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ORIGINAL ARTICLE

# The New Lithotripsy Index predicts success of shock wave lithotripsy

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## Abstract

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

**Methods** Prospective data were collected on patients undergoing SWL treatment for kidney 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 without anaesthesia. The total amount of energy applied to the stone was calculated using the 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 or the detection of residual fragments < 4 mm that did not require further treatment.

**Results** A total of 1230 patients with kidney stones were included in the study. The mean age of the patients was 42.33 ± 11.78 (18–75), and the mean BMI was 28.47 ± 8.78 (19.25–38.52). During SWL, 75.6% of patients demonstrated excellent pain tolerance (930/1230). A total of 116 patients could not tolerate the pain during SWL (9.4%).

Treatment success was associated with fewer treatment sessions (2.34 ± 1.75 vs. 2.90 ± 2.04; $p < 0.001$), smaller stone size (7.52 ± 3.29 vs 8.60 ± 3.93; $p < 0.001$) and higher SMLI/stone size (25.11 ± 13.63 vs. 22.27 ± 14.50; $p < 0.001$). In the univariate and multivariate regression analysis, the factors affecting the success of the treatment were the number of sessions (OR 1.170), stone size (OR 1.142), number of shocks (OR 1.005), SMLI/stone size (OR 1.024) and pain tolerance (OR 0.692).

**Conclusion** In the treatment of kidney stones with SWL, stone site, 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

## 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, percutaneous nephrolithotomy (PCNL), as well as open or laparoscopic procedures. The application of these treatment methods differs for each patient and the response to the treatment may be different for each patient [5, 6].

SWL is a minimally invasive treatment method commonly used to treat patients with upper urinary tract stones. In high-volume centres, stone clearance percentages of 86–89%, 71–83%, 73–84% and 37–68% were determined for stones in the renal pelvis, upper calyx, middle calyx and lower calyx, respectively [7]. 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

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rates [8–10]. 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 [11, 12].

In Storz Medical SWL devices, the total energy applied to the stone is also measured with a proprietary Storz Medical Lithotripsy Index (SMLI). There are 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 kidney stones between January 2013 and May 2021 were included in 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.

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 teams of trained radiographers. The study protocol with a protocol of 4000 shocks at 2 Hz. 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 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 to 220 for most stones. However, depending on the individual stone characteristics, lower and higher values will suffice.

For example, a treatment report showing 4000 shocks at level 5.0 can have two different meanings. In the first case, nearly all shocks, except the increasing period of energy, have been applied at level 5.0; this will be an SMLI of approximately 268 (Fig. 1A). In the second case level 5.0 was reached only during the increasing period and due to the pain of the patient the treatment was performed at energy level 3.0. This corresponds to an SMLI of approximately 168. In the second case, the stone received significantly lower total energy and the fragmentation can be poor (Fig. 1B).

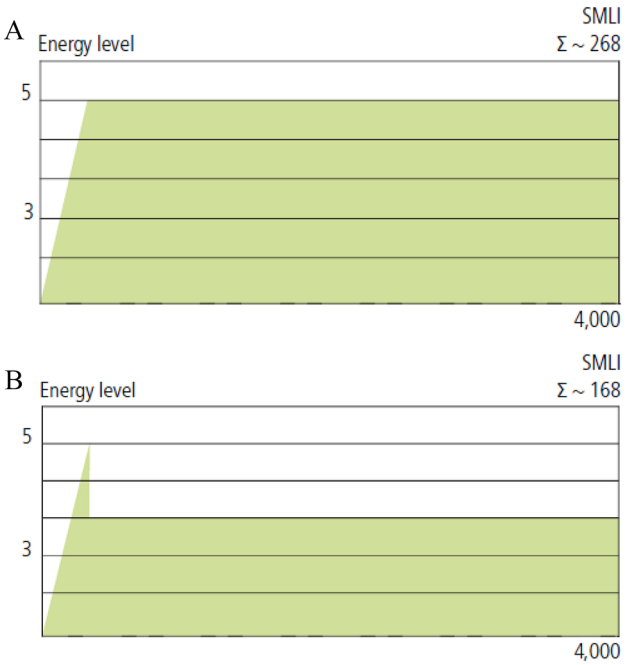


**Fig. 1** **A**, **B** SMLI values for cases 1 and 2

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

A routine analgesic protocol was not applied to the patients. They were informed that they could use paracetamol or NSAID in case of pain after the procedure. In case of severe pain, they were advised to apply to the emergency department.

All patients were evaluated for stone-free by X-ray at least 2 weeks after treatment. Also, NCCT was used to assess stone-free status. The success of the procedure was defined as the patient being stone free (SF) or the 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. Independent sample *t* test and Mann–Whitney *U* test were used. Factors affecting stone-free success were evaluated with univariate and multivariate logistic regression analysis.

ROC curves were created and areas under the curves (AUC) were calculated to compare the predictive power of different features. A significant $p$ value was determined as $<0.05$.

## Results

A total of 1230 kidney stone patients were included in the study. Of the patients, 650 were male and 580 were female. The mean age of the patients was $42.33 \pm 11.78$ (18–75), and the mean BMI was $28.47 \pm 8.78$ (19.25–38.52). In 42.8% of the patients, the stone was on the right side (526/1230) and on the left side in 57.2%. The patients received an average of $2.54 \pm 1.88$ (1–13) sessions of SWL. The mean stone size was $7.90 \pm 3.57$ (5–25) mm, the number of shocks was $2875.71 \pm 902.32$ (358–4000), the total energy applied was $5.02 \pm 0.99$ (1–8) joules and the radiation dose was $575.24 \pm 464.38$ mGy. The mean SMLI was $165.94 \pm 75.09$ and the mean SMLI/stone size was $24.10 \pm 14.01$ (Table 1).

During SWL, 75.6% of patients demonstrated excellent pain tolerance (930/1230). A total of 116 patients could not tolerate pain during SWL (9.4%). The procedure was mostly performed under X-ray guidance (90.7%) and in the supine position (92.4%).

Complete stone clearance was achieved in 30.9% (380/1230) of the patients. The number of patients with clinically insignificant residual fraction was 409 (33.3%). The overall success rate was therefore 64.2%. A total of 439 patients (35.7%) did not respond to treatment. While the highest success rate was in lower ureter stones (73.9%), the success rate was 65.5% in lower calyx stones.

Treatment success was associated with fewer sessions ($2.34 \pm 1.75$ vs. $2.90 \pm 2.04$; $p<0.001$), smaller stones ($7.52 \pm 3.29$ vs $8.60 \pm 3.93$; $p<0.001$) and higher SMLI/stone size ($25.11 \pm 13.63$ vs. $22.27 \pm 14.50$; $p<0.001$) (Table 2). Better success and fewer treatment sessions were seen in the patient group with better pain tolerance ($p=0.005$). A significant positive correlation was found between SMLI and the number of shocks and energy levels ($r=0.509$ for number of shocks, $r=0.324$ for energy levels).

In the univariate and multivariate regression analysis, the factors affecting the success of treatment were the number of treatment sessions (OR 1.170), stone size (OR 1.142), number of shocks (OR 1.005) SMLI/stone size (OR 1.024) and pain tolerance (OR 0.692) (Table 3).

In the ROC Curve analysis for SMLI/stone size, a cut-off value of 19.68 has a sensitivity of 69% and a specificity of 65.3% (AUC 0.671, CI 95% 0.567–0.698; $p<0.001$).

## Discussion

This study in line with other research demonstrates that the success of SWL depends on stone size, stone localization and number of treatment sessions. Patients who can tolerate the pain have fewer sessions and their success in treatment

**Table 1** Patient demographics

| | $n=1230$ |
|---|---|
| Treatment counts | $2.54 \pm 1.88$ (1–13) |
| Stone size(mm) | $7.90 \pm 3.57$ (5–25) |
| Number of shocks | $2875.71 \pm 902.32$ (358–4000) |
| Energy level | $5.02 \pm 0.99$ (1–8) |
| SMLI | $165.94 \pm 75.09$ |
| SMLI/stone size | $24.10 \pm 14.01$ |
| Radiation dose | $575.24 \pm 464.38$ |
| Side | |
| Right | 526 (42.8%) |
| Left | 704 (57.2%) |
| Patient position | |
| Supine | 1136 (92.4%) |
| Prone | 94 (7.6%) |
| Imaging | |
| X-Ray | 1116 (90.7%) |
| Ultrasound | 114 (9.3%) |
| Site | |
| Lower calyx | 558 (45.4%) |
| Middle calyx | 475 (38.6%) |
| Upper calyx | 197 (16%) |

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

| | Succesfull | Unsuccesfull | $p$ |
|---|---|---|---|
| Treatment counts | $2.34 \pm 1.75$ | $2.90 \pm 2.04$ | $<0.001$ |
| Stone size (mm) | $7.52 \pm 3.29$ | $8.60 \pm 3.93$ | $<0.001$ |
| Number of shocks | $2904.15 \pm 890.25$ | $2824.46 \pm 922.48$ | 0.138 |
| Energy level | $5.04 \pm 0.96$ | $4.98 \pm 1.03$ | 0.293 |
| SMLI | $167.62 \pm 73.35$ | $162.91 \pm 78.13$ | 0.292 |
| SMLI/stone size | $25.11 \pm 13.63$ | $22.27 \pm 14.50$ | $<0.001$ |
| Radiation dose | $582.67 \pm 415.83$ | $561.88 \pm 541.25$ | 0.451 |
| Side | | | |
| Right | 338 | 188 | 0.511 |
| Left | 453 | 251 | |
| Patient position | | | |
| Supine | 729 | 407 | 0.823 |
| Prone | 62 | 32 | |
| Imaging | | | |
| X-Ray | 714 | 402 | 0.159 |
| Ultrasound | 72 | 34 | |
| Site | | | |
| Lower calyx | 366 | 192 | 0.168 |
| Middle calyx | 308 | 167 | |
| Upper calyx | 117 | 80 | |

**Table 3** Univariate and multivariate analysis

| | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| | *p* | OR | CI %95 | *p* | OR | CI %95 |
| Treatment counts | < 0.001 | 1.157 | 1.081–1.238 | < 0.001 | 1.170 | 1.090–1.207 |
| Stone size (mm) | < 0.001 | 1.123 | 1.057–1.193 | < 0.001 | 1.142 | 1.084–1.174 |
| Number of shocks | 0.016 | 1.012 | 0.999–1.002 | 0.001 | 1.005 | 1.000–1.225 |
| Energy level | 0.432 | 1.190 | 0.880–1.351 | | | |
| SMLI | 0.052 | 0.998 | 0.997–1.000 | | | |
| SMLI/stone size | 0.018 | 1.016 | 0.995–1.037 | 0.006 | 1.024 | 0.997–1.148 |
| Radiation dose | 0.788 | 1.002 | 0.978–1.012 | | | |
| Side (ref: right) | 0.475 | 0.937 | 0.783–1.121 | | | |
| Patient position (ref: supine) | 0.425 | 0.835 | 0.737–1.112 | | | |
| Imaging (ref: X-ray) | 0.347 | 0.749 | 0.410–1.368 | | | |
| Site (ref: lower ureter) | 0.068 | 1.331 | 0.979–1.809 | | | |
| Pain tolerance (ref: excellent) | < 0.001 | 0.641 | 0.530–0.776 | < 0.001 | 0.692 | 0.650–0.843 |

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 [11, 13]. 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 [8]. According to the literature, while the success of SWL is 80–85% in stones less than 20 mm, the success falls between 30 and 65% in stones over 20 mm [14–16]. 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, 17–19]. In our study, the success of SWL in lower calyceal stones was found to be 65.5%.

The patients' ability to tolerate the 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. This results in better stone-free status in a reduced number of SWL sessions [20]. 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 [21]. 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 500 $mm^3$, the success rate dropped to 27% [22]. In a similar study, stone size was determined as the most important parameter in predicting the success of SWL [23]. 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 the 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. If a consistent number of shockwaves accurately target the stone, it would be expected that higher SMLIs would be associated with greater treatment success [24]. 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 a study using SMLI to evaluate complications after ESWL [25], excessive SMLI was a risk factor, but the severity of hematoma was not correlated with SMLI. Excessive SMLI may be a risk factor for renal hematoma in frail or small patients. 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. The successful SMLI/stone size threshold value was determined as 19.68. 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. The fact that Hounsfield units were not evaluated is another limitation of the study. It can be used with SMLI Storz brand lithotripters and is not compatible with other brand

ESWL devices. Further studies evaluating the effect of SMLI in more homogeneous patient groups are needed.

## Conclusion

In the treatment of urinary tract stones with SWL, stone site, stone size, SMLI, and pain tolerance are the factors affecting treatment success.

The SMLI, an assessment of the power provided by the Storz Modulith lithotripter, is a useful index of applicability to the stone and may have some predictive value in treatment success.

**Author contributions** SKK: Protocol/project development, Data collection or management, Manuscript writing/editing. C Lovegrove: Data analysis. MS: Data collection or management. BT: Protocol/project development, Manuscript writing/editing.

**Data availability** All data conducted and used for this study is stored and available for sharing whenever this is necessary. Corresponding author will be responsible for responding to such requests.

### Declarations

**Conflict of interest** None.

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