Urol Res (2012) 40:377–381
DOI 10.1007/s00240-011-0430-6

ORIGINAL PAPER

Value of focal applied energy quotient in treatment of ureteral lithiasis with shock waves

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Received: 6 April 2011 / Accepted: 4 October 2011 / Published online: 15 October 2011

Abstract The treatment of ureteral lithiasis by extracorporeal shock wave lithotripsy (ESWL) is progressively being abandoned owing to advances in endoscopic lithotripsy. The purpose of this paper is to analyze the causes as to why ESWL is less effective—with a measurable parameter: focal applied energy quotient (FAEQ) that allows us to apply an improvement project in ESWL results for ureteral lithiasis. A prospective observational cohort study with 3-year follow-up and enrollment period was done with three groups of cases. In Group A, 83 cases of ureteral lithiasis were treated by endoscopic lithotripsy using Holmiun:YAG laser. In Group B, 81 cases of ureteral lithiasis were treated by ESWL using Doli-S device (EMSE 220F-XXP). In Group C, 65 cases of ureteral lithiasis were treated by ESWL using Doli-S device (EMSE 220F-XXP) (FAEQ >10). Statistical study and calculation of RR, NNT, Chi-square test, Fisher's exact test, and Student's *t* test were done. Efficiency quotient (EQ) and focal applied energy quotient [FAEQ = (radioscopy seconds/number of shock waves) × ESWL session J] were analyzed. From the results, the success rate of the treatment using Holmium:YAG laser lithotripsy and ESWL is found to be 94 and 48%, respectively, with a statistically significant difference ($p < 0.001$). Success rate of endoscopic laser lithotripsy for lumbar ureteral stones was 82% versus 57% of ESWL ($p = 0.611$). In Group B, FAEQ was 8.12. In Group C, success rate was 93.84% with FAEQ of 10.64%. When we compare results from endoscopic lithotripsy with Holmium:YAG laser in Group B with results from ESWL with FAEQ >10, we do not observe absolute benefit choosing one or the other. In conclusion, the application of ESWL with FAEQ >10, that is, improving radiologic focalization of the calculus and increasing the number of Joules/SW, makes possible a treatment as safe and equally efficient as Holmium:YAG laser lithotripsy in ureteral lithiasis less than 13 mm.

Keywords FAEQ · ESWL · Ureteral lithiasis · Ureteroscopy

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Introduction

It is known that treatment by ESWL has a success rate of 67–90% in ureteral calculi even during acute obstruction stage [1, 2]. However, other researchers defend the endoscopic treatment of ureteral lithiasis by semirigid and flexible ureteroscopes [3, 4], especially in distal ureteral calculi, where the endoscopic lithotripsy with kinetic energy or laser is successful in 90–96% of cases [3–5]. Antegrade or retrograde flexible ureteroscopy and Holmiun:YAG laser lithotripsy have proven to be effective in lumbar and proximal ureteral calculi [4–6]. Other studies report that ESWL is successful in 83.6% of cases of calculi ≤1 cm, and only 42.1% in calculi >1 cm, and ureteroscopy is recommended in calculi >1 cm and those in mid and distal ureteral calculi [7, 8]. Advances in endoscopic lithotripsy have caused a gradual abandonment of treatment of ureteral lithiasis with ESWL.

Our working hypothesis is that ESWL can be improved by optimizing both the application of shock wave and focal applied energy quotient (FAEQ). Such optimization will allow the treatment of ureteral lithiasis with similar results

and effectiveness to Holmium:YAG laser endoscopic lithotripsy with less morbidity.

The purpose of this paper is to compare the ESWL efficiency quotient (EQ) versus endoscopic lithotripsy with Holmium:YAG laser and to analyze causes of less ESWL effectiveness, with a measurable parameter, that allows us to apply an improvement project.

Materials and methods

Two-stage observational prospective cohort study with a 3-year enrollment and follow-up period (2007–2010). An ITT results analysis was performed and later an improvement project was applied to improve the treatment of ureteral lithiasis with shock waves.

The study was conducted in 229 cases divided into three groups; during the first stage, Group A and B patients were included for treatment with endoscopic lithotripsy with Holmium:YAG laser or ESWL, with the aim to analyze the EQ of both procedures, and FAEQ in Group B. In Group C, during the second stage, the efficacy of ESWL was studied, applying shock waves with an optimized focal energy quotient.

Group A comprised 83 cases of ureteral lithiasis (39 men and 44 women); average age was 54; 48 cases presented with lithiasis in the pelvic ureter, 18 in the iliac ureter, and 17 in the lumbar ureter. They were treated by ureteroscopy and endoscopic lithotripsy with Holmium:YAG laser.

Group B comprised 81 cases of ureteral lithiasis (58 men and 23 women); average age was 49; 46 cases presented with lithiasis in the pelvic ureter, 14 in the iliac ureter, and 21 in the lumbar ureter. ESWL with Dornier Doli-S device (EMSE 220F-XXP) was performed.

Group C comprised 65 cases of ureteral lithiasis (55 men and 10 women); average age was 54; 38 cases presented with lithiasis in the pelvic ureter, 11 in the iliac ureter, and 16 in the lumbar ureter, nonimpacted or moderate degree of ureteral obstruction. ESWL with Dornier Doli-S device (EMSE 220F-XXP) was performed. (Improvement project, FAEQ >10) (Table 1).

This study was carried out at San Cecilio University Hospital, Lithotripsy and Endourology Unit, Granada, Spain.

The inclusion criteria were lithiasis located in the lumbar, iliac or pelvic ureter <2 cm.

The exclusion criteria were pregnancy, coagulation disorders, abdominal aortic aneurysm, active urinary tract infection and/or urogenital tract abnormalities.

In all cases, diagnosis was made by clinical and radiological study with plain X-ray, and ultrasonography or urography.

In Group A, endoscopic laser lithotripsy with a 7.5–8.5 Ch semirigid and flexible ureteroscope was performed, under analgesia and sedation with midazolam and fentanyl. The energy used during laser lithotripsy ranged between 1,500 and 2,500 mJ/pulse with a median of 2,071 mJ/pulse at 3–6 Hz frequency applied with 600 micron fiber with average of shock pulses 1,105 ± 711.36 and 2,515.33 ± 1,505.71 J.

In Group B, ESWL was performed, between one and three sessions per patient, under analgesia and sedation with midazolam and meperedine. The energy used was between 37.5 and 87.5 mJ/shock wave, 3,524 ± 435.88 shock waves applied and 190.7 ± 55.6 J, radioscopy time 1–4 min (mean of 2 min 30 s). In 11 cases, percutaneous nephrostomy was performed as a urinary diversion prior to ESWL.

We analyzed the efficiency and differences in both the procedures. Statistical study was done with calculation of NNT, Chi-square test, Fischer's exact test, and Student's *t* test. Analysis of EQ in both procedures and FAEQ in ESWL group.

$$\mathrm{EQ} = \%\ \text{stone} - \text{free patients}/(100\% + \%\ \text{re-treatment} + \text{auxiliary maneouvers})$$

$$\mathrm{FAEQ} = (\text{seconds of radioscopy}/\text{number of shock waves}) \times (\text{ESWL session Joules})$$

After analyzing and assessing results from both groups, a study was carried out in Group C. In this group, ESWL with Dornier Doli-S device (EMSE 220-XXP) was performed, under analgesia and sedation with midazolam and fentanyl (applying therapeutic improvement criteria, FAEQ >10). Range of energy applied between 45.3 and 96.6 mJ/sw, 3,163 ± 425.65 shock waves and 177.1 ± 60.3 J, radioscopy time 2–5 min (mean of 3 min 10 s).

Patients treated with ESWL stayed in hospital for 1–2 h and those treated with endoscopic laser lithotripsy for 3–6 h. Pain and tolerance to treatment with analgesia-sedation were assessed. Assessment of results was conducted at 3 weeks with plain X-ray, and ultrasonography or urography. Stone-free cases were considered as success. Open surgery, ESWL retreatment or endoscopic laser lithotripsy were suggested as alternative treatments to patients. We explained to them both advantages and disadvantages of each procedure and they signed the informed consent form.

Results

In Group A, lithotripsy with Holmium:YAG laser was performed in 83 patients. In 80% of cases, a DJ catheter was placed. After the first session of endoscopic laser lithotripsy, in 78 of 83 cases, no residual lithiasis was observed, 94% (Table 2). The rate of success in lumbar, iliac and pelvic ureter was 82, 94 and 98%, respectively

Table 1 Characteristics of patients

	Group A	Group B	Group C
Number of patients	83	81	65
Average age	54 ± SD 13.37	49 ± SD 11.07	54,2 ± SD 12.3
Average size of calculi	11.9 mm ± SD 4.32	12.13 mm ± SD 7.55	10.4 mm ± SD 2.2
Men:women	39:44	58:23	55:10
Localization			
PU/IU/LU	48/18/17	46/14/21	38/11/16
Composition			
CaO/CaOP/CaP/UA/C	51/21/4/5/2	49/25/5/2/0	40/19/6/0/0

Localization: *PU* Pelvic ureter, *IU* Iliac ureter, *LU* Lumbar ureter

Composition: *CaO* Calcium oxalate, *CaOF* Calcium oxalate and phosphate

CaP Calcium phosphate, *UA* Uric acid, *C* Cistine

(Table 3). Laser lithotripsy failures for the first session (5 cases) were resolved with lasertripsy (2 cases), lasertripsy and ESWL (1 case), and ESWL (2 cases). The overall success of endoscopic laser lithotripsy was 96.4% with good tolerance to treatment with midazolam and fentanyl. Laser application time was 2 min and 20 s (from 40 s to 5 min), surgical time of 35 min (15–60 min). Two cases of ureteral stenosis were noted after laser treatment (2.4%), renal colic-like pain in eight cases, and urinary infection in nine cases. Size and composition of calculi in Table 1. Holmium:YAG laser lithotripsy EQ = 96.4%/(100% + 3.6% + 81%) = 0.52.

In Group B, ESWL was performed in 81 patients (percutaneous nephrostomy was made prior to ESWL in 11 cases). After the first ESWL session, in 39 of the 81 patients, no residual lithiasis was observed, 48% (Table 2). In the lumbar ureter, success rate was 57%, in the iliac ureter, 43% and in the pelvic ureter, 45.6% (Table 3). A mean of 3,524 shock waves was delivered with 150 s of radioscopy (0.043 s/wave, 54 mJ/wave) and 190.7 J, that is translated into a FAEQ of 8.12. FAEQ for successful cases was 9.22 versus 6.47 for failures ($p < 0.005$), we observe relationship between FAEQ >6 and pain and intolerance to treatment. Retreatment for ESWL first session failures (42 cases) was made with endoscopic laser lithotripsy, successful in all cases (100%), and with a second session of ESWL in 36 cases, effective in 11 of them (30.5%). A third treatment was required in 25 cases: 10 with effective laser lithotripsy, 1 patient chose open surgery; 14 opted for ESWL again that only was successful in two cases (14%). A fourth treatment was required by 12 patients; 10 with laser lithotripsy with a 100% rate of success, and 2 refused to continue with instrumental treatment and chose medical treatment. Therefore, the re-ESWL was of 1.49, with success of 64%; 9 cases of renal colic after ESWL were reported, and 5 cases of urinary infection. Size and composition of calculi are given in Table 1. ESWL EQ was: EQ = 64%/(100% + 49% + 13%) = 0.39.

Table 2 Results treatment ESWL versus URS (EQ–FAEQ)

	Success 1 session	Success 2 sessions	Success 3 sessions
Group A	94%	95%	96.4%
Group B	48%	61.7%	64%
Statistics	$p < 0.001$. NNT = 2	$p = 0.001$. NNT = 3	$p < 0.005$. NNT = 3

EQ ESWL = 64%/(100% + 49% + 13%) = 0.39

EQ URS = 96.4%/(100% + 3.6% + 81%) = 0.52

FAEQ ESWL = (150 s/3,524 waves) × 190.7 J = 8.12

Comparing results from one session with Holmium: YAG laser lithotripsy (rate of success, 94%) versus one session of ESWL (rate of success, 48%), we obtained a statistically significant difference ($p < 0.001$) in favor of Holmium:YAG laser lithotripsy of 46% [IC 95% (33.8%–57.9%)], that is, for every 100 subjects treated with lasertripsy, we obtained 46 more stone-free patients than if they were treated with ESWL, that matches NNT of 2 [IC 95% [2, 3]]. In lumbar ureter, the rate of success for endoscopic laser lithotripsy was 82% versus 57% for ESWL, being the difference non-statistically significant ($p = 0.611$; Fischer's exact test).

After comparing results from two sessions of ESWL with one session of Holmium:YAG laser lithotripsy, the rate of success for ESWL was 61.7% versus 94% for laser lithotripsy, being the statistically significant difference ($p = 0.001$). That means an absolute benefit in favor of one session of laser lithotripsy of 32.2% IC 95% (20.5–44%), with NNT of 3 (IC 95% [2–5]). If we compare results from two ESWL sessions with one ESWL, we see that the rate of success of two ESWL sessions is 61.7% whereas with one ESWL session, it is 48.1%, and this difference is not statistically significant ($p = 0.173$).

In Group C, ESWL was performed in 65 patients. After the first ESWL session, rate of success of 93.84% (in 61 of the 65 cases no residual lithiasis was observed). For lumbar ureteral calculi success was in 94.7%, iliac ureteral calculi, 90.9%, and pelvic ureteral calculi, 93.7% (Table 3). A mean of 3,163 shock waves was delivered with 190 s of radioscopy (0.060 s/wave, 56 mJ/wave) and 177.1 J, with a FAEQ of 10.64. Retreatment for first ESWL session had four failures while endoscopic laser lithotripsy was

Table 3 Percentage of success localization of lithiasis

	Ureter (%)	Pelvic ureter (%)	Iliac ureter (%)	Lumbar ureter (%)
Group A	94	98	94	82
Group B	48	45.6	43	57
Group C	93.8	94.7	90.9	93.7

FAEQ ESWL: Group C = (190 s/3,163 waves) × 177.1 J = 10.64

successful in all cases (100%). Six cases of renal colic and two of urinary infection after ESWL were observed. Size and composition of calculi are detailed in Table 1. ESWL EQ = 93.84%/(100% + 0% + 0%) = 0.93.

If we compare the rate of success for first ESWL session in Group C with the rate of success for first laser lithotripsy session in Group A, there are no significant differences ($p = 0.75$), however, the success for first ESWL session in Group C (93.8%) was higher than success for first ESWL session in Group B (48%), with statistically significant differences ($p < 0.001$). There was absolute benefit in favor of ESWL with FAEQ >10 of 45.8%, that is, for every 100 subjects treated with ESWL and FAEQ >10, we obtained 46 more stone-free patients than if they were treated with ESWL and FAEQ <10, that matches NNT of 2 (IC 95% [2, 3]) (Table 4). Comparing results from endoscopic lithotripsy with Holmium:YAG laser in Group A with those with ESWL with FAEQ >10 we did not observe absolute benefit choosing one or the other.

Discussion

In cost-effectiveness study of extracorporeal lithotripsy in lumbar ureteral calculi versus endoscopic lithotripsy with semirigid ureteroscope and Holmium:YAG laser lithotripsy, the rate of success for cases treated with laser lithotripsy [10] is 92.3% and EQ = 0.51 (DJ catheter in 78% of cases). The first session of extracorporeal lithotripsy was effective in 61% of cases; difference in favor of laser lithotripsy is statistically significant but ESWL is more effective, EQ = 0.61. Average cost of one laser lithotripsy session was 778$ versus 920$ of one ESWL session.

Table 4 Results in three groups (first session)

	Success	Failure
Group A	78	5
Group B	39	42
Group C	61	4

Chi-Square test: Between Group A and B, significative differences, $p < 0.001$

Between Group A and C, no significative differences, $p = 0.75$

Between Group B and C, significative differences, $p < 0.001$

Huang carried out a cost/effectiveness study of 448 cases of ureteral lithiasis, 360 treated with ESWL and 88 with ureteroscopy and kinetic lithotripsy with lithoclast, and obtained a similar EQ for both groups, 0.62 in the group treated with ESWL and 0.65 in the group treated with lithoclast [11]. Cost of treatment was higher in the ESWL group; however, the rate of success was higher in the group treated with lithoclast, 89.8% versus 71.7%.

In our study, retrograde ureteroscopy has been performed under analgesia and sedation in ambulatory settings [12], and results from endoscopic ureteral lithotripsy with Holmium:YAG laser are similar to those reported by other authors, rate of success of 94% versus 48.1% of one ESWL or 61.7–64.2% of 2–3 ESWL sessions, statistically significant differences in favor of endoscopic lasertripsy as a treatment of ureteral lithiasis.

In lumbar or proximal ureteral lithiasis, nonetheless, differences in favor of laser lithotripsy have not been significant. We agree with Lam that ESWL must be first-line treatment in lumbar ureteral calculi, because of its lesser morbidity [13, 14], and endoscopic lithotripsy with Holmium:YAG laser as an alternative, especially in calculi >1 cm [15], obstructive or ESWL failure since in lumbar ureteral calculi. The efficiency of Holmium:YAG laser is higher than other energy sources [16]. In Group C results, we can see that in nonimpacted proximal ureteral calculi or moderate degree of ureteral obstruction, the ESWL applied with FAEQ >10 is successful in 93.7% of cases versus 82% with endoscopic laser lithotripsy. EWSL EQ is variable, depending on characteristics of calculi (size, composition, and density), degree of impaction on excretory tract, type of generator, and shock wave application parameters [9]; calculus must be kept within the focal point and we must apply shock waves and energy enough to get fragmentation.

Sighinolfi with a Dornier Doli-S EMSE 220F-XXP device gets an EQ = 0.80, retreatment rate of 1.14, and percentage of stone-free patients of 93.3, 67.6, and 94.5% in lumbar, iliac, and pelvic ureter, respectively [17]. In this study, it has been proven that in ureteral calculi of 10.4 ± 2.2 mm, nonimpacted, and without the need for urinary diversion, the ESWL treatment with FAEQ >10, gets an EQ = 0.93, without retreatment and stone-free rate of 93.7, 90.9, and 94.7% in lumbar, iliac, and pelvic ureter, respectively, along with a good tolerance to treatment

under analgesia and sedation with midazolam and fentanyl. This EQ is justified by selection of patients with nonimpacted calculi <12 mm and shock wave application with good control of focal point that facilitates tolerance to treatment under analgesia and sedation (midazolam/fentanyl). In ureteral lithiasis, we must use higher energy shock waves than in renal lithiasis and with a higher degree of analgesia and sedation in order to keep the calculus within therapeutic focus and optimize the FAEQ, consequently, we must not consider the need for anaesthesia as a discriminating factor regarding endoscopic laser lithotripsy, as other authors defend [19].

If we compare the rate of success between one and two ESWL sessions, we have observed that there are no significant differences in applying one or two to three ESWL sessions. Therefore, we consider that if one ESWL session has not been effective on ureteral calculus, ESWL retreatment is not very effective and treatment with Holmium:YAG laser lithotripsy is recommended after first ESWL failure. ESWL EQ ranges between 0.39 and 0.93 versus 0.52 in Holmium:YAG laser endoscopic lithotripsy and we think that efficiency for both procedures can be improved by limiting the use of DJ catheter or auxiliary maneuvers, especially in patients with mid and distal ureteral calculi treated with endoscopic laser lithotripsy, as recommended by Shao [19]. ESWL efficiency can be optimized if we apply more energy shock waves (mJ/ShW) but mainly with a better focalization of the calculus, being necessary to increase both the degree of analgesia-sedation and tolerance to treatment [9–20]; in this study we see a correlation between higher FAEQ and therapeutic success.

Conclusions

In nonimpacted ureteral calculi or moderate degree of ureteral obstruction, ESWL gets similar results to Holmium:YAG laser lithotripsy and less morbidity, therefore, must be recommended as the first choice of treatment for ureteral lithiasis <13 mm. We recommend increasing the control of the focal applied energy and the degree of analgesia and sedation to optimize and get better results from ESWL.

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