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Prediction of the outcome of the treatment of urinary stone by using extracorporeal shock wave lithotripsy

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ABSTRACT

INTRODUCTION: ESWL remains the predominant therapy for renal calculi. The proper selection of patient for therapy by evaluating some stone related factors: size, density, skin-stone distance, and renal anatomy based on a non-contrast computed tomography, in addition to patient's clinical factors will allow the patient to be treated with the most efficient method to achieve a stone free status with low morbidity.

OBJECTIVE: To investigate the effect of stone attenuation, skin-to-stone distance and stone size measured by non-contrast computerized tomography on the outcome of the treatment of renal stone by extracorporeal shock wave lithotripsy.

METHODS: A comparative study was performed at Department of Urology, Medical City Complex in Baghdad from July 2010-December 2013. Patients with renal stone who were referred for extracorporeal shock wave lithotripsy were included in this study. Some physical features of the stone were assessed by non-contrast computed tomography. The physical features of the stone were linked to the outcome of the treatment.

RESULTS: After SWL, 32 (40%) were stone free, 19 (24%) had complete fragmentation, and 29 (36%) of 80 patients had incomplete fragmentation. The stone attenuation of the successfully treated patients (stone free and complete fragmentation groups) was 837 + 277 Hounsfield units (HU) vs 1092 + 254 HU for those with treatment failure (incomplete fragmentation; P <0.01). The mean SSD also differed: 9.6 cm + 2.0 vs 11.1 cm + 2.5 for the successful treatment group vs the treatment failure group, respectively (P <0.01).the mean stone size also differed: 9.2+2.2 vs 10.6+2.7.

CONCLUSION: A stone attenuation of <950 HU, skin-to-stone distance of <9.5 cm, and stone size of < 10 mm can be used to predict the success of treatment of renal stone by extracorporeal shock wave lithotripsy. Stone location and body mass index can not be used as predictor for success of such treatment.

Key words: Extracorporeal shock wave lithotripsy (ESWL), renal stone, skin-to-stone distance (SSD).

INTRODUCTION

Although calculi in the kidney were rare before the industrial revolution, the existence of nephrolithiasis was known to Hippocrates, who described the symptoms of renal colic. It is not certain that Hippocrates performed surgery on patients with renal calculi.[1] The alleged first surgical attempt to remove a stone from a patient's kidney is the case of the French archer of Bagnolet. Little is known of the authenticity of this tale of a condemned man afflicted with a renal calculus who agreed to allow surgery on the affected kidney on the condition that if he survived, he would be freed. According to the anecdote, the man survived the open surgical stone removal and was freed in 1474.[2]

In 1872, William Ingalls of Boston City Hospital performed the first recorded nephrolithotomy in America.[3] Heineke, in 1879, first described a pyelotomy incision for the extraction of calculi.[4]

Zuckerkandl described an inferior pyelonephrolithotomy in which a pyelotomy incision was extended into the lower pole of the kidney. In 1889, Kümmell was the first surgeon to perform a partial nephrectomy for calculous pyonephrosis.[5] Lower, in 1913, revived interest in pyelolithotomy when he suggested that this technique may be a safer and easier method of removing renal calculi than nephrolithotomy.[6]

An important advance in the open surgical approach to the kidney was the intrasinusally extended pyelolithotomy, pioneered by Gil-Vernet in 1965. Smith and Boyce described an atrophic nephrolithotomy. Although stone-free rates of these modern surgical techniques were excellent, morbidity was significant, and the search for new techniques and technologies continued.[7]

The last decades of the past century had witnessed an impressive change in the management of urinary stone disease. Before the 1980s, open surgery represented the treatment of choice for most renal and ureteral stones.[2] Meanwhile, open surgery for stones nearly vanished by the continuous refinement of minimal invasive surgical procedures such as ureterorenoscopy and percutaneous nephrolitholapaxy as well as by the introduction of extracorporeal shock wave lithotripsy (ESWL).[8]

The first use of lithotripter on human was made in February 1980 by Dornier, since then ESWL has been established as the preferred treatment for renal and several ureteral calculi due to its noninvasive character and its favourable clinical outcome.[8] ESWL causes certain amount of structural and functional renal damage. Microscopic and macroscopic haematuria, and oedema are common; while perirenal haematomas are much less common about 0.5% detected on ultrasound with modern machines. There are data suggesting that ESWL may increase the likelihood of development of hypertension. Acute renal injury may be more likely to occur in patients with preexisting hypertension, prolonged coagulation time, coexisting coronary heart disease, diabetes mellitus, and in those with solitary kidneys. Absolute contraindications are pregnancy and uncorrected blood clotting disorders (including use of anticoagulation).[9-11]

Stones of varying composition respond differently to shock wave fragmentation. Subsequently, fragility of calculi is also recognized to represent an essential factor for the success rate of ESWL.[12] The outcome of stone clearance after ESWL is strongly related to stone disintegration and clearance of the fragments.[13] Stone disintegration is affected by several factors including stone factors (burden, number, composition); patient factors (obesity, body habitus); operator experience; and machine factor (type of lithotritor, shock wave number, shock wave energy).[14-16]

The diagnosis of urinary tract calculi begins with a focused history. Key elements include past and family history of calculi, duration and evolution of symptoms, and signs or symptoms of sepsis. The physical examination is often more valuable for ruling out nonurologic disease.[17] Noncontrast helical CT (NCCT) is being used increasingly in the initial assessment of renal colic.[17] NCCT identifies most kidney stones, with an overall accuracy of 96-98% (95% sensitivity and 98% specificity) and provides precise information about the stone size and location.[18,19] The choice of stone management continues to be determined principally by the above mentioned factors. In an attempt to better identify calculi susceptible to ESWL, investigators have evaluated the role of stone attenuation and skin-to-stone distance (SSD) to predict fragmentation by ESWL.[20-23]

Identifying the predictive factors of outcome of ESWL would help streamline the care of patients with stones; otherwise, failure of ESWL results in unnecessary exposure of renal parenchyma to shock waves and its possible complications. Invariably, alternative treatments are then needed. This study is made to investigate the effect of stone attenuation, SSD and the stone size measured by non-contrast computerized tomography on the outcome of treatment of the renal stone by ESWL.

METHODS

Type of the study and settings: A comparative experimental study was performed at Department of Urology, Medical City Complex, Baghdad, Iraq from July 2010 to December 2013.

Inclusions and exclusion criteria: All patients who were referred to our department with a diagnosis of renal stone and planned to be treated by ESWL were enrolled in this study if they fulfilled these criteria:

- Having ESWL as the initial stone treatment.
- Stone size 5-20 mm.
- A solitary radio-opaque renal stone.
- Visible before treatment by kidney/ureter/bladder (KUB) radiography and preoperative NCCT.

Patient who had any of the following criteria were excluded from the study:

- Had multiple stones on the same side.
- Radiolucent stone.
- Lower calyceal stone.
- Stone required a double J stent.
- Development of steinstrasse.
- Presence of active urosepsis during therapy.
- Having Chronic medical illnesses like hypertension, diabetes mellitus and ischemic heart disease.

A full medical history and comprehensive physical examination were done for all participants. Basic laboratory investigations were done including urine for culture and sensitivity. Diagnosis of stones were made using imaging studies: KUB, US and NCCT scan. The study details and aims were fully explained for each participant and informed consent was taken.

Procedure: A Storz Medical Modulith SLX-F2 lithotripter was used to treat all patients. A maximum of 3500 shock waves were delivered to maximum power of 22-24 at 120 shocks per minute to each stone, the power was gradually increased during the first minute of treatment. This machine has a 12 to 20 kV variable potency electromagnetic generator, which delivers a pressure of 189 to 1056 bar in a focal area (F2) of 28 X 6 mm. The stone had localized and monitored by fluoroscopy during the procedure.

To minimize the pain for patients we used intramuscular injection of diclofenac sodium (voltaren) Novartis 75 mg before the procedure. For those who gave a history of asthma or gastrointestinal problems tramadol injection 100 mg were used instead.

Stone size were categorized based on stone NCCT characteristics. The NCCT scans were obtained axially from the diaphragm to the pubis with 3.00 mm collimation. Stone size was defined as the greatest length in any dimension.

The stone Hounsfield Unite (HU) density was calculated by elliptical region of interest incorporated largest cross-sectional area of stone without including adjacent soft tissue. The average SSD was calculated by measuring three distances from the edge of the stone to the skin at 0°, 45° and 90° degrees on an axial scan of NCCT, then the average of these three values was calculated to represent the SSD for each stone.

Another ESWL session was performed after three weeks if follow-up plain KUB showed significant residual fragments (>4 mm for radio-paque stones).

Primary end points: At six weeks after the procedures, Patients were followed up by plain XR (KUB). The outcome is classified as follows:

1. Stone Free (SF): Those who showed no radio-opaque shadow in the renal area (calcification).
2. Complete fragmentation (CF): presence of remaining calcifications of < 4 mm in diameter.
3. Incomplete fragmentation (ICF): presence of a calcification of ≥ 4 mm in diameter.

The treatment is considered successful if we achieve a stone free or complete fragmentation after one or two sessions. While we considered it failure if we had incomplete fragmentation after the therapy.

In order to determine the criteria that can predict ESWL outcome we compared some physical parameters of stone between treatment failure and treatment success groups.

Statistical analysis: Univariate and multivariate statistical analyses were performed. Chi-squared tests and 2-tailed t tests were performed as appropriate for univariate statistics, and then multivariate (logistic regression) analyses were performed. Odds ratios and 95% confidence intervals (CIs) were calculated.

RESULTS

Eighty patients were included in this study. Age ranges between 20-55 years, and the mean stone size was 9+3.4 mm. Forty-five patients (56.25%) had a stone size of >10 mm. Table 1

At 6 weeks, 32 (40%) were SF, 19 (23.8%) had CF, and 29 (36.2%) of 80 patients had incomplete fragmentation. The overall success rate (SF+CF) for a single session was 63.8% (51 of 80).

No differences in stone location were detected. However, the stone size did differ (Table 1 and 2), with SF patients more likely to have

Table 1: Comparison of demographic information.

Variable		Stone-Free	Complete Fragmentation	Incomplete Fragmentation	P Value
Patients (n = 80)		32 (40%)	19 (23.8%)	29 (36.2%)	—
Age + SD (y)		48 + 11	47 + 13	54 + 12	NS*
BMI + SD (Kg/m2)		27 + 8	25 + 5	28 + 8	NS*
Median shockwaves (n)		3500	3500	3500	NS*
Location	Renal pelvis	9 (31%)	8 (33%)	13 (48%)	NS†
	Upper calix	11 (38%)	9 (37%)	7 (26%)	NS†
	Middle calix	9 (31%)	7 (30%)	7 (26%)	NS†
CT stone diameter + SD (mm)		7.3 + 1.7	9.2 + 3.1	9.9 + 3.4	<0.01*
KUB stone diameter + SD (mm)		8.2 + 3.1	11.5 +5.4	11.9 + 4.4	<0.01*
SSD (cm)		10.0 + 2.0	9.0 +1.9	11.1 +2.5	0.01*
Stone attenuation + SD (HU)		801 + 228	893 + 338	1092 + 254	<0.01*

CT=computed tomography; KUB=kidney/ureter/bladder; SSD=skin-to-stone distance; SWL=shock wave lithotripsy; HU=Hounsfield unit.

*= Three-way analysis of variance.

†= X2 test.

Table 2: Outcome of ESWL treatment according to stone attenuation, size and it's distance to the skin

		Stone free	Complete fragmentation	Incomplete fragmentation	Total
Stone attenuation	≤ 950HU	24	12	7	43
	>950 HU	9	7	21	37
	Total	33	19	28	80
Skin stone distance	≤9.5 cm	11	8	5	24
	>9.5 cm	12	20	24	56
	Total	23	28	29	80
Stone size	≤ 10mm	17	10	8	35
	>10 mm	11	14	20	45
	Total	28	24	28	80

stones ≤ 10 mm. A highly significant correlation existed between the stone diameter measured on CT and KUB ($r2 = 0.88$, $P < 0.001$). The stone attenuation range was 267-1571 Hounsfield units (HU). Successfully treated patients (SF + CF) had a significantly lower mean stone attenuation than did those with treatment failure (837 ± 277 HU vs 1092 ±254 HU, respectively; P <0.001). The mean SSD also differed between the successful treatment group and treatment failure group (9.6 cm ±2.0 and 11.1 cm ± 2.5, respectively; P>0.001). The stone attenuation threshold that best distinguished between the outcome groups was 900 HU (OR 6.2, 95% confidence interval [CI] 2.5-15.1). Stones <900 HU were 6.2 times more likely to be treated successfully with ESWL than were stones >900 HU (84% vs 43%, respectively; P<0 .001). The SSD threshold that best distinguished between outcome groups was 9 cm (OR 2.8, 95% CI 1.1-7.2). A SSD of ≤ 9 cm was associated with a 78% success rate compared with a SSD >9 cm, which had a 57% success rate (P = 0.02). The stone size threshold that best distinguished between outcome groups was 10 mm (OR 2.2, 95% CI 1.1-6.7). A stone size of ≤10 mm was associated with a 76% success rate compared with a stone size >10 mm, which had a 55% success rate (P=0.03)

Patients were then stratified into 8 risk categories: density of stone < 900 HU, SSD < 9 cm, and stone size < 10 mm; density of stone < 900 HU, SSD ≤ 9 cm, and stone size >10 mm; density of stone < 900 HU, SSD > 9 cm, and stone size ≤10 mm; density of stone ≤ 900 HU, SSD >9 cm, and stone size >10 mm; density of stone > 900 HU, SSD ≤ 9 cm, and stone size ≤ 10 mm; density of stone > 900 HU, SSD ≤ 9 cm, and stone size > 10 mm; density of stone > 900 HU, SSD > 9 cm , and stone size ≤10mm; and density of stone > 900 HU, SSD > 9 cm, and stone size > 10 mm. The corresponding ESWL success rates were 91%, 82%, 79%, 71%, 58%, 49%, 43% and 36% respectively (P<0.001). Patients who had a SSD of <9.0 cm and stone attenuation of <900 HU and stone size ≤10mm were 7.1 times more likely to have successful ESWL compared with all other risk groups (OR 7.1, 95% CI 1.6%-32%, 91% vs 59.7%, respectively; P =0.01). The stone diameter correlated with stone attenuation ($r2= 0.5$; P <0.001). Larger stones had a tendency toward greater attenuation values compared with smaller stones. Stone attenuation also correlated with SSD ($r2 = 0.21$; P= 0.03).

DISCUSSION

Correlation between stone attenuation and stone fragility was first demonstrated in vitro.[7] As the attenuation value of calcium stones increases, a greater number of shock waves are needed for fragmentation.[20] Likewise, in a clinical retrospective review, patients with calculi >1000 HU were 10.5 times more likely to need three ESWL sessions compared with those with calculi of <1000 HU.[9] Several clinical studies have since verified that ESWL failure is associated with greater stone attenuation.[21-23,24,25]

Our results lend support to the findings of these studies. The mean stone attenuation of those with ESWL success (SF+CF) was significantly lower than that for those with treatment failure (ICF) (837 - 277 HU vs 1092 - 254 HU, respectively; P - 0.001). The attenuation threshold that best distinguished stones likely to fail to be fragmented by ESWL was 950 HU (OR 6.2, 95% CI 2.5-15.1). Similarly, Joseph et al.[21] reported a 95% success rate for calculi <1000 HU versus 55% for stones >1000 HU (P < 0.01). Other density thresholds were not assessed.

SSD can also be an important predictor of ESWL outcome. In a review of 64 patients with lower pole calculi, Pareek et al[10] found SSD to be a significant predictor (OR 0.32, 95% CI 0.29-0.35, P <0.01) with a cutoff of 10 cm predicting for ESWL failure. In our series, SSD threshold of 9.5 cm best distinguished ESWL outcomes (OR 2.8, 95% CI 1.1-7.2). On stratifying patients into 8 risk categories; SSD < 9.5 cm, stone attenuation <950 HU and stone size <10 mm was associated with a 91% ESWL success rate. Conversely, for patients with SSD >9.5 cm and stone attenuation >950 HU and stone size >10 mm, the SWL success rate was only 41%. On multivariate analysis, stone attenuation, SSD and stone size were the only pretreatment factors that independently predicted the ESWL outcome. Stone attenuation was the most important one.

Pareek et al[23] demonstrated that BMI independently predicted the ESWL outcome. They suggested that patients with stones > 900 HU and a BMI > 30 kg/m2 would be more suitable treated by endoscopic manipulation. In another study by Pareek et al,[24] SSD outweighed BMI as an independent predictor, suggesting that SSD might more accurately link obesity with ESWL failure. In our study, the variation of BMI was relatively small and did not affect the ESWL outcome.

To what extent volume averaging influences the association between stone attenuation and ESWL outcome has been raised by several investigators.[20,25-27] As a consequence of volume averaging, the zone of interest when measuring stone attenuation will, to a certain extent, incorporate the surrounding soft tissue, thus smaller stones will yield artificially low attenuation values to a greater extent than will larger stones, particularly when the CT collimation widths are > 3 mm.[27] Smaller stones are more likely to fragment with ESWL. Accordingly, stones with lower attenuation values can be expected to have a better ESWL outcome. In our study, CT was performed at a standard resolution (5-mm collimation width), and, as expected, stone attenuation did correlate with stone size ($r2 = 0.45$, P <001). Although univariate analysis demonstrated that both stone size and attenuation were predictive of ESWL fragmentation, on multivariate analysis, stone attenuation independently predicted for ESWL outcome. A well-controlled in vitro model of ESWL, reported in 2005, also demonstrated that increasing stone attenuation and size are independently predicted for poor fragmentation by ESWL.[28]

At small collimation widths of 3 mm in vitro and in vivo studies have shown that the CT attenuation values can discriminate between stone compositions; however, in the present study, the small sample size prevented accurate statistical comparison of the stone composition with the attenuation value. Better patient selection is paramount to improving ESWL outcomes. Dretler[12] first suggested that calculi traditionally treated by ESWL might be better managed by other modalities, depending on the CT attenuation values. Several investigators have since shown that ESWL is more likely to fail for patients with renal calculi >750-1000 HU and these patients should be considered for other treatment modalities.[21,25,29] In addition, SSD and stone size are emerging as a useful predictor of ESWL success.[24] Our results have confirmed that stone attenuation, SSD and stone size are important predictors of ESWL success. A cutoff stone attenuation of >950 HU, SSD of >9.5 cm and stone size of >10 mm were the best discriminates of stones likely to fail ESWL.

CONCLUSIONS

The results of our study have shown that a stone attenuation of <950 HU, SSD of <9.5 cm, and stone size of<10 mm are good predictors for ESWL success for renal stone. While stone location, and body mass index are not. We should consider stone density, SSD and stone size when making decision on the treatment of renal stone.

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