Original Article

Comparative Study Between Percutaneous Nephrolithotomy and Extra Corporeal Shock Wave Lithotripsy in Managing Renal Stones.

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Abstract:

To find out better treatment option in treating renal stone safely, expeditiously. A total of 90 patient were prospectively randomized for Percutaneous Nephrolithotomy (PCNL) (40) and Extra Corporeal Shock Wave Lithotripsy (ESWL) (50). Stone clearance, adjuvant procedures, hospital stay, post procedure morbidity were compared for both methods. Stone clearance in PCNL and ESWL group was 87.50 and 66 percent respectively with a significant difference of clearance (P<0.05). Considering the stone size, in smaller stones, clearance was 87.50% and 72.50% among PCNL and ESWL group respectively without any significant difference (P>0.05). But in larger stones, stone clearance was 87.50% and 60.72% among PCNL and ESWL group respectively with significant difference in clearance between the groups (P<0.05). The rate of adjuvant procedures in PCNL and ESWL group was 12.50% and 34% respectively. Requirement of adjuvant procedures were significantly higher in ESWL group (P<0.05). Post procedure hospital stay was significantly shorter in ESWL group than PCNL group (1.32 0.47 vs 4.52 1.99) with P value <0.05. Steinstrasse and Haematuria were significantly higher in ESWL group than PCNL group. Bleeding requiring transfusion, urinary cutaneous fistula and fever were significantly higher in PCNL group than ESWL group. PCNL is more effective than ESWL in clearing larger renal stones.

Introduction:

Urolithiasis is the third most common disease of the urinary tract, exceeded only by urinary tract infections and pathologic conditions of the prostate.[1]

Renal stone disease may be complicated by pyonephrosis, septicaemia, pyelonephritis, hydronephrosis, renal failure and even death. So, early and appropriate treatment is necessary to protect renal function and to avoid some grave complications. Management of urolithiasis ranges from conservative watchful waiting to traditional open surgical procedure. In between these two, there exist a spectrum of procedures, which includes the recently developed non-invasive to minimally invasive procedures like ESWL, PCNL, URS and Laparoscopic removal. But one option can supplement other for total stone clearance.[2]

The revolution of minimally invasive surgery began in 1976 when Fernstrom and Johannson performed the first percutaneous nephrolithotomy (Fernstrom and Johannson, 1976). The development of instruments designed for percutaneous nephrolithotomy permitted percutaneous techniques to evolve to a point where, at least theoretically, any stone could be removed from urinary tract with reasonable economy and morbidity.[3,4] PCNL although a relatively more invasive mode of therapy, offers a greater stone free rate and a decreased rate of complications and secondary unplanned procedures.

ESWL has revolutionized the treatment of urinary stones with the concept to fragment stones. It was discovered in 1950 in Russia. The first clinical application with successful fragmentation of renal calculi was in 1980. Since then, there have been several modifications of the models of the instruments and are still continuing.[5]

The noninvasive nature, requirement of minimal or no anaesthesia and high level of patient acceptance, have made ESWL a preferred treatment for majority of symptomatic renal calculi requiring intervention.[6]

Stone related factors (size, number, location and composition), renal anatomy and patient's clinical factors should all be considered in conjunction with various surgical modalities and the availability of equipment before the preferred surgical approach is selected.

Stone burden (size and number) is perhaps the single most important factor in determining the appropriate treatment modality for a patient with renal calculi.[7]

Today, despite the pervasiveness of shock wave lithotripsy, percutaneous stone removal remains the procedure of choice in many clinical situations and a viable alternative in others.[8]

Many studies have been done in different parts of the world to compare the recent development of various modalities of treatment of renal stones. In the light of recent development of various modalities of treatment of renal stones, this study has been designed to compare the results of treatment of renal calculi by PCNL and ESWL.

Methods:

Between July 2005 to August 2006,this study was carried out in the Department of urology, Bangabandhu Sheikh

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Mujib Medical University (BSMMU), Dhaka. Patients with renal calculus attending in urology department of BSMMU,Dhaka were included in the study population. Those with Stone size 1.5 to 2.5 cm, absence of complete obstruction,Sterile urine,eexcreting kidney in IVU were included in this study. These group included 90 patients randomly treated with PCNL(40)or ESWL(50).Random sampling technique was applied to collected sample from study population.Exclusion criteria was bladder outlet obstruction,pregnant women, bleeding disorder.

All the patients were evaluated by history,clinical examination and investigations having similar protocol.The partinent investigations were total blood count, blood urea, serum creatinine, fasting blood sugar and blood sugar 2 hours after breakfast, coagulation profile, routine urine examination and urine culture,ultrasonogram of kidney, ureter and bladder region with post-voidal residue, plain x-ray KUB region (A/P & Lateral view) and intravenous urography (IVU). Electrocardiography and other relevant tests were done also.Total 90 patients who fulfiled the criteria secleted and divided into PCNL group(40) and ESWL group (50).Stone size was measured in this study by largest diameter in both anterior posterior and lateral view of plain x-ray KUB.In this study 1.5 to 2cm was considered as smaller stone and 2 to 2.5cm was considered as larger stone.

ESWL: ESWL monotherapy with Siemens Lithostar plus (3rd generation) lithotriptor was used to fragment the renal stone. Patients were placed in supine on the ESWL table. Stone was focused with the help of fluoroscopy and stones were fragmented. Prophylactic ureteral stents were not inserted before ESWL. The amount of shock wave given in each patient ranges from 2000 to 2500 per session. One to four session of ESWL was given to the patients in an interval of 1 to 2 weeks. Patients were discharged from lithotripsy unit on the same day or next day in some cases if no post procedure complications like haematuria, pain, fever occur. All the patients were under antibiotic prophylaxis during the procedure. Patients were advised to come after 7 days with a plain X-ray of KUB region. If necessary successive session of up to 4 session of ESWL was given at one to two week interval. If the stone were failed to clear even after 4 session of ESWL, the patients were then observed up to 90 days to see total stone clearance.

PCNL:Patients under General anaesthesia were placed in lithotomy position. After placement of ureteral catheter, patients were repositioned into prone. Under fluoroscopic guidance puncture of appropriate calyx was made with translumber angioplasty needle. The needle was removed after insertion of a floppy tip J guide wire. Then the tract was dilated over the guide wire up to 28 to 30 Fr by using dilators and an Amplatz sheath was introduced. Then nephroscope was placed through the sheath. Smaller stones were removed using forceps or a basket but larger stones were fragmented prior to extraction. At the end of procedure a nephrostomy tube was left within the tract and D-J stent was kept in ureter. Plain x-ray of KUB region routinely and nephrostogram in selected cases were performed in 24-48 hours and the tube was removed if there was no extravasation or retained calculi. The procedure were considered successful if the patient was either free of stones or had only clinically insignificant residual fragments after treatment. Clinically insignificant residual fragments were defined as asymptomatic fragments less or equal to 4 mm in diameter. The patients were discharged on 3rd post-operative day with an advice to come after 2-4 weeks depending on necessity of a 2nd procedure or for removal of stent in situ. Patients were then observed up to 90 days for at least three follow up session.

Statistical analysis:

After collection of data and meticulous checking, statistical analysis was done using computer SPSS 12.0 version and manual technology. Test of significance was done by using students t-test, z-test and 2 test. A probability value (p-value) of <0.05 was considered significant.

Results:

Both groups were comparable regarding age,sex and stone size(table 1,2,3). Stone clearance in ESWL group was 72.27% and 60.71% among smaller and larger stones respectively. No statistically significant difference was observed (P>0.05).(table 4)

Stone clearance in PCNL group was 87.5% and 87.5% among smaller and larger stone respectively.Here also no statistically significant difference was observed (P>0.05).(table 5)

Stone clearance in PCNL and ESWL group was 87.50 and 66 percent respectively. Statistical analysis shows significant difference of clearance (P<0.05).(table 6)

Considering the stone size, in smaller stones, clearance was 87.50% and 72.50% among PCNL and ESWL group respectively without any significant difference (P>0.05).(table 7).But in larger stones, stone clearance was 87.50% and 60.72% among PCNL and ESWL group respectively and there was a statistically significant difference in clearance between the groups (P<0.05).(table 8)

The rate of adjuvant procedures in PCNL and ESWL group was 12.50% and 34% respectively. Requirement of adjuvant procedures were significantly higher in ESWL group (P<0.05).(table 9)

Considering stone size, in smaller stone, rate of adjuvant procedures in PCNL and ESWL group was 12.50 and 27.27 percent respectively. No statistically significant difference in requiring adjuvant procedures was observed (P>0.05).(table 10) In larger stone, rate of adjuvant procedures in PCNL and ESWL group was 12.50 and 39.28 percent respectively. Here statistically significant difference in requiring adjuvant procedures was observed (P<0.05).(table 11)

Post procedure hospital stay was significantly shorter in ESWL group than PCNL group (4.52 1.99 vs 1.32 0.47) with P value <0.05. In case of smaller stones, average ESWL session was 1.6 and in larger stones average session was 2.7.(table 12)

Steinstrasse and Haematuria were significantly higher in ESWL group than PCNL group. Bleeding requiring transfusion, urinary cutaneous fistula and fever were significantly higher in PCNL group than ESWL group. There were no significant difference in loin pain and lower urinay tract symptoms among the groups(table 13).

Table 1: Age (in years) distribution of the sample.

Groups	Age in years			t	P value	Comment
	Mean ± SD	Minimum	Maximum	0.38	>0.05	Not significant
PCNL Group	40.87±10.77	15	62			
ESWL Group	39.98±11.26	17	65			

Table 2: Sex distribution of the study population.

Groups	Male		Female		Total	x^2	p value	Comment
	No.	Percent	No.	Percent				
PCNL Group	26	65	14	35	40	0.24	>0.05	Not significant
ESWL Group	30	60	20	40	50			

Table 3: Distribution of the study population according to stone size.

Groups	Total	Stone size				x^2	p value	Comment
		1.5 to 2 cm		2 to 2.5 cm				
		No.	Percent	No.	Percent			
PCNL Group	40	16	40	24	60	0.15	>0.05	Not significant
ESWL Group	50	22	44	28	56			

Table 4: Stone clearance in ESWL group: Comparison of clearance between smaller and larger stone.

Gro ups	Total no.	Stone clearance		$?^2$	p value	Comment
		Cleared	Not cleared			
Smaller stone (1.5 to 2 cm)	22	16 (72.72%)	6 (27.28%)	0.79	>0.05	Not significant
Larger stone (2 to 2.5 cm)	28	17 (60.71%)	11 (39.29%)			

Table 5: Stone clearance in PCNL group: Comparison of clearance between smaller and larger stone.

Groups	Total	Stone clearance		$?^2$	p value	Comment
		Cleared	Not cleared			
Smaller stone (1.5 to 2 cm)	16	14 (87.5 0%)	2 (12.5 0%)	0	>0.05	Not significant
Larger stone (2 to 2.5 cm)	24	21 (87.5%)	3 (12.5 0%)			

Table 6: Comparison of stone clearance between groups.

Groups	Total	Stone clearance		$?^2$	p value	Comment
		Cleared	Not cleared			
PCNL Group	40	35 (87.5%)	5 (12.5 0%)	5.56	<0.05	Significant
ESWL Group	50	33 (66%)	17 (34%)			

Table 7: Comparison of stone clearance between groups in smaller stone (1.5 to 2 cm).

Groups	Total no.	Stone clearance		$?^2$	p value	Comment
		Cleared	Not cleared			
PCNL Group	16	14 (87.5 0%)	2 (12.50%)	1.22	>0.05	Not significant
ESWL Group	22	16 (72.50%)	6 (27.27%)			

Table 8: Comparison of stone clearance between groups in larger stone (2 to 2.5 cm).

Groups	Total no.	Stone clearance		$?^2$	p value	Comment
		Cleared	Not cleared			
PCNL Group	24	21 (87.50%)	3 (12.50%)	4.71	<0.05	Significant
ESWL Group	28	17 (60.72%)	11 (39. 28%)			

Table 9: Comparison of number of adjuvant procedures needed between groups.

Groups	Total	Adjuvant procedures adopted		z	p value	Comment
		No.	Percent			
PCNL Group	40	5	12.5	1.9 7	<0.05	Significant
ESWL Group	50	17	34.0			

Table 10: Comparison of number of adjuvant procedures needed between groups in smaller stone (1.5 to 2 cm).

Groups	Total	Adjuvant procedures adopted		z	p value	Comment
		No.	Percent			
PCNL Group	16	2	12.50	1.18	>0.05	Not significant
ESWL Group	22	6	27.27			

Table 11: Comparison of numbers of adjuvant procedures needed between groups in larger stone (2 to 2.5 cm).

Groups	Total	Adjuvant procedures adopted		z	p value	Comment
		No.	Percent			
PCNL Group	24	3	12.50	2.34	<0.05	Significant
ESWL Group	28	11	39.28			

Table 12: Post procedure hospital stay in two groups.

Groups	Hospital stays in days			t	p value	Comment
	Mean ± SD	Minimum	Maximum			
PCNL Group	4.52±1.99	3	10	7.27	<0.05	Significant
ESWL Group	1.32±0.47	1	2			

Table 13: Complications in two groups.

Complications	PCNL Group		ESWL Group		z	P value	Comment
	No	Percent	No.	Percent			
Bleeding requiring transfusion	5	12.5	Nil	Nil	2.39	<0.05	Significant
Haematuria	11	27.5	35	70	4.40	<0.05	Significant
Loin Pain	36	90	38	76	1.82	>0.05	Not Significant
Fever	19	47.5	10	20	2.83	<0.05	Significant
Lower urinary tract symptoms	14	35	22	44	0.87	>0.05	Not Significant
Steinstrasse	Nil	Nil	11	22	15.6	<0.05	Significant
Urinary cuteneous fistula	6	15	Nil	Nil	2.65	<0.05	Significant

Discussion:

The present study has been designed to compare the outcome of PCNL and ESWL for the management of renal stone disease having stone size between 1.5 to 2.5 cm.

In this study, the age distribution of the patients was 15 to 65 years. In PCNL group, the age range was 15 to 62 years with mean age 40.87 years. In ESWL group, the age range was 17 to 65 years with mean age 39.98 years. There was no significant difference (P>0.05) in age among the groups.

In a comparative study by Mays N. et al. (1988) age range was reported between 14-84 years in PCNL group and between 11-90 years in ESWL group.[9]

In another study done by Saxby M.F et al. (1997), age range was 2-90 years in PCNL group and 6-85 years in ESWL group.[10]

In these two studies, the highest age of the patients was 90 years in both the groups, which is higher than the present study. These may be due to long life expectancy of that country and elderly people attending for stone treatment. There is also difference between lowest age of the patients with the present study. These may be due to the fact that, ESWL in paediatric age group has not been started yet in our centre. Dietary habit and hot weather, however, might have some influence in formation of renal stones in the early age in our country.

The sex distribution of the study population did not have significant different between the groups. In PCNL group, male and female ratio was 1.85:1 and 1.5:1 in ESWL group. This results agrees well with results of Saxby M.F. et al. (1997), where male to female ratio was 2:1 for PCNL group and 1.8:1 for ESWL group.[10]

In present study, in PCNL group, 40% patients were in stone size between 1.5-2 cm and 60% were in stone size between 2-2.5 cm. In ESWL group 44% were in stone size between 1.5-2 cm and 56% were in stone size between 2-2.5 cm.

The above distribution does not correlate with study done by Saxby M.F. et al. (1997) having stone size between 1-2 cm and 2-3 cm in each group and Mays N. et al. (1988) having stone size between 5-20 mm and 21-30 mm in each group.[10,9] This might be due to small sample size in the present study.

In this study, stone clearance in ESWL group was 72.72% and 60.71% for smaller stone (1.5 to 2 cm) and larger stone (2-2.5 cm) respectively. Though there is a better clearance of smaller stones, statistical analysis shows no significant difference of clearance rate (P>0.05).

The study done by Saxby, M.F et al. (1997), using a spark gap second generation lithotriptor (Sonolith 3000) showed stone clearance in ESWL group 75% and 57% for stone size 1-2 cm and 2-3 cm respectively.[10] This clearance rate roughly correlates with the present study.

In another study done by Lingeman JE et al. (1987) using HM-3 Dornier lithotriptor found stone clearance in ESWL group 75% and 43% for 1-2 cm and 2-3 cm stone size respectively.[11] This result is roughly comparable for smaller stone but there is difference for larger stone. The difference between results might be due to the fact that their maximum stone size was 3 cm.

In the current study, stone clearance in PCNL group was 87.5% and 87.5% for smaller stone (1.5 to 2 cm) and larger stone (2-2.5 cm) respectively. There is no statistically significant difference of clearance between size (P>0.05). Therefore, increasing stone burden did not reduce the effectiveness of PCNL. In this study however, the larger stone size was not too large.

In the study conducted by Saxby, M.F, (1997) and Lingeman JE et al. (1987) showed same stone clearance of 91% and 90% for stone size 1-2 cm and 2-3 cm.[10,11] This observation is close to the present study.

In a study done by El-Kenawy MR et al. (1992) the overall clearance of stone was 93.7% which is also close to the present series.[8] The difference between the results might be due to the fact that minimum follow up period was 6 months in their study or due to lack of availability of adequate instruments in our set up.

In the present study, stone clearance was 87.5% and 66% among PCNL and ESWL group respectively. Here statistical analysis shows significant difference of clearance (P<0.05).

In this study, for the smaller stones, it is seen that the rate of stone clearance in PCNL and ESWL group was 87.50% and 72.50% respectively. Although there is some difference is clearance of stones between the groups, statistical analysis shows no significant difference of clearance (P>0.05).

This is close to study done by Saxby M.F, (1997) and Lingeman JE. et al. (1987) where stone clearance was 91% and 75% in PCNL group and ESWL group respectively for stone size 1-2 cm.[10,11]

Mays N. et al. (1988) using second generation lithotriptor showed stone clearance in PCNL and ESWL group 92% and 59% respectively for stone size 5-20 mm.[9] In their study, patients were defined as free of stones if no stone was visible on radiography. But in our study, clinically insignificant residual fragments were defined as asymptomatic fragments less or equal to 4 mm in diameter. This might be the cause of difference in stone clearance in ESWL group or might be due to other factors that may interfere with the clearance rate.

Other factors for low clearance rate are type of lithotriptor used, number of session of ESWL and the duration of follow up period given for observing stone clearance, stone characteristics or anatomical abnormality of kidney itself.

In the study conducted by Charig CR et al. (1986), reported stone clearance 87% and 98% in PCNL and ESWL group for less than 2 cm stone respectively.[12] They have used number of shocks limited to that required to render the stones into particles that could be passed spontaneously (roughly 2 mm in diameter). These might be the cause of increased clearance rate for ESWL in their study.

In the present study, for the larger stone (2-2.5 cm) it is shown that clearance rate of stone in PCNL and ESWL group 87.50% and 60.72% respectively. Here statistical analysis shows significant difference of clearance among groups (P<0.05).

In a comparative study, Saxby M.F et al. (1997) reported stone clearance in PCNL and ESWL group 90% and 57% respectively for stone size 2-3 cm.[10] This result is roughly

comparable with the present study.

In another comparative study, Lingeman JE et al. (1987) reported clearance of stone in PCNL and ESWL group 90% and 43% respectively for stone size 2-3 cm.[11] Though the clearance rate in PCNL group is comparable with present study but there is difference in ESWL group. In their study maximum stone size was 3 cm but in this study maximum stone size was 2.5 cm. This may be the cause of difference.

In the current study, adjuvant procedures among PCNL and ESWL failed group was 12.5% and 34% respectively. Here also statistically significant difference in requiring adjuvant procedures was observed ($P<0.05$).

In the study conducted by Saxby MF et al. (1997), adjuvant procedures among PCNL and ESWL failed group were 11% and 24% respectively.10 This is close to the results of present study.

In this study, in smaller stone, adjuvant procedures were 12.5% and 27.27% in PCNL and ESWL group respectively. No statistically significant difference in requiring adjuvant procedures was observed ($P>0.05$). In larger stone, adjuvant procedures were 12.50% and 39.28% in PCNL and ESWL group respectively. Here statistically significant difference in requiring adjuvant procedures was observed ($P<0.05$).

In this study, mean post procedure hospital stay in PCNL and ESWL group was 4.52 and 1.32 days respectively. The mean hospital stay in days much less in ESWL group than PCNL group and this difference was statistically highly significant ($P<0.001$).

Lingeman JE. et al. (1987) showed mean post procedure hospital stay in PCNL and ESWL group, 5.9 days and 3.0 days respectively.[11]

In another study Carlsson P. et al. (1992), reported mean hospital stay were longer in PCNL group than ESWL.[13] This result correlates with the present study.

In the present study, number of average ESWL sessions was 1.6 and 2.7 in smaller and larger stone respectively. For each session, one day required for treatment.

In the present study, complications were less in ESWL group than PCNL group. Loin pain and fever were less among patients of ESWL group then PCNL group. Haematuria and lower urinary tract symptoms were common in ESWL group. Steinstrasse was present only in ESWL group. Bleeding requiring transfusion, and urinary cutaneous fistula were only present in PCNL group. All complications were treated conservatively.

Conclusion:

Considering the findings of the present study, it can be concluded that PCNL is more effective than ESWL in clearing larger renal stones.

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