentage. Both groups were compared for stone-free status by using a chi-square test. P-value≤0.05 was considered significant. Data was stratified for age, gender, location of stone, duration and size of stone. Post-stratification, both groups were compared for stone-free status by using the chi-square test for each stratum. P-value≤0.05 was considered significant.

RESULTS

In the micro-PCNL Group, the mean age of participants in the group was 37.2 ± 13.6 years. There were 30.4% (n=14) females and 69.6% (n=32) males in the study group. None of the stones were located in the upper pole. 39.13% (n=18) stones were located in the mid-kidney, 30.45% (n=14) were located in the lower pole, and 30.45% (n=14) were located at the renal pelvis. The stones were located in 54.3% (n=25) in the right kidney and 45.7% (n=21) in the left kidney. Patients had symptoms on average for 7.41±4.16 months. Mean Stone size was 14.5 ± 0.50 mm. (Range: 13.5-15mm.) Stone free rate was 63% (n=29). In the ESWL Group, the mean age of participants in the group was 34.5 ± 12.1 years. There were 21.7% (n=10) females and 78.3% (n=36) males in the study group. 4.3% (n=2) were located in the upper pole. 19.6% (n=9) stones were located in the mid-kidney, 26.1% (n=12) were located in the lower pole, and 50% (n=23) were located at the renal pelvis. The stones were located in 50% (n=23) in the right kidney and 50% (n=23) in the left kidney. Patients had symptoms on average for 5.72 ± 7.17 months. Mean Stone size was 11.8 ± 2.64 mm (Range 5.6-15mm). Stone-free rate was 65.2% (n=30).

Table 1: Stone characteristics in study groups

Variables	Micro-PCNL N = 46	ESWL N = 46	p-value
Age (years)	37.2 ± 13.6	34.5 ± 12.1	**0.317(t)**
Gender (M/F)	30.4%/69.6%	21.7%/78.3%	**0.344(c)**
Duration of Symptoms (weeks)	7.41±4.16	5.72 ± 7.17	**0.170(t)**
Stone Size (mm)	14.5 ± 0.50	11.8 ± 2.64	**<0.001(t)**
Stone Size (Range)	13.5-15	5.6-15	
Side of Kidney			
Right Kidney	25(54.3%)	23(50%)	**0.678(c)**
Left Kidney	21(45.7%)	23(50%)	
Location of Stone			
Upper Pole	0(0%)	2(4.3%)	**0.061(c)**
Mid Kidney	18(39.1%)	9(19.6%)	
Lower Pole	14(30.4%)	12(26.1%)	
Renal Pelvis	14(30.4%)	23(50%)	
Stone Free	29(63%)	30(65.2%)	**0.828(c)**

(c) Chi square test, (t) Independent sample t-test

The odds ratio for stone clearance if age is less than 50 years for the ESWL group was 0.31. The odds ratio for stone clearance if age was less than 50 years was 0.62 for the micro-PCNL group. The odds ratio for stone clearance if the stone was present in the left kidney was 1.33, as compared to if the stone was present in the right kidney, which had an odd of stone clearance of 0.75. The odds of stone clearance in the ESWL group for stones located at the mid-kidney, lower pole, and renal pelvis were 2.13, 0.41, and 1.46, respectively, and for the micro-PCNL group, the odds were 1.29, 1.71, and 0.45, respectively. Odds of stone-free rate for ESWL vs Micro-PCNL: (5/12) / (29/17): 0.41/1.70= 0.24.

Table 2: Association of stone size (13.1–15 mm) with stone-free status in ESWL and micro-PCNL groups

		Stone Size 13.1-15mm		Total	OR
		ESWL	Micro-PCNL		
Stone free	Yes	5(29.41%)	29(63.04%)	34	0.24
	No	12(70.59%)	17(36.96%)	29	
Total		17	46	63	
p-value		0.018			

DISCUSSION

Our results found that, on average, patients were in their 3rd decade of life when they presented with renal stones and that between the two groups, no significant difference existed in age. This is keeping in mind that most people affected are usually between the ages of twenty and fifty thus our participants mostly fell in this category.[16] Similarly, we found that 73.9% were males, nearly three times as affected as compared to females. This is also keeping in view with the epidemiological trend of men being affected more commonly than women by 2 to 3 times.[17] There was no difference between the two groups in terms of gender, with a p-value of 0.34 computed. Stones in our cohort were most commonly found at the pelvis at 40.2%, followed by the mid kidney and the lower pole at 29.3% and 28.3% each. The upper pole had the least incidence of 2.2%. International literature suggests that lower pole stones are the most common; however, in our patients, this was the third most common position.[18] However, some authors believe that the most common location is the renal pelvis, where the urine forms and leaves the kidney. The renal pelvis was found to be the most common site in our cohort, affecting nearly half of all patients.[19] In our cohort, the right kidney was more commonly affected at 52.2% of cases, however, data from Pakistan previously suggested that the left kidney is more commonly affected.[20] However, there is limited literature determining which site is more commonly affected, and our data seems to indicate that there is no specific predilection. We had 16 participants who were older than 50 years, and half of these were stone-free. It was determined that age was not an independent factor determining stone-free status (P-value=0.19). Overall, participants had a stone-free rate of 64.1%. A review of the literature determined that stone-free status is highly variable regardless of the modality used and may range from 12% to 97%. Most commonly, however, the stone-free status lies between 60% to 70% for most series. There is no standard acceptable stone-free status rate, and thus it is hard to establish the efficacy of a modality, especially since stone-free status is determined for primary intervention and then secondary intervention. Most studies seem to show that stone-free status improves after a second session or intervention, regardless of the technique or intervention modality used. PCNL, however, may be superior to other modalities, while ESWL may require the more repeated sessions.[21-25] Stone-free status was 63% for our micro-PCNL group and 65.2% for our ESWL group. There was no difference in the stone-free status between the two groups, p-value 0.82. For the ESWL group, it was found that stones less than 10mm had greater clearance as compared to larger stones with a p-value of 0.01 showing significance. However, in the ESWL group, age and symptom duration were not significantly correlated with stone-free status. Similarly, in the micro-PCNL group, age and symptom duration were not significantly correlated with stone-free status. Since the micro-PCNL group only had stones of sizes 13mm to 15mm, it was determined what the stone-free status was for this stone size in ESWL vs micro-PCNL. With ESWL, stone sizes greater than 13mm were cleared in 29.4% of cases and the odds of clearing stones smaller than 13mm were 15 times higher. In micro-PCNL, 63% of stones sized 13mm to 15mm were cleared, nearly three times that for ESWL. Thus, even though our data was not able to show that stone-free status was different between the two groups, a subgroup analysis has shown that clinically significant stone clearance occurs with micro-PCNL for larger stones as compared to ESWL and may be the preferred minimally invasive intervention. For stone sizes between 10 and 13mm, ESWL was able to achieve 71% (n=10, N=14) clearance. Thus, it is reasonable to conclude that ESWL is a good modality for stones of sizes less than 13mm; however, for stone sizes between 13mm and 15mm, micro-PCNL may be a better alternative modality for stone clearance in a single session. Table 30 compares the rates of stone clearance for both these modalities for stones less than 20mm and stones between 13 and 15mm in size. A study done in India comparing micro-PCNL to ESWL found that renal pelvic stones were the most common, followed by lower pole and middle calyx stones. They found that the stone-free rate was higher for the micro-perc group in a single session, 89.1%, as compared to ESWL, where more than 20% of patients needed a second sitting, and 5% needed a third, after which an overall stone-free status of 88% was achieved. However, a stone size grouping and analysis were not available. Patients with stones of 20mm or larger underwent initial micro-PCNL, whereas patients with smaller stones underwent ESWL followed by micro-PCNL if treatment failure occurred. Sub-group analysis of stone-free status based on stone size would immensely add to the existing literature, as we have done with our study, and enhance decision-making processes.[26] Another study done by Saygan H *et al* shared their experience with micro-PCNL. They found that stones were present in both the left and right kidneys at similar rates.[29] The lower pole was the most common location, followed by the pelvis. For stones less than 10mm 87.1% success rate was determined, for stones 10-20mm 83.8% success rate was determined. Upper pole and renal pelvic stones had the highest success rate at 100% and 95.7%, respectively. In our study for our micro PCNL group, we observed that in the renal pelvis, 50% of stones achieved clearance, 71.4% in the lower pole, and 66.6% in the middle calyx. Whereas in the ESWL group, 69.5% achieved stone-free status at the pelvis, 50% in the lower pole, 77.7% at the middle calyx, and 50% for the upper pole. Though there is an appreciable difference in the stone-free status, this would be highly surgeon-dependent and expertise-dependent, and dependent on stone size. Individual studies would best be conducted keeping stone size homogenous and then assessing stone free status based on location to better make generalizations. However, our data does suggest that since no location incurred a stone-free status of less than 50%, both interventions are acceptable for stones of sizes up to 15mm, regardless of the location in the kidney. A study done by Gao X *et al* found that stone-free status was 90% after micro-PCNL for stone sizes between 10 to 20mm.[28] They conducted this study as they believed that stones of this size are either offered RIRS or ESWL and stones are fragmented and fragments left in situ to clear, this is similar to the concept of micro-perc where stone fragments are not removed thus it provides an alternate, viable option with a small sized tract with decreased tract size morbidity and complications. Their study strengthens the claim that micro-PCNL has a higher stone-free status than ESWL in a single session, as can be seen in our study data.

A study done by Saygin *et al* compared the stone free status for patients undergoing micro-PCNL and ESWL. Stone sizes included were less than 20mm. Stone free status for ESWL was 70% and for m-PCNL was 93.3%.[29] This shows a stark difference between clearance rates overall. The mean stone size for ESWL was 1.0cm, whereas for micro-NL it was 1.2cm, showing that ESWL had a data bias with smaller stones. Further, the identified clearance is based on the stone's location in the kidney. ESWL had a stone clearance of 33.3% for the lower pole while micro-PCNL had 90.9%. This is similar to our study, where ESWL only cleared 50% of lower pole stones while micro-PCNL cleared 71.4% of stones. The effect of stone size on ESWL has been documented, and the evidence points to stone sizes less than 15mm having nearly 2 times higher odds of clearance than stones larger than 15mm. Future studies with more stringent cut-offs for stone sizes to draw comparisons are likely to show and find similar results as ours, where ESWL is more efficacious for smaller stones, less than 13mm, as compared to stones larger than 13mm.[30]

A systematic review of m-PCNL found a 89% stone-free status for a mean stone size of 13.9mm. Our mean stone size was 14.5mm, which may be the reason why our overall stone-free rate was 63% due to a larger mean stone size. This is an important consideration to understand our results in light of those of the literature, and renders our results comparable to the literature.[31] The results of these studies[11,32,33] are further elaborated in the table below.

Wagenius *et al*[34] found that for ESWL in stones smaller than 20mm, stone size was an independent factor for stone clearance, and small stones were more likely to be cleared. They recorded the chances of stone-free status with a 10mm stone were up to 90%, for a 13mm stone up to 80%, and this decreased further to 60% for stone sizes exceeding 15mm. Our results for ESWL have similar findings for that age group. Another study that compared ESWL success in renal stones and stone size found that overall success was 64.7%, which was similar to our patients. They found that stone sizes between 50 to 10mm had successful ESWL in 54.9% of patients, while those with 1-2 cm-sized stones had success in 45.1% of patients. We were able to demonstrate a higher success rate for stones smaller than 13mm as compared to the 54.9% that was found in this study, and a much smaller percentage was successful in the 13mm to 15mm category. However, from this study as well it is clear that smaller stones are amenable to ESWL as compared to larger stones.[35]

The odds ratio for stone clearance being 1.33 for the left kidney suggests slightly better clearance rates. This could be due to anatomical differences, as the left kidney is positioned higher and may be more accessible during procedures. Additionally, technical and physiological factors, such as renal blood supply, might contribute. Previous studies have noted such differences in renal treatment outcomes. Further research is needed to explore the specific factors affecting these outcomes.

Overall, we can garner from the literature that micro-PCNL performs better than ESWL for stones larger than 1cm but less than 2cm, which is also refuted by our study findings. There is less morbidity and cost of repeated sessions as well. Micro-PCNL from the literature shows less variable results for stone clearance, ranging between 80% to 90%, and our study has a lower stone-free rate of 63%, likely due to a higher mean stone size of 14.5mm. Micro-PCNL presents the urologist with a minimally invasive technique to fragment small-sized stones and clear them, as compared to ESWL, where stone clearance rates shown are far more variable, ranging from 25% to 100% in the literature. Notably, micro-PCNL is a new and emerging technique, and there is very limited data available before allowing the technique to become agreeable as a gold standard for small-sized stones. More studies, both small-scale and large-scale scale will be needed to generate enough data for a robust meta-analysis to consider micro-PCNL as the procedure of choice for small renal stones. The study was limited in comparison by unequal distribution of stone size in the study groups and presents as an effect-modifying variable. Statistical analysis was done to decrease this effect and draw applicable comparisons. Long-term follow-up data would strengthen and add to the study to see how many stones recur and the duration of stone-free status.

Stone Free Status				
	Stone Size	Stone Size	Stone Size	Stone Size
Study Name	ESWL	Micro-PCNL	ESWL	Micro-PCNL
	<20mm	<20mm	13-15mm	13-15mm
Present Study	65.2%	63%	29.4%	63%
Halinski *et al*[26]	88% (1-3 sessions)	89.2%	-	-
Sabnis *et al*[27]	-	82.1%	-	83.8%
Gao X *et al*[28]	-	90%	-	-
Saygin *et al*[29]	70%	93.3%		
Sharma *et al*[11]	-	97.1%	-	-
Olcucuglu *et al*[32]	-	80.9%	-	-
Wagenius *et al*[34]	46.7%	-	-	-
Qattan *et al*[35]	64.7%	-	45.1%	-

CONCLUSION

There was no significant difference in the stone-free rates between the Micro-PCNL and ESWL groups. However, Micro-PCNL was more effective for stones larger than 13mm, showing better results in clearing these compared to ESWL. Both treatments were effective, but Micro-PCNL showed superior outcomes for larger stones.

LIMITATIONS

Nonavailability of ESWL in the same hospital and losing patients during referral

SUGGESTIONS / RECOMMENDATIONS

Micro-PCNL has an acceptable stone-free rate for small-sized renal stones and is a preferable modality for stones larger than 13mm as compared to ESWL.

CONFLICT OF INTEREST / DISCLOSURE

There is no conflict of interest.

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