ORIGINAL RESEARCH

A study to evaluate prospectively the success of treatment with regards to stone clearance between the two groups ESWL and PCNL in patients with renal stones of size 1-2cm

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ABSTRACT

Background: Extracorporeal shock wave lithotripsy (ESWL)is considered a standard treatment for patients with upper-tract stones that are less than 10 mm in diameter, whereas stones that are larger than 20 mm are best managed with PCNL. The management of kidney stones between these sizes remains controversial. **Aim:** The aim of this study was to evaluate the prospectively the success of treatment with regards to stone clearance between the two groups ESWL and PCNL in patients with renal stones of size 1-2cm. **Material & Methods:** This study included 100 patients with moderate-sized kidney stones (range: 1–2 cm) who were posted for surgery for either with PCNL or with ESWL. Success rate, need for auxiliary procedure, duration of hospital stay, retreatment rates, complications, need for blood transfusion and emergency admission were recorded and analyzed. **Results:** Results of Eighty one patients of renal stones l-2cm size were evaluated in the study with 50 in the ESWL and 50 in the PCNL group . Both the groups were well matched with regards to age and sex distribution. 50 patients underwent ESWL and26/50 patients had stone clearance in 48% months. 50 underwent PCNL out of which 50/47 patients had stone 6% clearance. Complications were mostly minor and found in 8% in patients undergoing ESWL while same were seen in 28% of those undergoing PCNL. **Conclusion:** PCNL has proved superior to ESWL for renal stones of 1-2 cm in size. It has also got lower auxiliary and retreatment rates but has its own share of complications.

Keywords: Renal Stone, ESWL, PCNL

INTRODUCTION

Urolithiasis is one of the most prevalent urologic disease. The worldwide prevalence ranging from 7-13% in North America, 5-9% in Europe, and 1-5% in Asia [1]. This problem has confronted clinicians since vedic period of Sushruta and times of Hippocrates. At present, lifetime risk of developing renal stone is around 12% [2].Even after treatment of first renal stone ,the recurrence rate of stone formation is estimated to be 10–23% per year, 50% in 5–10 years, and 75% in 20 years of the patient [3].

The incidence of urolithiasis is increasing. According to National health and nutrition examination survey 2012 10.6% of men and 7.1% of women in United states are affected by renal stone disease compared to just 6.3% of men and 4.1% of women in 1996. In India the incidence shows wide regional variation with high number of cases reported from west and north compared to south[4]. Currently evidences suggests that urolithiasis is associated with systemic diseases like chronic kidney diseases, Obesity, Diabetes, Hypertension and Cardiovascular disease. Urolithiasis places a significant burden on the health care system, which is likely to increase with time [5].

The increasing prevalence of Urolithiasis obviates safe, efficacious, and affordable treatment. Majority of renal stones diagnosed today are below 2 cm in size due to easy and early accessibility to x-ray and ultrasonography. The three most common procedures performed to remove upper urinary tract stones are Extracorporeal shockwave lithotripsy (ESWL),

Retrograde Intra Renal Surgery(RIRS), and percutaneous nephrolithotomy (PCNL). Technological advances and changing treatment patterns have had an impact on current treatment recommendations, which have clearly shifted towards endourologic procedures. The preferred treatment of less than 1cm renal stone is extracorporeal shockwave lithotripsy(ESWL) ,while standard of care for renal stone more than 2cm is percutaneous nephrolithotomy(PCNL) [6]. Procedure of choice for 1-2 cm renal stone is still a subject of debate.Controversy exists with regard to optimum management of these stones by percutaneous nephrolithotomy(PCNL) and extracorporeal shockwave lithotripsy(ESWL) with reference to stone clearance, hospital stay and complications [7].

The primary goal while treating renal stones is to achieve complete clearance, while causing minimum morbidity to the patient. Treatment of renal stone depends upon the size of stone, location and patient related factor including anatomy of pelvicalyceal system. Treatment should be individualized considering above mentioned factors as well as available expertise and instruments. The reported lower calyceal stone clearance rates with ESWL ranges lower, between 37% and 61% as compared to PCNL.[8] So ESWL is not favoured as first line of treatment for lower calyceal stones in most urolithiasis guidelines. For lower calyceal stones 1-2 cm in size, there is a decline in the use of ESWL with a parallel increase in use of PCNL and retrograde intrarenal surgery (RIRS), since they are associated with better stone-free rates [9].

This study has been undertaken to formulate a better understanding of management of renal stones of size 1-2 cm located in upper calyx,middle calyx and renal pelvis(i.e. non-lower pole renal stones) in our patients.

MATERIALS AND METHODS

A prospective study was carried out to evaluate stone clearance of ESWL vs. PCNL in patients with renal stones of size 1 -2 cm. The protocol of the study was approved by the ethical committee of institute and the study was conducted at Department of Urology, Meenakshi Mission Hospital & Research Centre (MMHRC), Madurai, Tamil Nadu between the period april 2017 to March 2019.

SAMPLE SIZE

We studied 100 patients who were fulfilling eligibility criteria of study and they were divided in two groups, ESWL group (n=50, including patients who were undergoing ESWL) and PCNL group (n=50, including patients who were undergoing PCNL).

INCLUSION CRITERIA

- Patients with solitary renal stone size 1-2 cm who get admitted for ESWL and PCNL, will be enrolled into the study.

EXCLUSION CRITERIA

- Patients with age less than 18 years.
- Patients with transplant kidney, horseshoe kidney,or with ureteropelvic junction obstruction.
- Patients with anomalous kidney.
- Patients with lower calyceal stone.
- Pregnant patients.
- Morbidly obese patients.
- Patients with bleeding disorders.
- Patients with advanced cardiorespiratory disease.
- Patients who are not willing to give consent for participation in the study.

PRE - OPERATIVE EVALUATION

Baseline information and a brief clinical history was taken and general and physical examination performed. Preoperative blood investigations included complete hemogram, random blood sugar, renal function tests, coagulation profile and viral markers. Urine for routine & microscopy and culture sensitivity taken and performed. Chest X-ray and electrocardiogram was done. Radiologic evaluation included X-ray Kidney Ureter and Bladder (KUB) or ultrasonography of KUB and CT urogram (CTU) to determine site and size, fine anatomical details and other associated urological condition. Patients were optimized and anaesthesia fitness was taken as required.

ESWL STUDY TECHNIQUE

INTRA - OPERATIVE EVALUATION

All patients were treated in supine position by one doctor and one technician. Initially double -J stent was placed in all patients .All patients underwent ESWL using the Dornier compact sigma lithotripter. The fragmentation of stone during therapy will be monitored by ultrasound. Lithotripter activated only when there is a clear view of the stone and the probe position was fixed. Initial 500 shocks were given at low intensity & gradually increased for the next 1000-2500 shocks. Shocks were given at the rate of 60-80 per minute. Average duration of one session of ESWL was in between 35-50 minutes. The session was stopped when stone disintegrates satisfactorily, or patient was in discomfort or machine's upper limit of shock wave per session (3000) was reached. Adequate hydration and analgesia were given during and after the procedure.

POST - OPERATIVE EVALUATION

Post-ESWL instructions were advised, rest for one to three days , plenty of oral fluids, to pass urine in a strainer for collection of stone , antibiotics for three days, with on demand analgesics till next visit. Post procedure X-ray KUB or ultrasound or visualisation under c-arm(VCA) was done to document fragmentation and clearance at one month. If there were fragments of significant size a second session of ESWL was planned. In between two sessions minimum thirty days gap was maintained and

maximum two sessions of ESWL given in specified study period. However if there were only insignificant fragments the patients were re-evaluated after 3 months and final results were considered. The ESWL procedure was considered successful if the patient is either stone-free or has any clinically insignificant residual fragments (CIRFs), defined as fragments less than or equal to 4 mm, non- obstructive, non-infectious, and asymptomatic residual fragments.Data were recorded including clearance after first and second session, any blood transfusion ,emergency readmission,auxillary procedure and hospital stay. The complications were classified according to modified Clavien-Dindo grading system.

PCNL STUDY TECHNIQUE

INTRA - OPERATIVE EVALUATION

All PCNL procedures were done by standard technique in general anaesthesia in prone position.Initially in lithotomy position, cystoscopy and insertion of a ureteral catheter over guidewire under c-arm guidance was done . Patients were then placed prone and percutaneous access was obtained using fluoroscopy (bull's eye or triangulation technique) or ultrasound guidance. Tract was dilated serially using Alken's serial dilator and appropriate size Amplatz sheath was placed. Nephroscopy performed with a rigid nephroscope of appropriate size(12-22 French size) .Stones were identified and fragmented with pneumatic lithoclast and retrieved out by grasper or flushed out.Stone clearance was confirmed intra-operatively by fluoroscopy.Double-J stent was placed using the antegrade approach at the end of the procedure. An external ureteral catheter left in situ if the patient was planned for relook PCNL. A nephrostomy tube of appropriate size was placed into the renal pelvis or the punctured calyx at the end of the procedure.Any intra-operative complications or untoward incidents were noted.

POST - OPERATIVE EVALUATION

Serum electrolytes and hemoglobin levels (if significant bleeding present intra-operatively) were obtained in all patients postoperatively. On postoperative Day one , X-ray or USG –KUB ,seum creatinine and hemoglobin (if needed) was done.If complete stone clearance was documented and the urine was not significantly hematuric, the nephrostomy tube as well as the ureteric catheter (if left in situ) were removed on postoperative Day one. After 24 hours, if there was no urine leak from the nephrostomy site the urethral Foley's catheter was removed. DJ stent was removed after four weeks. If residual fragments were seen on postoperative X-ray, then re-look PCNL using either the same tract or new tract was done after two to four days,once patient was stable. All patients were then followed up at one month and three months after discharge from the hospital with X-ray KUB or ultrasound or visualisation under c-arm(VCA) to document stone clearance.The PCNL procedure was considered successful if the patient is either stone-free or has any clinically insignificant residual fragments (CIRFs), defined as fragments less than or equal to 4 mm, non- obstructive, non-infectious, and asymptomatic residual fragments.Data were recorded including clearance at one and three months, any blood transfusion , emergency readmission ,auxillary procedure and hospital stay. The complications were classified according to modified Clavien-Dindo grading system.

STATISTICAL ANALYSIS

The Statistical analysis was performed on a computer by SPSS-v25 and Minitab-17.

OBSERVATION AND RESULT

TABLE 1: AGE DISTRIBUTION

Age (Years)	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
18 – 40	17	34.0%	15	30.0%	32	32.0%	0.411	0.649
41 – 60	27	54.0%	27	54.0%	54	54.0%		
>60	6	12.0%	8	16.0%	14	14.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 34.0% patients with age (Years) 18 - 40, and the PCNL group had 30.0% patients in this subgroup. The ESWL group had 54.0% patients with age (Years) 41 - 60, and the PCNL group had 54.0% patients in this subgroup. The ESWL group had 12.0% patients with age (Years) >60, and the PCNL group had 16.0% patients in this subgroup. The mean age (years) in the ESWL group was 45.26 (±11.67) (range 22 - 75), and in the PCNL group was 47.68 (±12.51) range (21 - 72). There was no significant difference noted between two groups with respect to age of patients.

TABLE 2: GENDER DISTRIBUTION

Gender	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
Male	32	64.0%	28	56.0%	60	60.0%	0.667	0.541
Female	18	36.0%	22	44.0%	40	40.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 64.0% male and 36.0% female patients. PCNL group had 56.0% male and 44.0% patients. The gender ratio in the ESWL group was M:F = 1:0.6, and in the PCNL group was M:F = 1:0.8. There was no significant difference noted between two groups with respect to gender of patients.
There was no significant difference noted between two groups with respect to laterality of stones.

TABLE 3: SIZE OF STONE

Size of Stone (mm)	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
10 - 15	30	60.0%	22	44.0%	52	52.0%	2.564	0.161
16 - 20	20	40.0%	28	56.0%	48	48.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 60.0% patients with size of stone (mm) 10 - 15, and the PCNL group had 44.0% patients in this subgroup. The ESWL group had 40.0% patients with size of stone (mm) 16 - 20, and the PCNL group had 56.0% patients in this subgroup. The mean size of stone (mm) in the ESWL group was 14.94 (±2.85) (range 11 - 20), and in the PCNL group was 16.08 (±2.75) range (11 - 20). There was no significant difference noted between two groups with respect to size of stones.

TABLE 4: STONE CLEARANCE AT 1 MONTH

Stone Clearance at 1 Month	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
Complete	26	52.0%	47	94.0%	73	73.0%	22.374	<0.001
Incomplete	24	48.0%	3	6.0%	27	27.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 52.0% patients with complete stone clearance at 1 month, and the PCNL group had 94.0% patients in this subgroup. The ESWL group had 48.0% patients with incomplete stone clearance at 1 Month, and the PCNL group had 6.0% patients in this subgroup. Stone Clearance at 1 month was significantly higher in the PCNL group, as compared to the ESWL group (p value < 0.001).

TABLE 5: INCIDENCE OF COMPLICATIONS

Incidence of Complications	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
Present	4	8.0%	14	28.0%	18	18.0%	6.775	0.017
Absent	46	92.0%	36	72.0%	82	82.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 8.0% patients with Complications present, and the PCNL group had 28.0% patients in this subgroup. The ESWL group had 92.0% patients with no complications , and the PCNL group had 72.0% patients in this subgroup. Incidence of complications was significantly higher in the PCNL group as compared to the ESWL group.

TABLE 6: MODIFIED CLAVIEN-DINDO GRADES OF COMPLICATIONS

Clavien-Dindo Grade of Complications	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
Grade 0 (NIL)	46	92.0%	36	72.0%	82	82.0%	7.886	0.070
Grade 1	3	6.0%	6	12.0%	9	9.0%		
Grade 2	1	2.0%	5	10.0%	6	6.0%		
Grade 3	0	0.0%	2	4.0%	2	2.0%		
Grade 4	0	0.0%	1	2.0%	1	1.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 92.0% patients with Clavien-Dindo grade 0 (i.e.no complications), and the PCNL group had 72.0% patients in this subgroup. The ESWL group had 6.0% patients with Clavien-Dindo grade 1, and the PCNL group had 12.0% patients in this subgroup. The ESWL group had 2.0% patients with Clavien-Dindo grade 2, and the PCNL group had 10.0% patients in this subgroup. The ESWL group had 0.0% patients with Clavien-Dindo grade 3, and the PCNL group had 4.0% patients in this subgroup. The ESWL group had 0.0% patients with Clavien-Dindo grade 4, and the PCNL group had 2.0% patients in this subgroup. There was no significant difference in the two groups in terms of different Clavien-Dindo grades of complications.

TABLE 7: DURATION OF HOSPITAL STAY

	Procedure				Students t-test	
	ESWL		PCNL			
	Mean	SD	Mean	SD	t	P Value
Duration of Hospital Stay	1.14	1.09	4.92	1.48	-14.535	<0.001

The mean duration of hospital stay (days) in the ESWL group was 1.14 (±1.09) (range 0 - 4), and in the PCNL group was 4.92 (±1.48) range (3 - 10). The duration of hospital stay was significantly longer in the PCNL group as compared to the

TABLE 8: REQUIREMENT OF AUXILLARY PROCEDURE

Requirement of Auxiliary Procedure	Procedure				Total		Chi-Square Test	
	ESWL		PCNL					
	N	%	N	%	N	%	χ^2	P Value
Required	6	12.0%	2	4.0%	8	8.0%	2.174	0.269
Not Required	44	88.0%	48	96.0%	92	92.0%		
Total	50	100.0%	50	100.0%	100	100.0%		

The ESWL group had 12.0% patients, who required auxiliary procedure and the PCNL group had 4.0% patients in this subgroup. The ESWL group had 88.0% patients ,who did not required auxiliary procedure and the PCNL group had 96.0% patients in this subgroup.Thus, auxiliary procedure rate in ESWL group was 12% and in PCNL group was 4%.There was no significant difference noted between two groups with respect to requirement of auxiliary procedure.

DISCUSSION

In the last three decades newer technologies –ESWL and PCNL have completely replaced the open surgery for renal stone management. Incidence of renal stone has shown increasing trend in the last decade but widespread use and availability of diagnostic imaging –USG and CT scan has led to detection of stones when they are small (< 2cm). ESWL being a non-invasive day care technique is favoured by many urologists as the treatment of choice for < 2cm renal stones because of patients acceptance. With improvement in optics and fragmentation energy source PCNL is also gaining popularity for treatment of such stones. Consensus still eludes over right choice between PCNL versus ESWL for the management of renal stones 1-2 cm in size.[10]

In our study we have excluded lower calyceal stones because of the reported poor clearance with ESWL[1] [1]and comparing non-lower calyceal stones of 1-2 cm size for better comparability and to make better understanding of management of this group of stones. PCNL is the most preferred modality for treating lower calyceal stones with unfavorable anatomy in view of limited clearance of fragments after ESWL.In a survey done by Bandi et al., the proportion of urologists preferring PCNL increased and more urologists preferred PCNL to ESWL for managing lower calyceal stones [12] .

As experience with these two modality increased, more number of researchers tried to define the place of ESWL and PCNL in the management of renal calculi of various size,location and composition. Several surgical studies by urologists have compared these two techniques for renal stones 1-2 cm in terms of stone clearance rate, cost-effectiveness, morbidity, and complications.[13] Similar to the latest studies, this research work also reports consistent results.

This prospective study has been designed to compare the outcomes of these techniques in terms of success and complications for 1-2 cm size non-lower calyceal renal stone in our population.The ESWL group had 60.0% patients with stone size 10 – 15 mm, and the PCNL group had 44.0% patients in this subgroup. The ESWL group had 40.0% patients with stone size 16 – 20mm, and the PCNL group had 56.0% patients in this subgroup.

In our study stone clearance at one month for ESWL (single session) was 52% , while overall clearance at 3 months (with maximum two sessions of ESWL) improved to 78%. It is nearer to result of Saxby et al [14]in 1997, reporting stone clearance of 75% for similar size stones.

One of the initial study done by Charig et al[6] in 1986 reported stone clearance of 92% by ESWL probably because of unmodified Dornier and liberal use of shock waves till all the fragments got cleared,whereas we used compact sigma lithotripter and restricted number of shockwaves to 2500-3000 per session with time limit of 35-45 minutes.

Okan Bas et al[13]in 2014 in their retrospective study observed stone free rate of 86% by ESWL, which is greater than our study .It is because in this study mean number of session of ESWL was 2.6, whereas in our study maximum number of session was two.This study included only pelvic stones of 1-2 cm size , similarly in our study separately renal pelvic stones has stone clearance of 80%, which is also lesser as compared to this study .In similar study done by Wiesenthal JD[15] in 2015 and by Aboelkher KM [16] in 2017 for medium sized renal stone , stone clearance after two sessions of ESWL was 79.2% and 77.5% ,respectively and almost similar to our study.

Rao et al [17] in 2001 in a prospective study done on 257 patients reported success rate of 69.3% at the end of 12 weeks by ESWL. Mild difference in success rate after ESWL could be use of different Lithotripter machines (Sonolith versus compact Sigma lithotripter in our study) and other patient and stone variables.

We found stone clearance of 94% for PCNL group in our study, which is closely similar as were reported by other observers – Rao et al. [31] (94%) , Joshua D.Wiesenthal et al. (95.3%), Oken Bas et al. (98%), N H Wankhede et al. (97%) and Aboelkher KM et al.(93.3%) in 2017.

While similar studies done for lower calyceal stone had stone clearance for PCNL group, nearly likewise as done by Albala et al. (92%), Young Duk You et al.(100%), Yuruk et al. (2010) (100%), Perminger et al. in 2006 (92%), N H Wankhede et al. (97%).

The nearly identical success rates of different investigators attest to the fact that PCNL is not affected by other stone variables that affect ESWL outcomes. It was observed that success of PCNL does not depend on location of stone.It was also seen that in 1-2 cm stone all the fragments are removed during PCNL itself so there is less possibility of CIRF.The earlier studies have a slightly lower success , probably because the technique was still evolving at that time.In the recent study of Anup kumar et al.[18] which had lower success rate after PCNL (86.1%) is probably because of difficulty in monitoring radiolucent stones under fluoroscopy.

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PCNL itself so there is less possibility of CIRF.The earlier studies have a slightly lower success , probably because the technique was still evolving at that time.In the recent study of Anup kumar et al. [41] ,which had lower success rate after PCNL (86.1%) is probably because of difficulty in monitoring radiolucent stones under fluoroscopy. In our study,overall stone clearance was 78% and 94% among ESWL and PCNL group respectively.Here statistical analysis shows a significant difference of clearance ($p<0.05$).In our study, the ESWL group had 8.0% of patients with complications , and the PCNL group had 28.0% patients in this subgroup. The ESWL group had 92.0% patients with no complications, and the PCNL group had 72.0% patients in this subgroup .Incidence of complications was significantly higher in the PCNL group as compared to the ESWL group with p value 0.017.

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The mean Duration of hospital Stay (Days) , we found in the ESWL group was 1.14 (±1.09) (range 0 – 4 days), and in the PCNL group was 4.92 (±1.48) (range 3 – 10 days). The duration of hospital stay was significantly longer in the PCNL group as compared to the ESWL group($p=0.0001$).

Saxby et al. noted similar findings (PCNL 5.7 days), while McDougall et al. noted a higher stay of 2.5 days for ESWL but at that time patients were treated under anaesthesia.In most series like ours , hospital stay was more in PCNL as compared to ESWL group .Neto et al. (ESWL 0.3 PCNL 3.1), Albala et al. (ESWL 0.55,PCNL 2.66), Joshua D .Wiesenthal et al. (ESWL 0.17,PCNL 2.9), Anup Kumar (ESWL 0.13,PCNL 3.1) etc.

In our study, auxiliary procedure rate in ESWL group was 12% and in PCNL group was 4% .There was no significant difference noted with respect to requirement of auxiliary procedure (p value 0.269).Results were quite similar to series of Anup kumar (ESWL 20.2%,PCNL 8.8%).We found ,retreatment rate of 48% in ESWL group was and in PCNL group, it was 10%.

The retreatment rate in the ESWL group was significantly higher than that of the PCNL group ($p <0.001$).we gave maximum two sessions of ESWL during specified study period.The retreatment rates in two groups was similar as in study done by,Anup kumar et al. (63.4% vs 2.2%) in ESWL and PCNL respectively whereas Deem et al. found retreatment rates of 67% for ESWL.In our study no statistically significant differences were noted between the two groups with respect to requirement of auxillary procedures and emergency readmission rate.

CONCLUSION

From our study it can be concluded that ,taking primary objective as stone clearance , PCNL has proved superior to two sessions of ESWL for non-lower pole renal stones of 1-2 cm in size. PCNL has also got lower auxiliary and retreatment rates but has more incidence of complications. Longer hospital stay is another important factor in PCNL. Although ESWL necessitates repeated treatments for optimal efficacy, it is less invasive, safe and comparably effective.Grade 1, 2 and 3 complications, which were managed conservatively or by minimally invasive endourological procedures constituted the main bulk of complications (>90%) while Grade 4 and 5 complications are extremely rare.

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