Predictors of success following extracorporeal shock-wave lithotripsy in a contemporary cohort

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Abstract

Objectives: The objectives of this study are to determine the predictors of success following extracorporeal shock-wave lithotripsy (ESWL) in a contemporary cohort at a high-volume stone center.

Methods: We conducted a retrospective review all patients who underwent an elective ESWL within our institution over a 24-month period (January 2014 to December 2015). Data on patient demographics, stone variables, and inpatient treatment outcomes were evaluated.

The presence of residual stone fragments larger than 4 mm on follow-up imaging was considered to be treatment failure. Using this threshold, clinically relevant variables between the treatment success and failure groups were identified. Multivariable logistic regression analyses (MVA) of clinically relevant variables were used to determine the independent factors predicting ESWL success.

Results: Of 446 study eligible patients, 421 patients had complete follow-up data and were included in the analysis. Treatment was successful in 72.2% of patients in this study. Stone size, number of shocks delivered, and maximum treatment intensity were statistically different in the two groups. In a MVA where stone size, location, density, presence of ureteric stent, skin-stone distance (SSD), number of shocks, and maximum shock intensity were included, only stone size of <10 mm (odds ratio [OR] 3.4 [95% confidence interval [CI]: 1.98–5.84]) and SSD <15 cm (OR: 0.133, [95% CI: 0.027–0.65]) were the independent predictor of ESWL success.

Conclusion: We have demonstrated "real world" outcomes with high-volume use of ESWL. In our experience that with diligent patient selection, ESWL remains an effective tool for the management of upper tract calculi.

Keywords: Extracorporeal shock-wave lithotripsy, lithotripsy, upper tract stones

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INTRODUCTION

Urolithiasis is one of the most common conditions treated by an urologist. The lifetime reported risk of urinary stone disease has been estimated to be 12% in men and 6% in women.[1] Several studies have demonstrated that the incidence and prevalence of urolithiasis continue to rise, both globally and locally in New Zealand.[2-4]

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The modern urologist has multiple modalities in their armamentarium in the management of urolithiasis including ureteroscopy (acute or elective), extracorporeal shock-wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL) as well as open or laparoscopic procedures. With increasing population demand and constantly evolving technological advancements, decision-making remains complex and increasingly evidence driven.

ESWL is a well-established and effective way for treating renal and ureteric calculi, with variable success rates of up to 90% reported in the literature.[5] However, effective stone clearance can be dependent on many factors, including stone size, location, density and composition, patient's body mass index, and renal anatomy.

Although the literature suggests relatively high success rate with ESWL, in practice results can be variable as the majority of studies have strict inclusion criteria and are conducted within the confines of clinical trials. This variable success rate has been cited as one of the reasons for a proportional decline in ESWL utilisation in both Australia and New Zealand.[6,7]

The aim of this study was to determine the practical "real world" results from a high-volume stone center with a dedicated ESWL service and to assess the factors that influence the outcomes in actual day to day practice.

METHODS

Study population

Following appropriate Institutional Ethical Committee approval, the local electronic database was searched for all patients who underwent an elective ESWL within our institution from January 2014 to December 2015.

Auckland City Hospital is the only referral hospital for the management of acute ureteric colic for a population of over 1.5 million people. The unit has a dedicated ESWL machine and theater within an elective satellite hospital facility. Furthermore, the electronic health records for all patients in the region are accessible, ensuring complete capture of data. A noncontrast computerized tomography (CT) is performed for all patients before being scheduled for the procedure.

At our institution, we use ESWL for the treatment of upper tract stones only. Anatomically, this incorporates calyceal stones, stones in the renal pelvis, and proximal ureter. Indications for the treatment were the presence of symptoms (pain, recurrent urinary tract infections, and bleeding), enlarging calyceal stones or stones lager than 10 mm.

Our exclusion criteria included pregnancy, oral anticoagulation, untreated aneurisms, untreated urinary tract obstruction, or infection. We are less likely offer ESWL treatment in patients with skin to stone distance (SSD) larger than 15 cm, stones larger than 20 mm or patients with stones with densities larger than 1500 HU; however, selected patients with only one of the latter "unfavorable" characteristics may still be offered ESWL.

For the purpose of this study, treatment success was defined as successful fragmentation of the index stone with fragments either being absent or insignificant at ≤4 mm on follow-up imaging (plain abdominal X-ray at 6 weeks). This corresponds to a "Stone Free Rate" level of '4X', as per the proposed definitions by Somani *et al*.[8]

Procedure

All patients are admitted on the day of the procedure. The procedure is carried out under conscious intra-venous sedation with assistance of a specialist anesthetist. Rarely, if patients are not tolerating the procedure, general anesthesia is used.

A Dornier Lithotripter (DoLi S-II: Dornier MedTech, Germany) is used in our institution. Patients are placed in the supine position with shocks delivered to the flank posteriorly. Coupling gel is used to minimize air pockets in the patient-lithotripter interface, ensuring maximal energy delivery to the stone. All stones are visualized with fluoroscopy before the patients being sedated. If visualization is difficult, ultrasound imaging can also be utilized to improve stone localization.

Once the stone is localized and the appropriate sedation achieved, the treatment is commenced. Initially, lowest device delivery intensity at the frequency of 60–90 shocks per minute is delivered. The intensity is gradually increased, often to a maximum of 4 units. Fluoroscopy is used throughout the procedure to ensure optimal stone localization and to assess treatment response. Treatment is concluded when there is radiological evidence of successful stone fragmentation. Duration of the treatment is left to the discretion of the treating physician.

All patients are discharged with oral analgesia following the procedure and are followed up in the outpatients' clinic at 6 weeks with a plain abdominal X-ray. Plain films are convenient and cheap to obtain with minimal radiation exposure (0.7 mSv). In addition, they have an impressive sensitivity of 87.5% for stones >5 mm, making them ideal to identify the patients requiring further surgical intervention in our cohort.[9]

Analysis

In this retrospective review, we considered patient, stone, and treatment-related factors. All images were viewed and analyzed using ICIS View Version 2014.1 (Agfa HealthCare, Mortsel, Belgium).

Patient factors included age, gender, stone laterality (left or right) and the SSD. Stone factors included anatomical location, size, and density. Stone location was defined as upper pole, mid pole, lower pole, renal pelvis, and proximal ureter based on preprocedure radiological imaging. Mid-pole stones were defined as being present between the upper and lower poles and outside of the renal pelvis, within the inter-polar calyces of the kidney. Stone size was defined as the maximum length of the stone on an axial image of the stone. SSD was the minimum CT distance between the stone and skin of the posterior body wall. Stone density was based on the Hounsfield Units (HU) calculation of our local radiology software.

Treatment factors such as frequency, number of shocks delivered, and maximum shock intensity were also recorded.

Statistical analysis

Continuous variables with non-normal distribution were presented as median (interquartile range [IQR]) and groups were compared using the Mann–Whitney U-test. Categorical variables were compared using the Chi-squared test.

Multivariable logistic regression analyses of clinically relevant variables were used to assess the factors predicting ESWL success. The variables included were stone size, location, density, presence of ureteric stent, SSD, number of shocks, and maximum shock intensity.

Statistical analyses were performed using the SPSS version 21 software (IBM SPSS Statistics, Armonk, NY, USA: IBM Corp). Statistical significance was accepted at $P < 0.05$.

RESULTS

From January 2014 to December 2015, 446 patients underwent elective ESWL for upper tract stones at our institution. Follow-up data were available for 421 patients who were included in the study.

Patient parameters

Median patient age was 51 years (IQR: 42–62). 261 patients were male, with 159 female patients. Left sided stones were more common (59%, $n = 250$). In our cohort, no statistically significant difference was observed when considering age, gender, and stone laterality in terms of treatment success.

Stone parameters

Median stone size for the entire cohort was 9 mm (IQR: 7.0–12.0). Majority of stones (41%) were located in the lower pole with a median diameter of 9.5 mm (IQR: 7.0–12.0). The distribution of the stone location was similar for proximal ureter (15%), mid pole (14%), upper pole (14%), and renal pelvis (16%). The median stone size in the renal pelvis was 12 mm, which was significantly larger than stones in the other locations (12.0 vs. 9.0 mm, $P < 0.001$).

Median stone density (HU) for the stones in this population was 1100 (IQR: 834–1297). In this cohort, the stones in the mid-pole location had significantly lower median HU compared to stones in all other locations (989 vs. 1120, $P = 0.009$).

Treatment parameters

Median SSD for the entire cohort was 10 cm (IQR: 8.2–11.8). The longest SSD was seen in patients treated with stones in the proximal ureter (12.5 vs. 9.7 cm, $P < 0.001$), followed by those with renal pelvis stones (10.9 cm, [IQR: 9.5–12]).

Median number of shocks delivered was 2500 (IQR: 2000–3000), with stones in the mid-pole receiving lower number of shocks compared to stones in all other locations (2184 vs. 2500, $P = 0.003$). Median treatment delivery intensity was 4 (IQR 4–4) for the entire cohort, with similar distribution for all stone locations.

Ureteric stent was present in 75 (18%) of the patients at the time of ESWL treatment. In patients with proximal ureteric calculi, 44% were stented at the time of the procedure, followed by renal pelvis (29%), lower pole (14%), mid pole (3%) and upper pole (3%).

Treatment outcomes

Treatment was successful in 72.2% of patients in this study. Treatment failure rates were proportionally higher for stones in the renal pelvis (37%) compared to those in the proximal ureter (30%), upper pole (27%), mid-pole (26%) and lower pole (24%). However, these differences were not statistically significant.

In patients who failed treatment, the median residual stone size was 7 mm (IQR 6.0–10.0), with largest residual fragments seen in renal pelvis stones (8 mm, [IQR 7.0–10.0]), followed by proximal ureter stones (7.5 mm, [IQR 6.0–9.0]).

Stone size, number of shocks delivered, and maximum treatment intensity were statistically different in the two groups. Table 1 summarizes the stone parameters in the successful and unsuccessful treatment groups.

In a multivariable analysis where stone size, location, density, presence of ureteric stent, SSD, number of shocks, and maximum shock intensity were included, only stone size of <10 mm (Odds ratio [OR] 3.4 [95% Confidence interval [CI]: 1.98–5.84]) and SSD <15 cm (OR: 0.133, [95% CI: 0.027–0.65]) where independent predictor of ESWL success [Table 2].

Readmissions were observed on 76 (18%) of patients. Thirty-two (7%) patients presented with pain or haematuria and were treated conservatively. Two patients presented with urinary tract infection requiring intravenous antibiotics. Two patients developed subscapular renal hematomas and were treated conservatively.

Forty (9%) patients presented with residual ureteric fragments which required further surgical intervention in the form of retrograde ureteroscopy with holmium laser lithotripsy of fragments.

Severe life-threatening complications with ESWL are rare[10] and were noted in one of our patients who presented with a splenic injury post treatment. After initial stabilization and resuscitation, this patient proceeded to laparotomy and subsequent splenectomy.

Table 1: Comparison of patient, stone and treatment parameters in successful and unsuccessful extracorporeal shock-wave lithotripsy treatment groups

Variables	Success		*P*
	No	Yes	
Age	52 (44-62)	50.5 (41-62)	0.440**
Gender			
Male	76 (65)	187 (62)	0.575*
Female	41 (35)	117 (38)	
Side			
Right	48 (41)	122 (40)	0.825*
Left	68 (59)	182 (60)	
Location			
Any location	75 (64)	174 (57)	0.224*
Lower pole	42 (36)	130 (43)	
Pre-double J stented			
No	100 (85)	246 (83)	0.321*
Yes	17 (15)	58 (19)	
Stone size (mm)	11 (9-14)	9 (7-11)	<0.001**
Hounsfield units	1100 (834-1295)	1100 (846-1300)	0.979**
Skin to stone distance (cm)	10.5 (8-12)	9.83 (8-12)	0.100**
Number of shocks delivers	2750 (2000-3000)	2500 (2000-3000)	0.004**
Maximum recorded intensity	4 (4-5)	4 (4-4)	0.009**
Residual fragment size (mm)	7 (6-10)	0	<0.001**

*Chi square test, ** Mann-Whitney U-test

Table 2: Multivariate analysis of independent predictors of extracorporeal shock-wave lithotripsy success

Variables	OR (95% CI)	*P*
Stone size (mm)		
≤10 versus >10	3.40 (1.98-5.84)	<0.001
Stone location		
Lower pole versus any location	1.53 (0.899-2.62)	0.117
Stone density (HU)		
≤1000 versus >1000	1.03 (0.594-1.76)	0.927
Number of shocks		
≤2500 versus >2500	1.09 (0.627-1.89)	0.759
Maximum intensity		
≤4 versus >4	0.70 (0.386-1.26)	0.236
Double J stent		
Yes versus no	1.61 (0.803-3.20)	0.180
Skin to stone distance (cm)		
0-10	Reference	0.041
10-15	0.777 (0.456-1.325)	0.355
>15	0.133 (0.027-0.65)	0.013

OR: Odds ratio, CI: Confidence interval

DISCUSSION

In this study, we aimed to assess "real world" outcomes following ESWL treatment within a dedicated stone service. In our series, an overall stone-free rate of 72.2% was achieved. This is comparable, albeit on the lower end of the spectrum, to stone-free rates throughout the literature which are quoted between 68% and 90%.[5] In our experience, we only identified two independent predictors of treatment success-stone size of <10 mm and a SSD <15 cm.

ESWL and ureteroscopy remain the two-most common intervention modalities presently used to treat urinary calculi in an attempt to achieve maximal stone clearance with minimal patient morbidity. The success of both modalities is strongly influenced by patient and stone-related factors.

Stone size is an important variable to consider when determining suitability for ESWL. Our data have shown that a stone <10 mm is an independent predictor of success in ESWL, in keeping with findings in other studies.[5,11,12] The European Association of Urology (EAU) supports ESWL treatment for stones up to 2 cm. However, stones >2 cm may require multiple attempts to achieve clearance and should be managed with alternative treatment options such as PCNL (Grade A recommendation) which has higher success rates regardless of stone size.[13]

Stone location is another important factor that determines stone-free rates in ESWL. Recent well-conducted systematic reviews and Cochrane studies have demonstrated that the endoscopic management of ureteric stones provides higher stone-free rates compared to ESWL, but at the cost of longer hospital stays and higher complication rates.[14,15] In our analysis, 70% of patients with proximal ureteric stones had successful clearance on post-operative imaging, supporting the role of ESWL in this context. Accordingly, despite the higher success rates of endoscopic management, the EAU guidelines recommend ESWL as the first-line treatment for proximal ureteric stones <10 mm. Canadian Urology Association (CUA) guidelines advocate the use of either modality in ureteric stone treatment provided adequate patient counseling has been provided.[13,16]

The intra-renal location of the stone has a significant bearing on ESWL success rates. Although the disintegration efficacy of ESWL is not limited by location, fragments in the lower pole often remain in the calyx limiting stone-free rates and cause recurrent stone formation. Other anatomical factors that are unfavourable for the treatment with ESWL include the presence of a narrow infundibulum and steep infundibular-pelvic angles. EAU guidelines support the use of ESWL for renal stones <20 mm as long as there are no unfavourable anatomical characteristics.[13] The majority of stones in our study were located in the lower pole (41%), with similar distribution in the other locations. Despite their unfavorable location, we achieved stone-free rates as high as 76% for lower pole stones in our analysis, much higher than corresponding studies in the literature.[11] This may reflect our selective approach to patient inclusion, where we often avoid offering ESWL to patients with multiple unfavourable characteristics.

Stone composition is another variable impacting on stone clearance rates. In many instances, the exact stone composition is not known before treatment, or if the patient is a recurrent stone former the composition may have changed in up to 21% of patients.[17] The use of stone density on CT has been postulated as a surrogate marker for stone composition in the literature, and that fragmentation of stones with ESWL can be predicted based on stone density in HU on non-contrast CT.[16] Higher HUs suggest harder stones which may include brushite, calcium oxalate monohydrate, or cysteine which are difficult to fragment. Stone density of >1000HU has been shown to be an independent predictor of ESWL failure rate on multivariate analysis by El-Nahas *et al*. in 2007.[18] Both the EAU and CUA guidelines also conclude that ESWL is not recommended for stones >1000 HU as it leads to poor stone clearance rates.[13,16] Although the median stone density of 1100HU in our study is higher than the recommended guidelines for treatment, this factor did not achieve statistical significance or translate into an independent predictor of success in our series.

Patient factors such as an increased BMI have also been identified as predictors for treatment failure in the literature.[18] There are multiple technical challenges associated with the treatment of morbidity obese patients, including difficulty positioning of the patient, dampened shock waves, and difficult stone localisation. Reflecting this, the SSD has been identified as an independent predictor of stone-free status following ESWL. In a large retrospective review of 1282 ESWL treatments, a SSD >10 cm was associated with lower stone free rates on multivariate analysis.[19] Although not statistically significant, the median SSD for our cohort was 10 cm, with the longest distance associated with stones in the proximal ureter as would be expected.

The role of ureteral stenting in ESWL patients has long been debated. However, there is now good evidence to show that that stenting is not necessary in patients and actually impedes the passage of fragments, limiting stone-free success rates.[20,21] Stented patients have been found to require more adjuvant procedures to render them stone free[22] and does not diminish the risk of steinstrausse or infections following ESWL.[23] In our series, the presence of a stent was not a statically significant factor and did not impact on the treatment success rates. This may reflect the small number of patients who were stented in our cohort (18%, n = 75), and a larger dataset is required to further comment on the role of stenting in our practice.

In addition to patient- and stone-related factors, it is imperative to optimize the treatment algorithm with ESWL. In our practice, we follow the EAU guidelines which incorporates the adequate use of coupling gel to maximize energy transfer, adequate patient sedation, and analgesia as well as careful fluoroscopic stone monitoring throughout treatment.[13] Pace *et al*. determined that the optimal shock-wave frequency to achieve maximal stone free rates is 1.0–1.5 Hz, consistent with our practice of delivering 60–90 shocks per minute.[24] In addition, we employ the principle of step-wise intensity ramping of shocks. This has been demonstrated to reduce renal injury by inducing renal vasoconstriction, which is protective in reducing the rate of renal hematomas.[25-27] Finally, our median number of shocks delivered was 2500 in the successful group and 2750 in the unsuccessful group. This is in keeping with the CUA guidelines of a maximum of 3500 shocks for proximal stones, ensuring that adverse effects such as renal damage are minimized while maximizing treatment efficacy.[16,28]

Our data suggest that only SSD and stone size were the independent predictors of success and other traditionally known variables such as location, density, and treatment factors were not as influential. This is likely related to our selective approach to patient inclusion. It is possible that in presence of one or two unfavorable features, treatment outcomes may still be acceptable, as long as other patient and stone characteristics are favorable, and the treatment delivery is optimized.

As the data collection was retrospective, this study has a number of limitations. Follow-up imaging in clinic was a plain abdominal X-ray, which could have the potential to underestimate the size of residual fragments compared to cross-sectional CT scans. In addition, we only considered ESWL in the treatment of upper tract stones. Thus, no comment can be made on our treatment efficacy for mid and lower ureteric stones, an important distinction compared to other studies in the literature.

CONCLUSION

In real-world setting of clinical practice and with appropriate patient selection, ESWL remains an effective tool for the management of upper tract calculi.

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Conflicts of interest

There are no conflicts of interest.

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