Original Research Article

Current ESWL Practice and Outcome using a Direx Electromagnetic Lithotripter- Experience from Tertiary care centre of North India

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Abstract

Introduction: Forty years after its introduction, extracorporeal shockwave lithotripsy (ESWL) is still first-line treatment for selected renal and upper ureteric stones. We conducted a longitudinal descriptive study to assess the results of shock wave lithotripsy by Direx electromagnetic ESWL machine. **Objective**: The objective of this study isto describe overall outcome of ESWLin the treatment of renal stones and upper ureteric stonesin terms of stone clearance, complications, and stone free rates in relation to stone size. **Material and methods:**Case records of three hundred forty-eight patients who were treated for renal and ureteric stones in urology department of IGMC, Shimla from 2018-2020 were retrieved. Forty-six patients were excluded because they could not turn up for scheduled sessions.Mean age of patients was 40.7 years ranging from 13 years to 80 years. There were 226 (64.94%) males and 122 (35.06%) females in our study. Eighty-one patients (23.28%) presented with hydronephrosis and flank pain in emergency. Double DJ stent was inserted in 109 patients (31.32%) prior to ESWL owing to hydronephrosis or flank pain. Mean stone size was 12.75 mm ranging from 5 mm to 24 mm. Mean HU was 918 ranging from 620 to 1250. Two hundred thirty-eight patients(78.80%) had complete stone clearance on or before three sessions of ESWL. Sixty-four patients had residual stones after 3rd session of ESWL out of which forty-four (12.64%) opted for additionali.e. 4th session of ESWL. Stone free status was not achieved in 13 patients in spite of four sessions of ESWL.Thus, total of 33 patients were labelled as failure and they were planned for PCNL/RIRS. Stone free rate according to stone size was 95.2%, 71.96% and 55.55% in ≤1cm, 1.1-2 cm and >2cm stone size subgroup respectively.Twelve patients (3.45%) required DJ stenting, after ESWL, and ancillary procedure i.e. URSL and ESWL for down migrated obstructing stone fragment in ureter was required in 7 and 2 patients respectively. Moderate to severe pain was experienced during ESWL in 4.89% patients requiring medical management and reduction in intensity and frequency of shockwaves. Complications i.e.,Hematuria, Urinary tract infections associated with fever was seen in 14.86% and 8% patients respectively. **Conclusion:**ESWL results can be optimised by proper selection of patients and following newer technical aspects of procedure. Improvements in technique along with strict patient and stone selection criteria will help ESWL to remain a mainstay in the treatment of Renal and upper ureteric stone disease.

Keywords ESWL, Renal stones, Ureteric stones.

Introduction

The first lithotripter for the treatment of human kidney stones, the HM1 (Human Model 1, Dornier, Germany;now Dornier MedTech America, Inc., Kennesaw, GA, USA), was introduced in 1980[1]. Forty years after its introduction, extracorporeal shockwave lithotripsy (ESWL) is still first-line treatment for selected renal and upper ureteric stones. ESWL is minimally invasive, requires minimal analgesia and optimal results in selected patients. The shockwaves are generated and focussed from lithotripter, resulting in pulverization of stones into small fragments which results in its spontaneous expulsion. ESWL, RIRS and PCNL remains most common modality at present for patients with stone size less than 2 cm. Despite need of auxiliary procedures associated with SWL, its completely non-invasive nature makes it an attractive choice.The current third- and fourth-generation ESWL machines are user-friendly, safe and treatment outcomes are good. ESWL procedure is conducted under analgesia or sedo-analgesia as a day care procedure[2,3].

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Material and methods

We conducted longitudinal descriptive study of patients treated for renal and ureteric stones by Direx electromagnetic lithotripter. Case records of three hundred forty-eight patients who were treated for renal and ureteric stones in urology department of IGMC, Shimla from 2018-2020 were retrieved. Written informed consent for ESWL procedure was obtained from all patients. Forty-six patients were excluded because they could not turn up for scheduled sessions.The case record forms of patients (n=302)treated for renal and upper ureteric stone disease with ESWL were analysed for clinical presentation, size, location andHounsfield units of stone, PCS anatomy, number of shockwave sessions given, post ESWL complications and need for ancilliary procedures. Patient's operative details if any i.e., Cystoscopy, DJ stenting, PCN, and details of

urological surgery if any pertaining to renal or ureteric stones were noted. The analysis of above retrieved data was done by epi info software 7.3.2.2.Patients were positioned properly on treatment table and SWL was done under IV antibiotic cover.Intravenous diclofenac and paracetamolwas used for analgesia. ESWL was done by using Direx electromagnetic lithotripterhaving the facility of X ray and/or ultrasonic imaging device to localize the stone. The treatment was started on a lower energy setting with a step-wise power ramping, gradual increase of shock-wave frequency (1kV to 20 kV; 60-90 ppm) and maximum of 3000 shocks were delivered in one session. Intermittent visualization ensured accurate focusing and change in stone size, outline or separation/fainting indicated stone fragmentation. In post-procedural period, an alpha-blocker drug was prescribed and patients were reviewed at 2nd and 3rd week to assess the SFS. Patients were subjected to a maximum of 3 sessions of ESWL with a gap of 3 weeks.Patients with ureteric calculi were defined as stone free if no stone or fragment of size <2mm in size was seen on follow-up imaging. Patients with renal calculi were defined stone free if no stone or CIRF of <4mm was seen on follow up imaging as determined by X-ray KUB and USG KUB for maximum of three weeks following the last session. 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 required, ancillary procedures and complications if any were noted. Data was entered in Microsoft excel spreadsheet, cleaned for errors and was analysed using Epi Info software version 7.2.2.4. Descriptive statistics were used to summarize the data. Frequencies and their percentages were used to describe categorical variables. Quantitative data was summarized as Means and their standard deviation.

Results

Mean age of patients was 40.7 years ranging from 13 years to 80 years. There were 226 (64.94%) males and 122 (35.06%) females in our study.Ten patients had comorbid conditions like Diabetes Mellitus, Chronic Obstructive Pulmonary Disease, Hypertension. One eighty-six patients (61.58%) had upper calyceal or renal pelvic stone, 86 had ureteric stones (28.48%) and 30 (9.93%) had lower calyceal stones. Most patients presented with flank pain, incidental detection,hematuria. Eighty-one (23.28%) presented with hydronephrosis and flank pain in emergency. Double DJ stent was inserted in 109 patients (31.32%) prior to ESWL owing to hydronephrosis or flank pain or large stone burden.Table 1.

Mean stone size was 12.75 mm ranging from 5 mm to 24 mm.Mean HU was 918 ranging from 620 to 1250. One hundred eight patients (31.03%), 73 patients (20.97%), 77 patients (22.12%) received first, second and third session of ESWL respectively. Stone free status was achieved in 238 patients (78.80%) on or before 3 sessions of ESWL.Sixty-four patients had residual stones after 3rd session of ESWL,out of which forty-four (12.64%) opted for additional i.e., 4th session of ESWL. Stone free status was not achieved in 13 patients in spite of four sessions of ESWL. Thus, total of 33 patients (10.92%) were labelled as failure and they were planned for PCNL/RIRS.More than 3 sessions were given only to clear residual stone fragments in patients willing for the same

Table 1: Clinico- Epidemiological Profile of study participants (n=302)

Characteristics	Number (%)
Gender	
Male	226(64.94)
Female	122(35.06)
Mean age	40.7 years
Status of DJ stenting	
Pre ESWL	109(31)
Post ESWL	12(3.45)
Stone Clearance	
On or before 3 sessions	238(78.80)
On 4 sessions	31(10.26)
Ancillary Procedure	
URSL	7(2.3)
ESWL	02(0.66)
ESWL failure	33(10.92)

Stone free rate in subgroup of stone size ≤10 mm was 95.2 %, in 10.1 mm–20 mm it was 71.96% whereas in the subgroup of stone size of more than 20mm stone free rate was 55.55%. Steinstrasse developed in 19 patients (5.46%) after ESWL.Twelve patients (3.45%) required DJ stenting, after ESWL for pain, fever, hydronephrosis or steinstrasse. After ESWL sessions down migration of obstructing stone fragment into ureter was noted in 9 patients who required ancillary procedure i.e. URSL and ESWL in 7 and 2 patients respectively. Patients were stratified according to size location and stone free rate as shown in table 2.

Table 2: Stone free status in subgroups of stone size

Stone size subgroup	No. of Patients	Stone free rate (%)
≤10 mm	93	95.2
10.1-20 mm	198	71.96
>20 mm	11	55.55

The complication rate in our study was 17.9%.Nausea and vomiting developed in 4.5% patients which was controlled with antiemetics. Moderate to severe pain was experienced during ESWL in 4.89% patients requiring medical management and reduction in intensity and frequency of shockwaves. Dysuria and pain were more in patients with DJ stent in situ (22.56%) compared to those without DJ stent (9%).Most patients had hematuria immediately after procedure, however hematuria between sessions was noted in 14.86%. Hematuria was present in 22.56% patients with DJ stent compared to 9% of those without DJ stent.Eight percent of patients developed post-procedure urinary tract infection associated with fever and managed by antibiotics according to urine c/s.

Discussion

ESWL is the initial treatment of choice for most renal calculi because of its non-invasive nature, requirement of minimal anaesthesia, and tolerability by patients. Since the improvements in the mechanics of lithotripters and better understanding of shock wave physics and increasing availability of equipment's 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. 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. Many studies found clearance rate ranging from 82.4% to 94% for Renal and upper ureteric stones less than 2 cm when ESWL was used as the treatment modality[4-8].We lowered the shock wave rate, improved coupling, and power ramping to optimise our results. Lowering shock wave frequency from 120 to 60-90 shock waves/min improves stone free rate (SFRs) and decreases tissue damage[9].Adequate acoustic couplingbetween the cushion of the treatment head and the patient's skin is important as improper application of coupling gel can cause air pockets which can deflect shock waves[10].Supervision by consultants leads to better results with careful planning and control of procedure[11]. Most studies advocatemedical expulsive therapy after SWL for ureteral or renal stones as adjunct to expedite expulsion and to increase SFRs. Medical expulsion therapy (MET) might also reduce analgesic requirements[12,13].We used MET in all our patients after ESWL sessions.The most significant outcome measurement of any procedure are the stone-free rates and complications. In our study, of the 302 patients subjected to ESWL 78.90% (238/302) of patients were stone freeon or before three sessions of eswl whereas adding further sessions increased success to 89.07%.Our stone free rates are lower compared to, Ghafoor andhalim[7] etal (94%), Padhye[8] et al (91.7%), Gnanapragasa[6] etal(90%), whereas higher than Logarakis[12] et al (72.3%), Al Marhoon[14] 74% and Lingeman[5] et al (82.4%). In the present study, the stone free rate in subgroup of stone size ≤10 mm was 95.2 % whereas in the subgroup of stone size 10.1 mm–20 mm the stone free rate was71.96%. Stones located in upper pole calyces, renal pelvis and ureteropelvic junction, are associated with the better stone-free rates when treated by SWL as seen in our study as well as previous studies[15].We analysed that large Stone size and unfavourable PCS anatomy are predicators of ESWL failure. It appears that HU value can predict the fragmentation of stone by ESWL and should be used to optimize the ESWL outcome but was not an independent predictor[16].Successful treatment outcome of ESWL drops down when stone size increases beyond 2 cm and such patients may be better managed with percutaneous nephrolithotomy (PNL)[17]. However, we included11 patients with stone size of more than 2 cm with ESWL, when PCS anatomy and HU were favourable. In this group of patient's clearance rate was 42.33% and it increased to 55.55% after giving additional sessions of ESWL.ESWL is not without complications albeit mostly minor compared to PNL and ureterorenoscopy (URS)[18].The complication rate in our study was 17.9%. It is significantly lower than the complication rate observed by Al-Marhoon et al[14]and marginally higher than that observed by Wazir et al[19].Moderate to severe pain was experienced during ESWL in 4.89% patients in our study, requiring medical management and reduction in intensity and frequency of shockwaves. Loin pain was most common complication in the studies by Al-Marhoon[14] et al(21.2%) and in study by Wazir[19]et al. (9.76%). Hematuria was lesser in our study as compared to the other two studies.Careful control of pain during SWL is necessary to limit pain-induced movements and excessive respiratory excursions[20].DJ stent prior to ESWL was inserted in patients with flank pain, hydronephrosis, deranged creatinine, solitary kidney and those with large volumetric stones. Hematuria was present in 22.56% patients with DJ stent compared to 9% of those without DJ stent. Dysuria and pain were more in patients with DJ stent in situ 22.56% compared to those without DJ stent (9%).In a study dysuria was present in 21 % patients indicating chronic stent related symptoms. Clearly, the incidence of infectious complications and especially bothersome LUTS is higher with such an indwelling foreign body[20].Steinstrasse developed in 19 patients (5.46%) after ESWL in our study compared to2.72% patients in study by Wazir[19] et al. All patients of steinstrassein our study had significant bulk of stones especially in Renal pelvis.Stone size and site were the significant factors predicting steinstrasse formation[21].

Conclusion

The Direx electromagnetic lithotripter is a safe and effective ESWL machine for treating renal and ureteric stones. ESWL results can be optimised by proper selection of patients and following newer technical aspects of procedure. Improvements in technique along with strict patient and stone selection criteria will help ESWL to remain a mainstay in the treatment of Renal and upper ureteric stone disease.

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Abbreviations

ESWL -Extracorporeal Shock wave Lithotripsy;SWL- Shockwave lithotripsy;RIRS -Retrograde Intrarenal surgery;URS- Ureteroscopy; PCNL -Percutaneous Nephrolithotomy;MET- Medical expulsive therapy;HU- Hounsfield Units;DM- Diabetes Mellitus ;COPD - Chronic obstructive Pulmonary Disease;UTI- urinary tract Infections;HTN -Hypertension;DJ- Double J stent;CT- Computed Tomography;IVP- intravenous Pyelography;IGMC -Indira Gandhi Medical college

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