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Role of Extracorporeal Shock Wave Lithotripsy in Management of Upper Ureteric Stones

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Extracorporeal shock wave lithotripsy;
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Upper ureteric calculus

Abstract
Introduction: The treatment options for upper ureteric stones range from open surgeries to minimally invasive and non invasive techniques. Presently the two most frequently used options for upper ureteric calculi that require intervention are extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopy (URS) with contact lithotripsy applied by attaining endoscopic access to the calculi.
Objective: The objective of this study is meant to evaluate ESWL in the treatment of upper ureteric stones ≤2 cm in terms of stone free rates, complications and procedure time.
Patients and method: Seventy six patients were subjected to ESWL as primary modality for treatment of upper ureteric stone. ESWL group had mean stone size of 10.58 mm. The stone free rate was 93.4% for ESWL. The sample size was adequate as it was determined by statistician by applying pertinent formulas.
Results: It was observed that the stone free rate in ESWL group was higher (97.7%) when the stone size was ≤10 mm and when the duration of symptoms was <1 month. ESWL was advantageous in terms of procedural time with no requirement of anaesthesia. The complications in ESWL were minor in nature and were not statistically significant.
Conclusion: In conclusion, this study shows that ESWL is an important modality in treating upper ureteric calculi ≤2 cm in size and we strongly recommend ESWL as the first choice of procedure in solitary upper ureteric calculi ≤10 mm size.

Introduction

Although the present day urologists' armamentarium is so replete with tools to treat urolithiasis, management options are by no means less controversial today to what it were nearly a decade back.

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Each individual stone, presents the physician and the patient with a dilemma in the era in which a myriad of management options are available. Evolution of technology in the last two decades has revolutionized the treatment of ureteric calculi. In 1882 ureterolithotomy by dorsal lumbotomy was first described. In 1885 and 1889 transperitoneal and extraperitoneal ureterolithotomy were reported respectively [1]. With the advent of lithotripsy in 1982, management of urolithiasis has taken a quantum leap. Now with high safety and comparable efficacy profile, lithotripsy has also become a leading modality in the treatment of ureteric stones. A guideline panel by the AUA society to review the treatment outcomes for upper ureteric stones have also recommended ESWL as first line treatment for patients with uncomplicated proximal ureteral stones of 1 cm or less [2] .They also concluded that the stone free rate after one year of treatment approaches 85%.Other more important factors in favour of ESWL are cost reduction, ease of monitoring, lack of exposure to ionising radiations in ultrasound monitoring, decreased morbidity and more patient acceptability [3]. Presently the two most frequently used options for ureteric calculi that require intervention are SWL and URS with contact lithotripsy applied by attaining endoscopic access to the calculi. In the present study we would present data from our institution on the usefulness of SWL in the treatment of upper ureteric stones less than 2 cm in size.

Patients and methods

The prior permission from Institute Ethics committee was taken and all the patients were told about study and their role in study. The consent from patients were also taken. The study was a prospective study conducted from July 2012 to April 2014. A total of 76 patients were included in the study with their proper consent.

The study is a prospective study meant to evaluate ESWL in the treatment of upper ureteric stones. The upper ureter was defined as the segment between the ureteropelvic junction and the superior margin of the sacroiliac joint.

The patients with having stones $\leq$2 cm, solitary stones, radio opaque stones, and having upper ureteric stones were included. Whereas those subjects where stones are greater than 2 cm in size, radiolucent stones, stones at any other position other than upper ureter, stones in an abnormal ureter like congenital ureteric abnormality or ureteral reimplantation, patients having renal insufficiency, uncorrected coagulaopathy and morbidly obese patients and acute infection in an obstructed kidney were excluded.

Patient's history was taken and clinical examination done. Investigations in the form of radiography (X ray KUB) and ultrasonography (Abdomen and Pelvis), IVP along with laboratory parameters were assessed. The stone size was noted as per X-ray KUB dimension and the maximum diameter was defined as the stone size. The laboratory investigations done were as follows: Hemogram, Renal function tests, blood sugar level, coagulation profile, urinalysis,urine culture and sensitivity. Appropriate antibiotics were given preoperatively in cases where the urine culture showed evidence of infection. The findings were recorded in the standard Proforma. The form of treatment was explained to the patients and the written informed consent was taken.

All cases were treated as day care procedures, without any anaesthesia. Dornier Sigma (third generation), an electromagnetic shock wave lithotripter was used. Patients were given supine position on lithotripsy table and the calculus was localised by using both X-ray and USG. All sessions were performed by a single technician under the supervision of a consultant. Shock waves were delivered at the rate of 60–80 per minute with a maximum of 2500 shocks per one session of treatment. We started with low energy waves and increased energy as per tolerability of the patient. Maximum of 3 sittings spaced two weeks apart were given. All patients were asked to drink lots of fluids and maintain active lifestyle and skipping exercises if possible. Prior to every sitting an X-ray KUB was obtained to see for the state of clearance of stone. Study end points included stone free status which was defined as either no visible fragments or fragments less than 3 mm, which were considered as clinically insignificant residual fragments as determined by X-ray KUB and USG KUB for maximum of three months following the last sitting. Patients not responding after 3 sittings of ESWL were deemed failures and other modalities of treatment were explained to them. Number of sessions of ESWL and complications if any were noted. In cases of failures ancillary procedure done was also noted.

Statistical analysis

The distribution of incidence of various qualitative characteristics will be shown as n (% of cases), while the distribution of various quantitative characteristics will be shown using Mean $\pm$ Standard deviation across two intervention groups. The statistical comparison of continuous variables across two study groups was done using independent sample 't' test after confirming the underlying normality assumption. The significance of difference of categorical variables across two groups will be tested using Fisher's exact probability test. The entire statistical analysis will be performed using Statistical Package for Social Sciences (SPSS version 12.0; Chicago, IL) for MS Windows and GraphPad's software. Categorical and qualitative data between the groups was analyzed by Fisher's exact test from a 2×2 contingency table. Level of significance was expressed as probability value (P-value). P-value of <0.05 was considered statistically significant.

Results

The majority of the patients undergoing ESWL were in the age group of 31–60 years being 59.2% of cases followed by patients who were less than 30 years of age. Males accounted 76.3% (58/76) whereas females accounted for 23.7% (18/76). Pain was the most common symptom affecting 81.6% (62/76) patients followed by hematuria which was in 10.5% (8/76) patients undergoing ESWL. Only 7.9% (6/76) patients reported incidental detection of stones. The duration of symptoms was $\leq$1 month in 92.1% (70/76) of patients. 57.9% (44/76) patients had stones of $\leq$10 mm in size while 42.1% (32/76) patients had stones between 10.1–20 mm in size. 76.3% (58/76) underwent a single sitting of ESWL and 14.5% (11/76) underwent two sittings of ESWL. In only 9.2% (7/76) of patients three sittings of ESWL had to be given. Of the 76 patients subjected to ESWL 93.4% (71/76) of patients were stone free whereas in only 6.6% (5/76) of patients ESWL proved to be a failure. Hence the average stone free rate was 93.4%.

Table 1 Stone free rate as per stone size — ESWL subgroup.

Size	Stone free	Failure	P value
≤10 mm	43(97.7%)	1(2.3%)	0.1553
10.1–20 mm	28(87.5%)	4(12.5%)	
Total	71	5	

Table 2 Duration of symptoms and stone free rates — ESWL.

Duration of symptoms	Stone free rate	P value
≤1 month	94.3%	0.3449
>1 month	83.3%	

Table 3 Complications of ESWL.

Complication	Number of patients	Percentage
Hematuria	2	2.6%
Colic	4	5.2%
Steinstrasse	3	3.95%
Fever	3	3.95%
Nausea/vomiting	2	2.6%

Size of stone and stone free rate

When sub group analysis was done it showed that in ≤10 mm group the stone free rate was 97.7% (43/44) while in 10.1 mm–20 mm group the stone free rate decreased to 87.5% (28/32) (Table 1).

Conclusion: By using the Fischer's exact test, P-value was 0.1553; therefore there is no significant difference in the stone free status between the two subgroups of ESWL.

Duration of symptoms and stone free rates

A total of 66/70 patients (94.3%) who had symptoms of ≤1 month duration were stone free. In the group where the duration of symptoms was more than 1 month only 5/6 patients (83.3%) were stone free. (Table 2).

Conclusion: By using the Fischer's exact test, P-value was 0.3449; therefore there is no significant difference in the stone free status between the two subgroups of ESWL.

Complications

A total of 14/76 (18.4%) patients had complications in ESWL group. The various complications encountered were as follows: Among the patients undergoing ESWL in the study, 2.6% (2/76) had hematuria, 5.2% (4/76) developed colic, 3.9% (3/76) developed Steinstrasse, 3.9% (3/76) had fever and 2.6% (2/76) suffered from severe nausea/vomiting. (Table 3).

Procedure time

In our study, it was found that in patients undergoing ESWL, the procedure time was dependent on number of sessions and shock waves and was found to range from 15 to 65 min. The mean procedure time in ESWL was 25.13 min.

Discussion

With the advent of lithotripsy management of urolithiasis has taken a quantum leap. Now with high safety and comparable efficacy profile lithotripsy has also become a leading modality in the treatment of ureteric stones. Main goal of any procedure for calculus disease is to achieve complete stone clearance. Failure in achieving this goal can be due to various factors related to patient, stone and technique used. Thus many factors determine stone clearance rate in a patient. ESWL is the initial treatment of choice for most renal calculi because of its noninvasive nature, requirement of minimal anaesthesia, and tolerability by patients and physicians. ESWL has been recommended as the first line treatment of upper ureteric calculi in many studies with a success rate of 80–90%. Since the improvements in the mechanics of lithotriptors and better understanding of shock wave physics and increasing availability of equipments and trained personnel have made this modality more effective. Stones can be successfully fragmented by application of shock waves, but the ability of kidney and ureter to clear the resulting fragments is by far more important in terms of successful treatment outcome. Increasing experience show some advantages, cost reduction, permanent monitoring, lack of exposure to ionising radiation in ultrasound monitoring during the procedure [3]. With the advent of small calibre and flexible ureteroscopes, the paradigm of treatment of upper ureteric stones has shifted towards ureteroscopy with success rates approaching 95% but not without its share of complications. ESWL on the other hand is non invasive and less morbid with a low complication rate. Various authors like Lingeman et al. [4], Gnanapragasam et al. [5], Gafoor and Halim [6], Padhye et al. [7] have in their studies found clearance rate ranging from 82.4% to 94% for upper ureteric stones less than 2 cm when ESWL was used as the treatment modality. Since our hospital is located in the urban area draining population who is highly educated and compliant, the follow up schedule was strictly adhered to by the patients. This good compliance ultimately led to better clearance rates of stones and hence the good results.

There is dedicated and trained team of medical personnel who could localise the stone fluoroscopically and ultrasonographically with high degree of precision during ESWL, hence it resulted in high rates of success. The number of cases in the study were deemed to be adequate after doing a statistical analysis as mentioned in the study.

Outcome of treatment

The three most significant outcome measurement of any procedure are the stone-free rates, the associated complications and procedural time

Stone free rate

In the present study, of the 76 patients subjected to ESWL 93.4% (71/76) of patients were stone free whereas in only 6.6% (5/76) of patients ESWL proved to be a failure. Hence the average stone free rate was 93.4%. Various other authors have shown the stone free rates ranging from 82.4% to 94%. Hence our study compares favourably to the other studies. (Table 4)

In the present study, the stone free rate in subgroup of stone size ≤10 mm was 97.7% whereas in the subgroup of stone size 10.1 mm–20 mm the stone free rate was 87.5%. Various other

Table 4 Average stone free rates.

Study	Average clearance rate (%)
Lingeman et al. [4]	82.4%
Gnanapragasam et al. [5]	90%
Ghafoor and Halim [6]	94%
Padhye et al. [7]	91.7%
Logarakis et al. [8]	72.3%
Present study	93.4%

Table 5 Stone free rate as per stone size.

Study	Stone size	Stone free rate
Ghafoor and Halim [6]	≤10 mm	100%
	10.1–20 mm	75%
Logarakis et al. [8]	≤10 mm	79.6%
	10.1–20 mm	63.6%
Akal [9]	≤10 mm	76%
	10.1–20 mm	54%
Present study	≤10 mm	97.7%
	10.1–20 mm	87.5%

Table 6 Types of complications.

Complications	Al-Marhoon et al. [11]	Wazir et al. [12]	Present study
Dysuria	3%	–	–
Loin pain	21.2%	9.76%	5.2%
Hematuria	6.1%	3.2%	2.6%
Hospital admission	6.1%	–	–
Steinstrasse	–	2.72%	3.9%
Fever	–	1.12%	3.9%
Loin pain with hematuria	3%	–	–
Nausea/vomitting	–	–	2.6%

authors have noted lesser results for the subgroup where the stone size was more than 10 mm, hence our study apparently shows better results of ESWL as compared to other studies. (Table 5)

Duration of symptoms and stone free rates

In the present study, we observed that ESWL resulted in better stone free rate when the symptom duration was ≤1 month (94.3% stone free rate) as compared to patients in whom the duration of symptoms was >1 month (83.3% stone free rate). These observations matched favourably with the observations of Padhye et al. [7] and Chang et al. [10] in their studies on ESWL who also observed that the success rate of ESWL drops with increasing duration of symptoms of the patient

Complications

In the present study, loin pain was the most common complication affecting 5.2% of patients in the ESWL group followed by fever in 3.9%, Steinstrasse in 3.9%, nausea in 2.6% and hematuria in 2.6% of patients. Loin pain was also the most common complication in the other studies also being 21.2% in study by Al-Marhoon et al. [11] and 9.76% in study by Wazir et al. [12]. There was a lower incidence of steinstrasse in other studies as compared to our study. Hematuria was lesser in our study as compared to the other two studies. (Table 6)

Table 7 Complication rate.

Study	Complication rate
Al-Marhoon et al. [11]	39.4%
Wazir et al. [12]	16.8%
Present study	18.4%

The complication rate in our study was 18.4%. It is significantly lower than the complication rate observed by Al-Marhoon et al. [11] and marginally higher from that observed by Wazir et al. [12]. (Table 7).

Conclusions

The findings from our study thus support use of ESWL in upper ureteric stones of stone size ≤10 mm. The erroneous perception of futility of ESWL in upper ureteric stones of size ≤10 mm among many urologists, which make them perform more URS in upper ureteric stones, should undergo correction. Patients should be informed about possibility of requiring more than 1 sitting of ESWL and need to follow active lifestyle and jumping exercises if possible, with lots of fluid consumption. This may lead to better stone clearance rate.

Conflict of interest

We all declare no conflict of interest among ourselves.

Authors' contribution

Dr Ravi Batra: He is the principal investigator for the study. Main concept of study was put forth by him only. He is the one who has dealt with patients in the OPD of hospital. Later on he has contributed in data analysis and statistical analysis. He is the guarantor of the study.

Dr Pooja Batra: She is also the key person in concept making and designing the basic plan of study. She has helped in doing extensive literature search. She has also helped in data analysis and statistical analysis. Later on she has contributed in manuscript writing and reviewing it time to time.

Dr Pradeep Bokariya: Right from the beginning he has helped in study design. Sample size estimation was done by him only. Later on he has contributed in data entry, data analysis.

Dr Ruchi Kothari: Her role in this study is also tremendous. Through her skills of IT she has helped in finding relevant literature so that further planning can be made. She has good command on language so she has helped in manuscript writing and later on editing as per reviewers suggestions.

Ethical committee approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Approval of Ethics committee were duly taken.

Consent form the patients

A written informed consent was obtained from each individual participated in this study.

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