ORIGINAL ARTICLE

Single-session extracorporeal shock wave lithotripsy for urinary calculi: Factors predicting success after three weeks of follow-up


Servicio de Urología, Hospital Militar de Santiago, Chile
Facultad de Medicina, Universidad de los Andes, Chile
Servicio de Imágenes, Hospital Militar de Santiago, Chile

Received 3 March 2011; accepted 27 April 2011
Available online 13 January 2012

KEYWORDS
Urolithiasis; Lithotripsy; Multivariate analysis

Abstract

Introduction: The aim of this study was to identify predictive factors of success following a single-session of shock wave lithotripsy (SWL) at 3 weeks of follow-up in our center.

Material and methods: The medical records of 116 patients with solitary urinary calculi who underwent single-session SWL in our department between October 2007 and August 2009 were reviewed. All preoperative unenhanced computed axial tomographies were reviewed by two radiologists blinded to clinical outcome. Success was defined as complete clearance or the persistence of fragments ≤2 mm on a plain film at 3 weeks of follow-up. The impact of clinical and radiological factors on success was assessed by univariate and multivariate analyses.

Results: The single-session SWL success rate at 3 weeks was 49.1%. Stone size <8 mm, stone area <30 mm², stone location (mid- and distal ureter), stone density <1000 HU and intraoperative fragmentation showed a significant association with SWL success in the univariate analysis (p < 0.05). Stone area (OR 2.9), ureteral stone location (OR 3.4) and intraoperative fragmentation (OR 4.2) were the only predictors of success in the multivariate analysis.

Conclusions: Stone area and ureteral stone location provide important information when deciding about the indication of a SWL in a patient with stone disease. However, successful resolution of only half of the cases after a single session at 3 weeks in our series undermines the relevance of informing patients about the potential need for additional treatment.

© 2011 AEU. Published by Elsevier España, S.L. All rights reserved.

Please cite this article as: Vivaldi B, et al. Factores predictivos de éxito tras una sesión única de litotricia extracorpórea de cálculos urinarios a las tres semanas de seguimiento. Actas Urol Esp. 2011;35:529–33.

* Corresponding author.
E-mail address: ferrancibia@yahoo.com (M.I. Fernández).

2173-5786/$ - see front matter © 2011 AEU. Published by Elsevier España, S.L. All rights reserved.
Factores predictivos de éxito tras una sesión única de litotricia extracorpórea de cálculos urinarios a las tres semanas de seguimiento

Resumen
Objetivo: Identificar factores predictivos de éxito después de una sesión única de litotricia extracorpórea por ondas de choque (LEOC) a las tres semanas de seguimiento.

Material y métodos: Se revisaron los registros clínicos de 116 pacientes con cálculos urinarios únicos sometidos a LEOC entre octubre 2007 y agosto 2009. Las tomografías axiales computarizadas preoperatorias de todos los pacientes fueron revisadas por dos radiólogos en desconocimiento del desenlace clínico. El éxito fue definido como la desaparición completa del cálculo o la persistencia de fragmentos ≤ 2 mm en la radiografía simple realizada durante las tres primeras semanas de seguimiento. El impacto de factores clínicos y radiológicos fue evaluado utilizando regresión logística.

Resultados: La tasa de éxito de LEOC a las tres semanas de seguimiento fue del 49,1%. Tamaño < 8 mm, área del cálculo < 30 mm², localización en el uréter distal, densidad < 1.000 UH y fragmentación intraoperatoria demostraron una significativa asociación con éxito en el análisis univariado (p < 0,05). Área del cálculo < 30 mm² (OR: 2,9), localización en uréter distal (OR: 3,4) y fragmentación intraoperatoria (OR: 4,2) fueron factores predictivos de éxito en el análisis multivariado (p < 0,05).

Conclusiones: El área del cálculo y la localización en el uréter distal son útiles en el momento de decidir acerca de la realización de una LEOC. Sin embargo, la resolución exitosa de solamente la mitad de los casos bajo los criterios evaluados recalca la relevancia de informar al paciente de la eventual necesidad de tratamientos adicionales después de una sesión única de LEOC.

© 2011 AEU. Publicado por Elsevier España, S.L. Todos los derechos reservados.

Introduction

Extracorporeal shock wave lithotripsy (ESWL) continues to be one of the most accepted and used therapies for the treatment of urinary lithiasis.\(^1\) Computed axial tomography (CT) without contrast is the method of choice for the evaluation and selection of the patients who will eventually be subjected to this procedure. The decision will be determined mainly by the size and location of the stone.\(^2,3\) Numerous studies have described predictive factors of preoperative success for ESWL, mainly based on the findings of the CT without contrast.\(^4\) The distance skin-calculus (DSC), the density of the calculus (determined in the CT without contrast), and the body mass index (BMI) have been described as success factors.\(^5,6\) However, as a result of a great heterogeneity in the definitions of outcome, different success rates (46–91%) have been published depending on the number of sessions and time of follow-up.\(^6,7\) Moreover, and most importantly, there is no consensus in the definition of success. Some authors have defined the success of ESWL as the absence of stones or insignificant residual fragments on plain X-ray at 6 weeks after a single session.\(^8,9\) Others have defined it as the absence of stones or fragments under 4 mm after the third month from the last treatment, with a maximum of three sessions.\(^4\) The aim of this study was to identify clinical and radiological predictive factors of success after a single session of ESWL for the three weeks of follow-up.

Material and methods

We conducted a retrospective review of records of patients who underwent ESWL between October 2007 and August 2009 in our center. We identified patients with solitary radiopaque urolithiasis, confirmed by CT without contrast, and controlled with simple vesical and renal X-ray during the first three weeks after the intervention. In this period, 207 ESWL were performed at our center, considering 116 patients with complete data for the analysis. The reason for this loss of patients is that our center works as a simple procedure operator on a great number of occasions, treating patients, the beneficiary of welfare schemes of the armed forces living in other regions of the country, therefore, performing follow-ups in those places. On the other hand, a significant number of procedures are performed to patients who are not beneficiaries and who continue their check-ups in other health centers. It should be noted that the Military Hospital of Santiago is one of the leading centers for ESWL in Chile since it was the first center to have this technology in 1990.

During the ESWL session, patients received conscious sedation with intravenous midazolam and fentanyl. The calculus was found using biplanar fluoroscopy. We used a 60 Hz frequency and the intensity was increased according to the tolerance of the patient. Until April 2009, we used a conventional electromagnetic lithotripter (Modulith\(^6\) SLK; Storz Medical); and since then, the equipment used was a dual focus electromagnetic lithotripter (Modulith\(^6\) SLX-F2; Storz Medical).

The demographic and clinical characteristics were obtained from clinical records. All diagnostic (CT) and control imaging (plain X-rays) were reassessed by two radiologists who were blinded to the clinical outcome.

The CTs without contrast were performed on two helical multi-slice CT scanners: 64-channel Somatom Sensation and 16-channel Somatom Emotion (Siemens). With the technique of 120 kV and 160 mA, 5-mm cuts, 0.6-mm cutting collimation, 0.75-mm reconstruction, 1.4-mm pitch, and 5.0-s rotation time. In order to determine the density in
Hounsfield units (HU) of the calculi, we selected the largest cross-sectional area of the calculus in the axial cuts; then, with the oval tool ROI (Region of Interest), a representative central area was chosen and the average attenuation was measured avoiding the periphery of the calculus and surrounding tissue. The DSC was determined as previously described: it was measured from the center of the calculus to the skin by drawing three lines: one perpendicular, one horizontal, and one at 45° between the other two. We considered the average of these measurements. So as to determine the area of the calculus, it was first observed in the axial, coronal and sagittal reconstruction planes. We immediately selected the plane in which the largest diameter was found, and the boundary of the calculus was delimited with the oval ROI tool, obtaining the estimated area. Mild hydronephrosis was defined as that in which secondary calyces were evidenced; that in which there was dilation of these greater than 3 mm and lower than 1.5 cm was defined as moderate. Finally, severe hydronephrosis was defined as that in which secondary calyces had over 1.5 cm dilation.

Success was defined as the complete disappearance of the calculus or the persistence of fragments ≤2 mm in simple renal and vesical X-ray performed until day 21 after a single session of ESWL. The persistence of stones >2 mm in this control was considered therapeutic failure. Also, the performance of any auxiliary procedure during this period (installation of ureteral catheter, performance of a second ESWL, or performance of endoscopic or percutaneous surgery) was also considered a failure.

Patient groups were compared with the impact of clinical factors (preoperative and intraoperative) and radiological ones (Student's 't'-test for continuous variables, and Chi-square test for categorical variables). Procedural success was evaluated using univariate and multivariate logistic regression models, estimating the odds ratio for those factors that were significant. Statistical analysis was performed using the software STATA 10.1 (StataCorp, College Station, TX, USA).

**Results**

The clinical, radiological, and intraoperative characteristics according to the outcome are detailed in Table 1. Of the 116 patients, 79 were men and 37 women. The average age was 49.8 (SD: 12.6 years) and BMI 27.3 (SD: 4.4 kg/m²), no significant differences being observed according to the outcome.
The length and area of the calculi were significantly lower in patients with a successful procedure. On the other hand, we observed a significantly lower proportion of patients with estimates of density >1000 HU in the group with positive results. There were no significant differences in the DSC.

The technical conditions under which ESWL was performed were not different according to location in the clinical outcome, using a frequency of 60 beats per minute in 90% of the cases, reaching a maximum intensity equal to or greater than 8 in 51.4% of the procedures and with a 3000 average firing (IQR: 1200–4000). No statistically significant differences were observed according to the lithotripter used.

The overall success rate of ESWL for the three weeks of follow-up was 49.1%, the results being summarized by location in Table 2. Out of 50.9% of failures, 25 cases (42.3%) corresponded to the persistence of the calculus on plain X-ray, 19 (32.2%) to the performance of a second ESWL, 8 (13.6%) required endoscopic resolution, 6 (10.2%) required the installation of a ureteral catheter, and 1 patient (1.7%) underwent open surgery.

The variables that showed significant association with success in the univariate analysis were: size <8 mm, area of the calculus <30 mm², location in the distal ureter, density <1000 HU and intraoperative fragmentation (p < 0.05). In the multivariate analysis, the area of the calculus <30 mm² (OR 2.9), location in the distal ureter (OR 3.4) and intraoperative fragmentation (OR 4.2) were predictive factors of success (p < 0.05; Table 3).

### Discussion

The CT without contrast is considered the ‘gold standard’ for the diagnosis of urolithiasis due to its high sensitivity and specificity (95 and 98%, respectively). It also gives precise information on the number, size, and location of the urinary calculi. Numerous studies have investigated the impact of the characteristics of the calculus detected by CT without contrast in the success of the ESWL. In our work, the overall success of a single session of ESWL at three weeks of follow-up was 49.1%. The only independent predictive factors of success were the location of the stone in the distal ureter and a calculus area <30 mm². Apart from these preoperative factors, we also identified intraoperative fragmentation as an independent predictive factor.

The density of the calculus and the DSC have shown a significant predictive power of success for ureteral and renal stones in previous studies. While we observed a significantly lower proportion of patients with stones (no estimates) of density <1000 UH in the group with favorable results, this factor was not significant in the multivariate analysis. On the other hand, no significant differences with respect to the DSC were observed, and beyond that, neither regarding the BMI of the patients. This may be due to the low number of patients and the variable nature of the calculi treated, considering that some of the studies describing the DSC as a predictive element of success only included lower renal pole calculi, which have different depuration features.

The length and area of the calculus were significantly lower in patients with a successful procedure (11.5 ± 4.8 mm vs. 8.3 ± 3.2 mm and 36 mm² vs. 25 mm², respectively), which agrees with what was described by previous studies. An important issue to discuss is the heterogeneous definition of success of the ESWL used in the different works published in the literature. This differs significantly according to the follow-up, the number of sessions and the size of the residual fragments. On the other hand, a minimal number of studies incorporates the CT without contrast as a control method, despite its known best performance in the evaluation of urolithiasis, keeping monitoring with plain X-ray in the great majority. El-Nahas et al. defined success as the complete absence of stones or the presence of residual fragments <4 mm after three months follow-up after the last session of ESWL, including a maximum of three sessions. In contrast, Wiesenthal et al. defined success as the complete absence of stones or the presence of residual fragments ≤4 mm at three months, but this time after a single session. Finally, Pareek et al. defined it as the absence or presence of stone fragments ≤2 mm at 6 weeks of follow-up. There is no discussion in the success of the absence of calculi, however, we believe that the acceptable size to classify a fragment as clinically insignificant should be 2 mm or less. There is evidence that 4-mm renal residual fragments are associated with acute pain and/or infection up to 40%, requiring surgery in up to 57% of cases. On the other hand, it seems inappropriate to propose a solution period longer than 4 weeks, with the resulting uncertainty for the patient regarding their evolution during this period. Consequently, we define more rigorous criteria than those usually postulated in the literature. Our low overall success rate of 49.1% can be explained by this, an improvement of this being expected at a longer follow-up, according to the studies mentioned above.

A limitation of our criterion of success is, incidentally, the use of plain X-ray as a control method, which could overestimate the success rate of the procedure; however, this is more suited to our national reality in response to its lower cost. The evaluation of results after only one session, unlike numerous previous reports, which include up to three sessions, responds to the need to match criteria in response to the increasing availability and improvement of other surgical techniques for urolithiasis (endoscopic and percutaneous surgery). These methodologies have proved highly

### Table 2

Success rate according to location.

<table>
<thead>
<tr>
<th>Location</th>
<th>Success rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal</td>
<td>32.4%</td>
</tr>
<tr>
<td>Proximal</td>
<td>41.2%</td>
</tr>
<tr>
<td>Medium</td>
<td>44.4%</td>
</tr>
<tr>
<td>Distal</td>
<td>75.0%</td>
</tr>
<tr>
<td>Overall</td>
<td>49.1%</td>
</tr>
</tbody>
</table>

### Table 3

Multivariate logistic regression.

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (CI 95%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area &lt; 30 mm²</td>
<td>2.9 (1.1–7.9)</td>
<td>0.042</td>
</tr>
<tr>
<td>Intraoperative fragmentation</td>
<td>4.2 (1.4–12.6)</td>
<td>0.011</td>
</tr>
<tr>
<td>Location: distal ureter</td>
<td>3.4 (1.2–9.9)</td>
<td>0.023</td>
</tr>
</tbody>
</table>
effective, becoming real alternatives to ESWL. Accordingly, it is necessary to handle success rates that can be compared with these procedures, which are characterized by a lower reintervention rate and a high resolutive capacity.\textsuperscript{2,21} However, the lack of invasiveness, its ambulatory character, and being able to do without anesthetic support are still significant advantages of the ESWL. In addition, endoscopic procedures often require hospitalization, the use of ureteral catheters (which must then be removed), and they have higher postoperative complication rates.\textsuperscript{2,21} Finally, they require expensive technology that is not available in many centers of our country. The reasons mentioned probably influence in relation to the prevalence of ESWL in our environment when deciding on therapy.

A relevant point of our study is the type of lithotripter, which in this case changed after habilitating the new institutional building in April 2009. The first team (Modulith\textsuperscript{®} SLK; Storz Medical) was a mobile unit with an adapted X-ray equipment, which did not meet criteria for optimum quality. The new lithotripter (Modulith\textsuperscript{®} SLX-F2; Storz Medical) is a fixed unit with integral X-ray equipment, resulting in better image quality. Despite this being a subjective impression, better results were obtained actually with the new unit; however, this difference was not statistically significant and, therefore, it was not a predictive factor of success in multivariate analysis.

Our study is limited by being retrospective with a limited number of patients with renal and ureteral stones. The prospective registry of new cases will make it possible to update our report in the future, increasing the statistical power of the analysis.

According to our results, the area of the calculus and the location in the distal ureter are useful when deciding on the performance of ESWL in a patient with urolithiasis. However, these factors must be considered along with other preoperative variables of the calculus to determine the best therapeutic option. The successful solution of only about half of the cases under the strict criteria evaluated stresses the importance of informing the patient of the possible need for additional treatment after a single session of ESWL. A properly informed patient will play a relevant role when choosing treatment options, knowing the advantages and disadvantages of each of them.

Conflict of interest

The authors have no conflict of interest to declare.

References