Journal of Pediatric Urology (2015) 11, 84.e1—84.e6

A new nomogram for prediction of outcome of pediatric shock-wave lithotripsy

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Keywords
Pediatric; Stone; Shock wave lithotripsy; Nomogram; Success

Received 20 September 2014
Accepted 22 January 2015
Available online 5 March 2015

Summary

Introduction
Despite the fact that shock-wave lithotripsy (SWL) remains a very good treatment option for smaller stones, it is being challenged by endourologic treatment modalities, which offer similar or even higher success rates in a shorter time, with minimal morbidity and invasiveness. The present study aimed to bring a new and practical insight in order to predict the outcomes of pediatric SWL and to provide objective information about pediatric SWL outcomes.

Objective
To design a nomogram for predicting the outcomes of pediatric shock-wave lithotripsy.

Study design
The study was conducted with a retrospective design and included 402 renal units who underwent SWL between January 2009 and August 2013. Patients with known cystine stone disease and cystinuria, with internal or external urinary diversion, were excluded. Analysis was performed on 383 renal units. Postoperative imaging was performed by plain abdominal graphy and ultrasonography with 3-month intervals. Patients who were completely free of stones were considered to be a success and statistical analysis was done regardingly Multivariate analysis was conducted by logistic regression analysis and a nomogram was developed.

Results
The male/female distribution was 216/167, with a mean age of 48 ± 40 months and a mean stone size of 9 ± 3.5 mm. The overall stone-free rate was 70% (270/383) and efficacy quotient was 0.57. Mean follow-up was 11 ± 11 months (3—54 months). The number of shock waves and amplitude of energy were higher in failed cases. Multivariate analysis showed that gender, stone size, number of stones, age, location of the stone, and history of previous intervention were found to be the independent prognostic factors for assessing the stone clearance rates. A nomogram was developed using these parameters. In this nomogram, the points achieved from each parameter are summed and total points correspond to the risk of failure in percent.

Discussion
A previous nomogram study by Onal et al. showed that younger age (<5 years), smaller stone burden (<1 cm), absence of previous stone treatment history, single stone, pelvis or upper ureter location (in girls) were favorable prognostic factors for successful outcome. As being the first pediatric study, it had some shortcomings. The study included 381 patients within a time period of 16 years. The present study included a similar number of cases within a 4-year period, which may reflect more homogeneity of data collection. Another issue is concern about the practical use of that nomogram. It constitutes two pages, which is a limiting factor for daily use. From a statistical point of view, they performed 200 bootstrapings with the aim of internal validation, which is less than the ideal number of 1000 bootstrapings, which was performed in the present nomogram. The presented nomogram is more practical, in that the pre-operative factors can be placed on the nomogram, the points can be added up and the parents can be given the approximate percentage of predicted stone-free rate after a single session.

The expected treatment modality shown to the parents and patients ought to be the least minimally invasive, have the highest success rate, the least complication rate, and show the efficacy in one procedure at a time within the shortest period. However, SWL does not completely meet these criteria. The results gained from the present critical analysis of SWL in children, which was based on a strict definition of success, showed that outcome after a single session is not that good. Therefore, defining the patients who will benefit the most became one of the main issues. A more objective and skeptical look at SWL data enabled a nomogram to be developed that brings a new and practical insight in order to predict the outcomes of pediatric SWL.

Conclusion
In most of the pediatric stone cases, SWL is the first-line treatment option. However, it is wise to define the patients who will benefit the most. Therefore, nomograms can be useful for this purpose. The nomogram in the present study revealed that gender, stone size, number of stones, age, location of the stone, and history of previous intervention were found to be the independent prognostic factors for assessing the stone clearance rates. This nomogram can practically be used to inform the parents, and for proper patient selection for SWL.

http://dx.doi.org/10.1016/j.jpurol.2015.01.004

Introduction

Stone disease in the pediatric population is an important health concern for some geographical areas of world [1] and is showing an increasing incidence [2]. For most of the pediatric stone cases, shock-wave lithotripsy (SWL) constitutes the first line of treatment [3]. Several factors can affect the outcome of the procedure: size, localization, composition and number of stones are well-described factors that affect the outcome of SWL treatment and have been utilized for selecting the patients who would most benefit from SWL treatment. For practical purposes, nomograms have been established in adults [4] and recently, a pediatric nomogram was developed [5]. Over the years, improvements in instruments have placed endurological intervention into a very favorable position, even for very young pediatric cases. Despite the fact that SWL remains a very good treatment option for smaller stones, it is being challenged by endourologic treatment modalities, which offer similar or even higher success rates in a short time, with minimal morbidity and invasiveness. The present study aimed to bring a new and practical insight for predicting the outcomes of pediatric SWL and to provide objective information about pediatric SWL outcomes.

Materials and methods

The present study was conducted with a retrospective design and included 402 renal units who underwent SWL between January 2009 and August 2013. Patients with known cystine stone disease and cystinuria, with internal or external urinary diversion were excluded. Analysis was performed on 383 renal units.

A Siemens Lithostar Modularis (Siemens AG, Muenchen, Germany) machine performed shock-wave lithotripsy, and shock waves were produced electromagnetically. The procedure was performed under sedo-analgesia (propofol plus midazolam). Focusing was performed either by ultrasonography or fluoroscopy. The amplitude of the shock waves was increased gradually. The parents were informed about the procedure itself, the probable efficacy and the possible complications. The children were evaluated 2 weeks later for the status of fragmentation.

Each child had at least one of the imaging modalities pre-operatively. All were evaluated by means of serum chemistry, complete blood count, urinalysis and urinary culture. Routine perioperative antibiotics were not used unless the child had a persistent UTI.

Postoperative imaging was performed by plain abdominal graphy and ultrasonography. Children who were completely free of stones were considered to be stone free. Fragments smaller than 4 mm were accepted as clinically insignificant residual fragments and larger fragments were considered as a failure. However, during statistical analysis, success was defined only as the stone-free state. The time interval between two sessions was at least 2 weeks.

Statistical analysis was conducted by using the Statistical Package for Social Sciences (SPSS) 17.0 for Windows. The Chi-squared test was used for analysis of proportions. The Mann–Whitney U (MWU) test and *t*-test evaluated the medians and means, where appropriate. A *P*-value <0.05 was considered to be statistically significant.

Stone-free status was considered as the primary outcome of the study. Univariate and multiple logistic regression analysis were used to determine the variables that affect the stone-free status. Box-Tidwell transformation was applied to test the linearity assumption between continuous independent variables and logit. The term x*ln(x) was added in the logistic regression model for continuous independent variables. A nomogram was constructed, based on the model results, to obtain the predicted probabilities of being stone free. The bootstrap method with 1000 replicates was used for the internal validity of model. The 'validate' function in the RMS package was used to calculate the bias-corrected c-index that measures the predictive discrimination of the model. The c-index is the probability of concordance between predicted probability and response. Bias-corrected c-index is calculated by using a Somers' Dxy rank correlation such as Dxy = 2(c-0.5). A bootstrapped calibration plot was drawn by the 'calibrate' function in the RMS package. Statistical analyses were performed using the R version 3.0.2 software.

Results

The demographic features and patient characteristics are shown in Table 1. Children underwent a median of one session of SWL and the stone-free rates for each session were as follows: 60% (229/383) for the first, 47% (35/75) for the second and 46% (6/13) for the third session. The overall

Table 1 Patient characteristics.

Parameters	Distribution
Gender: Male/Female (*n*)	216/167
Hydronephrosis grade: none/minimal/ moderate/severe (*n*)	188/104/77/14
Side: Right/left (*n*)	196/187
Mean age ± SD, range (months)	48 ± 40 (5–200)
Mean stone size ± SD, range (mm)	9 ± 3.5 (3–30)
Number of stones: single/multiple (*n*)	346/37
Stone location: upper calyx/middle calyx/lower calyx/renal pelvis/ proximal ureter (*n*)	41/105/83/109/45
Previous history of intervention: yes/no (*n*)	92/291
Anatomic abnormality: yes/no (*n*)	21/362
Metabolic abnormality: none/ hypercalciuria/hyperoxaluria/ hypocitraturia/hypocitraturia + hyperoxaluria/not available (*n*)	59/7/39/36/67/175
Mode of presentation: pain/nausea/ infection/incidental/hematuria/ not available (*n*)	184/23/72/57/ 32/15
Mean number of shock waves ± SD, range (*n*)	1790 ± 320 (1000–2800)
Mean energy ± SD, range (joules)	1.4 ± 0.3 (0.5–2.3)
Follow-up ± SD, range (months)	11 ± 10 (3–54)