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Original article

Success of electromagnetic shock wave lithotripter as monotherapy in large renal calculi—Our experience

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KEYWORDS
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Abstract
Objectives: To evaluate the success of shock wave lithotripsy (SWL) as monotherapy for solitary renal stones larger than 2 cm without ureteral stenting. Hence, if our study result demonstrates acceptable success and safety, we can recommend ESWL as a treatment option for patients with large renal calculi.
Subjects and methods: This is a prospective study conducted in the Department of Urology, Regional Institute of Medical Sciences, Imphal, India, from January 2011 to December 2012. A total of 104 patients aged between 20 and 70 years with solitary large (>2 cm) renal stones underwent ESWL using the Dornier Compact Sigma Lithotripter. Stone size was calculated by measuring the largest dimension of the stone in KUB plain films. In each session, 3000–3500 shocks at frequency 60–90 min^{-1} and intensity between 1 and 4 were given. A maximum number of six sessions were given. Successful treatment was defined as complete clearance or residual stones smaller than 4 mm on KUB performed 3 months after the first session.
Results: Total number of patients was 104. The M:F ratio was 1:1.4. The stone size ranged from 21 to 55 mm. The overall success rate was 73%. For stones >30 mm, the success rate was only 62.2% ($n = 28$). The number of sessions required increased as the stone size increased. The most common complication encountered was haematuria.

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Conclusion: ESWL remains the cornerstone of therapy for renal calculi less than 2 cm. Our study reveals that multiple sessions were required for solitary renal calculi, with higher rate of ancillary procedures. The success rate of ESWL for both non-staghorn and staghorn calculi with size above 2 cm is low, so other treatment modalities like PCNL should be considered as the first treatment option. However, with appropriate patient selection, significant improvements in stone-free rates may be achieved.

Introduction

Urinary stone disease is one of the mankind's most ancient ailments, currently remaining a common cause for both office and emergency room referrals. The goal of renal stone management is to achieve maximal stone clearance with minimal morbidity to the patient. Multiple options are currently available. The introduction of extracorporeal shock wave lithotripsy (ESWL) for the treatment of renal stones by Chaussy et al. in 1980 has been a very significant milestone [1]. ESWL has revolutionized the treatment of kidney stone disease and the majority of "simple" renal calculi (about 80–85%) can be treated satisfactorily with ESWL [2]. Multiple studies have reaffirmed the relation of stone free rates with stone size, stone location and stone number [3,4]. ESWL has traditionally constituted the favoured approach for small to moderate sized intrarenal calculi. In contrast, PCNL, although more invasive and often associated with higher morbidity, achieves better stone-free rates and is not affected by stone size [2]. For stones >20 mm in largest dimension, percutaneous nephrolithotomy (PCNL) is the first-line treatment. This is due to the higher retreatment rates and lower likelihood of achieving stone-free state with ESWL in comparison of PCNL [5]. The AUA Nephrolithiasis Clinical Guidelines Panel on Staghorn Calculi concluded that ESWL monotherapy is not recommended as a first-line treatment for large renal calculi and that it should only be used in combination with PCNL, whereas the PCNL being performed after ESWL [6].

This study was aimed to assess the success rate of ESWL as monotherapy for larger renal stones and the safety of this therapy without prophylactic DJ stenting. We studied the outcome of ESWL monotherapy in patients with solitary renal stones greater than 2 cm who opted for it after knowing the various options of treatment.

Subjects and methods

This study is a prospective study conducted in the Department of Urology, Regional Institute of Medical Sciences, Imphal, India, from January 2011 to December 2012.

Patients aged between 20 and 70 years with nephrolithiasis with solitary radio-opaque large (>2 cm) renal stones were included in the study. The treatment was carried out using "Dornier Compact Sigma Lithotripter (Dornier Medtech, Germany)", a third generation electromagnetic lithotripter with an integrated Ultrasound for stone localization and monitoring.

Ethical clearance was taken from the ethics committee of our institute prior to the commencement of the study. All the patients were informed about the other available options (like pyelolithotomy, PCNL) available in our institute to deal with these kinds of stones. In this part of the country, the patients prefer a non-invasive mode of treatment initially. Hence, we even have 6 cases of lower calyceal stones in our study. All the patients were explained about the procedure and the possibility that their treatment may be unsuccessful and we might have to resort to other modes of treatment to clear their stones. Informed written consent was taken from all the patients. Patients with congenital anomalies of the kidney, patients with a percutaneous nephrostomy and patients having a history of previous renal surgery on the affected side were excluded from the study. Also excluded were patients with bilateral calculi, gross hydronephrosis, those having features of obstruction, patients with solitary kidney and patients with deranged renal function. The variables studied were age, sex and the location and size of the renal calculi. Pre-treatment KUB plain films, ultrasonography and intravenous urography were performed in all patients. Routine investigations included a complete hemogram, bleeding time (BT), coagulation time (CT), electrocardiogram (ECG), urine R/E and C/S, kidney function test (KFT), random blood sugar level. For patients with lower calyceal stones, only those patients having an obtuse infundibulo-pelvic angle, wide and short infundibular length were included in the study. Stone composition was not evaluated in the present study.

Stone size was calculated by measuring the largest dimension of the stone in KUB (kidney, ureter and bladder) plain films. Patient preparation included liquid diet after bowel preparation with 2 tablets dulcolax and 4 tablets charcoal previous night after dinner and patients were given analgesic medication in the form of Diclofenac 75 mg intramuscular injection just before starting the session. All were treated in supine position with number of shocks per session ranging between 3000 and 3500 at the frequency of 60–90 min^{-1} and intensity between 1 and 4 depending on the tolerance level of the individual. Proper antibiotics, analgesics and haemostatics were prescribed post procedure. All patients were instructed to report even the minor complications after treatment and were kept under a close follow-up. One week after the treatment, X-ray or ultrasound was used to check the existence of haematoma or the evolution of the lithiasis. If the residual fragment size was more than 4 mm a repeat session was advised, otherwise patients were discharged from the treatment regimen. A maximum number of six sessions were given after which it was labelled unsuccessful. We did not contemplate doing repeat serum creatinine during the study period as we did not do any case with bilateral stones, deranged renal function, etc., which could have raised the creatinine during the ESWL sessions. Successful treatment was defined as complete clearance or residual stones $\leqq$4 mm on KUB performed 3 months after the first session.

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS 16.0) for windows. All categorical data were presented using frequencies and percentage. Associations

Table 1 Patient and stone characteristics.

Number of patients	104
Male:female	1:1.4
Male	44 (42.3%)
Female	60 (57.7%)
Age group	20–70 years (mean = 39.4 years)
Stone location	
Upper calyx	03 (2.9%)
Middle calyx	02 (1.9%)
Lower calyx	06 (5.8%)
Pelvis	72 (69.2%)
Pelvicalyx	21 (20.2%)
Laterality	
Right	58 (55.8%)
Left	46 (44.2%)
Stone size	21–55 mm

between categorical variables were assessed using Chi-square test with Yates' correction and ANOVA test. A P value less than 0.05 was considered statistically significant.

Results

During this study period, a total number of 353 patients underwent ESWL for either renal or ureteral calculi. Out of this, 104 were those patients who were enrolled in our study, i.e. those who underwent ESWL for solitary large renal stones. No patient left the study in between. The male:female ratio was 1:1.4 (M = 44, F = 60).

The mean age of the patients was 39.4 years. More than 70% of the patients were in the age group of 30–60 years. Table 1 shows the distribution of each category of cases among these 104 patients.

The stone size ranged from 21 to 55 mm. Of all the 104 cases, 58 had involvement of the right kidney (55.8%) while the remaining 46 cases had calculus in the left kidney (44.2%). The maximum number of calculi ranged between 21 and 30 mm (56.7%).

Table 2 shows the number of cases as per the different sizes of the renal calculi in the present study as well as their laterality.

The mean number of ESWL sessions required to break the stones varied with the size as well as the location of the renal calculi. For stones located in the upper calyx, the mean number of sessions received was 2, in the middle calyx was 3.2, in the lower calyx was 3.9, in the pelvis was 3.22 and in the pelvicalyx was 3.93. All of our patients could tolerate the procedure with a single intramuscular injection of Diclofenac 75 mg before each session. However, there were some patients who complained of pain during the procedure. In such cases, we stopped the procedure for some time, or decreased the frequency/intensity. None of the patients required any other form of anaesthesia.

Table 2 Size and laterality of the stones.

Stone size (mm)	Total number of cases		Total no. of cases (%)
	Right kidney	Left kidney	
21–30	33	26	59 (56.7)
31–40	14	12	26 (25)
41–50	09	07	16 (15.4)
51–55	02	01	03 (2.9)

The results of our study are shown in Table 3. The success rate is depicted based on the imaging findings at 3 months.

The overall success rate was 73%. But if we consider those cases with stone size >30 mm, the success rate is only 62.2% ($n = 28$). There were 5 (4.8%) cases in which, even after three sessions, there was minimal to nil stone fragmentation. Hence, such cases were not subjected to further ESWL. Overall, the failure rate was 26.9% ($n = 28$). The failure cases underwent surgical procedure for stone retrieval. Two of the failure patients underwent PCNL while the remaining 26 patients underwent open pyelolithotomy for stone clearance. We did not perform more of PCNL as is has been recently introduced in our centre and we are still in the learning curve. The mean number of sessions increased as the stone size increased while the success rate decreased with increasing stone size. Among the complications encountered, the most common was that of haematuria (38%) followed by steinstrasse (18.3%). The complications encountered are presented below in Table 4. Haematuria was transient, mild and subsided within 2–3 days with the help of oral tranexamic acid thrice a day for 3 days and adequate bed rest and fluid intake. It was found to be more in cases who underwent ESWL at a higher intensity. The incidence of steinstrasse was highest in the group with stone size >4 cm (26.3%). Eight (42%) of the patients were symptomatic, having features like flank pain, fever and nausea. The remaining cases were diagnosed incidentally on the follow-up X-ray KUB. All of the patients were initially treated by conservative management using adequate hydration, tamsulosin (0.4 mg HS) and analgesic on demand for a maximum of 2 weeks. If even after this period there was minimal or no stone clearance, they were taken up for URSL (ureteroscopic lithotripsy) using pneumatic energy. Twelve (63.2%) of the steinstrasse cases were managed conservatively whereas the remaining seven (36.8%) underwent URSL for clearance. None of the patients had to under open ureterolithotomy. Two (1.92%) patients developed perirenal haematoma after

Table 3 Success of ESWL as monotherapy in large renal calculi.

Stone size (mm)	No. of cases	Number of sessions (mean ± SD)	Stone free patients (including clinically insignificant fragments)	Non stone free patients	Overall success rate (%)
21–30	59	3.28 ± 1.98	48	11	81.3
31–40	26	3.58 ± 1.94	17	09	65.4
41–50	16	4.83 ± 3.05	09	07	56.2
51–55	03	3.66 ± 2.77	02	01	66.7

Table 4 Complications of ESWL in the present study.

Complication	Total no. of cases (%)
1. Haematuria	39 (38)
2. Steinstrasse	19 (18.3)
(a) *Stone size*	
21–30 mm	10/59 (16.9)
31–40 mm	04/26 (15.4)
41–55 mm	05/19 (26.3)
(b) *Presentation*	
Symptomatic	08/19 (42)
Incidental	11/19 (58)
(c) Management	
Conservative	12/19 (63.2)
URSL	07/19 (36.8)
3. Skin bruise	21 (20)
4. Perirenal haematoma	02 (1.92)

the fourth session which subsided in a period of 3 months with conservative management.

Discussion

While extracorporeal shock wave lithotripsy (SWL) is considered a highly effective treatment for upper urinary tract stones, concerns about the efficacy of SWL have dampened enthusiasm for the treatment [7,8]. These concerns have been heightened by the fact that second generation and more recent lithotripters appear less effective at breaking stones [9–11]. Till date, the unmodified HM-3 lithotripter (Dornier Medtech Europe GmbH, Wessling, Germany) is considered the most effective lithotripter in terms of success rates, having showed high stone-free rates (SFRs) that have not been matched with later-generation lithotripters and it is the reference standard against which the outcome of treatment on other machines is compared. Also, as the stone size increases there is a significant reduction in stone-free rates for single renal calculi treated with ESWL monotherapy with reported mean stone-free rates of 79.9% (range 63–90%), 64.1% (range 50–82.7%), and 53.7% (range 33.3–81.4%) for stones less than 10 mm, 11–20 mm, and larger than 20 mm, respectively [12–14].

In the 1980s, ESWL monotherapy was applied for stones >2 cm; however, the need for multiple treatments, the high incidence of adjunctive procedures required and the low stone-free rate prompted the recommendation that large calculi should be treated with combination therapy (PCNL + ESWL)[15]. In their first report of clinical data on ESWL, Chaussy et al., reported a SFR of ≈90% [16]. In the landmark US cooperative study of ESWL, Drach et al. reported a SFR of 77.4% with the HM-3 at 3 months after treatment [17].

According to NIH consensus conferences recommendation, patients with stones larger than 2 cm, should be approached with PNL initially, followed if needed by ESWL due to high retreatment rates and the need for ancillary procedures [18]. However, many of the centres across the globe treat these patients with ESWL monotherapy with good success rates [19]. A decade ago, the results of ESWL monotherapy for solitary renal stones >2 cm were variable and stone-free rate was varying from 33% to 65% [20]. The advancement of technology and current expertise in ESWL has yielded much higher stone-free rates [19]. In our study, 104 patients with solitary large renal stones above 2 cm in size underwent ESWL with electromagnetic Dornier compact Sigma Lithotripter without DJ stenting. When we consider the outcome of ESWL in stone size of 2–3 cm, the success rate was around 82%, which is at par with the 90% success rate of PCNL [5].

Abe et al. reported 46% stone clearance and 54% residual fragments among 267 patients with renal stones with size between 20 and 30 mm in their series of 3024 patients treated with ESWL monotherapy. All patients had DJ stenting prior to ESWL monotherapy. Their overall stone-free rate was 65.1%, and the success rate was 85.7% when they analyzed all the patients with stone size varying between 4 and 30 mm [21]. In another such study, Psihramis et al. reported on 94 renal stones larger than 2 cm treated with ESWL, the success rate was only 33%. Patients with multiple stones had a similar stone-free rate of 32% [22]. As observed in this study, success rate was not significantly different with respective of stone location. This may be because the cases are not equally distributed according to location. The number of cases seen in upper, middle and lower calyces is quite low.

ESWL is not complication-free despite its relatively non-invasive nature. The estimated rate of overall complications reported for ESWL therapy for staghorn calculi ranged from 13% to 19% [6]. The most common complication encountered in our study was haematuria, which was mostly mild and transient, and which was reported in 38% of the patients. Another common complication was that of steinstrasse which was seen in 18.3% of our cases ($n = 19$). Interestingly, its incidence was more common in patients with stone size >30 mm. Goyal et al. [23], observed a 11.1% incidence of steinstrasse following ESWL for stones between 2 and 3 cm and 18.5% in stones >3 cm. Kim et al. [24], observed a 0.3% incidence of steinstrasse for stones <1 cm compared with 18.8% for stones >4 cm. The role of pre-ESWL JJ stenting for large renal stones still remains a topic of discussion. Libby et al. found that pre-treatment placement of DJ stents reduced the requirement of auxiliary procedures from 15% to 6% and complications from 26% to 7% [25]. Shouman et al. stated that DJ stenting is not required for a successful ESWL for even larger stone burden [19]. Kumar et al. [26] have shown that SWL monotherapy for renal stones without stenting is safe even in solitary kidneys. Despite the inter-observer variations regarding pre-ESWL stenting, before ESWL monotherapy, our study showed that pretreatment stenting, it can safely be stated that closer follow-up is required in all the cases to ensure successful and uninterrupted passage of the stone fragments.

Conclusion

Shock wave lithotripsy is non-invasive and requires the least anaesthesia among the treatment modalities and therein lays its popularity. In the last decade, however, there have been changes in thinking regarding the 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 our study of ESWL for large solitary renal calculi above 2 cm in size, the patients with large renal calculi required multiple ESWL sessions and the rate of ancillary procedures are high. The success rate of ESWL in large renal calculi above 2 cm in size is low, so for both non-staghorn and staghorn calculi with size above 2 cm, other treatment modalities like PCNL should be considered as the first treatment option. But in

patients who are not fit for invasive surgeries like PCNL and open surgery or those reluctant to undergo an invasive procedure, ESWL can be considered as a viable, alternative treatment option. For stone size between 2 and 3 cm, especially those in the renal pelvis or pelvicalyx, ESWL can be considered as the first treatment option. With appropriate patient selection, based on a comprehensive evaluation of stone related factors (size, number, location, and composition), renal anatomy, and patient clinical factors, significant improvements in stone-free rates may be achieved.

Conflict of interest

None declared.

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