Factors predictive of shockwave lithotripsy failure for ureteral stones: why we need to hurry

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ABSTRACT

BACKGROUND: The aims of this study are to evaluate the prognostic factors of extracorporeal shockwave lithotripsy in patients with ureteric stones, and to identify which patients might directly benefit of an endoscopic treatment.

METHODS: We performed a prospective study from January 2013 and July 2016 on patients with single ureteric stone and undergoing extracorporeal shockwave lithotripsy (SWL). We divided patients into two groups: first group (success group) included cases resolved with SWL only, and a second group (failure group) including patients with stone not resolved by SWL and requiring an endoscopic treatment. We evaluated age, weight, height, body mass index, stone size, hydronephrosis, laterality, location, days elapsed from onset of symptoms to SWL and stone density when computed tomography was performed. In case of stone fragments >4 mm, the procedure was repeated up to a maximum of three times. SWL was considered as failed if patients had a residual stone of any size after a follow-up of 3 months or if a complication occurred.

RESULTS: 274 patients completed follow-up and were enrolled in the study. Mean age was 53.22 years (standard deviation: 13.98). SWL overall success rate was 84.3% (231 patients successfully treated with shockwaves) and failure rate was 15.7% (43 patients underwent auxiliary endoscopic procedure). At the univariate analysis, we observed a statistically significant difference for hydronephrosis (P=0.006), time elapsed from symptoms onset (P=0.013), patients' age (P=0.06) and mean stone density (0.023). In the multivariate logistic regression, patients' age (OR: 1.517), and time elapsed from obstruction to SWL (OR: 3.005) were independent predictive factors for SWL failure. Furthermore, moderate and severe hydronephrosis seemed to be independent predictive factors for SWL failure, presenting an OR of 2.451 and 4.207 respectively. High stone density resulted to be a predictive factor for SWL failure (OR: 2.293 if density was higher than 1100 Hounsfield Units).

CONCLUSIONS: We report a large series of patients undergone primary SWL for ureteric stones. Our data demonstrated the role of hydronephrosis, time elapsed from obstruction onset to treatment and stone density as independent predictive factors of SWL failure.

KEY WORDS: Extracorporeal shockwave therapy; Lithotripsy, Ureteroscopy; Calculi; Urolithiasis.

Ureteric stones are the most frequent cause of renal colic and may lead to obstructive uropathy if not treated.

The goal of ureteric stones treatment is to achieve complete stone removal with minimal morbidity and discomfort for patients. Thanks to the technical advancements of the past 20 years, open surgery is no longer the treatment of choice, and should be avoided in the majority of cases; extracorporeal shockwave lithotripsy (SWL) and ureteroscopic stone disintegration or extraction (URS) play a pivotal role in stone treatment today. Even though there is now a consensus on the preference of using the least invasive approach

as possible, the debate continues on whether SWL and URS should be the first line of treatment in patients with ureteric stones.[1]

The optimal treatment for the patient is decided taking into consideration several factors including stone composition, location and size, equipment availability, patient's comorbidities and surgeon skills.[2] Currently, both SWL and URS may be chosen for efficiently treating ureteral stones at all levels, and the preference between the two is influenced by advantages and disadvantages.[3] SWL is a non-invasive procedure, and can be performed with only intravenous sedation and analgesics. However, its most important disadvantage is the lower stone free rate in relation to URS, and the need for retreatment in a significant percentage of patients.

URS requires a much lower number of retreatment but the procedure must be performed under general anesthesia in an operating room. Furthermore, it can determine a higher risk of complications.[4] In terms of outcomes, a direct comparison of the two procedures is complex, and many studies contain bias regarding the length of the follow-up.[1]

Regarding SWL, it is not sure which factors can influence the outcomes.[5-7] Choi *et al.* reported,[8] in a series of 153 patients who underwent SWL for ureteral stone, that stone size (>10 mm) and presence of perinephric fat stranding are independent influencing factors for failure of the procedure. Furthermore, Hwang *et al.*[9] presented a paper on how ESWL failure can be predicted in case of obesity (elevated Body Mass Index [BMI]), stone size exceeding 1 cm, mid-ureteral location of the stone and severe hydronephrosis.

We sought to define which factors determine a failure of SWL, leading to URS in second instance, with the aim of identifying which patients may benefit from URS directly.

Materials and methods

We enrolled patients in a prospective observational study, between January 2013 and July 2016, who underwent SWL because of a single ureteral stone diagnosed at our Institute. Our study was carried out according to the principles of the Declaration of Helsinki. The study was approved by our Ethic Committee; patients were regularly informed about the study and inserted in the protocol after having signed an informed consent. However, this study protocol did not differ from our usual practice.

The inclusion criterion was patients with a single ureteral stone larger than 4 mm. Exclusion criteria included urinary tract infections, ureteric strictures from patient's history and/or previous imaging, blood coagulopathy or anticoagulant users, neurogenic bladder. Furthermore, we excluded children and pregnant women. We divided patients into two groups: first group (success group) included cases resolved with SWL only, and a second group (failure group) including patients with stone not resolved by SWL and requiring an endoscopic treatment.

Additional information were: age, weight, height, BMI, stone size, hydronephrosis, laterality, location, days elapsed from onset of symptoms to SWL and mean stone density (measured in Hounsfield units). All patients had a CT scan without contrast of the urinary tract to confirm diagnosis. The severity of obstruction was scored as none if absent, mild if only pelvis dilation was evident, moderate if mild calix dilation was present. In case of severe calix dilation or atrophy of renal parenchyma, the hydronephrosis was considered severe. Furthermore, location was divided in proximal ureter, mid ureter and distal ureter.

Lithotripsies were performed by using Lithotron Lithotripter (Healthtronics, Atlanta, GA, USA) under fluoroscopic or ultrasound guidance, by 3 different urologists beyond their learning curve for this particular procedure. Treatments started with a power of 14 kV and were progressively increased up to 22 kV, if necessary. A maximum of 3200 shockwaves were administered to patients and the frequency used was 1 Hz in all treatments.

In case of stone fragments >4 mm, the procedure was repeated up to a maximum of three times. We considered SWL as failed if patients had a residual stone of any size after a follow-up of 3 months or if a complication occurred, such as untreatable pain, urosepsis or higher grade of hydronephrosis. Every patient was followed up monthly, and if needed re-treated, for a total period of three months. Stone free rate status was confirmed with a further CT scan at the end of follow-up.

Statistical analysis

Statistical analysis was performed with SPSS v. 17.0 software. We compared the clinical features between the two group (SWL group *versus* URS group) by univariate analysis. Variables with significant association were re-tested with multivariate logistic regression and adjusted odds ratio (OR) to identify the independent predictors of treatment failure. P values <0.05 were considered significant.

Results

A total of 274 patients fulfilling inclusion and exclusion criteria completed the follow-up and were enclosed in our study. Characteristics of our patients are reported in Table I and II. Our SWL overall success rate was 84.3% (231 patients successfully treated with shockwaves) and failure rate was 15.7% (43 patients underwent auxiliary endoscopic procedure).

One hundred and twenty-four patients (45.1%) enrolled in our series had a distal stone. According to European Urological Association guidelines, in these cases the treatment of choice should be URS and not SWL. However, due to a longer waiting list for URS than SWL we usually purpose an extracorporeal approach at first.

In case of SWL failure, patients were treated endoscopically. Out of 43 patients, 16 (37.20%) were later treated because of residual stone (mean time elapsed after SWL: 171.19±43.48 days), 18 patients (41.86%) because of colic pain (mean time elapsed: 29.89±15.88 days), six patients (13.97%) due to a worsening of hydronephrosis observed during follow-up (mean time elapsed: 63.50±15.43 days), two patients (4.65%) because of a worsening of renal function (mean time: 17.50±11.92 days), and one patient (2.32%) because of urosepsis (27.91±36.78 days).

Table I.—*Patients' demographic data.*

Parameters	Value
Age, years	53.22±13.98
Weight, kg	74.70±15.47
Height, m	1.72±0.08
Body Mass Index, kg/m²	25.23±4.38
Stone size, mm	9.38±3.36
Number of shockwaves	2703.89±649.83
Power, kV	17.89±1.745
Stone density	798.65±305.1
Time between obstruction onset and SWL, h	44.29±28.10
Hydronephrosis	71 (26.9%)
None	84 (34.8%)
Mild	78 (31.3%)
Moderate	18 (7.0%)
Severe	274 (100.0%)
Total	84 (34.8%)
Location of the stone	
Proximal	67 (24.5%)
Intermediate	83 (30.4%)
Distal	124 (45.1%)
Total	274 (100.0%)
Laterality	
Left	159 (58.2%)
Right	115 (41.8%)
Total	274 (100.0%)
Stent pre-SWL	
No	236 (86.1)
Yes	38 (13.9)
Total	274 (100.0)

Data expressed as mean±SD or as number of patients (proportion).

Table II.—*Comparison of success group* versus *failure group by univariate analysis.*

Parameters	Success group	Failure group	P value
Age, years	52.61 (49.69-55.53)	56.65 (51.68-61.62)	0.06
Time between obstruction onset and SWL, h	32.44 (22.07-52.82)	53.08 (16.94-89.22)	0.013
Stone size, mm	9.47 (8.88-10.06)	10.12 (8.32-11.92)	0.499
Stone density	772.5 (492.5-928.4)	870.47 (740.9-1041.7)	0.023
N. of shockwaves	2737.04 (2607.43-2866.65)	2880.00 (2727.40-3032.60)	0.257
Power, kV	17.83 (17.50-18.17)	18.56 (17.79-19.33)	0.185
Weight, kg	74.13 (71.71-77.71)	74.96 (68.13-81.78)	0.696
Height, m	1.71 (1.69-1.72)	1.72 (1.68-1.76)	0.974
BMI, kg/m²	25.40 (24.54-26.26)	25.03 (23.28-26.78)	0.713
Location			0.671
Proximal	58 (21.24%)	9 (3.29%)	
Intermediate	71 (26.0%)	12 (4.39%)	
Distal	101 (36.99%)	22 (8.05%)	

Data presented as mean (95% CI) or as number of patients (proportion).

Out of 274 patients, 102 (37.22%) required a second SWL treatment and 34 (12.40%) underwent a third SWL.

At the univariate analysis, laterality, stone location, stone size and BMI did not seem to have statistical significance in terms of SWL outcomes. However, we observed a statistically significant difference for hydronephrosis (P=0.006), time elapsed from the meet of symptoms (P=0.013, with a mean time in success group of 32.44 days and 53.08 days in failure group), patients' age (P=0.06, with a mean age of 52.61 in success group *versus* 56.65 years in failure group) and stone density (P=0.023, with a mean stone density of 772.5 HU in the success group *versus* 870.47 HU in the failure group). Data from the univariate analysis is reported in Table II. In Figure 1 are reported the percentages of success of SWL in comparison with different degrees of hydronephrosis, the higher degree of hydronephrosis, the lower stone free rate. In the multivariate logistic regression, patients' age (OR: 1.517, CI: 0.383-1.952), and time elapsed from obstruction and SWL (OR: 3.005, CI: 1.998-4.012) were independent predictive factors for SWL failure (Table III). Furthermore, moderate and severe hydronephrosis seemed to be independent predictive factors for SWL failure, presenting an OR of 2.451 (CI: 1.812-3.789) and 4.207 (CI: 2.308-5.648) respectively (Table III). We decided to test by multivariate analysis stones with a mean density included between 900 and 1100 HU and over 1100 HU. We observed that a stone density higher than 1100 resulted to be a predictive factor for SWL failure, with an OR of 2.293 (CI: 1.865-2.861).

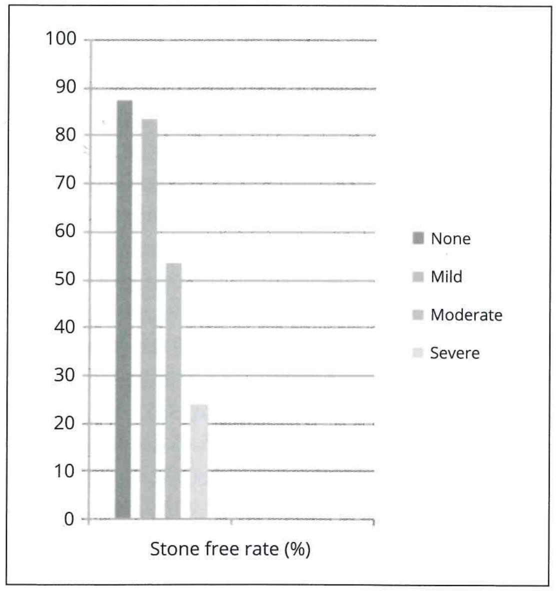

Figure 1.—Stone free rate of SWL in patients with different grade of hydronephrosis.

Table III.—*Predictive factors analysis by multivariate logistic regression.*

Parameters	P value	Adjusted odds ratio	95% CI
Age	0.046	1.517	0.383-1.952
Time elapsed	0.015	3.005	1.998-4.012
Stone location			
Proximal	0.412	0.925	0.285-1.348
Intermediate	0.208	1.128	0.645-1.465
Distal	0.765	1.852	0.521-2.234
Stone size	0.387	0.925	0.775-1.104
Stone density			
900-1100 HU	0.521	1.947	0.921-2.23
>1100 HU	0.013	2.293	1.865-2.861
BMI	0.538	0.964	0.857-1.084
Hydronephrosis			
Mild	0.568	0.971	0.214-1.521
Moderate	0.027	2.451	1.812-3.789
Severe	0.002	4.207	2.308-5.648

Discussion

Since this procedure was introduced in 1982, the use of SWL has become effective, safe and well tolerated, with reproducible results.[10] In literature, the success rate for ureteral stone treatment varies from 75% to 90%.[1, 2, 8, 10-12] On the other hand, success rate after URS varies from 85% to 100%.[3] Peculiarities of SWL treatments are its non-invasive nature, high level of patients' acceptance and lack of need for general anesthesia. URS proponents suggest immediacy of stone-free status, lower cost and wider availability of equipment.[13] Despite authors have similar outcomes with SWL for ureteric stones, positive and negative prognostic factors remain controversial.[14]

Our study was designed to better define which patients can benefit from SWL and who are the most at risk of failure and, if indeed at risk, redirect them to other valid treatment options.

The choice of SWL or URS for ureteric stone treatment is actually one of the most commonly debated controversies in urology, and this may be partly determined by technology advancement in both fields. In a systematic review, Aboumarzouk *et al.*[13] reported the results of 7 randomized controlled trials, reporting lower stone-free rate in SWL group comparing to URS group (OR: 0.84, 95% CI: 0.73-0.96). However, re-treatment rates were lower in URS group (OR: 6.18, 95% CI: 3.68-10.38). Furthermore, SWL patients needed fewer auxiliary procedures than URS groups (OR: 0.43, 95% CI: 0.25-0.74), fewer complications (OR: 0.54, 95% CI: 0.33-0.88), and shorter hospital stay (mean time: -2.55 days, 95% CI: -3.24 to -1.86). One needs to point out, however, that these studies presented some bias, in particular in three of them the randomization process was unclear and all of them presented an unclear risk of performance and detection bias.

Similar results are reported by Tiselius.[15] In this systematic review on 20,659 patients with ureteric stone, a significantly higher retreatment rate for the patients treated with ESWL than for those treated with URS was reported, although the average retreatment for URS was only 2.2% compared with 12.1% for SWL (P=0.007).

At our univariate analysis, hydronephrosis, time elapsed from obstruction onset, patient's age and mean stone density are in association with SWL success (P=0.006, P=0.013, P=0.06 and 0.023 respectively). In multivariate analysis, only moderate (P=0.027, OR: 2.451, 95% CI: 1.812-3.789) and severe hydronephrosis (P=0.002, OR: 4.207, 95% CI: 2.308-5.648) had a strong correlation with SWL success. Moreover, time elapsed from obstruction onset resulted to be a predictive value (P=0.015, OR: 3.005, 95% CI: 1.998-4.012). Furthermore, a high mean stone density is associated more frequently with SWL failure (P=0.013, OR: 2.293, 95% CI: 1.865-2.861). Age seemed to be a predictive factor, however due to that fact that the confidence interval overlaps 1, this data should not be considered significant (P=0.046, OR: 1.517, 95% CI: 0.383-1.952).

Despite the results of other studies, we have not observed a correlation with BMI, stone size and location of the stone.

Regarding the meaning of hydronephrosis, it is still unclear whether the dilation of the urinary tract lead to a lower wash out of the stones after SWL and It may be the result of a prolonged ureteral obstruction. Impacted stones, in fact, produce more important obstruction, leading to more severe degrees of hydronephrosis. In our series we confirm a strong correlation between stone free rate after SWL and hydronephrosis. In fact, the probability of treatment success decreases as the degree of hydronephrosis increase (patients with moderate and severe hydronephrosis showed an increased risk respectively of 2.451 and 4.207). Several authors report a correlation of hydronephrosis with SWL failure.[16-18] Furthermore, the degree of hydronephrosis seems to affect the final result of the procedure for stones of different size, and the impact is more important in patients with stones > 10 mm. However, other investigators found that the presence and degree of hydronephrosis did not affect ESWL success rates.[19, 20] In the series of el-Assmy *et al.*,[18] hydronephrosis correlated with the final result only in patients with ureteral stones larger than 20 mm. The same author reported that hydronephrosis significantly increases the re-treatment rate. Additionally, Turna *et al.*[21] reported a trend in achieving higher stone free rate for ureteral calculi without severe/moderate dilatation (80% *versus* 92.9%), but this did not cause a statistical difference. Similarly, the degree of obstruction did not affect the stone free rate in the proximal ureter (86.2% *versus* 86.7%).

In our data, another interesting factor emerged: the success rate after SWL was higher if time elapsed from obstruction onset and treatment were lower. In our success group we observed a mean time of 34.42 days *versus* a mean time in failure group of 53.08 days. Indeed, the relative risk of SWL failure was 3.005. These data suggest that the SWL option for ureteric stone should be prompt. Our work is in line with other studies, which correlate SWL outcomes and timing.[22, 23] Choi *et al.*[24] observed that in case of early SWL (less than 48 hours from onset), the stone free rate and re-treatment rate were significantly lower than delayed SWL group. However, this data was significant if the stones were <10 mm. Furthermore, the superiority of early SWL was more important for proximal ureteric stones.

If hydronephrosis is the result of an impacted stone, which is on the same time the effect of a prolonged obstruction, we could speculate that an important factor that urologist has to consider in case of ureteric stone is time elapsed. If it is short SWL will have a high success rate. Otherwise, URS will lead to better results.

In our study, BMI did not seem to be a prognostic factor. The utility of body mass index as predictor of success in SWL is variable, and there is no current consensus. In fact, despite in some series the BMI correlates with stone free rate,[9, 25] in other papers it is not associated with final result.[8] It is possible to speculate that the BMI is indirectly related with skin-to-stone distance, which strongly correlates with success rate. However, body fat distribution varies significantly between gender, age and race.[26] For these reasons it should not be used as surrogate for skin-to-stone distance.

Regarding stone size, several authors report that stones larger than 10 mm in their largest dimension determine a lower SWL success rate.[16, 27] In the study by Hwang *et al.*,[9] in case of stones larger than 10 mm the success rate was 10.5 fold in comparison with stones smaller than 10 mm (95% CI: 3.0-36.2). Furthermore, at all locations in the ureter, the success rate for stones smaller than 10 mm was better compared to that for stones larger than 10 mm.[8]

Regarding the stone location, it's not clear if it can determine a different outcome. In a retrospective analysis by Delakas *et al.*,[27] it was observed that lower ureteric stones were associated with a greater risk of failure (61.5%) than proximal and middle ureteral stones (82.9% and 75.6% respectively). Authors explained this phenomenon supposing that interposed bony pelvis and buttock musculature may attenuate shockwaves, resulting in a lower success rate. Another explanation should be that tracing and focusing a lower ureteral stone is more difficult than upper and middle ureteral stone. Furthermore, in case of radiolucent stones of the middle ureter, a correct focusing is close to impossible.

Limitations of the study

Our study has a limitation; we were not able to verify the stone biochemistry. Few studies have been carried out in order to correlate stone composition with its fragility and success of the extracorporeal treatment.[16-18] It is known that stone biochemistry influences dramatically the outcomes of the procedure. Ansari *et al.* reported their results on 290 patients with renal or upper ureteric stone who underwent SWL.[19] For each patient some stone fragments were collected during micturition and urine filtration, with the aim of defining stone composition by X-ray diffraction. In their study, a lower success rate in patients with calcium oxalate monohydrate and apatite in comparison with struvite or uric acid stones was reported. Similarly, the mean number of shockwaves, voltage and number of re-treatment was significantly higher for calcium monohydrate and apatite in comparison to uric acid or struvite. A second limitation present in this study is the lack of skin-to-stone distance, which have been reported as influencing factors of SWL success and should be considered in decision making processes.[28]

Conclusions

We report a large series of patients undergone SWL for ureteral stone. In our study we did not observe a correlation between SWL success and stone size, location and body mass index. Furthermore, patient's age could have a role in determining the stone-free rate, but this data requires further investigations. We demonstrated the role of hydronephrosis, time elapsed from obstruction onset and stone density as negative independent predictive factors.

Our data underline the role of timing in the treatment of these patients. SWL resulted to be an effective procedure if prompt, this is why we need to hurry.

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