Storz Medical Lithotripsy Index Predicts Success of Shock Wave Lithotripsy in Ureteric Stones

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Purpose: The aim of this study is to evaluate the factors affecting treatment success in patients who underwent Shock wave lithotripsy (SWL) for ureter stones and to investigate the effect of Storz Medical Lithotripsy Index (SMLI) on treatment effectiveness in ureteric stones.

Method: Prospective data were collected on patients undergoing SWL treatment for ureter stones between January 2013 and May 2021. Stone location, number, and size were determined with Non contrast CT (NCCT) for all patients. All patients underwent SWL with a Storz Modulith SLK lithotripsy machine with local anaesthesia. The total amount of energy applied to the stone was calculated using the Storz Medical Lithotripsy Index (SMLI). All patients were evaluated for stone-free status by X-ray at least 2 weeks after treatment. The success of the procedure was defined as the patient being completely stone free (SF) or detection of residual fragments < 4 mm that did not require further treatment

Results: A total of 1199 patients with ureter stones were included in the study. The mean age of the patients was 43.11 ± 10.65 (18-73), and the mean BMI was 27.87±8.12(19.02-38.65). During SWL, 89.3% of patients demonstrated excellent pain tolerance (1070/1199). A total of 119 patients could not tolerate pain during SWL (10.7%). Treatment success was associated with fewer treatment sessions (2.04±1.64 vs. 2.50 ± 1.48; $p < 0.001$), smaller stone size (7.35±2.99 vs. 9.02 ± 3.81; $p < 0.001$) and higher SMLI/stone size (29.70 ± 17.48 vs. 24.98±16.01; $p < 0.001$). In the univariate and multivariate regression analysis, the factors affecting the success of the treatment were the number of sessions (OR: 1.147), stone size (OR: 1.112), SMLI/stone size (OR: 1.115) and pain tolerance (OR: 0.740).

Conclusion: In the treatment of ureteral stones with SWL, number of sessions, stone size, SMLI/stone size, and pain tolerance are the factors affecting success. SMLI per stone size is a statistically significant factor for predicting SWL success.

Keywords: urolithiasis; SWL; treatment; predictive factor; SMLI; ureteric stones

INTRODUCTION

Urolithiasis is one of the most common diseases treated by urologists[1]. In recent years, the prevalence of urolithiasis has increased to 10.6% in men and 7.1% in women. High recurrence rates (39% at 15 years) are seen in both genders[2]. Urinary stones have the potential to recur in two-thirds of patients within 20 years, and stone recurrence can be lifelong[3]. Therefore, with the important developments in technology, minimally invasive treatment options have gained great importance in order to minimize the cost and harms of repetitive treatments[4].

Numerous options are available for the treatment of urolithiasis, including shock wave lithotripsy (SWL), ureteroscopy, as well as open or laparoscopic procedures[5, 6]. The application of these treatment methods differs for each patient and the response to the treatment may be different for each patient[7,8].

SWL is a minimally invasive treatment method commonly used to treat patients with upper urinary tract stones. Stone clearance rates were determined between 69-96% for ureteral stones in high-volume centers[9]. Treatment success depends on appropriate patient selection, improved SWL efficacy, and optimal disease management. In the current literature, there are various reported factors that can affect stone clearance rates [10,11]. Clinical parameters such as the patient's body mass index, stone location, skin-to-stone distance, stone diameter or stone volume, and Hounsfield unit values are among the strong predictive parameters for treatment success[8,12,13].

In Storz Medical SWL devices, the total energy applied to the stone is also measured with a proprietary Storz Medical Lithotripsy Index (SMLI). There is very limited data about the effectiveness of treatment success according to the dose of applied energy[4]. The aim of this study is to evaluate the factors affecting treatment success in a large cohort of patients who underwent SWL and to investigate the effect of SMLI on treatment effectiveness.

METHODS

Patients who received SWL treatment for ureteral stones between January 2013 and May 2021 were included in

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Table 1. Patient demographics

		n=1199
Treatment Counts		2.18 ± 1.60(1-10)
Stone Size(mm)		7.85 ± 3.34(2-23)
Number of Shocks (median(IQR)		2790 (200-3000)
Energy Level		6.27 ± 1.32(1-8)
SMLI		193.98 ± 91.25
Radiation Dose (median(IQR)		480 (100-750)
Side	Right	498 (41.5%)
	Left	701 (58.5%)
Patient Position	Supine	1087 (90.7%)
	Prone	112 (9.3%)
Imaging	X-Ray	1179 (98.3%)
	Ultrasonud	20 (1.7%)
Site	Upper Ureter 671(55.9%)	
	Lower Ureter 528(44.1%)	

the study. Written informed consent was obtained from each patient. The study was designed in accordance with the Declaration of Helsinki.

Stones were detected with non-contrast computed tomography (NCCT). Patients with pregnancy, multiple kidney stones, active urinary infection, irregular coagulopathy and using anticoagulants were excluded from the study.

The study design is retrospective. The sample size was obtained with all patients who met the inclusion criteria between the specified dates.

Stone localization, number and stone size of the patients were determined with the help of NCCT. All patients were treated on a Storz Modulith SLK-F2 lithotripsy machine without anaesthesia. X-ray and ultrasound were used to target the stone. SWL was performed by one of the team of trained radiographers. The study protocol with a protocol of 4000 shocks at 2Hz.The total amount of energy applied to the stone was recorded using the Storz Medical Lithotripsy Index (SMLI). No patients had stents in situ and no medical expulsive therapy was given before or after the treatment.

Recording only the maximum energy level and the number of shocks in the treatment reports may be misleading and it may not be understood whether sufficient energy has been applied to the stone. SMLI was created by STORZ MEDICAL to control the applied energy.

SMLI refers to the energy applied during a shock wave therapy. SMLI gives a net number representing the total energy dissipated in an average area of 12 mm.

Typical values for SMLI observed in clinical practice range from 180-220 for most stones. However, depending on the individual stone characteristics, lower and higher values will suffice.

The number of shock waves, energy level, SMLI values, patient position, stone targeting method (X-ray or ultrasound), radiation dose received, and patient pain tolerance evaluations during SWL were recorded.

An experienced operator is required to provide pain control. While the pain tolerance of patients who can tolerate appropriate energy during ESWL is evaluated as excellent, lowering the energy level due to pain or interrupting the procedure is classified as pain intolerance[14].

All patients were evaluated for stone-free by X-ray at least 2 weeks after treatment. Ultrasonography or NCCT was used to assess stone free status. The success of the procedure was defined as the patient being stone free (SF) or detection of fragments < 4 mm.

Statistical analysis

Data were evaluated with SPSS 25.0 (IBM, NY, USA) statistics program. The normality of the distribution of the data was questioned with the Kolmogorov-Smirnov test and Q-Q plot. Independent sample t-test and Mann Whitney U test were used. Factors affecting stone-free success were evaluated with univariate and multivariable logistic regression analysis(Model: Tretment Counts, Stone Size(mm), Number of Shocks, Energy Level, SMLI, SMLI/Stone Size, Radiation Dose, Side (Ref:right), Patient Position(Ref:supine), Imaging (Ref:X-ray), Site (Ref:Lower ureter), Pain Tolerance (Ref:Excellent); (assumption linearity 69.9%)). ROC curves were created and areas under the curves (AUC) were calculated to compare the predictive power of different features. Significant *p* value was determined as < 0.05.

RESULTS

A total of 1199 patients with ureter stones were included in the study. The mean age of the patients was 43.11 ± 10.65(18-73), and the mean BMI was 27.87 ± 8.12(19.02-38.65). During SWL, 89.3% of patients demonstrated excellent pain tolerance (1070/1199). A total of 119 patients could not tolerate pain during SWL (10.7%). Demographic characteristics of the patients are given in **Table 1**.

During SWL, 89.3% of patients demonstrated excellent pain tolerance (1070/1199). A total of 119 patients could not tolerate pain during SWL (10.7%). The procedure was mostly performed under X-ray guidance

Table 2. Comparison of the factors affecting the success of ESWL

	`	Succesfull(n=838)	Unsuccesfull(n=361)	*p*
Treatment Counts		2.04 ± 1.64	2.50 ± 1.48	< 0.001
Stone Size(mm)		7.35 ± 2.99	9.02 ± 3.81	< 0.001
Number of Shocks		2822.40 ± 1938.60	2696.99 ± 906.63	0.240
Energy Level		6.29 ± 1.33	6.24 ± 1.32	0.574
SMLI		194.19 ± 92.04	193.48±89.53	0.920
SMLI/Stone Size		29.70 ± 17.48	24.98 ± 16.01	< 0.001
Radiation Dose		479.47 ± 393.23	466.48 ± 370.46	0.594
Side	Right	355 (42.4%)	143 (39.6%)	0.375
	Left	483 (57.6%)	218 (60.4%)	
Patient Position	Supine	765 (91.3%)	322 (89.2%)	0.279
	Prone	73 (8.7%)	39 (10.8%)	
Imaging	X-Ray	823 (98.2%)	356 (98.6%)	0.585
	Ultrasonud	6(1.8%)	4(1.4%)	
Site	Upper Ureter	470(56.1%)	224(62%)	0.032
	Lower Ureter	368 (43.9%)	137 (38%)	

Table 3. Univariate and multivariable analysis

		Univariable Analysis			Multivariable Analysis	
	p	OR	CI %95	p	OR	CI %95
Tretment Counts	0.008	1.120	1.077-1.195	< 0.001	1.147	1.090-1.207
Stone Size(mm)	< 0.001	1.163	1.085-1.146	<0.001	1.112	1.084-1.141
Number of Shocks	0.162	1.000	1.000-1.002			
Energy Level	0.593	0.961	1.046-1.316			
SMLI 0.681	0.998	0.997-1.000				
SMLI/Stone Size	0.001	1.001	0.998-1.003	< 0.001	1.115	0.997-1.122
Radiation Dose	0.976	1.002	0.978-1.012			
Side (Ref:right)	0.889	0.937	0.783-1.121			
Patient Position(Ref:supine)	0.425	0.835	0.737-1.112			
Imaging (Ref:X-ray) 0.321	0.749	0.410-1.368				
Site (Ref:Lower ureter)	0.227	1.331	0.979-1.809			
Pain Tolerance (Ref:Excellent)	< 0.001	0.716	0.625-0.821	< 0.001	0.740	0.650-0.843

(98.3%) and in the supine position (90.7%).

Complete stone clearance was achieved in 50.4% (604/1199) of the patients. The number of patients with clinically insignificant residual fraction were 228 (19.5%). Overall success rate was therefore 69.9%. A total of 361 patients (30.1%) did not respond to treatment.

Treatment success was associated with fewer treatment sessions (2.04 ± 1.64 vs. 2.50 ± 1.48; $p < 0.001$), smaller stone size (7.35 ± 2.99 vs. 9.02 ± 3.81; $p < 0.001$) and higher SMLI/stone size (29.70 ± 17.48 vs. 24.98 ± 16.01; $p < 0.001$) (**Table 2**). Better success and fewer treatment sessions were seen in the patient group with better pain tolerance ($p = 0.001$). A significant positive correlation was found between SMLI and the number of shocks and energy levels (r = 0.567 for number of shocks, r = 0.409 for energy levels).

In the univariate and multivariate regression analysis, the factors affecting the success of the treatment were the number of sessions (OR: 1.147), stone size (OR: 1.112), SMLI/stone size (OR: 1.115), and pain tolerance (OR: 0.740) (Table 3).

In the ROC Curve analysis for SMLI/stone size, a cut-off value of 18.92 has a sensitivity of 74% and a specificity of 66.9% (AUC: 0.699, CI 95%: 0.588-0.712) .

DISCUSSION

This study, in line with other research demonstrates that the success of SWL depends on stone size, number of treatment sessions. Patients who can tolerate pain have fewer sessions and their success in treatment increases. This study is the first to evaluate the value of SMLI and SMLI/stone size.

SWL is an effective, minimally invasive treatment method with similar effects and complication rates as retrograde urethrography in the treatment of many stones[12,15]. Among the factors affecting the success of SWL, there are many factors related to the technical features of the device, stone characteristics and the structure of the patient[10]. According to the literature, while the success of SWL is 80-85% in stones less than 20 mm, the success falls between 30-65% in stones over 20 mm[16,17]. The decrease in the chance of success, especially in lower pole stones, was seen as a challenge for SWL. However, several studies have demonstrated good outcomes with lower pole stones[4,18-20]. In our study, the success of SWL in lower calyceal stones was found to be 65.5%.

The patients' ability to tolerate pain during SWL both reduces the number of sessions and affects the success of the treatment. Patients that tolerate the treatment well allow better stone targeting and reduced stone excursion due to respiration and patient movement. An experienced operator is required to ensure that adequate coupling is achieved for pain control. It is also extremely important for the operator to increase the voltage in gradual increments to aid the development of pain tolerance. Our study is based on the fact that a patient’s pain tolerance affects SWL treatment and its clinical outcomes. Energy levels are reduced for patients with lower pain threshold making total stone disintegration less likely. It shows that under simple non-opioid analgesia, there are a number of independent predictors for increased pain tolerance during SWL. This results in better stone-free status in a reduced number of SWL sessions[21]. In our study, it was determined that the treatment success was better in the group that tolerated the pain and indirectly the number of sessions was less. With the widespread use of NCCT, the burden of urinary tract stones has been evaluated more easily. The size of the stone is typically measured as its maximal diameter. Due to the irregular structure of the stones, 3D stone volume measurements have also been used [22]. In a study in which the effect of stone burden on the success of SWL was evaluated, a significant difference was found between the mean stone volumes in the successful and fragmented groups. For stone volumes over 500mm3, the success rate dropped to 27% [23]. In a similar study, stone size was determined as the most important parameter in predicting the success of SWL [24]. In our study, stone size was found to be larger in the group with unsuccessful SWL treatment ($p < 0.001$, OR: 1.112).

SMLI is a measure of total power delivered by the machine in a treatment session

This reflects ramping up or down of the energy settings throughout the treatment and any adjustments in frequency (Hz). It does not reflect how much power hits the stone. i.e. even if the targeting is not accurate it could still record a high SMLI. Assuming that a consistent number of shockwaves accurately target the stone, it would be expected that higher SMLIs would be associated with greated treatment success. In a small study of 109 patients the SMLI/stone size ratio was significant[4]. However, the sample size of the study is small. In this study, a cut-off value for SMLI was not specified and it was argued that it could be done in further studies. In our study conducted with a total of 2429 patients, it was found that the SMLI value had an independent effect on the success of SWL. Successful SMLI/stone size threshold value was determined as 20.72. With these findings, increasing the power proportionally to the stone size and determining the effective power in patients who underwent SWL will significantly affect the success of stone-free.

The study is the first in which SMLI was evaluated and a threshold score was found to be a factor affecting the success of SWL. The study has some limitations. The first of these is that the study was conducted retrospectively. Another limitation is the short follow-up period after SWL. Due to the heterogeneity of the patients, the sensitivity of the SMLI cut-off score was low. Further studies evaluating the effect of SMLI in more homogeneous patient groups are needed.

CONCLUSIONS

In the treatment of urinary tract stones with SWL, stone site, stone size, SMLI, and pain tolerance are the factors affecting treatment success. SMLI is a surrogate for the power delivered by the Storz Modulith lithotripter and may have some predictive value in treatment success.

CONFLICT OF INTEREST

None as declared by the authors.

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