A Prospective, Randomized Trial of Management for Asymptomatic Lower Pole Calculi

Emrah Yuruk, Murat Binbay, Erhan Sari, Tolga Akman, Erkan Altinyay, Murat Baykal, Ahmet Y. Muslumanoglu and Ahmet Tefekli*

From the Department of Urology, Haseki Teaching and Research Hospital and Department of Nuclear Medicine, Taksim Teaching and Research Hospital (EA), Istanbul, Turkey

Abbreviations and Acronyms

CT = computerized tomography

DMSA = dimercapto-succinic acid

MAG-3 = mercaptoacetyltriglycine

PNL = percutaneous nephrolithotomy

SWL = shock wave lithotripsy

URS = ureterorenoscopy

Submitted for publication July 26, 2009.

Study received Haseki Teaching and Research Hospital human ethics committee approval.

Presented at annual meeting of American Urological Association, Chicago, Illinois, April 25-30, 2009.

* Correspondence: Department of Urology, Haseki Teaching and Research Hospital, 34096 Istanbul, Turkey (telephone: +90 212 529 4400; FAX: +90 212 529 4481; e-mail: atefekli@yahoo.com).

Purpose: We determined the natural course and compared the deleterious effects in kidneys of shock wave lithotripsy, percutaneous nephrolithotomy and observation for asymptomatic lower caliceal stones.

Materials and Methods: Between April 2007 and August 2008 patients with asymptomatic lower caliceal calculi were enrolled in the study. To assess stone status noncontrast abdominal helical computerized tomography was done 3 and 12 months after intervention. All patients were evaluated by dimercapto-succinic acid renal scintigraphy 6 weeks and 12 months after intervention.

Results: A total of 94 patients were prospectively randomized to percutaneous nephrolithotomy (31), shock wave lithotripsy (31) and observation (32). Mean ± SD followup was 19.3 ± 5 months (range 12 to 29). In the percutaneous nephrolithotomy group all patients were stone-free at month 12. Scintigraphy revealed a scar in 1 patient (3.2%) on month 3 followup imaging. In the shock wave lithotripsy group the stone-free rate was 54.8%. Scintigraphy revealed scarring in 5 patients (16.1%). In the observation group 7 patients (18.7%) required intervention during followup. Median time to intervention was 22.5 ± 3.7 months (range 18 to 26). One patient (3.1%) had spontaneous stone passage. Scintigraphy did not reveal scarring in any patient.

Conclusions: Stone related events were noted in more than 20% of patients with asymptomatic lower caliceal stones observed expectantly. To manage lower caliceal stones percutaneous nephrolithotomy has a significantly higher stone-free rate with less renal scarring than shock wave lithotripsy. Thus, patients with asymptomatic lower caliceal stones must be informed in detail about all management options, especially focusing on percutaneous nephrolithotomy with its outstanding outcome.

Key Words: kidney; kidney calculi; nephrostomy, percutaneous; lithotripsy; cicatrix

EVEN after many years of research and advancement in stone treatment the appropriate management for asymptomatic lower pole caliceal stones remains controversial. Observation, which is expected to require intervention in more than 50% of cases of asymptomatic caliceal stones in 5 years, is a topical approach.[1,2] PNL has the advantage of achieving the highest stone-free rate for these calculi but it is the most invasive technique.[3] SWL is accepted as the less invasive treatment alternative due to minimal anesthesia requirements, and high patient and physician acceptance but it is associated with poor clearance of fragments from the lower pole, leading to a low

0022-5347/10/1834-1424/0
THE JOURNAL OF UROLOGY®

Vol. 183, 1424-1428, April 2010
Printed in U.S.A.
DOI:10.1016/j.juro.2009.12.022

stone-free rate.[3,4] Recent studies comparing SWL and flexible URS for lower caliceal stones showed similar success rates and these data must be evaluated in further studies in terms of cost-effectiveness.[5]

To date studies of lower caliceal stones have generally focused on the success rate of treatment modalities but there are insufficient quantitative data on their effects on renal function. Detecting the renal parenchymal loss and scarring that occur after PNL and SWL is possible with ^{99m}Tc-DMSA scintigraphy, which has widely been used to detect renal cortical defects.[6]

We determined the natural course of asymptomatic lower caliceal stones and compared the deleterious effects of SWL, PNL and observation in kidneys when managing asymptomatic lower caliceal stones.

MATERIALS AND METHODS

The study protocol was approved by the Haseki Teaching and Research Hospital human ethics committee. Between April 2007 and August 2008 patients with asymptomatic lower caliceal calculi 20 mm or less in greatest diameter were evaluated with urine culture, serum creatinine, excretory urography and ^{99m}Tc-DMSA renal cortical scintigraphy. Patients with radiolucent calculi, high serum creatinine, solitary kidney, recurrent urinary tract infections, additional renal anomalies, previous renal parenchymal scarring and a dilated pelvicaliceal system were excluded from study. A total of 99 patients with asymptomatic lower caliceal stones were prospectively randomized into SWL, PNL and observation groups.

PNL was done beginning with cystoscopy and ureteral catheter insertion, as previously described.[7] Briefly, the patient was then placed prone. Percutaneous access was achieved by the attending urologist at a single setting using C arm fluoroscopy. After proper caliceal puncture the tract was dilated with a high pressure NephroMax™ balloon dilator and a 30Fr Amplatz sheath was placed. Nephroscopy was performed with a rigid 26Fr nephroscope. Stones were fragmented using a Swiss Lithoclast® Master combined pneumatic and ultrasonic lithotriptor. Stone clearance and collecting system integrity were confirmed intraoperatively by antegrade nephrostography. A 14Fr nephrostomy tube was placed at the end of the case as indicated.

SWL was done without anesthesia by the same experienced urologist using a Compact Sigma® electromagnetic lithotriptor. Therapy was usually started at low 14 kV power and gradually increased to 24 kV. A total of 3,000 shocks per session were delivered or until complete stone fragmentation occurred. Patients were evaluated 1 week after session 1 by x-ray of the kidneys, ureters and bladder. If there was no stone disintegration after 3 SWL sessions, the case was considered a SWL failure.

In the observation group symptoms related to ureteral/caliceal obstruction, stone growth, recurrent urinary infections and hematuria were defined as disease progression. These patients were referred for SWL, PNL or flexible URS after prompt medical treatment.

Renal scintigraphy was done by a single specialist using an e.Cam® dual detector single positron emission CT camera. Scintigraphic images (128 × 128 matrix) were acquired during 5 minutes from posterior and posterior-oblique projections 2 hours after the injection of 5 mCi ^{99m}Tc-DMSA with the patient supine. Qualitative measurements were made when renal parenchymal scarring was seen.

All patients were evaluated by urine culture and serum creatinine every 3 months. To assess stone status patients in the observation group were assessed by x-ray of the kidneys, ureters and bladder every 3 months, and in the SWL and PNL groups noncontrast abdominal helical CT was done 3 and 12 months after intervention. All patients were evaluated by single positron emission CT renal scintigraphy 6 weeks and 12 months after intervention or after study enrollment in the observation group to determine renal parenchymal scars, which were iatrogenic after SWL or PNL, or due to the stone in the observation group.

All groups were compared using 1-way ANOVA or the Kruskal-Wallis test for continuous variables, and the chi-square or Fisher exact test for categorical variables. ORs were calculated and statistical determinations were within the 95% CI. All p values were 2-tailed with $p < 0.05$ considered statistically significant. Data are shown as the mean ± SD. Data were entered into an Excel® database and analyzed with SPSS®, version 16.0.

RESULTS

From April 2007 to August 2008 a total of 99 patients with asymptomatic lower pole stones were randomized to PNL, SWL or observation (33 each). Mean followup was 19.3 ± 5 months (range 12 to 29). Five patients withdrew from the study due to the lack of followup data. The table lists final patient demographics and stone characteristics.

Stone analysis with x-ray diffraction analysis in 49 patients showed calcium oxalate stones in 43 (87.8%) and calcium phosphate stones in 6 (12.2%). In the SWL group 14 patients (82.3%) had calcium oxalate monohydrate stones and 3 (17.6%) had calcium oxalate dihydrate stones.

In the PNL group all patients underwent single access procedure. Mean operative time was 46.7 ± 5.9 minutes (range 40 to 65) and nephrostomy tube removal time was 1.3 ± 0.8 days (range 0 to 2). Eight patients (25.8%) underwent tube-free PNL. The mean hemoglobin decrease was 1.3 ± 0.6 mg/dl (range 0.3 to 3.9). Postoperatively fever in 1 patient (3.2%) was treated with parenteral antibiotics and 1 (3.2%) had bleeding necessitating blood transfusion. One patient (3.2%) passed residual fragments spontaneously. All patients were stone-free at the end of month 12. Followup DMSA scintigraphy revealed lower pole access site scarring in 1 patient (3.2%) on month 3 and 12