

Comparison Of Eswl And Mini-Pcnl For Treatment Of Kidney Stone Of 1-2 Cm In Size With Hounsfield Unit ≤ 750

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Abstract:

Background: Renal Stone Disease Is A Persistent Medical Disorder With A Recurrence Rate Of 50% And Consequently Has A Significant Influence On Health-Related Quality Of Life. Management Of Urolithiasis Ranges From Conservative Watchful Waiting To Traditional Open Surgical Procedure. In Between These Two, There Exist Spectrums Of Procedures, Which Include The Recently Developed Non-Invasive To Minimally Invasive Procedures. Now The Preferred Treatment Of Less Than 1 Cm Stone Is ESWL While Standard Of Care For Renal Stone More Than 2 Cm Is Standard PCNL But The Procedure Of Choice For 1 To 2 Cm Renal Stone Is Still A Subject Of Debate. Therefore, The Present Study Will Be Conducted To Compare The Stone Clearance And Complications Of ESWL (Extracorporeal Shock Wave Lithotripsy) With Mini-PCNL (Mini Percutaneous Nephrolithotomy) In Treatment Of Kidney Stones 1-2 Cm With Hounsfield Unit ≤ 750 That Will Help Us To Obtain A Better Understanding Of The Management Of Renal Stones Of Size 1-2 Cm.

Materials And Methods: This Study Included All The Patients With Renal Stone 1-2cm In Size With Hounsfield Unit ≤ 750 With Age Range 18 To 75 Years. A Total Of 82 Patients Were Assigned To Receive ESWL Or Mini-PCNL For Treatment Of Stone Were Enrolled In The Study And The Results Were Compared In Terms Of Stone Free Rate (SFR), Requirement Of Ancillary Procedure, Hospital Stay In Days And Complications.

Results: The SFR Was Statistically Higher In The Mini PCNL Group For All Locations. The SFR For The ESWL Group Was Low After 1st Session; However, It Increased With Multiple Sessions. There Was No Statistically Significance Difference Between The Two Group In Terms Of Need For Ancillary Procedure But Mean Hospital Stay In Mini-PCNL Group Was Statistically Higher. We Had A Total Of 13 Complications In Both Groups, Which Was Statistically Insignificant.

Conclusion: This Study Showed That The Mini PCNL Is A Viable, Safe Option For The Treatment Of 1-2 Cm, Having Superior Sfrs Compared To ESWL With Statistically Insignificant Complications. It Can Be Offered As First Line Option For The Management Of Such Stones.

Keywords: Extracorporeal Shock Wave Lithotripsy, Kidney Stones, Mini Percutaneous Nephrolithotomy

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I. Introduction

Renal stone disease is a persistent medical disorder with a recurrence rate of 50% and consequently has a significant influence on health-related quality of life^{1,2}. Renal stone disease may be complicated by hydronephrosis, pyonephrosis, septicaemia, 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 spectrums of procedures, which include the recently developed non-invasive to minimally invasive procedures. One option can supplement the other for total stone clearance³. Technological advances in minimally invasive surgery e.g., Extracorporeal Shockwave Lithotripsy (ESWL) and percutaneous nephrolithotomy (PCNL), have improved the efficacy and outcome of renal stone management^{1,4}. ESWL has revolutionized the treatment of urinary stones with the concept of stone fragmentation⁵. Extracorporeal Shock Wave Lithotripsy (ESWL) is the main modality of treatment in renal stones <2.0cm in size⁶. 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 intervention⁷. Although ESWL is an effective treatment of urinary calculi, it can cause complications like stone colic, renal hematoma, delayed stone fragment passage or obstructed ureter due to steinstrasse (column of stone fragments) may occur⁵.

PCNL is now considered the 'gold standard' treatment for managing simple as well as complex renal stones, with a success rate of >90%^{1, 8, 9}. The complication rates have been reported to be up to 25%¹⁰. With advancements in techniques and technologies, miniaturized PCNL (mini-PCNL), defined as a PCNL involving the use of smaller nephroscope and sheath¹¹, can be performed effectively to manage kidney stones with high stone free rates and decrease morbidity, analgesic requirement and hospital stay¹². Standard PCNL is done with sheath size of 24 to 30 F, whereas the mini PCNL is done with sheath 14 to 20 F.^{10, 11}

Treatment of renal stones depends on stone factors such as size and location and patient related factors including anatomy of pelvicalyceal system. The treatment should be individualized considering the above the mentioned factors as well as available expertise and instruments. Now preferred treatment of less than 1 cm stone is ESWL while standard of care for renal stone more than 2 cm is standard PCNL but the procedure of choice for 1 to 2 cm renal stone is still a subject of debate.

Therefore, the present study will be conducted to compare the stone clearance and complications of ESWL with mini-PCNL in treatment of kidney stones 1-2 cm with Hounsfield unit ≤ 750 that will help us to obtain a better understanding of the management of renal stones of size 1-2 cm.

Material And Methods

This was a nonrandomized study. The study included 82 patients with renal stone 1-2cm in size with Hounsfield unit ≤ 750 with age range 18 to 75 years who attended the Department of Urology, Regional Institute of Medical Sciences (RIMS), Imphal from April, 2021 to March 2023. The patients were divided into two groups with 41 of them undergoing ESWL and the other 41, mini-PCNL. Patients with radiolucent stone, ureteropelvic junction obstruction or distal obstruction or urethral stricture, patients suffering from chronic kidney disease, bleeding diathesis, presence of infection, pregnancy were excluded from study. All patients gave written informed consent. Institutional ethical committee clearance was obtained before starting the study (Ref no. A/206/REB Comm (SP)RIMS/2015/801/143/2021).

Inclusion criteria:

1. Patients who attended RIMS Urology department with renal stone 1-2cm in size with Hounsfield unit ≤ 750 who will be undergoing ESWL or mini-PCNL.
2. Either sex
3. Aged between 18 years to 75 years.,

Exclusion criteria:

1. Radiolucent stone
2. Ureteropelvic junction obstruction or distal obstruction or urethral stricture.
3. Patients suffering from chronic kidney disease.
4. Patients with bony deformities precluding ESWL positioning or lithotomy positioning.
5. Bleeding diathesis
6. Pyonephrosis
7. Pregnancy
8. Transplant recipients
9. Advance cardio respiratory disease
10. Poorly controlled diabetes mellitus
11. Presence of infection
12. Not giving consent

Procedure methodology

All patients underwent routine investigations like Hb, TLC, DLC, ESR, RBS, Urine-R/M, Urine-C/S, Blood Urea, Serum Creatinine, Serum Electrolytes, BT, CT, ECG, Chest X ray.

Ultrasound KUB was done to make out the site, size of calculus, proximal pelvicalyceal and ureteric dilatation (hydronephrosis). Plain X-ray KUB was done (kidney, ureter, bladder) to make out the size and location of stone. NCCT KUB was done to make out the size, location and Hounsfield unit of stone. Intravenous pyelogram (IVP) or CT-urogram was done to make out the degree of obstruction caused by the calculus and excretion status of the renal units.

Treatment options were discussed with patient and his/her relatives with a detailed explanation of involved procedure and complications as well as the available other alternative. Informed written consent was obtained.

fragment the target stones or presence of residual fragments ≥ 4 mm in size at one month after the last sessions of ESWL in X-ray KUB. While success was defined as complete stone clearance or insignificant fragment size less than 4mm in X-ray KUB at one month after last session of ESWL. Incomplete clearances will be defined as having stone fragments ≥ 4 mm in size at one month after last session of ESWL. Clinically

insignificant residual fragments (CIRF) are defined as having stone fragments of 4mm or less in size in asymptomatic non struvite patients at one month after last session of ESWL. They were advised to attend emergency department in case of fever, severe pain and haematuria.

Mini-PCNL Technique:

All the patients who underwent mini-PCNL under general or regional anaesthesia as per the anaesthetic choice. With the patient under anesthesia, a 5 to 6 Fr ureteric catheter was inserted in the ipsilateral ureter, which later allowed for injection of contrast material for opacification and distension of the collecting system to aid in making an appropriate puncture. After ureteral catheterization, the patient's position was changed to the prone position on a C-arm compatible table. Percutaneous antegrade access into the pelvicalyceal system was done by PCN puncture needle (18G) under fluoroscopy and entry into PCS was confirmed by free flow of contrast/urine from PCN needle. After gaining access into the PCS, a hydrophilic guidewire (0.035) was passed through the needle under C Arm guidance and needle was removed and keeping the guide wire in the collecting system. A small skin incision was made from the site of needle. The needle was removed and tract was dilated over the guide wire. The tract was first dilated with 16fr single step dilator. An Amplatz sheath (18/20 Fr) was introduced over the single step dilator and positioned under fluoroscopy.¹³ A Mini-Nephroscope was introduced for stone identification. Stone was broken with the Pneumatic Lithotripter under continuous irrigation of normal saline and fragments were removed.^{14,15,16} After evacuation of stone fragments, stone clearance was checked on C arm and antegrade 5/6 Fr ureteric stent was placed. Nephrostomy tube was kept across the tract, to serve the triple function of hemostasis, drainage and provision for relook nephroscopy, kept clamped for 24 hours then removed after 48-72 hours. Intra-operative parameters like operation time, blood loss during surgery. Postoperative parameters like wound infection, urinary leakage, time of convalescence, length of hospital stay and analgesic requirements were recorded as per the proforma of the study. Patients were discharged as soon as they were fit. Patients were asked to report as when required if any complications occur following discharge. plain x- ray/USG/NCCT-KUB was taken on 3rd postoperative day and decision to subject the patient for relook mini-PCNL, repeat surgery or any ancillary procedures were required. The patients were followed up again at 2 weeks with plain x- ray/USG/NCCT-KUB and DJ stent was removed (if there no significant residual stones) and any ancillary procedures like relook nephroscopy, ESWL etc to be provided (if there have significant residual stones) Stone clearance were decided from the plain x- ray/USG/NCCT-KUB at 3 month and the x- ray/USG/NCCT-KUB were read by an uninformed radiologist/urologist. Patients were followed up for at least three months and final result was noted. All data were recorded in a performa specially designed for the study. Complications were classified according to modified Clavien grading system.

ESWL Technique:

All the patients underwent ESWL were given 2 tablets dulcolax and 4 tablets charcoal previous night after dinner and morning X ray KUB was taken before starting the session in all the patients. Appropriate prophylactic antibiotics administered before the procedure and continued in the post procedure periods. Each patient was given an intramuscular injection of diclofenac 75mg 30 minutes prior to the procedure to control the pain. All patients were treated in supine position. The ESWL carried out by using "Dornier Compact Sigma lithotripter, a third generation electromagnetic lithotripter with ultrasound for stone localization and monitoring. The focal length of the lithotripter was 14 cm; the focal zone was 4.7x 5.7mm. Shock waves were delivered at a rate of 60 shocks /minute with intensity started at level 1 and gradually increased to next level after 500 shocks till level 3. The treatment protocol included 3000 shockwaves in each session or till the stone is completely fragmented, whichever occurs earlier. Post ESWL instructions physical rest for 1 day, plenty of oral fluids, to pass urine through a strainer for the collection of stone. Patients / attendants were explained about possible complications. Appropriate analgesics, antibiotics, haemostatic agents and Alpha-blockers were routinely advised in all patients.

Follow-up with plain x- ray/USG/NCCT-KUB obtained 1 week after treatment and ESWL were repeated for maximum of 3 session, if a ≥ 4 mm residual stone was still evident.

The patients were followed up again with plain x- ray/USG/NCCT-KUB after 1 month of the last setting of ESWL. Stone clearance were decided from the X-ray KUB/USG at 1 month after the last session, the plain x- ray/USG/NCCT-KUB was read by an uninformed radiologist/urologist & final result were noted. In evaluation of results of ESWL, failure was defined as inability to

fragment the target stones or presence of residual fragments ≥ 4 mm in size at one month after the last sessions of ESWL in X- ray KUB. While success was defined as complete stone clearance or insignificant fragment size less than 4mm in X-ray KUB at one month after last session of ESWL. Incomplete clearances will we defined as having stone fragments ≥ 4 mm in size at one month after last session of ESWL. Clinically insignificant residual fragments (CIRF) are defined as having stone fragments of 4mm or less in size in

asymptomatic non struvite patients at one month after last session of ESWL. They were advised to attend emergency department in case of fever, severe pain and haematuria.

Statistical analysis

Statistical analysis was done by using IBM SPSS Version 21 for windows. Descriptive statistics as mean, proportion, percentage was used to present results. Chi square test was used as a test of significance for comparing the outcome variables. P-value <0.05 was taken as statistically significant.

III. Result

Table 1: Comparison of demography, stone characteristics and stone free status , ancillary procedures & hospital stay between two groups

| | | ESWL (n=41) | MINI PCNL(n=41) | P |
|------------------------------|--------------|---------------------|--------------------|---------------|
| Age(year) | Mean ±SD | 40.92 ±12.90 | 39 ±10.06 | 0.4545 |
| | Range | 18-75 | 18-75 | |
| Gender, n (%) | Male | 23 (56%) | 28(68.29%) | 0.2542% |
| | Female | 18(44%) | 13(31.70%) | |
| Location, n(%) | Pelvis | 14 (34.1%) | 16 (39.02%) | 0.6457 |
| | Upper calyx | 13 (31.7%) | 7 (17.07%) | 0.1252 |
| | Middle calyx | 3 (7.3%) | 3 (7.31%) | 1.000 |
| | Lower calyx | 11 (26.8%) | 15 (36.58%) | 0.344 |
| Laterality, n(%) | Right | 21(51.2%) | 15(36.58%) | 0.184 |
| | Left | 20(48.8%) | 26(63.41%) | 0.185 |
| Size of stone(mm) | Mean±SD | 15.20 ± 2.62 | 15.52 ± 2.76 | 0.5918 |
| | Range | 1-2 | 1-2 | |
| Stone Attenuation Value (HU) | Mean±SD | +669.04±36.94 | +678.53±37.12 | 0.2494 |
| Stone free status, n (%) | | 30 (73.17%) | 38 (92.68%) | 0.019 |
| Residual stones | | 11 (26.83%) | 3 (7.31%) | 0.001 |
| Ancillary procedures | | 7 (17.07%) | 3 (7.31%) | 0.1795 |
| Hospital stay(days) | Mean±SD | 0 | 5.7±1.78 | 0.0001 |

ESWL: Extracorporeal shock wave lithotripsy, PCNL: Percutaneous nephrolithotomy, SD: Standard deviation, SFR: Stone-free rate, HU: hounsefield unit

Table -2 : Complications as per modified clavien dindo grade

| Complications (Modified clavien dindo grade) | ESWL(41) | Mini-PCNL(41) | P-Value |
|--|-------------------|-------------------|-------------|
| None | 37(90.24%) | 32(78.04%) | |
| I | 3 (7.31%) | 7 (17.07%) | 0.17 |
| II | 0 | 2 (4.87%) | 0.15 |
| III.a | 1(2.43%) | 0 | 0.31 |
| III.b | 0 | 0 | |
| IV | 0 | 0 | |

| | | | |
|-------|-----------|------------|------|
| V | 0 | 0 | |
| Total | 4 (9.76%) | 9 (21.95%) | 0.13 |

No statistical difference was found between the two groups with regard to demography and stone characteristics [Table 1]. Moreover, 41 and 41 patients were present in the ESWL and mini-PCNL groups, respectively. The SFR was significantly higher in the mini-PCNL group for all locations [Table 1]. Overall SFR was 92.68% in mini-PCNL group. Only three patients had residual stone after mini-PCNL, subjected to ESWL, and had complete clearance. The SFR for the ESWL group was low after the first session. However, it increased with subsequent sessions. The overall clearance was significantly lower post ESWL for all locations [Table 1].

Even after the completion of 3 sessions of ESWL, 11 patients had residual stones.

The mean hospital stay in Mini-PCNL group was 5.7 ± 1.78 days, while ESWL group were not admitted. There was statistically significant difference between the two groups in terms of Hospital stay [Table 1].

In this study complications were found in 4 (9.7%) patients in ESWL group and 9 (21.95%) patients in Mini-PCNL group, which was statistically insignificant (Table-2). Grade-I complications were seen in 3 patients in ESWL group and 7 patients in mini-PCNL group. Grade-II complications were seen in 0 in ESWL group and 2 in Mini-PCNL group. Grade-III complication were seen in 1 patient in ESWL group and 0 in Mini-PCNL group. Most common grade-I complication was haematuria followed by fever, which was managed conservatively. Grade-II complication was bleeding in mini-PCNL group managed by blood transfusion. Grade-III complications were steinstrasse in ESWL group requiring of ureteric stenting and/or URSL. This study summarized the complications as per the Clavien–Dindo classification system grading [Table 2].

IV. Discussion

The stone size, composition, and location are important factors affecting the outcome of treating kidney stones¹⁷. Due to the limitations of the success rate and the complications of SWL, other minimally invasive modalities for kidney stones such as PCNL, Mini-PCNL and retrograde intrarenal surgery (RIRS) are widely used. The treatment of renal stones with size of (1–2 cm) is controversial and the ultimate aim of the treatment should be minimally invasive techniques and provide the highest SFR with less procedures and the lowest complication rate¹⁸. There is a great debate and discrepancy about HU both in recent guidelines and in literature. A study concluded that obesity and increased stone density (>1000 HU) as detected by NCCT are significant predictors of failure to fragment renal stones by SWL¹⁹. Others stated that the cut of the level of HU for better fragmentation with SWL were 750 and 900 HU²⁰. In this study, a total of 82 patients were included, who had renal stones (size of 1 to 2cm with ≤ 750 HU). These patients either underwent ESWL [Group 1(n=41)] or Mini-PCNL [Group 2 (n=41)]. Both the Groups in our study were comparable in terms of number of patients, age, sex, stone size, stone attenuation value, stone location as there were no statistically significant differences between them.

In this study stone clearance was 73.17% and 92.68% in ESWL and Mini-PCNL group respectively. There was statistically significant difference between the two groups in terms of stone clearance. Multiple studies also found similar results which were comparable with our study. Most of the published data dealing with mini-PCNL reported success rates in the same neighborhood ranging from 83.3% to 100% with Knoll et al²¹. Mishra et al²² reported a success rate of 96% for mini-PCNL for stones of 10–20 mm. Fayad et al²³ evaluated success rate of 93% for mini-PCNL for stones smaller than 2 cm at the terminal calyx. This study had an SFR of 73.17% for the ESWL group. Fankhauser et al²⁴ had an SFR of 68.2% for stones of 5–20 mm in size, which was similar to this study. Bas et al²⁵ reported an SFR of 86% for renal stones of 10–20 mm. Another study by Javanmard et al²⁶ compared the ESWL and URS for pelvic stones in obese patients and had an SFR of 71% with ESWL. These wide variations in results explain that SFR in ESWL depends on many variables including stone density (Hounsfield unit), intrarenal anatomy, skin-to-stone distance, and the location and number of stone. It is a procedure having varied results in terms of success, whereas mini-PCNL is a trustworthy procedure having persistent high success rates in different studies. Consequently, the same was proven in this study where SFRs of 73.17% and 92.68% in ESWL and Mini-PCNL group respectively. Thus, the mini-PCNL gives very high success rates for stones in any location. Moreover, the retreatment rate is quite high in the ESWL-treated patients and has been shown in numerous papers.

Regarding the safety between the two procedures, the complication rates in the ESWL group 9.7% were statistically insignificant compared with those in the mini-PCNL group 21.95%. This study revealed a complication rate of 21.95% in the mini-PCNL group that is comparable with the reported complication rates in literature ranging from 16% to 28%^{27,28}. On grading the complications as per the Clavien–Dindo grading, complications in the ESWL group were grade 1 and grade 3. Grade-1 managed conservatively and grade-3 required intervention in ESWL group. Moreover, the majority of complications in the mini-PCNL group were grade 1 and grade 2.

Grade-1 complications managed conservatively and grade- 2 complications required one unit blood transfusion in two patients of the Mini-PCNL group. Other patients of both groups did not require a blood transfusion which was comparable with that of the study by Mahboubeh saleh,dinyar khazaeli et al²⁹ and Rao PP et al³⁰. Complications seen in the ESWL group were 9.7% in our study and were similar with the complications mentioned by other studies in the literature^{31,32}.Furthermore, a study by Srivastava for the management of 1–2 cm renal stones revealed similar results in terms of efficacy and safety³². In this study, the need for auxiliary procedure was 7 (17.07%) in ESWL and 3 (7.31%) in Mini-PCNL [p value 0.1795%] in addition to the primary treatment method. Mahboubeh saleh,dinyar khazaeli et al²⁹ showed that the need for an auxiliary method is seen in 10% of cases in Mini- PCNL method and 60% of cases in ESWL method. Albala et al³³ showed that the need for an auxiliary method is seen in 10% of cases in PCNL method and 20% of cases in ESWL method.Deem et al³¹ reported that the need for secondary methods and re-treatment of patients underwent ESWL method was significantly higher compared to PCNL method.The mean postoperative hospitalisation time was 5.7 ± 1.78 days in Mini-PCNL group while the patients in the ESWL group were not hospitalized. In the study of Mahboubeh saleh,dinyar khazaeli et al³², mean postoperative hospitalisation time was 1.3 ± 0.57 days in Mini-PCNL group while the patients in the ESWL group were not hospitalized.which was comparable with that of the study by Resorlu et al³⁴, Carlsson et al³⁵.The drawback of our study is small sample size and it needs larger sample size of the two groups to come to a definitive conclusion about the rate of complications and ancillary procedures requirement.

V. Conclusion

Patients with stones size of (1–2cm) with ($HU \leq 750$) need an individualized approach for each case with respect to the stone site, burden, and HU density. Both procedures have comparable results as regards final stone free rate and both are complementary to each other.This study showed that the mini-PCNL is a viable and safe option for the treatment of 1–2cm renal stones with $HU \leq 750$ having superior SFRs compared with ESWL with slightly increased minor complications. It can be offered as a first-line option for the management of such stones provided that the patient is fit for anesthesia and ready for admission in the hospital.

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