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Extracorporeal Shock Wave Lithotripsy in the Treatment of Single Ureteric Stone. Initial Data from Iraq

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Abstract

Background: Extracorporeal shock wave lithotripsy (ESWL) became the first line in the treatment of ureteric stone after failure of conservative treatment because of its safety, simplicity and effectiveness. It is not invasive procedure and can be done on outpatient basis without anesthesia and with few complications which is most probably temporary and treatable. The objective of this study is to evaluate the efficiency and safety of ESWL in treatment of ureteric stone in Iraq. Materials and Methods: A total of 112 Iraqi patients with ureteric stones were participated in this prospective observational study in which patients scheduled for ESWL treatment for a period of 6 months. Patients were divided into 2 groups: 1) Group 1: 52 patients with proximal ureteric stone; 2) Group 2: including 60 patients with distal ureteric stone. Pre-operatively all patient underwent bowel preparation and were asked to fast for 8 hours before the procedure. Results: The age ranged between 22 and 55 with mean of 42 (SD = 5) years. Around 46% had proximal ureteric stone and the rest were in distal ureter. Around 44% needed one session and 40% needed two sessions to be stone-free respectively. In regards to associated symptoms, 74% had ureteric colic, 3% haematuria, 43% microhematuria and 12% UTI. Mild hydronephrosis was found in 90% of the cases and 30 reported had previous intervention. Success rate was 90%. Conclusions: ESWL is safe and effective in treatment of ureteric stone with few complications and must be regarded first choice after conservative treatment in a patient with uncomplicated ureteric stone.

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Keywords

Ureteric Stones, Extracorporeal Shock Wave Lithotripsy (ESWL), Iraq

1. Introduction

Since its introduction in the 1980 [1], extracorporeal shock wave lithotripsy (ESWL) has become the standard convenient, non-invasive outpatient procedure used for treatment of renal and ureteric stones and since then the management of nephrolithiasis has undergone a complete revolution [1]. Shock waves that are generated by a source external to the patient propagate through the body before being focused on a kidney stone. These waves cause stone fragmentation directly by producing mechanical stress or indirectly by collapsing of cavitation bubbles formed by the negative pressure in their trail. The initial result of ESWL was promising, with a greater than 90% success rate achieved [1] [2]

After ESWL introduction in 1980s, the technological developments have resulted in more advanced lithotripters with shorter focal length and narrower focal breadth, which help reduce the level of pain and ultimately obviate the need for anaesthesia and hospital admission for the procedure [3].

ESWL is best applied in certain selected situations. Although all stones can be treated by ESWL theoretically, the ideal situation is a stone of size less than 2 cm presenting in a normal urinary tract [2]. However, the most recent guidelines (2014) from European Association of Urology (EAU) recommend ESWL for proximal ureteral stones <10 mm and ESWL is considered equivalent option with ureteroscopy for proximal ureteral stones <10 mm and for distal ones <10 mm [4]. In addition to that, according to recommendation of American Urological Association Stone Guidelines Panel in 1997, ESWL is still the first line method of treatment for ureteral and renal stones of size smaller than 2 cm [4]-[6].

There are some contraindications for ESWL including uncontrolled urosepsis, uncontrolled hypertension, distal obstruction for stone passage, pregnancy, stone greater than 2 cm and cystine stone [7]. Besides these contraindications, the main complications associated with this procedure are the vascular injury resulting in haematoma formation. However, the incidence of clinically significant haematoma was reported to be less than 1% [8]. Other immediate complications include stone fragment related complications such as ureteric colic and steinstrasse. Moreover, there are some long-term complications of ESWL, including increased incidence of new onset hypertension in the elderly [9] and new onset diabetes [2] [10].

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, and invariably alternative treatments are then needed, incurring additional medical expenses [11]. A number of stone characteristics such as fragility, size, location and composition are known to affect outcome [11].

This study is an analysis of patients with ureteric stone calculi at different levels treated with ESWL in order to evaluate the efficiency, safety and duration of treatment of this procedure in an Iraqi hospital located in Capital, Baghdad as for the best of our knowledge which was first done in Iraq.

2. Material and Methods

This is a prospective observational study in which patients scheduled for ESWL were included in this study for the period of 6 months between May 2014 and November 2014 at Al-Karamah Teaching Hospital, Baghdad, Iraq. Patient who fulfilled the inclusion criteria were called for participation after signing informed consent. Inclusion criteria were: 1) adult aged 20 years and above, 2) single stone, 3) stone of less than 1 cm in size, 4) failed to pass spontaneously after conservative treatment for 2 - 4 week, 5) uncomplicated ureteric stone, 6) unimpacted stone. However, the exclusion criteria included 1) obstructive symptoms, 2) single kidney, 3) persistenthematuria or 4) intolerable pain, 5) abnormal renal function test.

A total of 114 patients were deemed sufficient to detect a difference of 25% of clearance rate between proximal and distal ureteric stone with power of 80% at significance level of 5%.

The study was approved by the ethics committee of AlKaramah teaching hospital.

3. Procedure

Patients were treated as inpatient/outpatient. Full medical examination was done for all patient to exclude any risk factor of the surgery or the presence of other condition that might affect the outcome of the procedure. Investigations included: GUE, RFT, CBP, LFT, RBS, coagulation profile, culture & sensitivity of urine were done. Imaging study include: KUB, ultrasound & IVU. Patients were categorized into 2 groups: 1) Group 1: 52 patients with proximal ureteric stone which represent the part of ureter from pelviureteric junction to the narrow part of the ureter where it crosses the iliac vessels, which reflecting technical impediment for rigidureteroscopy (Segura *et al.*, 1997); 2) Group 2: include 60 patients with distal ureteric stone which represent the segment from below the narrow part of ureter where it grosses the iliac vessels to the vesicoureteric junction. Pre-operatively all patient underwent bowel preparation and were asked to fast for 8 hours before the procedure. Gentamycin 80 mg was given intravenously.

The ESWL procedure was done under IV sedation by the same surgeon for all patients. Fluoroscope used for localization of the stone & after that fragmentation was performed with KARL STORZ HM-3 LITHOTRIPTER; Every Patient was give 3000 shock wave per session. Water was used in the procedure as transmitter for the shock wave. Patients have significant residual fragment more than 4 mm were scheduled for a second session. Patients allowed for maximum of 3 sessions with 1 week apart.

Evaluation of the patient was done 1 week after ESWL by clinical assessment. LAB findings of GUE & Culture, B urea, S creatinine, KUB & abdominal ultrasound. Follow up done on weekly basis up to 4 week and of up to three sessions.

Success was defined as being stone free state or appearance of a symptomatic less than 4 mm stone after 4 weeks or earlier.

Failure of treatment was defined as failure of stone expulsion after end of the study or appearance of complications like severe obstruction or acute pyelonephritis and attack of severe ureteric colic. Number of session, shocks and energy were recorded.

4. Statistical Analysis

Descriptive statistics produced for the study variables. Numerical variable was described with mean and standard deviation while categorical variable with frequency and percentage. Chi square test was used to test the difference in the proportion while “independent t test” to test the mean difference between two groups.

5. Results

Distribution of the study sample is shown in **Table 1**. The age ranged between 22 and 55 with mean of 42 (SD = 5) years. Among the 112 participants, there was 86% males. Around 46% had proximal ureteric stone and rest were in distal ureter. Around 44% and 40% needed one and two session to be stone free respectively. In regards to associated symptoms, 74% had ureteric colic, 3% frank haematuria 43% microhematuria and 12% UTI. Mild hydronephrosis was found in 90% of the cases and 30 reported had previous intervention. Success rate was 90% (**Table 1**).

The distribution of the site of the stone by selected explanatory variable is shown in **Table 2**. It is observable that there was no significant difference in the proportion of gender, site of the stone, use of analgesic between patients with distal and proximal ureteric stones. Of the total sample, 8 patients showed insignificant residual surgical fragment less than 4 mm. Failure of stone clearance occur in 12 patients after 1 month of treatment, so they are underwent uretroscope. However, the number of session needed to clear the stone has shown a difference.

Those with proximal stone needed one session more than the patients with distal ureteric stones. In turn the need for two or three session was significantly higher among patients with proximal stones. Age, stone size and time needed to be free were not significantly different between the two groups. However the visual analogue scale of pain (VAS) was significantly higher among patient with proximal ureteric stone (**Table 2**).

The most common complications after ESWEL is transient hematuria in 90% of cases, ureteric colic in 82% of cases. Exactly 4 cases developed perinephric & sub capsular hematoma diagnosed with ultrasound. Febrile urinary tract infection was developed in 12 cases.

Table 1. Descriptive statistics of the sample.

		N	%
Gender	Male	96	86
	Female	16	14
Site	proximal	52	46
	distal	60	54
Number of session needed	Single session	44	44
	Two session	40	40
	Three session	16	16
Need for ureteroscopy failure	No	100	90
	Yes	12	10
Ureteric colic	No	22	18
	Yes	90	74
Gross haematuria	No	108	97
	Yes	4	3
Micro haematuria	No	64	57
	Yes	48	43
Lower ureteric symptoms	No	62	55
	Yes	50	45
UIT	No	99	88
	Yes	13	12
Hydronephrosis	No	11	10
	Yes	101	90
Previous intervention	No	78	70
	Yes	34	30
Age mean (SD)	42(5)		

6. Discussion

Urolithiasis is common problem in Iraq because of its geographical location in Middle-East (Middle-East lies within the stone belt region extending from Indonesia to North Africa), economic and dietary factors, dehydration, exposure to heat and possible genetic factors [12]. However, with the development of advanced instruments and techniques, minimally invasive surgical procedures have gradually replaced open surgery for treating proximal ureteric stones [13]. To choose between active stone removal and conservative treatment, it is important to take into account all individual circumstances that may affect treatment decisions.

We studied a total of 112 Iraqi patients have ureteric stones who underwent treatment by ESWL. The decision has been taken to perform ESWL because their stones initially did not respond to conservative approach of treatments of ureteric stones to get spontaneous clearance of the stones. ESWL treatment was performed before other options which consist of endoscopic manipulation, and open surgery.

Spontaneous clearance of ureteric stones depends mainly on the stone size and, to a lesser extent, on other factors like observation time. The incidence of spontaneous passage of ureteric stones of about 4 mm in diameter is reported to range between 59% and 69%, and decreases markedly with increase in stone size, with the spontaneous elimination of stones about 6 mm being exceptional and frequently accompanied by complications

Table 2. Association of site of stone and explanatory variables.

		Proximal	Distal	p
Gender	Male	44	52	0.757
		45.80%	54.20%	
	Female	8	8	
		50.00%	50.00%	
Site	Right	27	28	0.579
		49.10%	50.90%	
	Left	25	32	
		43.90%	56.10%	
Stone free	No	8	4	0.137
		66.70%	33.30%	
	Yes	44	56	
		44.00%	56.00%	
Analgesic	No	39	49	0.391
	Yes	44.30%	55.70%	
		13	11	
		54.20%	45.80%	
Number of session	One	24	20	0.056
		54.5%	45.5%	
	Two	12	28	
		30.0%	70.0%	
	Three	8	8	
		50.0%	50.0%	
	Additional	8	4	
		66.7%	33.3%	
Mean age		24 - 55	20 - 53	
Stone size (mm)		6.8 (1.7)	6.7 (1.8)	0.763
VAS (0 - 10)		6.42 (1.34)	5.44 (1.32)	<0.001
Time to free (d)		6.6 (12.4)	8.5 (5.8)	0.313
Mean X-ray time (min)		295	345	0.427
Average no of sessions		1.846	1.860	0.766
Average energy (J)		213	208	0.072
Average shock/session		3000	3000	1.0
Average shock per case		5.530	5.600	0.859

VAS: visual analogue scale.

like recurrent intractable pain, obstruction and infection [3] [14] [15]. In our study, the treatment of ureteral stones using ESWL were delayed for 2 - 4 weeks after the diagnosis. Same was followed by other studies [3] [13] [16].

In current study we performed ESWL mono therapy in patients with stone size less than 1 cm, this fact explain the higher overall stone free rate which is 100 from 112 patients, this rate is comparable to the rate reported by other authors using different machine [17] [18]. Ureteric stones are often more difficult to locate and, therefore, more difficult to target with the shock wave. However, several studies have demonstrated stone-free rate close to 100% for the treatment of proximal ureteric stone with ESWL [16]. However, stone free rate appears to decline to 70% for mid-ureteral stone for many lithotripters [19].

In our study pain was the main complication which is treated by analgesia, because, ESWL was less invasive and was performed as an outpatient procedure with adequate pain management; it did not need hospital admission or an operating theater. Although the re-treatment rate was very high because of larger stone (>10 mm) and those causing hydroureteronephrosis, usually required more treatment session [20] [21].

The machine used in this study was KARL STORZ HM-3 lithotripter system which utilize an electromagnetic shock wave generator and water balloon coupling mechanism. It has several advantages including small size, a multifunctional table, as well as fewer servicing and clinging requirements, these machines tend to have much smaller focal areas and may be less powerful so patient positioning and stone localization must be exact. Augustin H., 2007 [22], stated that the newer generation of lithotripters use smaller focal zones, allowing higher peak-point pressures. These lithotripter machine has the advantages of greater comfort for the patient during the procedure, better imaging because of the very high quality of the fluoroscopy, and a great comminution of the stone, achieving a success rate of 74% for renal stones and 88% for ureteric stones (90% in our study), and decreasing the need for auxiliary manoeuvres [23].

Like any other urological procedure, ESWL is also associated with complications, mainly obstructive and infective. ESWL therapy is noninvasive, anesthesia-free and can be administered in an outpatient setting. Therefore, ESWL remains the first choice for treating renal and ureteric stones [22]. Hence, in our study, hematuria observed in few patients and this was transient and mild in all patients, while, perinephric hematoma happened in 4 patients with age above 50 and have history of Hypertension, it is treated conservatively by enhanced fluid intake & bed rest. So the overall treatment complication rate of current study is the minimum, with the majority being minor complications, and no major complications were reported in the present study; however, in other studies [11], acute renal failure has been reported after ESWL [24], massive retroperitoneal hemorrhage after ESWL leading to patient death has also been reported [25]. Besides renal injury [26], ESWL is not completely free from other serious complications, such as gastrointestinal injury in1.8% of cases, including colonic perforation or duodenal erosions [27]. However, there was no association between ESWL and the subsequent long-term risk of hypertension [11] [28].

The study is perceived to have the following strength: 1) first study of its kind from Iraq; 2) sufficient sample size; 3) well-defined protocol for data collection and intervention. Although measures were taken to achieve the objectives with optimum precision, the inclusion of patients from a single centre might limit the generalization of the results.

7. Conclusion

ESWL using KARL STORZ HM-3 lithotripter is a valuable therapeutic option, and a safe, effective and convenient non-invasive treatment for ureteric stone. According to our findings, ESWL with its high stone-free rates and negligible complications is the first choice after failure of conservative treatment to be preferred in the treatment of ureteric stones in Iraqi.

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Conflicts of Interest

No financial or other relationships that might lead to a conflict of interest.

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