

NON-INVASIVE TREATMENT OF RENO- URETERAL LITHIASIS. EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY THE REPORT OF FIRST 1000 CASES

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Abstract: Being a noninvasive method, extracorporeal shock wave lithotripsy (SWL), it became popular due to its simplicity, effectiveness and low mortality rate in the treatment of reno-ureteral lithiasis. This method is based on the disintegration of calculi by shock waves produced outside the body, which penetrate the tissues without affecting them. The objective is to demonstrate the efficiency and safety of the procedure made on the first 1000 patients, but also some various associations, for the patients who undergo the extracorporeal lithotripsy procedure done with third generation Modulith SLK, in the treatment of kidney and ureteral calculi. The retrospective study showed the existence of statistically significant associations between patient's gender and the calculus type, but also for the positioning of the calculus (renal or ureteral) and between the stent variable (Yes/No) and calculus position (renal / ureteral).

Key words: extracorporeal shock wave lithotripsy, reno-uretral lithiasis, efficiency, safety.

1. Introduction

Urinary lithiasis is a frequently met disease, with a peak incidence in the 3rd or 4th decade of life [15], with a prevalence of 2% to 3% within the general population.

It has been 34 years since the first patient was treated by extracorporeal shock wave

lithotripsy in the early 1980s [2], in the Grosshardern Urology Clinic, University of Medicine in Munich (Germany). Being a noninvasive method, it became popular due to its simplicity, effectiveness and low mortality rate. The shock waves are very short impulses, with pressure points of approximately 10 to over 150 MPa, the

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equivalent of 100-1500 times the atmospheric pressure. This method is based on the disintegration of calculi by shock waves produced outside the body, which penetrate the tissues without affecting them, acting through various mechanisms and dynamic forces, of which the most important is cavitation. [11]

From the beginning until now, there has been a genuine technological process of the extracorporeal shock wave lithotripsy equipment, currently almost 90% of reno-ureteral calculi have treatment indication of extracorporeal shock wave lithotripsy.

According to the European Association of Urology Guidelines for 2014, extracorporeal shock wave lithotripsy remains the first intention method for calculi < 2 cm situated in the renal pelvis and upper and lower calyces, the success of the procedure depending on many factors, such as type of lithotripter used, the size of the calculus, the position of the calculus, its composition but also the physician's experience in performing the procedure. Due to the technological progress present at the moment in extracorporeal lithotripsy, but also in endoscopic techniques, upper urinary tract lithiasis can be successfully treated using minimally invasive procedures.

Extracorporeal Shock Wave Destruction (SWL) is accepted as a first-line procedure of treatment for patients with ureteral lithiasis, the efficiency of the procedure decreasing with the size of the calculus [8]. Recently, extracorporeal shock wave lithotripsy treatment was also reconsidered for large calculi.

2. Objectives

The objective is to demonstrate the efficiency and safety of the procedure, but also the various associations between the

patient's gender, age, the position of the calculus, the side on which the calculus is identified, its composition, size, the number of sessions and the presence or absence of a double J ureteral stent for patients who undergo the extracorporeal lithotripsy procedure done with third generation Modulith SLK, in the treatment of kidney and ureteral calculi.

3. Material and methods

Between May 2011 and January 2014, in the 'Sfantul Constantin' Multidisciplinary Private Clinic of Brasov, we evaluated retrospectively the first 1,000 patients aged between 15 and 85, with kidney and ureteral lithiasis, symptomatic or asymptomatic, which came to our service and who were treated by non-invasive extracorporeal lithotripsy. The patients were diagnosed, through imaging techniques, with kidney and ureteral calculi, radiopaque or radiolucent, solitary or multiple, with sizes up to 2.5 cm.

The patient's age, gender, the size of the calculus, its position and the side on which it was identified were investigated, as well as the presence or absence of a double J stent, if the calculus was radiopaque or radiolucent, the number of sessions required for the complete fragmentation, the number of impulses used, their intensity and frequency.

Extracorporeal Shock Wave Destruction (SWL) was practiced either "in situ" in the kidneys or ureter, or after pushing some ureteral stones back, in the pyelocalyceal system by retrograde semirigid ureteroscopy.

The Imaging Diagnostic protocol included, for all patients who were diagnosed with kidney or ureter lithiasis, symptomatic or not, one or more of the following means of imaging diagnostic: ultrasound of the upper and lower urinary

tract, kidneys and bladder radiography, intravenous urography, CT, MRI.

Patients with stones in the lower calyceal group level were also investigated by intravenous urography (IVU), in order to see the anatomy of the lower calyceal group and the possibilities to remove the stone.

All patients had urinalysis and urine culture performed before the procedure. Patients under long-term anticoagulant therapy were scheduled after the previous discontinuation of the anticoagulant therapy at home for seven days and its replacement by low-molecular weight heparins administered hypodermically. The preparation of the bowel was made with Simethicone, 3 days before the procedure, and diet.

The procedure did not require general anaesthesia, intravenous analgesia being sufficient, each patient received non-steroidal anti-inflammatory drugs and analgesics slow perfusion throughout the procedure. A relaxed and cooperative patient during the procedure ensures the maintenance of the calculus in a stable position for optimal fragmentation.

The shock wave energy was progressively increased up to the standard procedure (up to 65 in the case of kidney calculi and up to 85 for ureteral calculi), but also taking into account the patient's pain tolerance. The progressive increase in the shock wave energy level prevents fragmentation, since the beginning of the procedure, in large fragments that can migrate to the renal cavities or the ureter, triggering renal colic.

For the ultrasonic lithotripsy procedure, an electromagnetic lithotripsy, 3rd generation Modulith SLK (Storz Medical AG, Tagerwilen, Switzerland) was used, which combines a large focal depth and a wide opening of the device, designed

especially for urological interventions, although the lithotripsy has a broad spectrum of action and can be used for disintegration of stones in gastroenterology and otolaryngology, as well as for various orthopaedic procedures. In urinary calculi lithotripsy, a large focal depth is very important to reach the calculus, especially in obese patients.

The lithotripsy Modulith SLK is equipped with an electromagnetic cylindrical source, of medium size, flexible, mounted on a joined arm which helps intuitive and easy positioning of the patient and provides a wide range of energy for all the extracorporeal lithotripsy indications. The therapeutic head can be adjusted directly in the treatment position, depending on the patient's anatomy.

The cylindrical source has a central opening which is ideal for installing an ultrasound transducer.

The stone was located using the dual imaging system (simultaneous X-ray localization or ultrasound). For the positioning of the calculus, the navigation system that complements the lithotripsy device (Lithotrack system) was used, a revolutionary system for precise location of the calculus. Lithotrack Polaris Vicra is used to align the therapeutic source in the treatment position determined beforehand by two X-ray projections.

The stereoscopic camera "looks" at the therapy head and can determine its position and orientation in space. The resulting data is visualized in a virtual 3D scenario allowing the attending physician to position the therapy head easily.

The fragmentation monitoring was performed throughout the procedure, either through ultrasound or radiologically, depending on the composition of the urinary calculus. The mixed radiological and ultrasound localization increases the

scope of the extracorporeal lithotripsy to the entire ureter, however there is still less satisfactory results at the iliac ureter level due to the difficult identification and focusing of the calculi.

For kidney and the upper lumbar calculi, the procedure was performed with the patient in the prone position and for the medium lumbar and the pelvic calculi the procedure was carried out with the patient in supine position. The position of the calculus was calculated both at 0 and 30 degrees, by rotating the electromagnetic source.

All the procedures were done in accordance with the moral and ethical principles stated in the Helsinki Declaration of Human Rights, the most important factor taken into account being the safety of the patients during the procedure. All patients signed an informed consent prior to the procedure, agreeing and understanding the way the procedure would be carried out, the possibilities of treatment available and any possible complications that may occur after the procedure, which may involve general anaesthesia, endoscopic manipulations at the upper urinary tract level and ureteral stent placement. Patients were informed that they would have to come for a check-up according to the directions received and that there is the possibility of an incomplete fragmentation of the calculus, which involves additional costs for other future sessions.

The female patients being in their fertile period have signed on their own responsibility that they were not pregnant when the procedure was performed.

The patients were hospitalised for 1 day. After the procedure, they stayed in hospital about two hours, after which they left the hospital. All patients received expulsion therapy when leaving the hospital. At the

end of the procedure, the patients were informed about the exact time when they have to come for a check-up and the reasons for the emergency, in case of macroscopic hematuria, renal colic, fever or chills. The check-up was done after 3-4 weeks by ultrasound or radiological, depending on each case, in order to assess the degree of fragmentation. In cases requiring a new shock wave session, it was done immediately or a short time after the follow-up. The residual fragments less than 5 cm were considered a success of the procedure, being considered as spontaneously eliminable.

The data gathered from patients were statistically processed using SPSS 20.0 (the Statistical Package for the Social Sciences, version 20.0, SPSS INC. Chicago, Illinois, USA). Criteria, such as: gender, age, type of calculus, position of the calculus, side on which the calculus was identified and number of sessions were taken into account.

Specific tests were used: Student's t test, the correlation coefficient, the Mann Whitney test, the Kruskal Wallis test, the Pearson's Chi Square. The value $P < .05$ was considered statistically significant.

4. Results and discussion

The sample group included a total of 1000 participants, aged between 15 and 85, with an average age of 47. Patients were assigned by gender as follows: 530 (53%) males and 470 (47%) females.

A total of 810 patients (81%) were diagnosed with kidney calculi and 186 patients (18.6%) had calculi at the ureteral level (upper, middle and pelvic). Both the patients with kidney calculi and those with ureteral calculi were divided into subcategories, depending on the location of the calculus. For the kidney calculi, 136

patients (13.6%) had the calculus in the upper caliceal group, 199 patients (19.9%) had the calculus located in the middle caliceal group, 209 patients (20.9%) had the calculus in the lower caliceal group and 449 patients (44.9%) had calculi in the renal pelvis. A number of 7 patients (0.7%) had calculi in the caliceal diverticulum or in horseshoe kidneys.

Extracorporeal shock wave lithotripsy was performed on four patients, where the ureteral stent could not be extracted because the calculi fragments were set at the distal and proximal volutes level (in 3 patients on the distal volutes and in one patient on both volutes). After the SWL procedure, the ureteral stents were successfully extracted.

Among the patients on whom the lithotripsy procedure was performed, 752 (75%) did not have JJ ureteral stent placed before the procedure and 248 patients (24.7%) have JJ ureteral stent placed.

The radiopaque calculi were more common in 619 patients (61.9%) compared to the radiolucent ones, which were met in 381 patients (38.1%).

Depending on the size of the calculus, 4 groups were created: calculi with sizes between 5 mm and 1 cm, identified on 369 patients (36.8%), calculi between 1 cm and 1.5 cm, identified on 388 patients (38.7%), calculi between 1.5-2 cm, identified on 215 patients (21.4%) and calculi between 2-2.5 cm, identified on 27 patients (2.7%).

Of the total number of 1000 patients, 930 (93%) were able to eliminate the calculus fragments and become "stone free" after a maximum of 6 extracorporeal lithotripsy sessions. The other 90 patients (9%), for which the extracorporeal lithotripsy procedure failed, underwent minimally invasive surgical procedures for extracting the calculus: percutaneous nephrolithotomy or retrograde ureteroscopy.

In terms of gender, we examined the association between the variable "gender" and the following: type of calculus, position of calculus, side on which the calculus was identified.

Association relation between gender and the position of the stone

Table 1

		Gender		Significance test
		Male N (%)	Female N(%)	
Calculus type	Radiopaque	312(31,2%)	307(21,8%)	$\chi^2(1)=4.39, p = .036.$
	Radiolucent	218 (30,7%)	63 (16,3%)	
Position	Renal	411 (41,3%)	399 (40,1%)	$\chi^2(1)=7.46, p =.006$
	Ureteral	115 (11,5%)	71 (7,1%)	
Calculus Side	Left	236 (23.6%)	209 (20.9%)	$\chi^2(1) =.001, p= .985$
	Right	294 (29.4%)	261 (26.1%)	

The χ^2 tests revealed the existence of statistically significant associations for the type of calculus and its position. It has been shown that there is an association relation between the gender of the patient and the type of calculus, the presence of

certain types of calculi being different for men compared to women: $\chi^2(1) = 4.39, p = .036$. Thus we emphasize that there is a difference in the calculi distribution on gender, the most radiopaque calculi being identified on male patients.

There is an association relation between gender and the position of the calculus, $\chi^2(1) = 7.46$, $p = .006$ (Table 1).

In terms of age, the “t” test for independent samples reveals no statistically significant differences for age, depending on the type of calculus (patients with radiopaque calculus have an average age $M = 47.95$, $SD = 14.591$, while the ones with radiolucent calculus have an average age $M = 46.25$, $DS = 15.29$), $t = 1.742$, $p = .085$.

Moreover, the relationship between the age and the calculus size is not statistically significant: the Spearman correlation coefficient showed no statistically significant associations between age and the calculus size, $r(997) = -.052$, $p = .099$.

The variable number of sessions is not normally distributed (Skewness = 2.29, Kurtosis = -.83), that’s why a nonparametric test was used to reveal if the number of required sessions is different, depending on the type of calculus.

The Mann Whitney test showed no statistically significant differences, depending on the type of calculus, $z = -.039$, $p = .969$ (both patients with radiopaque calculus, as well as those with radiolucent calculus require, on average, one session of SWL).

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Regarding the relationship between the number of sessions depending on the calculus type, the Mann Whitney test did not show statistically significant differences, $z = -.944$, $p = .345$, both patients presenting kidney calculus, and those with ureteral calculus require, on average, one extracorporeal lithotripsy session.

Regarding the relationship between the number of sessions and the calculus subcategory, no statistically significant association was obtained: the Kruskal Wallis test showed no significant differences in terms of number of sessions depending on the calculus subcategory: $\chi^2(7) = 3.007$, $p = .884$. However, the result is not conclusive as, for certain subcategories, the number of cases was too small to highlight statistically significant differences. High incidence of calculi was observed, in both men and women, positioned at the bassinet level (Table 2).

The “ χ^2 ” association test shows a statistically significant association between the stent variable (Yes/No) and the position of the calculus (renal/ureteral), $\chi^2(1) = 4.12$, $p = .042$ (Table 3).

Regarding the relationship between the calculus subcategory and the presence of the stent, the association is not statistically significant, but irrelevant because there are many categories with a small number of cases: $\chi^2(7) = 3.15$, $p = .871$.

Table 2

Relationship between the number of sessions and the stone subcategory

	N	%	Mean	Std. Deviation	Std. Error	Minimum	Maximum
upper-calyceal	136	13.6	1.42	.83	.07	1	5
middle-calyceal	199	19.8	1.37	.68	.04	1	4
lower-calyceal	209	20.8	1.40	.70	.04	1	4
pelvic	448	44.8	1.38	.77	.03	1	6
calculus in the right middle calyceal diverticulum	2	0.2	1.50	.70	.50	1	2
Bassinnet calculus in the right radiopaque hemi-kidney. Horseshoe kidney	2	0.2	2.00	1.41	1	1	3
Calyceal calculus in the right lower hemi-kidney	2	0.2	1.00	.00	.00	1	1
Ureteral lithiasis in the upper right radiopaque hemi-kidney	1	0.1	1.00	.	.	1	1

Association between the stent variable and the position of the stone

Table 3

		Stent		Significance test
		YES N (%)	NO N (%)	
Position	Renal	210 (21.10%)	600 (60.24%)	$\chi^2 (1) = 4.12, p = .042$
	Ureteral	35 (3.5%)	151 (15.16%)	

The time for an extracorporeal lithotripsy session ranged between 40-45 minutes, while the total number of impulses in an extracorporeal lithotripsy session ranged from 3000-4000, with an average number of impulses of 3200, at a voltage situated between 11 to 20kV. The energy level was up to 65 for kidney calculi and up to 85 for the ureteral ones. The frequency of the shock waves that was used was most commonly 2 Hz, specifying that, for 30 patients (3%), both 2 Hz and 1 Hz frequencies were alternately used.

The procedure was abandoned for 2 patients due to the pain caused by the procedure and for 1 obese patient, due to the impossible guiding of the calculus. No serious complications were encountered to

determine radical surgery or endangering the patients' life.

Complications were encountered in 134 patients (13.4%) with kidney lithiasis and ureteral lithiasis. The most common complications were macroscopic hematuria (shown in 80, 59.7% patients with kidney lithiasis and in 22,16,4% patients with ureteral lithiasis), lumbar pain of various intensity, up to renal colic, resistant to treatment (for 19, 14.1% of the patients with renal lithiasis, and for 7 of the 5,2% patients with ureteral lithiasis), steinstrasse highlighted in 4, 2.9% patients with ureteral lithiasis, which required retrograde ureteroscopy. A total number of 6, 4,4%, patients returned with fever over 38° C.

There were no cases of major complications (renal or perirenal haematomas, acute pyelonephritis).

5. Discussion

The success rate of the procedure for kidney calculi and ureteral calculi was 93%. The data are comparable with those in the literature, showing a procedure success rate of over 90% [4], [9], [17].

The retrospective study showed the existence of statistically significant associations between patient's gender and the calculus type, but also for the positioning of the calculus (renal or ureteral) and between the stent variable (Yes/No) and calculus position (renal / ureteral).

Only part of the patients needed indwelling of a stent before performing the procedure, the majority of them had renal colic resistant to treatment, fever, renal insufficiency due to obstruction. Some authors report a lower rate of fragmentation after introducing a ureteral stent, most likely due to problems identifying the calculus and the stent interfering with the shock waves [1], [14]. There are studies showing that the insertion of a ureteral stent before performing the procedure does not influence the rate of "stone free", but reduces the risk of renal colic [12].

According to studies on animal models, in humans extracorporeal lithotripsy procedure can also cause acute kidney injury [9]. In 2009, Navarro noted in the 4819 cases of extracorporeal lithotripsy performed in his clinic, in Mexico, 6 cases of subcapsular and perirenal hematoma (<1%). [13] After the 1000 extracorporeal lithotripsy procedures performed, we had no cases of renal or perirenal hematoma.

In 2002, Madbouly concluded that the risk for developing steinstrasse is higher

for the calculi larger than 2 cm, more commonly for kidney calculi, for dilated pyelocalyceal systems and while using higher energies (>22kV) [7]. As a result of the performed procedures, we had a total number of 4 patients who developed steinstrasse, which were pushed out by retrograde semi-rigid ureteroscopy.

There is still controversy about the long-term complications of SWL, including increased risk of developing arterial hypertension in elderly patients [5] and the development of diabetes [6]. However, in 2008, Sato compared the patients with arterial hypertension and early onset diabetes, who had kidney lithiasis or ureteral lithiasis treated by extracorporeal lithotripsy and showed no difference in the way it first appeared [16].

Obese patients should be informed, before the procedure, about the lower success rate of the procedure, due to the larger distance between the skin and the calculus.

A total number of 346 patients had ureteral stent before the procedure, the stent was placed in patients with calculi larger than 2 cm, in patients with ureteral calculi, when push-back retrograde ureteroscopy was performed and in patients with febrile renal colic or renal colic, unresponsive to medication. Data from the scientific literature say that the ureteral stent does not bring real benefits in terms of rates of elimination or dissolving of steinstrasse, but it has statistical significance in decreasing the rate of renal colic [10].

Introducing the latest generation lithotritors, that are easy to use and have less pain rate, has increased the "stone free" rate but, in order to minimize the side effects of the procedure, it is however necessary to select the candidate patients for this procedure.

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