Prospective Randomized Study of Treatment of Large Proximal Ureteral Stones: Extracorporeal Shock Wave Lithotripsy Versus Ureterolithotripsy Versus Laparoscopy

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Abbreviations and Acronyms

CT = computerized tomography

KUB = plain x-ray of the kidneys, ureters and bladder

LAP = laparoscopic ureterolithotomy

SWL = extracorporeal shock wave lithotripsy

URS = semirigid ureterolithotripsy

Submitted for publication March 28, 2011.

Study received institutional review board approval.

Nothing to disclose.

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Editor's Note: This article is the fifth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 364 and 365.

Purpose: The best treatment modalities for large proximal ureteral stones are controversial, and include extracorporeal shock wave lithotripsy, ureterolithotripsy, percutaneous nephrolithotripsy, laparoscopic ureterolithotomy and open surgery. To the best of our knowledge extracorporeal shock wave lithotripsy, semirigid ureterolithotripsy and laparoscopic ureterolithotomy have not been previously compared for the treatment of large proximal ureteral stones. Therefore, we compared these modalities for the treatment of large proximal ureteral stones.

Materials and Methods: A total of 48 patients with large proximal ureteral stones (greater than 1 cm) were prospectively randomized and enrolled in the study at a single institution between 2008 and 2010. Eligible patients were assigned to extracorporeal shock wave lithotripsy, semirigid ureterolithotripsy or laparoscopic ureterolithotomy.

Results: Extracorporeal shock wave lithotripsy had a 35.7% success rate, semirigid ureterolithotripsy 62.5% and laparoscopic ureterolithotomy 93.3%. Stone-free rates showed a statistically significant difference among the groups ($p = 0.005$). Patients treated with laparoscopic ureterolithotomy vs semirigid ureterolithotripsy vs extracorporeal shock wave lithotripsy required fewer treatment sessions (mean $\pm$ SD 1.9 ± 0.3 vs 2.2 ± 0.6 vs 2.9 ± 1.4, $p = 0.027$). Neither major nor long-term complications were observed.

Conclusions: Proximal ureteral stone treatment requires multiple procedures until complete stone-free status is achieved. Laparoscopic ureterolithotomy is associated with higher success rates and fewer surgical procedures, but with more postoperative pain, longer procedures and a longer hospital stay. Although it is associated with the highest success rates for large proximal ureteral calculi, laparoscopic ureterolithotomy remains a salvage, second line procedure, and it seems more advantageous than open ureterolithotomy. At less well equipped centers, where semirigid ureterolithotripsy or extracorporeal shock wave lithotripsy is not available, it remains a good treatment option.

Key Words: clinical trial, ureteral calculi, laparoscopy, ureteroscopy, lithotripsy

THE best treatment modalities for large proximal ureteral stones are still controversial. Available modalities include medical expulsive therapy, extracorporeal shock wave lithotripsy, ureterolithotripsy using semirigid or flexible

0022-5347/12/1871-0164/0
THE JOURNAL OF UROLOGY®

Vol. 187, 164-168, January 2012
Printed in U.S.A.
DOI:10.1016/j.juro.2011.09.054

devices and pneumatic or laser lithotripters, percutaneous nephrolithotripsy, laparoscopic ureterolithotomy and open surgery.[1] The current literature comprises numerous reports with variable success rates.[2–6] The aim of treatment is to achieve a stone-free status as soon, as safely and as minimally invasively as possible. Several factors may influence results including stone size, degree of impaction, time of impaction, gender, age and treatment modality. Previous studies have compared URS vs SWL,[2,7–9] URS and LAP,[10] and URS, SWL and percutaneous treatments.[11] However, to the best of our knowledge SWL, URS and LAP have not been compared for the treatment of large proximal ureteral stones. Therefore, we prospectively compared SWL, URS and LAP for the treatment of large proximal ureteral stones.

MATERIALS AND METHODS

A total of 48 patients with large proximal ureteral stones (1 cm or larger) were prospectively randomized and enrolled in the study at a single institution between March 2008 and March 2010. Inclusion criteria comprised patients with proximal ureteral stones 1 cm or larger, located between the ureteropelvic junction and the pelvic brim, and diagnosed with excretory urography or CT. Stone size was measured using KUB or CT. Eligible patients were assigned with equal probability to 1 of the 3 groups. Randomization envelopes with numbers from 1 to 3 were opened and the patient was assigned to the chosen treatment of SWL, URS with pneumatic lithotripsy (Swiss LithoClast®) or LAP. In situ SWL was performed with the Dornier Compact Delta S (Dornier Inc., Munich, Germany) with the patient under intravenous sedation. URS was performed with the patient under spinal or general anesthesia using 7.5Fr semirigid URS (Karl Storz, Tuttlingen, Germany) as described elsewhere.[12] Laparoscopic ureterolithotomy was performed through a transperitoneal or retroperitoneal route according to surgeon preference and with the patient under general anesthesia. Clinical data were collected before, during and after treatment, and posttreatment pain was assessed using a visual scale (1 to 5).

Exclusion criteria were pregnancy, concomitant requirement of additional procedures and incomplete followup during or after treatment. Two patients from the SWL group were lost to followup after treatment and were excluded from the study. One patient from the LAP group was excluded from the study in the operating room because immediate preoperative KUB revealed an additional calyceal stone. Percutaneous nephrolithotomy was performed successfully through the same route for both stones.

Postoperative followup protocol included KUB and/or CT after 2 weeks and 2 months. Success was defined as complete stone clearance or residual fragments 3 mm or smaller. The efficiency quotient for treatment modalities was calculated using the formula, (% stone-free × 100) / (100 + % re-treatment + % auxiliary procedures).[13] Statistical analysis was performed using SPSS® 13.0 with ANOVA for parametric data, and the chi-square and Fisher exact test for nonparametric values. The institutional review board approved the present study and all patients signed an informed consent form.

RESULTS

Detailed data for the 3 groups are provided in tables 1 and 2. Presenting symptoms included pain (84.4%), microscopic or gross hematuria (42.2%) and abdominal pain (17.8%), and stone was diagnosed as an incidental finding in 8.9% of patients. In 33.3% of patients urinary tract infection and/or significant leukocyturia was diagnosed, and pretreatment antibiotics were administered.

SWL was completed in all patients under general anesthesia with a mean duration of 44.5 ± 10.3 minutes. All procedures were performed under fluoroscopic guidance with a mean radiation exposure of 4.8 ± 4.8 minutes. The impulse rate per treatment varied from 2,500 to 5,500 (mean 4,328) at a mean power setting of 4 (range 3 to 6) and a frequency of 80 to 120 Hz. After failure of the first procedure, 10

Table 1. *Patient demographics and pretreatment characteristics*

	SWL	URS	LAP	Total	p Value
No. pts	14	16	15	45	
Mean pt age (SD)	46.0 (13.5)	49.6 (15.5)	46.0 (13.6)	47.3 (14.1)	0.503
% M/F (No.)	50/50 (7/7)	62/38 (10/6)	60/40 (9/6)	58/42 (26/19)	0.771
Mean cm stone size (SD)	13.8 (2.5)	14.4 (4.1)	15.9 (4.1)	14.7 (3.7)	0.217
% Rt/Lt (No.)	43/57 (6/8)	62/38 (10/6)	40/60 (6/9)	49/51 (22/23)	0.395
Mean mos stones impacted (SD)	7.8 (5.8)	6.8 (10.2)	12.6 (16.1)	9.1 (11.6)	0.304
% Pain (No.)	92.8 (13)	75.0 (12)	86.7 (13)	84.4 (38)	0.386
% Hematuria (No.)	50.0 (7)	25.0 (4)	53.5 (8)	42.2 (19)	0.218
% Hydronephrosis (No.)	71.4 (10)	93.7 (15)	100.0 (15)	88.9 (40)	0.382
% Previous urinary stones (No.)	35.7 (5)	50.0 (8)	46.7 (7)	44.4 (20)	0.719
% Previous stone treatments (No.)	0 (0)	6.2 (1)	20.0 (3)	8.9 (4)	0.150
% Family history of calculi (No.)	28.6 (4)	25.0 (4)	33.3 (5)	28.9 (13)	0.878
Mean mg/dl creatinine (SD)	1.0 (0.4)	0.9 (0.2)	1.0 (0.2)	1.0 (0.4)	0.558
Mean HU CT attenuation (SD)	893.4 (518.9)	1,165.0 (1,053.6)	1,276.3 (206.9)	1,104.9 (529.6)	0.301