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Prediction of Success Rate after Extracorporeal Shock-wave Lithotripsy of Renal Stones

A Multivariate Analysis Model

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Objectives: To define prognostic factors that affect the success rate after extracorporeal shock-wave lithotripsy (ESWL) of renal calculi and to estimate the probability of stone-free status using a regression analysis model.
Material and Methods: Between February 1992 and February 2002, 2954 patients with single or multiple radiopaque renal stones (<30 mm) underwent ESWL monotherapy. The results of treatment were evaluated after 3 months of follow-up. Treatment success was defined as complete clearance of the stones with no residual fragments. The stone-free rate was correlated with stone features and patient characteristics using the χ^2 test. Factors found to be significant using the χ^2 test were further analyzed using multivariate regression analysis.
Results: At 3-month follow-up, the overall stone-free rate using ESWL monotherapy was 86.7%. Failure to disintegrate the stones was observed in 7.3% of cases ($n = 216$) and failure to clear the fragmented stones occurred in 6% ($n = 177$). Repeat ESWL was needed in 53% of cases. Static steinstrasse occurred in 4.9% of cases ($n = 146$) and post-ESWL auxiliary procedures were required in 4% ($n = 118$). Using the χ^2 test, patient age ($p < 0.001$), stone size ($p < 0.001$), location ($p < 0.001$), number ($p < 0.001$) and nature ($p = 0.003$), radiological renal picture ($p < 0.001$) and congenital renal anomalies ($p < 0.001$) had a significant impact on the stone-free rate. Multivariate analysis excluded stone nature from the logistic regression model while other factors maintained their statistically significant effect on success rate, indicating that they were independent predictors. A regression analysis model was designed to estimate the probability of stone-free status after ESWL. The sensitivity of the model was 83%, the specificity 91% and the overall accuracy 87%.
Conclusion: Patient age, stone size, location and number, radiological renal features and congenital renal anomalies are prognostic factors determining stone clearance after ESWL of renal calculi. Our regression model can predict the probability of the success of ESWL with an accuracy of 87%.

Key words: extracorporeal shock-wave lithotripsy, prognostic factors, renal calculi.

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The efficacy of extracorporeal shock-wave lithotripsy (ESWL) for kidney stones depends on the size, location and composition of the stones (1). ESWL results for stones up to 10 mm in size are satisfactory independent of their location in the kidney, whereas the stone-free rate for stones 11–20 mm in size is lower, particularly for lower pole calculi (2–4), for which it ranges from 41% to 73% (2–5). Other workers examined lower pole caliceal anatomy as a predictor of the success of ESWL for lower caliceal stones. Sampaio et al. (6) first proposed the lower infundibulopelvic angle (IPA) as a prognostic factor for the clearance of lower pole stones. Subsequently, other authors analyzed additional factors, including lower infundibular length (IL), infundibular width (IW) (7–9) and caliceal pelvic height (CPH) (10).

Herein, we report our experience with 2954 patients with renal calculi who underwent ESWL monotherapy with the aim of defining prognostic factors influencing stone clearance and to estimate the probability of stone-free status using a logistic regression model. This model can help to select patients who will respond well to ESWL in a prospective manner. Notably, all patients were treated at one institution using a single lithotripter (Dornier MFL 5000) over a 10-year period.

MATERIAL AND METHODS

Patients

Between February 1992 and February 2002, a total of 2954 patients with single or multiple radiopaque renal

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calculi underwent ESWL monotherapy. All patients were treated with the same lithotripter (Dornier MFL 5000). The study included 2111 males (71.5%) and 843 females (28.5%) and the mean age was 39.2 ± 9.7 years (range 4–78 years). Preoperatively, patients were evaluated by means of serum creatinine level, urinalysis, urinary culture, coagulation profile, plain abdominal X-ray (KUB) film, i.v. urography and/or renal ultrasound. The mean serum creatinine level was 1 ± 0.3 mg/dl. Exclusion criteria were the presence of ureteric strictures, coagulopathies and non-functioning kidneys. Among the entire group of treated patients, 80 (2.7%) had congenital renal anomalies: 39 horseshoe kidneys, 26 ectopic iliac or pelvic kidneys and 15 duplex.

Stones

The features of the treated stones, i.e. size, location in the kidney, nature (de-novo or recurrent) and number, are shown in Table I. All the treated stones were <30 mm in size. Residual stones after percutaneous nephrostolithotomy (PCNL) or open renal surgery were excluded. The mean size for a single stone (longest diameter) was 13 ± 5.3 mm (range 5–24 mm) while it was 17.6 ± 6.2 mm (range 10–28 mm) for multiple stones (sum of the longest diameters for each stone).

Table I. *Patient characteristics and stone features in correlation with stone-free rate (χ^2 test)*

Variable	n	%	Stone-free rate [/][a]	Stone-free rate %	p
Age (years)					
≤40	1526	15.7	1361/1526	89	<0.001
>40	1428	48.3	1200/1428	84	
Sex					
Male	2111	71.5	1825/2111	86.5	0.536
Female	843	28.5	736/843	87.3	
Site of stone(s)					
Upper calyx	215	7.3	192/215	89.3	<0.001
Middle calyx	263	8.9	228/263	86.7	
Lower calyx	734	24.8	604/734	82.3	
Renal pelvis	1370	46.4	1266/1370	92.4	
Multiple sites	372	12.6	271/372	72.8	
Size of stone(s) (mm)					
≤15	2075	70.2	2019/2075	89.7	<0.001
>15	879	29.8	686/879	78	
Nature of stone(s)					
De-novo	2598	88	2270/2598	87.4	0.003
Recurrent	356	12	291/356	81.7	
Number of stone(s)					
Single	2324	78.7	2097/2324	90.2	<0.001
Multiple	630	21.3	464/630	73.7	
Radiological renal picture					
Perfect	2256	76.4	1996/2256	88.5	<0.001
Pyelonephritic	130	4.4	103/130	79.2	
Obstructed	568	19.2	462/568	81.3	
Congenital anomalies					
No	2874	97.3	2503/2874	87.1	<0.001
Yes	80	2.7	58/80	72.5	

[a] [/] = stone-free cases/total number of patients.

Technique

Ureteric JJ stents were placed in 142 patients (4.8%) before ESWL. Indications for ureteral stenting were solitary kidneys in 103 patients (3.5%) and calcular anuria in 39 (1.3%). Percutaneous nephrostomy (PCN) was required in another six cases of anuria (0.2%) to relieve renal obstruction, followed by ESWL. Adequate sedoanalgesia was given to the patients in the form of meperidine·HCl (100 μg/kg) and/or fentanyl (1.5 μg/kg). ESWL therapy is usually started at a low voltage of 14 kV until the patient becomes accustomed to the shocks, and the voltage is then gradually increased to a maximum of 20 kV. The average number of shocks per session was 2500–3000. In 65 children (2.2%), general anesthesia was needed. All the patients were treated in the supine position with the exception of some patients with congenital renal anomalies and those with vertebral deformities, who were treated in the prone position.

Follow-up

Patients were reviewed 1 week after the first ESWL session using a KUB film and renal ultrasound to assess fragmentation and the presence of renal obstruction. Repeat treatment was carried out if there was inadequate fragmentation of the stone. If there was no response after three sessions, the case was considered an ESWL failure. Follow-up using a KUB film and renal ultrasound was continued every 2 weeks until there was complete stone clearance. All follow-up data were analyzed after the 3-month visit. Treatment success was defined as complete stone clearance with no residual fragments (RFs).

Statistical analysis

The stone-free rate was correlated with patient characteristics and stone features using the χ^2 test. Factors with a significant impact on success rate using the χ^2 test were further analyzed using multivariate analysis (stepwise logistic regression model with backward elimination using the likelihood ratio) to identify independent predictors of the success of ESWL.

RESULTS

At 3-month follow-up, an overall stone-free rate of 86.7% (2561/2954) was obtained using ESWL monotherapy. Repeat treatment was needed in 1566 of cases (53%). Among the re-treatment group, 896 patients (30.3%) needed more than two sessions to ensure complete disintegration. The mean number of sessions per stone was 2.2 ± 0.6. The mean number of shocks per stone in total was 5900 ± 1800, the mean voltage was 17.5 ± 1.6 kV and the mean power delivered to the stones was 1032 ± 383 kV. The mean power delivered to the stones = (the mean number of shocks × the mean voltage)/100 (11).

Failure to fragment the stones after three consecutive sessions of ESWL was recorded in 216 cases (7.3%). Failure to completely clear the stones (i.e. the presence of RFs) was observed in 177 cases (6%). The RFs were classified into two groups: significant residual fragments (SRFs; ≥ 4 mm) in 39 cases (1.3%) and clinically insignificant residual fragments (CIRFs; <4 mm) in 138 (4.7%). Of the 39 patients with SRFs, 30 (1%) needed repeat ESWL, the remaining nine (0.3%) being treated by PCNL. Patients with CIRFs were followed up for a mean period of 45 ± 15 months. During follow-up, CIRFs passed spontaneously in 58 patients (42%), remained stable in 55 (40%) and became SRFs in 25 (18%), who subsequently required intervention (repeat ESWL in 20, PCNL in two and ureteroscopy in three). Failure of complete clearance of the stones was strongly correlated with stone location, 57% (101/177) being located in the lower calyx ($p < 0.001$). The overall results of the 2954 cases are summarized in Fig. 1.

Post-ESWL complications are listed in Table II. Static steinstrasse were recorded in 146 cases (4.9%), and passed spontaneously in 73 (50%). Complicated steinstrasse (73 cases) were treated with ureteroscopy and extraction of the leading stone in 63 cases; in the remaining 10 cases, the fragment passed spontaneously after decompression of the obstructed renal units by means of JJ stents in seven and PCN in three. Post-ESWL auxiliary procedures are listed in Table III. In the present study, an efficiency quotient (EQ) of 0.55 could be achieved using the following formula (12): EQ = percentage of stone-free patients/(100% + retreatment percentage + percentage of post-ESWL auxiliary procedures)

Table II. *Post-ESWL complications*

Complication	*n*	%
Subcapsular renal hematoma	4	0.1
Septicemia	6	0.2
Anuria	7	0.2
Urinary retention	3	0.1
Static steinstrasse	146	4.9
Total	166	5.5

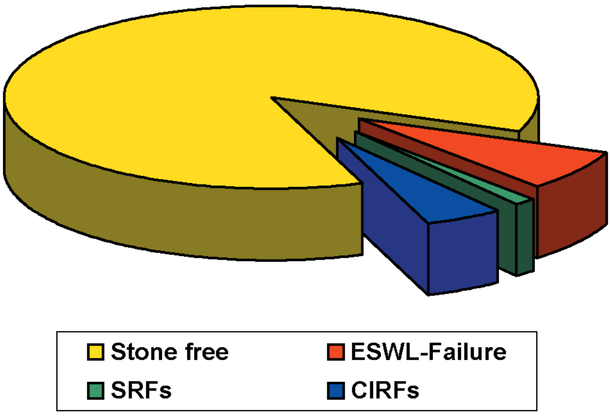

Fig. 1. Overall results of ESWL monotherapy of 2954 renal calculi, showing stone-free cases ($n = 2561$; 86.7%), failures ($n = 216$; 7.3%), SRFs ≥ 4 mm ($n = 39$; 1.3%) and CIRFs <4 mm ($n = 138$; 4.7%).

The stone-free rate was correlated with patient characteristics and stone features using the χ^2 test (Table I). Of the eight prognostic factors studied, seven had a significant impact on success rate, namely patient age ($p < 0.001$), the site ($p < 0.001$), size ($p < 0.001$), number ($p < 0.001$) and nature of the stones ($p = 0.003$), the radiological renal picture ($p < 0.001$) and congenital renal anomalies ($p < 0.001$). These seven factors were further analyzed using a logistic regression model, which resulted in the exclusion of the nature of the stones from the model, while the other prognostic factors maintained their statistically significant effect on ESWL outcome, indicating that they acted independently (Table IV). The sensitivity of the model was 83%, the specificity 91% and the overall accuracy 87%. Using the regression model, we can define the stone-free ratio of a certain category in comparison to the reference category (Table IV). For example, the probability of stone-free status is 1.94 times greater for patients with stones ≤ 15 mm in size in comparison to patients with stones >15 mm in size.

The equation for logistic regression is Z = −0.834 + B for patient age + B size for stone (s) + B number for stone (s) + B site for stone (s) + B for radiological renal features + B for congenital renal anomalies, where Z is the linear combination of the variables, B is the regression coefficient and −0.834 is the constant of the model. The probability of the patient being stone-free is $1/(1 + e^{-Z})$, where e is the base of the natural logarithm (= 2.718).

If the estimated probability is >0.5, we predict that the patient will be free of stones. If the probability is

Table III. *Post-ESWL auxiliary procedures*

Procedure	*n*	%
JJ stent placement	29	1
Percutaneous nephrostomy	7	0.2
Endoscopic metotomy	3	0.1
Visual litholapaxy	6	0.2
Ureteroscopy	73	2.5
Total	118	4

Table IV. *Prognostic factors maintained in stepwise logistic regression model*

Variable	B[a]	Exp B[b]	*p*
Age (years)			
$\leq$40	0.3246	1.3835	0.0045
>40 (reference)	0	1	
Size of stone(s) (mm)			
$\leq$15	0.6630	1.9406	0.000
>15 (reference)	0	1	
Number of stone(s)			
Single	0.6419	1.9000	0.0000
Multiple (reference)	0	1	
Site of stone(s)			
Upper calyx	0.5951	1.8132	0.0158
Middle calyx	0.1314	1.1404	0.5332
Renal pelvis	0.8643	2.3733	0.0000
Multiple sites	0.1574	1.1705	0.3985
Lower calyx (reference)	0	1	
Radiological renal picture			
Normal	0.3164	1.3722	0.0236
Pyelonephritic	0.0306	1.0311	0.9050
Obstructed (reference)	0	1	
Congenital renal anomalies			
No	1.0793	2.9426	0.0001
Yes (reference)	0	1	

[a] Regression coefficient.

[b] Stone-free rate when the category of a certain variable is compared to the reference category.

<0.5, we predict that the patient will have residual stones. For example, if we have a patient aged 30 years with a single stone <15 mm in size in the upper calyx in a radiologically and anatomically normal kidney then $Z = -0.834 + 0.3246 + 0.663 + 0.6419 + 0.5951 + 0.3164 + 1.0793 = 2.7863$. The probability of the patient being stone-free = 0.94.

DISCUSSION

In this study, as in others (2, 3, 13–15), stone size was a significant predictor of ESWL outcome. Lalak et al. (16) evaluated the outcome of ESWL of 500 renal calculi using the Dornier compact Delta lithotripter. The overall stone-free rate for stones <10 mm in size was 76% at 3 months. For 10–20 mm stones, the rate was 66%, while the rate for stones >20 mm in size was 47%. The authors do not recommend ESWL as primary therapy for stones >20 mm in size (16). In another study (17), 246 cases of lower pole renal calculi <20 mm in size were treated with the Doli 50 lithotripter. The overall stone-free rate was 78%, 73%, 43% and 30% for stones <5, 6–10, 11–15 and 16–20 mm in size, respectively. The authors concluded that stone size rather than lower pole caliceal anatomy is predictive of treatment outcome (17).

For upper and middle calyceal stones, stone-free rates range from 70% to 90%, whereas those for such calculi located in the lower calyces range between 50% and 70% (5, 18, 19). In the present study, the probability of success of ESWL is 2.37 and 1.81 times greater, respectively for stones located in the renal pelvis and upper calyx in comparison to lower calyceal stones. Coz et al. (20) analyzed the successes and failures of ESWL in the treatment of 2016 urinary calculi using a Modulith SL-20 lithotripter. The stone-free rates were 89.2%, 90.5%, 84.8% and 86% for stones located in the upper calycx, middle calycx, lower calycx and renal pelvis, respectively. For calculi >24 mm, the re-treatment rate increased and the success rate dropped sharply (20).

Obek et al. (21) compared the efficacy of ESWL of isolated lower pole calculi with that for isolated middle and upper caliceal calculi in 714 renal units. The EQ of ESWL was 36%, 46% and 41% for lower, middle and upper pole calculi, respectively ($p = 0.4$). The overall stone-free rate was 66% and 63%, 73% and 71% for lower, middle and upper caliceal stones, respectively ($p = 0.1$). For the group with stones >2 cm^2, the overall stone-free rate decreased to 49% and 53%, 60% and 23% in lower, middle and upper caliceal locations, respectively. The authors concluded that ESWL should be the primary treatment of choice for stones <2 cm^2 in all caliceal locations (21).

In our study, the probability of stone-free status was 1.9 times greater for patients with single compared to multiple stones. Ackermann et al. (22) studied prognostic factors influencing treatment outcome after ESWL using multivariate analysis. In patients with solitary calculi ($n = 160$), age, body mass index (BMI), stone location, stone burden and serum calcium level were significant predictors of success. In patients with single and multiple calculi ($n = 210$), BMI and stone number were the only significant predictors. The authors concluded that the number of stones seemed to be more important than the stone burden in patients with a small-to-medium stone burden (22).

Our logistic regression model had an accuracy of 87% for the prediction of stone-free status, with a sensitivity of 83% and a specificity of 91%. Poulakis et al. (23) evaluated predictors of success of ESWL of lower caliceal calculi in 310 patients using an artificial neural network (ANN) and a logistic regression model. The accuracy of ANN was 94%, with a sensitivity of 95%, a specificity of 92% and a receiver operating characteristic (ROC) curve area of 0.966. These results were significantly better than those yielded by logistic regression analysis: accuracy 77%, sensitivity 75%, specificity 81% and ROC curve area 0.779. Patients with lower renal caliceal stones appear to have the best chance of successful ESWL when their BMI and urinary transport are normal, the IW is >15 mm and the infundibulo–ureteropelvic angle (IUPA) is >45°. Stone size and composition, as factors of stone clearance, are not statistically significant (23).

We found that obstructed and pyelonephritic kidneys had a significantly lower stone-free rate compared with normal kidneys ($p < 0.001$). This may be due to weak peristalses that lead to poor clearance of the fragments. In a recent study of 680 patients with lower pole calculi, Poulakis et al. (24) reported that the pattern of dynamic urinary transport represented the most influential predictor of stone clearance, followed by a measure of the IUPA, BMI, CPH and stone size. ANN had an accuracy of 92% for correctly predicting lower pole stone clearance.

The management of lower caliceal stones remains controversial (2). Although PCNL is associated with a higher stone-free rate (85%), most urologists reserve this procedure for lower pole calculi >20 mm because of its higher morbidity (25). In a prospective, randomized study, Elbahnasy et al. (7) noted that the stone-free rates for ESWL and PCNL were 29% and 86%, respectively for lower pole calculi ranging in size from 10 to 20 mm. A combination of unfavorable factors, such as IPA <90°, IL >30 mm and IW <5 mm, is a poor indication of success, with a success rate of only 17% being achieved in these patients (7). In the study of Gupta et al. (8), a 72% clearance rate of lower pole calculi was achieved at 6 months. IW >5 mm and IUPA >45° were statistically significant factors of stone clearance following ESWL. Sumino et al. (26) reported an overall stone clearance rate of 54% in 63 patients with lower pole calculi. Multivariate logistic analyses revealed that lower IL:diameter ratio, infundibular diameter (ID) and number of minor calices were independent predictors of successful stone clearance. The 13 patients (20.6%) who showed all three favorable anatomical factors (lower IL:diameter ratio <7, ID >4 mm and a single minor calyx) achieved a stone clearance rate of 84.6%. In contrast, the stone clearance rate was only 6.7% in the 15 patients who showed none of these factors (26). In the present study, the overall success rate for lower caliceal calculi was 82.3%.

Madbouly et al. (9) reported that none of the three lower pole anatomical factors (IPA, IL and IW) had any significant impact on the stone-free rate. Renal morphology was the only significant predictor of success, as stone clearance was significantly less in pyelonephritic kidneys ($p = 0.001$). Tuckey et al. (10) showed that a CPH <15 mm was associated with a stone clearance rate of 92%, whereas it was only 52% with a CPH >15 mm ($p < 0.05$). The authors found that 74% of patients with an IW >5 mm were rendered stone-free, compared to 40% of those with an IW <5 mm ($p < 0.05$) (10).

Stone-bearing horseshoe kidneys present a challenge for ESWL. The more anterior nature of these kidneys and the medial location of the lower calyx makes stone localization difficult. Additionally, the high insertion of the ureter, with its anterior course over the isthmus, may prevent fragment passage after ESWL. Nevertheless, surprisingly high stone-free rates, ranging from 50% to 85%, have been reported (27, 28). Many authors (18, 27, 28) concluded that ESWL represents the treatment of choice in horseshoe and malrotated kidneys with small caliceal calculi (<20 mm) similar to a normal anatomic situation. In our series, the probability of stone-free status was 2.94 times higher for patients with normal kidneys in comparison to those with congenital renal anomalies ($p < 0.001$).

In the present study, 18% of patients with CIRFs required intervention during long-term follow-up. Rassweiler et al. (15) showed that clearance of CIRFs occurs asymptomatically in most patients, i.e. auxiliary intervention is rarely required. Khatin et al. (29) evaluated the significance of CIRFs in 75 patients who were followed up for a mean period of 15 months. During follow-up, 59% of patients developed one or more complications and required intervention. The authors reported that 53% of CIRFs located in the renal pelvis passed spontaneously and that most CIRFs in a caliceal location became SRFs (29). Candau et al. (30) followed 83 patients with CIRFs after ESWL for a mean period of 40 months. Stone-free status or a decreased, stable or increased number of RFs occurred in 33%, 1%, 29% and 37% of cases, respectively. During follow-up, 22% of patients required auxiliary procedures (30).

Lingeman et al. (2) reported that the type of lithotripter impacts on the treatment outcome of lower pole calculi, as the original HM3 instrument is more effective than the newer lithotripters. In the present study, an EQ of 0.55 was achieved using the Dornier MFL 5000 lithotripter. Logarakis et al. (31) compared operator-specific success rates of ESWL performed by 12 urologists at one center (the study included 5769 renal and ureteral stones treated with the Dornier MFL 5000). They found clinically and statistically significant intra-institutional differences in success rates, the best results being obtained by the urologists who treated the greatest number of patients, used the highest number of shocks and had the longest fluoroscopy time (31). In a recent experimental study, Paterson et al. (32) reported that slowing the shock rate during ESWL significantly improves stone fragmentation.

Joseph et al. (33) evaluated the CT attenuation value of renal calculi as a predictor of successful fragmentation using ESWL in 30 cases. The success rate for stones with an attenuation value of >1000 HF units was significantly lower than that for stones with a value of <1000 HF (6/11 vs 18/19; $p < 0.01$). The mean attenuation value and the number of shocks required for calculous fragmentation correlated significantly

($p < 0.001$). The authors concluded that the CT attenuation value of renal calculi could help to define stones that are likely to fragment easily on ESWL (33).

CONCLUSION

Patient age, the size, site and number of stones, the radiological renal picture and congenital renal anomalies are the most important prognostic factors affecting stone clearance of renal calculi after ESWL. A regression analysis model can predict the probability of stone-free status with an accuracy of 87%. With the help of this model, we can select patients who will respond well to ESWL in a prospective manner and can define whether any subgroups of patients would be best treated using PCNL.

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