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Research Article
Ultrasonographic Assessment of the Outcomes and Complications of Extracorporeal Shock Wave Lithotripsy Treatment of Renal Stones

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Abstract

Background and Objective: Extracorporeal shock wave lithotripsy (ESWL) was introduced in the early 80s and has since become the gold standard for the treatment of urinary stones. It is the most widely performed procedure for stone treatment, treating all sizes and locations of stones, the results of which have been widely published. This study was designed with an aim to assess the outcomes and complications of the ESWL treatment of renal stones by using ultrasonography (US). **Materials and Methods:** A total of 100 patients with renal stones, treated using the Modulith SLX-F2 were recruited prospectively for a period of 12 months between April, 2017 and April, 2018. Renal US was conducted using Mindray's DC-60 machine, to follow the outcome of stone clearance for up to 3 months after the first ESWL session. All data was analyzed by mean±SD and student t-test was used to compare the variables at $p<0.05$. **Results:** Out of total number of patients, 60 were males and 40 females. The mean stone size and serum creatinine level were 15±1.8 mm and 2.8±0.2 mg dL^{-1}, respectively. US revealed an ESWL treatment success in most cases (83%), with an ESWL treatment sensitivity, specificity and accuracy of 98.81, 89.47 and 97.09%. **Conclusion:** This study concluded that ultrasonographic assessment showed 83% acceptable success rate for renal stone fragment passage and complete stone disintegration post- ESWL treatment.

Key words: Abdominal B-scan ultrasonography, extracorporeal shock wave lithotripsy, renal stones, ultrasonographic assessment

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Management of renal stones has changed dramatically during the past 20 years. Minimally invasive techniques, especially the development and introduction of extra corporeal shock wave lithotripsy (ESWL), virtually have replaced open surgical stone removal. Even large and complex renal stones may be treated effectively with these minimally invasive techniques. Surgical removal of renal stones had been reserved for those patients with persistent symptoms or recurrent urinary tract infections associated with the presence of the stone[1].

Since its introduction in the 1980s, ESWL has been confirmed as the standard convenient, least invasive outpatient procedure and the most widely used treatment of renal and proximal ureteric stones[2-4]. ESWL focusing and imaging devices have been modified over the years to improve the precise delivery of shock waves to the stone. Despite a decreased power delivery that often implies multiple sessions, second and third-generation machines do not require the use of anesthesia, thus achieving greater patient comfort and tolerance[5].

Naturally, like any other treatment, ESWL has the potential for serious side-effects and complications, although it has been shown in large series to be a reliable and an effective method[6,7]. The outcome of ESWL is measured in terms of stone fragmentation and clearance. Failure of ESWL results in unnecessary exposure of renal parenchyma to shock waves and complications, invariably alternative treatments are then needed, incurring additional medical expenses. A number of stone characteristics such as fragility, size, location and composition are known to affect outcome[8].

On the other hand, ultrasonography (US) is an accessible, relatively inexpensive imaging method that comes without the risks of exposure to ionizing radiation[9]. Stafford *et al.*[10] reported the ability to detect stones as small as 2 mm using US imaging in a porcine model more than 30 years ago. With an ability to demonstrate radiopaque and radiolucent stones, hydronephrosis, renal inflammation, ruptured fornices, ureteric jets and resistive index, US can provide valuable clinical information but in most cases cannot be used for ureteral stones[1]. In addition, US has many desirable characteristics for imaging of renal stones during ESWL. Ultrasound monitor fragmentation in real time and can localize radiolucent stones. Furthermore, sonography-guided lithotripsy can reveal other diseases in the affected kidney that may require further evaluation[11].

Only a few studies have been conducted on the Sudanese population evaluated the ESWL treatment of renal stones. The sensitivity, specificity and accuracy of such treatment have not been studied. This study was designed to assess the sensitivity, specificity and accuracy of ESWL treatment of renal stones using the US, to make ESWL a reliable therapeutic protocol.

MATERIALS AND METHODS

Selection and description of patients: After receiving approval from the local ethics committee, a group of 100 patients with renal stones, treated at Omdurman Military Hospital, Sudan, using the urological workstation Modulith SLX-F2 (Modulith, Storz Medical, Tägerwilen, Switzerland), were recruited for a period of 12 months between April, 2017 and April, 2018 in this prospective study. A waiver of informed consent was granted in accordance with institutional guidelines.

To ensure the credibility of the obtained results, inclusion and exclusion criteria for this study were in line with the European Association of Urology (EAU) guidelines on Interventional treatment for urolithiasis[12]. Inclusion criteria, were: (i) All adult patients, including males and females (age: $\geq$18 years) and (ii) With renal stones >7 mm in size. Exclusion criteria were: (i) Pregnancy or gravidity, (ii) Uncontrolled urinary tract infection (UTI), (iii) Uncontrolled alterations of coagulation and bleeding disorders, (iv) Aortic and/or renal artery aneurysm, (v) Serious skeletal malformations, (vi) Serious obesity (>225 kg, due to technical difficulty in placing the patient in focus), (vii) Renal insufficiency/failure, (viii) Abnormal heart rhythm and (ix) Uncorrected obstruction distal to the stone.

Patient preparation before ESWL: Regarding patient preparation before ESWL, patients taking Aspirin, Ibuprofen and Warfarin or other blood thinners were asked to stop taking these medications well, one week prior to the date of the procedures to avoid interfering with patients' blood's ability to clot properly. As most patients have the ESWL under general anesthesia, bowel preparation with Bisacodyl and fasting for at least 6 h before the procedure. Also, patients last urine culture was checked to be negative prior to having the ESWL session. Renal Staghorn stones were excluded and a temporary indwelling double J (DJ) stenting was inserted prior to ESWL for stones >20 mm to provide better clearance, comfort and a modest improvement in outcome with fewer sittings and steinstrasse.

Description of ESWL treatment session: All ESWL treatment sessions were carried out using intravenous (IV) analgesia in

the form of Diclofenac and Midazolam. The ESWL treatment was administered to the sample of the study for a maximum of 3 sessions. Evaluation of the treatment results was made by conducting an abdominal ultrasound examination. Treatment success for renal stones was defined as a stone-free with no residual stone or the presence of clinically insignificant residual fragments of <4 mm. At the end of treatment, patients were discharged on anti-inflammatory and analgesic oral medications for 2 weeks.

Renal ultrasound examination protocol: Prior to ESWL treatment sessions, renal ultrasound was performed to confirm the presence of renal stones, measure stones diameters, presence of hydronephrosis, renal masses, cysts and anatomical abnormalities. All renal US examinations either pre or post-treatment sessions were performed in a supine position in a thermally controlled room of (26°C, 78°F) by the same sonographer. The renal US examination was conducted using Mindray's DC-60 ultrasound system (Mindray, Shenzhen Mindray Biomedical Electronics Co., Ltd, Seoul, Republic of Korea), equipped with a lower frequency (3.5 MHz) curvilinear probe. The initial US examination was performed under high gain (80-90 dB) and low gain (60-70 dB) sensitivity for more detailed inspection. After 10-14 days of ESWL treatment sessions, renal ultrasound was repeated again to assess stones fragmentation. Also, patients were followed for the outcome of stone clearance for up to 3 months after the first ESWL session.

It should be noted that, the used guidelines for patient preparation before ESWL, description of ESWL treatment session and performing renal US examination were in line with the European Association of Urology (EAU) guidelines on Interventional treatment for urolithiasis and the American Institute of Ultrasound in Medicine (AIUM) practice parameter for the performance of an US examination in the practice of urology[12,13].

Statistical analysis: All measurable data were initially summarized as a Mean±Standard Deviation (SD) in a form of comparison tables and graph. Student's t-test (unpaired t-test) and p-value were used when comparing variables and for the significance of the results. The results were considered significant when $p<0.05$. The statistical diagnostic test was used to detect sensitivity, specificity and accuracy of the ESWL treatment success for renal stones. Statistical analysis was performed using the standard Statistical Package for the Social Sciences (IBM Corporation, Armonk, NY, USA) version 20 for windows.

RESULTS

In this prospective study, from a total of 100 patients who underwent ESWL, there were 60% male and 40% female patients. The mean age±SD was 41±1.3 years with age ranges from 20 up to 70 years. Depending on renal US prior to ESWL treatment sessions, renal stones involved the right kidney in 47% of patients and the left kidney in 53%. Renal obstructive changes were detected in 67% of patients, while the rest 33% does not present any obstructive features. In addition, the mean serum creatinine level was 2.8±0.2 mg dL^{-1} and ranged from 1.7 up to 4.2 mg dL^{-1} (Table 1). No significant difference was observed between gender, age and serum creatinine levels regarding stone clearance rate ($p = 0.305$, 0.660 and 0.635, $t = 1.369$, 0.511 and 0.512), respectively (Table 2).

The majority of ESWL treatment complications were of mild form, where loin pain was the most frequent complication (22%) registered due to ESWL treatment. Much more, obstructive changes (3%) were the least detected side effects. The rest of the complications were shown in Fig. 1.

ESWL treatment success of renal stones was achieved in 83% of patients. The diagnostic testing revealed a 98.81% sensitivity, 89.47% specificity and 97.09% accuracy for the

Table 1: Characteristics of the study population (n = 100)

Characteristics of the study population	
Number of patients (n(%))	100 (100%)
Males (n(%))	60 (60%)
Females (n(%))	40 (40%)
Mean age±SD, age range (years)	41±1.3, 20 up to 70
Stone location, right kidney (%), left kidney (%)	(47%, 53%)*
Solitary stone site, minor calyces (n(%)), major calyces (n(%)) and renal pelvis (n(%))	1(3.9%), 9(34.6%), and 16 (61.5%)*
Multiple stone site, minor calyces (n(%)), major calyces (n(%)) and renal pelvis (n(%))	9 (12.2%), 18 (24.3%) and 47(63.5%)*
Mean stones diameter±SD, stone diameter range (mm)	15±1.8, >7 up to >20*
Renal obstructive changes, vs. non-obstructive changes (n(%))	67 (67%), 33(33%)*
Mean serum creatinine±SD, serum creatinine range (mg dL^{-1})	2.8±0.2, 1.7 up to 4.2*

*Values obtained pre-ESWL treatment sessions

Table 2: Stone clearance rate after ESWL treatment sessions with respect to patient gender, age and serum creatinine level

Parameters	Number of patients (n)	Stone clearance rate, n(%)	p-value	t-value	Mean±SD, (n)
Gender					
Male	60	39 (65.0)	0.305*	1.369	50±14.1, 2
Female	40	32 (80.0)			
Age (years)					
<35	68	55 (80.9)	0.660*	0.511	50±25.5, 2
>35	32	19 (59.4)			
Serum creatinine (mg dL^{-1})					
1.7-2.7	33	26 (78.8)	0.635*	0.512	33±31.5, 3
2.8-3.9	65	40 (61.5)			
4-<5	2	1 (50.0)			

*By conventional criteria, this difference is considered to be not statistically significant

Table 3: Performance of the ESWL treatment for renal stones

ESWL treatment success for renal stones		Number of cases (n)
True positive		83
True negative		17
False positive		2
False negative		1
Performance of the ESWL treatment for renal stones	Values (%)	95% CI
Sensitivity (%)	98.81	93.54-99.97
Specificity (%)	89.47	66.86-98.70
Accuracy	97.09	91.72-99.40
Positive predictive value (PPV) (%)	97.65	91.79-99.35
Negative predictive value (NPV) (%)	94.44	70.66-99.17

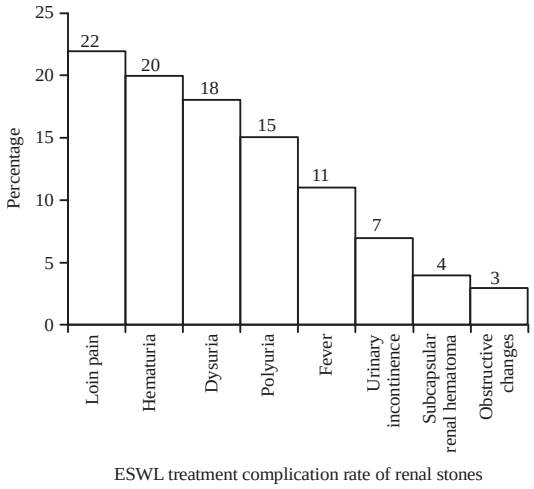

Fig. 1: Demonstrates the ESWL treatment complication rate of renal stones

performance of ESWL treatment for renal stones. Furthermore, results showed positive predictive value (PPV) of 97.65% and negative predictive value (NPV) of 94.44% for the ESWL performance too (Table 3).

DISCUSSION

In the current study, the mean age of the patients was 41 years (Table 1). Similar results were also reported by Wazir *et al.*[14], Butt *et al.*[15] and Khalique *et al.*[16], where the mean age was 40.2,37.7 and 38.2 years, respectively. In addition, the results demonstrate that out of 60 patients, the vast majority were males, with a male to female ratio of 1.5:1 (Table 1). Such findings could be compared to the results of Wazir *et al.*[14] and Rajput *et al.*[17], where they reported a male to female ratio of 3.8:1 and 4:1. The current results demonstrated that there is no significant difference between gender, age and serum creatinine levels with the stone clearance rate post- ESWL (P = 0.305, 0.660 and 0.635, t = 1.369, 0.511 and 0.512), respectively (Table 2). These findings were compatible with the results of Khalique *et al.*[16], where in their study the stone clearance rate post- ESWL presented an absence of significant difference by gender, age and serum creatinine levels too. Much more, Butt *et al.*[15] and Coz *et al.*[18] reported stone clearance rates of 87 and 96.5%, respectively. Their results present a frequency of stone clearance 70.5% in males and 72.4% in females. These findings were proved to be statistically insignificant different. Similarly, they proved no significant difference was observed between stone clearance rate post- ESWL and serum creatinine levels.

ESWL is the non-invasive treatment modality for urinary and biliary stones. It was developed in the early 1980s in Germany and within very short period, became a treatment of choice for the majority of the stones in the upper urinary tract. Its importance can be appreciated by the fact that more than 1 million patients are treated annually with ESWL in United

States of America (USA) alone. It has not only reduced hospitalization time and morbidity but is also cost effective. Like any other urological procedure, ESWL is also associated with complications, mainly infective and obstructive. ESWL therapy is non-invasive, anesthesia-free and can be administered in an outpatient setting. Therefore, ESWL remains the first choice for treating renal and upper and middle ureteric stones[19-22]. The technical features of the Modulith SLX-F2 enable reliable fragmentation of deep stones, even in extremely obese patients and under difficult conditions, with low side effects and of great comfort for the patient during treatment sessions[23]. These technical advantages of the Modulith SLX-F2 have had a positive effect on the ESWL treatment success rate (83%) for renal stones that authors achieved during this study. Moreover, the results revealed an ESWL treatment sensitivity, specificity and accuracy of 98.81, 89.47 and 97.09% as shown in Table 3. It is, however, not completely free of complications. These include, hematuria, steinstrasse, renal colic, HTN, abdominal discomfort and exceptionally, death[24]. Where in the current study, the majority of complications were of a mild nature, where loin pain was the most frequent complication (22%) and obstructive changes (3%) were the least detected side effects as shown in Fig. 1. Also, it should be noted that ESWL treatment failed in (17%) of the patients. Thus, additional treatment procedures were followed as percutaneous nephrostomy (PCN) placement and open or laparoscopic stone surgery in 14(82.4%) and 3(17.6%), respectively. Such results could be compared to the auxiliary procedures reported by Al-Marhoon *et al.*[5], Lalak *et al.*[25] and Tomescu *et al.*[26].

This study is limited by the unevenness of the population as a result of the randomized selection process, which unfortunately might affect the accuracy of the measurement parameters and in fact significantly reduce the power of the conclusions, because it makes other age groups have a lower statistical credibility if applied in future studies. Despite the above limitation, the importance of the current study lies upon it is one of the recent studies that assess the outcomes and complications of ESWL treatment of renal stones using US in Sudanese patients affected with renal stones, which is more likely to be modest in magnitude in this case since the study was a population based in its nature.

CONCLUSION

Ultrasonographic Assessment showed an acceptable success rate of (83%) for renal stone fragment passage and complete stone disintegration post-ESWL treatment with sensitivity, specificity and accuracy of 98.81, 89.47 and 97.09%, respectively. Factors as patient age, gender and serum creatinine level had no significant effect on renal stone clearance and they can be neglected before start any ESWL treatment.

SIGNIFICANCE STATEMENT

This study shows that US have an acceptable success rate of 83% for renal stone fragment passage and complete stone disintegration post- ESWL treatment sessions. Therefore, the ESWL treatment using the Modulith SLX-F2 can be beneficial, appropriate, non-invasive and effective treatment modality for renal stones. In addition, This study discovered that factors as patient age, gender and serum creatinine level have no significant effect on the complete stone clearance rate and they can be neglected before the start of any ESWL treatment session. Also, this will help to uncover the critical areas of ESWL that many researchers were not able to explore. Thus a new theory on ESWL treatment of renal stones may be arrived at.

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