Extracorporeal Shock Wave Lithotripsy in Impacted Upper Ureteral Stones: A Prospective Randomized Comparison Between Stented and Non-stented Techniques

Islam A. Ghoneim, Mohamed N. El-Ghoneimy, Ashraf E. El-Naggar, Khaled M. Hammoud, Mohamed Y. El-Gammal, and Ahmed A. Morsi

OBJECTIVES To assess the need for pre-extracorporeal shock wave lithotripsy (pre-ESWL) stenting in management of impacted upper ureteral stones of size ≤ 2 cm and to verify whether stenting would influence the success of therapy.

METHODS Between 2007 and 2008, a total of 60 patients with solitary, radio-opaque impacted upper ureteral stones measuring ≤ 2 cm were divided into 2 equal groups: a stented group with a Double-J stent fixed pre-ESWL and a non-stented group treated by in situ ESWL. All patients were treated by ESWL using Dornier Doli S lithotripter. Results were compared in terms of clearance rates, number of shock waves and sessions, morbidity, and incidence of complications. Pretreatment KUB (kidneys, ureters, and bladder) and intravenous pyelogram and post-treatment KUB were used to evaluate fragmentation and clearance.

RESULTS Overall stone-free rate was 88.3%. No significant statistical difference was observed in stone-free rate between the stented and non-stented groups being 90% and 86.7%, respectively ($P = .346$). One session was required in 28.3% of patients, whereas multiple sessions were required in 71.7% of patients. No significant statistical difference was noted in re-treatment rate in the 2 groups. Patients in the stented group significantly complained of side effects attributable to the stent predominantly dysuria, urgency, frequency, and suprapubic pain.

CONCLUSIONS ESWL is an effective and reasonable initial therapy in the management of impacted upper ureteral stones measuring ≤ 2 cm. Pre-ESWL ureteral stenting provides no additional benefit over in situ ESWL. Moreover, ureteral stents are associated with significant patient discomfort and morbidity. UROLOGY 75: 45–50, 2010. © 2010 Elsevier Inc.

Urinary stone disease has plagued human civilizations since long. Stone treatment has evolved tremendously from the times of perhaps the first urologists in Ancient Egypt to modern stone disintegration by shockwaves.[1] Extracorporeal shock wave lithotripsy (ESWL) remains an effective, well-established method for treating ureteral calculi.[2] However, ESWL for impacted upper ureteral calculi is considered a challenge as they are more resistant to shock wave disintegration than stones lying in the renal pelvis. This has been explained by the expansion space theory, which states that stones impacted in the ureteral mucosa have no natural expansion space and so respond poorly to ESWL.[3,4] Ureteral calculi in severely obstructed systems are often considered a contraindication to in situ ESWL. The Working Party on Lithiasis of the European Association of Urology recommended pre-ESWL stenting or endoscopic treatment for these stones.[5] However, stenting is considered a relatively invasive procedure as it requires general or regional anesthesia and involves some degree of endoscopic manipulation.

Several groups have reported that JJ stent insertion does not improve the results of ESWL.[6] In situ ESWL may be regarded a less invasive option and has the advantage of dealing with the obstruction and the stone at the same time, as fragmentation would result in relief of obstruction and subsequent clearance. Obviously, where stones are associated with sepsis, the obstruction should be relieved first and the infection should be dealt with before treating the stone.[7]

From the Department of Urology, Kasr Al-Ainy Hospital, Cairo University, Egypt and Ahmed Maher Hospital, Cairo, Egypt

Reprint requests: Mohamed N. El-Ghoneimy, Department of Urology, Cairo University, Egypt. E-mail: mghoneimy@kasralainyurology.net

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This prospective randomized study was conducted to assess the need for pre-ESWL stenting in management of impacted upper ureteral stones measuring ≤ 2 cm and to verify whether stenting would influence the success of therapy.

PATIENTS AND METHODS

Between June 2007 and June 2008, a total of 60 patients were treated with ESWL using the Dornier Doli S device (Dornier MedTech, GmbH, Germany). Randomization was done according to the day of presentation; patients presenting on even-numbered days were assigned to the stented arm of the study and those presenting on odd-numbered days were included in the non-stented arm.

Entry criteria were a solitary, radio-opaque, impacted upper ureteral stone, of size ≤ 2 cm. The stone was considered impacted if it caused moderate to severe hydronephrosis above its level, with a nonvisualized ureter below it on excretory urography. Fluoroscopy was chosen as the method of localization to eliminate the interoperator variability of ultrasound localization; hence, radiolucent stones were excluded. Patients with bleeding disorders, congenital renal abnormalities, and residual renal or ureteral fragments after previous ESWL, open surgery, or endoscopy were also excluded.

All patients had serum blood urea nitrogen and creatinine, bleeding profile (prothrombin time and concentration, bleeding time), and complete urinalysis done before ESWL. Patients with elevated serum creatinine were excluded. Patients with infected urinalysis were treated with appropriate antibiotics according to urine culture before ESWL or stenting.

Preprocedural imaging comprised KUB (kidneys, ureters, and bladder) and intravenous urography films. Acutely obstructed renal units, as evidenced by nonvisualization, were further evaluated by ultrasound of the kidney and upper ureter. Post-procedural imaging was performed by KUB films immediately after the session to evaluate fragmentation, at 2 weeks to detect clearance and assess the need for further treatments, as well as at 1 and 3 months to evaluate complete clearance. Ultrasound performed at 2 weeks and 3 months evaluated the relief of obstruction.

Informed consent for ESWL and inclusion in the study was obtained. Consent included endoscopy and stent placement in the stented arm of the study. Randomization resulted in 2 groups; the stented group (group 1) was treated with ESWL after JJ stenting, whereas the non-stented group (group 2) was treated with in situ ESWL. Accrual stopped when both groups had an equal number of patients.

In the stented group, a single coil silicone 6F JJ stent (Rusch International, Kernen, Germany) was fixed 1 week before ESWL, owing to the logistic arrangements at our institution.

Technique of ESWL

All patients received intravenous analgesia in the form of 1 mg/kg meperidine hydrochloride and/or 1.5 μg/kg fentanyl. Intravenous fluids were given to all patients throughout the procedure. Patients were treated in the supine position using an ungated technique. Fluoroscopy was used for stone localization. Therapy started at a low power of 14 kV, which was then gradually increased to 24 kV. A total of 4000 shocks were planned for each session. The session was terminated if complete stone fragmentation, as judged by still images during fluoroscopy, was noted. On discharge, patients were instructed to drink plenty of fluids and to check for expected hematuria, passage of stone fragments, and fever. Oral analgesics were prescribed; stented patients received a prescription for anticholinergics.

A 2-week interval between sessions was allowed for fragments to pass. On follow-up, patients in whom fragments were retained (> 4 mm) were considered candidates for another session. Each session was filed with separate entries for power and number of shockwaves. Stents were removed after radiological evidence of no sizeable fragments.

Successful ESWL was defined as either complete stone clearance with the lack of any visible fragments on radiological studies or the presence of clinically insignificant fragments of size ≤ 4 mm as defined by Delvecchio et al.[8] The lack of disintegration or fragmentation after 3 sessions of ESWL as detected on KUB was considered failure and these patients were scheduled for ureteroscopy.

Patient discomfort was evaluated using an Arabic questionnaire based on the ureteral stent symptom questionnaire developed by Joshi et al[9] and was administered to both groups alike. Health-related quality of life, including pain in the loin, bladder or other areas, bothersome storage and/or voiding symptoms, and incontinence were recorded. Those reporting one or more symptoms were considered to have discomfort, whereas higher scores indicated worse outcomes. Patients also maintained a diary of usage of analgesics and/or anticholinergics.

In determining the sample size, a survey of the published reports revealed no prospective randomized study comparing both techniques for impacted stones. A prospective study by Danuser et al was used to estimate stone-free rates for non-stented ESWL (96%).[10] A randomized trial by Chandhoke et al was used to determine stone-free rates for stented ESWL (77%).[11] These figures were used to determine sample size by a two-sided test with power of 0.80 and a significance level of 0.05 using a two-sample comparison of proportions on Stata/SE 10.0 by StataCorp LP. This power analysis returned 60 as the number of patients required. Statistical analysis was carried out using the χ^2 and t tests with $P \leq .05$ considered significant.

RESULTS

Total accrual was 60 patients: 39 males and 21 females. Mean age was 41.9 (± 11.05 years). Stones were on the right side in 31 patients and on the left side in 29 patients. Table 1 summarizes patient characteristics in the stented and non-stented groups as follows: age, sex, stone side, stone recurrence, surgical history, stone length, and stone width. For comparison, stented patients were designated as group 1 and non-stented as group 2. Seven patients (11%) with positive urinalysis were treated with appropriate antibiotics before ESWL or stenting. The stenting procedure was successful in all patients, with no incidence of perforation or extravasation. The stone was inadvertently pushed back into the kidney in 3 patients. Stent length varied between 24 and 26 cm and the mean stenting duration was 3.3 weeks (range 2-6). Two patients (6.67%) asked for stent removal before complete clearance due to intractable lower urinary tract symptoms. Fragments subsequently cleared completely in these cases.

Table 1. Patient and stone characteristics

Characteristic	Stented Group (n = 30)	Non-Stented Group (n = 30)	P
Age			
Mean ± SD	43.10 ± 11.505	40.73 ± 10.638	.487
Range	27-72	22-62	
Sex (%)			
Male	17 (56.7%)	22 (73.3%)	.176
Female	13 (43.3%)	8 (26.7%)	
Stone side (%)			
Right	14 (46.7%)	17 (56.7%)	.438
Left	16 (53.3%)	13 (43.3%)	
Stone nature (%)			
De novo	25 (83.3%)	23 (76.7%)	.519
Recurrent	5 (16.7%)	7 (23.3%)	
Previous surgery (%)			
−ve history	23 (76.7%)	21 (70%)	.559
+ve history	7 (23.3%)	9 (30%)	

Stone characteristics and ESWL parameters were compared and found to show no statistical significance between the 2 groups (Table 2). Stones < 1 cm in size showed excellent fragmentation on ESWL and a stone-free rate of 95.7%, whereas stones > 1 cm in size showed a less favorable response (stone-free rate 83.8%). Relationship of stone size (mm) to discomfort, morbidity, number of sessions and shockwaves, energy level, and stone-free rate is demonstrated in Fig. 1. The 1-cm cut-off shows that as stone size increased, stone-free rates decreased, residual fragments increased, number of sessions and re-treatment rates increased, as well as discomfort and morbidity increased.

Seventeen patients (28.3%) required 1 session for complete stone fragmentation: 7 (23.3%) in the stented group and 10 (33.3%) in the non-stented group. Multiple ESWL sessions (re-treatment rate) were required in 43 patients (71.7%), including 23 (76.7%) in the stented group and 20 (66.7%) in the non-stented group. The difference was not found to be statistically significant ($P = .436$).

Overall stone-free rate at 3 months was 88.3% (53 patients), comprising 27 (90%) in the stented group and 26 (86.7%) in the non-stented group. This difference was not statistically significant ($P = .346$), as shown in Table 2. ESWL failed to clear the stone in 7 patients (11.7%), including 3 (10%) in the stented group and 4 (13.3%) in the non-stented group. These 7 cases were considered ESWL failures. The mean number of sessions required to attain stone-free status was 1.98, varying from 2 ± 0.743 in the stented group to 1.97 ± 0.850 in the non-stented group.

Only a single case in the non-stented group compared with none in the stented, had steinstrasse (3.3%) which cleared spontaneously, with no need for secondary intervention. Three patients (5%), 1 (3.3%) in the stented group and 2 (6.7%) in the non-stented group, experienced self-limited fever (< 38.5°C). None of them needed hospitalization nor progressed to urosepsis. The difference was not statistically significant ($P = .719$).

Table 3 shows post-ESWL discomfort and morbidity, demonstrating that patients in the stented group had a significantly higher incidence of morbidity than those in the non-stented group. A statistically significant difference was found between the 2 groups as follows: suprapubic pain, dysuria and frequency of micturition, pyuria, and microscopic hematuria. These symptoms were all found to be higher in the stented group. Although positive post-ESWL urine culture and gross hematuria were found to be higher in the stented group, the difference was not statistically significant. To rule out infection as a cause of pain, we excluded cases of positive culture and analyzed the remaining patients for suprapubic pain. The difference in pain attributable to the presence of the stent was statistically significant ($P = .042$, Fisher exact test).

COMMENT

Urinary obstruction caused by an impacted stone is a serious problem as it may lead to progressive kidney dysfunction or severe complications, including pyonephrosis and sepsis. Stone impaction was thought to influence the success of fragmentation during ESWL. This fear has led many urologists to recommend JJ stenting before ESWL to create an artificial chamber, with an improved stone-fluid interface, for better fragmentation during ESWL and to relieve the obstruction.[12] However, this view has been challenged by some, who showed that the results of treatment are similar whether the stone is pushed back or treated in situ, with or without a stent. In patients with impacted ureteral stones undergoing urgent in situ ESWL, urine (water) is present in the ureter above the stone, and there are no associated factors that may diminish the efficacy of shock wave energy.[13] Other studies have shown that ESWL can relieve obstruction and even though disintegration may be partial after the first ESWL session, the obstruction is often relieved.

We conducted a prospective randomized trial to assess the efficacy of ESWL in the treatment of patients with impacted upper ureteral calculi and to verify whether pre-ESWL ureteral stenting would affect the outcome in these patients.

At 3 months, the overall stone-free rate was 88.3%. Stone-free rate was 90% in the stented group and 86.7% in the non-stented group. This difference was not statistically significant, which shows that insertion of a JJ stent did not add to the results and that this additional procedure may not be necessary. We found that there was no statistically significant difference between the average number of sessions per patient, re-treatment rates, and number of shockwaves in both the stented and non-stented groups; all were higher for the stented group. This was found to be comparable to previous results published by other working groups.[14] An ungated technique allowed the therapy to proceed without the need for car-

Table 2. Stone characteristics and ESWL parameters in non-stented vs stented groups

Parameter	Group	Mean	SD Mean	Lower 95% CI	Upper 95% CI	*P*
Length	Non-stented	10.00	0.43	9.11	10.89	.343
	Stented	10.23	0.38	9.46	11.01	
Width	Non-stented	5.07	0.20	4.65	5.48	.323
	Stented	5.20	0.21	4.78	5.62	
Sessions	Non-stented	1.97	0.16	1.65	2.28	.436
	Stented	2.00	0.14	1.72	2.28	
SWs	Non-stented	6511.67	558.53	5369.35	7653.98	.111
	Stented	7425.00	486.59	6429.80	8420.20	
Energy	Non-stented	18.20	0.44	17.29	19.11	.19
	Stented	18.73	0.41	17.89	19.58	
Stone free	Non-stented	0.87	0.06	0.74	1	.346
	Stented	0.90	0.06	0.79	1.01	

SWs = shockwaves.

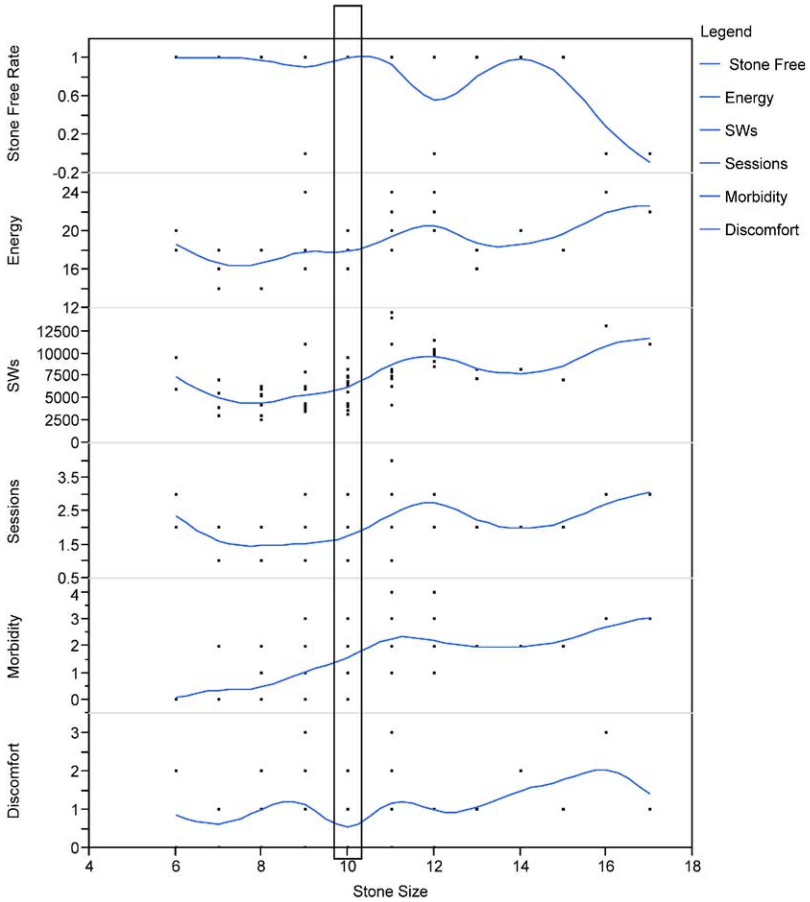

Figure 1. Relationship of stone size (mm) to discomfort, morbidity, number of sessions and shockwaves (SWs), energy level and stone-free rate. The 1-cm cut-off has been marked.

diac pharmacologic manipulation (atropine) to increase heart rate, and hence shock wave delivery.[15] We attempted to evaluate the efficacy of each technique (in situ ESWL vs pre-stenting then ESWL) with an intent-to-treat analysis. Hence, the cases in which the stone was inadvertently pushed back into the kidney or stents removed prematurely, were analyzed in the stented group despite the established better results of ESWL in the kidney in comparison with the ureter. Medical expulsive therapy was not used to allow evaluation of the ureteral ability to clear fragments with or without a stent in place. Unless used in all cases this would confound the results and complicate the analysis.

KUB was used for follow-up to reduce costs and radiation exposure. All stones were radio-opaque, and thus fragmentation and clearance were readily assessed on plain radiographs. Fragments not sizable enough to be detected on KUB were deemed clinically insignificant.

Insertion of a JJ stent is an invasive procedure, usually requiring general or regional anesthesia, thus increasing the risk and morbidity of the procedure, especially in elderly patients with associated multiple comorbidities.

Table 3. Discomfort and morbidity in stented vs non-stented cases

Condition	Overall	Non-Stented	Stented	*P*
Microscopic hematuria	31	8	23	.0001*
Pyuria	38	13	25	.0005*
Dysuria	25	7	18	.001*
Suprapubic pain	13	3	10	.014*
Culture	11	3	8	.049*
Gross hematuria	5	1	4	.084
Loin pain	20	9	11	.295
Fever	3	2	1	.719
Steinstrasse	1	1	0	.837

* Statistically significant.

Stent placement is often performed in a setting that may also allow immediate management of the stone by ureteroscopy and laser lithotripsy, obviating the need for staged treatment. Despite the efficacy of laser lithotripsy, ESWL is a first-line treatment for upper ureteral stones because of its noninvasive nature.[16] Stent placement can also be technically difficult, particularly in an acute and completely obstructed system with the risk for ureteral perforation approaching 11% and failure rate approaching 20% even in the presence of a well-trained urologist.[17] Unless a suture is tied to the distal end of the stent before insertion, an additional procedure will be necessary for stent removal adding to the cost and risk of complications. Moreover, JJ stents are associated with some morbidity in the form of intractable discomfort, urgency, and hematuria.[18]

We believe that the postulated benefit of a space-creating effect by a bypass stent may be negated by the stent itself, as it impedes shock wave propagation and energy transmission. Several studies showed that stents may cause ureteral irritation, spasm, and constriction as well as impede stone clearance instead of facilitating it. The presence of a stent may thus be detrimental, necessitating a higher power index to achieve the desired effect, which may in turn increase the complication rate.[19,20]

We evaluated the stone-free rate in accordance with stone size with a 1-cm cut-off and analyzed the results. We found that, as stone size increased, session parameters (number of shockwaves, number of sessions, and re-treatment rates) increased, whereas stone-free rates decreased. Re-treatment rates were 52.2% for stones of size < 1 cm and 83.8% for stones of size ≥ 1 cm. Our findings are in concordance with those of Sinha et al who stated that stone size and location seem to be more predictive of treatment outcomes than impaction. However, we conclude that though harder to fragment, larger stones exhibit an insignificantly lower clearance rate than comparable smaller stones. We refrained from analyzing the effect of stone size on discomfort and morbidity as we believed that this analysis would be confounded by the presence of the stent in some patients.

In our study, the degree of obstruction was routinely followed up by ultrasound. The relief of the obstruction seemed to correlate with the fragmentation and progression of the fragments after ESWL. However, it was difficult to compare the rapidity of the relief of obstruction after ESWL for the 2 groups due to practical limitations; for example, it cannot be reliably assessed in the stented group until the stent is removed. With the relief of symptoms, decreasing degree of obstruction on ultrasound, complete clearance of the fragments on KUB and retrieval of all/some of the spontaneously passed fragments after ESWL, it was felt appropriate to assume that the obstruction was relieved, and hence not to repeat the excretory urography.

The reported case of steinstrasse in our study was in the non-stented group. However, steinstrasse may occur even in the presence of a ureteral stent. El-Assmy et al[14] found that the incidence of steinstrasse was doubled in the stented vs the non-stented patients (4.3% vs 2.1%).

Three patients had self-limited fever; 1 patient in the stented group and 2 in the non-stented group. Other studies reported systemic sepsis after attempted endoscopic manipulation or JJ stent insertion in impacted stones. The stent itself may act as a nidus of infection and stone encrustation leading to irretrievable stents, especially in stone formers, as longer stent indwelling times are often required in patients who undergo lithotripsy. Ureteral perforation and failure to pass the stent are also complications of this procedure.

Moreover, the incidence of lower urinary tract discomfort and morbidity was significantly higher in the stented compared with the non-stented group. This finding can be corroborated by a previous study reporting a higher incidence of post-ESWL morbidity in stented patients.[19] A randomized study found that soft stents compared with firm stents may improve symptoms of dysuria and suprapubic pain. However, the stent firmness did not impact the incidence of urgency, frequency, nocturia, or hematuria.[21] In our study, the same make and model of stent was used in all patients obviating the need to analyze results for stent firmness. Our study was limited by the lack of a validated Arabic translation of the ureteric stent symptom questionnaire. This however, could be an area of further research.

We could conclude that stented patients have frequent and evident lower urinary tract symptoms and hematuria, which are clearly attributed to bladder irritation by the stent itself acting as a foreign body. These symptoms may be severe enough to have a significant impact on patient's quality of life.

CONCLUSIONS

ESWL is an effective and reasonable initial therapy in the management of impacted upper ureteral stones measuring ≤ 2 cm. Pre-ESWL ureteral stenting provides no additional benefit over in situ ESWL in their management. Moreover, stents are associated with significant patient discomfort and morbidity.

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