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ARTICLE

Prediction of stone-free rates following extracorporeal shockwave lithotripsy in a contemporary cohort of patients with stone densities exceeding 1000 HU

Wilmar Azal Neto[a], Leonardo Oliveira Reis[a,b] and Renato Nardi Pedro[a]

[a]Department of Urology, State University of Campinas, Unicamp, Campinas, Brazil; [b]Department of UroScience, Pontifical Catholic University of Campinas, PUC-Campinas, Campinas, Brazil

ABSTRACT

Purpose: Nephrolithiasis is a common urologic problem, and its incidence is increasing. Shockwave Lithotripsy (SWL) has better results for patients with stones <1000 HU. We attempted to identify SWL stone-free (SF) predictors for >1000 HU stones.

Methods: From January 2013 to September 2019, patient shared decision consecutive SWL for the treatment of a single >1000 HU renal stone diagnosed by non-contrast computed tomography (NCCT). Endpoints: Fragmentation and SF or clinically insignificant residual fragments ≤ 4 mm at 4 weeks. Age, gender, stone side, location, size and density, number and average energy (Joules) of shocks were explored on uni- and multivariate regression analysis.

Results: All sixty-one patients included were diagnosed with renal stone between 5 and 20 mm (maximum length) and underwent one SWL session only: 62.3% males, median age 48 (21–80) years, mean stone size 9.43 ± 2.9 mm (6.0–20.0), mean density 1210 ± 135 HU (1000–1558). There were 39 (63.9%) cases of SF, 16 (26.2%) of partial success and six (9.8%) of no success. Stone size was the only independent predictor of fragmentation, OR = 1.83, 95% CI = 1.32–2.55, $p = 0.0003$, and SF OR = 1.91, 95% CI = 1.31–2.78, $p = 0.008$. The best discriminatory stone size on ROC analysis was 1 cm.

Conclusion: Stone size was the only significant success predictor in our cohort, with 76% SF rate for stones <1 cm in 4 weeks follow-up, supporting that renal stones >1000 HU may be suitable to SWL.

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Introduction

Urolithiasis is a common and increasing urologic problem [1,2], correlated with obesity, poor dietary habits, hypertension and diabetes that are also rising worldwide and can explain the ascendant slope of kidney stone prevalence. It has high recurrence rates of up to 40–50% in 11 years, and about 20–30% of the patients with nephrolithiasis have to undergo interventional treatment [3–6].

Currently, minimally invasive procedures are the main treatments for this disease, such as endoscopic approaches and extracorporeal shockwave lithotripsy (SWL) in which the waves are concentrated, transmitted through the liquid and directed to cause fragmentation of the urinary calculi, with posterior elimination of the fragments.

Even though the number of endourological procedures has risen in the last few years [7–9], SWL remains a first-line treatment option for renal stones <20 mm or ≤ 10 mm in lower pole [1,2]. SWL not only reaches stone-free (SF) rates up to 90% when indicated for favorable cases but also corresponds to the non-invasive interventional treatment associated with the best cost-benefit and lowest morbidity [10–12]; therefore, it has presented an overall absolute growth in number as well; yet, SWL share of global interventional kidney stone treatment has decreased by 14.5% due to many factors including provider compensation and market pressures [7].

SWL efficiency is negatively impacted largely by stone high burden and density, specially >1000 Hounsfield units (HU) [10–12], genitourinary malformations, ureteral stent, and obesity or patient body habitus [1,2]. Scoring systems incorporate the main established metrics such as stone density and volume and body habitus by skin-to-stone distance (SSD) to predict SWL outcomes [13]. Nonetheless, the evidence is limited to small retrospective short-term cohorts and few studies include enough high-density stones treated by SWL.

Acknowledging peculiarities of each active stone treatment and recent guidelines in a patient shared decision context, we attempt to identify SWL success predictors in >1000 HU stones.

Methods

We retrospectively evaluated data from consecutive patients who actively participated in the decision-making process and have picked SWL – one session only – over endoscopic alternatives for the treatment of a single HU >1000 renal stone from January 2013 to September 2019 in our center.

CONTACT Leonardo Oliveira Reis reisleo.l@gmail.com Professor Livre Docente, Department of UroScience, Pontifical Catholic University of Campinas, PUC-Campinas, Campinas, SP, Brazil, Av. John Boyd Dunlop – Jardim Ipaussurama, Campinas CEP: 13034-685, Brazil

Before the procedure, all patients underwent a non-contrast computed tomography (NCCT) to access stone location, size, density, and skin-to-stone distance (SSD).

Exclusion criteria were patients with multiple renal calculi, congenital genitourinary malformations, ureteral stent, BMI (body mass index) $\geq 30\,kg/m^2$, SSD $> 10\,cm$, urinary tract infection (UTI), pregnancy, coagulopathy, abdominal aneurysm $> 4.0\,cm$, anatomic or functional obstruction of the collecting system or ureteral obstruction distal to the stone [1,2].

All SWLs were performed with the same electromagnetic lithotripter (SIEMENS Variostar®, Erlanger, Germany) by the same senior urologist, under intravenous sedation conducted by an anesthesiologist. Intra-operative stone targeting was accomplished by ultrasound (US, SIEMENS G20 and X300) and fluoroscopy was done when needed.

SWL energy level protocol was: lowest energy setting (0.1 Joules, J) from 0–100 shockwaves, then gradually increasing 0.2 J in energy at every additional hundred shocks so that when 500 shockwaves were delivered the related energy would be 1.0 J. From this point on, energy increase was 0.3 J for every new 150 shockwaves until the minimum energy for stone fragmentation seen on US and fluoroscopy or maximum 3000 shockwaves or 3.5 J energy.

Fragmentation was constantly monitored by US and fluoroscopic shots were done at the beginning, middle and at the end of the procedure, for better appreciation of stone fragmentation [2] and classified as complete (stone broke into small fragments), absent (stone remained whole) and partial (fragmentation was evident but not uniform). After the procedure, patients stayed in the recovery room under medical observation for around 2 h.

All patients were followed up for symptoms (i.e. pain, macroscopic hematuria, UTI) 1 week after SWL and then 3 weeks later to evaluate SWL success with plain radiography of kidneys, ureters and bladder (KUB) and US.

The accessed variables were: age, gender, side (left/right), location (upper, mid, lower and pielic), stone size (mm, continuous and categorical), stone density (HU, continuous and categorical), number of shocks (continuous and categorical), and average energy (continuous and categorical).

Outcomes were: (a) stone free (SF) or clinically insignificant residual fragments ($\leq 4\,mm$); (b) "partial success" if residual fragments $> 4\,mm$; and (c) "no success" if no variation in stone size.

We used Statistic Analysis System (SAS) for Windows, 9.4 version, uni- and multivariate logistic regression analysis to discover potential outcome predictors, ROC analysis to define cut-off and chi-square test to compare groups. The significance level adopted was 5%.

Results

The study included 61 patients, 62.3% males and 37.2% females, median age 48 years (21–80). Stone mean size 9.43 ± 2.9 mm (6.0–20.0) and density 1210 ± 135 HU (1000–1558), mean delivered shocks 2199.18 ± 258.60 (1700–2750) and energy 1.94 ± 0.27 J (1.4–2.7) (Table 1). There were no complications reported.

Table 1. Demographic data.

Patients (*n*)	61
Age (median, SD)	48.44 ± 11.62 (21–80)
Gender	
Male (%)	38 (62.3)
Female (%)	23 (37.7)
Side	
Right (%)	30 (49.2)
Left (%)	31 (50.8)
Stone location	
Lower calyx (%)	12 (19.7)
Mid calyx (%)	16 (26.2)
Superior calyx (%)	13 (21.3)
Renal pelvis (%)	20 (32.8)
Stone size (mm)	9.4 ± 2.9 (6.0–20.0)
Stone density (HU)	1210 ± 135 (1000–1558)
1000–1150 (%)	25 (41)
1150–1300 (%)	23 (37.7)
>1300 (%)	13 (21.3)
Shocks (*n*)	2199 ± 258 (1700–2750)
<2000 (%)	22 (36.1)
2000–2500 (%)	37 (60.6)
>2500 (%)	2 (3.3)
Energy (mean, J)	1.94 ± 0.27 (1.4–2.7)
>2 (%)	38 (62.3)
<2 (%)	23 (37.7)
Fragmentation	
Absent (%)	4 (6.6)
Partial (%)	14 (22.9)
Complete (%)	43 (70.5)
Achievement	
No success (%)	6 (9.8)
Partial success (%)	16 (26.2)
Stone free (%)	39 (63.9)

During the procedure 43 (70.5%) patients had complete stone fragmentation and, among those with incomplete stone fragmentation, 14 (22.9%) showed partial fragmentation and four (6.6%) no fragmentation. At 4 weeks follow-up, there were 39 (63.9%) SF cases and, among the non-SF, 16 (26.2%) showed partial success and six (9.8%) no success. Complete fragmentation during SWL failed in predicting SF at 4 weeks follow-up in five of 43 patients (11.6%). Table 2 shows results based on fragmentation (complete versus incomplete) and success (SF versus non-SF).

Table 3 describes factors impacting stone free (SF) and complete fragmentation outcomes at univariate analysis logistic regression. Stone size on multivariate analysis was the only complete fragmentation, OR = 1.83, 95% CI = 1.32–2.55, $p = 0.0003$, and SF, OR = 1.91, 95% CI = 1.31–2.78, $p = 0.008$, independent predictors.

The best discriminatory stone size on ROC analysis was 1 cm, AUC = 0.8045, 74.42% and 72.22% sensitivity and specificity, respectively. Stones < 1 cm showed significantly more complete fragmentation in 32 (86.5%, $p = 0.0007$) and SF in 28 (75.7%, $p = 0.0177$), compared to 11 (45.8%) of fragmentation and SF in stones ≥ 1 cm, respectively (Table 4).

Discussion

According to a recent systematic review that evaluated worldwide trends of urinary stone treatment for the past 20 years, in Brazil SWL showed an increase in its share of the total disease therapy – despite the decrease in the world's share [1].

Prior studies have described stone density as an independent predictor of success, and kidney stone treatment guidelines consider a medium attenuation value > 1000 HU associated with unfavorable results [1,2,14–16], discouraging and limiting literature on the issue. Additionally, many backstage aspects involved in the urolithiasis treatment, such as provider compensation and market pressures, might play against the non-invasiveness, low morbidity, patient preference and cost-effectiveness of SWL over endourological alternatives.

Even though guidelines define 1000 HU as a reasonable threshold value, SWL studies report different stone densities (750–1350 UH) that could be suitable for this procedure [17–20]. Wiesenthal et al. [21], in a multivariate analysis, found that calculi attenuation < 900 HU were associated with favorable outcomes, while in a prospective study Ouzaid et al. [22] affirmed that stones up to 970 HU were associated with better SWL outcomes; finally, El-Assmy et al. [23] concluded that 1000 HU was their cut-off value for considering SWL.

Joseph et al. [24] reported an SF rate of 55% for stones > 1000 HU in a 6-week follow-up period, this finding was similar to another series published by Abdelhamid et al. [15], who demonstrated SF of 52% for stones > 1000 HU. Our cohort showed a similar, although higher, overall SF rate of 63.9% in 4 weeks follow-up, which might be explained by SWL protocol and operator experience, in addition to our exclusion criteria of SSD < 10 cm and BMI ≤ 30. More importantly, the present study demonstrated that SWL for stones > 1 cm with > 1000 HU failed in more than half of the cases (54.2%); nevertheless, the SF rate can be as good as 76% for stones < 1 cm with > 1000 HU.

It has been published that a higher stone burden is associated with worse SWL outcomes [15,16]. Abdelhamid et al. [15], in a prospective study, pointed out that stone sizes of 10.8 ± 3.9 mm had better SWL SF rates than those of 13.7 ± 4.4 mm. Similarly, Nakasato et al. [18] found that maximum stone length was a predictor of SWL success, by showing a mean stone length of 10.4 mm presenting better SF rates compared to 14.0 mm.

A recent study has claimed that kidney stone features such as density and size might be more important than renal anatomy itself to predict SWL effectiveness [25], and Elkoushy et al. [26] reported that SWL SF rates were higher in patients with smaller (8.3 ± 3.5 vs. 13.6 ± 5.4 mm, $p < 0.001$) and lower density stones (675 ± 254 vs. 1075 ± 290 HU, $p < 0.001$), concluding that stones < 10 mm resulted in significantly greater SF rates than stones ≥ 10 mm (82.5% vs. 70.7%, $p < 0.02$).

Interestingly, our outcomes of 75.7% SF were as high as those of the Elkoushy et al. study for calculi < 10 mm, even

Table 2. Results based on fragmentation and success (SF).

	Fragmentation		Achievement	
	Incomplete *n* (%)	Complete *n* (%)	Non-SF *n* (%)	Stone free (SF) *n* (%)
Gender				
Male	12 (66.7)	26 (60.5)	15 (68.2)	23 (59.0)
Female	6 (33.3)	17 (39.5)	7 (31.8)	16 (41.0)
Side				
Right	11 (61.1)	20 (46.5)	13 (59.1)	18 (46.1)
Left	7 (38.9)	23 (53.5)	9 (40.9)	21 (53.8)
Stone location				
Lower calyx	3 (16.7)	9 (20.9)	6 (27.3)	6 (15.4)
Mid calyx	5 (27.8)	11 (25.6)	5 (22.7)	11 (28.2)
Upper calyx	2 (11.1)	11 (25.6)	3 (13.6)	10 (25.6)
Renal pelvis	8 (44.4)	12 (27.9)	8 (36.4)	12 (30.8)
Density (HU)				
1000–1150	5 (27.8)	20 (46.5)	8 (36.3)	17 (43.6)
1150–1300	7 (38.9)	16 (37.2)	8 (36.4)	15 (38.5)
>1300	6 (33.3)	7 (16.1)	6 (27.3)	7 (17.9)
Mean Energy (J)				
≤2	10 (55.6)	28 (65.1)	13 (59.1)	25 (64.1)
>2	8 (44.4)	15 (34.9)	9 (40.9)	14 (35.9)
Shocks (*n*)				
≤2000	8 (44.4)	14 (32.6)	9 (40.9)	13 (33.3)
>2000	10 (55.6)	29 (67.4)	13 (59.1)	26 (66.7)
Size (cm)				
<1	5 (13.5)	32 (86.5)	9 (24.3)	28 (75.7)
≥1	13 (54.2)	11 (45.8)	13 (54.2)	11 (45.8)

Table 4. Results based on size vs. fragmentation vs. achievement ($p = 0.0007$ and 0.0177, respectively).

	Fragmentation		Achievement	
Stone size (cm)	Incomplete *n* (%)	Complete *n* (%)	Non-SF *n* (%)	Stone free (SF) *n* (%)
<1 ($n = 37$)	5 (13.5)	32 (86.5)	9 (24.3)	28 (75.7)
≥1 ($n = 24$)	13 (54.2)	11 (45.8)	13 (54.2)	11 (45.8)
Total = 61	18	43	22	39

Table 3. Factors impacting stone free (SF) and complete fragmentation outcomes at univariate analysis – logistic regression.

		Stone free (SF)		Complete fragmentation	
Variable	Category	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)
Age	continuous	0.20	1.03 (0.98–1.08)	0.66	1.01 (0.96–1.06)
Gender	M × F	0.48	1.49 (0.50–4.48)	0.65	1.31 (0.41–4.15)
Side	R × L	0.33	1.68 (0.58–4.85)	0.30	1.81 (0.59–5.54)
Stone location	RP × LC × MC × UC	0.53	3.33 (0.60–18.54)	0.51	1.83 (0.25–13.47)
Size (cm)	continuous	**0.002**	**1.52 (1.17–1.97)**	**0.0003**	**1.83 (1.32–2.55)**
Density (HU)	continuous	0.30	1.00 (1.00–1.01)	0.15	1.00 (1.00–1.01)
	<1150 × 1150–1300	0.68	1.13 (0.34–3.76)	0.26	1.75 (0.47–6.57)
	<1150 × >1300		1.82 (0.46–7.22)		3.43 (0.79–14.85)
Mean Energy (J)	continuous	0.82	1.25(0.18–8.85)	0.46	2.17 (0.27–17.19)
	≤2 × >2	0.70	1.24 (0.43–3.610	0.48	1.49 (0.49–4.59)
Shocks (*n*)	continuous	0.89	1.00 (1.00–1.00)	0.80	1.00 (1.00–1.00)
	≤2000 × >2000	0.55	1.38 (0.47–4.08)	0.38	1.66 (0.54–5.12)

OR, Odds ratio; CI, confidence interval; M, male; F, female; R, right; L, left; RP, renal pelvis; LC, lower calyx; MC, middle calyx; UC, upper calyx.

though all patients in our group had >1000 HU stones, while for stones ≥ 10 mm our SF rate goes down to 45.8%.

While some authors preferred to evaluate also stone volume or surface area, the rationale is the same, once the stone size is a surrogate parameter for the stone burden [27]. Buchholz et al. [28] reported that the maximum stone length accurately reflects the size of a renal stone. Therefore, the measurement of maximum length, as generally practiced, seems to be appropriate for the assessment of stone size before SWL [29]. Also, in a clinical nomogram created to predict the effectiveness of SWL for kidney stones, not only mean density, SSD, BMI, and age, but also the stone size was significant enough to be part of the equation [30].

Tran et al. [13] and Ng et al. [14] both concluded that the most significant values to expect efficiency were the triple **D**s: **d**istance (stone-to-skin), **d**ensity, and **d**imension (stone burden). More importantly, they concluded that centers should define their own cut-off values based on their particular SWL device, settings, and experience.

Regarding the SWL follow-up period, while most urolithiasis fragments are cleared within a short period after the SWL [31], some may take up to 3 months [22]. Some authors [15,25] have extended follow-up until 8 weeks in case of residual stone at 4 weeks. If our endpoint follow-up was at 4 weeks, such as other studies [22,26], it might have underestimated the real SF rates.

Our study has limitations. First, it is a retrospective analysis, with its intrinsic drawbacks. Second, although SSD is a valuable parameter to access SWL success, the exact value was not reported and statistically analyzed in the cohort – it was only limited to SSD <10 cm and BMI ≤ 30. Also, no metabolic study was performed; however, although stone composition can be suggested before treatment by a metabolic evaluation, no precise information is obtained before the stone can be accessed. Lastly, even though some studies evaluate their outcomes using KUB alone [16,24,26,28], or KUB plus US [15,32], a post-procedure NCCT would have been more accurate to evaluate SF rates.

Considering that SWL is the non-invasive interventional treatment with the best cost-benefit and lowest morbidity [10–12], further studies are necessary to confirm our results and to support future guidelines that might include SWL as a first-line treatment option in the future not only to <20 mm or ≤ 10 mm in lower pole [1,2], but probably also ≤ 10 mm >1000 HU renal stones.

Conclusion

Stone size was the only significant success predictor in our cohort, with a 76% SF rate for stones <1 cm in 4 weeks follow-up, supporting that renal stones >1000 HU may be suitable to SWL.

Research involving human participants

The authors certify that the study was performed under the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Author contributions

WAN: data analysis, manuscript writing. LOR: project development, manuscript editing. RNP: project development, data collection, manuscript editing

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ORCID

Leonardo O. Reis https://orcid.org/0000-0003-2092-414X.

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ORCID

Leonardo Oliveira Reis https://orcid.org/0000-0003-2092-414X

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