A Randomised Prospective Analysis of Effectivness of ESWL vs PCNL in Renal Stone Size 1-2 cm and Review of Literature

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ABSTRACT

Introduction: Majority of renal stones diagnosed today are below 2 cm. The preferred treatment of <1cm stone is extracorporeal shockwave lithotripsy (ESWL) while standard of care for renal stone >2 cm is percutaneous nephro-lithotomy (PCNL). The procedure of choice for 1-2 cm renal stones is still a subject of debate. This study was undertaken to formulate a better understanding of management of renal stones of size 1-2cm in this patient population

Material and methods: A prospective study was carried out to evaluate clearance of ESWL vs PCNL in patients with renal stones of size 1-2 cm. Complete follow up data were available for 281 patients 140 in PCNL and 141 in ESWL group, 12 patients were lost to follow up.

Results: Both the groups were well matched with regards to age and sex distribution. 141 patients underwent ESWL and 103/141(73%) patients had stone clearance in 1-3 months. 140 patients underwent PCNL out of which 133 (95%) patients had stone clearance. Complications were mostly minor and found in 9.7% in patients undergoing ESWL while same were seen in 30% of those undergoing PCNL.

Conclusion: The primary objective in stone management is total stone clearance. Considering this as priority PCNL has proved superior to ESWL in our study for renal stones 1-2 cm in size. It has also got lower auxiliary and retreatment rates but has its own share of complications and longer hospital stay are other important factors in PCNL.

Keywords: ESWL, PCNL, Renal Stone

INTRODUCTION

Urolithiasis is a problem that has confronted clinicians since vedic period of Sushruta and times of Hippocrates. At present urinary stone prevalence is estimated at 3% in general population and lifetime risk of developing kidney stones is around twelve percent.Even after treatment of first renal stone the recurrence rate of 50% has been observed in ten years.

The incidence of urinary tract stone disease is increasing. According to the National Health and Nutrition Examination Survey 2012-10.6% of men and 7.1% of women in the United States are affected by renal stone disease, compared to just 6.3% of men and 4.1% of women in 1996.In India incidence shows wide regional variation with high number of cases reported from west and north compared to south

Majority of renal stones diagnosed today are below 2 cm-perhaps due to easy and early accessibility to X -ray and ultrasonography. The preferred treatment of <1cm stone is extracorporeal shockwave lithotripsy (ESWL) while standard of care for renal stone >2 cm is percutaneous nephro-lithotomy (PCNL).

The procedure of choice for 1-2 cm renal stones is still a subject of debate. Controversy exists with regard to optimum management of these stones by PCNL and ESWL with reference to stone clearance, hospital stay and complications This study was undertaken to formulate a better understanding of management of renal stones of size 1-2 cm in this patient population.

MATERIAL AND METHODS

A prospective study was carried out to evaluate 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.

Altogether 326 patients with kidney stones (fulfilling the inclusion criteria) visited RIMS, Ranchi, Jharkhand, between the period 1st March 2017 to 30th September 2019, 323 agreed to participate 144 and 149 in PCNL and ESWL respectively. Complete follow up data were available for 281 patients 140 in PCNL and 141 in ESWL group, 32 patients were lost to follow up.

Inclusion criteria

Patient with solitary renal stone size 1-2 cm.

Exclusion criteria

1 Bilateral stone
2 Radiolucent stone
3 Stone size>2 cm
4 Age<12 yrs or >75 years
5 Bleeding diathesis
6 Pyonephrosis
7 Severe hydronephrosis
8 Pregnancy
9 Transplant recipients
10 Advanced cardiorespiratory disease
11 Poorly controlled diabetes mellitus
12 Refusal to participate in the study.

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A randomisation table was used, Patients in group A were allocated for PCNL while Group B included patients who underwent ESWL.

The treatment options were then discussed with patient and his/her relatives with a detailed explanation of the involved procedure and complication as well as the available other alternative. Informed written consent was obtained from all subjects enrolled in the study.

The patients were subjected to clinical history, physical examination, radiological studies (Plain X-ray film, USG, Intra Venous Urogram (IVU) and Non contrast CT (NCCT), haematology, biochemical and urine tests, to determine the site and size.

The data were recorded as per study Performa. Patients were divided into subgroups based on their stone location, composition, size for better subgroup analysis. The treatment outcomes were recorded and analysed as per study Performa. An auxiliary procedure was considered as any additional procedure (s) to render patient stone free. For failed ESWL the auxiliary procedures were ureteroscopy /PCNL. For failed PCNL ESWL / ureteroscopy were used as auxiliary procedures.

The patients were followed up at one and three months by routine postoperative x-ray and ultrasound if required.

PCNL study technique

All PCNL procedures were done by standard technique in general anaesthesia in prone position. Percutaneous access was obtained using C-armed fluoroscopy and retrograde contrast pyelogram. X-ray KUB and routine blood examination was performed on 3rd postoperative day.

PCNL procedure success was defined as no residual stone visible on X-ray KUB. Success included stone-free, i.e., complete stone clearance, or clinically insignificant residual fragments (CIRF) ≤ 4 mm at three months. Complications were classified according to modified Clavien grading system.

ESWL study technique

Patient of solitary renal calculus of 1–2 cm were evaluated similar to PCNL. All patients underwent ESWL using The Siemens. The fragmentation of the calculus during the therapy was monitored by fluoroscopy. Post procedural plain X- ray was done to document fragmentation and clearance at the end of one and three months.

Success included stone-free, i.e., complete stone clearance, or CIRF with no symptoms at 3 months after ESWL. Failure was defined as residual stone fragments, i.e., clinically significant residual fragments> 4 mm after three sessions of ESWL.

Before ESWL all patients had NCCT with 3 mm contiguous sections, A TOSHIBA ACQUILLION, high-speed CT scanner was used at 120 - 135 kV, 81 mAs, and 1.4:1 pitch.

Patients were followed up at 1 month after ESWL with a plain abdominal film. If there were fragments of significant size a second session of ESWL was planned. In between two sessions minimum 30 days gap was maintained. However, if there were only insignificant fragments the patients were re-evaluated after 1 month. The final results were considered after 3 months from the first ESWL session.

STATISTICAL ANALYSIS

The data was subjected to statistical analysis with SPSS version 17 statistical software and Microsoft excel. The p- value <0.05 was considered significant. Results were analysed using Student's t -test and chi-square test, Fischer exact test multivariate analysis and one-way ANOVA.

RESULTS

Age

N patients	ESWL (141)	PCNL (140)	P value	CI
Age (years)	40.92 ± 12.90	39 ± 10.06	0.5720	-3.664 to 6.588

Age range of the patients - 18 to 65 years.In PCNL group, the age range was 18 to 60 years with mean age 39 ±10.06 years. In ESWL group, the age range was 18 to 65 years with mean age 40.92 ±12.90 years. There was no significant difference in age among the groups, p value 0.65 and 95% CI (-3.7 to 5.9).

Body Weight

N patients	ESWL (141)	PCNL (140)	P value	CI
Body weight (mean)	57.60 ± 11.29	56.42 ± 10.6	0.6482	-3.72 to 5.95

The mean weight was 57.60 ±11.3 in ESWL group and 56.425 ±10.6 in PCNL group with a p value = 0.65 and 95% CI (-3.7 to 5.9).

Sex Distribution

Sex	Male	Female	P value
ESWL	73(52%)	68(48%)	0.287
PCNL	71(50.7.%)	69(49.3%)	Chi square
Total	144	137	

The male to female ratio was 1.6: 1, with 73 males in ESWL (52%) and 71 (50.7%) male in PCNL group. The number of females was 68 (48%) and 69 (49.3%) p value=0.287. The sex distribution of the study population did not have significant different between the groups.

Laterality

Lateralisation	Right	Left	P value
ESWL	71(51.2%)	70(45%)	0.1800
PCNL	64(48.8%)	76(55%)	Chi square

In the ESWL group right side stone was 71(51.2%) while in PCNL group right side stone was seen in 64(35%), p value = 0.18.The left side stones were seen in 45% and 55% in ESWL and PCNL respectively.

Stone Location

Stone location	ESWL	PCNL	Fisher exact test
Upper	33(31.7%)	27(17.5%)	0.2758
Middle	23(7.3%)	23(7.5%)	1.0000
Lower pole	41(26.8%)	45(37.5%)	0.3474
Pelvis	44(34.1%)	45(37.5%)	0.8189

The distribution in ESWL and PCNL IN UPPER, MIDDLE, LOWER POLE and PELVIS was 33(31.7%) and 2 7(17.5%) p =.27;23(7.3%) and 2 3(7.5%), p=1.0;41 (26.8%)and 45(37.55), p=0.3474 and 44(34.1%) and 45 (37.5%), p=0.82 respectively.

Stone Size

N patients	ESWL (41)	PCNL (40)	P value	CI
Largest diameter (mm) (Stone size)	15.20 ± 2.62	15.52 ± 2.76	0.5944	-1.5 to 0.8

The mean stone size in ESWL group was 15.2 ±2.62 mm and 15.52 ±2.76 in PCNL with a p value 0.59 and 95% CI (-1.5 to 0.87).

Stone Clearance

Efficacy	ESWL	PCNL	P value
Success	103(73.17)	133(95%)	0.0069
Failure	38(26.83%)	7(5%)	Chi-square test

The Over -all Success rate at 3 months was 103(73.17%) in ESWL and 133 (95.00%) in PCNL group, p value 0.0069 (<0.05) by Chi square test. The overall failure was 45 (16.05%) with 38 (26.83%) and 7(5%) in ESWL and PCNL respectively.

Auxiliary Procedure

N patients	ESWL (41)	PCNL (40)	P value
Auxiliary procedure	7(17.07%)	2(5%)	0.1691

The need for Auxiliary procedurewas 7(17.07%) in ESWL and 2(5%)with p value =0.1691 by Chi square test.

Hospital Stay

The mean hospital stay in the two groups was 0.2 ± 0.89 days(range 0-3 days) and 5.725 ±1.78 days(range 4- 11 days) with a p value =0.0001 (95% CI 4.90 to 6.14) in ESWL and PCNL respectively.

Re Treatment Rates

The retreatment rates in two groups was 79/141(56%) and 7(5%) p value =0.0001 in ESWL and PCNL respectively.

Complications (Modified Clavien Grade)

Complications were mostly minor and found in 9.7% in patients undergoing ESWL as compared to 30% in patients undergoing PCNL.

The two-tailed P value equals 0.0446.Grade 1 complications were seen in 13(7.3%) and 17(12.19%), Grade II complications were seen in 3(2.4%) and 5(12.19%), Grade III complications seen in 0 and 5(5%) of ESWL and PCNL respectively.

Blood Transfusion

The blood transfusion in ESWL was 0 and 17(12.5%) in PCNL group, P =0.01.

Emergency Admission

The emergency admission rate was 10(7.3%) and 3(2.5%) in ESWL and PCNL groups respectively, p value = 0.6259.

ESWL and stone clearance overall at one and three months based on density(HU)

At 4 weeks, overall success rate <1000 HU 47/71 (57%) and > 1000 HU 21/70(30%), P=0.000592, Chi square test. At 12 weeks, overall success rate <1000 HU, 58/71(85%) for > 1000HU, 42/70(60%) (P=0.06Chi Square Test).

ESWL outcomes based on stone size and density at three months

Success for stones less than 150 mm, <1000 HU, 36/36(100%), but >1000HU it was 23/32(71.4%), p= 0.06, Fischer Exact Test. Success for stones 150 mm or greater <1000 HU, 24/35(70%), but >1000 HU it was 20/38(53.84%) (p=0.43, Fischer Exact Test)

DISCUSSION

First percutaneous removal of stone under image intensifier was done by Fernstrom and Johannson[1] in 1976.

About thirty years back, Chaussy et al.[2] in 1980 described the first treatments of patients by ESWL for renal and ureteric calculi.

Gradually ESWL due to its non-invasive nature gained popularity and widespread acceptability by patients but this initial enthusiasm of ESWL in every size of stone was met with poor outcomes in many patients.

PCNL being invasive has its own limitations but due to its better one time clearance in bigger stones its use has increased in last twenty years.

As experience with these two modality increased researchers tried to define the place of ESWL and PCNL in the management of renal calculi of various size, location and composition.

The first reports in literature came in 1985 when C R Charig et al.[3] compared 350 cases each of open stone removal, PCNL, and ESWL.

A summary of subsequent published results is summarised in Table 3 and compared with the present study. Seven studies are RCTs[5,7,8,9,12,13,14], while six were prospective[2,3,10,11,15] and four were retrospective[1,4,6,16] (Table 1). Four studies were for lower pole only (Neto et al[4], Cass et al[6], Albala et al[9], Yuruk 2010 et al[13]) while one excluded lower pole stones (Deem et al[14]) while Okan et al[16] studied only pelvic stones.

One study included only radiolucent stones (Anup kumar et.al) while most included a mixed opacity population but we excluded radiolucent stones because of no flexible nephroscope which makes it difficult to monitor clearance under fluoroscopy.

In this study, the age distribution of the patients was 18 to 65 years. In PCNL group, the age range was 17 to 60 years with mean age 39 ±10.06 years. In ESWL group, the age range was 17 to 65 years with mean age 40.46 ±12.90 years. There was no significant difference in age among the groups.

In the study by Mays N. et al.[2] (1988) age range was reported between 14-84 years in PCNL group and between 11-90 years in ESWL group. In another study done by Saxby M.F et al.[8] (1997), age range was 2-90 years in PCNL group and 6-85 years in ESWL group. In these studies, the highest age of the patients was 90 years in both the groups, which is

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Researcher	Year	Type of study	Participants ESWL	Participants PCNL	Size stone	Success ESWL	Success PCNL	Success 1-2cm	Follow up
C R Charig, et al[1]	1985	Retrospective	352	350	Two groups <2CM>	92%	83%	NA	12 weeks
Mays et al[2]	1988	Prospective, multicenter	933	195	5mm-3cm	58%	86%	E59% P92%	12 weeks
Elspeth M. McDougall et al[3]	1989	Prospective	35	29	Three groups <1, 1-2, >2	57%	85%	E50% P66%	12 weeks
Neto et al[4]	1991	Retrospective	24	23	1.22cm 1.42cm	79.2%	93.6%	E79% P93%	12 weeks
Carlsson et al[5]	1992	RCT	30	25	4-30mm	77%	94%	Na	1 year
Cass et al.[6]	1996	Retrospective	968	Historical studies	4-30mm	71.2%		E59% P	12weks
Shimon Meretyk et al[7]	1997	RCT	27	23	Staghorn	22%	74%	NA	6-Month
Saxby et al[8]	1997	RCT	618	390	<2 cm>	83%	80%	E74% P85%	
Albala et al [9]	2001	RCT	60	68	<3cm	37%	95%	E23% P92%	3 months
Pradeep P Rao et al[10]	2001	Prospective	257	77	<2 cm	69.3%	94.03%	E69.3% P94%	12 weeks
Young Duk You et al[11]	2006	Prospective	39	22	<2cm	63.6%	100%	E 63.6% P 100%	12 Week
Perminger et al[12]	2006	RCT	T=121		<3cm	21%	92%	E21% P92%	12 Months
Yuruk 2010 et al[13]	2010	RCT	33	33	<2cm E139.4m P153.m	54.8%	100%	E 54.8% P 100%	12 Months
Deem et al[14]	2011	RCT	20	12	10-20mm	33%	85%	E33% P85%	12Weeks
Joshua D. Wiesenthal et al[15]	2011	Prospective	53	43	1-3cm	60.4%	95.3%	NA	12 weeks
Okan Bas et al[16]	2014	Retrospective	52	50	1-2 cm	86%	98%	E 86% P98%	12 weeks
Anup Kumar et [17]	2014	RCT	45	45	1-2cm	73.8%	86.1%	E 73.8% P 86.1%	
Current study	2019	Prospective, RCT	141	140	1-2 cm	73.17%	92.68%	E 73.2% P 92.7%	12 weeks

Table-1: Summary of major research studies comparing ESWL and PCNL

higher than the present study. This may be due to different ethnic backgrounds and longevity in other parts of the world. The sex distribution of the study population did not have significant different between the groups. male and female ratio was overall 1.6: 1. In PCNL group, ratio was 2.07:1 while it was 1.27:1 in ESWL group. This results agrees well with results of Saxby M.F. et al.[8] (1997), where male to female ratio was 2:1 for PCNL group and 1.8:1 for ESWL.

In 2015 James F. Donaldson et al[18] in a systematic review and meta -analysis of studies concluded that PCNL is associated with high stone free rate at the expense of high complication rate, blood loss and longer hospital stay.

In our study the overall success in ESWL group at the end of three months was 73.17% for ESWL with Siemens. It is close to result of Saxby et al[8] (1997) reporting stone clearance of 75% for similar size stones.

Mc dougall et al.[5] (1989) in a prospective study reported poor outcome -50% stone clearance at the end of 12 weeks by ESWL in similar renal stones present at lower pole. Rao et al[10] in a prospective study done on 257 patients reported success rate of 69.3% at the end of 12 weeks by ESWL.

Okan Bas et al.[16] (2014) observed stone free rate of 86% after mean of 2.6 sessions ESWL where they had studied only pelvic stones. In a similar prospective study done by Anup et al.[17] (2014) on radiolucent stones, stone free rate of ESWL was 73.8%.

S Meretyk et al[7] (22%), Albala et al[9] (23%), Perminger et al[12] (21%), Yuruk et al[13] (54.8%), Deem et al[14] (33%) had a poor ESWL outcomes then ours. The later researchers undertook the study in lower pole stones only. Another variable could be the use of different lithotripter by different groups.

On comparison of stones in lower pole group we have a success of 45.45%. The definition and size of CIRF as well as the post procedural method of assessment (like use of NCCT) probably accounted for such large variations in ESWL outcomes, we did not used NCCT in follow up because of economic and radiation hazards, but both Yuruk et al[13] and Deem et al[14] used NCCT as well as used a lower stone free cut off < 3mm, also the follow up in Deem's group was up to one year. In comparison we have a cut off 4mm and follow up of 3 months only as well we used only x-rays for follow up and that is why we were more likely to miss the residuals thus a better stone free rate.

Young duk et al.[11] in 2006 reported a clearance rate of 63.6% at the end of 12 weeks and another study by Yuruk et al[13] (2010) had a success rate of 54.8%.

One of the initial studies done by Chariag et al.[3] (1986) reported stone clearance of 92% by ESWL probably because of unmodified Dornier use. However the complication in this series was 11%. Difference in success rate after ESWL could be use of different lithotripter machines, different definitions of CIRF, the duration and modality of follow-up and other stone variables.

In the current study, stone clearance in PCNL group after one sitting was 95.00% which closely matches the result of Saxby M F[5] et al. (1997).

Similar results were also reported by other workers - Albala et al.[9] (92%), Rao et al.[10] (94%), Young Duk You et al.[11] (100%), Yuruk 2010 et al.[13] (100%), Deem et al[14] (85%), Joshua D. Wiesenthal et al.[15] (95.3%), Okan Bas et al.[16] (98%).

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.

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[17] the lower success rate after PCNL (86.1%) is probably because of difficulty in monitoring radiolucent stones under fluoroscopy.

Auxiliary Procedure

In this study, the need for auxillary procedure was 24(17.07%) in ESWL and 7(5%) in PCNL (p value =0.1691, Chi square), similar to series of Anup Kumar[17] (ESWL 20.2%, PCNL 8.8%).

Retreatment Rates

The re treatment rates in two groups was 79/141(56%) and 7/140(5%) (p value =0.0001) in ESWL and PCNL respectively. Anup Kumar et al[17] observed similar rates (63.4% vs 2.2%) in ESWL and PCNL respectively.

Hospital Stay

The mean hospital stay in the two groups was 0.2 ± 0.89 days (range 0-3 days) and 5.725 ±1.78 days (range 4- 11 days) with a p value =0.0001 (95% CI 4.90 to 6.14) in ESWL and PCNL respectively.

Complications

Complications were mostly minor in our study - in 9.7% patients undergoing ESWL but in 30% of patients treated by PCNL. The two-tailed P value equals 0.0446. The blood transfusion was 18(12.5%) in PCNL group, while none in ESWL (P =0.01)

Grade 1 complications were seen in 13(7.3%) and 17(12.19%), Grade II complications were seen in 3(2.4%) and 17(12.19%), Grade III complications seen in 0 and 7(5%) of ESWL and PCNL respectively.

These complications rate as per modified Clavien grade are similar to those observed in contemporary series.

In Okan Bas et al[16] study Grade 1 complications were seen in 4% and 4%, Grade II complications were seen in 1.3% and 4%, Grade III complications seen in 1.3% and 4% of ESWL and PCNL respectively.

In the study of Anup et al.[17] Grade 1 complications were seen in 2% and 8%, Grade II complications in 1% and 2% in ESWL and PCNL respectively. No Grade III complications were seen.

CONCLUSION

The primary objective in stone management is total stone clearance. Considering this as priority PCNL has proved superior to ESWL in our study for renal stones 1-2 cm in size. It has also got lower auxiliary and retreatment rates but has its own share of complications and longer hospital stay are other important factors in PCNL.

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