

Factors Affecting the Outcome of Extracorporeal Shockwave Lithotripsy in Urinary Stone Treatment

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ABSTRACT

Objectives: We sought to evaluate the factors affecting the outcome of extracorporeal shockwave lithotripsy (ESWL) in urinary stone treatment. Methods: We conducted a retrospective review of 235 adult patients treated with ESWL, for radiopaque renal or ureteric stones between January 2015 and December 2016. Patient's age, sex, stone size, laterality, location, density, skin-to-stone distance (SSD), and presence of double J stent were studied as potential predictors. At the end of three months, the patients were divided into success and failure groups and the significance was determined. *Results:* Of the 235 patients (188 males and 47 females) analyzed, ESWL was successful in 79.1%. Univariate analysis of both groups revealed no significant difference in patient's age and stone laterality. Statistically significant differences in gender, stone size, stone site, stone density, SSD, and patients with stents were observed. Statistically significant factors in multivariate logistic regression analysis were sex and stent. Females had three-times higher risk for ESWL failure than males (odds ratio (OR) = 3.213; 95% confidence interval (CI): 1.194–8.645; p = 0.021) and a higher failure rate when a stent was used (OR = 6.358; 95% CI: 2.228 - 18.143; p = 0.001). *Conclusions:* This study revealed that ESWL can treat renal and ureteric stones successfully with an inverse association between outcome and predictors such as stone size and density, SSD, and stent presence. These factors can help us in improving patient selection and ensure better results at lower cost.

xtracorporeal shockwave lithotripsy (ESWL) was first introduced in 1980 by Chaussy et al.¹ It has since become a preferred treatment modality for uncomplicated renal and ureteral stone < 20 mm in diameter, as it is safe and non-invasive.²⁻⁵ 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 anesthesia, at the expense of less energy delivery and, therefore, lower success rates and higher retreatment rates.^{6–8} Studies have shown that the Storz Modulith SLX-F2 lithotripter is clinically effective in the management of solitary renal and ureteral stones.^{9,10}

The success rate of ESWL has a wide variation ranging from 46% to 91%.¹¹⁻¹⁸ 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, severity of obstruction, urinary tract anatomy, obesity, and ESWL machine type.^{19–28} The chemical composition of urinary calculi in vivo has been found to be the main factor in determining the outcome of ESWL.^{29,30} These days, non-contrast computed tomography (NCCT) has become the diagnostic modality of choice to evaluate urolithiasis and its ability to detect density differences as low as 0.5, thus helping in determining the outcome of ESWL.^{24,31–33}

Although ESWL is a non-invasive and safe procedure compared to other treatment modalities, it may also cause complications such as hemorrhage, steinstrasse, renal hematoma, infection, and flank pain.^{34–37} 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.^{25,38} 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.

METHODS

We conducted a retrospective review for adult patients with renal or ureteric stones, treated with ESWL at Armed Forces Hospital (AFH), Oman, between January 2015 and December 2016. The inclusion criteria were radiopaque stone size > 4 mm, on the pretreatment plain abdominal X-ray of the kidney, ureter, and bladder (KUB). Pregnant women and patients with uncontrolled coagulopathy, ongoing urinary tract infection, stone secondary to anatomical obstruction, congenital anatomical abnormalities, any previous renal surgery or ESWL on the ipsilateral side, and gross obesity body mass index $\ge 35 \text{ kg/m}^2$) were excluded from the study. The case summary, hematological, biochemical, radiological investigations, and followups were charted. All the patients underwent X-ray KUB, ultrasonography, and NCCT KUB for initial diagnosis.

Of the 294 patients treated, 59 were not included in the study (29 patients due to non-availability of NCCT, 30 lost to follow-up, and the rest as per exclusion criteria). Therefore, the final analysis, results, and conclusions were based on 235 patients. NCCT was used to determine stone characteristics such as size, location, laterality, density, and SSD.²⁴ In AFH, NCCT KUB was performed using Philips Brilliance 64 MSCT with slice thickness 3 mm from the diaphragm to pubic symphysis. The largest dimension of the stone with soft tissue window in coronal view represented the stone size. Hounsfield units (HUs) of stones were calculated by mean attenuation of three consistent (area 0.02 cm²), nonoverlapping regions of interest chosen from stones in bone windows.³⁹ Measurement of SSD on axial computed tomography view was done by calculating the mean value of three distances from the center of the stone to the skin surface (horizontally, perpendicular and at 45 degrees between the first two directions using radiographic calipers for renal and upper ureteric stones).¹⁷ SSD for lower ureteric stone was calculated by measuring the distance between the center of the stone to the skin surface

of anterior abdominal wall, at right angle to the horizontal plane. A double J stent was inserted in patients with stones > 15 mm in size, high-grade hydronephrosis (grades 3 and 4 defined by The Society of Fetal Ultrasound), and impaired renal functions before ESWL.

The patients in the study were subjected to ESWL using Storz Modulith SLX-F2, third generation lithotripter with electromagnetic shockwave source after written and informed consent. ESWL was done under pethidine sedation. The procedure was performed under the supervision of the same urologist. Under intermittent fluoroscopic or ultrasonic guidance, the targeted stone was struck by a maximum of 4000 shocks per session at the rate of 60–90 shocks per minute with gradually increasing intensity to level 4 and 4.5 to 7 for renal stones and ureteric stones, respectively. Stone localization was achieved by fluoroscopy or a combination of ultrasound and fluoroscopy. Reassessment of stones was done after 2-3 weeks using X-ray KUB and ultrasonography to assess the fragmentation. Those patients with no or insignificant stone fragmentation (fragment > 4 mm) were given another session of ESWL. After the first ESWL session, patients were followed-up for three months for the outcome of stone clearance. At the end-point, patients were evaluated with X-ray KUB, ultrasonography, and/or NCCT KUB. Stone clearance, stone fragmentation, number of ESWL sessions, requirement of auxiliary procedure, and complications were documented. Treatment was defined as successful in cases of complete clearance of ureteric stones and stone-free (complete clearance or the presence of asymptomatic, non-infectious, and non-obstructive fragments \leq 4 mm) for renal stones. Treatment failure was considered in case of no fragmentation or residual stone fragments > 4 mm after three sessions of ESWL or if the patient required another mode of treatment.

At end-point evaluation, patients were categorized into success and failure groups. Data were described using frequency, percent, and mean score. To test the statistical significance of the relationship between ESWL outcome and the factors affecting it, data were analyzed using chi-square test, independent samples *t*-test, and correlation. Thereafter, the significantly associated variables were tested with multivariate logistic regression analysis to identify the independent predictors of treatment failure. A two-tailed level of significance was set at 0.05.

baseline parameters.	
Parameters	Values n (%)
Patients, n	235
Age, mean ± SD, years	37.6 ± 10.8
Gender	
Male	188 (80.0)
Female	47 (20.0)
Stone laterality	
Right	106 (45.1)
Left	129 (54.9)
Stone size, mean ± SD, mm	9.0 ± 2.5
< 10	179 (76.2)
> 10	56 (23.8)
Stone location	
Upper calyx	5 (2.1)
Middle calyx	15 (6.4)
Pelvis	22(9.4) 48(20.4)
Upper ureter	67 (28.5)
Lower ureter	78 (33.2)
Stone density, mean ± SD, HU	859.0 ± 241.0
SSD, mean ± SD, mm	106.0 ± 22.0
Stent	
Present	48 (20.4)
Absent	187 (79.6)
ESWL sessions, mean ± SD	1.8 ± 0.9
Shock waves, mean ± SD	7259.0 ± 3920.0

Table 1: Patients demographic characteristics and baseline parameters.

SD: standard deviation; HU: hounsfield unit; SSD: skin-tostone distance; ESWL: extracorporeal shockwave lithotripsy.

All statistical analysis was carried out using SPSS Statistics (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

RESULTS

A total of 235 patients (188 males and 47 females) with renal or ureteric stones who received ESWL treatment from January 2015 to December 2016 were analyzed.

ESWL was successful in 79.1% (186/235) of patients and failed in 20.9% (49/235). The baseline demographic characteristics and predictors of all patients are presented in Table 1. In univariate analysis, as shown in Table 2, patient's age and stone laterality were not significantly different in the two groups. However, differences in gender, stone size, stone site, stone density, SSD, number of ESWL sessions, number of shocks required, and patients with stents were statistically significant.

Table 2: Univariate	analysis of the factors affecting
outcome of extracor	poreal shockwave lithotripsy.

Variable	Success group n (%)	Failure group n (%)	<i>p</i> -value
Patients, n	186 (79.1)	49 (20.9)	
Age, mean ± SD, years	37.3 ± 10.5	38.8 ± 11.6	0.385
Gender			
Male Female	155 (82.4) 31 (66.0)	33 (17.6) 16 (34.0)	0.017*
Stone laterality			
Right Left	86 (81.1) 100 (77.5)	20 (18.9) 29 (22.5)	0.523
Stone size, mm			
< 10 > 10	150 (83.8) 36 (64.3)	29 (16.2) 20 (35.7)	0.004*
Stone location			0.040
Upper calyx	5 (100.0)	0 (0.0)	
Middle calyx	12 (80.0)	3 (20.0)	
Lower calyx	17 (77.3)	5 (22.7)	
Pelvis	36 (75.0)	12 (25.0)	
Upper ureter	46 (68.7)	21 (31.3)	
Lower ureter	70 (89.7)	8 (10.3)	
Stone density, mean ± SD, HU	807.5 ± 213.8	1052.7 ± 242.6	< 0.001*
SSD, mean ± SD, mm	103.9 ± 21.3	111.6 ± 22.4	0.027*
Stent, n (%)			
Present Absent	23 (47.9) 163 (87.2)	25 (52.1) 24 (12.8)	< 0.001*
Number of ESWL sessions, mean ± SD	1.6 ± 0.6	2.6 ± 1.3	< 0.001*
Number of shock waves, mean ± SD	6397.3 ± 2788.9	10530.6± 5579.3	< 0.001*

*Statistically significant.

SD: standard deviation; HU: hounsfield unit; SSD: skin-tostone distance.

The overall complication rate was 26.4% (62/235). Most complications were minor with the commonest being loin pain seen (18.7%; 44/235). However, in 6.0% (14/235) of patients, severe renal or ureteric colic was observed mandating a visit to the accident and emergency department, of which 3.4% (8/235) required inpatient care for pain control. Steinstrasse occurred in four patients, of which two were treated with ureteroscopy. The other two patients were treated conservatively with a further ESWL session leading to successful stone fragmentation. Patients with dysuria were 17.0% (40/235), of which symptomatic bacteriuria was diagnosed in three patients. There was gross



Figure 1: Extracorporeal shockwave lithotripsy outcome according to gender.

hematuria observed in 11.9% (28/235) of patients, which improved spontaneously within two to three days. No major complications, such as hemorrhage (which could have necessitated transfusion), severe infection, or injury to other organs, occurred in any patients.

In the multivariate logistic regression analysis, only two variables were found to statistically significantly predict the failure of ESWL; sex and stent. Compared to males, females had three-times higher risk for ESWL failure (odds ratio (OR) = 3.213; 95% confidence interval (CI): 1.194–8.645;



Figure 2: Extracorporeal shockwave lithotripsy outcome according to stone size.



Figure 3: Extracorporeal shockwave lithotripsy outcome according to stone density.

p = 0.021). Logistic regression analysis also showed a higher failure rate when stent was used (OR = 6.358; 95% CI: 2.228–18.143; p = 0.001).

The success rate of ESWL in males was 82.4% compared to 66.0% in females [Figure 1] and this result was statistically significant in both univariate and multivariate analysis.

Success rate of treatment in stones ≤ 10 mm was 83.8% compared to that of only 64.3% in stone > 10 mm [Figure 2] with *p*-value of 0.004.

A stone free rate of 56.2% was observed in patients with stones > 1000 HU density



Figure 4: Extracorporeal shockwave lithotripsy outcome according to presence or absence of a double J stent.



compared to 87.7% with a stone density \leq 1000 HU [Figure 3].

Inferior ESWL outcome was observed in patients with stent. Only 47.9% of patients with stent showed good response to treatment, while 87.2% without stent had notable treatment benefit [Figure 4] with a *p*-value < 0.001.

DISCUSSION

Since the introduction of ESWL in 1980, it has become an established and preferred treatment for uncomplicated renal and ureteral stone (< 20 mm in diameter) as it is safe as well as non-invasive.¹⁻⁵ The success rate of ESWL varies from 46% to 91% and is measured in terms of stone fragmentation and clearance.¹¹⁻¹⁸ Previous studies have demonstrated that predicting factors such as stone size, stone location, SSD, stone density, severity of obstruction, urinary tract anatomy, obesity, and type of ESWL machine can have an influence on the success rate of ESWL.²¹⁻²⁸ We evaluated some of the factors affecting the outcome of ESWL as well as safety of treatment and observed a success rate of 79.1%.

Many studies have discussed factors affecting outcome of ESWL, but only few have considered age of any significance. One study of 3023 patients with renal and ureteric calculi treated with ESWL revealed that older patients had a significantly poorer stone-free rate.¹¹ Another multivariate analysis of 2954 patients with renal stones treated with ESWL, revealed that patients aged > 40 years had significantly poorer stone-free rate.¹⁹ However, another study by same group on ureteric stones found that age did not affect ESWL outcome.⁴⁰

In our study, age was not a significant factor affecting the outcome of ESWL. However, only 10 patients were above the age of 60. The reason for the possible poorer stone-free rate of renal calculi in elderly patients is unknown. However, age-related sclerotic kidney may affect the acoustic impedance and lower efficacy of ESWL. Further studies are needed to confirm age as a predictor of ESWL outcome.

Many studies have shown that gender is not a significant predictor of ESWL outcome. A retrospective study of 145 patients with renal stones treated with ESWL reported a success rate of 47.25% in males (43/91) and 50% (27/54) in females, which was not statistically significant.²⁴ A study of 153 patients with ureteric stones treated with ESWL reported 83.33% (75/90) success in males compared to 82.54% (52/63) in females, which was also not statistically significant.²¹

In the present study, success rate of ESWL in males was 82.4% compared to 66.0% success in females and this result was statistically significant in both univariate and multivariate analysis.

Our study reports gender as a predicting factor of ESWL success, which is not in agreement with previous studies. We found the threshold for pain in females was lower compared to males. Many of our female patients could not tolerate higher energy shockwave during treatment and some presented to the emergency department with pain after their first session of ESWL, which eventually needed admission and another treatment modality. All these factors might have influenced lower success rate in females. Considering the limitations of this study, another prospective study is needed to confirm gender as predictor of failure of ESWL treatment.

Previous studies have shown that stone size is a significant predictor of ESWL treatment success. The larger the size of stone, the higher is the risk of ESWL failure. In a study of 2954 patients with renal stones, the authors observed a success rate of 89.7% for stones < 15 mm and of 78% for stones >15 mm (p < 0.001).¹⁹ In another study of 427 patients with renal stones, the success rate of ESWL for stones \leq 10 mm was 90% and 70% for stones > 10 mm (p < 0.050).²⁰

Stone size was also a significant predictor of ESWL outcome for ureteral stones. In a prospective study of 130 patients, the overall ESWL treatment success rate was 94.6%, while it was only 77.7% for stones > 15 mm. The authors also noted that the number of ESWL sessions increased with increasing stone size.⁴¹ Another retrospective study of 153 patients observed a success rate of 90.2% for stones \leq 10 mm and 68.6% for stones > 10 mm.²¹ In the same study, multivariate analysis revealed that stone size was an independent predictor of failure of ESWL in each group (stone size \leq 10 mm; OR = 50.005; 95% CI: 6.207–402.852; *p* = 0.013 and stone size > 10 mm; OR = 19.718; 95% CI: 1.600–243.005; *p* = 0.020).

Similarly, in our study stone size was one of the important factors determining ESWL success. Success rate of treatment in stones ≤ 10 mm was 83.8% (150/179) compared to that of only 64.3 (36/56) in stones > 10 mm (p = 0.004). A larger stone required a greater mean number of ESWL sessions for successful fragmentation. Stones \leq 10 mm required 1.4 mean sessions while stones > 10 mm required 2.1 mean sessions. The mean number of shocks required for fragmentation of stones \leq 10 mm were 5940.3 whereas 8301.5 shocks were required for stones > 10 mm. A positive correlation between the stone diameter (in mm) and the number of shock waves delivered was noted (r = 0.414; p = 0.000). Stone size was a significant predictor of ESWL success in univariate analysis; however, it was not found to be an independent predictor in multivariate analysis.

Calyceal stones have poor outcome with ESWL treatment compared to renal pelvic and ureteral stones, whereas lower pole renal calculi have poorer results with ESWL compared to middle and upper pole calculi.²⁰

The role of ESWL treatment for lower calyceal stones has always been controversial. Various studies have observed a variable free rate for lower pole stones. One study showed that the success of ESWL treatment was only 47% in the lower calyceal stone compared to that of 79% for other site stones (chi-square = 6.3, df =1, p = 0.012).²² However, some studies favor ESWL treatment of lower calyceal stone, especially for low burden stones. A stone-free rate of 84% for lower calyceal stones between 5 to 15 mm with piezoelectric ESWL has been documented.⁴² A recent study revealed a stone-free rate of 75% for lower calyceal stone (size ranging from 10–20 mm) with ESWL treatment.⁴³

We found stone site was a significant predictor of ESWL outcome. We compared the success rate of lower calyceal stones with stones at other sites. The success rate of ESWL for lower calyceal stones was 77.3% compared to 79.3% for stones at all other sites (p = 0.786). Patients with lower calyceal stones ≤ 10 mm in size had a success rate of 93.8% (15/16) compared to stones > 10 mm in size where the success rate was noted to be 33.3% (2/6). The clearance of the fragments was lower due to the unfavorable spatial anatomy of the lower pole collecting system.¹ As ESWL is a non-invasive modality, it can still be offered for lower calyceal stones with low burden and favorable anatomy.

Recently, many studies have shown that the measurement of mean stone density by NCCT plays

an important role in predicting ESWL success. In a prospective study of 120 patients, a stone density > 1000 HU was an independent predictor of ESWL failure (p = 0.020).⁴⁴ Evidence from prospective study noted a stone-free rate for stones of < 970 HU was 96% versus 38% for stones of ≥ 970 HU (p = 0.001) and identified linear relationship between the stone density and ESWL success rate.²⁵

Our study supports the above findings. We observed a stone-free rate of 56.2% in patients with stones > 1000 HU density compared to that of 87.7% with a stone density \leq 1000 HU. Thus by calculating stone density with NCCT, one can predict the ESWL outcome and decrease the cost of management by reducing failure rate and number of ESWL sessions.

It has been noted in previous studies that the failure of ESWL is related to greater SSD. The mean SSD for ESWL success was 8.12 ± 1.74 cm against 11.53 ± 1.89 cm in the ESWL failure group (p < 0.010).³⁹ In another study, the mean SSD in the stone free group was 83.3 ± 21.9 mm compared to the residual stone group where the mean SSD was 107.7 ± 28.9 mm (p < 0.050) and a multivariate regression analysis revealed that SSD was the only significant independent predictor of treatment outcome.²⁷

In our study, the success group showed a mean SSD of 103.9 ± 21.3 cm while the mean SSD in the failure group was 111.6 ± 22.4 cm with a *p*-value of 0.027. Our study also demonstrated that SSD was a predictor of ESWL failure in univariate analysis, but the similar effect was not observed on multivariate analysis.

The use of a double J stent prior to ESWL treatment is rather controversial. Numerous studies have shown the use of double J stents is not much benefit prior to ESWL treatment. A prospective randomized study also revealed that the use of double J prior to ESWL did not improve treatment outcome.45 The authors reported a three-month stone-free rate of 88% in the stented group and 91% in the unstented group. Another study also concluded that the presence of ureteric stent resulted in a higher rate of ESWL failure.⁴⁶ A comparative cross-sectional study noticed that pre-ESWL double J stenting for a 2 cm \pm 2 mm renal stone reduces the risk of renal colic and obstruction, but does not reduce formation of steinstrasse or infective complications. The same study also noticed the cost of the treatment doubled



in the stented group, which is an important factor in the authors' country (Pakistan).⁴⁷

Our study supports the findings of previous studies. Our study observed inferior ESWL outcome in patients with stent. Only 47.9% of patients with stent showed good response to treatment, while 87.2% without stent had notable treatment benefit (p < 0.001).

Stent was found to be independent predictor of ESWL failure in multivariate analysis. A higher failure of ESWL could be due to several difficulties such as difficulty in targeting, energy loss, and effect of the stent on peristalsis of ureter leading to reduced clearance of fragments. In our study, an indication for stenting was the presence of a stone > 15 mm in diameter. Considering the findings of previous studies and this study, routine stenting for stones < 20 mm should not be recommended as it does not prevent the formation of steinstrasse or the incidence of infective complications and might even lead to decreased stone clearance. However, it can be used in cases of sepsis and in patients with deteriorating renal function due to obstruction or with intolerable pain.^{2,46,47}

A series of minor complications can occur after ESWL. A prospective study of 3241 patients treated with ESWL reported 4075 common complications, including renal colic (40%), gross hematuria (32%), steinstrasse (24.2%), symptomatic bacteriuria (9.7%), and perirenal hematoma or subclinical subcapsular haematoma (4.6%).⁴⁸ All complications were managed conservatively or with minimal intervention. Another study noted an overall complications and were treated conservatively.³⁴

The overall complication rate in this study was 26.4%. All complications were minor, including loin pain (18.7%), gross hematuria (11.9%), and steinstrasse (1.7%). Patients with dysuria were 17.0%, of which symptomatic bacteriuria was diagnosed in 1.3% of patients. No major complications occurred in any patient, such as hemorrhage (which could have necessitated transfusion), severe infection, or injury to other organs. ESWL is not completely free from major complications such as massive retroperitoneal hemorrhage, renal, or other organs injury. However, each of these complications, recognition, and correction of concomitant diseases or infection, and using ESWL in the most efficient and safe way.^{34,48}

Some of the limitations of the present study are mentioned herewith. We conducted a retrospective review and included a small number of patients. To reduce expected selection bias, a urologist was blinded to the results of ESWL, who assessed the predictors by NCCT. The measurement of the stone size was done in accordance with maximum diameter and not as per the surface area. Plain radiography and ultrasonography was used instead of NCCT for follow-up protocol to confirm treatment success. Stone composition has significant influence on outcome of ESWL, which was not evaluated. Chemical analysis of the retrieved stone fragment was not done. The patients with ureteral stents were not randomized prior to ESWL into stented and non-stented groups. However, the study provides strong evidence that patient's gender, stone size, stone site, stone density, SSD, and use of double J stent affect the ESWL outcome, which can be very useful for patient selection to improve ESWL outcomes to save time and treatment costs.

CONCLUSION

This single institution experience, renal and ureteric stones treatment with ESWL showed good results. Any single potential predictive factor cannot determine likely outcome of ESWL treatment individually. Therefore, modern approach should consider all the predictors collectively. Failure of ESWL was observed to more in the case of females, stone size > 10 mm, stone density > 1000 HU, and patient with stents. Considering the limitations of this study, development of a nomogram on the basis of prospective randomized studies, may help to further improve patient selection and treatment outcome, thus decreasing the time and cost of treatment by reducing the failure rate.

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