Efficacy and Outcome of Extra Corporeal Shockwave Lithotripsy in the Treatment of Kidney and Upper Uretericstone: A Single Centre Experience

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ABSTRACT

Introduction: Although shockwave lithotripsy is introduced 3 decades ago still it is the first line surgical management to meet huge burden of urinary stones worldwide, despite availability of other newer modalities of effective treatment. For developing countries like India, it is very helpful and promising to meet demand of huge burden of patients with less number of urologist. Our aim was to study the efficacy and outcome of this procedure in our institute and how it is influencing the guidelines.

Materials and methods: A prospective study over a period of two years was conducted in the department of urology in VIMSAR, Burla with patients 15 -60 years age having single solitary stone of below 2cm size in the kidney and below 1 cm size for upper ureteric stone. Efficacy and outcome were calculated as rate of stone clearance, percentage of complications. Statistical analysis was performed.

Results: A statistically significant 85.3% of patients get cleared and labelled stone free. Whereas 14.7% of patients having incomplete clearance switched over to other modality of treatment. A 20.6% of patients reported transient pain and other complication treated with appropriate medication which gradually subsided in follow-up.

Conclusion: ESWL is the first line of management for renal and upper ureteric calculus in properly selected patients as it is non-invasive, economical, efficacious with minimal complication and can be done as day care procedure.

Keywords: Efficacy and Outcome, Extra Corporeal Shockwave Lithotripsy, Kidney and Upper Uretericstone

INTRODUCTION

Extra corporeal shockwave lithotripsy is a newer modality in the treatment of urinary stones particularly kidney and upper ureteric stones. Though this procedure has been introduced in the year 1980, it is still considered first line management in the treatment of urinary stones as it is cost effective, non-invasive and can be done as day care procedure with minimal complications. A stone clearance rate of more than 80% has been reported for stone size smaller than 2 cm in the upper calyx, middle calyx and pelvis of the kidney and smaller than 1 cm in upper ureter.

This procedure which termed as ESWL derived from three words "extra corporeal: outside the body, shockwave: high energy waves and lithotripsy: fragmentation of stones" works by the principle of stone fragmentation by high energy pressure waves. These waves are generated by lithotripter Dornier delta II, a 3rd generation machine which targeted

from outside focussed by x- ray fluoroscopic imaging in a series of pulsation and can be repeated in multiple sessions. The stone clearance can be monitored subsequently by series of x ray imaging and ultrasonography. However the effectiveness depends upon a number of factors such as stone size, stone density, location, skin to stone distance, BMI to facilitate stone expulsion.² Our aim was to study the efficacy and outcome of this procedure in our institute and how it is influencing the guidelines.

MATERIAL AND METHODS

A prospective study was conducted in the department of Urology, VSS Institute of Medical Science and Research, Burla after receiving clearance from institutional ethical committee. It was conducted over a period of 2 years from September 2016 to September 2018. After obtaining informed consent 158 no. of patients of 15 to 60 years of age of both sexes enrolled in the study, all the patients were selected were subjected to history taking, clinical examination laboratory investigation including biochemical, urine routine microscopic examination, culture and radiological imaging such as X-ray KUB, IVP, Ultrasound sonography and CT Scan of KUB to include in the study.

Inclusion criteria taken into consideration are age group of 15-60 years of both sexes, single renal stone of size smaller than 2cm and upper ureteric stone of size smaller than 1 cm, stone density less than 1000 HU and skin to stone distance less than 10cm.

The exclusion criteria were pregnancy, uncontrolled coagulopathy, diabetes mellitus, renal insufficiency, urinary tract infection, obesity (BMI more than 30), multiple stones

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and stones with distal obstruction, hypertensive patients, and those cases who lost to follow up.

The selected patients were given shockwave therapy of maximum up to 3000 shocks for a duration of 30 minutes to 60 minutes per session up to maximum three sessions. All patients were given 1 amp of inj.diclofenac with adequate water intake prior to session. In post procedural period all patients were given drug Tamsulosin hydrochloride 0.4mg for a period of 2-4 weeks to facilitate stone expulsion. All the patients were advised to follow up regular interval of two weeks and to report of any symptoms like pain, hematuria, fever, hypertension, urinary tract infection. Serial X-rays KUB film and ultrasonogram and CT Scan KUB in selected cases were done to evaluate stone clearance status and to detect presence of steinstrasse. (fig 2-8)

In this study the patients with no radiological evidence of stone were considered as complete clearance in follow up period of three months. Incomplete stone clearance or failed treatment assigned to patients with persistence stone of size more than 5mm, even after 3 sessions of ESWL. Any symptoms of pain or hematuria or hypertension or urinary tract infection and steinstrasse were noted as complication and given appropriate treatment.

Data were collected by filling in pro forma datasheet which included their consent for study, demographic profiles, investigation reports and follow-up report after each session. All the data were taken for statistical analysis using frequency and percentage and discrete variable evaluated by descriptive and frequency analysis. Successful outcome defined by calculating the percentage as number of patients having stone free after treatment divided by total number of patients subjected to study. Efficacy of ESWL calculated as the percentage of patients having stone free without complication out of total number of patients.

RESULTS

A total of 158 patients enrolled in this study from September 2016 to September 2018 of which 22 patients lost in the follow up (table-1). A total of 136 patients completed the study successfully with mean age of 39.69 years and with a

	Total no. of patients	Minimum range	Maximum range	Mean value
Age	136	18.0	60.0	39.69
Size in mm	136	8.0	19.0	12.01

Table-1 shows A total of 136 patients in study treated successfully with mean age of 39.69 years and with a mean stone size of 12.015mm

Table-1: Distribution of age with stone size with average value

Gender	Frequency	Percent		
M	87	64.0%		
F	49	36.0%		
Table 2 shows 87patients (64.0%) are male and 49 patients (36.0%) are female patients.				
Table-2: Gender distribution				

Complete clearance	Frequency	Percentage		
Yes	116	85.3%		
No	20	14.7%		
Table 3 shows 85.3% (116)natients have stone clearance, 14.7% (20) natients have no complete clearance in three sessions				

Table 3 snows 83.5% (110)patients have stone clearance. 14.7%(20) patients have no complete clearance in three sessions

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No.of session	Total no. pts undergone in this session ESWL therapy	Total no. of patients cured in this session	Complete clearance at session	Incomplete clearance %
1st session	136	71	52.2%	47.8%
2 nd session	65	33	50.7%	49.3%
3 rd session	32	12	37.5%	62.5%
Total	136	116	-	-

Table 4 shows complete clearance in 1st, 2nd 3rd sessions are 52.2%,50.7% and 37.5% respectively

Table-4: Outcome of shockwave lithotripsy in relation to number of session

Size	Total no. pts of size undergone ESWL therapy	Total no of patients	Complete clearance %	Incomplete clear- ance %
5-10 mm(small)	64	64	(100%)	nil
10.1-15mm (medium)	51	33	(64.70%	35.3%
15.1-20 mm (large)	21	09	(42.8%)	57.2%
Total	136	116	-	-

Table 5 shows decrease stone clearance rate with respect to increase size of stone

Table-5: Overall comparision of size of stone with clearance

	Frequency	clearance	Percentage of clearance
Upper ureter	63	63	100
Upper calyx of kidney	32	28	87.5
Middle calyx of kidney	41	25	60.9

Table-6 shows clearance of stone in relation to location of the stone where 100% clearance in upper ureter and less clearance 60.9% middle calyx of kidney.

n.b.- lower calcyx of kidney not taken included in the study

Table-6: Comparison by location of stone with percentage of clearance

	Frequency	Percent
NC - no complication	109	80.1%
PAIN - loin pain and backache	16	11.8%
UTI - urinary tract infection	6	4.4%
STNSTR - steinstrasse	3	2.2%
HMTR - hematuria	2	1.5%
HTN -Hypertension	nil	nil

Table 7 shows that the majority of complications are minimal and temporary which resolved over medication and complications like steinstrasse (2.2%) and hematuria (1.5%) that are not resolved undergone other modality of treatment.

Table-7: Post procedural complications



Figure-1: Shows that patient undergoing ESWL therapy in our setup by DORNIER DELTA II lithotripter



Figure-2: Pre-operative shows left side upper ureteric stone; **Figure-3:** Post operative photo shows complete clearance after the procedure

meanstone size of 12.015 mm.

Out of which 87(64.0%) were male and 49(36.0%) were female patients.(table-2)

Table -3 shows, a total of 116 patients had complete stone clearance in three sessions of ESWL. Remaining 20 patients with renal stone have undergone percutaneous nephrolithotomy for clearance. So overall stone free rate was found to be 85.3%.





Figure-4: Shows left PUJ kidney stone (preoperative); **Figure-5:** Shows partial clearance after 1st session





Figure-6: Shows complete clearance after the procedure;

Figure-7: Shows preoperative left kidney stone



Figure-8: Shows post operative complete clearance after the procedure

Table-4 Shows that 52.2%,50.7%,37.5% patients cleared at 1st, 2nd and 3rd session respectively. In this study it was found that there was difficulty of clearance towards later session. Hence further treatment with ESWL is of decreasing value. So these patients have been advised for other treatment

modality

Table 5 shows the clearance rate was 100% for smaller size of stone 5.1 to 10mm, 64.70% for

medium size 10.1 to 15mm,42.8% for larger size stone 15.1 to 20 mm respectively. Hence there was a gradual decline of clearance rate with increasing stone size. (table -5). When we compared stone size with clearance we found that, a complete clearance of 100% is achieved with small stone and gradual decline of clearance rate with increasing stone size. A decrease value of 42.8% with larger stone size of 15.1 to 20mm.

Table no. 6 shows the overall clearance of upper ureteric stone is 100%. The stone clearance rate for upper and middle calyx of kidney was 87.5% and 60.9% respectively.

It is found that (table-7) patients undergoing shockwave lithotripsy procedure 80.1% did not reported any complication. Among 19.9% patients the major symptom was pain. Other symptoms like hematuria, fever, urinary tract infection subsided in follow up by appropriate medication. Overall complication is very minimal. Most of the patients recovered very well during follow up.Out of 3 patients 1 patient has undergone uretero-scopic removal and other two patients stone clearance was achieved by medical expusive therapy.

DISCUSSION

As per the studies by Chaussy et al SWL therapy is currently regarded as first-line therapy for most renal and upper ureteral calculi of maximum size of 2.0 cm selected as per patient selection based on EAU/ESPU guidelines.3 Tekgul S et al study shows when following with American Urological Association(AUA) guidelines which consider SWL to be a first-line option along with URS for renal or ureteral calculi of size less than 2.0 cm. Hence we followed EAU guidelines for best outcome got a overall clearance rate of 85.3% which signifies its efficacy and good outcome which can be compared to these studies. In this study it is observed that smaller size stone less than 10mm cleared in the first session with 100% where larger stone > than 15.1 to 20 mm required multiple session with a clearance rate of 42.8%. It signifies that the clearance rate is inversely proportional to stone size. Nilesen et al⁴ and Coz et al⁵ who reported a clearance rate of 89.0% and 84.3% respectively in their studies which revealed that a number of factors which should be taken in inclusion criteria influence good outcome of this procedure.6 Hence our study based on those inclusion criteria reflected as result of 85.3% clearance rate which is similar to above studies we have taken in inclusion criteria are responsible for good outcome.

Scand et al found that few complications are associated with modern ESWL treatment.⁷ most of the complications which are arises due to procedure are transient and subsided with appropriate medication in a couple of weeks.in this study we found that majority of complications are minimal and temporary which resolved over medication and complications like steinstrasse (2.2%) and hematuria (1.5%) that are not resolved undergone other modality of treatment

which can be comparable to other author studies. Hence it is considered to be the first line surgical management^{1,8,9}, despite all available newer modalities of treatment

The most recent study of Nafie et al.¹⁰ who reported overall clearance of 49% which include difficult location of stone in lower pole of kidney, which is significantly different from our study and others studies who have not taken appropriate selection criteria has poor outcome.¹¹ That is why appropriate selection of inclusion criteria is mandatory for optimum and effective treatment by ESWL.¹²

The studies of Salem H K et al and others found no significant difference in outcome with different procedures like percutaneous nephrolithotomy, ureteroscopic-removal of stone, extracorporeal shockwave lithotripsy for renal and upper ureteric stones. ¹⁵ The extracorporeal shockwave lithotripsy proved to be first line management for renal and upper ureteric stone as it is non-invasive, cost effective and can be done as day care procedure with mild sedation only with out anaesthesia with fewer complication and with a success rate of 80-90%. ^{16,17}

CONCLUSION

ESWL is the first line of management for renal and upper ureteric calculus in properly selected patients as it is non-invasive, economical and efficacious with minimal complications and can be done as day care procedure.

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