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# CLINICAL AND RADIOLOGICAL FACTORS INFLUENCING EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY OUTCOME

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**ABSTRACT** **Introduction:** Extracorporeal shockwave lithotripsy (ESWL) was first introduced in 1980. It has become a preferred treatment modality for uncomplicated renal and ureteral stone less than 20 mm in diameter, as it is safe and non-invasive. The success rate ranges from 46% to 91%. The results are measured on basis of stone fragmentation and clearance, which is influenced by stone size, stone location, skin-to-stone distance, stone composition, severity of obstruction, urinary tract anatomy, obesity, and machine type. **Objectives:** Primary Objective To estimate the success rate of ESWL **Secondary Objective:** To study the clinical and radiological factors that influence the of extracorporeal shock wave lithotripsy outcome **Methodology:** Our study is a prospective Observational study done in department of Urology, Government Medical College, Thiruvananthapuram in patients undergoing ESWL. In patients who underwent ESWL using an siemens modularis variostar electromagnetic lithotripter, postoperative X ray /USG was taken to assess the fragmentation. The result of treatment was evaluated by plain Xray/USG at 2 weeks after each ESWL. Residual fragments were considered significant if it was 6mm or more and ESWL was said to be unsuccessful. The study variables were age, gender, BMI, size of stone, skin to stone distance, stone location, stone density in HU. **Results:** We found a statistically significant association between ESWL success rate and BMI, size of the stone, Hounsfield unit and skin to stone distance. From our study we were able to better understand the outcome predictors of ESWL. **Conclusion:** ESWL is a useful, non-invasive modality of treating certain types of upper urinary tract calculi. The overall success rate of ESWL in this study was 58.29% in treating upper urinary tract calculi. The prognostication of the success of ESWL is possible by identifying patient and stone factors.

**KEYWORDS :** ESWL, outcome, success

## INTRODUCTION

Extracorporeal shockwave lithotripsy (ESWL) was first introduced in 1980 by Chaussy et al. It has become a preferred treatment modality for uncomplicated renal and ureteral stone < 20 mm in diameter, as it is safe and non-invasive[1]. After the introduction of original first generation electrohydraulic lithotripter, numerous modifications have been made in subsequent models. These modifications made the procedure more comfortable and tolerable for patients without anaesthesia, at the expense of less energy delivery and, therefore, lower success rates and higher re treatment rates [2]. The success rate of ESWL has a wide variation ranging from 46% to 91%[3,4] .The results of ESWL are measured depending on the stone fragmentation and clearance, which is influenced by some predicting factors such as stone size, stone location, skin-to-stone distance (SSD), stone composition, urinary tract anatomy, obesity, and ESWL machine type[5]. The chemical composition of urinary calculi in vivo has been found to be the main factor in determining the outcome of ESWL[6]. Now non-contrast computed tomography (NCCT) has become the diagnostic modality of choice to evaluate urolithiasis and its ability to detect density, thus helping in determining the composition and fragility of urinary stones and the outcome of ESWL[7]. Patient factors associated with decreased probability of SWL success include increasing patient age [8], body mass index (BMI) or skin-to- stone distance (SSD)[9] longer infundibular length [10], ureteropelvic junction diameter. Other unfavourable stone characteristics include higher Hounsfield unit (HU) density[11], larger stone diameter and volume and greater number of stones, greater stone heterogeneity[12] and stone location in the kidney compared to the ureter. Technical factors such as frequency of shock waves used, energy levels, accuracy of targeting the stone, focus size and patient breathing patterns will also affect SWL efficacy. Although ESWL is a non-invasive and safe procedure compared to other treatment modalities, it may also cause complications such as haemorrhage, steinstrasse, renal hematoma, infection, and flank pain[13].In cases where ESWL fails, the unnecessary exposure of renal parenchyma to shock waves may lead to complications and further alternative treatments leading to additional medical expenses[14,15]. Therefore, it is important to investigate the predictors influencing ESWL outcome to decide the treatment strategy for preventing unnecessary complications and the cost and treatment time after the diagnosis of urinary stone.

## AIMS AND OBJECTIVES

**Primary Objective :** To estimate the success rate of ESWL

**Secondary Objectives:** To study the clinical and radiological factors that influence the of extracorporeal shock wave lithotripsy outcome

## METHODOLOGY

**Study design:** Prospective Observational study

**Study Setting:** Department of Urology, Government Medical College, Thiruvananthapuram

**Study Population:** Patients undergoing ESWL

**Inclusion Criteria:**

1. Patients with renal and upper ureteric stones detected by imaging (Kidney, Ureter, and Bladder X-ray (KUB), USG or CT) with ESWL indicated as a primary management
2. Stone size less than 2cms
3. Solitary stones
4. Radiopaque stones

**Exclusion Criteria:**

1. Patients with skin disease or hypersensitivity
2. Patients with elevated serum creatinine level more than 2mg/dl,
3. Patients with bleeding disorders
4. Patients more than 120 kg body weight
5. Patients with incisional lumbar hernia
6. Patients with active urinary tract infection or urosepsis
7. Patients with ureteral stricture
8. Patients with neurogenic bladder
9. Patients with polycystic kidney

**Study Period:** Patients were recruited over a period over one year

**Sample Size:** 175

**Sample Size Calculation:**

In the study by Halen w cui et al 15, the overall stone-free rate was 79.6%. The formula used to calculate the sample size is:

$N = (Z1-\alpha/2)2 \times p \times q$

$d2$

$Z1-\alpha/2 = 1.96$

p = success rate of ESWL = 79.6%

d = absolute precision = 7%

$N = (1.96)2 \times 79.6 \times 20.4 / 72 = 175$

Thus the minimum sample size for the study is 175.

**Sampling Technique:** Consecutive sampling till the sample size is achieved

**Study Variables:**
1. Age
2. Gender
3. BMI
4. Side of stone
5. Size of stone
6. Skin to stone distance
7. Stone location
8. Stone density in HU
9. Follow up Xray
10. Post op complications
11. Success

**Ethical Concerns:**
Study was started only after getting the Institutional Ethics Committee clearance. Written informed consent was be obtained from all the participants. Confidentiality of the patient was ensured and maintained throughout the study. No additional expenditure was incurred from the patient for the purpose of my study

Personnel responsible for data collection: Self
Personnel responsible for data analysis: Self
Funding Agency: Nil

**Study Tools & Study Procedure In Detail:**
Patients who satisfy the inclusion criteria who are treated with ESWL as primary modality were selected. Data was collected from these patients according to the proforma which included Preoperative investigations: 1. Routine Blood Examination, 2. Renal function tests ,3. Urine routine & culture, 4. Coagulation profile, 5. Non-Contrast CT KUB –side, size of stone, stone location, stone density in HU, 6. Patient demographic data – Age, Gender and BMI, 7. Skin to stone distance was calculated preoperatively from NCCT as the average distance from stone to skin at 0,45,90 degree. The patients underwent ESWL using an electromagnetic lithotripter in the department of Urology at Medical College Thiruvananthapuram. A maximum of 3,300 shock waves was be delivered to a maximal power of 20 to 24 kV at 60-120 shocks/min during one session. In postoperative patients were assessed for postoperative complications. After 2 weeks patients were be followed up in outpatient department with Xray KUB or USG. The result of treatment was evaluated by plain radiography or by USG at this time. Residual fragments were be considered significant if it is 6 mm or more. So, less than 6 mm fragments were considered clinically insignificant stone fragments and procedure is said to be successful. When there was a large fragment with a long diameter >6 mm, a second sitting was considered. This outcome was associated with the clinical and radiological factors which were collected according to the proforma and statistical analysis will be done. Also, the success rate of ESWL was calculated. The demographic data, intra- operative & post-operative records of the patients was be recorded in Microsoft Excel spreadsheet.

**Statistical Analysis:**
The presentation of the Categorical variables was done in the form of number and percentage, on the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range).

The following statistical tests were applied for the results:
1. The association of the variables which were quantitative in nature were analysed using independent t test.
2. The association of the variables which were qualitative in nature were analysed using Chi-Square test.

If any cell had an expected value of less than 5 then Fisher's exact test was used.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0.

For statistical significance, p value of less than 0.05 was considered statistically significant

## RESULTS

The study was conducted in Department of Urology, Government Medical College, Thiruvananthapuram. 175 patients with renal calculi who underwent ESWL were included in the study. The demographic data, procedural & post-procedural data of the patients were recorded and results are as follows. Majority of our study population were in fourth and fifth decade of life and age ranged between 19-76yrs. 64% of our study population was males and 36% were females.59.43% had stone size less than 1.5cms and the smallest stone size was 0.8cm. Most of our study population had HU ranging 850 to 1233 and lowest HU was 456. About 91 had HU less than 1000 and rest had HU more than 1000.The major proportion of the stones was in pelvis that is 27.43%, the distribution in upper calyx was 21.14%, mid calyx was around 23.43% ,18.86% in lower calyx and least in the upper ureter of about 9.14%. Most of our sample population about 63.43% was in overweight category with only 9.14% in obese category and rest in normal range. Majority 73.71% had a skin to stone distance between 4-8cms with only 9.71% had skin to stone distance more than 10cms and rest had skin distance of 8.1-10cm. In our study we got a success rate of 58.29%. Most of the people (77.14%) had no complications whereas pain was found in 12% and haematuria occurred in 6.86%, infection was found in 2.86% and hematoma was found in 1.14.

**Analysis**

**Table 1:-Association of age(years) with outcome.**

| Age(years) | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| 19-30 | 9 (42.86%) | 12 (57.14%) | 21 (100%) | 0.925* |
| 31-40 | 13 (43.33%) | 17 (56.67%) | 30 (100%) | |
| 41-50 | 19 (43.18%) | 25 (56.82%) | 44 (100%) | |
| 51-60 | 16 (37.21%) | 27 (62.79%) | 43 (100%) | |
| 61-70 | 13 (48.15%) | 14 (51.85%) | 27 (100%) | |
| 71-80 | 3 (30%) | 7 (70%) | 10 (100%) | |

‡ Independent t test, * Fisher's exact test
We found no statistical correlation between age and success of ESWL

**Table 2:-Association of gender with outcome.**

| Gender | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| Female | 28 (44.44%) | 35 (55.56%) | 63 (100%) | 0.583† |
| Male | 45 (40.18%) | 67 (59.82%) | 112 (100%) | |
| Total | 73 (41.71%) | 102 (58.29%) | 175 (100%) | |

† Chi square test
There was no statistical correlation with gender and success of ESWL

**Table 3:-Association of stone size(cm) with outcome.**

| Stone size(cm) | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| <=1.5 | 28 (26.92%) | 76 (73.08%) | 104 (100%) | <.0001† |
| >1.5 | 45 (63.38%) | 26 (36.62%) | 71 (100%) | |
| Mean ± SD | 1.62 ± 0.24 | 1.35 ± 0.27 | 1.46 ± 0.29 | <.0001‡ |
| Median(25th-75th percentile) | 1.6 (1.4-1.9) | 1.3 (1.2-1.575) | 1.4 (1.3-1.7) | |
| Range | 1.1-2 | 0.8-1.9 | 0.8-2 | |

‡ Independent t test, † Chi square test

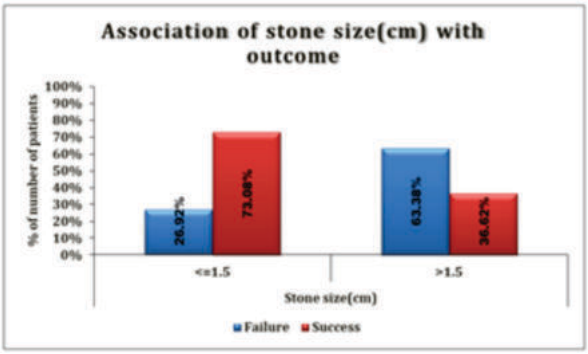


**Figure 1:-Association of stone size(cm) with outcome**

Using chi square test we found a statisitical correlation between stone size and eswl success. When the stone size is less than 1.5cm, more is the success rate than with a size more than 1.5cm.

**Table 4:-Association of stone density (Hounsfield unit) with outcome**

| Stone density (Hounsfield unit) | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| <=1000 | 27 (29.67%) | 64 (70.33%) | 91 (100%) | 0.0008† |
| >1000 | 46 (54.76%) | 38 (45.24%) | 84 (100%) | |
| Mean ± SD | 1125.32 ± 241.4 | 945.6 ± 241.4 | 1020.57 ± 256.59 | <.0001‡ |
| Median(25th-75th percentile) | 1121 (932-1346) | 959.5 (767.25-1064) | 987 (850-1233) | |
| Range | 630-1500 | 456-1500 | 456-1500 | |

‡ Independent t test, † Chi square test

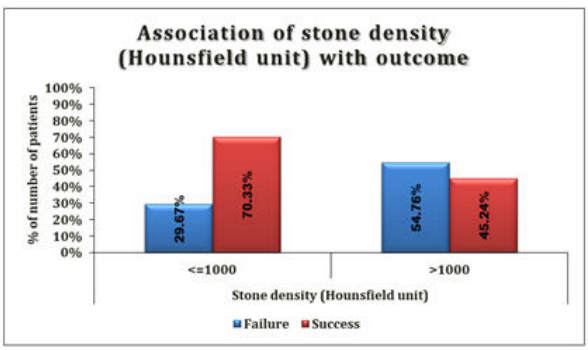


**Figure 2:-Association of stone density (Hounsfield unit) with outcome**

When Hounsefield and ESWL success was compared we found a statistical correlation, when HU was less than 1000 more the success, as the stone gets harder lesser it broke

**Table 5:-Association of location with outcome**

| Location | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| Upper calyx | 15 (40.54%) | 22 (59.46%) | 37 (100%) | 0.527† |
| Mid calyx | 19 (46.34%) | 22 (53.66%) | 41 (100%) | |
| Lower calyx | 17 (51.52%) | 16 (48.48%) | 33 (100%) | |
| Upper ureter | 5 (31.25%) | 11 (68.75%) | 16 (100%) | |
| Pelvis | 17 (35.42%) | 31 (64.58%) | 48 (100%) | |
| Total | 73 (41.71%) | 102 (58.29%) | 175 (100%) | |

† Chi square test

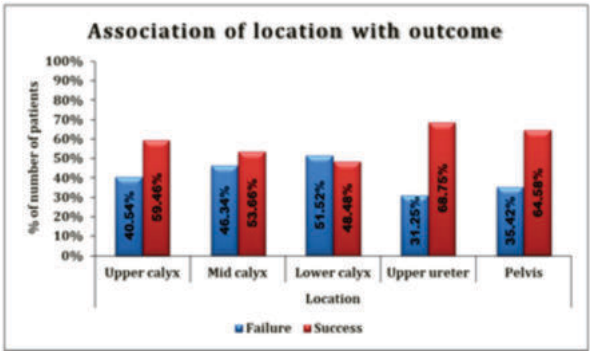


**Figure 3:-Association of location with outcome**

When comparing location of the stone we found no statistical significance. This may be due to other confounding factors such as size, HU, BMI, SSD.

**Table 6:-Association of body mass index(kg/m²) with outcome**

| Body mass index(kg/m²) | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| 20 to 24.99 kg/m² | 12 (25%) | 36 (75%) | 48 (100%) | <.0001† |
| 25 to 29.99 kg/m² | 45 (40.54%) | 66 (59.46%) | 111 (100%) | |
| >=30 kg/m² | 16 (100%) | 0 (0%) | 16 (100%) | |
| Mean ± SD | 27.78 ± 2.52 | 25.79 ± 1.58 | 26.62 ± 2.24 | <.0001‡ |
| Median(25th-75th percentile) | 27.8 (25.9-29.7) | 25.6 (24.6-26.875) | 26.4 (24.9-27.9) | |
| Range | 22.4-33.3 | 22.1-29.7 | 22.1-33.3 | |

‡ Independent t test, † Chi square test

In BMI we found statistical correlation with success, lower the BMI larger is the success rate.

**Table 7:-Association of skin to stone distance(cm) with outcome**

| Skin to stone distance(cm) | Failure(n=73) | Success(n=102) | Total | P value |
|---|---|---|---|---|
| 4-8 | 38 (29.46%) | 91 (70.54%) | 129 (100%) | <.0001† |
| 8.1-10 | 18 (62.07%) | 11 (37.93%) | 29 (100%) | |
| >10 | 17 (100%) | 0 (0%) | 17 (100%) | |
| Mean ± SD | 7.98 ± 1.98 | 6.34 ± 1.08 | 7.03 ± 1.72 | <.0001‡ |
| Median(25th-75th percentile) | 7.8 (6.2-9.2) | 6.2 (5.3-7.1) | 6.5 (5.8-8.1) | |
| Range | 4.2-12.2 | 5-9.2 | 4.2-12.2 | |

‡ Independent t test, † Chi square test

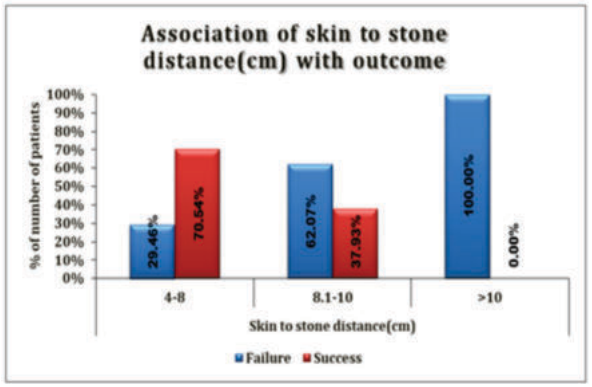


**Figure 4:-Association of skin to stone distance(cm) with outcome**

SSD also showed significant correlation with success. Highest success rate was found in those who have SSD between 4 to 8cms and lowest success in SSD more than 10cms

## DISCUSSION:

The ultimate goal of any modality of treatment of upper urinary tract stones is to achieve a 100% stone clearance without causing any morbidity to the patient. The current treatment modalities include percutaneous nephrolithotomy (PCNL), extracorporeal shock wave lithotripsy (ESWL), retrograde intrarenal surgery (RIRS) and in rare cases laparoscopic or open stone surgery. ESWL being a noninvasive technique has added an important dimension to the treatment of stone disease wherein the vast majority of small calculi within the renal system (80 - 85%) can be managed satisfactorily. ESWL is the preferred modality of treatment for renal stones less than 2cm. However stone free rate (SFR) after treatment has never been near 100%. Factors affecting stone clearance can be classified into to stone factors (size, composition, number, location), renal factors pertaining to anatomy and factors related to the patient.

In our study when we compare the age and sex with the success of ESWL we could not get any statistical correlation. In a study by Mohammad Al- zubi etal [16] they found that, there was no significant difference in success when associated with patient's age or sex. In another work by El-Assmy et al [17] age and sex have no effect on ESWL success rate. Lo S-H, Wu J-C, Liu M-C, et al [18] found that age did not affect the three month stone free rate of ESWL

BMI >30 is a significant factor affecting the success of treatment of upper tract stones. In our study we found a statistical correlation of BMI with success. Greater the BMI lesser the success rate. Success was 75% when BMI less was than 25 and obese patients had poor outcome. Pareek et al [19] studied the effect of BMI on stone clearance rates. An increased BMI was associated with poor outcomes, which was comparable to this study. Thomas & Cass [20] also reported an overall stone free rate of 68% in obese patients compared to 80 - 85% in non-obese patients. On the contrary, Hammad et al [21] did not find BMI to be a predictor for ESWL outcome.

Size of the stone is the most important factor determining success of ESWL. Stone size was a significant predictor of a favourable outcome in our study. 73.08% success was reported for stones less than 1.5cm. Khalil et al [22] in their analysis of stone free rates after ESWL based on stone size reported that stone free rates for stones less than 1 cm, 1-2 cm, and more than 2 cm are at 50.2 %, 39.6%, and 10.2% respectively. Abdel-Khalek et al [23] reported stone free rate as 89.7% for stones less than 15 mm.

In our study when we compared Hounsfield unit with success of ESWL we found that success rate approaches to 70.33% when HU is less than 1000. Perks et al [24] in his study on the role of ESWL for a solitary renal stone of 5–20 mm found the stone attenuation of the successfully treated patients (stone free and complete fragmentation groups) was 837 +/- 277 versus 1092 +/- 254 HU for those with treatment failure . Pareek et al [25] in another prospective study found the difference in the mean HU values for the stone-free patients was 577.8 +/- 182.5 and residual stones groups were statistically significant (910.4 +/-190.2). Joseph et al [26] reported a 95% success rate for calculi <1,000 HU vs. 55% for stones >1,000 HU ($p<0.01$). Ouzaid et al [27] found a 970 HU threshold for predicting success. Higher values of HU than this resulted in failure. AUA states that HU more than 900 to 1000 results in failure.

In our study, the rate of disintegration for stones in the lower calyx is comparable with stones in other locations within the urinary tract. This may be due to other confounding factors such as size, HU, SSD and BMI. But the spatial anatomy of lower calyx in unfavourable for the complete clearance of the fragments. Obek et al [28] in their study about patients with isolated lower pole calculi treated with ESWL reported a stone-free rate of 63% and stone-free rate of 71% for upper and 73% for middle calyx. In one study [29], it was seen that success of ESWL for lower calyceal stones was only 47% when compared to 79 % for other sites. Chen and Streem etal [30] reported a stone-free rate at 1 month following ESWL was 48% and a longer-term stone-free rate after ESWL was 54.3% with isolated lower pole calculi. In a study by Lingeman et al [31] the limitations of ESWL for lower pole stones are highlighted. Patients who underwent ESWL were reviewed and the result was a poor overall stone clearance rate of 60% against 80% with upper pole calculi. Furthermore, higher re- treatment rate was observed when comparing the lower calyx with other intra renal locations. However, Psihramis and colleagues [32] reported a higher success rate for lower-calyceal (53%) than for middle- (43%) and upper- (45%) calyceal stones. An analysis was done considering 9 different published series on the management of 8000 stones with ESWL. The stone-free rates for renal pelvic stones varied from 80% for stones measuring less than 10 mm to 56% for larger stones. Pace et al [33] reported a significantly better response to shock wave application in proximal ureteric stones than to those in the distal ureter. Park et al [34] managed 301 patients with upper ureteral stones with ESWL. The success rate achieved was 84.3% for stones < 10 mm after a single session.

In our study we found the success is more when the skin to stone distance is less. Success rate of 70.54% was found when SSD was less than 8 cm success rate was poor when the distance was more than 10cm. In a study by Pareek et al [19] it was concluded that the mean SSD was 8.12 +/- 1.74 cm for the success group versus 11.53 +/- 1.89 cm for the residual stone group. An SSD greater than 10 cm predicted treatment failure. In another study by Park BH et al [35] in 2012 found that the stone size in the success group had a shorter mean skin-to-stone distance 78.25 to 92.03 mm and failure groups was 10.55 to 12.9 mm, respectively. In another study Müllhaupt, G., Engeler, D.S., Schmid, HP. et al [36] found Median SSD was 125 mm (range 81– 165 mm) in the group treated successfully and 141 mm (range 108–172 mm) in the patients with treatment failure.

## CONCLUSION

ESWL is a useful, noninvasive modality of treating certain types of upper urinary tract calculi. The overall success rate of ESWL in this study was 58.29% in treating upper urinary tract calculi. The prognostication of the success of ESWL is possible by identifying patient and stone factors. This enable us to easily select the patient group for whom this treatment can be given. Age and sex of the patient have no role in predicting the successful outcome of ESWL. BMI of the patient had a significant inverse correlation with successful outcome of ESWL. Calculi with lesser stone density (< 1000), those with skin to stone distance less than 8cms and the size of the stone less than 1.5cms had greater success rate. In our study location of the stone had no relation with success this may be due to other confounding factors such as size, skin to stone distance and density of the stone.

### Abbreviations

ESWL - Extracorporeal shock waves lithotripsy SWL –Shockwave lithotripsy
KUB - Kidney, Ureter, Bladder USG – Ultrasonogram
IVU –Intravenous Urogram CT –Computed Tomography HU – Hounsfield Unit
RFT – Renal function test UPJ – Ureteropelvic junction
PCNL – Percutaneous Nephrolithotomy BMI – Body Mass Index
SSD – Skin to stone density SFR – Stone free rate
IBM-International business machines cooperation SPSS –Service product for statistical solution

Conflict of interest: The authors have no conflict of interest to declare.

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