Arab Journal of Urology

ISSN: (Print) 2090-598X (Online) Journal homepage: https://www.tandfonline.com/loi/taju20

Clinical experience with shock-wave lithotripsy using the Siemens Modularis Vario lithotripter

Mohamed E. Hassouna, Samir Oraby, Wael Sameh & Ahmed El-Abbady

To cite this article: Mohamed E. Hassouna, Samir Oraby, Wael Sameh & Ahmed El-Abbady (2011) Clinical experience with shock-wave lithotripsy using the Siemens Modularis Vario lithotripter, Arab Journal of Urology, 9:2, 101-105, DOI: 10.1016/j.aju.2011.06.004

To link to this article: https://doi.org/10.1016/j.aju.2011.06.004

Arab Journal of Urology (2011) 9, 101–105

Arab Journal of Urology
(Official Journal of the Arab Association of Urology)

www.sciencedirect.com

STONES/ENDOUROLOGY

ORIGINAL ARTICLE

Clinical experience with shock-wave lithotripsy using the Siemens Modularis Vario lithotripter

Mohamed E. Hassouna *, Samir Oraby, Wael Sameh, Ahmed El-Abbady

Department of Urology, Faculty of Medicine, Alexandria University, Egypt

Received 10 February 2011, Received in revised form 20 February 2011, Accepted 27 February 2011
Available online 9 September 2011

KEYWORDS

Shock-wave lithotripsy;
Kidney;
Ureter;
Stones

ABBREVIATIONS

EQ, effectiveness quotient;
KUB, plain abdominal film of the kidney, ureter, and bladder

Abstract *Purpose:* To assess the effectiveness of a lithotripter (Modularis Vario; Siemens, AG Healthcare, Munich, Germany) in the management of renal and ureteric stones.
Patients and methods: In all, 1146 adult patients with renal or ureteric stones were treated at one urological centre using the latest model of the Modularis Vario lithotripter. The effectiveness of lithotripsy and re-treatment rate were assessed. Data were obtained on stone location, stone size, shock wave usage, success rate, and complications.
Results: Between May 2007 and November 2009, 698 patients with renal stones and 448 with ureteric stones underwent extracorporeal shock-wave lithotripsy (ESWL). The mean (SD) renal stone size was 12.8 (3.8) mm; a mean of 1.36 sessions was required, with a mean (SD) number of 3744 (1961) shocks delivered per renal stone. After 3 months, the success rate defined as the patient being stone-free or with residual fragments of <4 mm; for renal stones the rate was 91.1%, with a 6.9% complication rate in the form of steinstrasse and severe renal colic. The mean (SD) ureteric stone size was 10.4 (2.7) mm. A mean of 1.37 sessions was required, with a mean (SD) of 4551 (2467) shocks delivered for each ureteric stone. The success rate for ureteric stones was 89.5%, with a 5.6% complication rate. The overall efficiency quotient was 0.66.
Conclusion: The Siemens Modularis Vario lithotripter is a safe and effective machine for treating renal and ureteric stones.

Introduction

Since 1980, when Chaussy et al. [1] first reported the efficacy of the Dornier prototype lithotripter HM1, ESWL has become a

* Corresponding author. Address: Faculty of Medicine, Alexandria University, 21 Aly Hussein St., Loran #29, Alexandria, Egypt.
E-mail address: mhassouna@hotmail.com (M.E. Hassouna).

Peer review under responsibility of Arab Association of Urology.
doi:10.1016/j.aju.2011.06.004

Production and hosting by Elsevier

convenient, noninvasive outpatient procedure used to fragment most urinary stones. Since that landmark introduction, ESWL has become the standard noninvasive treatment for renal and proximal ureteric calculi. After the introduction of the original electrohydraulic Dornier HM-3 and its high-power delivery, lithotripters have been developed with new sources for generating shock waves, such as electromagnetic and piezoelectric sources. Furthermore, lithotripters have been reduced in size, and now they occupy less space. ESWL focusing and imaging devices have been modified over the years to improve the precise delivery of shock waves to the stone. Despite a decreased power delivery that often implies multiple sessions, second- and third-generation machines do not require the use of anaesthesia, thus achieving greater patient comfort and tolerance. Although numerous studies have examined treatment success rates with nearly all of these new and developing models, there are no data to support the results of the Modularis Vario lithotripter (Siemens, AG Healthcare, Munich, Germany).

The ability of anaesthesia-free treatment and easy handling (flat table and coupling bellows) made ESWL treatment an outpatient procedure [2]. Improved localisation due to the efficient integration of shock waves and imaging methods, increase in focal zone accuracy and growing expertise in the field, the use of lithotripters has lowered re-treatment rates, complications, and morbidity. The Modularis Vario lithotripter is a recent addition to the range of lithotripters. The claimed advantages are an efficient electromagnetic shock wave emitter, better penetration depth of 140 mm, an aperture angle of 55°, and an adjustable shot frequency of 60/90/120 pulses/min. Other specifications include a high energy of 12–113 mJ with a focal width of 12.5 mm.

We report our results on a large series of patients using the Modularis Vario at the Alexandria Lithotripsy Centre. It represents the most recent compact electromagnetic lithotripter from Siemens. At our centre, we assessed its efficiency in the management of renal and ureteric stones, and compared its results with those reported previously using other lithotripter machines.

Patients and methods

Adult patients with single renal or ureteric radio-opaque stones, treated at the Alexandria Lithotripsy centre using the Modularis Vario lithotripter, were recorded between May 2007 and November 2009. Complete case-notes and X-rays were evaluated, and follow-up noted in these patients. All patients had serum blood urea nitrogen, bleeding profile (prothrombin time and concentration), and complete urine analyses before ESWL.

Only patients with single renal stones up to 25 mm and single ureteric stones up to 20 mm were included in the study. Exclusion criteria were renal stones > 25 mm and ureteric stones > 20 mm, uncorrected coagulation and bleeding disorders, pregnancy, gross obesity (> 130 kg; due to technical difficulty in placing the patient in focus), obstructed urinary tract distal to the stones, radiolucent, and multiple stones. Stone size was determined by the widest diameter for renal and ureteric stones. Stones were stratified according to stone size into < 10 and 11–20 mm diameter. In renal stones an empirical third group of stones of 20–25 mm was added. Pre-treatment plain abdominal films of the kidney, ureter, and bladder (KUB), and IVU, ultrasonography or non-contrast-unenhanced CT were used for the initial diagnosis, and KUB and ultrasonography 2 weeks after each session were used to evaluate fragmentation and clearance.

The Modularis Vario is a mobile, fully integrated, newest-generation lithotripter with an electromagnetic shockwave source, and fully integrated fluoroscopic guidance. Energy levels start with E0.1 and gradually increase to a maximum of E8.0 in 38 steps. The average and maximum energy levels, as well as the total energy delivered are automatically shown at the end of each session.

Patients were treated while supine, using an un-gated technique; fluoroscopy was used to locate the stone. ESWL therapy is usually started at a low voltage and E0.1 for 100 shocks until the patient becomes accustomed to the shocks, and then raised to E1.0 for the next 250 shocks, and the voltage is then gradually increased up to a maximum of E4.0 for the kidney and E8.0 for the ureter. The shock waves were delivered empirically at a variable rate of 90–120/min. The number and energy of shock waves used were tailored until adequate fragmentation was achieved or the maximum number of shocks was reached. A maximum of 3500 shocks were planned for each session for the kidney stones and 4000 shocks for the ureter.

All treatments were administered on an outpatient basis for a maximum of three sessions. No fragmentation or residual fragments of > 4 mm were considered as a failure and patients were offered alternative treatment. All treatments were meant to be carried out using intravenous analgesia in the form of 0.3 mg/kg nalbuphine HCl. The stones were re-assessed initially after 10–14 days, using KUB to assess fragmentation. Repeat treatment was applied immediately after follow-up if there was no or inadequate fragmentation of the stone. Patients were followed up for the outcome of stone clearance for up to 3 months after the first ESWL session. The number of shock waves, intensity of shock waves, shock-wave energy, stone-free rate, auxiliary procedure rate, re-treatment rate, complication rate and effectiveness quotient (EQ) were assessed. Treatment success was defined as complete clearance of ureteric stones, while being stone-free or the presence of clinically insignificant residual fragments of < 4 mm were considered as a success for renal stones. The success rate was correlated with the stone size and site.

The EQ determines the stone-free rate in relation to repeat lithotripsy, as well the number of auxiliary procedures used to render the patient stone-free, and is calculated as the number of successes divided by the total number of procedures (primary + re-treatment + auxiliary) [3]. Patient age, sex, analgesia/anaesthesia, nature of presentation (emergency vs. elective), site of stone, size of stone, number of shock waves, power, energy delivered, number of sessions, and requirement for auxiliary procedures before or after ESWL were recorded. Student's *t*-test was used for the statistical evaluation, with the level of significance set as $P < 0.05$.

Results

Of 1146 patients who underwent ESWL, 698 (60.9%) had renal stones and 448 (39.1%) had ureteric stones. The mean (SD, range) stone size in this study was 11.5 (3.1, 7–25) mm; 69.7% of the patients were male and 30.3% were female, with a ratio of 2.3:1. The mean (SD, range) age of the patients was 41.4 (7.9, 16–78) years.

Of 698 patients with renal stones, 59.1% had pelvic stones, 13.8% had upper calyceal stones, and 10.6% and 16.6% had middle and lower calyceal stones, respectively. The mean (SD) renal stone size was 12.8 (3.8) mm. A single session was required in 68.2% of patients; the mean (range) number of sessions required for clearance of renal stones was 1.36 (1–3). The necessity for three sessions was significantly affected by stone size ($P = 0.001$). A higher proportion of stones of > 20 mm (31.6%) needed three sessions, compared with only 7.9% of stones of < 10 mm and 16.9% of stones 11–20 mm in largest diameter (Table 1). The mean (range) required power was E2.5 (0.8–4.0). The mean (SD, range) total energy delivered for renal stones per session was 112 (34, 60–179) J; a higher power (159 J) was required to clear stones of 21–25 mm.

After 3 months, the overall success rate for stones of < 10 mm was 95.9%, for 11–20 mm was 91% and for 21–25 mm was 73.7%, regardless of the site of the stone in the kidney. There was a statistically significant association between stone size and the outcome of disintegration ($P < 0.001$; Table 2). Stones in the renal pelvis had a success rate of 93.5%, while it was 90.6% for upper, 90.5% for middle and 83.6% for lower calyceal stones. However, this difference was not statistically significant ($P = 0.306$; Table 2).

Treatment complications were detected in 48 patients (6.9%); 13 developed distal ureteric steinstrasse, and most of them had renal stones of > 20 mm. We did not recommend the use of prophylactic JJ stents; the steinstrasse completely cleared under meticulous follow-up. In three patients, an additional ESWL session was given for a large leading fragment. Severe renal colic mandating a visit to the emergency room was reported in 34 patients. One elderly patient (aged 74 years) developed a perirenal haematoma associated with severe haematuria for 6 days. He was hospitalised and managed conservatively. CT showed a progressive resolution of the perinephric haematoma over the next 3 weeks.

In this series, 448 patients had a single ureteric stone (Table 2), 70.5% of them were in the upper ureter, 7.6% in the middle third and 21.9% in the lower third. The mean (SD, range) ureteric stone size was 10.4 (2.7, 7–20) mm. The mean (SD, range) number of sessions required for managing ureteric stones was 1.4 (1–3). When compared with stone size, stones of < 10 mm required a mean of 1.22 sessions, while the mean was 1.55 for stones of 11–20 mm. More sessions were required to evacuate stones in the lower third of the ureter (1.6).

Table 1 Distribution of all 1146 calculi by size and number of sessions. There was a significant relation between stone size > 20 mm and the need for two and three sessions ($P < 0.05$).

Size, mm	Session, *n* (%)			
	1	2	3	Total
< 10	343 (77.1)	67 (15)	35 (7.9)	445 (38.8)
11–20	416 (62.7)	135 (20.4)	112 (16.9)	663 (57.9)
> 20	71 (8.4)	19 (50)	12 (31.6)	38 (3.3)
Total	766 (66.9)	221 (19.3)	159 (13.8)	1146 (100)

For all ureteric stones the mean (SD, range) power used per session was E3.0 (2.1–3.6), the maximum power was E4.5 (2.8–7.5) and mean delivered energy per session was 148 (56, 84–302) J. The highest required energy was for stones in the middle third of the ureter (168 J) and the lowest energy in lower third stones (112 J). The mean (SD) number of shocks required per ureteric stone was 4551 (2467).

The overall success rate for ureteric stones was 89.5%; for stones of < 10 mm the success rate was 92.2%, whereas stones of 11–20 mm had a less favourable response of 85.6%. Large middle and lower-third stones had a significantly lower success rate (Table 2).

Treatment complications were detected in 25 patients (5.6%); 11 developed distal ureteric steinstrasse, but four of them were completely cleared conservatively, while the other seven required an additional ESWL session for the leading stone. Renal colic was reported by most of the patients and was managed conservatively. Severe renal colic mandating a visit to the emergency room was reported in 14 patients. Of 1146 patients with renal and ureteric stones, 32 (2.8%) required an adjunctive procedure, such as insertion of a JJ stent in 12, or ureteroscopy and retrieval of fragments in 20. Given these data, and using the formula above, the EQ was 0.66.

Table 2 Outcome vs. size and site in renal and ureteric stones; there was no significant difference between the site of the renal stone and success rate ($P = 0.306$). There was a significant association between renal stone size and the outcome of ESWL ($P < 0.001$). There was no significant difference between the outcome and ureteric stone site ($P > 0.05$).

Site	Patients			
	Success, *n* (%)			Stone size, mm
	< 10	11–20	21–25	Total
Renal				
Renal pelvis	78 (96.2)	312 (93.9)	22 (77.3)	412 (93.5)
Upper calyx	22 (100)	68 (89.7)	6; 4*	96 (90.6)
Middle calyx	18 (94.4)	52 (90.4)	4; 3*	74 (90.5)
Lower calyx	30 (93.3)	80 (81.3)	6; 4*	116 (83.6)
Total	148 (95.9)	512 (91.0)	38 (73.7)	698 (91.1)
Ureteric thirds				
Upper	190 (94.7)	126 (88.9)	–	316 (93.3)
Middle	24 (87.5)	10; 8*	–	34 (85.3)
Lower	54 (85.2)	44 (77.3)	–	98 (81.6)
Total	268 (92.2)	180 (85.6)	–	448 (89.5)

* *n* patients; *n* successful.

Discussion

ESWL therapy is noninvasive, anaesthesia-free and can be administered in an outpatient setting. Therefore, ESWL remains the first choice for treating renal and upper and middle ureteric stones. Patients generally favour this procedure. In the era of third-generation lithotripters, the need to evaluate the efficiency of different lithotripters is essential. More than previously, there are now many and various lithotripter machines. The role of the urologist is to provide adequate data on the outcome of each machine. The newer generation of lithotripters use smaller focal zones, allowing higher peak-point pressures [4].

The Modularis Vario lithotripter 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 > 90% in our experience, and decreasing the need of auxiliary manoeuvres. The success rate for renal stones was 90.5–93.5%, and for stones in the upper ureter was 93.3%. These results are comparable with and even superior to those reported for most other lithotripters. Many reports on the treatment of renal stones in normal kidneys, using second- and third-generation lithotripters, give success rates of 40–91% [5–9]. Patients with stones of < 10 mm had a success rate of 98% in the kidney and 92.6% in the ureter. Comparable rates were reported for treating stones in normal kidneys using the HM3 lithotripter, but with a lower re-treatment rate [10,11].

The EQ of the Modularis Vario lithotripter was 0.66, and this compares favourably with those for most available lithotripters. There is a gradual increase in EQ with successive machines; although success rates (85–88.8%) have remained constant, the EQ has improved. Most recent studies report an EQ of 0.36–0.67 [12]. This is largely due to reduced auxiliary procedure rates and reduced re-treatment rates. Only lower calyceal stones show a lower success rate of 83.7%. After the first session, lower calyceal stones had a success rate of only 54%. Persistent follow-up with recommendation of body-tilting manoeuvres followed by second and third sessions resulted in improving the success rate by 30%. We admit that defining success as residual fragments of < 4 mm added particularly to the success rate of the group of patients with lower calyceal stones. However, these results are comparable with those reported previously [5–8]. Lower calyceal stones of < 10 mm showed an excellent result (93.3%), which is comparable to those in other renal sites. The success rate for stones up to 20 mm in the lower calyx was a satisfactory 81.3%. We think that this result is good enough to offer these patients ESWL as a first choice of management.

Renal stones of 21–25 mm have a lower success rate than for smaller stones. We support a size threshold of 20 mm for ESWL [13]; however, we still offer the patient the chance to choose ESWL as one of the available options for treating slightly larger renal stones, with a reasonable success rate of 73.7%, and with the possibility of receiving two to three sessions with higher energy to clear the stone.

Patients with stones of > 10 mm required 1.2–1.8 sessions to clear their stones. Overall, 31.8% of the patients required more than one session for managing renal stones. We tend to counsel patients with stones of > 10 mm about the probability of receiving more than one session of ESWL before starting the treatment. Re-treatment was needed in 33.1% of the present patients; re-treatment rates were 22.9% for stones of < 10 mm and 37.3% for stones of 11–20 mm. Others reported a variable re-treatment rate, as low as 13% or as high as 63% [11,14–16]. We agree with the statement of Chaussy and Bergsdorf [2], that the higher need for re-treatment in ESWL is overvalued and can be disregarded as a real problem, because ESWL is noninvasive and anaesthesia-free, and any successive treatment can be administered without considerable effort. Re-treatment should be considered a part of staged therapy, especially in patients with large lower calyceal stones and lower-third ureteric stones.

Patients with ureteric stones had a success rate comparable to those reported previously [14]. Lower-third ureteric stones had a lower success rate of 81.6%. (85.2% for stones of < 10 mm and 77.3% for stones 11–20 mm). Severe pain elicited at the site of delivery of the shock waves was a limiting factor which prevented us from delivering a higher power and energy to clear such stones, and hence resulted in lower success rate for lower ureteric stones. More shocks were used to overcome the lower power used. Patients with middle-third stones could tolerate higher energy and power, and hence had slightly better results than those with lower-third ureteric stones (85.3% vs. 81.6%, respectively). General anaesthesia was used in 19 (1.4%) patients, required either due to intolerance of pain or a previous painful experience with ESWL using an electrohydraulic lithotripter.

The larger the stone the more shocks were required to clear the stone, regardless of its composition. Total energy delivered per session is automatically shown by the machine at the end of each session. We think that this is an advantage of the Modularis Vario lithotripter. If this is adopted in the software of every lithotripter, it could be used as the basis of a more standardised method of comparison between different lithotripters. It would also allow us to define the required amount of energy to be delivered instead of depending on the number of shocks.

The Modularis Vario electromagnetic shock-wave emitter is capable of delivering up to 2,000,000 shock waves of consistent quality. This makes the machine more cost-effective. By contrast, an electrohydraulic spark-gap electrode requires frequent changes and thus potentially jeopardises the shock wave quality in terms of the pressure and size at F2 [15]. The improved efficiency of the Modularis machine could also be attributed to better treatment strategies and increasing experience.

The usual limitations of ESWL studies also affect the present study. We failed to examine fragmentation and stone-free rates based exclusively on stone composition. We did not examine the causes of failure. Most patients seen after treatment were evaluated with a KUB, a method with inherent diagnostic limitations. However, the cost associated with the reference standard CT after lithotripsy is a problem and, as such, it is rarely used. We agree that CT would have resulted in a lower success rate. Chaussy and Bergsdorf [2] stated that a plain abdominal X-ray (KUB) is accepted as the first-line diagnostic method for follow-up examination after stone therapy, but mostly overestimates the stone-free rate. Non-contrast spiral CT seems to be the most sensitive radiological tool for detecting residual fragments after stone therapy [2]. Auxiliary procedures were minimal in the present series; the auxiliary treatment rate was similar to that recently reported by Lalak et al. [16], and was 11.6–27.4%.

In conclusion, the Siemens Modularis Vario lithotripter is a safe and effective machine for treating renal and ureteric stones. Our data from this large, single-centre series show a high success rate of 90.5% and an EQ of 0.66. The Modularis Vario seems to be an appropriate and effective tool for treating urinary calculi, especially up to 20 mm in diameter.

References

[1] Chaussy C, Brendel W, Schmiedt E. Extracorporeally induced destruction of kidney stones by shock waves. *Lancet* 1980;**2**: 1265–8.

[2] Chaussy C, Bergsdorf T. The preferred treatment for upper tract stones is extracorporeal shock wave lithotripsy (ESWL) or ureteroscopic: Pro ESWL. *Urology* 2009;259–63.

[3] Denstedt JD, Clayman RV, Preminger GM. Efficiency quotient as a means of comparing lithotriptors. *J Endourol* 1990;**4**(Suppl.): 100.

[4] Augustin H. Prediction of the stone-free rate after ESWL. *Eur Urol* 2007;**52**:318–20.

[5] Jonathan M, Fialkov A, Hedican SP, Fallon B. Reassessing the efficacy of the Dornier MFL-5000 Lithotriptor. *J Urol* 2000;**164**:640–3.

[6] Weld KJ, Montiglio C, Morris MS, Bush AC, Cespedes RD. Shock wave lithotripsy success for renal stones based on patient and stone computed tomography characteristics. *Urology* 2007;**70**:1043–7.

[7] Teichman JM, Portis AJ, Cecconi PP, Bub WL, Endicott RC, Denes B, et al. In vitro comparison of shock wave lithotripsy machines. *J Urol* 2000;**164**:1259–64.

[8] el-Damanhoury H, Schärfe T, Rüth J, Roos S, Hohenfellner R. Extracorporeal shock wave lithotripsy of urinary calculi: experience in treatment of 3, 278 patients using the Simens Lithostar and Lithostar Plus. *J Urol* 1991;**145**:484–7.

[9] Jamshaid A, Ather MH, Hussain G, Khawaja KB. Single center, single operator comparative study of the effectiveness of electrohydraulic and electromagnetic lithotripters in the management of 10 to 20 single upper urinary tract calculi. *Urology* 2008;**72**:991–5.

[10] Obek C, Onal B, Kantay K, Kalkan M, Yalc V, Oner A, et al. The efficacy of extracorporeal shock wave lithotripsy for isolated lower pole calculi compared with isolated middle and upper caliceal calculi. *J Urol* 2001;**166**:2081–5.

[11] Samuel F, Graber A, Danuser H, Hochreiter WW, Studer UE. A prospective randomized trial comparing 2 lithotriptors for stone disintegration and induced renal trauma. *J Urol* 2003;**169**: 54–7.

[12] White W, Kleinfive F. Five-year clinical experience with the Dornier Delta lithotripter. *Urol* 2006;**68**:28–32.

[13] Segura JW, Preminger GM, Assimos DG, Dretler SP, Kahn RI, Lingeman JE, et al. Ureteral stones – Clinical Guidelines Panel summary report on the management of ureteral calculi. American Urological Association. *J Urol* 1997;**158**:1915–8.

[14] Nabi G, Baldo O, Cartledge J, Cross W, Joyce AD, Lloyd SN. The impact of the Dornier Compact Delta Lithotriptor on the management of primary ureteric calculi. *Eur Urol* 2003;**44**:482–6.

[15] Tailly GG. Consecutive experience with four Dornier lithotriptors. HM4, MPL 9000, Compact, and U/50. *J Endourol* 1999;**13**:329–38.

[16] Lalak NJ, Moussa SA, Smith G, Tolley DA. The Dornier Compact Delta lithotriptor: the first 150 ureteral calculi. *J Endourol* 2002;**16**:645–8.