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ORIGINAL PAPER

Prediction of outcome of extracorporeal shock wave lithotripsy in the management of ureteric calculi

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Abstract The present study was designed to evaluate the clinical outcome of using extracorporeal shock wave lithotripsy (ESWL) in the treatment of ureteric calculi and to establish a predictive model for the stone-free rate in patients receiving the treatment. A total of 831 patients with ureteric calculi were accepted in this study. Several parameters, including stone site, stone number, stone size, history of urolithiasis, renal colic, hydronephrosis, and double-J ureteric stent, were analyzed using univariate and multivariate analyses. A prediction model was established based on the logistic regression analysis of the significant factors, and the goodness-of-fit of the model was evaluated by employing the Hosmer–Lemeshow test. At a 3-month follow-up after ESWL treatment, the overall stone-free rate was 96.8% (804/831) with no serious complications being found, while the treatment failed in 3.2% (27/831) of the patients. Five factors, including stone number, stone size, history of urolithiasis, renal colic, and double-J ureteric stent contributed significantly to the clinical outcome of the ESWL treatment. The prediction model had a sensitivity and overall accuracy of 99.8 and 96.9%, respectively. The results show that ESWL remains an effective method for treating ureteric calculi. The prediction model established in this study could be used as a method for estimating prognosis in patients following ESWL treatment.

Keywords Extracorporeal shock wave lithotripsy · Ureteric calculi · Prediction model · Logistic regression analysis

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Introduction

Ureteric calculi are a common urological disorder. Conventional treatments include ureteroscopic extraction, extracorporeal shock wave lithotripsy (ESWL), and open surgery. Since its introduction in the early 1980s, ESWL has been proven to be an effective and non-invasive treatment for ureteric calculi [1]. With the development of fluoroscopic imaging, stones can be located and treated throughout the ureter, although stones at different locations in the ureter offer different degrees of difficulty during the treatment. The increasing interest in less invasive treatment modalities for ureteric calculi as well as the favorable clinical outcome following ESWL treatment has made ESWL the method of choice for treating ureteric calculi [2]. The overall stone-free rates have been reported to be 80–90% in many prospective and retrospective studies [3, 4]. However, there is no unanimity of support for the use of ESWL due to its intrinsic disadvantages. For example, patients treated by ESWL are not immediately stone-free, and some require repeated treatment with ESWL owing to stone recurrence or regrowth [5]. Moreover, a small percentage of large ureteric stones may not be fragmented by ESWL, and the fragmentation rate after ESWL in elderly patients is relatively poor [6, 7]. Nowadays, ESWL remains the primary modality for treating ureteric calculi, which may be associated with the use of ureteroscopy for treatment of very large stones.

Several factors have been reported to influence the stone-free rate after ESWL treatment, including patient demographic characteristics, such as age and sex, and stone features, such as stone site and size [8, 9]. It has been demonstrated that stone site and size, especially the transverse diameter, are the major factors that determine the clinical outcome of ESWL. However, other factors, such as stone number, history of urolithiasis, renal colic, and double-J ureteric stent, should not be underestimated. It has been suggested that an accurate estimation of the individual's probability of stone clearance is essential for a proper selection of treatment to maximize the benefits of ESWL treatment [10]. However, an effective prediction model for the success rate of ESWL is rare. This present study was designed to establish a prediction model for the success rate of ESWL, based on a large-scale clinical study focusing on multiple prognostic factors. It is hoped that such a model will benefit both the patients who have the disease and the physicians treating them, in terms of making the right clinical decision.

Patients and methods

Patients

A total of 1,654 consecutive patients with ureteric calculi were treated with ESWL at our hospital between May 2008 and April 2009. All the patients included in the present study conformed to the following criteria: (1) ureteric calculi without calculi at other locations; (2) detailed follow-up data available; (3) no ESWL treatments prior to the current ESWL; (4) no other treatments other than ESWL for the disease; and (5) no malformation of the urethra. As a result, 831 patients were accepted in the present study. Of them, 586 were males (70.5%) and 245 were females (29.5%). The median age of the patients was 48 years (ranging in age from 8 to 86 years). The following data were collected: (1) age; (2) sex; (3) stone side (left, right); (4) stone site (proximal, middle, distal); (5) stone number (single, multiple); (6) stone size (measured through Type-B ultrasonic diagnosis or X-ray analysis); (7) history of urolithiasis (<60 days, ≥60 days); (8) renal colic (yes, no); (9) hydronephrosis (none, mild, moderate); and (10) placement of double-J ureteric stent (yes, no). This prospective study was approved by the Institutional Review Board of the hospital.

ESWL treatment

The ESWL treatment for all patients was accomplished using the same lithotriptor (Piezolith 2300, Richard Wolf GmbH, Germany). Patients with stones in the proximal (upper third) ureter were treated in the supine or lateral position, while patients with stones in the middle or distal thirds of the ureter were treated in the prone position. Intestine cleansing treatment was performed prior to ESWL treatment (especially for the patients with stones in the middle or distal thirds of the ureter), and stone location was identified through type-B ultrasonic diagnosis. X-ray analysis was used to assist in stone location for those patients where type-B ultrasonic diagnosis failed in the identification. In addition, type-B ultrasonic diagnosis and X-ray analysis were also used during the ESWL treatment to monitor fragmentation of the stones. The patients were required to drink at least two liters of water per day following ESWL. An interval of 7 days between treatments was required for those patients undergoing repeated sessions of ESWL.

Follow up

To determine the stone fragments and the presence of renal obstruction, Type-B ultrasonic diagnosis and X-ray analysis of kidney ureter bladder (KUB) were performed at 2 weeks, 4 weeks, and 3 months after the first ESWL treatment, respectively. Repeated ESWL treatment was performed if inadequate fragmentation of the stone was observed. The ESWL treatment was considered successful if complete stone clearance was observed in the ureter at the 3-month follow-up appointment; otherwise, the case was classified as an ESWL failure.

Statistical analysis

The data were analyzed employing the Statistical Package for Social Sciences (SPSS) software version 11.5. Univariate analysis of the influencing factors on the stone-free rate was performed using the rank sum test, Fisher's exact test, and the chi square test, whereas multivariate analysis was performed using logistic regression analysis (the Enter method) [11]. The prediction model for the success rate of ESWL treatment was established, with the goodness-of-fit being evaluated by the Hosmer–Lemeshow test. The difference was considered statistically significant when the P value was less than 0.05.

Results

Clinical outcome

The median stone size for the patients was 1.0 cm (range 0.6–2.3 cm) prior to ESWL treatment. For the ESWL procedures, the median number of shocks per stone was 1,000 (range 110–7,300), with the number being less than 2,000 in the majority (697) of the treated patients.

Repetitive sessions of ESWL treatment were performed for a total of 163 patients (19.6%). The overall stone-free rate at 3 months following ESWL was calculated as 96.8% (804/831), and no serious complications were observed. Post-ESWL auxiliary treatment, transurethral ureteroscopic lithotripsy was required in 27 patients (3.2%) who failed to respond to the ESWL treatment.

Univariate and multivariate analyses

As shown in Table 1, the success rate of ESWL was significantly affected by stone site, stone number, stone size, history of urolithiasis, renal colic, hydronephrosis, and double-J ureteric stent ($P < 0.05$), but not age, sex, and stone side ($P > 0.05$). Additionally, five factors, stone number, stone size, history of urolithiasis, renal colic, and double-J ureteric stent, were among the significant contributors to the success rate of ESWL, with the odds ratios (OR) being 4.731, 7.635, 3.388, 0.340, and 4.478, respectively (Table 2, $P < 0.05$).

Establishment of the prediction model

The prediction model for the success rate of ESWL (P, %) was deduced from the results of the multivariate analysis, as shown in Table 2:

$$P = \frac{1}{1 + e^{-(1.554X_1 + 2.033X_2 + 1.220X_3 - 1.078X_4 + 1.499X_5 - 9.058)}}$$

where X_1, X_2, X_3, X_4, and X_5 represent stone number, stone size, history of urolithiasis, renal colic, and double-J ureteric stent ($P < 0.05$), respectively, and e is the base of the natural logarithm (=2.718). The significance of the prediction model was evaluated using the chi square test, indicating that the regression equation was significant and, therefore, the inclusion of the five factors in the model was reasonable and justified. The goodness-of-fit of the prediction model was assessed using the Hosmer–Lemeshow test. The data were divided into ten subgroups, as shown in Table 3. The result of the Hosmer–Lemeshow test indicated that the prediction model could represent the data well ($\chi^2 = 4.520$, $df = 8$, $P = 0.807$).

Evaluation of the prediction model

The efficiency of the prediction model was evaluated employing the classification table, with the boundary probability being set at 0.5, meaning that ESWL was considered successful when the probability calculated was larger than 0.5 and considered to have failed when smaller than 0.5. As shown in Table 4, the sensitivity of the prediction model was 99.8% (802/804), the specificity was 11.1% (3/27), and the overall rate of accuracy was 96.9% (805/831). In order to validate the accuracy of the prediction model, the prediction model was further assessed using another set of data, in which the overall stone-free rate was 91.2% for the 520 patients (not involved in the present study) at 3 months after ESWL. Likewise, the boundary probability was set at 0.5. As shown in Table 5, the sensitivity of the prediction model was 97.5% (462/474), and the specificity was 26.1% (12/46). The overall rate of accuracy was 91.2% (474/520). Therefore, it was considered that the current prediction model sufficed for the requirement of accuracy and could be used to predict the success rate of ESWL.

Table 1 Univariate analysis of the influencing factors on the success rate of ESWL

Variable	Success	Failure	*P*
Age (years)[a]	47.50 (37.0–55.0)	51.00 (39.0–57.0)	0.534
Stone size (cm)[a]	1.00 (0.90–1.10)	1.30 (1.10–1.60)	<0.001
Sex			
Male	568	18	0.655
Female	236	9	
Stone side			
Left	423	15	0.763
Right	381	12	
Stone site			
Proximal	330	14	0.024
Middle	76	6	
Distal	398	7	
Stone number[b]			
Single	788	23	0.003
Multiple	16	4	
History of urolithiasis			
<60 days	775	19	<0.001
≥60 days	29	7	
Renal colic			
Yes	60	11	<0.001
No	744	16	
Hydronephrosis			
No	30	0	<0.001
Mild	719	17	
Moderate	55	10	
D-J stent			
Yes	659	5	<0.001
No	145	22	

[a] Rank sum test; [b] Fisher's exact test; others (chi square test)

Discussion

Since the 1980s, ESWL has been established as the preferred method for treating ureteric calculi, due to its

Table 2 Multivariate analysis of the influencing factors on the success rate of ESWL

Variable	B	OR	95% CI		P
			Lower level	Upper level	
Age	0.134	1.143	0.441	2.964	0.783
Sex	0.000	1.000	0.966	1.036	0.994
Stone side	−0.137	0.872	0.356	2.139	0.765
Stone site	0.038	1.039	0.629	1.718	0.881
Stone number	1.554	4.731	1.104	20.279	0.036
Stone size	2.033	7.635	1.386	42.062	0.020
History of urolithiasis	1.220	3.388	1.056	10.877	0.040
Renal colic	−1.078	0.340	0.127	0.912	0.032
Hydronephrosis	0.240	1.272	0.471	3.433	0.635
D-J stent	1.499	4.478	1.220	16.434	0.024
Constant	−9.058				

B regression coefficient, *OR* odds ratio, *CI* confidence interval

Table 3 Detailed information of the classification table used to evaluate the goodness-of-fit of the prediction model

Groups	Result of ESWL = success		Result of ESWL = failure		Total
	Observed	Expected	Observed	Expected	
1	83	82.710	0	0.290	83
2	83	82.644	0	0.356	83
3	84	83.594	0	0.406	84
4	83	82.545	0	0.455	83
5	84	83.493	0	0.507	84
6	83	82.445	0	0.555	83
7	83	83.342	1	0.658	84
8	80	81.452	3	1.548	83
9	79	78.120	4	4.880	83
10	62	63.655	19	17.345	81

Table 4 Evaluation of the prediction model using the data from the current sample

	Predicted results		Rate of accuracy
	Success	Failure	
Actual results			
Success	802	2	99.8
Failure	24	3	11.1
Overall rate of accuracy			96.9

Table 5 Evaluation of the prediction model using the data from another sample

	Predicted results		Rate of accuracy
	Success	Failure	
Actual results			
Success	462	12	97.5
Failure	34	12	26.1
Overall rate of accuracy			91.2

minimally invasive character, no requirement for anesthesia, and low morbidity. It is considered suitable for stones in all locations within the ureter, especially for the proximal stones, as ureteroscopy treatment is technically more difficult in the upper ureter [12]. Although the stone-free rate following ESWL has been reported to be high in follow-up studies, a total of 10–20% of patients were found to fail ESWL treatment. An ideal stone therapy should ensure high effectiveness with minimal disability and low complication rate. However, ESWL may not always meet these criteria [10]. Consequently, it is necessary to further investigate the influencing factors on the clinical outcome of ESWL in order to opt for the most appropriate maneuver.

In the present study, a total of ten factors were studied to determine their relationship to the success rate of ESWL, including age, sex, stone side, stone site, stone number, stone size, history of urolithiasis, renal colic, hydronephrosis, and double-J ureteric stent. Of all the factors studied, five of them (stone number, stone size, history of urolithiasis, renal colic, and double-J ureteric stent) were defined as being significant contributors. Research on the influence of patient age has been rare in previous literature. It has been demonstrated that the clinical outcome of ESWL for upper-third ureteric calculi of the elderly patients was inferior to that of the younger patients [13]. In addition, the mean age of the patients successfully treated with ESWL was significantly lower than that of the failure group, which may be due to the fact that younger patients had better renal excretion and higher contraction strength of the ureteral muscle. However, this finding has been challenged by other researchers, and patient age was not considered as a significant factor for the success rate of ESWL [14]. Our result supported the latter conclusion, as there was no significant difference with regard to patient age between the successful group and the failure group. In addition, patient sex and stone side were not significant factors for the success rate of ESWL.

It has been generally accepted that stone size affects the clinical outcome of ESWL, with patients with larger stones failing the treatment and requiring other intervention. Different success rates of ESWL have been reported for patients with different stone sizes, with the worst outcome being seen in those with the largest stones [15]. Larger stones also required more treatment sessions of ESWL. Our results supported these observations. It is considered that the space between the stone and the ureterovesical junction is decreased in patients with larger stones, and therefore, it would be more difficult for the smashed stones to be separated. Additionally, contact between the urine and the stones is to some extent restrained for larger stones, which makes it hard for the stones to be excreted. Research on the influence of stone site supported the finding that the stone-free rates for the proximal and distal stones are superior to those of the middle stones [16, 17]. In the present study, different stone-free rates of 98.2, 84.5, and 96.7% were observed for the proximal, middle, and distal stones, respectively, confirming the previous reports. The relatively easier locations of the proximal and distal stones were generally considered to be the reason for the superior success rates. However, the multivariate analyses in the present study indicated that stone site was not a significant factor in determining the clinical outcome in comparison with the other contributory factors.

The influence of stone number on the success rate of ESWL has been debated for a long time, with different conclusions being drawn from different investigators [18]. In the present study, we found that stone number was also a significant factor, and a better outcome was obtained for single stones. It was considered that the presence of multiple stones may increase the difficulty of stone excretion, due to changes in the fluidity of urine. Renal colic has been shown to be a positive factor on the success rate of ESWL [19], which was confirmed in the present study. Although the detailed mechanism is not fully understood, it is considered that the occurrence of renal colic is a symptom indicating ureteric calculi does not conglutinate with the ureterovesical junction. In addition, renal colic promotes higher peristalsis frequency and contraction strength of the ureter, facilitating excretion of the stones.

History of urolithiasis has been reported to be a negative factor influencing the success rate of ESWL [13]. It was shown in the present study that the stone-free rate for patients with histories of urolithiasis longer than 2 months was inferior to the other patients. A long history of urolithiasis may result in serious consequences, such as the conglutination of stones with the ureterovesical junction and inflammation/edema of the ureteric mucosa. Consequently, the stones were difficult to be excreted even if ESWL was successful. With regard to hydronephrosis, previous research has indicated that hydronephrosis has a significant influence on the success rate of ESWL for treating distal ureteric calculi, although its influence on the overall stone-free rate is not significant [20]. In the present study, patients with mild and moderate hydronephrosis were accepted for ESWL treatment, whereas transurethral ureteroscopic lithotripsy was performed for the patients with serious hydronephrosis. Our results from the univariate analysis indicated that the success rate of ESWL for patients with no or mild hydronephrosis was better, while the multivariate analysis showed that the success rate of ESWL was not significantly influenced by hydronephrosis. This discrepancy may be due to the interaction between the factor of hydronephrosis and other factors, such as stone size and renal colic; thus, the contribution of the hydronephrosis was somehow weakened. In addition, placement of double-J ureteric stent was shown as a significant contributor to the stone-free rate of ESWL treatment by both the univariate and the multivariate analyses in the present study, which was consistent with the results of the study performed by Wada et al. [21]. Although the use of double-J ureteric stent was criticized by other researchers due to a decreased success rate observed [6], double-J ureteric stent was required in patients for whom the stones caused a severe degree of obstruction.

One of the most important results of the present study was the newly established prediction model, based on logistic regression analysis to estimate the stone-free rate of ESWL. Logistic regression analysis is a method used for predicting the probability of occurrence of an event by fitting the data to a logistic curve. Although the influencing factors have been comprehensively investigated in previous studies, developing a prediction model has rarely been reported. The method for prediction of the stone-free rate of ESWL has been widely investigated. Early attempts were attributed to the studies performed by Chaussy and Elbahnasy et al. in which the stones were examined using KUB and intravenous urography (IVU). Chaussy et al. [22] report that if the transmission density of the stone is larger than that of the vertebra, ureteric calculi are difficult to treat using ESWL. Elbahnasy et al. [23] measured the spatial anatomy of the lower pole seen on preoperative IVU, e.g., the infundibular length and width and the infundibulopelvic angle of the stone-bearing calix and predicted the stone-free rate based on these measurements. Although encouraging findings have been made, it is considered that the use of KUB and IVU is limited, as these methods rely on subjective observations. Recently, non-contrast helical computerized tomography (NCHCT) has been reported to predict the stone-free rate of ESWL. Pareek et al. [24] evaluated 50 patients who underwent ESWL for 5–10 mm upper urinary tract stones. They reported significant differences with regards to the Hounsfield unit (HU) values for the stone-free groups and the residual stone groups, and suggested that HU measurement of urinary calculi on pretreatment NCHCT may predict the stone-free rate. Additionally, Mandhani et al. [25] investigated fragility of urinary calculi by measuring stone mineral content (SMC) with the use of dual X-ray absorptiometry. They report that when SMC is greater than 1.27 g, 95% of the stones would not fragment or need more than 3,000 shock waves. Despite these attempts, more and more studies have suggested that the success rate of ESWL is determined by many factors, which cannot be analyzed using a single subject. The two typical multivariate analyses of the influencing factors on the success rate of ESWL were performed by Abdel-Khalek et al. [26] and Gomha et al. [27]. Abdel-Khalek et al. [26] investigated the relationship between the stone-free rate and patient characteristics (e.g. age, sex, and radiological renal picture) and between the stone-free rate and stone features (e.g. site, side, length, width, nature, opacity, and the presence of ureteral stents). Three factors, including stone site, stone transverse diameter, and the presence of ureteral stents were found to be statistically significant and were further studied using a logistic regression model. A limitation of this study was that the logistic regression model was not evaluated for its efficiency. Gomha et al. [27] carried out a study on the influence of ten factors on the stone-free rate using a logistic regression model and an artificial neural network (ANN). Only two factors, stone site and stent use, were defined as significant. The sensitivity and overall rate of accuracy of the logistic regression model were 100 and 93.2%, respectively, both comparable to the results of the present study (99.8 and 96.9%, respectively). However, a total of five factors were found to significantly contribute to the stone-free rate of ESWL, and this was considered to be caused by the different patients/different exclusion criteria that were accepted into the study. In addition, one limitation involved in the present study was that stone composition was not investigated. Although stone composition was considered as an important factor influencing the success rate of ESWL treatment, the primary aim of the present study was to develop an effective model to predict the clinical outcome of ESWL treatment in the management of ureteric calculi. Because stone composition was generally not available prior to ESWL treatment, it was not involved in the present study. This issue will be investigated in future study.

Conclusions

ESWL can be performed as an effective method for treating ureteric calculi on the condition that patients accept the re-treatment rate and prefer to avoid a surgical procedure. Stone number, stone size, history of urolithiasis, renal colic, and double-J ureteric stent are the significant influencing factors on the success rate of ESWL. The prediction model we have developed based on logistic regression analysis could be employed to provide pre-clinical evaluation of ESWL and to allow physicians and patients to opt for the most appropriate method of choice.

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