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Predictive Factors of Efficacy of Extracorporeal Shock Wave Lithotripsy in the Treatment of Kidney Stones of Size <20 Mm: Prospective Monocentric Study

Ziani I*, Ibrahimi A, Bellouki O, El Bote H, El Sayegh H and Nouini Y

Department of Urological Surgery"A", Ibn Sina University Hospital of Rabat, Morocco,Faculty of Medicine of Rabat, Mohammed V University in Rabat, Morocco

***Corresponding author:** Idriss Ziani, Department of Urological Surgery"A", Ibn Sina University Hospital of Rabat, Morocco,Faculty of Medicine of Rabat, Mohammed V University in Rabat, Morocco, Email: idrisszianI20@gmail.com

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Abstract

Extracorporeal shock wave lithotripsy (ESWL) is one of the most commonly used therapeutic procedures for the treatment of urolithiasis thanks to its noninvasive approach and satisfactory success rates. However, this technique has certain limitations that have led to several debates concerning the redefinition of its indications. The main objective of our work is to determine the ESWL success' predictive factors in order to select the right candidates to this procedure. For this, we did a prospective study carried out in the Urology A department of the Ibn Sina University Hospital in Rabat over a period of 12 months, involving 150 patients suffering from kidney stones of size lesser than 20 mm, without history of treatment with ESWL and for whom this technique was indicated, The statistical study was carried out using the software SPSS 13.00. The univariate analysis of our study defined four statistically significant factors associated with the failure of extracorporeal lithotripsy which were:

- Multiple number of stones (p 0.015);
- BMI> 35 (p 0.009);
- Lower calyx location (p 0.028);
- Density greater than 1000 HU (p 0.04).

A multivariate analysis by logistic regression model using all the significant factors of the univariate study also showed that the same factors would have significant impacts on the outcome of the ESWL at three months. Defining the predictors of success and failure helps to better define the candidates for this technique and to establish a nomogram adapted to each patient.

Keywords: Extracorporeal Shock Wave Lithotripsy; Urolithiasis; Success of Extracorporeal Shock Wave Lithotripsy; Univariate Analysis; Multivariate Analysis

Abbreviations: ESWL: Shock Wave Extracorporeal Lithotripsy; EMW: Electromagnetic Waves; CT: Computed Tomography; BMI: Body Mass Index; PCNL: Percutaneous Nephrolithotomy PCNL; SF: Stone-Free.

Introduction

Background

Shock wave extracorporeal lithotripsy (ESWL) has revolutionized the management of urinary tract stones. Chaussy, who was the first to use this technique, said that renal stones lesser than20 mm were the best indication for the use of ESWL. It is also known, for more than twode Cades, that stones between 20 and 30 mm represent a good indication for this technique [1-3]. The objective of this article is to evaluate the efficacy and safety of ESWL in the management ofurolithiasis, as well as to determine its predictors of success and failure via a prospective study carried out in the Urology A department of the Ibn Sina University Hospital in Rabat, involving patients who are being treated for kidney stones of size <20 mm by ESWL using an electromagnetic lithotripter.

Methods

Study Design

This is a prospective descriptive and analytical monocentric.

Settings

This study was spread over 12 months, from January 2017 to January 2018 with a 12-month follow-up after the LEC sessions, carried out within the urology department A of the CHU Ibn Sina in Rabat.

Study Population

Sample: 150 patients suffering from kidney stones of size less than 20 mm, without history of treatment by ESWL and for whom this technique was indicated.
Sample Size*:* We included all patients who met the inclusion criteria.
Criteria for Inclusion: We included patients with:

- Radiopaque calculi of kidney stones of size less than 20 mm.
- And whose calculi were treated for the first time by the ESWL.

Criteria for non-inclusion*:* We excluded patients with

- Lower urinary tract calculi.
- Stones larger than 20 mm.

Judgment Criteria

The endpoint in our study was obtaining the stone-free, in our study the Stone-Free defined by the complete fragmentation of the calculus or the persistence of residual fragment <5mm, 3 months after treatment with ESWL. On an abdominal scanner without injection.

Proceedings of the Sessions

The ESWL sessions were held at the University Hospital of Rabat which is equipped with a DORNIER-MedTech® electromagnetic lithotripter. Depending on the location of the calculus, two positions were used: the supine position for renal and lumbar ureterstones, and the prone position for distal ureterstones, the lumbar region being placed on the dome of convergence of electromagnetic waves (EMW). The patients were kept in a position where the stone was best targeted by the focal spot.

The emission power of the shock waves has been gradually increased from level 1 to level 4, with a firing frequency of 90 rounds per minute. These parameters (frequency and power) were adjustable on the lithotripter and recorded in the study report.

The ESWL was performed on an outpatient basis, after a premedication with level 1 analgesic and anxiolytics. The number of shocks required to destroy the stone was left to the operator, but not to exceed 3,500 shocks. The duration of the session is, on average, 40minutes. The post-shock wave lithotripsy evaluation is based on a KUB X-ray study 15 days after every session to ensure the fragmentation of the calculus, and to decide whether or not a second or even a third session is necessary.

Data Collection

The data of our study were collected from the patients' medical records, pretherapeutic assessments, the data from KUB X-ray studies and non-contrast abdominal CT which can provide specific patients and stones characteristics. Subsequently, these data were reported on a pre-established data collection sheet.
All of our patients at the time of treatment had:

- Kidney, Ureter and Bladder (KUB) X-ray study,
- Non-contrast abdominal CT to precise the size and density of the calculus, and to rule out the presence of an underlying obstructive uropathy.
- Cyto-bacteriological examinations of urine to eliminate a urinary tract infection.
- Hemostasis assessment depending on the hemorrhagic risk.

Pre-therapy variables, including patient age, BMI, the stones number, size, density and location and the obtention of Stone-Free, are recorded from the sheets dedicated to each patient

Bias

In order to minimize the bias as much as possible, we have selected a population that meets very specific criteria.

Statistical Analysis

Qualitative variables are expressed in number and percentage, and quantitative variables in mean and standard deviation or median and interquartile range depending on the type of distribution. The association between the different variables and the failure of shock wave extracorporeal lithotripsy were assessed using univariate and multivariate statistical analysis using The SPSS® software, to predict treatment outcomes and determine factors for failure and success of ESWL.

Results

Presentation of the Sample

The average age of our patients was 50, 93 ± 17, 16 years with extremes ranging from 28 years to 76 years. A clear male predominance with a male/female sex ratio of 1, 5. 5, 4 % % of our patients had severe obesity defined by a body mass index between 35 and 40.

A total number of 57 medical histories have been reported by our patients, and can be distributed as follows: 40 cases of hypertension, 13 cases of diabetes, 2 cases of pulmonary tuberculosis, 2 cases of Inflammatory bowel diseases (ulcerative colitis), 2 cases presenting a urinary tract malformation (ureteropelvic junction obstruction).

There were 35 cases of patients with urolithiasis history never treated by ESWL: 23 cases were treated by open surgery for renal lithiasis, 8 cases that were treated by percutaneous nephrolithotomy (PCNL) and 4 cases of ureteroscopy treatment Table 1.

Surgical Treatment	Number of Cases	Percentage
Ureteroscopy	4	2%
PCNL	8	4%
Open surgery	23	18%
Nothing	115	75%

Table 1: Distribution of patients according to surgical treatment history in relation to lithiasic pathology.

Clinical Presentation

The circumstances of discovery of urolithiasis are essentially clinical. The main symptom was flank pain (100 cases), other symptoms were reported, like renal colic (33 cases), hematuria (6 cases), voiding disorders (11 cases) and urinary tract infection (4 cases). One hundred twenty patients had unilateral lithiasis (80 %), 70on the right side (60%) and 60 on the left side (40%). Only 30 patients (20 %) had bilateral lithiasis.

The indications of double-J stent placement included the following: hydronephrosis due to obstructive nephrolithiasis and to prevent, or circumvent, a ureteral obstruction. Double-J stent placement was performed before ESWL in 50 (35%) of our 150 patients.

Radiological Presentation

Pyelic renal localization was the most frequent found in 50% of our patients, followed by the upper calyx 20%, 15% of the cases in the middle calyx, 15% of the cases in the lower calyx. Moreover, ureteral location was present in 28% of the cases. The lumbar ureteral location was predominant with 16% of ureteral stones, against 10% in the pelvic ureter and 2% in the iliac ureter.

In our series 86% of our patients had a single calculus, compared to 14% patients with multiple lithiasis. The average size of the lithiasis at the time of treatment was 13mm with extreme values ranging from 8 to 20mm.In our series, 76% of the patients had stones between 10 and 20 mm, 33% of the cases were less than 10 mm in size.

The average density of stones treated by ESWL was 1027 HU with extremes ranging from 540 HU to 1550 HU. There is a slight predominance of density calculations above 1000 UH with a percentage of 52% Table 2.

Calculs Size in Millimeter	Number of Cases	Percentage
< 10mm	50	33%
10-20mm	100	67%
TOTAL	150	100%
Average size		13mm

Table 2: Distribution of lithiasis by size.

Evaluation of the Results of the ESWL

The evaluation of the results of the ESWL consists in carrying out a radiological control (KUB X-ray) 15 days after each session and one to 3 months of the last session. Patients are considered to be cured or Stone-Free (SF) when the stone is completely fragmented and eliminated after one, two or three ESWL sessions.

Failure is defined by the complete absence of modification of the calculation or the persistence of a residual fragment> 5 mm. After the third session, a minimum period of 3 months was respected before concluding that the treatment by ESWL has failed and deciding on another treatment. In our series, the average number of shocks provided per session was 3000 strokes on average, with a level of shock wave emission power progressively increasing from 1 to 4. The average duration was 34 minutes.

Among the 150 patients treated with ESWL for 1 to 3 sessions, the success rate was 80.5% (absence of residual fragments or a residual fragment <5 mm) against 19.5 failures. The overall success rate was 90% for pyelic stones, 89% for the upper chalice, 72% for the middle chalice, 25% for the lower chalice. The stones with a density less than 1000UH achieved a success rate of 86% while it was 45% for stones with a density greater than 1000UH. The success rate was 70% for single lithiasis, while it was 31% for multiple lithiasis.

Study of the Impact of the Variables Included

The univariate analysis defined four statistically significant factors associated with the failure of CEL which were: Table 3.

- Multiple number of stones (p 0.015);
- BMI> 35 (p 0.009);
- Lower calyx location (p 0.028);
- Density greater than 1000 HU (p 0.04).

On the other hand, the prior installation of a ureteral stent would probably be a factor favoring the elimination of kidney stones (odds ratio 0.56).

	Odds Ratio	CI 95%	p-value
AGE	1,00	0,11-0,14	0,73
BMI>35	3,35	1,80-5,74	0.009
Stone's size >15mm	1,15	0,34-1,23	0.6
Stone's number	2,33	1,44-5,89	0,015
Density >1000UH	1,02	1,31-2,01	0,04
Location			
-Superiorcalyx	4,84	-	0,99
-Superiorcalyx	3,00	1,93-2,39	0,23
-inferior calyx	2,20	1,89-4,82	0,028
-pyelic stones	3,23	0,86-1,85	0,174
Endo ureteral prosthesis	0,56	0,34-0,87	0,16

Table 3: Univariate analysis to predict Stone-free 3 months after ESWL.

The multivariate analysis was conducted using a logistic regression model in which all the significant factors of the univariate study were taken in consideration. This analysis has shown that these same factors would also have significant impacts on the result of the ESWL at three months, these factors are: Table 4

- Stones' number (p 0.009);
- BMI > 35;
- Lower calyx location (p 0.063);
- Density greater than 1000 HU (p 0.004).

ESWL application has been intuitively connected to complications. These are related mostly to residual stone fragments, infections and effects on tissues. In our study, 65 patients presented moderate flank pain, 44 patients had hematuria, 15 patients had a urinary tract infection and 8 patients had a renal colic attack. None of these patients required hospitalization.

	Odds Ratio	CI 95%	p-value
Stone'snumber	4,85	1,52-6,81	0,009
BMI>35	3,24	2,86-4,2	0,04
Location			
-Superiorcalyx	2,59	-	0,99
-Superiorcalyx	0,96	0,49-0,98	0,49
-inferior calyx	3,80	1,89-4,82	0,03
-pyelic stones	0,81	0,97-1,87	0,17
Density >1000UH	5,96	1,02-8,26	0,004

Table 4: Multivariate analysis to predict Stone-free 3 months after ESWL.

Discussion

In the scientific literature, we find that in most clinical studies, the success of an ESWL is defined by obtaining stone-free (SF), regardless of the stone's size. In daily practice, residual fragments of less than 5 mm are considered to be a successful result, as long as the patient is asymptomatic. Any other result is considered as a failure of ESWL. These small fragments do not require additional treatment, but expose to an increased risk of recurrence.

In theory, non-contrast abdominal CT is ideal to define success after ESWL. In daily practice, a simple KUB X-ray study is sufficient for follow-up. A minimum period is necessary before definitively concluding that ESWL has failed and deciding on another treatment, three months for the kidney and one month for the ureter [4,5]. In our study, we find a success rate of 80.5% at 3 months, after 1 to 3 ESWL sessions, without taking into account the location and size of the stones, nor the other parameters. This rate is lower than

Traxer and Coll's, having a success rate of 90% after 1 to 4 sessions [6].

The type of lithotripter and the lithotripsy technique used are important factors. In order to have good fragmentation, the lithotripter must allow real-time location, have a wide focal spot and adjustable energy parameters [7,8]. The results of ESWL also depend on the operator's experience, power, frequency, number of shock waves and number of sessions [6]. During fragmentation, the wave energy (in mJ) used is more important than the pressure, which generates less fragmentation effect [9].

Currently, it is better to use lithotripters with a large focal spot. The focal spot should, if possible, be wider than the stone to obtain good fragmentation, due to the movements of the stone during breathing and to offer a better distribution of pressure (squeezing) on the surface of the stone [10]. Many authors have shown, quite consensually, that the results of extracorporeal lithotripsy at three months depend on the initial location of the lithiasis within the pyelo-caliceal cavities [11]. For pyelic stones, the success rate was 90%, 89% for the upper calyx and 72% for the middle calyx calculations. This rate was much lower for calyx calculations below 22%.

These poor results for stones from the lower calyx can be explained by the declining position of the calyx, by the particular anatomical arrangement of the lower pole of the kidney or by a long and / or narrow caliceal rod [12]. However, the negative influence of the location of the calculus in the lower calyx is discussed, it was not proven in the Danuser study of 96 patients treated with ESWL for a single calyx calculus. The quality of the disintegration of the calculus would depend more on the characteristics of the calculus itself than on the anatomical characteristics of the lower calyx [12].

Size is an important predictor of failure. A stone larger than 2 cm or more than 400mm^2 would be a predictor of failure, especially if it is associated with other failure factors, such as lower calyx location or renal malformation. However, EAU guidelines say that the treatment by ESWL for large stones may be indicated for renal pelvic, soft, single stones after double-J stent placement [13].

The number of lithiasis also affects the results of extracorporeal lithotripsy. If the overall success rate after extracorporeal lithotripsy for single or ureteral renal lithiasis reaches 70%, this rate decreases to 31% after treatment of 2 or more lithiasis. This is in line with the rates observed in the literature [14], since the rate of SF was 64% for single lithiasis against 43% of patients with multiple lithiasis.

The stone's density would also be a good predictor. The fragmentation threshold would be 750 or 1000 HU [15]. The 1000 HU threshold seems to be the most commonly accepted. In our series, the SF rate was 86% for stones below 1000 HU, and 45% for stones above 1000 HU. In Perks's study, the 3-month SF rate was 46% for stones below 1000 HU and 17% for stones above 1000 HU. In addition, hard stones are fragmented, after ESWL, into large fragments [15].

In a prospective study on the identification, using a non-contrast abdominal CT, of the predictors of fragmentation of the stones, the failure factors of an electromagnetic ESWL were a high BMI and a stone's density above 1000 HU. The only predictor of residual fragments was a density above 1000 HU [15]. In our series, the FS rate was 86% for density calculations below 1000 HU and 45% for density calculations above 1000 HU.

The efficacy of ESWL is also correlated with the composition of stones. Graff, et al. Obtained respective residual fragments levels of 81 and 83 for uric acid or calcium oxalate dehydrate stones; the result is not the same for cystine, brushite, or calcium oxalate monohydrate stones. Several authors do not recommend the ESWL in first intention for this type of stones if their size exceeds 10mm.

This parameter was not taken into account in our study. The factors associated with good ESWL results have been discussed in the literature for the past two decades. In his multivariate analysis, based on a logistic regression model, Abdel-Khalek, et al. Have defined the size of the calculus and the presence of a ureteral stent as factors having a significant impact on the treatment outcome [16].

Shiroyanagi pointed out that size and location, independently of the other elements, were success factors for fragmentation of lithiasis in his multivariate analysis [17]. Size is an important predictor of failure. A stone larger than 2 cm or more than 400 mm^2 would be a predictor of failure, especially if it is associated with other failure factors, such as lower calyx location or renal malformation [18].

Impaired kidney function has been cited as a factor in failure [19]. Kanao, et al. Developed a nomogram from a multivariate analysis with logistic regression in 435 patients. The lithotripter used was a DORNIER D®. The predictors of success were the size, the location and the number of stones. With this nomogram, the probability of Stone-Free at three months was 94% for single stones measuring less than 5mm and located at the proximal ureter.

This probability at three months was 10% for one of the multiple stones measuring more than 2 cm [20].

In our study, the predictors of failure were:

- Multiple number of stones;
- Severe obesity;
- Lower calyx and density greater than 1000 HU

Other factors such as the composition of the stones, studied via crystalluria analysis, must be incriminated in studies in order to specify their predictive values on the efficacy of treatment by ESWL.

For follow-up, the risk of renal colic and urinary infection after ESWL is 20—25% and 5%, respectively [3].

In our series, 116 patients presented pain of moderate intensity, 52 patients had hematuria in the process of resolution and 8 patients had a crisis of renal colic. After an ESWL session, there may be bruises or skin hematomas. It is not deleterious for the inner ear [15]. Iliac artery stenosis has been reported [15]. The use of ESWL on distal ureter stones cans cause density and motility modification of sperm, but reversibly in three months [17]. Long-term effects on sperm quality are not known [20]. The risk of steinstrasseis 2—8%. It takes place in 80% in the distal ureter. The risk increases with size (<1 cm: 4%; 1—2 cm: 16 %;> 2 cm: 24%), location (calyces :< 10%; renal pelvis: 19%) and density of the calculus (650 HU). An asymptomatic and uncomplicated steinstrasse must be monitored every two to four weeks, otherwise an ESWL session can be performed before indicating ureteroscopy [20].

Kidney damage from ESWL is mainly due to the pressure and energy density created by the cavitation of the shock wave. High pressures induce lesions of vasoconstriction, vascular rupture and ischemia [19]. In order to limit these lesions, it is recommended to start at a low power and increase it gradually and to use low frequencies. Generators with wide focal spots should be preferred with a low energy density, and the use of maximum generator power levels should be avoided [18].

The number of shock waves per session should be limited to 3000 [18]. The minimum delay between two ESWL sessions is at least 15 days, with a recommended delay of one month, especially for electromagnetic and electrohydraulic shock waves [3]. In children, the number of shock waves must be limited. However, the impact of ESWL on renal function could be due to the intermittent obstruction created by the migration of fragments [20].

In a cohort study, including patients with urinary tract lithiasis who have been treated or not by ESWL from 1985 to 2004, it was demonstrated, at 19 years, an increased risk of hypertension and diabetes mellitus in patients who have had an ESWL session [30]. The ESWL was performed for kidney or the proximal ureter stones. The risk factor for hypertension was bilateral lithotripsy, and, for diabetes, it was the number of sessions and the intensity of the ESWL [14]. Our Study has as strong point, the prospective character; we only included patients with a calculus <20 mm, therefore the good candidates for the ESWL, we eliminated any selection bias from our studies.

Limitations of the Study

Despite the positive points raised by our cohort, it has certain limitations, in particular the small number of patients, as well as the absence of the study of preoperative crystalluria in order to include the compositions of the stones in the variables studied.

Conclusion

ESWL is an effective treatment in the management of lithiasis of the upper urinary tract. This was demonstrated by the results obtained in our prospective study in the Urology A department at the Ibn Sina University Hospital in Rabat.

Despite the relative simplicity of the technique and its low morbidity, the indication must be carefully considered, in view of the complications it can cause.
In our study, the predictors of failure were;

- Multiple numbers of stones;
- Body mass index> 35;
- Lower calyx and Density greater than 1000 HU;

In addition, through our study, we can conclude that the results can be improved by better patient selection, the use of ultrasound tracking, without forgetting to carry out a metabolic exploration which will allow us to complete urological treatment and therefore reduce the risk of recurrence. Other important factors, such as knowing the composition of the stones before treatment by performing crystalluria analysis, which can refine the choice of technique. These factors must be studied in order to specify their predictive values on the efficacy of extracorporeal shock wave lithotripsy in the treatment of upper urinary tract stones.

Competing Interests

The authors declare that they have no conflit of interest.

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