Retrograde Intrarenal Surgery Monotherapy Versus Shock Wave Lithotripsy for Stones 10 to 20 mm in Preschool Children: A Prospective, Randomized Study

Ibrahim A. Mokhless, Hussein M. Abdeldaeim,* Ashraf Saad and Abdel Rahman Zahran

From the Urology Department, Alexandria University, Alexandria, Egypt

Abbreviations and Acronyms

ESWL = extracorporeal SWL

JJ = Double-J®

RIRS = retrograde intrarenal surgery

SWL = shock wave lithotripsy

Accepted for publication August 26, 2013.

Study received local ethics committee approval.

* Correspondence: Urology Department, Alexandria University, Alexandria, Egypt (telephone: 00201223421863; FAX: 002034860029; e-mail: h_abdeldaeim@hotmail.com).

Purpose: We compared the outcome of retrograde intrarenal surgery monotherapy vs shock wave lithotripsy for stones 10 to 20 mm in preschool children.

Materials and Methods: This prospective study included 60 children with a mean ± SD age of 2.4 ± 1.3 years. Patients were randomly divided into 2 groups. Group 1 underwent shock wave lithotripsy and group 2 underwent retrograde intrarenal surgery as monotherapy. Retrograde intrarenal surgery was started using a 7.5Fr semirigid ureteroscope (Storz®) and the holmium laser, and completed by the Flex X™2 flexible ureterorenoscope. A ureteral access sheath was not used and only hydrodilatation was performed. Patients were evaluated preoperatively by ultrasound and plain abdominopelvic x-ray. Followup was 3 months.

Results: The stone-free rate after a single session treatment was 70% and 86.6% in groups 1 and 2, respectively. Mean operative time was 27.9 ± 3.5 and 40 ± 7.8 minutes, mean fluoroscopy exposure time was 60 ± 42 and 50 ± 35 seconds, and mean hospital stay was 6 ± 2 and 12 ± 8 hours, respectively. No major complication occurred in either group and no child in either group received blood transfusion. Nine group 1 patients needed a second shock wave lithotripsy session, of whom 2 required a third session. At 3 months the overall stone-free rate was 93.3% and 96.6% in groups 1 and 2, respectively.

Conclusions: Retrograde intrarenal surgery is an option for treating medium sized renal stones in preschool children with results comparable to those of shock wave lithotripsy and a safe short-term outcome.

Key Words: kidney; calculi; lithotripsy; lithotripsy, laser; endoscopes

Shock wave lithotripsy has revolutionized the management of upper urinary tract stones in children. It is now considered the procedure of choice by many pediatric urologists for renal stones less than 2 cm.[1,2] However, the success rate of SWL decreases significantly with an increase in stone size and the need for additional sessions also increases as stone size increases.[3,4]

Today managing renal calculi in children by endourological techniques is possible with the availability of smaller equipment.[2] RIRS is now performed at many centers in cases that were previously managed by SWL or percutaneous nephrolithotripsy.[5] The technique seems feasible but more data are needed for comparison with the results of other treatment modalities for stones in infants and preschool children.

We compared the outcome of RIRS monotherapy vs SWL for stones 10 to 20 mm in preschool children.

0022-5347/14/1915-1496/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2013.08.079
Vol. 191, 1496-1500, May 2014
Printed in U.S.A.

MATERIALS AND METHODS

This prospective study was done in 60 children with a mean ± SD age of 2.4 ± 1.3 years (range 1 to 6). All children had renal stones 10 to 20 mm in maximum dimension. No child had received previous stone treatment. Study exclusion criteria included cystinuria, radiolucent stones and renal anomalies. Approval of the local ethics committee was obtained before beginning the study. The parents of all patients provided informed consent after the procedure and possible complications were explained.

Sample size was calculated based on the assumption of the success rate of 1 session of RIRS and SWL for 1 to 2 cm stones at our institution (91% and 63%, respectively). Using the 95% CI, an α error of 5% and a power of 80% the resulting minimum sample size was 27 patients in each study group, which was increased to 30 per group.

Our main hypothesis was that the RIRS success rate would be better than that of SWL. We also evaluated other outcome parameters that may also affect the surgeon decision to perform either study technique, for example fluoroscopy use, operative time and hospital stay.

Patients were randomly divided into 2 groups. Unblocked, restricted block randomization was done to ensure a 1:1 allocation ratio between the 2 study groups. Allocation was done by concealment rather than blinding. Blinding was not appropriate for the 2 treatments since the patient, caregiver, outcome assessor and surgeon could not be blinded to them. Randomization was computer generated using the Excel® RAND function and distributed in a closed envelope with an identifier indicating the patient number. The trial was registered.

Group 1 underwent SWL and group 2 underwent RIRS as monotherapy. Metabolic evaluation in all patients included urine pH, and measurement of serum calcium, phosphorus, uric acid and creatinine. Determination of 24-hour urinary calcium, uric acid, oxalates and phosphorus was also done before stone treatment. Urine was sterilized preoperatively in all cases of infection using culture based antibiotics. Stones were evaluated by renal ultrasound and plain abdominopelvic x-ray. However, 10 patients were referred to us after noncontrast computerized tomography was performed elsewhere.

Group 1 patients underwent SWL using the Modularis Variostar Lithotripter (Siemens®) under general anesthesia while supine. All SWL cases were performed by a single urologist. Each session began at the lower power and gradually escalated in steps every 100 shocks until the power was set to between 14 and 17 kV. The rate of shocks delivered was 60 to 90 per minute. Shocks were given based on stone dissolution. The number of shock waves was limited to 2,000 per session. The therapy head of the electromagnetic lithotripter was positioned below the treatment table and conductive gel was applied.

In group 2 patients RIRS was performed under general anesthesia while in the lithotomy position. Lead aprons were placed under the patient, covering all areas except the abdomen. The procedure began by placing a 0.035-inch hydrophilic coated guidewire through the channel of a 7.5Fr semirigid ureteroscope. Ureteral access was achieved using hydrodilatation assisted by a hand irrigation pump. Neither balloon dilation nor a ureteral access sheath was used.

The ureteroscope was introduced under direct vision up to the renal pelvis until the stone was identified. Irrigation was minimal. Fragmentation was performed using a holmium:YAG laser with 270 and 365 μm fibers at settings of 0.8 J at 8 Hz and 1.0 J at 10 Hz. The stones were vaporized.

When fragmentation was complete or a stone was no longer accessible by the semirigid ureteroscope, another guidewire was placed through the ureteroscope channel. The flexible Flex-X2 ureteroscope, which has a 7.5Fr tip size and an 8.5Fr mid shaft size, was introduced by back loading over the guidewire under fluoroscopic guidance. The flexible ureteroscope was used to inspect the collecting system and any stones found were fragmented by the holmium:YAG laser. Lower and middle calyceal stones were relocated into the renal pelvis or upper calyx by basketing before lithotripsy. Before JJ stent placement contrast material was injected to confirm absent extravasation.

Low pressure was maintained in the bladder using an 8Fr suprapubic catheter in males, which was placed at the beginning of the procedure as needed and removed before recovery from anesthesia. In females a 4Fr or 6Fr feeding tube was placed beside the ureteroscope. The JJ stent was removed at 2 weeks using general anesthesia.

Stone-free status was assessed in each group by plain abdominal x-ray and renal ultrasound. Images were interpreted by a single radiologist. Cases were classified as completely stone free, significant residual stone greater than 3 mm or insignificant residual stone less than 3 mm. Patients were followed for 3 months by urinalysis and ultrasound. All data were analyzed using SPSS®, version 21 with $p < 0.05$ considered statistically significant. For analytical statistics we used the Student t-test, and the chi-square and Fisher exact tests.

RESULTS

During preoperative assessment 8 patients in group 1 and 6 in group 2 had a urinary tract infection and were treated with culture based antibiotics. Metabolic disorders were found in 35 patients (58%), including hypercalciuria in 18, hyperuricemia in 11 and hyperoxaluria in 6. All patients presented with an initial stone episode. The total male-to-female ratio was 2:1. Of the 60 renal units in the study 35 were on the left side and 25 were on the right side. Of the 5 group 1 patients with only calyceal stones the stones were in the upper calyx in 3 and in the middle calyx in 2. Of the 7 group 2 patients with only calyceal stones the stones were upper in 5 and middle calyceal in 2. Five of 16 patients with combined pelvic and calyceal stones had small lower calyceal stones, including 2 in group 1 and 3 in group 2. The largest of these lower calyceal stones was 8 mm in maximum dimension. The 2 patients with lower calyceal stones in group 1 became stone-free after 1 session of SWL.

Single session treatment operative time was 22 to 35 minutes in group 1 and 30 to 55 minutes in