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## Original Article

# PROGNOSTIC FACTORS OF SUCCESS OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL) IN THE TREATMENT OF RENAL STONES.

Md. Masud Zaman[1], Md. Jamal E Rabby [2], Mohammad Ali[3],
Md. Kabirul Hassan [4], Md. Mustafizur Rahman[5], ATM Ashaduzzaman[6]

**Abstract**

**Background:** Renal calculi are common approximately 50% of patient between the ages of 30 and 50 years. The development of endourological and extracorporeal lithotripsy techniques led to an increasing number of options for the management of renal calculi.

**Objective:** To define factors those have a significant impact on the success rate after extracorporeal shock wave lithotripsy (ESWL) for treatment of renal stones.

**Materials and Methods:** Between April 2008 & December 2008, 64 patients with single or multiple radiopaque renal stones (≤30mm) were treated with ESWL monotherapy using Stortz Modulith SLX-F2 lithotriptor.The results of treatment were evaluated after 3 months of follow-up Treatment success was defined as complete clearance of the stones or presence of clinically insignificant residual fragments (≤4mm).The results of treatment were correlated with the patient characteristics (age, sex, body mass index) and stone features (size, site, nature & radio density).

**Results:** At 3-months follow-up, the overall success rate is 76%. Among them, repeated ESWL sessions are required in 19 patients (53.9%). Post-ESWL complications are recorded in 8 patients (12.5%). Using the x2 test, only three factors have a significant impact on the success rate, namely: stone site, size (the largest diameter of the stone), stone number & BMI (Body Mass Index). The success rate is highest for stones located in the upper calyx (15/15; 100%) and lowest for those located in the lower calyx (10/16; 62.5%) (p=.005). Stones with a largest diameter of ≤ 15mm are associated with a success rate of 90.2% (37/41), compared to 52.2% (12/23) for those with a diameter of >15mm (p=.001). The success rate is also higher for single stone (46/56; 82%) than multiple stones (3/8; 37.5%) (p=0.005).Patients with lower BMI (<24) have a better success than higher BMI (>25) (p=0.01)

**Conclusion:** The success rate of ESWL for the treatment of renal stones can be predicted by stone size, location, number and patient BMI.

**Key words:** Renal stone, ESWL, Prognostic factors.

1. Assistant Professor, Department of Urology, Jessore Medical College.
2. Junior Consultant, Department of Surgery, Shaheed Ziaur Rahman Medical College Hospital (SZMCH), Bogra.
3. Junior Consultant, Department of Surgery, Sadar hospital, Brahmanbaria.
4. Junior Consultant, Department of Surgery, Gaibandha.
5. Registrar, Department of Surgery, SZMCH, Bogra.
6. Assistant Professor , Department of Surgery, Dhaka Medical College.

**Correspondence to:** Dr. Md. Masud Zaman, Assistant Professor, Department of Urology, Jessore Medical College. Tel.: +8801711180280, E-mail: dshovon@yahoo.com

**Introduction:**

Urolithiasis is a problem that has confronted clinicians since the time of Hippocrates and the prevalence of urolithiasis is approximately 2 to 3 percent in general population and the estimated lifetime risk of developing a kidney stone is about 12 percent for white males. Approximately 50 percent of patients with urinary calculi have a recurrence within 10 years.[1]

The development of endourological and extracorporeal lithotripsy techniques led to an increasing number of options for the management of renal calculi. Each of the methods available needs to be evaluated in terms of its stone clearance rate, potential morbidity and cost effectiveness. Extracorporeal shock wave lithotripsy (ESWL) is an effective, well established method for treatment of renal calculi.[2]

The goal of renal stone treatment is to achieve maximal stone clearance with minimal morbidity to the patient. Multiple options are currently available including extracorporeal shock wave Lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIR's), and in selected cases, open stone surgery. ESWL has revolutionized the treatment of renal stone disease and the majority of renal calculi can be treated satisfactory with ESWL.[3]

For most renal stone smaller than 20mm, ESWL is the most effective primary treatment modality. ESWL is effective for stones in all caliceal locations which are less than 20mm. The efficacy of extracorporeal shock wave lithotripsy (ESWL) for kidney stones depends on many factors such as-stone size, location and composition of the stones.[2] ESWL results for stones up to 10mm in size are satisfactory independent of their location in the kidney, whereas the stone free rate for stones 11-20mm in size is lower, particularly for Lower pole calculi for which it ranges from 41% to 73%.[4] Other workers like Sampio et al. examined lower caliceal anatomy as a predictor of success of ESWL for lower caliceal stones.[5]

**Materials and Methods:**

This prospective observational and analytical study had conducted at department of Surgery, Shaheed Ziaur Rahman Medical College Hospital (SZMCH), Bogra from April 2008 to December 2008, total 64 patients, age≥ 18 years irrespective of sex, BMI with renal stones and the largest diameter of each stone is ≤ 30mm irrespective of location of the stone were enrolled in this study. Residual stones after open surgery were also included. Follow-up data for all of them were available at three months. There was no limitation as regards to patient's body weight, but height <3 ft was excluded. The presence of ureteric strictures, features of obstructive uropathy and non-functioning kidney, any variety of congenital anomalies including horseshoe kidney, ectopic kidney, pelvic kidney, duplex kidney and stone number more than 3 in each kidney were also excuded.

All patients were treated as inpatients with same lithotriptor (stortz modulith®SLX-F2). Samples were collected in purposive manner. Stone size was determined by the measuring scale in plain x-ray KUB along its largest diameter. Ureteric double-J stents were placed in 3 patients before ESWL. All the stents were placed during open surgery where residual stones were in situ. Gut preparation were done by ultra carbon and laxena before operation. Routinely all patients were fasting over the night before the day of ESWL. Anticoagulants such as aspirin and aspirin like compounds were stopped one week prior to start the ESWL procedure. Diclofenac suppository was used routinely as a analgesia prior to start the ESWL. A prophylactic broad spectrum antibiotics and intravenous line were started just before start of ESWL.

All patients were treated in the supine position on treatment table depending upon the side of the stone (Right or left side). ESWL therapy was started at low voltage (0.5kv) until the patient accustoms to the shock and the voltage was then gradually increased to a maximum of 6.5kv. Maximum 4000 shock waves were used until X-ray shows adequate pulverization in each patient. The average number of shocks per patients was 4883±2382 in three sessions. The average BMI in each patient was 23.27±1.68 (ranges from 19.78 to 26.22). The shockwaves were delivered at rates 120/min in all patients. The stone was positioned in the focus of the shock wave by using fluoroscopy imaging. The shock tube is then pressed and "coupled" with some gel-like material. Treatment time was varied according to the size and hardness of the stone. Progress of the treatment was determined by fluroscopy. After treatment, in order to assist passge of the particles, inj. frusemide was given to all patients and were adviced to drink large quantities of water. The patients were discharged in the next day.

Patients were reviewed after 24 hours of ESWL session to assess fragmentation and the presence of renal obstruction by plain X-ray and USG of KUB region. After three weeks repeat treatment was carried out if there was inadequate fragmentation of the stone. If there was no response or presence of residual fragments > 4mm after three sessions, the case was considered as ESWL failure.Follow-up was continued every 3 weeks until there was complete stone clearance by plain X-ray of KUB region. Highest three ESWL sessions were given in each patient at every 3 weeks intervals. All the follow up data were analyzed after 3 months visit.

Treatment success was defined as a complete stone clearance or clinically presence of insignificant residual fragments (CIRFs) (stone size <4mm). Failure was define as presence of significant residual fragment (SRFs) after 3rd month.

**Results:**

At 3-month follow up of 64 cases complete stone-free were observed in 44 patients (68.8%), clinically insignificant residual fragments(CIRFs) were observed in 5 patients (7.8%) & significant residual fragments (SRFs) were observed in 15 patients (23.4%).Stone clearance rate is summarized in Table-1 & Fig-1.

**Table 1**

Stone Clearance rate (N=64)

| | No. of Patients | % |
|---|---|---|
| **Success** | | |
| Stone-free | 44 | 68.8 |
| CIRFs | 05 | 7.8 |
| **Failure** | | |
| SRFs | 15 | 23.4 |
| **Total** | **64** | **100** |

CIRFs, clinically insignificant residual fragments; SRFs, significant residual fragments;

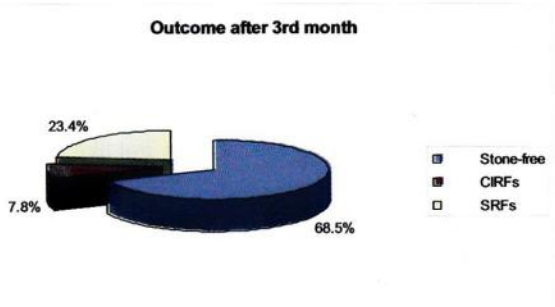


**Fig.1** Pie diagram of stone clearance rate after ESWL monotherapy of 64 renal calculi after 3th month showing stone-free cases (n=44; 68.8%), CIRFs (n=5; 7. 8%) and SRFs (n=15; 23. 4%).

So at 3-months follow up, no. of over all success were 49(76.6%) & no. of failure were 15(23.4%) & shown in Fig -5. Among 64 cases, 30 patients (46.9%) were needed single sessions of ESWL for success. Repeated treatment was needed in 34 patients (53.1%). Among the re-treatment group 19 patients (55.9%) were needed two and or three sessions of ESWL to ensure success. The mean number of shocks per patient was 4883±2382. The mean voltage was 5.76±.68 Kv. Among the failure group 2 patients were treated with open surgery and rest of them were referred to an urologist for post ESWL auxiliary procedure. Among the 64 cases, Post ESWL complications were encountered in 8 patients (12.5 %).

In this study, the success rate was correlated with characteristics of the patients and stone features using the chi-square test. Here, seven prognostic factors were studied, among them four prognostic factors had significant impact on success rate, namely stone size, site, number & patient BMI. On the other hand patient age, sex & stone radiodensity had no significant impact on success rate (Table-2).

**Table 2**

Patient characteristics and stone features of 64 cases in correlation with success rate.

(N=64)

| Variable | No. of pts | % | Number of success rate | %of success rate | p-value |
|---|---|---|---|---|---|
| Age(years) | | | | | . 476 |
| ≤40 (18-40) | 35 | 54. 68 | 28 | 80 | (NS) |
| >40 | 29 | 45. 31 | 21 | 72. 4 | |
| Sex | | | | | .738 |
| Male | 36 | 56. 25 | 27 | 75 | (NS) |
| Female | 28 | 43. 75 | 22 | 78. 6 | |
| BMI | | | | | .010 |
| ≤24 (19-24) | 43 | 67. 18 | 37 | 86 | |
| >24 (24.01-27) | 21 | 32. 81 | 12 | 57. 1 | |
| Stone size | | | | | .001 |
| ≤15mm (>4-15) | 41 | 64. 06 | 37 | 90. 2 | |
| >15mm (16-30) | 23 | 35. 93 | 12 | 52. 2 | |
| Stone site | | | | | .005 |
| Upper calyx | 15 | 23. 43 | 15 | 100 | |
| Middle calyx | 13 | 20. 31 | 10 | 76. 9 | |
| Lower calyx | 16 | 25 | 10 | 62. 5 | |
| Renal pelvis | 12 | 18. 75 | 11 | 91. 7 | |
| Stone nature | | | | | .005 |
| Single | 56 | 87. 5 | 46 | 82. 1 | |
| Multiple | 08 | 12. 5 | 03 | 37. 5 | |
| Stone radiodensity | 37 | 57. 81 | 30 | 81. 1 | 559 (NS) |
| <12$^{th}$ rib | 15 | 23. 43 | 11 | 73. 3 | |
| =12$^{th}$ rib | 12 | 18. 75 | 08 | 66. 7 | |
| >12$^{th}$ rib | | | | | |

NS, non-significant, chi square test

In 64 cases, post-ESWl complications were encountered in 8 patients (12.5%). Among them, 3 patients (4.7%) were developed severe pain, 3 patients (4.7%) were massive haematuria & pain. Two patients (3.1%) were recorded ureteric obstruction along with haematuria and pain.

**Discussion:**

At 3-months follow-up, the overall success rate was 76.6%. This result was matching with some similar previous studies that reported stone free rates were 75-85% for treatment of renal stones by ESWL[6]. This study examined only four factors that had a significant impact on the success rate, namely stone size, site, number and BMI of the patient. Other factors age, sex & stone radiodensity had no significant impact on the success rate.In this study, stone size was a significant predictor of ESWL outcome. The success rate for stones ≤15 mm was 90%, while it was 52 % for stone >15 mm (p= 0.001).

Abdullah Al-Ansari et al. did a prospective study under 427 patients with single or multiple stones (<30mm) underwent ESWL monotherapy using SL20 lithotriptor. At 3- months follow-up, the over all success rate was 78%. There 10 prognostic factors were studied, 5 had a significant impact on the success rate, namely: renal morphology, congenital anomalies, stone size ,stone site and number of treated stones, other factors including age, sex, nationality ,stone nature and ureteric stenting had no significant impact on the success rate.[7]

In the present study, the success rate for stones located in the renal pelvis , upper , middle and lower calyces were 100%, 91% 76% & 62% respectively (p= 0.005). This finding was supported by similar previous studies, where for upper and middle calyceal stones free rate ranges from 90% to 70% respectively, where as that for lower calyceal and multiple site stones ranges from 70% to 50% respectively. All the studies had shown that better stone clearance rate were in the renal pelvis, upper & middle calyx than stone in lower calyx.[8]

However, the treatment for lower pole calculi especially for stones larger than 1cm in size remains controversial. The comparison of stone clearance rate between ESWL & more invasive treatments such as PCNL was done by many authors.[4]

In the present study, stone number had a significant impact on stone clearance by ESWL. The success rate for single stone was 82.1% & 37.5% for multiple stones. This result is similar to that of Mohamed Abdel-Khalek et al, here the authers did a sudy under 2954 patients with single or multiple radiopaque renal stones (<30mm) underwent ESWL monotherapy.The result of treatment were evaluated after 3 months of follow-up. By a multivariate regression model analysis the authors found that success rate was lower in multiple renal stones than single stone.[6] This aggrement was also proved by Jan H. Ruffer et al. and Abdullah Al-Ansari et al.[7] All the studies the authors examined that, the success rate was lower by ESWL for multiple renal stones than single stone.

In the present study, stone radio density alone was not a useful parameter for outcome of extra corporeal shock wave lithotripsy. This findings was supported by Mina S et al.[9] The authors studied 211 patients with solitary renal pelvic stones <2cm by Dornier Doli 50 lithotriptor under general anesthesia. The radiologist was compared to ipsilateral 12th rib. Following after 3 months follow up they declared that there was no co-relation between stone radio density and stone composition. For stone ≤10mm within renal pelvis, the SFRs were similar (71-74% regardless of stone radio density). For stone between 11and 20 mm, the SFR was 60%,if the stone had a radio density >12th rib compared to a SFR of 71%, if the stone radio density was ≤ 12th rib.How ever, these differences in SFRs were not statistically significant.

In this study, we also had shown that, success rate was gradually decreasing with increasing the radiodensity of stone, but it was not statistically significant. (p=0.559)

In the present study, success rate was significantly higher (86%) in patients with BMI 19 to 24 compared to BMI 24 to 27 (57%).[10] This result was also matching with Ackermann et al, studied that BMI influences the outcome of ESWL. They found that body mass index [BMI] and stone number were the only significant predictors. The authors studied that the best chance of success for ESWL was found in patients with BMI 20 to 28.10 But Robert et al. found patients with a BMI >25 had a worse outcome after ESWL,[11] that matched with present study.

In the present study, it was statistically proved that the ESWL success rate was gradually decreased with increasing the patients BMI. (p <0.005)

In this study, patient age & sex had no significance that affects stone clearance of renal calculi after ESWL. This result was also similar with other study done by Abdullah Al-Ansari et al.[7]

But Mohamed Abdul-Khalek et al. did a multivariate regression model analysis; here the authors found that age of the patient had a significant impact on the renal stone free rate.[6]

**Conclusion:**

The overall success rate of Stortz Modulith SLX-F2 lithotriptor for treatment of renal stones at Shahid Ziaur Rahman medical college hospital was 77.6%. The success rate was gradually decreases in relation to increasing the size of the stone. Success rate was higher in the upper calyx, pelvis and middle calyx than in the lower calyx and multiple sites of kidney. Success rate was higher for patient BMI <25. Repeated sessions were needed in 53% and overall complication rate was 12.5%. Factors that significantly affected the success rate included: stone size, stone location, multiple stones & patients BMI.

The introduction of ESWL has revolutionized kidney stone management in the last 20 years. Through numerous clinical studies, ESWL has proven too safe and effective. It is used worldwide and millions of patients have been successfully treated.

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