Safety and efficacy of extracorporeal shock wave lithotripsy in infants

Gordon A. McLorie, MD,[3] Jeff Pugach, MD,[3] Dov Pode, MD,[2] John Denstedt, MD,[4] Darius Bagli, MD[3], Shimon Meretyk, MD,[2] R. John D'A Honey, MD,[4] Paul A. Merguerian, MD,[3] Amos Shapiro, MD,[2] Antoine E. Khoury, MD,[3] Ezekiel H. Landau, MD[1]

[1]Pediatric Urology Unit, Hadassah Hebrew University Medical Center, Jerusalem, Israel
[2]Department of Urology, Hadassah Hebrew University Medical Center, Jerusalem, Israel
[3]Division of Urology, The Hospital for Sick Children, Toronto, Ontario, Canada
[4]St. Joseph's Health Center, London, Ontario, Canada

MCLORIE GA, PUGACH J, PODE D, DENSTEDT J, BAGLI D MERETYK S, D'A HONEY J, MERGUERIAN PA, SHAPIRO A, KHOURY AE, LANDAU EH. Safety and efficacy of extracorporeal shock wave lithotripsy in infants. The Canadian Journal of Urology. 2003;10(6):2051-2055.

Purpose: *Extracorporeal shock wave lithotripsy (ESWL) in older children appears to have comparable results when compared to adults, no study has focused on its use in younger children. We reviewed our ESWL experience in children under age 3.5 years to evaluate its safety, and define optimal treatment parameters.*

Methods: *We retrospectively reviewed consecutive medical and diagnostic imaging records from three ESWL centers, pertaining to 34 children under 3.5 years of age (36 renal units-RU). The children were from two distinct populations served exclusively by the three centers. We analyzed patient presentation, etiology, age, weight, stone size, preoperative interventions, energy settings, number of shock waves, number of treatments, success (stone fragments < 2 mm), and complications. We performed all forty-nine procedures under general anesthesia and modified the Dornier MFL 5000 table and the Dornier HM3 gantry to improve coupling and localizing of the calculi.*

Results: *In each population, we noted similar presentations, etiologies, and treatment parameters. Patient age ranged from 6 to 40 months (mean 23.4 months). Stone size ranged from 4 mm to 22 mm diameter (average 13 mm). ESWL parameters included an average of 2210 shocks (range 900-3400) at average of 20.9 kV (range 19 kV-25 kV). Preoperative ureteral stent placement was not shown to be beneficial. Our one and multiple treatment ESWL success rates were 66% and 86%, respectively. No major acute or long-term complications occurred.*

Conclusions: *We successfully performed ESWL using treatment parameters similar to adults in 86% of children under 3.5 years without major complications. Modifications of the positioning device improved coupling and localization in smaller patients. Routine preoperative ureteral stenting for large stones is not recommended.*

Key Words: stones, kidney, children, lithotripsy

Accepted for publication September 2003

Address correspondence to Ezekiel H. Landau, MD, Pediatric Urology Unit, Hadassah Hebrew University Medical Center, P.O.Box 12000, Jerusalem, Israel 91120

Introduction

Recent advances in technology have dramatically altered the approach to urolithiasis. Since its

introduction in 1982,[1] ESWL has become the treatment mainstay for adult urolithiasis. Pediatric urolithiasis management has enjoyed the same advances and, several reports have documented the efficacy and safety of ESWL in older children.[2-8] Concern has been expressed, however, when adult technology has been applied to infants and young toddlers. While small children have traditionally been grouped with older children, they present several treatment dilemmas. Endoscopic manipulation is difficult in this patient population because standard instrumentation is not well adapted to their small size. Positioning small children on lithotripsy units is hampered by relatively large patient support mechanisms, designed for adults. In infants and small children, the potential for pulmonary injury is greater because of the proximity of the lower lobe of the lung to the kidney. While treatment parameters are well established for older patients, they have not been determined for this age group. Because of the smaller ureteral caliber, the ability to pass fragments is unknown. We review our ESWL experience in small children to clarify the treatment parameters associated with safe and effective clearance of calculi.

Patients and methods

Patient selection

We identified our patient population by retrospective review of consecutive medical and diagnostic imaging records for patients under 3.5 years treated at three lithotripsy referrals during the last decade. The three referral centers are similar, each providing exclusive care to their respective populations of 10 million (Ontario, Canada) and 6 million (Israel) people.

Pre-operative assessment

We assessed patient sex, age, weight, blood pressure, presentation, stone location, stone size, metabolic disorders, medications, urologic abnormality, and prior interventions. The indication for the study, which led to the diagnosis of the calculus, was considered the presenting complaint. Stone size was calculated by summation of the largest dimensions of all calculi in a given renal unit on preoperative radiographs. Metabolic evaluation, including serum and 24 hour urine studies, was performed in all the patients Table 1.

Lithotripsy parameters

All 49 procedures were carried out at three centers, under general anesthesia utilizing the Dornier MFL 5000 (Toronto and London, Canada) or the Dornier HM3 (Jerusalem, Israel) lithotripsy unit. We modified the MFL 5000 table by placing the infants on a transparant 'sling', thereby letting them fall down onto the treating head, to achieve better coupling. Rarely, we used gel bags for patient stabilization. The HM3 was adapted for infants by placing the patients in a hammock made of gauze tied to the HM3 gantry as previously described.[9] This lithotriptor has a tub that did not require any modification. Maximal voltage used and number of shocks delivered were determined from operative records. Indications for inserting a percutaneous nephrostomy prior to treament, included pyonephrosis, and minimally or non-functioning kidneys. The latter were assessed by DMSA renogram prior to the decision for treatment; ESWL or nephrectomy. Indications for ureteral stenting included renal stones more than 15 mm, or failure to insert a nephrostomy as indicated. During the time frame of our study, we noted such good passage of large stone fragments that we ceased using stents for this indication. We inserted ureteral catheters for patients with radiolucent calculi and to improve targeting of ureteral stones. These catheters were removed at the completion of the lithotripsy.

All Canadian patients were treated as outpatients, while the Israeli infants were discharged in the following morning.

TABLE 1. **Etiology of urolithiasis**

Metabolic	Hypercalciuria	6
	Hyperuricemia	4
	Hyperuricosuria	1
Total		**11**
	Cloacal anomaly	2
Anatomic	VACTERL	1
	Vesicoureteral Reflux	1
	Myelomenigocele	1
Total		**5**
Infection	Proteus	1

Outcome

Patients with calculi less than 2 mm on KUB at 60 days post lithotripsy were considered treatment successes.[1,3] Those rendered stone fragments less than 2 mm after multiple treatments were considered multi-treatment successes; those with fragments greater than or equal to 2 mm were considered failures. X ray crystallography stone analysis results were obtained from the medical records. We performed a comparison of patient weight, stone size, number of shocks, and voltage for those undergoing

successful and unsuccessful treatment. The effect of pre-operative stent placement was evaluated by comparing patient weight, age, stone burden, and treatment parameters and success rate. All patients were followed by the pediatric nephrology services for detection of possible post-treatment hypertension.

Statistical analysis

Statistical analysis was performed using unpaired, two tailed T test (InStat 2.0 for MacIntosh1992, 1993 GraphPad Software).

Results

Patient demographics

Thirty-four patients (36 RU) underwent a total of 49 ESWL treatments. Twenty-four patients (25 RU) underwent 34 procedures in Jerusalem, Israel; seven patients (7 RU) underwent 10 procedures in Toronto, Ontario, Canada; three patients (4 RU) underwent five procedures in London, Ontario, Canada. One patient was lost to follow up. Presenting signs included urinary tract infection (18), pain (15), hematuria (5), reflux/genitourinary anomaly evaluation (4), and incidental (1). The metabolic and anatomic results are summarized in Table 1. All 24 patients managed in Jerusalem underwent metabolic evaluation, and 9 of them demonstrated metabolic abnormalities. Four of the patients treated in Canada underwent metabolic work-up, and two of them had metabolic abnormalities. One patient received oral furosemide during the neonatal period. No other children received diuretics. Five infants had anatomical changes, but no one had pelvic-ureteral junction obstruction. One patient with reflux also had hypercalciuria. Two patients underwent open pyelolithotomy prior to ESWL. The calculi were located on the left in 14, the right in 18 and were bilaterally in 2 patients. Calculi were located in the kidney (n=28) and ureter (n=7). The male to female ratio was 1:1. The stone size ranged from 4-22 mm (average 13 mm). Stone analysis, available in six patients, revealed Calcium oxalate (3), Calcium phosphate (1), uric acid (1) and struvite (1).

TABLE 2. **Patient population (n-34)**

	Average	**Range**
Age	24 months	10-40 months
Weight	11.9 kg	5.79-20 kg
Stone size	13 mm	4-22 mm

Ten patients had ureteral stents placed by the treating physician. Seven percutaneous nephrostomy tubes were placed prior to treatment because of infection (3), large stone size (2) and inability to place an internal stent in a retrograde fashion (2).

Patient characteristics at initial ESWL are noted in Table 2.

We delivered 900-4000 shocks (average 2210) at 16-25 kV (average 20.9 kV). No further interventions or hospital visits were required in the immediate post-operative period. We performed lithotripsy as a planned staged procedure in seven cases.

Follow-up diagnostic imaging evaluation was available for 33 patients. After the initial procedure, 66% (21/33) of renal units were stone free Table 3. We found no significant difference between patients successfully treated on initial ESWL and those unsuccessfully treated based on stone size, patient weight, or voltage. Patients treated successfully with a single ESWL session were actually younger (average 21.6 versus 32.4 months). Patients treated with a single ESWL received fewer shocks (1991 versus 3150) in comparison to those receiving multiple ESWL treatments with successful outcome. Those undergoing multiple ESWL treatments received more shocks at initial ESWL than patients who failed treatment (3150 versus 2123) did. We noted no difference in these parameters for initially successful patients compared to those failing therapy.

Of patients undergoing a second ESWL, 44% (4/9) were rendered stone free. Two patients are under observation after the second treatment. All three patients who underwent a third lithotripsy were rendered successful. One 40-month-old patient

TABLE 3. **ESWL treatment summary**

Treatment	**# RU treated**	**Stone size (mm)**	**Shocks (kV)**	**Voltage stone free**	**Number**	**Success**
Initial	36	13	2159	20.5	24	66%
Secondary	9	9	2333	21.8	4	44%
Tertiary	3	6	2467	22.7	3	100%
Overall	36	12	2210	20.9	31	86%

successfully underwent ureteroscopy with stone extraction after the first ESWL treatment of a 5 mm Calcium oxalate calculus. The overall success rate was 86%. Children stented prior to the initial procedure had a significantly lower success rate after initial ESWL (22% versus 74%) and overall (30% versus 93% Table 4. Although not statistically significant (p=0.13), patients with calculi greater than 15 mm had a lower success rate on initial ESWL when compare to patients with calculi less than 15 mm.

No patients suffered acute or chronic complications. There were no cardiac or pulmonary complications noted. No patients have been noted to be hypertensive following lithotripsy.

TABLE 4. **Comparison of stented and unstented procedures**

	Stented	**Unstented**
Number	10	27
Weight	10.5 kg	11.8 kg
Age	2.0 years	2.1 years
Stone size	13.6	12.8
Shocks	2470	2039
Voltage*	21.8	19.9
Success rate after one ESWL	20%	74%
Overall success rate	30%	93%

*P=0.055; † p< 0.01

Discussion

The surgical approach to urolithiasis has changed dramatically in the last 15 years. Since its introduction in 1982,[1] ESWL has proven an effective alternative to open and endoscopic stone surgery in the adult population. Advances in instrumentation have made endoscopic treatment of calculi safer, easier and more effective. Although hesitation in applying adult treatments to the pediatric population exists, studies have shown ESWL to be safe in the developing rabbit model.[10,11] Several recent reports have documented the safety of ESWL in older children.[2-8,12] While many of these series have included infants and toddlers, our study has focused solely on the care of children this age and size.

Although retrospective and multi-institutional, our study benefits from our unique patient population. ESWL access is limited to the three centers in our respective regions; our ability to identify and track our patients is enhanced. Patients are less likely to go outside the system to seek medical care. As a result, these patients likely represent the only patients in our source populations undergoing ESWL.

Unlike older patients,[7,13] our patients were more likely to present for evaluation of a urinary tract infection or a diagnosed anatomic abnormality. Possibly as a result of an inability to communicate their symptoms, pain was less of a presenting complaint. Calculus size at initial treatment (average 13 mm) was similar to that found in adult and older pediatric populations.

Metabolic evaluation was available in 28 patients, and revealed abnormality in 11 of them (39.2%). Treatment of neonates with diuretics has been shown to increase the Calcium/Creatinine ratio, placing these patients at risk of developing urolithiasis.[14,15] Despite neonatal calculi being associated with furosemide administration, furosemide has been administered to only one of our patients. The presence of an anatomic abnormality did not exclude an associated metabolic disorder, as one patient with reflux also had hypercalciuria. While anatomic abnormalities are common in the patient population seen by pediatric urologists, urolithiasis remains relatively uncommon, and should be fully evaluated.

ESWL treatment parameters were similar to those in the adult population.[16] Preoperative ureteral stent placement did not confer an advantage. This may be due to the small ureteral size relative to currently available stents (the smallest being 3.7 F). We preferentially perform stentless lithotripsy because of the technical challenges inherent in placing stents in small children. Ureteral stents did not affect fragment passage in children following ESWL for ureteral calculi.[17] The same group showed that only 26% of small children who underwent ESWL for large renal calculi required a pre ESWL placement of a tube (nephrostomy or stent).[9] In that study the pediatric ureter was as efficient as the adult ureter in transporting stone fragments. Only 10 of our patients had ureteral stent installed before treatment, but seven patients required a percutaneous nephrostomy.

General anesthesia was necessary to immobilize patients and control diaphragmatic excursion throughout the procedure. While second generation lithotriptors are used without general anesthesia in older patients, we continue to recommend the use of general anesthesia in this population to improve localization and limit damage to adjacent structures.[12]

Our follow-up protocol included a post procedure KUB to assess residual fragments in all cases.

Treatment parameters were similar for successfully treated and unsuccessfully treated patients. While the successfully treated patients received more shocks,

patients who had success with single treatment received the lowest number of shocks. We were unable to link this to stone type as stone analysis was only available in six patients. Maximal voltage was similar for both groups. Although not statistically significant, increased stone size (>15 mm) was associated with decreased success on initial ESWL. Stone clearance post-lithotripsy approached rates seen in adults and older children, despite the small patient size compared with the stone burden. We theorize that increase ureteral pliability in this young patient population allowed for passage of proportionately large fragments. Based on these results, we feel that treatment parameters could be similar to those for the adult population.

Despite concern over possible increased complications in small children, none were noted in our population. We feel our modifications in positioning improved coupling and visualization leading to decreased morbidity.

Conclusions

In our population, patients were more likely to present for evaluation of a urinary tract infection or congenital anomaly than pain. Furosemide administration was not a major cause of stones requiring ESWL. Our overall success rate of 86% in-patients 3 years and under compares favorably with other adult and older pediatric series. Based on our success, we recommend 1) metabolic evaluation, 2) non-stented treatment, 3) general anesthesia, and 4) positioning modifications. With these treatment recommendations, effective extracoporeal shock wave lithotripsy can be performed safely, even in small children. □

References

1. Chaussy C, Schmiedt E, Jocham D. First clinical experience with extracorporeally induced destruction of kidney stones by shock waves. *J Urol* 1982.;27:412.
2. Newman DM, Cowry T, Lingeman JE. Extracorporeal shock wave lithotripsy in children. *J Urol* 1986;136:238-241.
3. Sigman M, Laudone VP, Jenkins AD, Howards SS, Riehle R, Keating MA, Walker RD. Initial experience with extracorporeal shock wave lithotripsy in children. *J Urol* 1987;138:839.
4. Kroovand RL, Harrison LH, McCullough DL. Extracorporeal shock wave lithotripsy in childhood. *J Urol* 1987;138:1106-1108.
5. Marberger M, Turk C, Steinkogler I. Piezoelectric extracorporeal shock wave in children. *J Urol* 1989;142:349-352.
6. Myers DA, Mobly TB, Jenkins JM, Grine WB, Jordan WR. Paediatric low energy lithotripsy with the lithostar. *Br J Urol* 1995;153:453-457.
7. Van Horn AC, Hollander JB, Kass EJ. First and second generation lithotripsy in children: Results, comparison and follow-up. *J Urol* 1995;153:1969.
8. Vandeursen H, Devos P, Baert L. Electromagnetic extracorporeal shock wave lithotripsy in children. *J Urol* 1991;145:1229-1230.
9. Gofrit ON, Pode D, Meretyk S, Katz G, Shapiro A, Golijanin D, Wiener DP, Shenfeld OZ, Landau EH. Is the pediatric ureter as efficient as the adult ureter in trasporting fragments following extracorporeal shock wave lithotripsy for renal calculi larger than 10 mm? *J Urol* 2001;166(5):1862-1864.
10. Kaji DM, Xie HW, Hardy BE, Sherron A, Huffman JL. The effects of extracorporeal shock wave lithotripsy on renal growth, function and arterial blood pressure in an animal model. *J Urol* 1991;146:544.
11. Van Arsdalen KN, Kurzweil S, Smith J Levin RM. J Urol Effect of lithotripsy on immature rabbit bone and kidney development. *J Urol* 1991;146:213.
12. Abara E, Merguerian PA, McLorie GA, Psihramis JE, Jewett MA, Churchill BM. Lithostar extracorporeal shock wave lithotripsy in children. *J Urol* 1990;144:489-491.
13. Milliner DS, Murphy ME. Urolithiasis in pediatric patients. *Mayo Clin Proc* 1993;68:241.
14. Ezzedeen F, Adelman RD, Ahlfors CE. Renal calcification in preterm infants. *J Pediatr* 1988 113:532.
15. Stafstrom CE, Gilmore HE, Kurtin PS. Nephrocalcinosis complicating medical treatment of posthemorrhagic hydrocephalus. *Pediatr Neurol* 1992;8:179.
16. Gillenwater JY. Extracorporeal shock wave lithotripsy for the treatment of urinary calculi, in Adult and pediatric urology. Gillenwater JY, Grayhack JT, Howards SS, Duckett, JW, Editor. 1991, Mosby. p. 695.
17. Landau EH, Gofrit ON, Shapiro A, Meretyk S, Katz G, Shenfeld OZ, Golijanin D, Pode D. Extracorporeal shock wave lithotripsy is highly effective for ureteral calculi in children. *J Urol* 2001;165(2 of 2):2316-2319.