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ORIGINAL PAPER

Complications and outcomes following extracorporeal shock wave lithotripsy: a prospective study of 3,241 patients

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Abstract Extracorporeal shock wave lithotripsy (SWL) has become the least invasive treatment modality with high success rates for urinary calculi; however, its established efficacy has been associated with a number of side effects and complications. This study sought to further evaluate the incidence rate and management of the post-SWL complications and also the efficiency of procedure in a large scale of patients. During a 51-month period, 3,241 consecutive adult patients with the mean age of 38.1 years (range 15–75) and urinary calculi (≥4 mm) underwent SWL at our referral center and were followed for 3 months prospectively. Overall, 3,614 stones [kidneys (83.5%), ureters (15.8%) and bladder (0.7%)] in 3,241 patients were treated requiring 7,245 SWL sessions. Stone-free state occurred in 71.5% calculi and success rate in 79.8% patients. The re-treatment was necessary in 37.2% patients. Auxiliary procedure and efficiency quotient were 5.6% and 0.50, respectively. SWL success rate decreased as the stone size increased ($P < 0.0001$). The stone-free rate was correlated with the location of the stone. During the study period, 4,075 complications occurred in our patients. Colicky pain (40%) was the most frequent symptom followed by gross hematuria (32%) and steinstrasse (24.2%). Symptomatic bacteriuria developed in 9.7% patients; *Escherichia coli* (30.4%) was the most causative organism. In conclusion, the complication rate following SWL was high in our study; however, the majority was mild and managed conservatively or with the minimal intervention. Moreover, the management of urinary calculi in adults using SWL was proved to be safe and efficient, particularly for ureteral stones <10 mm, renal pelvic stones <20 mm, and bladder stones <30 mm.

Keywords Extracorporeal shock wave lithotripsy · Urinary calculi · Outcome · Complication · Adult

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Introduction

Management of patients suffering from urinary calculi, considered as a health-care problem due to its high incidence and prevalence, has been revolutionized by the development of extracorporeal shock wave lithotripsy (SWL) in early 1980s [1]. SWL has become the least invasive treatment modality with high success rates for urinary tract calculi [2, 3]. However, the success rates differ based on the size, location and composition of the stone in the urinary tract, type of anesthesia, type of lithotripter used, shock wave rate and the anatomical characteristics [4–6]. Its established efficacy has been associated with a number of side effects and complications that are being increasingly recognized with its widespread availability and use. These complications are generally mild and related to fragment passage, infection and tissue effect; nevertheless, they should be observed seriously [7]. This study was carried out in order to further evaluate the incidence rate, management and prognosis of the complications following SWL as well as the efficiency of this technique in a consecutive set of patients during a 51-month period.

Materials and methods

Study population

During 5 years period, 3,241 consecutive adult patients with the definitive diagnosis of urinary tract stones underwent SWL at our referral center and were enrolled in this prospective study. The local ethical committee at our institute approved the study protocol. All patients provided written informed consent regarding the advantages and possible side effects of the procedure. The population consisted of 2,035 (67.2%) male and 1,206 (32.8%) female patients with a mean age of 38.1 years (range 15–75). The adult participants (15 years and older) had stones 4 mm and larger in size and were followed for a period of 3 months. Patients with non-functioning kidneys, hydronephrosis due to congenital anomalies, pregnancy, uncontrolled clotting disorders, calcified abdominal aorta or renal artery aneurysm, morbid obesity, obstruction distal to the stone, severe uncontrolled urinary tract infection (UTI) and/or those not amenable to follow-up were excluded from the study.

Pre-SWL evaluation, SWL procedure and post-SWL care

A complete clinical history and physical examination were performed before SWL application. The patients were evaluated with plain radiography of the urinary tract (KUB), excretory urography and ultrasonography. Stone size was measured as the maximal linear length in millimeter. Pretreatment laboratory evaluation included urinalysis and urine culture, serum creatinine level, blood urea nitrogen, serum uric acid level, complete blood count, coagulation profile, and pregnancy test in young women. Hematology and cardiology consultations were performed routinely in patients with coagulopathy and cardio-pulmonary disorders, respectively. Double-J stent was used in cases with stone $\geq$2 cm. In patients with positive urine culture, SWL was postponed until the infections were controlled using appropriate antibiotics. Nevertheless, prophylactic antibiotic was not routinely used.

Patients fasted for 12 h preoperatively. Mild intestinal preparation was done using laxatives. Then all patients underwent lithotripsy using an electromagnetic Siemens Lithostar (Siemens AG, Munich, Germany) on an outpatient basis by a one-team approach. Intravenous sedation was given only to patients who could not tolerate SWL using diazepam (10 mg), or pethidin (50 mg). Patients with renal or upper ureteral calculi were treated in the supine position. For middle or lower ureteral stones patients were turned prone. During SWL sessions, 1,000 cc serum half saline was infused intravenously.

After the completion of the procedure, patients were observed. If there was no sign and/or symptom of severe hematuria or urinary tract obstruction, patients were discharged on the same day. Follow-up included plain radiography and ultrasonography on the 1st day, 2 weeks, 1 month, 3 months and whenever patient had pain, hematuria and/or any other symptoms postoperatively. Furthermore, patients were asked to perform urinalysis and urine culture test after a week. Post-SWL pain medication was not performed routinely; on demand oral and/or suppository analgesics such as diclofenac sodium (50 mg) was the routine procedure for pain control. In addition, mild oral diuretic (hydrochlorothiazide 50 mg/12 h), overhydration and physical activity for 3 months were recommended. An interval of at least 1 week was maintained between SWL sessions, if required.

Treatment success was defined as asymptomatic, stone-free status without any evidence of obstruction on radiological studies 3 months after SWL performance, and treatment failure was based on the need for further intervention during the follow-up period or not becoming stone-free within 3 months. An efficiency quotient was determined for SWL, using the formula: stone-free percentage/100 + re-treatment percentage + auxiliary procedure percentage. During the study period, patient characteristics, stone and therapy features and complications were registered.

Statistical analysis

The data were analyzed by the Chi-square test or Fisher's exact test for dichotomous variables and the independent samples t test for continuous variables using Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) software. A value of $P < 0.05$ was considered significant.

Results

SWL outcome

Overall, 3,614 stones in 3,241 patients were treated requiring 7,245 SWL sessions. Calculi were on the left side in 1,902 (58.7%) cases, right side in 1,164 (35.9%) and bilateral in 175 (5.4%). Of 3,614 stones treated in our study, 3,018 (83.5%) were in kidneys, 572 (15.8%) in ureters and 24 (0.7%) in bladder. There were 2,342 (64.8%) new onset and 1,272 (35.2%) recurrent calculi.

Radiological evaluation performed 3 months after SWL revealed that the success rate in the whole patients' population, every one of whom had one stone, was 2,585/3,241

Table 1 Stone-free status in our series

Location	No. stones	No. stones 4–9 mm/total no. (%)	No. stones 10–19 mm/total no. (%)	No. stones 20–29 mm/total no. (%)	No. stones ≥ 30 mm/total no. (%)	Total/total no. (%)
Renal pelvis stone-free	2,234	287/312 (92)	787/938 (84)	546/738 (74)	111/246 (45)	1,731/2,234 (77.5)
Renal calyx stone-free	784	64/110 (58.1)	163/329 (49.5)	121/259 (46.7)	24/86 (27.9)	372/784 (47.4)
Proximal ureter stone-free	246	150/150 (100)	36/79 (45.5)	4/15 (26.7)	0/2 (0)	190/246 (77.2)
Middle ureter stone-free	69	43/43 (100)	11/25 (44)	0/1 (0)	–	54/69 (78.3)
Distal ureter stone-free	257	181/189 (95.8)	29/55 (52.7)	6/13 (46.1)	–	216/257 (84.1)
Bladder stone-free	24	12/12 (100)	7/7 (100)	3/4 (75)	0/1 (0)	22/24 (91.7)
Total stone-free (%)	3,614	816/3,614 (22.6) (90.3)	1,433/3,614 (39.6) (72.1)	1,030/3,614 (28.5) (66)	335/3,614 (9.3) (40.3)	3,614/3,614 (100) (71.5)

(79.8%). As shown in Table 1, we also achieved a stone-free rate in 2,585 of total 3,614 stones (71.5%). A total of 1,206 (37.2%) patients required re-treatment with the mean of 1.6 sessions per patient. The average number of SWL sessions per calculus and per patient was 2.0 and 2.2, respectively. Auxiliary procedures were performed in 5.6% of the patients. The efficiency quotient was 0.50 for SWL in this study. The initial voltage for each shock was 13 kV, which was gradually increased; the mean voltage for each patient was 18 kV. The mean number of shock waves administered for each patient was 2,800 and 3,900 in kidney and ureteral stones, respectively. The mean rate of shock waves was 90 per min.

The SWL results in regard to the calculi location are outlined in Table 2. The mean size of the treated stones in the proximal, middle and distal of ureter was 10.4, 9.7 and 9.1 mm, respectively. The stone-free rate for renal calculi was 69.7 and 80.4% for ureteral calculi, representing a significant difference ($P < 0.001$). Regarding the intrarenal stone location (calyceal and renal pelvis), there was a significant statistical association between the locations and the number of successfully treated calculi ($P < 0.0001$).

Table 2 Relation of patient age, stone characteristics and SWL procedures with SWL outcome

Characteristics	No. stones	No. success patients	No. failure patients	*P* value
Mean age ± SD (year)	–	37.6 ± 21	40.1 ± 19	<0.001*
Stone size (mm)				
4–9	816	737	79	<0.0001†
10–19	1,433	1,033	400	
20–29	1,030	680	350	
≥30	335	135	200	
Stone location				
Renal**				<0.001†
Renal pelvic	2,234	1,731	503	
Renal calyx	784	372	412	
Ureter***				
Proximal ureter	246	190	56	
Mid-ureter	69	54	15	
Distal ureter	257	216	41	
Bladder	24	22	2	
Mean treatment time ± SD (min)	–	42.7 ± 10	46.1 ± 14	<0.001*
Mean fluoroscopy time ± SD (s)	–	118 ± 15	121 ± 20	<0.01*

SD standard deviation

* Independent samples *t* test

† Chi-square test

** Differences between renal pelvic and calyx: $P < 0.0001$, Fisher's Exact test

*** Differences between proximal, mid and distal ureter: $P = 0.78$, Chi-square test

No difference was observed between the different locations for proximal, middle or distal ureteral stones ($P = 0.78$); however, the success rate was higher in distal than proximal ureteral stones (84.1 vs. 77.2%). Furthermore, it was noted that any increase in the stone size had an inverse relation with the SWL success rate. The mean treatment time, fluoroscopy time and patient age had a significant association with SWL outcome ($P < 0.001$, $P < 0.01$ and $P < 0.001$, respectively). None of the studied patients required general anesthesia.

Post-SWL complications

During the study period, 4,075 complications in 1,178 (36.3%) patients occurred. All complications are monitored and summarized in Table 3. The most frequent complication was severe colicky pain, observed in 1,296 (40%) patients; recurrent pain attacks was reported in 188 (14.5%) of these patients. They were successfully treated using antispasmodics, anti-inflammatory agents, overhydration and/or intervention. Macroscopic hematuria was presented in 1,037 (32%) cases; the condition recovered spontaneously in 48 h in 897 (86.5%) patients, 10 days in 119 (11.5%) and 1 month in 21 (2%) cases. Urinary obstruction due to stone fragmentations, the third most common complication, was reported in 1,001 (30.9%) subjects. The underlying cause of obstruction and the used treatment procedures are charted in Table 3. The obstruction was located in the distal, middle and proximal part of ureter in 73, 9 and 18% of the patients, respectively. The development of steinstrasse had a significant correlation with the size and the location of the treated stones ($P < 0.001$, $P < 0.01$, respectively). Perirenal or subcapsular hematomas were observed in 151 (4.6%) patients, of whom 18 (11.9%) were symptomatic. Therefore, the overall rate of symptomatic hematoma formation was 0.55%. In follow-up period, symptomatic bacteriuria was reported in 315 cases. The isolated organisms were as follows: *Escherichia coli* in 96 (30.5%) patients, *Klebsiella* in 61 (19.4%), *Enterococcus* in 52 (16.5%), *Pseudomonas* in 45 (14.3%), *Proteus* in 40 (12.7%) and other microorganisms in 21 (6.6%) patients. Pyelonephritis and sepsis occurred in three and two patients, respectively; all of which were successfully treated with appropriate antibiotics.

Before treatment, all of the patients had normal blood pressure and none of them developed new onset hypertension and/or skin lesion during the study period. Mortality occurred in two patients. One case was a 35-year-old woman who died on the 10th post-SWL day due to the rupture and bleeding of the cerebral artery aneurysm. Another case was a 55-year-old woman who passed away with cardiac arrest manifestations in the absence of any underlying diseases at 6 h after treatment.

Discussion

Although several technical limitations and potential adverse effects are being proposed, SWL in general is regarded as the first line treatment in the majority of urinary tract stones [7]. This study has analyzed prospectively the SWL efficiency and also the occurrence of short-term (first 3 months) complications in 3,241 adult patients who underwent SWL and achieved 79.8% success rate. Moreover, 4,075 complications occurred in our patients during the study period.

Various factors such as the stone size, stone location in the collecting system, stone type, stone radiopacity or computerized tomography (CT) attenuation values, anesthesia type, SWL machine type, the number of SWL sessions and the treatment rate determine the outcome of SWL for renal and ureteral stones [4–6]. The stone-free rate also seems to be related to stone location. Abdel-Khaled et al. [6] concluded that site, transverse diameter and presence of a ureteral stent are among the predictive factors for SWL success rate in ureteral calculi. In the current study, we observed significant differences in the results of urinary tract stone clearance regarding its location. Overall, renal stone-free rates have been reported to range from 60 to more than 90% during the 3-month follow-up [2, 8–10]; the rate was reported to be 69.7% in the present study. According to the specific anatomic locations of kidney stones, the stone-free rates were higher with renal pelvic stones (77.5%) compared to calyceal stones (47.4%). Many centers have reported the stone-free rates of 80–90% for ureteral calculi [3, 8–11], while in the current study, it was reported to be 80.4%.

The stone-free rate for proximal, middle and distal ureteral calculi treated with SWL has reported as 57–96%, 60–85% and 84–96%, respectively, while re-treatment or an adjuvant procedure has been required in 5–60%, up to 32% and 8–51% of cases in order [3, 11–13]. In our study, the stone-free rates for proximal, middle and distal ureteral stones were 77.2, 78.3 and 84.1%, respectively. It is noteworthy that 35.2% of our patients had been referred from other centers with the previous history of failed treatment and/or manipulations. Hence, this might be interacted with our SWL results. In line with other studies, we found that the SWL success rate decreased as the stone size increased [4, 7]. Moreover, our results revealed that treatment time, fluoroscopy time and patient age had significant affects on SWL outcome. According to our findings, using SWL for ureteral calculi <10 mm, renal pelvic calculi<20 mm and bladder calculi <30 mm was associated with high success rate. On the contrary, using SWL for any renal calyceal stones, ureteral stones ≥10 mm, renal pelvic stones ≥20 mm and bladder stones ≥30 mm may led to high failure rate.

Table 3 Complications, causes and treatment procedure following SWL in our study

Complications	No. (%)	Etiology	Treatment
During SWL procedure			
Nausea and vomiting	259 (8)	Increased in shock wave energy	Holding SWL temporarily
		Side effect of analgesics	Metoclopramide HCL
Immediate after SWL			
Tissue effect of SWL			
Macroscopic hematuria	1,037 (32)	–	Spontaneously resolved in
			48 h (86.5%)
			10 days (11.5%)
			1 month (2%)
Abdominal hematoma	151 (4.6)	–	Spontaneously resolved in most cases
Due to stone fragmentation			
Colicky pain	1,296 (40)	Partial or complete obstruction	Overhydration
			Antispasmodic + anti-inflammatory
			Intervention
Obstruction	1,001 (30.9)	Steinstrasse (78.5%)	Steinstrasse
		Type 1. (76.5%)	Conservatively (88.7%)
			Manipulation (11.3%)
		Type 2. (18.2%)	Re-treatment
		Type 3. (5.3%)	Re-treatment ± manipulation
		Single stone (21.5%)	Conservatively (47%)
			Re-treatment (25%)
			Re-treatment ± manipulation (15%)
			Manipulation (12.5%)
			Open surgery (0.5%)
Uremia	1 (0.03)	Obstruction	Open surgery
Infectious complication			
Bacteriuria	315 (9.7)	*E. coli* (30.5%)	Antibiotic therapy due to antibiogram
		Klebsiella (19.4%)	
		Enterococcus (16.5%)	
		Other (33.6%)	
Pyelonephritis	3 (0.09)	*E. coli* (2); *Pseudomonas* (1)	Parenteral antibiotic therapy
Sepsis	2 (0.06)	*E. coli* (1); *Pseudomonas* (1)	Parenteral antibiotic therapy
Infected hydronephrosis	1 (0.03)	*Klebsiella*	Parenteral antibiotic therapy + stone removal
Miscellaneous			
Sciatic nerve neuralgia	2 (0.06)	Unknown	Recovered spontaneously in 1 week
			Complete bed rest, antispasmodic and anti-inflammatory in 45 days
Acute tubular necrosis	1 (0.03)	Unknown	Dialysis
Broken stent	2 (0.06)	Delay in follow up	Percutaneous nephrolithotomy + ureteroscopy
			Open surgery
Stent migration	1 (0.03)	Unknown	Basket grasping
Mortality	2 (0.06)	Rupture of cerebral artery aneurysm	
		Sudden cardiac arrest	
Total	4,075	–	–

Generally, gross hematuria is the most frequent complication following SWL; it occurs due to the direct effect of the procedure on the renal tissue and resolves spontaneously in a few days. The symptomatic SWL perirenal and/or subcapsular hematomas following SWL are diagnosed in <1.5% of patients when ultrasonography is used. However, by using CT scan or magnetic resonance imaging (MRI) this rate may increase to as high as 30% [7, 14, 15]. Potential factors for hematoma formation include the type of lithotripter, number and intensity of shockwaves, bleeding diathesis, anti-coagulant medication, hypertension, obesity, diabetes mellitus and aging [7]. In our study, macroscopic hematuria developed in 32% patients and recovered spontaneously which was in line with other published reports [7, 16]. Perirenal or subcapsular hematomas and symptomatic hematomas were diagnosed in 4.6 and 0.55% patients, respectively. Only one patient, who represented hemodynamic instability, underwent surgery and received blood transfusion. These results which lie between those previously reported extremes, are explained by our routine use of post-SWL ultrasound imaging in all patients, not just symptomatic ones, while accepting that ultrasound is less sensitive than CT scan or MRI. Moreover, Dhar et al. [14] reported that the incidence of hematoma and symptomatic hematoma following electromagnetic SWL was 4.1 and 0.7%, respectively, when patients had been routinely screened with ultrasound after treatment, which it is in accordance with our findings.

It has been reported that the incidence of newly diagnosed diastolic hypertension after SWL does not differ from the general population (8 vs. 6%) [17–19]. However, a recent study has shown that patients undergoing SWL were more likely to develop hypertension and diabetes mellitus than controls at 19-year follow-up [20]. In our short-term follow-up, there was no case of new onset hypertension. The incidence of cardiac arrhythmias during SWL is reported as 11–59% [21]. They usually represent minor, unifocal premature ventricular contractions. In our study, cardiac monitoring was performed in 46.3% participants; arrhythmia was not detected in any patient. Lithotripsy was safely performed under the supervision of a cardiologist in three patients with pacemakers and eight patients with artificial valves.

Pulmonary contusions (hemoptysis), iliac vessel thrombosis, psoas abscess, retroperitoneal hemorrhage, and splenic rupture are the rarely reported complications arising from injury to adjacent organs following SWL [7, 22]. The risk of aortic aneurysm rupture is low and can be minimized by focusing the shock waves using low voltage and limited numbers of shock waves per treatment as well as frequent monitoring of vital signs [23]. None of the above complications were observed in our study. Moreover, a recent review has reported documented gastrointestinal complications including transient gastrointestinal erosions with mucosal bleedings, pancreatitis and peripancreatic hematoma and abscess formation, liver and spleen subcapsular hematomas, bile duct injury and small and large bowel perforation after SWL in 62 of the 3,423 (1.81%) studied patients [24]. In the present study, serious gastrointestinal problems was reported in none of patients; however, 8% of patients experienced nausea and vomiting during SWL performance.

Overall steinstrasse occurs in 1–4% of patients who undergo SWL. The occurrence rate increases in 5–10% of patients with large stone (>20 mm) and in up to 40% of patients with partial or complete staghorn calculi. In the case of large calculi (>20 mm), stenting before SWL reduces the risk of obstruction and steinstrasse [5, 25, 26]. Ather et al. [11] reported steinstrasse in 3% of the total 518 patients who had undergone SWL for ureteral stones. In our study, steinstrasse was observed in 24.2% patients. In other words, steinstrasse developed in 57.6% of the stones larger than 20 mm, in spite of using double-J stents for all of them. Hence, in our opinion, stenting for SWL should be considered and managed case by case instead of using routinely. Furthermore, in consistent with Kostakopoulos et al. [8], post-SWL colicky pain was the most frequent complication in our series.

Bacteriuria and bacteremia have been found in 7.7–23.5% and up to 14% of the patients who undergo SWL, respectively. Sepsis is reported in 1% of the cases; whereas for staghorn calculi the rate was increased to 2.7%. The risk of sepsis increases when urine culture is positive before SWL or in the presence of urinary obstruction [27, 28]. In the study conducted by Halachmi and associates [29], clinical UTI developed in 10.4% of the patients; all of them successfully responded to antibiotics and intravenous fluids. Ather et al. [11] observed urosepsis in 7% of their cases. In our study, symptomatic bacteriuria developed in 9.7% and successfully treated with appropriate antibiotics. Although a large number of the stones treated in our series (37.8%) are grater than 20 mm in size and we did not also use routine prophylactic antibiotics for our patients, the rate of bacteriuria and subsequently bacteremia are reasonable and are among the rates of other reports [7, 30]. Conversely, Pearle and Roehrbom [31] indicated that administrating prophylactic antibiotics in patients undergoing SWL is efficacious and cost effective and can decrease the need for inpatient urosepsis treatment. However, our findings demonstrate that using routine prophylactic antibiotic for all patients underwent SWL is questionable and should be limited to the specific conditions such as history of recurrent UTIs, positive urine cultures, etc.

We realize that our study could bear some limitations including: not performing the stone composition analysis

and metabolic evaluation, measurement of the stone size in maximal linear length and not in two dimensions, using plain radiography and ultrasonography rather than CT scan or MRI for follow-up scheme particularly for detecting the intra-abdominal hemorrhages, not differentiating between upper, middle and lower calyceal calculi, and also short-term follow-up period. However, prospectively evaluating the post-SWL outcomes and general complications in a large sample size could be considered as the strength and the importance of the present study. Further well-designed studies with long-term follow-up are warranted to fully comprehend the etiology and prevention of these complications.

Conclusion

The management of urinary calculi in adults using SWL particularly for ureteral stones <10 mm, renal pelvic stones <20 mm and bladder stones <30 mm was proved to be safe and efficient. During the study, 4,075 complications occurred in our patients; colicky pain followed by gross hematuria and steinstrasse were the most frequent symptoms. Although the post-SWL complications were high in our study, the majority was mild and treated conservatively or with minimal intervention and did not hamper the effectiveness of this method. Hence, SWL could be considered as the first choice therapy, especially for ureteral stones <10 mm, renal pelvic stones <20 mm and bladder stones <30 mm. Moreover, our findings do not support the routine use of prophylactic antibiotics for all patients before SWL, and also do not suggest stenting all patients with stone >20 mm.

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Conflict of interest statement The authors have no conflicts of interest to disclose.

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