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Efficacy of Extracorporeal shock wave lithotripsy Monotherapy in Complex Urolithiasis in the Era of Advanced Endourologic Procedures

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ABSTRACT

Purpose: It is believed that extracorporeal shock wave lithotripsy (ESWL) may be less effective than other modalities for treating stones in complex calculi. In this study, we investigated the efficacy of ESWL for treatment of complex stones.

Materials and Methods: Between September 2002 and October 2003, 250 complex cases of urolithiasis, including ureteral stones, staghorn stones, and stones in children, high risk patients, single kidneys, steinstrasse, and horseshoe kidneys were selected to be treated with Siemens Lithostar (Siemens AG, Munich, Germany) on an outpatient basis. Data were collected prospectively and the results of ESWL monotherapy on these complex patients were reviewed.

Results: The overall success rate was 91.2% for children and 77.7% for patients with single kidneys. Also, ESWL was efficient in the treatment of ureteral stones at the rate of 70.5% to 83.3%, depending on the location of the stone in the ureter and its size. The success rate of ESWL for patients with horseshoe kidneys, staghorn stones, and steinstrasse were marginal (66.6%, 66.0% and 33.3%, respectively). All of the cases were managed on outpatient basis and hospital admission was not required.

Conclusion: Outpatient ESWL can be safely performed as a minimally invasive treatment after proper patient selection, even for complex patients. Its successfulness in children, patients with solitary kidney, and for almost all of ureteral stones is quite acceptable. However, its usage in patients with horseshoe kidneys or steinstrasse, and those with staghorn stones is questionable and should be done only in carefully selected cases. Thus, with appropriate patient selection, significant improvements in stone-free rates may also be achieved in these cases.

KEY WORDS: extracorporeal shock wave lithotripsy, monotherapy, complex, urolithiasis

Introduction

For a long period of time, stone treatment in some patients has been a matter of controversy for urologists. Traditionally, complex stones were removed by surgical intervention, with results appearing satisfactory. With the advancements made in this field, new surgical methods were introduced and complete removal of the stones was the main therapeutic strategy for many years. The use of endourological methods, especially those assisted with percutaneous nephrolithotomy (PCNL), has facilitated the treatment of stones. With the rapid developments in endourology and with the clinical use of extracorporeal shock wave lithotripsy (ESWL), the need for surgery has enormously decreased over the past decade. As a less traumatic and more effective method, ESWL surpassed open

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surgery and PCNL. On the other hand, severe complications occurred less often than before the ESWL era. The indications for ESWL have changed over time in order to treat urolithiasis, but its usage in the treatment of some situations is the subject of controversy. The purpose of this study was to investigate whether ESWL could be recommended for complex cases including ureteral stones, staghorn stones, and stones in children, high risk patients, single kidneys, steinstrasse, and horseshoe kidneys or not.

Materials and Methods

Between September 2002 and October 2003, 250 complex cases of urolithiasis, including ureteral stones, staghorn stones, and stones in children, high risk patients, single kidneys, steinstrasse, and horseshoe kidneys were selected to be treated with ESWL on an outpatient basis. Overall, 268 stones in 256 urinary units were treated using Siemens Lithostar (Siemens AG, Munich, Germany) lithotripter apparatus.

The standard treatment protocol consisted of giving the recommended number of shocks per session, with retreatment protocols, if necessary. Double J stent was inserted in cases of single kidneys and those with high probability of steinstrasse (e.g. staghorn stones). Routinely, all patients undergoing ESWL were followed the day after the procedure and two weeks later. They were followed similarly by a regular assessment of kidney function, the degree of fragmentation of the stones, and stone clearance, assessed by KUB, Ultrasonography or IVP as needed. Median follow-up was 6 months. Successful treatment was defined as complete clearance or residual stones smaller than 4 mm on KUB performed 3 months later.

The patients were categorized as: children, surgically high risk patients, and those with horseshoe kidney, staghorn stones, single kidney, and steinstrasse. The data were collected prospectively from September 2002. The results of ESWL monotherapy on these complex cases were reviewed.

Results

Of 250 patients with complex stones, 174 were male (69.6%). Mean age of the patients was 42.5 (range 1.5 to 80) years. Table 1 shows the distribution of each category of cases among these 250 patients.

TABLE 1. *Patients' characteristics*

Number of Patients	**250**
Male/female	2.2
Patients age	1.5 to 80 years (42.5)
Clinical condition	
Children	23
Staghorn stone	59
Single kidney	9
Horseshoe kidney	6
Steinestrasse	3
High risk patient	2
Ureteral stone	148
Total	**250 (100%)**

The results of ESWL monotherapy applying on each category are as follows:

Children. A total of 26 treatment sessions were performed in 23 patients with 25 stones (mean stone burden = 10.5 mm). Ten children underwent general anesthesia and the others were only sedated. No percutaneous intervention or JJ insertion was done. Transureteral lithotripsy (TUL) or open surgery was not required. DMSA scan was performed in10 patients postoperatively that revealed no significant change in kidney function. No loss of kidney, nor any perirenal hematoma formation or hypertention (HTN) was recorded after treatment. All of the patients were followed after ESWL. Imaging study revealed an overall success rate of 91.2% after 3 months. Of the patients, 73.9% became completely stone-free (table 2).

TABLE 2. *Results of ESWL treatment*

	Mean sessions	**Stone-free Patients**	**Non-stone-free**		**Overall Success rate**
			clinically significant	**clinically insignificant**	
Staghorn stone	3.9	33.8%	33.8%	32.2%	66%
Horseshoe kidney	1.33	50%	23.2%	16.6%	66.6%
Single kidney	1.33	55.5%	22.2%	22.2%	77.7%
High risk groups	1	50%	50%	0%	50%
Children	1.13	73.9%	8.6%	17.3%	91.2%

Horseshoe Kidneys. Ten stones were treated in 6 horseshoe kidneys (mean stone burden = 11.7 mm). Three patients had multiple stones. There were not any serious complications such as perirenal hematoma or steinstrasse. No adjunctive procedures, such as PCNL or JJ stent placement were required. None of the patients presented with HTN during follow-up. Overall stone-free rate was 66.6% with complete stone clearance of 50%.

Steinstrasse. Three ESWL sessions were required in 3 patients with steinstrasse (mean stone burden = 10 mm). The calculi in these patients were lodged in lower ureter in 1 and in upper ureter in 2. In one of the patients, the impacted leading stone was completely fragmented by ESWL and steinstrasse resolved spontaneously. In another one (with stone in the upper ureter) ESWL was not effective and ureterolithotomy was done, subsequently. In the third patient (with stone in the lower ureter) fragmentation was only 30% and stone particles did not passed with conservative therapy, so that TUL was attempted. None of the patients presented with major complications after ESWL. Median fragmentation was 43.3% (complete in 1 and incomplete in 2).

Single Kidney. Nine patients with solitary kidney underwent 12 sessions of ESWL to treat 10 stones (mean stone burden = 13.6 mm). Three of them had stones in transplanted kidney. In 1 patient steinstrasse formation occurred (giving an overall incidence of 11.1%), which was managed by percutaneous nephrostomy (PCN) placement. All of the stones were passed in 2 weeks and no adjunctive procedure was required. Neither pathological laboratory findings nor renal insufficiency was recorded during the follow-up. Overall success rate was 77.7% three months after the treatment, with a mean fragmentation rate of 82.5%.

Surgically High Risk Patients. Two surgically high risk patients were treated with ESWL (mean stone burden = 19.5 mm). No adjunctive procedure, such as PCN or JJ stent placement was required. None of the patients had hematoma at the treatment site and no perirenal hematoma was noted on postoperative ultrasonography. Overall success rate was 50%.

Staghorn Stones. A total of 230 treatment sessions were required in 59 patients with 67 stones (mean stone burden = 23.4 mm). In 1 patient steinstrasse was formed (1.6%), and the stones were not passed with observation, so that ureterolithotomy was done. No serious complication was seen. None of the patients presented with HTN during the follow-up. Overall success rate was 66% and complete stone clearance achieved in 33.8% of cases. Mean number of treatment sessions was 3.9.

TABLE 3. *Results of ESWL in ureteral calculi*

	Proximal ureteral stones		Distal ureteral stones	
	>1cm	≤1cm	>1cm	≤1cm
Complete fragmentation	36%	65.7%	40%	29.4%
Overall success rate	79.3%	74.4%	83.3%	70.5%

Ureteral Stone. Overall, 149 ureteral stones in 148 patients were treated through 184 ESWL sessions. One hundred and twenty six stones were in the upper ureter and 23 were in the lower ureter. PCN was not placed in any of our patients and all of the stones were treated as in situ (i.e. no stone was pushed back into the pelvis).

Two patients with mean stone burden of 13 mm developed steinstrasse in upper ureter. In one of them, stones were passed with watchful waiting and in another one, TUL was performed. In the remainders no major complication occurred during and after the treatment. Results of this category are summarized in table 3.

Discussion

Nowadays, with the advent of modern endourologic procedures such as PCNL, TUL, and retrograde intrarenal surgery (RIRS), many authors believe that the role of ESWL has been waned especially in the so called "complex" patients. In the present study we investigated the efficacy of ESWL in such complicated settings and focused on benefits and disadvantages of ESWL as a noninvasive tool in each complex subcategory.

ESWL in Children. There is controversy regarding the optimal management of stones in pediatric population. Experience at our hospital, especially with staghorn calculi, showed that ESWL is safe in children with desirable results and minimal morbidity. In our series there was a low complication rate similar to that in the literature. Previously, others have noted that the passage of stone fragments in younger children is less difficult and is associated with significantly less pain than in older children and adults.[1]

Obstruction is rare and trends to resolve spontaneously. Because of these observations, stenting before ESWL is not routinely required even for staghorn calculi. ESWL provides good results and is minimally invasive and a nearly complication-free treatment method for children.[2] In our series, the stone-free rate of 73.9% was achieved by ESWL monotherapy with minimum morbidity. These findings are consistent with the study of Garat in Paris that achieved a 70% success rate.[3] Meanwhile, when Orsola et al used ESWL monotherapy for staghorn stones in children, they obtained a stone-free rate of 73.3% after an average of 2 ESWL sessions with Siemens Lithostar apparatus.[4] Notwithstanding, there have always been some worries regarding the effects of ESWL on growing kidneys. Traxer et al investigated this problem by evaluating post-ESWL renal parenchymal damage using DMSA-Tc99 scintigraphy; albeit short-term follow-up, they confirmed the innocuousness of ESWL for renal parenchyma even in infants.[5] Alternative treatment options, such as PCNL or open surgery, are more invasive. They have more potential negative impact on renal function and are associated with high morbidity and a high incidence of residual and recurrent stones. It seems that the interaction of ESWL with stones and/or urinary tract in children is somewhat different with that in adults. For example, as mentioned before, the chance of stone passage is much higher in children. Thus, the standards of therapy with ESWL should be changed when it is used in pediatrics. We recommend that ESWL monotherapy is currently the best treatment available for children with stone and should be the first choice even for staghorn calculi.

Horseshoe kidneys. Results of ESWL in horseshoe kidneys are greatly different in multiple series and stone-free rate has been reported to be 27% to 87%.[6-8] This wide variation may be due to the variability of stones size and location. Renal stones in horseshoe kidneys necessitate higher number of shock waves per session, as seen in our study. Because of particular anatomy and urinary stasis, all of the fragmented stones could not be passed, so that the probability of stone recurrence and need for retreatment is higher. Overall, stone-free rate of 66.6% was achieved in our study. In a study including 24 patients with malformed kidney, Theiss et al reported 61% stone-free rate. However, they mentioned the higher frequency of stone recurrence and regrowth, necessitating careful monitoring of these patients.[6] Similar results are confirmed by other authors.[7-8] It is noteworthy to say that all of the authors have stressed on careful selection of these patients and the best results were seen in patients with a mean stone burden of less than 1 cm. If properly selected, ESWL has satisfactory results in horseshoe kidneys.[9] When the stone is small and urinary drainage is proper, ESWL as a first-line treatment is reasonable, but with greater stone burden, the efficacy of ESWL would be reduced. For larger stones, PCNL is recommended. Results of PCNL and open surgery are superior to ESWL and stone-free rate of 78% to 100% will be expected.[10] If ESWL fails or is not possible because of anatomical reasons, we recommend PCNL and/or open surgery.

Single kidney. In patients with solitary kidney, open surgery will provide better results than ESWL therapy and particularly for some forms of staghorn calculi, open surgery and PCNL have proved more successful than ESWL.[11] Nowadays, ESWL appears to be the most useful therapeutic modality for stones in solitary kidneys, except for these cases.[11] The less invasiveness and the satisfactory results have encouraged urologists, so that ESWL has become the therapy of choice for these patients too.

Our experience demonstrated that ESWL should be accepted as the therapy of choice for stones in patients with solitary kidney. We had 77.7% overall success rate, with 11.1% incidence of steinstrasse and anuria. These results are comparable with series of Vuksanovic and that of Jimenez where they had a success rate of 89% and 82.1%, respectively.[12,13] To determine the potential long-term side effects of ESWL on renal function in patients with solitary kidney, Chandhoke et al compared long-term effects of ESWL and PCNL monotherapy on 31 patients with a solitary kidney and/or chronic renal insufficiency whose follow-ups were all more than 2 years; they concluded that there is no evidence to suggest that ESWL results in long-term renal function deterioration in patients with solitary kidney.[14] Therefore, this treatment modality prevents the harmful effect of open surgery, while enhancing the preservation of kidney tissue.

Urinary lithiasis after renal transplantation is a relatively uncommon complication. The predisposing factors and composition of the

calculi are similar to those of non-transplant patients. The least invasive treatment modality should be utilized according to the stone burden and the need to preserve renal function. Three of our cases had stones in transplanted kidneys that all became stone free with ESWL. Although we had limited cases, the results were in agreement with those of Rodrigo Aliaga et al who found ESWL a non-invasive tool, quite successful for the management of their 16 transplant patients suffering from stone in their allografts.[15]

Surgically High Risk Patients. To our knowledge there is no reported data about the effectiveness and complications of ESWL in surgically high risk patients. Some authors have studied the efficacy of ESWL on biliary stones. In these series, overall fragmentation has been 69% that is somewhat low.[16] This low rate could be due to the different composition of billiary and urinary stones. However, according to its non-invasiveness, ESWL is a reasonable modality in surgically high risk groups. However, we had few patients in our study and further studies should be taken.

Staghorn stones. Untreated staghorn stones may cause infection, obstruction, and secondary injury to kidney, which may eventually lead to chronic renal insufficiency, especially in bilateral cases. Due to these serious morbidities, treatment should not be delayed. In adults, the clearance rate of staghorn stones treated with ESWL has ranged from 31% to 85 %, depending on stone burden.[17] It is quite acceptable that ESWL monotherapy has marginal results in the management of adults with staghorn renal stones. Lam et al, in their series, compared the treatment results of ESWL monotherapy with PCNL in adult patients with staghorn renal stones. They found that even for staghorn calculi smaller than 50 mm, stone-free rate of ESWL is much lower than that of PCNL (63.2% versus 94.4%). They also condemned ESWL in these patients when found the 30.5% rate of post-ESWL obstruction in them.[17] In our series, although we had only a 1.6% rate of steinstrasse, the stone-free rate was disappointing (33.8%). It seems that this low rate of success is due to relatively large stone burden in our patients (23.4 mm). Thus, most urologists do not recommend ESWL as the primary treatment of staghorn stones and they insist on the better results of PCNL. The use of ESWL monotherapy in treating struvite stones may be particularly problematic, because residual fragments would prevent sterilization of the urine, increasing the risk of stone regrowth.[18] As a guideline, PCNL followed by ESWL should be used for most patients. Open surgery is appropriate in unusual situations, when a staghorn stone is not expected to be removed by a reasonable numbers of PCNLs and/or ESWLs. Nephrectomy is also a proper option for a poorly functioning kidney having staghorn stone.

Steinstrasse. ESWL is one of the common modalities used in the management of steinstrasse and in previous studies it has had high success and low complication rates. But it was not seen in our study, perhaps because of our limited patients. In our study, only 3 patients with steinstrasse were treated by ESWL, which was successful in only one of them. In this concept, we are in agreement with Fernandez et al for the use of ureteroscopy as a safe and highly effective approach for the management of steinstrasse following ESWL.[19] Madbouly et al, in an interesting study, developed a statistical model based on risk factors for the formation of steinstrasse after ESWL to predict this phenomenon. They found that stone size (more than 2cm), renal morphology, and shock wave energy are the significant predictive factors controlling steinstrasse formation. They also recommended prophylactic pre-ESWL ureteral stenting, if a patient has a high probability of steinstrasse formation.[20] It is surprising that although the use of J stenting before lithotripsy lowers the incidence of steinstrasse in patients with large stone burden, J stenting has no apparent effect on the mode of presentation or the subsequent management of steinstrasse and the incidence of steinstrasse will increase with the stone size, whether or not a J stent is present.[21]

Ureteral Stones. ESWL is one of the common treatment modalities in the management of the ureteral stones, but with appearance of TUL and ureteroscopy its indications have been greatly restricted.

We achieved stone-free rates of 79.3% and 74.4% for stones greater and less than 1 cm, respectively (table 3). Double J stent was inserted in none of our patients, although it is recommended for single kidneys containing stone, relief of pain, and stones that could not be well localized. Excellent results for TUL using holmium:YAG laser has been achieved for proximal as well as distal ureteral stones with a

mean stone-free rate of 94.9%, associated with a complication rate of 1%.[22] These results are superior to the results achieved by ESWL for proximal ureteral stones.

Meanwhile, when we used ESWL for 23 patients with distal ureteral stones of variable sizes, we observed the overall success rates of 83.3% and 70.5%, for stones greater and lesser than 1cm, respectively.

Strohmaier et al through a prospective study, compared the results of ESWL and ureteroscopy in the treatment of ureteral calculi. After randomizing their 146 patients with ureteral stones into two groups (ESWL and ureteroscopy), stone-free rate of 70.1% for ESWL was achieved, versus 94.9% after ureterscopy. Success rate of ESWL for ureteral stone was highly dependent on stone size and composition as well as the location of calculi, i.e. stone-free rate after ESWL was higher in distal ureteral stones in comparison with proximal ones.[22] Therefore, for all of the ureteral calculi, success rate of TUL is higher than that of ESWL with the expense of its more invasive nature and its need for general anesthesia. Lamotte et al also defined a therapeutic approach to ureteral stones, studying 152 ureteral calculi treatment: while ESWL eliminated 82% of all ureteral stones, TUL on the other hand, was successful for 100% of ureteral stones. Finally, they came into the conclusion that ESWL is the reference treatment for proximal ureteral stones and ureteroscopy gives excellent results for ESWL failures and for distal ureteral stones as the initial therapy.[23] Fernandez et al also found ureteroscopy as a safe and effective treatment modality for the management of calculi debris following ESWL of ureteral stones.[19]

Despite the improved results of TUL, we still favor ESWL as the initial approach for proximal ureteral stones, and ureteroscopy reserves as the initial treatment approach for distal ureteral stones and for ESWL failures. However, as discussed above, the relatively high success rate of ESWL for distal ureteral stone guarantees its application for surgically high risk patients.

Conclusion

Shock wave lithotripsy has been considered a mainstay of therapy in renal calculi for the last 20 years. Shock wave lithotripsy is noninvasive and requires the least anesthesia among the treatment modalities and therein lays its popularity. In the last decade, however, there have been changes in thinking regarding methods of patient selection for shock wave lithotripsy, changes in the technique of the existing shock wave lithotripters, and new technologies designed to increase the efficacy of shock wave lithotripters especially for "complex" patients. In this study, we specifically evaluated the role of ESWL in these patients. In brief, we can say that although success rates in some of these circumstances are acceptable, there is room for improvement. With appropriate patient selection, significant improvements in stone-free rates may be achieved. It is anticipated that improvements in lithotripter design will result in higher treatment success rates with reduced renal trauma and improved patient comfort.

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