ORIGINAL ARTICLE

IS THERE ANY IMPROVEMENT IN EFFICACY OF EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY THERAPY FOR TREATING RENAL STONES WITH INVENT OF NEW SHOCKWAVE MACHINES?

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Background: Renal stone disease is a very common medical problem in general population. As with invent of newer therapeutic modalities, ESWL is already losing its popularity. But we believe it as an effective way of treating renal stones. This study was conducted to evaluate any improvement in success rate of ESWL therapy for treating renal stones with latest shockwave lithotripsy machines. **Methods:** Study conducted from June 2016 until November 2017 in Alkhor hospital, Hamad Medical Corporation, Qatar. All patients undergoing ESWL for renal stones in mentioned period were included. Total 197 patients underwent ESWL using newer machines. Factors already studied to affect the success rate like stone size, location, consistency (measured by Hounsfield units on CT), presence of stent were taken in consideration. After a period of 3 months either complete stone clearance or stone fragments smaller than 4 mm were considered as a treatment success. These results were compared to the results from literature. **Results:** Patients were followed until 3 months after treatment. 170 patients (86.29%) had complete stone clearance. Eleven patients (5.58%) had residual stone less than 4 mm, thus achieving an overall success of 181 patients (91.88%). 42 patients (21.32%) needed repeat session of ESWL with a maximum number of 3 sessions. 16 patient's (8.12%) required auxiliary procedures like flexible ureteroscopy. Post-ESWL complications were recorded in 12 patients (6.09%). Success rate was affected mainly by stone size with negligible effect of stone location. Presence of stent affected the number of sessions but has no impact on stone clearance. **Conclusion:** Although the stone size and to a negligible extent, the stone location and presence of stent may affect the stone clearance, nevertheless a significant improvement in success rate has been observed by use of new shockwave lithotripsy machines.

Keywords: Kidney; Extracorporeal shockwave lithotripsy; Stone

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INTRODUCTION

Extracorporeal shockwave lithotripsy was first introduced by Chaussy and his coworkers in 1980 as an alternative method for treating renal stone to the conventional open surgical method.[1] ESWL remains one of the most commonly utilized treatments for patients with upper urinary tract calculi. In a study recently conducted by Panchal and colleagues, the overall success of ESWL was 82%. In this study, the final success of ESWL for sites like ureter, pelvis, mid or upper and lower calyx were 94.1%, 84%, 85.7% and 58% respectively. Furthermore, the size and density of the calculi were the most important predictors determining stone clearance after ESWL. Low success of ESWL was found if calculi size was >20 mm and highest clearance rates were achieved in patients with calculi densities <1000 HU.[2] This study concluded that ESWL should be considered a primary modality of treatment in patients with favorable factors with lesser size (≤20 mm), density (≤1000 HU), and calculi located at pelvic, ureteric, upper and/or middle calyx. ESWL is minimally invasive, requiring very minimal or no anesthesia and provides a successful stone-free rate compatible to others endoscopic modalities when used in the appropriately selected subjects.[3] ESWL is a well-established management for renal calculi and is the suggested first line treatment together with retrograde intrarenal surgery (RIRS) for stones smaller than 2 cm in the renal pelvis or upper/middle calyx, according to European Association of Urology (EAU) guidelines. Some studies have shown higher success rate following ESWL therapy for renal stones with overall success rate reaching up-to 93%.[4] Many factors influence success of ESWL which include patient selection, stone size, location, stone consistency derived by calculating Hounsfield units on CT KUB [5] along with type of lithotripter used.[6] Few studies have attempted to correlate the radiological findings on pre-treatment CT-KUB with ESWL outcomes.[7]

We aim to evaluated the factors affecting the outcome of ESWL and any improvement in the success rate of renal stone treatment by the new generation of shockwave lithotripter.

MATERIAL AND METHODS

The study was conducted in Urology Department of Alkhor Hospital, Hamad Medical Corporation from June 2016 until November 2017, using the Modularis

Vario lithotripter (Modularis Vario; Siemens, AG Healthcare, Munich, Germany). All patients who underwent ESWL for renal stone during this period were included in the study. A total number of 197 patients were included. All patients had complete blood count (CBC), serum chemistry, serum creatinine, coagulation profile, blood sugar levels, Urinalysis, and urine culture. X-ray KUB and non-contrast CT KUB determining the Hounsfield units of stone was routinely done to find the size, location and consistency of stone. Weight of the patient was not regarded as limitation to the therapy. All of our patients were treated as an outpatient. Patients with uncorrected coagulation and bleeding disorders, pregnancy, and obstructed urinary tract distal to the stones were excluded from study. The Modularis Vario is a mobile, fully integrated, new generation lithotripter. This lithotriptor uses electromagnetic waves for shock wave generation, water cushion for coupling and fluoroscopy or ultrasound for stone localization. All patients were treated in supine position. ESWL settings used were as follows: For the Kidney: Number of shockwaves; 3000–3500, maximum energy level; 3–4, The procedure was carried out using morphine 10 mg injection given intramuscularly 1 hour before starting with paracetamol 1 g intravenously as needed in some cases. During the procedure, the patients were monitored by checking the vital signs. After finishing the procedure, the patients were sent home on oral ibuprofen. They were followed up in clinic after 2 weeks with a repeat x-ray KUB and in some cases ultrasound abdomen if the stone was not visualized. Patient requiring further sessions of ESWL underwent maximum of 3 sessions and followed up for 3 months. No fragmentation or residual fragments of more than 4 mm were considered as a failure and patients were offered alternative treatment.

Chi-Square test was used for statistical evaluation. A p-value <0.05 was considered significant.

RESULTS

Our study included total 197 patients. Among them 174 patients 88.32% were male with the remaining 23 female patients 11.67%. Age range was 22–74 years (34.2±11.55), and BMI range 24–40 (28.74±5.25). 6 patients 3.04% were treated for the residual stone after undergoing PCNL. 31 patients 15.73% had JJ stent either inserted for stone larger than 20 mm or stone in the ureteropelvic junction causing renal obstruction. Fluoroscopic stone localization was achieved in 167 patients 84.77% with only 30 patients 15.23% requiring ultrasound guided stone localization.

Stone location was categorized in 4 groups including upper, middle, lower renal calyces and renal pelvis. Among all 197 cases, 37 patients 18.78% had upper calyceal, 24 patients 12.18% had middle calyceal, 91 patients 46.19% had lower calyceal and 45 patients 22.84% had renal pelvic stone.

Stone size was also divided into 4 categories: Patients with stone size 5–10 mm, 11–15 mm, 16–20 mm, and patient with stones larger than 20 mm. Those patients having stone size 5–10 mm, upper calyx stones were in 26 patients 13.20%, middle calyx 13 patients 6.60% lower calyx 44 patients 22.33% and renal pelvis 6 patient's 3.04%. Patients with stone size 11–15 mm, upper calyx stones were in 9 patient's 4.56%, middle calyx 14 patients 7.11% lower calyx 37 patients 18.78% and renal pelvis 9 patients 4.56%. Patients with stone size 16–20 mm, upper calyx stones were present in 7 patient's 3.55% middle calyx 4 patient 2.03%, lower calyx 13 patients 6.60% and renal pelvis 3 patients 1.52%. Lastly patients having stone size more than 20 mm 3 patients 1.52% had stone in the lower calyx and 9 patients 4.56% had stone located in the renal pelvis.

With regard to stone composition which was estimated on non-contrast CT KUB by calculating stone density in Hounsfield units, only 30 cases 15.23% were having stone density less than 500 Hounsfield's, and the remaining 167 patients 84.77% had stone density more than 800 Hounsfield units. These results were concluded by stone analysis showing majority of stone composition being calcium oxalate. 4 patients 13.33% with density less than 500 Hounsfield and 12 patients 7.18% with density more than 500 failed treatment. No significant effect of stone density was observed in success rate in this study (p-value =0.25)

Among 197 patients, 170 patients 86.29% had a complete stone clearance confirmed by ultrasound done on 3 months follow-up. Other 11 patients 5.58% had insignificant residual stone sized less than 4 mm. Therefore, a total success rate of 91.88% (n=181) was achieved. By further sub-categorizing these results according to stone location, we found the following; success rate in upper calyx 91.89% (n=34/37), middle calyx 91.66% (n=22/24), lower calyx 91.20% (n=83/91), and renal pelvis 93.33% (n=42/45) (p-value = 0.98).

Multiple sessions of ESWL with a maximum of 3 sessions were required in 42 patients 21.32%. Of these, 5 patients 2.54% had upper calyx stone, and from them 1 patient 0.51% had stone size 5–10 mm, another 1 patient 0.51% had stone size 11–15mm and remaining 3 patients 1.52% had stone size 16–20 mm. In 6 patients 3.04%, stone were located in middle calyx, with 4 patients 2.03% having stone size 11–15 mm and the other 2 patient 1.01% having stone size 16–20 mm. Lower calyx stone was present in 22 patients 11.16%, 3 patients 1.52% with the stone size 5–10 mm, 11 patients 5.58% with stone size 11–15 mm, 5 patients 2.54% with stone size 16–20 mm and 3 of them 1.52% having stone size larger than 20 mm. Renal pelvic stones were present in 9 patients 4.57%, 1 patient 0.51% had stone

size 5–10 mm 2 patients 1.01% with stone size 11–15 mm, 2 patients 1.01% with 16–20 mm and remaining 4 with stone size more than 20 mm 2.03% (*p*-value =4.5).

Considering the stone size, the number of patients having stone in upper calyces, failed to respond to the shockwave therapy were 3 from total of 37 patients 8.10%. All these stones sized between 11–20 mm. Patients with stone in middle calyces, failed to respond were 2 with total of 24 patients 8.33%, all sized again 11–20 mm. Lower calyceal stones, failed to respond were 8 out of 91 patients 8.79%. Most of this failure was observed in stone sized 16mm and larger. Patients with stone in renal pelvis who failed to respond to ESWL were 3 out of 45 patients 6.67%, most cases with stone larger than 20 mm in size (*p*-value = 0.005) (Table-1).

Table-1: Results of extracorporeal shockwave lithotripsy for renal stones.

Data	Upper calyx	Middle calyx	Lower calyx	Renal pelvis	*p*-value
Total Pts: 197 Male: 174 (88.32%) Female: 23 (11.67%)	37 (18.78%)	24 (12.18%)	91 (46.19%)	45 (22.84%)	0.35
Stone size: n (percent) 5–10 mm: 89 (45.17%) 11–15 mm: 69 (35.02%) 16–20 mm: 27 (13.70%) >20 mm: 12 (6.09%)	 26 (13.20%) 9 (4.56%) 7 (3.55%)	 13 (6.60%) 14 (7.11%) 4 (2.03%)	 44 (22.33%) 37 (18.78%) 13 (6.60%) 3 (1.52%)	 6 (3.04%) 9 (4.56%) 3 (1.52%) 9 (4.56%)	0.005
Multiple sessions: Total pts: 42 (21.32%) 5–10 mm: 5 (2.53%) 11–15 mm: 18 (9.14%) 16–20 mm 12 (6.09%) > 20 mm 7 (3.55%)	 5 (2.54%) 1 (0.51%) 1 (0.51%) 3 (1.52%)	 6 (3.04%) 4 (2.03%) 2 (1.01%)	 22 (11.16%) 3 (1.52%) 11 (5.58%) 5 (2.54%) 3 (1.52%)	 9 (4.57%) 1 (0.51%) 2 (1.01%) 2 (2.01%) 4 (2.03%)	4.2
Treatment success: Patients: 181 (91.88%)	34/37 (91.89%)	22/24 (91.66%)	83/91 (91.20%)	42/45 (93.33%)	
Treatment failure: Total pts: 16 (8.12%) 5–10 mm: 2(1.01%) 11–15 mm: 6(3.04%) 16–20 mm: 5(2.53%) > 20 mm: 3(1.52%)	 3 (1.52%) 2 (1.01%) 1 (0.51)	 2 (1.01%) 1 (0.51%) 1 (0.51%)	 8 (4.06%) 2 (1.01%) 2 (1.01%) 3 (1.52%) 1 (0.51%)	 3 (1.52%) 1 (0.51%) 2 (1.01%)	0.005
Stone Density: <500 HU: 30 (15.23%) >500 HU: 167 (84.77%)	<u>Success</u> 26 (86.66%) 155 (92.81%)		<u>Failed</u> 4 (13.33%) 0.25 12 (7.18%)		

DISCUSSION

Extracorporeal shock wave lithotripsy (ESWL) was considered preferable modality for treating urinary stones for many years. It significantly reduced the hospital stay; surgery related complications as well as cost effectiveness. It is a noninvasive therapy which can be done as an outpatient procedure with low complication create a very few contraindications for example pregnancy, bleeding disorders and aortic aneurysm.[7] In recent years, it decreased its popularity as it was observed that newer ESWL technology has been less effective at fragmenting stones than earlier devices.[8] It is known that the newer generation of lithotripters uses smaller focal zones, allowing higher peak-point pressures.[9] The Siemens Modularis Variostar lithotripter used in our Center has the advantages that it is more comfortable for the patient's with better imaging and stone location because of the very high quality of the fluoroscopy as well as the ultrasound machine, and an effective fragmentation of the stones. We achieved a success rate of 91.88% for renal stones in our experience. These results are much better than results of previous studies done previously with older machines. Alansari *et al*[10] in their study reported overall success rate of 78%. Al Marhoon and colleagues[11] reported success rate of 74% in renal stone using same machine.

Our study showed that location of stone did not affect much on the treatment failure (*p*-value =0.98). The percentage of patients failed to respond to therapy with maximum 3 sessions of ESWL were; in upper calyces 8.10%, middle calyces 8.33%, lower calyces 8.79% whereas renal pelvis 6.67%. These show only slight better results obtained in patients with stones in renal pelvis, with almost similar results in other locations. These results are contrary to some studies showing failure rates higher in lower calyceal stones.[12,13] Other studies show no difference success rate of ESWL with regard to stone location.[14,15]

A significant effect of stone size was observed for treatment failure in our study. Stone measuring 16 mm and above required multiple sessions and had comparatively higher failure rate (*p*-value =0.005). Thirty-nine patients had stone size 16mm and above and 8 patients had treatment failure 20.51%. Stone size 11–15 mm was found in 59 patients with 6 cases having failed treatment 10.16%. Whereas 2 out of total 89 patients 2.25% with stone size of 5–10 mm had failed

treatment. These results are well documented by most of studies.[15]

Although plain abdominal X-ray (KUB) is accepted as the first-line diagnostic method for follow-up examination after stone therapy non-contrast spiral CT seems to be the most sensitive for detecting residual fragments.[16] Auxiliary procedures were minimal in the present series; the auxiliary treatment rate was similar to what has been reported.[17] Only 16 patients (8.12%) cases had to undergo auxiliary procedures like flexible ureteroscopy. Most of these patients selected these procedures as they didn't like to go for two or more sessions of ESWL. Complications rate in our series was negligible with a total number of 12 patients (6.09%) with urinary tract infection seen in 4 (2.03%) cases, ureteric colic in 7 (3.55%) and Stein Strasse seen in 1 patient (0.51%) of cases. All cases were managed conservatively. We did not report any major complications in the present study; as noticed in some other studies, like acute renal failure, Massive retroperitoneal hemorrhage.[18,19]

CONCLUSION

The new lithotripters machines are much safe and effective for treating renal stones. Data from our center shows an improved success rate of 91.88% for renal stones with very minimal and conservatively manageable complications. Therefore, it will be more appropriate using this economic and effective therapy for treating urinary calculi, especially up to 20 mm in diameter. In the present study, factors most significantly affecting stone clearance was stone size. Location of stone as well as stone consistency and presence of stent had insignificant effect on stone clearance.

AUTHORS' CONTRIBUTION

NS: Literature search, conceptualization of study, data collection and analysis, data interpretation, write-up, proof reading and finalizing study and manuscript. AA & KMA: Final manuscript preparation.

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