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Shockwave Lithotripsy for Renal Stones: Outcome Prediction by Non-Contrast Computed Tomography

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ABSTRACT

Background: Upper urinary tract calculi are common with multi-modalities of treatment, with continuous invention of new modalities; one of these modalities is Extracorporeal shock wave lithotripsy [ESWL], which considered the modality of choice for renal stones less than 10mm with the advantage of being less invasive compared to other modalities.

Aim of the work: To identify the factors based on Non-Contrast Computed Tomography [NCCT] that will predict the success of shock wave lithotripsy for renal stones.

Patients and methods: A retrospective, single arm interventional study conducted by reviewing the medical files of all patients who underwent SWL for renal stones in the past 2 years. The study included 120 patients [82 males, 38 females; mean age: 52.1 y]. SWL was carried out. After three sessions, failure of disintegration was defined as no fragmentation of the stone. Univariate and multivariate analyses were used to assess the impact of patients' sex, age, and body mass index] as well as the stones' laterality, position, volume, mean attenuation value, and skin-to-stone distance on disintegration.

Result: The success rate of extracorporeal SWL at 3 mo. was 91.66% [110 of 120 patients]; 100 patients were stone free and 10 had residual fragments <4 mm. The significant predictors of residual fragments were stone density, skin-stone distance and stone diameter [p 0.018, < 0.001 and < 0.001, respectively].

Conclusion: Increased stone density, skin-stone distance and stone diameter as detected by NCCT are significant predictors of failure to fragment renal stones by SWL, alternative treatment should be devised for patients with stones having Hounsfield Unit [HU] >1000 HU and/or large skin-to-stone distance [SSD].

Keywords: Shock wave lithotripsy, Non-contrast computed tomography, Renal stones.

INTRODUCTION

There are various treatment options for proximal ureteral calculi, including medical treatment [medical expulsive therapy], extracorporeal shock wave lithotripsy [SWL], flexible ureteroscopy [URS], percutaneous nephrolithotomy [PNL] and open surgery [1].

The European Association of Urology [EAU] guideline recommends SWL as the preferred first-line therapy for all kidney stones less than 10 mm with URS as an alternative for selected cases and PCNL reserved for when SWL and URS have failed [2]. SWL has the advantages of being less invasive and resulting in lower complication rate compared to the endourology procedures [3].

Several parameters affecting the stone free rate [SFR] after SWL has been determined; these include stone size, location, composition, stone attenuation values on Non-contrast computed tomography [NCCT], skin-to-stone distance [SSD] pelvicalyceal anatomy, patients body mass index [BMI] and shockwave delivery frequency [4].

NCCT provides reliable information on stone site, size, number and total stone burden and therefore is recommended as the standard diagnostic imaging modality in urinary stone disease [5].

Tran *et al.* [6] reported a novel and simple nomogram [Triple D scoring system], which constitutes three NCCT-based parameters [SSD, stone density, and stone volume [SV] to screen for the most appropriate patients for SWL. Its clinical usefulness has been externally validated in different studies.

AIM OF THE WORK

To identify the factors based on NCCT that will predict the success of shock wave lithotripsy for renal stones. Also, the clinical usefulness of these factors will be evaluated

PATIENTS AND METHODS

This is a retrospective, single arm interventional study done by reviewing the medical files of all patients who underwent SWL for renal stones at Al-Azhar University Hospital, New Damietta, Egypt in the past 2 years. Only patient with complete medical records and pre-SWL NCCT were included in the study. In this study, we identify the factors based on NCCT that will predict the success of shock wave lithotripsy for renal stones.

The patients' medical records were reviewed for Pre-SWL data which included age, sex and Body Mass Index [BMI] and stone side, size, site, number and density [HU] pelvicalyceal anatomy and SSD as evaluated by pre-SWL Non contrast computed topography [NCCT].

The study protocol was approved by the local institutional review board [IRB] of Damietta Faculty of Medicine, Al-Azhar University.

All patients received intravenous analgesia in the form of 5mg Nalbuphine HCL [Nalufin®] and/or Tenoxicam [Epicotel®] vial/iv. An intravenous fluid administration was given to all patients throughout the procedure and all patients were treated in a supine position with the water cushion adjusted below the flank in the posterior approach and above the flank in anterior approach. Fluoroscopy was used for radio-opaque stone localization and Ultrasonography was used for radiolucent stone localization.

SWL was performed using the third-generation Dornier lithotriptor DELTA III [Dornier, Germany] that deploys electromagnetic shock waves for fragmentation. The maximum weight according to the equipment's instruction was 120 Kg.

An adjustment range of 11 energy levels [ranged from 1-11] was applied. Effective focus energy ranged from 5.5 to 67 mJ [Level 1= 5.5 mJ & Level 11= 67 milli Joul]. Focus pressure 7 to 59 MPa [Level 1= 7MPa & Level 11= 59 Mega Pascal]. Each treatment session started at energy level 1. This low energy level was to minimize the "startle" response from the patient when the first shocks are administered thus preventing the movement of the stone away from the focus of shock waves [SWs]. Then, the power gradually increased to another level every 100 shocks until the desired energy level is obtained according to the stone fragility and patient tolerance. The maximum intensity level was [11]. SWs were given at a rate of 70-80/minute for all patients.

We confirmed the positioning of the stone and monitored the progress of fragmentation by fluoroscopy and snap shot imaging at intervals of 300-500 shocks. The procedure was ended when satisfactory fragmentation [when fragments became nearly ≤4 mm] was seen on fluoroscopy or maximum energy level will reach [260 joul].

At the end of each session and on discharge, patients were instructed to drink liberal fluids. Oral analgesia [diclofenac potassium OD], Alpha blocker [Tamsulosin 0.4 capsule/24hs for a week] and antibiotic [ciprofloxacin/12hs for 5days] was also prescribed to be taken if needed. They were also instructed to document passage of fragments and re-check if they developed hematuria with clots, fever, and severe colic

All patients were investigated two weeks after the first session by plain [K.U.B] or ultrasonography in cases of radiolucent stones to assessed disintegration of stones and the need for further sessions, Successful treatment was considered if the KUB or ultrasound revealed stone free or presence of fragments ≤4mm [primary end point]. For patients who needed more than one session, the duration between each session was 2 weeks to give chance for tiny fragments to pass. If another session was done, it was added to the patient's own file with separate entries for the same items as in 1st session. Three sessions of SWL with no evidence of disintegration or fragmentation was considered as unsuccessful result and another treatment modality was chosen for the patient [failure of treatment].

At the end of study, records were collected and statistical analysis by suitable statistical tests [Fisher's exact test, Chi-Square test and T-test] and analytic programs [SPSS]. Treatment efficacy and safety analyses were performed for the per-protocol [PP] population. A two-sided probability value [*p*-value] of < 0.05 was considered significant.

RESULTS

In our study 82/120 [68.35%] patients were males and 38/120 [31.65%] of them were females, mean age ± SD was 52.1 ± 9 with ranged from 25 to 68 years, and the mean BMI ± SD was 26.043 ± 2.694 with ranged from 19 to 32 kg/m2 [Table 1].

Regarding stone characteristics: 84.2% of stones were solitary while 15.8% were multiple. The right kidney was involved in 50.83% while the left kidney was involved in 49.17%, solitary stone location 47.5% was present at pelvic, 17.5% at the upper calyx 2.5% at the middle calyx and 16.5% at Lower Calyx, depending on x-ray imaging, 79.2 % of stones were radio-opaque, while 20.8% were radiolucent stones. Depending on the Non-contrast CT imaging, the Mean stone diameter varied between 9 and 35 mm with a Mean ±SD were 16.27±4.480, we observed in our work that the mean stone diameter <20 mm were 103 cases [85.84%] and ≥20 mm was 17 cases[14.16], the stone surface area varied between 130 and 500 mm with a Mean ±SD was285.33 ± 82.455, while The Mean ±SD of Hounsfield unit was 959.68±302.901 with the limits between 210 and 1700., skin-stone distance varied between 80 and 115 mm with a Mean ±SD were 94.13 ± 6.538 [Table2]. Spontaneous stone fragment passage was reported within the first 24 hours after the procedure for 65 patients [59.1%].

The procedure took between 50 and 100 minutes on average. For one process, the number of shock waves ranged from 1550 to 7257, with an average of 87.85±15.869 [using a 60-120-180/min frequency]. The average amount of energy utilized was 101.153±30.9 j.

The majority of patients [110–91.66 %] had complete stone breakdown and stone fragment passage [as measured by ultrasonography and KUB 12 weeks after the procedure].

The average number of procedures was 1.22±0.522 with a range of 1 to 3. Regarding Post-ESWL complications [Table 3], 30 cases [25%] suffered from gross hematuria. These cases were managed conservatively at hospital for 48 hours by bed rest, IV fluids with proper antibiotic and Ethamsylate [Dicynone® amp/8hs] and tranexamic acid [Kapron® amp/8hs] with no need for intervention. regarding renal colic, 43 cases [35.8%] suffered from renal colic requiring analgesia, 12 cases [10%] suffered from post-eswl urinary tract infections antibiotics, but one case of urosepsis was recorded which requiring a more aggressive treatment in the form of IV fluids and antibiotic according to culture and sensitivity, Three renal hematomas [two small subcapsular and one larger retroperitoneal hematoma] were caused by renal concussion and were treated conservatively in the hospital for 72 hours with bed rest, IV fluids, and antibiotics, with no need for surgical management because the hematomas were not increasing and were not pulsatile. Steinstrasse was diagnosed in 6 cases [5%], 4 patients were able to spontaneously pass the stone fragments within 10 days as there was mild backpressure, small fragments no persistent pain or fever. The other 2 patients required retrograde ureteroscopy and active stone removal.

Patients were considered stone free if no signs of residual stone or insignificant small fragments ≤4 mm was detected on X-ray KUB or CTUT at the end of study [12 week].

The overall success rate was 91.66%. Stone clearance was achieved in 100 patients [83.33%] after 3 months of follow-up and 10 patients [8.33%] showed insignificant residual surgical fragments [<4 mm]. The failure of stone clearance occurred in 10 patients [8.34%], 4 out of them [3.33%] showed no change at all in stone size after 3 sessions of ESWL so they underwent PCNL and the remaining six patients [0.05%] showed partial disintegrations. Hence, they underwent flexible ureteroscopy.

A review of data [Table 4] identified that SFR was affected by, large stone diameter, high pressure fluid irrigation and severe degree of hydronephrosis, which was statistically significant, while the other data were statistically insignificant.

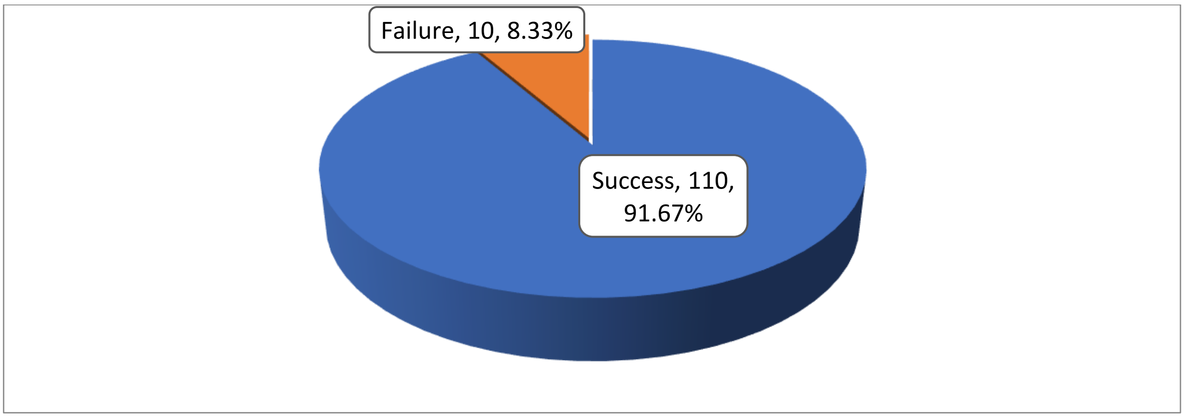

Figure [1]: Stone free rate

Table [1]: Demographics and comorbidity of studied populations

		N	%
Sex	Male	82	68.35
	Female	38	31.65
Age	Range	25-68	
	Mean ±SD	52.11±9	
BMI	Range	19-32	
	Mean ±SD	26.043±2.694	

Table [2]: Stone characters

		N	%
Stone side	Right	61	50.83
	Left	59	49.17
	Bilateral	0	**0**
Stone opacity	Radioopaque	95	79.2
	Radiolucent	25	20.8
Mean stone diameter	< 20 mm	103	85.84
	> 20 mm	17	14.16
Multiplicity	Solitary	101	84.2
	Multiple	19	15.8
Stone location	pelvic	57	47.5
	upper calyx	21	17.5
	Mid Calyx	3	2.5
	Lower Calyx	20	16.5
	Pelvic & upper & lower calyx	7	5.8
	upper & lower calyx	4	3.3
	Pelvic & lower calyx	4	3.3
	pelvic & upper Calyx	4	3.3
Mean stone diameter [mm]	Range	26 [9-35]	
	Mean ±SD	16.27±4.480	
stone Surface Area [mm2]	Range	370[130-500]	
	Mean ±SD	285.33±82.455	
Skin-Stone distane[mm]	Range	35[80-115]	
	Mean ±SD	94.13±6.538	
Hounsfield Unit [H/U]	Range	210-1700	
	Mean ±SD	959.68±302.9014	

Table [3]: Post-ESWL complications

Post-ESWL complication		No		Yes	
		N	%	N	%
Gross Hematuria		90	75	30	25
Peri-nephric Hematoma		117	97.5	3	2.5
Steinstrasse		114	95.00	6	5
Fever		89	74.2	31	25.8
Infection	**UTI**	108	90	12	10
	Urosepsis	119	99.2	1	0.8
Renal colic		77	64.2	43	35.8
Voiding symptoms		77	64.2	43	35.8
Ecchymosis		89	74.16	31	25.84

Table [4]: Factors affecting the stone free rate

		Stone free rate				p-value
		Success		Failure		
		N	%	N	%	
Sex	Male	76	69.00	6	60.00	**0.724**
	Female	34	31.00	4	10.00	
Age	Mean±SD	9±52.1		9.4±51.6		**0.853**
BMI	Mean±SD	2.672±25.97		1.549±28.80		**0.001***
Stone opacity	Radio opaque	85	77.27	10	100.0	**1.0**
	Radio lucent	25	22.73	0	0.00	
Mean stone diameter [mm]	Mean± SD	16.19±4.139		18.50±7.215		**0.119**
H/U	Mean± SD	949.93±304.52		1183±89.821		**0.018***
Stone diameter	< 20 mm	101	91.81	2	20.00	**<0.001***
	> 20 mm	9	8.19	8	80.00	
Time of operation [Minutes]	Mean± SD	50.641±7.382		56.000±16.971		**0.327**
Stone Surface Area [mm2]	Mean± SD	288.18±82.301		260±73.33		**<0.298***
Skin-Stone distance [mm]	Mean± SD	93.51 ± 65.885		100.40±8.771		**0.001***

DISCUSSION

Because it is safe and non-invasive, ESWL has become an established and recommended treatment for simple renal and ureteral stones [20 mm in diameter] since its inception in 1980 [7].

Unenhanced helical CT is highly sensitive [up to 98%] and specific [96–100%] in diagnosing urolithiasis and is the imaging modality of choice for the initial evaluation of patients with suspected urinary stones., and various CT parameters[such as stone attenuation [H/U], skin-to-stone distance, and Stone location] have been investigated to assess their ability to predict SWL success; however, despite a large number of studies during the past decade, there is still no consensus regarding the use of these parameters to guide management decisions [8].

Patients were considered stone free if no signs of residual stone or insignificant small fragments ≤4 mm were detected on X-ray KUB or CTUT at the finish of study.

Concerning the stone free rate [SFR] in our study, 110 of 120 cases [91.81%] were stone free. The failed 10 cases were due to increase skin-stone distance, HU and stone volume migration, which dealt with flexible URS and PCNL.

In our study, 82[68.35%] of patients were males and 38[31.65%] of them were females, which is in agreement with Sofia *et al*. [9] who reported that nephrolithiasis is more common in men than women in developing countries the ratio was [2:1]. In Iraq and Saudi Arabia, the ratio was 2.5:1 and 5:1, respectively.

In Egypt, nephrolithiasis is more common in men [65.1%] than in women [34.9%] [ratio 1.8: 1] and is more prevalent between the ages of 20 and 50 years [10].

Regarding age, in our study there was insignificant difference between the two groups regarding age. [Mean ± SD] of the success group was 52.1±9, while it was 51.6±9.4 in the failure group. Our results indicate that outcomes of ESWL are not affected by age. These results come near Gökce *et al*. [11] whose success group [Mean ± SD] was 40.6±9.8 while it was 41.5±10.5 failure group.

Regarding BMI, in our study, BMI was 25.97±2.672 for the success group and 28.80±1.549 for failure one, as Standard lithotripsy has a focal length less than 15 cm between the power source and target F2 that sometimes makes it impossible to treat obese patients so, BMI regarding as predictor factor for SWL, These results are in agreement with Pricop *et al*. who reported that The ESWL success rate in overweight and obese patients can be negatively influenced by BMI [12].

In our study, the percentage of stones less than 20 mm in the Success group was 91.81 percent, while the percentage of stones greater than 20 mm in the same group was 8.19 percent, and the percentage of stones less than 20 mm in the Failure group was 20%, while the percentage of stones greater than 20 mm in the same group was 80% [p = 0.001]. According to AbdelKhalek *et al*. [4] the success rate of ESWL for stones less than 15 mm was 89.7% and 78 percent for stones greater than 15 mm [p 0.001], while Al-Ansari *et al*. [13] found that the success rate of ESWL for stones less than 10 mm was 90% and 70% for stones greater than 10 mm [p 0.050] in a study of 427 patients with renal stones.

Regarding stone density, in our study, we observed the mean of HU was 949.93±304.52 of the success group while it was 1183±89.821 of the failure group with a significant difference between the two groups [p-value 0.018] that is in accordance with El-Nahas *et al*. [5] who reported a prospective study of 120 patients, the mean of HU was 544 ±218 of the success group while it was 773±303 of the failure group with a significant difference between the two groups [p-value 0.01].

Thus, by using NCCT to calculate stone density, one may forecast ESWL outcome and lower management costs by lowering the failure rate and number of ESWL sessions.

Regarding skin-stone distance, in our study the success group showed a mean SSD of 93.51 ± 65.885 mm, while the mean SSD in the failure group was 100.40±8.771 mm with a *p*-value of 0.001 as subcutaneous tissue is thought to absorb the shock wave energy and diminish the energy reaching the stone. which is in accordance with Patel *et al*., 2009 who reported that The mean SSD in the stone-free group was 83.321.9 mm against 107.728.9 mm in the residual stone group [p 0.050], and multivariate regression analysis revealed that SSD was the sole significant independent predictor of treatment outcome [14].

Regarding complications in our study, most of complications were minor, including Renal colic [35.8%], gross hematuria [25%], steinstrasse [5%], Peri-nephric hematoma [2.5%], fever [25.8%], and UTI [10%], Voiding symptoms [35.8%] and Ecchymosis [25.84%]. The only major complication that occurred was severe infection [Urosepsis] that occurs in one patient and managed conservatively at hospital for 72 hours by using proper antibiotics, good hydration and antipyretics. Salem *et al*. [15] reported that following ESWL, a number of mild problems might arise. Renal colic [40%], gross hematuria [32%], steinstrasse [24.2%], symptomatic bacteriuria [9.7%], and perirenal hematoma or subclinical subcapsular hematoma were among the frequent sequelae reported in a prospective study of 3241 individuals treated with ESWL [4.6%]. All problems were treated conservatively or with the least amount of intervention possible.

Some limitations were reported in our study; first, this was a single-center study and the success rates in altered periods may vary, which may have impacted definite outcomes. Better results may occur in less invasive multi-center adjacent studies conducted in a small period together with a distended sample size. In addition, we did a retrospective analysis with a small sample size of patients. A urologist was blinded to the results of ESWL and assessed the predictors using NCCT to reduce expected selection bias. For the follow-up regimen, plain radiography and ultrasonography were employed instead of NCCT to confirm therapy success. The composition of the stone has a considerable impact on the outcome of ESWL, which has not been studied. The found stone piece was not subjected to a chemical analysis. Prior to

ESWL, the patients with ureteral stents were not divided into stented and non-stented groups. However, the study shows that a patient's BMI, stone size, stone location, stone density, SSD and use of double J stent that affects the ESWL outcome, which can be useful for patient selection to improve ESWL outcomes to save time and treatment costs.

Conclusion: Increased stone density, skin-stone distance and stone diameter as detected by NCCT are significant predictors of failure to fragment renal stones by SWL, alternative treatment should be devised for patients with stones having Hounsfield Unit [HU] >1000 HU and/or large skin-to-stone distance [SSD].

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