Assessment of Extracorporeal Shock Wave Lithotripsy (ESWL) Therapeutic Efficiency in Urolithiasis

P. TOMESCU, A. PĂNUŞ, G. MITROI, O. DRĂGOESCU, L. STOICA, S. DENA, M. ENACHE

Department of Urology, University of Medicine and Pharmacy, Craiova; County Emergency University Hospital, Craiova

ABSTRACT Extracorporeal shock wave lithotripsy (ESWL) revolutionized the treatment of urolithiasis and gradually became the favorite treatment option so that today it is considered to be the first line of treatment for more than 75% of the patients with urolithiasis. The purpose of this study was the assessment of the therapeutic efficiency, complications and limitations of ESWL in urolithiasis in the initial experience using a third generation electromagnetic lithotripter. Between 2007 and 2008 we performed ESWL for 167 patients with urolithiasis. We recorded 92 patients with single stone (55.1%) and 72 with multiple lithiasis (44.9%). Stone size varied between 7 and 24 mm with an average of 12.3±7.1 mm. Radioopaque stones were found in 104 patients (62.3%) while radiolucent stones in 63 only (37.6%). Complete stone disintegration and clearance was achieved in most cases (86.2%). Complications were mostly minor and rare (transitory haematuria, renal colic). Severe complications (renal hematoma, steinstrasse) were diagnosed for a limited number of patients (3.6%) and their management was mostly nonsurgical or minimally invasive (retrograde ureteroscopy). ESWL is therefore the first line of treatment for uroliathiasis with stone size smaller than 2.5 cm. It has an efficiency rate above 85%, low procedure time, high safety and good tolerability (new generation lithotripters do not require anesthetia) and minimal complications.

KEY WORDS Urolithiasis, ESWL

Introduction

Extracorporeal shock wave lithotripsy was first used as routine therapy for urinary lithiasis in 1980 and shortly became the main therapeutic option for kidney stones with no spontaneous passage (before introduction of this method, open surgery was the main alternative). ESWL revolutionized the treatment of urolithiasis and became the preferred option for its treatment. Actually, it is considered first line of treatment for urinary stoned below 2.5 cm [1,2,3].

ESWL treatment of urolithiasis started on February 7 1980 in Munich using a Dornier HM-1 lithotripter (the device was designed by the aero-spatial company Dornier and was initially intended for testing supersonic planes components) [2,3,4]. In theory, extracorporeal lithotripsy is based on the fragmentation of urinary stones into smaller fragments (that can pass spontaneously through the urether) by shockwaves generated outside the body and focially transmitted to the stone. Fragmentation is achieved by direct shearing force, erosion or cavitation [1,2,3,5]. Shockwaves pass through the tissues with virtually no loss of strength, but at the liquid-stone interface they induce a powerful energy discharge due to the high variation of density and small impact surface. Lithotripters have 4 basic components: shockwave generation system, focalization system, coupling mechanism and stone localization system. The shockwaves can be generated in three different ways: electro-hydraulic, spark-gap or electromagnetic. Stone localization can be done by ultrasound and X-ray fluoroscopy. Fluoroscopy has the benefit of identifying both renal and ureteral stones and the use of contrast dyes for a better anatomical delimitation of the urinary tract. Ultrasound identifies both radio-opaque and radiolucent stones but in most cases cannot be used for ureteral calculi [1,2,6]. From the first generation of lithotripters (Dornier HM1 and HM3), they became smaller, cheaper and more versatile. Newer lithotripters have a double guiding system (ultrasound and X-ray) allowing combination of the two methods [1,7].

Third generation electromagnetic lithotripters provide a wide range of improvements such as high shockwave accuracy that in turn allows the
procedure to be performed with little or no analgesia as well as electromagnetic shockwave stability (due to the cylindrical source), wide wave energy range and the possibility of continuous therapy supervision and energy adjustment.

**Goals**

The study aims at evaluating the efficiency, complications and limitations of extracorporeal shock wave lithotripsy in urolithiasis in the initial experience of the Craiova Urology Department with a third generation Modulith SLK lithotripter.

**Method**

Between 2007 and 2008, 167 patients diagnosed with urinary lithiasis in our department underwent ESWL treatment.

Diagnosis work-up included physical examination, lab tests (including CBC, coagulation screening, urinalysis and urine culture), abdominal ultrasound, KUB, intravenous pyelogram and abdominal CT scan or retrograde pyelography for selected patients.

Lithotripsy indications were determined using the 2007 European Association of Urology Guidelines (Table 1).

**Table 1. Indications and contraindications of ESWL**

| ESWL Indications                                      | ESWL Contraindications               |
|-------------------------------------------------------|--------------------------------------|
| Kidney stones larger than 7 mm in Ø with functional kidney and unobstructed urine passage | Coagulation disorders                |
| Pelvic, upper or mid calyx stones smaller than 25 mm in Ø | Gravity                              |
| Mid calyx stones smaller than 15 mm in Ø              | Aortic and/or renal artery aneurism   |
| Ureteral stones at the vesicoureteric junction (using the vesical "window") | Abnormal heart rhythm               |
| *No procedures were performed on ureteral stones as the lithotripter is not equipped with a fluoroscopic C arm.* | Skeletal malformations               |

All procedures were performed using the ultrasound guided third generation electromagnetic lithotripter STORZ Modulith SLK.

**Results**

The patient sample included 88 (52.7%) male and 79 female patients (47.3%). Average age was 46 years with the limits between 15 and 74.

Solitary stones were found in 92 cases (55.1%) while 75 patients had multiple lithiasis (47.3%). Right kidney was involved in 87 patients (52.1%), left kidney in 73 (43.7%) and 7 patients had stones at the vesicoureteric junction (4.2%). From the total of 160 patients with kidney stones, 36 (22.5%) had bilateral lithiasis (Fig. 1).

Solitary stone location within the kidney was (Table 2): pelvic for 38 patients (41.3%), ureteropelvic junction (UPJ) for 21 patients (22.8%) and calyx for the other 33 (35.9%). Multiple stones location was: pelvis and calyx for 44 patients (54.6%), multiple calyces for 26 patients (34.6%), UPJ and calyx 7 patients (9.3%) and UPJ for 2 patients (2.6%).

Stone size varied between 7 and 24 mm with a mean of 12.3±7.1 mm (85 below 10 mm, 62 between 10 and 20 mm and 20 larger than 20 mm).

Depending on the x-ray imaging, we recorded 104 patients with opaque stones (62.3%) and 63 patients with radiolucent stones (37.6%).

Pain management during the procedure was performed on demand in select cases (12 patients 7.2%) using common painkillers. Most of the patients underwent the procedure with no need for pain management or sedation. All patients received NSAID, antibiotic and painkiller drugs following the procedure. Mean follow-up was 3 months and included abdominal ultrasound, KUB and, in select cases, IVP and/or chemical analysis of the stone fragments.

Patients with urinary tract infections (UTI) or fever during hospital stay (9 cases) had the procedures postponed (3 weeks with antibiotic treatment and sterile urine culture).

Usually the procedure was performed after double J ureteral catheter placement for patients with large stone burden (above 20 mm) – 12 cases (7.2%) or subsequent to ureteral stone push-back 37 cases (22.1%).

Spontaneous stone fragment passage was reported within the first 24 hours after the procedure for 128 patients (77%).

Mean duration of the procedure was between 30 and 50 minutes. The number of shock waves ranged between 1000 and 5500 with an average of 3697±378 for one procedure (using a 60-120-
Mean wave intensity was 4.8 ±0.9 kV.

Table 2. Case distribution based on stone location

| Location/characteristic | No. of cases | %      |
|-------------------------|--------------|--------|
| Left kidney             | 67 (69 solitary) | 52.1% (41.3%) |
| Right kidney            | 73 (55 solitary) | 43.7% (32.9%) |
| Bilateral               | 36           | 22.5%  |
| Vesico-ureteral junction (VUJ) | 7 | 4.2%  |
| Solitary stone          | 92           | 55.1%  |
| Pelvis                  | 38           | 41.3%  |
| Calyx                   | 21           | 22.8%  |
| JPU                     | 33           | 35.9%  |
| Multiple stones         | 75           | 44.9%  |
| Pelvis + calyx          | 41           | 54.6%  |
| Multiple calyces        | 26           | 34.6%  |
| JPU + calyx             | 7            | 9.3%   |
| JPU + pelvis            | 2            | 2.6%   |
| **Total**               | **167**     |        |

Complete stone disintegration and stone fragment passage (assessed at 12 weeks from the procedure by ultrasound and KUB/IVP) was achieved for most patients (144 – 86.2%). The number of procedures ranged between 1 and 14 with an average of 2.3± 0.8. Stone-free rate at 30 days was 73.6% (123 cases).

Chemical composition analysis was performed for 148 patients (88.6%) of the 167, as follows (fig.2): 81 calcium stones (54.7%), 22 of which were calcium oxalate monohydrate (14.8%) and 59 calcium oxalate dihydrate (39.8%), 44 uric stones (29.7%), 18 struvite (12.2%) and 5 cystine stones (3.4%).

Depending on stone composition, we observed a 90.9% 30 days success rate for softer uric acid stones, 79.6% for COD stones and 36.4% for harder COM stones. Unlike the COM, uric acid and COD stones usually were disintegrated into smaller fragments with easy spontaneous passage.

Most of the patients requiring more than 3 SWL procedures (91 cases) had either stones larger than 15 mm or COM stones. The procedures were usually repeated after 7-14 days.

For a better and objective assessment of stone fragmentation before the procedure, we analyzed ESWL efficiency for opaque vs. radiolucent stones. As we stated before, 62.3% of the patients were diagnosed with opaque stones while 37.6% had radiolucent stones.

We therefore calculated the mean number of shock waves required to achieve complete lithotripsy (stone-free) for both patient groups (fig.3). The value was significantly lower (p<0.05) for patients with radiolucent stones (6487±867 waves) when compared with patients bearing opaque stones (8214±742 waves). Moreover there was a significantly lower number of ESWL procedures (p<0.05) for patients with lucent stones 1.75±0.63 compared with those with opaque stones 2.47±0.51.

After assessing the stone-free rate depending on the number of procedures by Kaplan-Meier analysis, we obtained 59%, 86%, 93% and 97% values for patients with radiolucent stones at procedure I, II, III and IV respectively and 19%, 62%, 81%, 88% for patients with opaque stones. (fig. 3). However, these values can be biased by the stone-free diagnosis established by ultrasound only for the patients with lucent stones and by the combination of ultrasound and x-ray with a higher accuracy for the patients with opaque stones.

Complications included three renal hematomas produced by renal concussion (two small subcapsular and one larger retroperitoneal hematoma) that were treated conservatively with no need for surgical management.

Steinstrasse was diagnosed in 19 cases (11%), 12 patients being able to spontaneously pass the stone fragments within 3 days. The other 7 patients required retrograde ureteroscopy and active stone removal.

Minor complications included nausea during the procedure for 17 patients (10%), vomiting for 5 patients and postprocedural chills for another 2 patients. All instances required various duration pauses during the procedure.
Skin rash was noticed at wave entry location for 62 patients, but it disappeared within 24-48 hours after the procedures.

Discussions
Urinary stone disease management changed with the technological advances. Until the introduction of large scale use of minimally invasive treatments, the majority of the urinary stones with no spontaneous passage were usually managed by open surgery. Nowadays the rate of open surgical procedures addressing stone disease is below 5%. Modern therapies such as ESWL, Retrograde Ureteroscopy or Percutaneous Nephrolithotomy have replaced these procedures.

Extracorporeal shock wave lithotripsy has gradually become the first line of treatment for kidney stones worldwide as it is the least invasive (but not without any complications) of all methods and addresses 80-90% of the treatment indications [1, 2, 3, 7, 8].

European treatment guidelines advise active ESWL treatment for all stones larger than 6-7 mm [4]. Factors known to alter the extracorporeal lithotripsy outcome are: stone size, location, chemistry, number as well as patient anatomy. Stones larger than 15 mm and calcium oxalate monohydrate stones usually require several ESWL procedures for clearance. Uric acid, calcium oxalate dihydrate as well as struvite stones are much easier to be disintegrated. ESWL has poor results for stones located in the lower calyx (“stone free” rate of 41-70%) [1, 3, 5, 7, 8].

Our lithotripsy device has a high efficacy rate with straightforward handling and provides good patient comfort during the procedure. For optimum treatment, a good patient assistance is required particularly for the procedures performed without analgesia. This is even more important after the procedure when the patient compliance with the medical recommendations is expected (fluid intake, medication, scheduled follow-up).

Our patient sample did not include any cases with severe complications such as perirenal hematoma or urosepsis. As we stated, steinstrasse was treated with favourable outcome for most cases, but there were some patients requiring retrograde ureteroscopy and stone fragment active removal as well as double J catheter placement. P Transitory postprocedural haematuria is common in most cases, insignificant as volume and rarely lasts more than 24 hours.

Conclusions
ESWL is the first line of treatment for renal stones smaller than 2.5 cm and is indicated for more than 75% of patients with urinary lithiasis;

Depending on stone properties and location, each patient required between 1 and 14 ESWL procedures with a mean of 2.3±0.8. Previous double J stenting was performed for 29.3% of the patients.

In 77% of the patients, urinary stone fragments passage was noticed in the first 24 hours after the procedure. The 30 day “stone-free” rate was 73.6%. Complete stone disintegration and clearance was achieved in most cases - 86.2 %.

Last generation lithotripters (such as the one we used) significantly improved patient tolerance as well as the efficacy of the procedure. Analgesia during the procedure was rarely required (7.2 % of the patients).

ESWL complications were mostly minor and scarce (transitory haematuria, renal pain). More severe complications (steinstrasse) were rarely noted (3.65%) and were treated medically or by minimally invasive procedures (retrograde ureteroscopy).

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