A Prospective Study of Effectiveness of ESWL versus PCNL in Patients with Kidney Stone Size 1-2 cm

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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 effectiveness of extracorporeal shock wave lithotripsy with that of percutaneous nephrolithotomy for managing kidney stones measuring between 1 to 2 cm.

Material & Methods: This study included 81 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 1-2cm size were evaluated in the study with 41 in the ESWL and 40 in the PCNL group. Both the groups were well matched with regards to age and sex distribution. Forty one patients underwent ESWL and 30/41 (73%) patients had stone clearance in 1-3 months. Forty patients underwent PCNL out of which 38 (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: 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.
ultrasonography. The preferred treatment of <1 cm 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 percutaneous nephro lithotomy (PCNL) and extra corporeal shockwave lithotripsy (ESWL) with reference to stone clearance, hospital stay and complications. The primary goal while treating renal stones is to achieve complete clearance while causing minimal morbidity to the patient. Treatment of renal stone depends on stone size and location plus patient related factors including anatomy of pelvicaliceal system, Treatment should be individualised considering the above mentioned factors as well as available expertise and instruments. This study has been undertaken to formulate a better understanding of management of renal stones of size 1-2 cm in our patient population. Our aim of study was to evaluate prospectively the success of treatment with regards to stone clearance between the two groups ESWL and PCNL. Secondary aim was to study short term complications related to ESWL and PCNL.

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 SCBMCH, Cuttack between the period November 2015 to January 2018. From 126 patients with solitary renal stone size 1-2 cm, 93 agreed to participate in the study (44 and 49 in PCNL and ESWL respectively). Complete follow up data were available for 81 patients 40 in PCNL and 41 in ESWL group, 12 patients were lost to follow up. Bilateral stone, radiolucent stone, stone size >2 cm, Age <12 yrs or >75 years, bleeding diathesis, pyonephrosis, severe hydronephrosis, advanced cardiorespiratory disease and poorly controlled diabetes mellitus were excluded from the study. A randomization table was used, Patients in group A were allocated for PCNL while in 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 KUB, USG, Intra Venous Urogram (IVU) and Non contrast CT (NCCT), hematology, 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 and Hounsfield units for better subgroup analysis. The treatment outcomes were recorded and analyzed as per study performa. An auxiliary procedure was considered as any additional procedure to render patient stone free. For failed ESWL the auxiliary procedures were ureteroscopy/PCNL. 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-arm fluoroscopy and retrograde contrast pyelogram. Tract dilatation was performed with Amplatz fascial dilators' up to 30 Fr, as required. Nephoscopy was performed with 26 Fr
rigid nephroscope (Richard Wolf, Germany) and stone fragmentation was performed with pneumatic lithoclast. At the end of the procedure, stone clearance was checked on combined fluoroscopy and nephroscopy. Antegrade double -J (DJ) stent was placed in all patients. Nephrostomy tube was inserted at the end of the procedure. Duration of procedure was recorded from anesthesia note. Fluoroscopy time was recorded by single operator by total fluoroscopy number per case (with each number equal to one second of exposure). X-ray to KUB and routine blood examination was performed on 3rd postoperative day. Nephrostomy was removed if there was no evidence of residual fragment. DJ stents were removed after three to four weeks. 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 Technique**

Patient of solitary renal calculus of 1-2 cm. were evaluated similar to PCNL. Measurement of Hounsfield Unit of renal stone during CT was done. All patients underwent ESWL using The Dormer compact delta II. 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 clinically insignificant residual fragments (CIRF) < 4 mm 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. All patients were treated in supine position and by one doctor and one technician. The session was stopped when the stone disintegrated satisfactorily or the patient was in discomfort or machine's upper limit of shock waves per session (3000) was reached. Fluoroscopy time was recorded by single operator by total fluoroscopy number per case (with each number equal to one second of exposure). Post ESWL instructions were rest for 7 days, plenty of oral fluids, to pass urine in a strainer for collection of stone, antibiotics for seven days with on demand analgesics till next x-ray. Patient and attendant were explained about possible complications. 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. The data was subjected to statistical analysis with SPSS version 16 statistical software and Microsoft excel. The p-value <0.05 was considered significant. Results were analyzed using Student’s t-test and chi-square test, Fischer exact test multivariate analysis and one-way ANOVA.

**Results**

There was no significant difference in age among the groups, p value 0.57 and 95% CI (-3.62 to 6.5). 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). The male to female ratio was 1.6:1, with 23 males in ESWL(56%) and 27 (67.5% ) male in PCNL group. The number of females was 18 (44%) and 13 (32.5%) p value=0.287. The sex distribution of the study population did not have significant different between the groups. There were 35 stones on right and 46 on left (1.3:1). In the ESWL group right side stone was 21 (51.2%) while in PCNL group right side stone was seen in 14 (35%), p value = 0.18. The left side stones were seen in 48.8% and 65% in ESWL and PCNL respectively. (fig-1)
There were 20 upper polar, 6 middle pole, 26 lower polar and 29 renal pelvic stones. The distribution in ESWL and PCNL in upper, middle, lower pole and pelvis was 13 (31.7%) and 7 (17.5%) for ESWL and 15 (37.5%) and 15 (37.5%) for PCNL, respectively. The p value was calculated according to two-tailed Fisher exact test (fig-2).

**Fig 3 - Stone clearance**
The overall success rate at 3 months was 68 (83.95%) with 30(73.17%) in ESWL and 38(95.00%) in PCNL group, p value 0.0069 (<0.05) by Chisquare test. (fig-3)The overall failure was 13 (16.05%) with 11 (26.83%) and 2(7.32%)in ESWL and PCNL respectively.

Table-1 parameters studied

| Parameters               | ESWL(41) | PCNL(40) | P Value |
|--------------------------|----------|----------|---------|
| Auxiliary procedure      | 7(17.07%)| 2(5%)    | 0.1691  |
| Mean hospital stay       | 0.2±0.8918| 5.7 ±1.78| 0.0001  |
| Retreatment rate         | 23(56%)  | 2(5%)    | 0.0001  |
| Blood transfusion        | 0        | 5(12.5%) | 0.01    |
| Emergency admission      | 3(7.3%)  | 1(2.5%)  | 0.6259  |

The need for auxiliary procedure was 7(17.07%) in ESWL and 2(5%)with p value =0.1691by Chi square test. 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. The retraining rates in two groups was 23/41(56%) and 2(5%) p value =0.0001 in ESWL and PCNL respectively. The blood transfusion in ESWL was 0 and 5(12.5%) in PCNL group, P=0.01. The emergency admission rate was 3(7.3%) and 1(2.5%) in ESWL and PCNL groups respectively,p value -0.6259.(Table-1)

Table -2 Complications-modified Clavien grade

| Complications (Clavien grade) | ESWL(41) | PCNL(40) | TOTAL | P Value |
|-------------------------------|----------|----------|-------|---------|
| None                          | 37(90.2%)| 28(68.29%)| 65    |         |
| I                             | 3(7.3%)  | 5(12.19%)| 8     | 0.7371  |
| II                            | 1(2.4%)  | 5(12.19%)| 6     | 0.2033  |
| III. a                        | 0        | 2(5%)    | 2     | 0.168   |
| III. b                        | 0        | 0        | 0     |         |

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-I complications were seen in 3(7.3%) and 5(12.19%), Grade-II complications were seen in 1(2.4%) and 5(12.19%), Grade III complications seen in 2(5%) of PCNL.(Table-2)

Discussion

In the last three decades newer technologies-ESWL, URSL and PCNL have completely replaced the open surgery for renal stone management. ESWL being a non-invasive day care technique is favored by many urologists as the treatment of choice for less than 2 cm renal stones because of patient acceptance. With improvement in optics and fragmentation energy source PCNL is also gaining popularity for treatment of such stones. Consensus still eludes over the right choice between PCNL and ESWL for the management of renal stones 1-2cm in size. This prospective study has been designed to compare the outcomes of these two techniques in terms of success and complications for 1-2cm renal stones in our patient population. In PCNL group, 17 (42.5%) patients were in stone size between 1.0 cm to 1.5cm and 23(57.5%) were in stone size between 1.5-2.0 cm. In ESWL group 44 % were in stone size between 1.0-1.5 cm and 56% were in stone size between 1.5-2.0 cm. In our study the overall success in ESWL group at the end of three months was 73.17% for ESWL, It is close to result of Saxby et al reporting stone clearance of 75% for similar size stones.Okuna Bas et al. in their retrospective study observed stone free rate of 86% after mean of 2.6 sessionsESWL and complication rate evaluated by modified Clavien grading system was 7.6%.
In a similar prospective study done by Anup et al., on radiolucent stone of size 1-2 cm located at lower poles on Indian patients -3 month stone free rate of ESWL was 73.8% the retreatment rate was 63.4% and the auxiliary procedure rate 22.2%. However Mcdougall et al. (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. (2001) in a prospective study done on 257 patients reported success rate of 69.3% at the end of 12 weeks by ESWL. Young Duk et al. in 2006 reported a clearance rate of 63.6% at the end of 12 weeks and another study by Yuruk et al. had a success rate of 54.8%. Mild difference in success rate after ESWL could be use of different lithotripter machines and other patient and stone variables. One of the initial studies done by Chariag et al. (1986) reported stone clearance of 92% by ESWL probably because of unmodified Dormer and liberal use of shock waves till all the fragments got cleared. However the complication in this series was 11%. In the current study, stone clearance in PCNL group after one sitting was 95.00% which closely matches the result of Saxby MF et al. Similar results were also reported by other workers - Albala et al. (92%), Rao et al. (94%), Young Duk You et al. (100%), Yuruk et al. (100%), Deem et al. (85%), Joshua D. Wiesenthal et al. (95.3%), Okan Bas et al. (98%), NH Wankhade et al. (97%). The nearly identical success rates of different investigators attest to the fact that FCNL 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., the lower success rate after PCNL (86.1%) is probably because of difficulty in monitoring radiolucent stones under fluoroscopy. All the fragments are removed during PCNL itself so there is no issue of CIRF. In the present study, stone clearance was 73.1% and 95.0% among ESWL and PCNL group respectively. Here statistical analysis shows a significant difference of clearance (P<0.05). This is close to study done by Saxby M.F, Neto et al., P Rao et al. and Anup Kumar et al. In our study, mean post procedure hospital stay in PCNL and ESWL group was 5.72±1.78 and 0.2 ± 0.8 days respectively. The mean hospital stay is much less in ESWL group than PCNL group and this difference was statistically highly significant (p<0.0001). Saxby et al. noted similar findings. While M. Me Dougall 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 - 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 this study, the need for auxiliary procedure was 7(17.07%) in ESWL and 2(5%) in PCNL (p value =0.1691) similar to series of Anup Kumar (ESWL 20.2%, PCNL 8.8%). The re treatment rates in two groups was 23/41(56%) and 2/40(5%) (p value =0.0001) in ESWL and PCNL respectively. Anup Kumar et al. observed similar rates (63.4% vs 2.2%) in ESWL and PCNL respectively. 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 5(12.5%) in PCNL group, while none in ESWL (P =0.01). Grade-1 complications were seen in 3(7.3%) and 5(12.19%), Grade II complications were seen in 1(2.4%) and 5(12.19%), Grade III complications seen in 0 and 2(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. study Grade 1 complications were seen in 4 % and 4 %, Grade II complications were seen in 1.3 % and 4%, Grade III complications were seen in 1.3 % and 4% of ESWL and PCNL respectively. In a study of Anup et al. Grade 1 complications were seen in 2% and 8%, Grade II complications were seen in 2% and 8%.
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. Radiation exposure and longer hospital stay are other important factors in PCNL.

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