The effectiveness of extracorporeal shockwave lithotripsy in treating ureteral stones: a retrospective study in Misrata- Libya

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Abstract

The objective of this study was to evaluate the efficacy of extracorporeal shockwave lithotripsy in treating ureteral stones**.**

Methods and materials: this is a retrospective study, in which we reviewed A total of 60 cases (29 males and 31 females) with ureteral stones who were treated by extracorporeal shock wave lithotripsy (ESWL) from records of ESWL unit at Misrata Medical Center between January 2019 and December 2019. All Radiopaque ureteral stones of radiological stone size of ≤ 15 mm were included in the study. Number of sessions, energy used and complications were reported. The outcome of ESWL was also recorded.

Result: Of the 60 patients (29 males and 31 females) analyzed, extracorporeal shock wave lithotripsy was successful in 83.3%. Univariate analysis of both groups revealed no significant difference in patient's age and stone laterality. Statically significant differences in gender, stone size, stone site, number of extracorporeal shock wave lithotripsy sessions, and patients with stents were observed. Statically significant factors in multivariate logistic regression analysis were sex and stent. Females had three-time higher risk for extracorporeal shock wave lithotripsy failure than male (odds ratio (OR) = 3.213; 95% confidence interval (CI): 1.194–8.645; p = 0.021) and a higher failure rate when stent was used (OR = 6.358; 95% CI: 2.228–18.143; p = 0.001). This study reveals that extracorporeal shock wave lithotripsy can treat ureteric stones successfully with an invasive association between outcome and predictors such as stone size, site and presence of stent. These factors can help us in improving patient selection and ensure better outcome at lower cost.

INTRODUCTION:

In 1980 Extracorporeal shock wave lithotripsy was first introduced by Chaussy et al (1) and has become a safe and accepted treatment for urinary tract stones and as Improvement in its technology and advancement in lithotripsy design and fluoroscopic imaging has currently allowed successful identification and in situ treatment of calculi in the middle as well as the lower ureter (2). It has since become uncomplicated renal and ureteral stone < 20 mm in diameter, as it is safe and non-invasive (3–6). After the introduction of original first generation electrohydraulic lithotripter, numerous modifications have been made in subsequent models. These modifications made the procedure more comfortable and tolerable

for patients without anesthesia, at the expense of less energy delivery and, therefore, lower success rates and higher retreatment rates (7–9). Several studies have shown that the Storz Modulith SLX-F2 lithotripter is clinically effective in the management of solitary renal and ureteral stones (10, 11). The success rate of Extracorporeal shock wave lithotripsy has a wide variation ranging from 46% to 91% (12–19).The results of Extracorporeal shock wave lithotripsy are measured depending on the stone fragmentation and clearance, which is influenced by some predicting factors, such as stone size, stone location, stone composition, severity of obstruction, urinary tract anatomy, obesity, and Extracorporeal shock wave lithotripsy machine type (20–29). The chemical composition of urinary calculi in vivo has been found to be the main factor in determining the outcome of extracorporeal shock wave lithotripsy (30, 31). Now a days, non-contrast computed tomography (NCCT) has become the diagnostic modality of choice to evaluate urolithiasis and its ability to detect density differences as low as 0.5, thus helping in determining the composition and fragility of urinary stones and the outcome of Extracorporeal shock wave lithotripsy (25,32–34). Although Extracorporeal shock wave lithotripsy is a non-invasive and safe procedure compared to other treatment modalities, it may also cause complications such as hemorrhage, steinstrasse, renal hematoma, infection, and flank pain (34–37). In cases where extracorporeal shock wave lithotripsy fails, the unnecessary exposure of renal parenchyma to shock waves may lead to complications and further alternative treatments leading to additional medical expenses (26, 39). Therefore, it is important to investigate the predictors influencing extracorporeal shock wave lithotripsy outcome to decide the treatment strategy for preventing unnecessary complications and the cost and treatment time after the diagnosis of urinary stone.

Methods and Materials:

We conducted a retrospective review for adult patients with ureteric stones, treated with extracorporeal shock wave lithotripsy at Misrata Medical Center, Libya, between January 2019 and December 2019. Data was collected from medical records of ESWL unit of urology department at MMC. The objective of the study was to evaluate the efficacy of extracorporeal shockwave lithotripsy in treating ureteral stones.

The inclusion criteria were radiopaque ureteral stones of radiological stone size of ≤ 15 mm, on the pretreatment plain abdominal X-ray of the kidney, ureter, and bladder (KUB). Pregnant women and patients with uncontrolled coagulopathy, ongoing urinary tract infection, stone secondary to anatomical obstruction, congenital anatomical abnormalities, any previous renal surgery or Extracorporeal shock wave lithotripsy on the ipsilateral side, and gross obesity body mass index ⩾ 35 kg/m2) were excluded from the study. All the patients underwent X-ray KUB, ultrasonography, and non-contrast CT KUB for initial diagnosis. A double J stent was inserted in patients with stones > 15 mm in size, high-grade hydronephrosis (grades 3 and 4 defined by The Society of Fetal Ultrasound), and impaired renal functions before Extracorporeal shock wave lithotripsy. The patients in the study were subjected to extracorporeal shock wave lithotripsy using 18-20 kV with power on the average of 3000 (2000-4000) shock waves. The session intervals varied between 5 to 10 days and the stones which could not be fragmented satisfactorily at the end of five sessions were classified as failure of extracorporeal shock wave lithotripsy. Reassessment of stones was done using X-ray KUB and ultrasonography to assess the stone clearance and number of ESWL sessions, requirement of auxiliary procedure, and complications were documented. All statistical analysis was carried out using IBM SPSS Statistics 22.

Results:

A total of 60 patients (29 males and 31 females) with ureteric stones who received extracorporeal shock wave lithotripsy treatment from January 2019 to December 2019 were analyzed. Extracorporeal shock wave lithotripsy was successful in 83.3% of patients and failed in 16.7%.The baseline demographic

characteristics and predictors of all patients are presented in Table 1.

Table 1: Patients demographic characteristics and baseline parameters.

Parameters	Values n (%)
Patients, n	60
Gender	
Male	29 (48.3%)
female	31 (51.6%)
Stone laterality	
Right	27 (45%)
Left	33 (55%)
Stone size, mean ± SD,	**9.27 ± 2.85**
mm ≤ 10	**40 (66.6%)**
> 10	**20 (33.4%)**
Stone location	
Upper ureter	**23 (38.4%)**
Middle ureter	**19 (31.6%)**
Lower ureter	**18 (30%)**
double J stent	
Present	**25 (41.6%)**
Absent	**35 (58.4%)**
ESWL sessions, mean ± SD	**3.25 ± 1.4**

In univariate analysis, as shown in (Table 2), patient's age and stone laterality were not significantly different in the two groups. However, differences in gender, stone size, stone site, number of extracorporeal shock wave lithotripsy sessions, and patients with stents were statistically significant.

Table 2: Univariate analysis of the factors affecting outcome of extracorporeal shockwave lithotripsy.

Variable	Success group	Failed group	*P* value
No. of Patients	50 (83.3%)	10 (16.7%)	
Age, mean ±SD	**38.3 ± 10.5**	**39.8 ± 11.6**	**0.375**
Gender			**0.017***
Male	23 (79.3%)	6 (20.7%)	
Female	20 (64.5%)	11 (35.5%)	
Stone laterality			**0.523**
Right	22 (81.5%)	5 (18.5%)	
Left	25 (75.8%)	8 (24.2%)	
Stone size, mean ± SD, mm ≤ 10	34 (85%)	6 (15%)	**0.004***
> 10	13 (65%)	7 (35%)	
Stone location			**0.004***
Upper ureter	16 (69.6%)	7 (30.4%)	
Middle ureter	14 (73.7%)	5 (26.3%)	
Lower ureter	16 (88.9%)	2 (11.1%)	
D J stent			**< 0.001***
Present	12 (48%)	13 (52%)	
Absent	31 (88.6%)	4 (11.4%)	
ESWL sessions, mean ± SD	**1.5 ± 0.5**	**2.7 ± 1.3**	**< 0.001***

**Statistically significant.*

The overall complication rate was 26.7% (figure 1). Most complications were minor with the commonest being loin pain seen (18.3%). However, in 6.7% of patients, severe renal or ureteric colic was observed mandating a visit to the accident and emergency department, of which 3.3% required inpatient care for pain control. Steinstrasse occurred in five patients, of which three were treated with ureteroscopy. The other two patients were treated conservatively with a further extracorporeal shock wave lithotripsy session leading to successful stone fragmentation. There was gross hematuria observed in 11.7% of patients, which improved spontaneously within two to three days. No major complications, such as hemorrhage (which could have necessitated transfusion), severe infection, or injury to other organs, occurred in any patients.

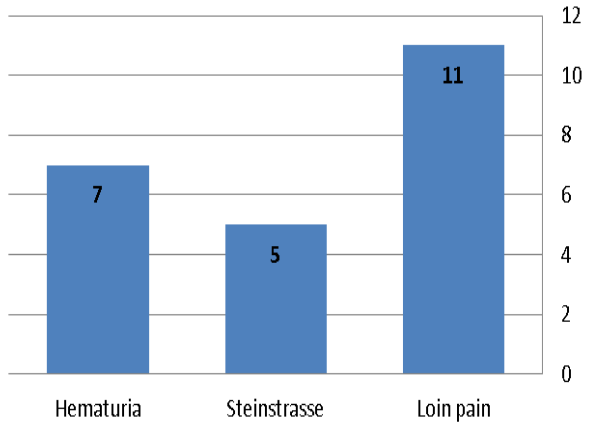

Figure 1: Distribution of Complication post extracorporeal shock wave lithotripsy

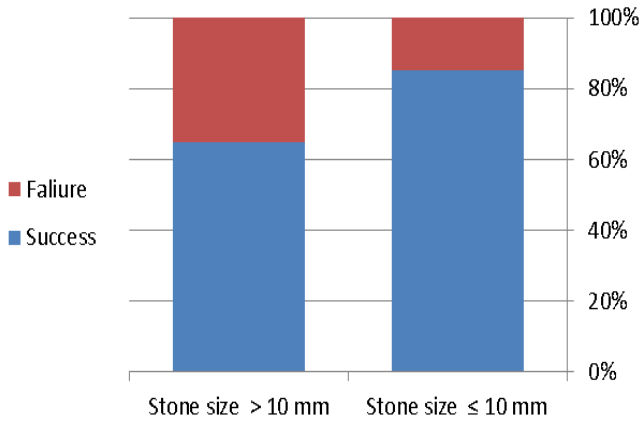

Figure 3: Extracorporeal shockwave lithotripsy outcome according to stone size

In the multivariate logistic regression analysis, only two variables were found to statistically significantly predict the failure of extracorporeal shock wave lithotripsy; sex and presence of double J stent. Compared to males, females had three-time higher risk for extracorporeal shock wave lithotripsy failure (odds ratio (OR) = 3.213; 95% confidence interval (CI): 1.194–8.645; p = 0.021). Logistic regression analysis also showed a higher failure rate when double J stent was used (OR = 6.358; 95% CI: 2.228–18.143; p = 0.001). The success rate of extracorporeal shock wave lithotripsy in males was 79.3% compared to 64.5% in females (Figure 2) and this result was statistically significant in both univariate and multivariate analysis. Success rate of treatment in stones ≤ 10 mm was 85% compared to that of only 65% in stone > 10 mm [Figure 2] with p-value of 0.004.

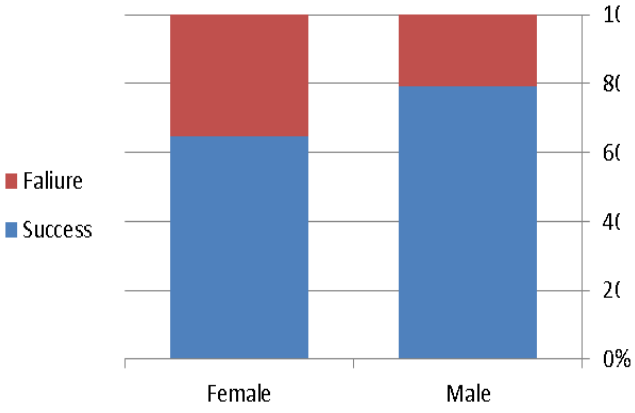

Figure 2: Extracorporeal shockwave lithotripsy outcome according to gender.

Inferior extracorporeal shock wave lithotripsy outcome was observed in patients with double J stent. Only 48% of patients with double J stent showed good response to treatment, while 88.6% without double J stent had notable treatment benefit (Figure 4) with a p-value < 0.001.

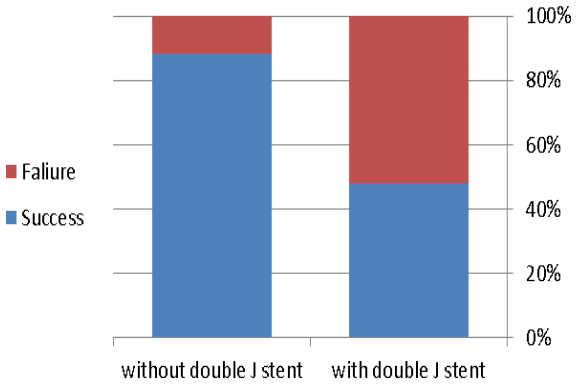

Figure 4: Extracorporeal shockwave lithotripsy outcome according to presence or absence of a double J stent.

Discussion:

Since the introduction of extracorporeal shock wave lithotripsy in 1980, it has become an established and preferred treatment for uncomplicated renal and ureteral stone (< 20 mm in diameter) as it is safe as well as non-invasive (1, 2-6). The success rate of extracorporeal shock wave lithotripsy varies from 46% to 91% and is measured in terms of stone fragmentation and clearance (12-19). Previous studies have demonstrated that predicting factors such as stone size, stone location, and severity of obstruction, urinary tract anatomy, obesity, and type of extracorporeal shock wave lithotripsy machine can have an influence on the success rate of extracorporeal shock wave lithotripsy (22-29). We evaluated some of the factors affecting the outcome of extracorporeal shock wave lithotripsy as well as safety of treatment and observed a success rate of 83.3% many studies have discussed factors affecting outcome of extracorporeal shock wave lithotripsy, but only few have considered age of any significance. One study of 3023 patients with renal and ureteric calculi treated with extracorporeal shock wave lithotripsy revealed that older patients had a significantly poorer stone-free rate (12). Another multivariate analysis of 2954 patients with renal stones treated with extracorporeal shock wave lithotripsy revealed that patients aged > 40 years had significantly poorer stone-free rate (20). However, another study by same group on ureteric stones found that age did not affect extracorporeal shock wave lithotripsy outcome (39). In our study, age was not a significant factor affecting the outcome of extracorporeal shock wave lithotripsy. However, only three patients were above the age of 60. The reason for the possible poorer stone-free rate of renal calculi in elderly patients is unknown. However, age-related sclerotic kidney may affect the acoustic impedance and lower efficacy of extracorporeal shock wave lithotripsy. Further studies are needed to confirm age as a predictor of extracorporeal shock wave lithotripsy outcome. Many studies have shown that gender is not a significant predictor of extracorporeal shock wave lithotripsy outcome. A retrospective study of 145 patients with renal stones treated with extracorporeal shock wave lithotripsy reported a success rate of 47.25% in males (43/91) and 50% (27/54) in females, which was not statistically significant (25). A study of 153 patients with ureteric stones treated with ESWL reported 83.33% success in males compared to 82.54% in females, which was also not statistically significant (22). In the present study, success rate of extracorporeal shock wave lithotripsy in males was 79.3% compared to 64.5% success in females and this result was statistically significant in both univariate and multivariate analysis. Our study reports gender as a predicting factor of extracorporeal shock wave lithotripsy success, which is not in agreement with previous studies. We found the threshold for pain in females was lower compared to males. Many of our female patients could not tolerate higher energy shockwave during treatment and some presented to the emergency department with pain after their first session of extracorporeal shock wave lithotripsy, which eventually needed admission and another treatment modality. All these factors might have influenced lower success rate in females. Considering the limitations of this study, another prospective study is needed to confirm gender as predictor of failure of extracorporeal shock wave lithotripsy treatment. Previous studies have shown that stone size is a significant predictor of ESWL treatment success. The larger the size of stone, the higher is the risk of extracorporeal shock wave lithotripsy failure. In a study of 2954 patients with renal stones, the authors observed a success rate of 89.7% for stones < 15 mm and of 78% for stones >15 mm ($p < 0.001$) (20). In another study of 427 patients with renal stones, the success rate of extracorporeal shock wave lithotripsy for stones $\leqslant$ 10 mm was 90% and 70% for stones > 10 mm ($p < 0.050$) (21). Stone size was also a significant predictor of extracorporeal shock wave lithotripsy outcome for ureteral stones. In a prospective study of 130

patients, the overall ESWL treatment success rate was 94.6%, while it was only 77.7% for stones > 15 mm. The authors also noted that the number of extracorporeal shock wave lithotripsy sessions increased with increasing stone size (40). Another retrospective study of 153 patients observed a success rate of 90.2% for stones ⩽ 10 mm and 68.6% for stones > 10 mm (22). In the same study, multivariate analysis revealed that stone size was an independent predictor of failure of ESWL in each group (stone size ⩽ 10 mm; OR = 50.005; 95% CI: 6.207 – 402.852; p = 0.013 and stone size > 10 mm; OR = 19.718; 95% CI: 1.600 – 243.005; p = 0.020). Similarly, in our study stone size was one of the important factors determining extracorporeal shock wave lithotripsy success. Success rate of treatment in stones ⩽ 10 mm was 85% compared to that of only 65% in stones > 10 mm (p = 0.004). A larger stone required a greater mean number of extracorporeal shock wave lithotripsy sessions for successful fragmentation. Stones ⩽ 10 mm required 1.4 mean sessions while stones > 10 mm required 2.1 mean sessions. The mean number of shocks required for fragmentation of stones ⩽ 10 mm were 5941.3 whereas 8321.5 shocks were required for stones > 10 mm. A positive correlation between the stone diameter (in mm) and the number of shock waves delivered was noted (r = 0.414; p = 0.000). Stone size was a significant predictor of extracorporeal shock wave lithotripsy success in univariate analysis; however, it was not found to be an independent predictor in multivariate analysis.

The use of a double J stent prior to extracorporeal shock wave lithotripsy treatment is rather controversial. Numerous studies have shown the use of double J stents is not much benefit prior to extracorporeal shock wave lithotripsy treatment. A prospective randomized study also revealed that the use of double J prior to ESWL did not improve treatment outcome (41). The authors reported a three-month stone-free rate of 88% in the stented group and 91% in the unstented group. Another study also concluded that the presence of ureteric stent resulted in a higher rate of extracorporeal shock wave lithotripsy failure (42). A comparative cross-sectional study noticed that pre extracorporeal shock wave lithotripsy double J stenting for a 2 cm ± 2 mm renal stone reduces the risk of renal colic and obstruction, but does not reduce formation of steinstrasse or infective complications. The same study also noticed the cost of the treatment doubled in the stented group, which is an important factor in the authors' country (Pakistan) (43). Our study supports the findings of previous studies. Our study observed inferior extracorporeal shock wave lithotripsy outcome in patients with stent. Only 48% of patients with stent showed good response to treatment, while 88.6% without stent had notable treatment benefit (p < 0.001). Stent was found to be independent predictor of extracorporeal shock wave lithotripsy failure in multivariate analysis. A higher failure of extracorporeal shock wave lithotripsy could be due to several difficulties such as difficulty in targeting, energy loss, and effect of the stent on peristalsis of ureter leading to reduced clearance of fragments. In our study, an indication for stenting was the presence of a stone > 15 mm in diameter. Considering the findings of previous studies and this study, routine stenting for stones < 20 mm should not be recommended as it does not prevent the formation of steinstrasse or the incidence of infective complications and might even lead to decreased stone clearance. However, it can be used in cases of sepsis and in patients with deteriorating renal function due to obstruction or with intolerable pain (3, 42, 43). A series of minor complications can occur after extracorporeal shock wave lithotripsy. A prospective study of 3241 patients treated with extracorporeal shock wave lithotripsy reported 4075 common complications, including renal colic (40%), gross hematuria (32%), steinstrasse (24.2%), and perirenal hematoma or subclinical subcapsular haematoma (4.6%) (44). All complications were managed conservatively or with minimal intervention. Another study noted an overall complication rate of 38.7%, which included all minor complications and were, treated conservatively (35). The overall complication rate in this study was 26.7%. All complications were minor, including loin pain (18.3%), gross hematuria (11.7%), and

steinstrasse (8.33%). No major complications occurred in any patient, such as hemorrhage (which could have necessitated transfusion), severe infection, or injury to other organs. Extracorporeal shock wave lithotripsy is not completely free from major complications such as massive retroperitoneal hemorrhage, renal, or other organs injury. However, each of these complications can be prevented by respecting contraindications, recognition, and correction of concomitant diseases or infection, and using extracorporeal shock wave lithotripsy in the most efficient and safe way (35, 44).

Conclusion:

This single institution experience of ureteric stones treatment with extracorporeal shock wave lithotripsy showed good results. Any single potential predictive factor cannot determine likely outcome of extracorporeal shock wave lithotripsy treatment individually. Therefore, modern approach should consider all the predictors collectively. Failure of extracorporeal shock wave lithotripsy was observed to more in the case of females, stone size > 10 mm, and patient with double J stents.

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