Extracorporeal Shockwave Lithotripsy: Initial Experience at Bahawalpur

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Place of Study: American Kidney Stone Centre (AKSC), Bahawalpur, a private setup.

Duration of Study: January 2005 to June 2007.

Design of Study: Prospective, Observational.

Material & Methods: A total of 250 patients were evaluated for ESWL results. The one session comprised of 1500-2500 shocks with intermittent fluoroscopy with X-Ray focusing. A period of 7 – 10 days was given between two sessions. The procedure was repeated till the clearance of stone no matter what was the number of sessions. The complications like pain, colic, hematuria were addressed adequately and immediately. The development of steinstrasse was initially observed and few required manipulation. The stone size is the only matter of concern in few patients especially lower pole stones.

Results: The stone clearance was achieved in 89% of patients. Auxillary procedures were required in 10.8% before ESWL and 9.6% of patients after ESWL. Which include Endoscopic stenting and manipulation with uretero-renoscopy and intracorporeal lithotripsy. Prophylactic insertion of DJ stenting reduced complication rate and incidence of steinstrasse.

Conclusion: ESWL can be safely recommended for patients of urolithiasis irrespective of age and stone size with promising results of stone clearance and patient acceptance.

Key Words: ESWL-Extracorporeal shock wave lithotripsy, URS-Ureterorenoscopy. ICL-Intracorporeal lithotripsy.

Introduction

Since the advent of Extracorporeal Shock Wave Lithotripsy in 1980s, the improvements in mechanics of lithotripters and better understanding of shock wave physics has made this mode of stone treatment, acceptable and more effective. The increasing availability of equipments and trained operating personnel has made ESWL an efficient mode of urinary stone treatment .The stone clearance achievement has also increased tremendously.

Many years after the first application, ESWL has gained world wide acceptance as first choice therapy for most of urolithiasis. Stones can be successfully fragmented by application of shock waves, but the ability of kidney and ureter to clear the resulting fragments is far more important in terms of successful treatment outcome. Increasing experience show some advantages, cost reduction, permanent monitoring, lack of exposure to ionizing radiation in ultrasound monitoring. ESWL is a safe procedure for the treatment of urolithiasis. Nevertheless follow-up of stone patients after ESWL is mandatory and ultimate goal for treating stones by whatever means is to get the patients stone free and prevent recurrence[1].Over the last two decades there has been gradual increase in utilization of ESWL due to patient desire[2].

The urological approach to urolithiasis has changed with introduction of ESWL that allows relatively non invasive removal of stones. Nevertheless ESWL does not change the propensity of recurrence in stone and importance of medical prevention remains of paramount importance in the management of renal stone disease[3].The optimal results of noninvasive procedures and advantages of ESWL for the patient like out patient and anesthesia free treatment and decreased morbidity has caused limited annual indications of open surgery for stone disease. Open surgery is now drastically reducing, endoscopic and extracorporeal methods are increasing[4].

Material and Methods

The present study was conducted at private setup, American Kidney stone Centre, Bahawalpur as public sector do not possess ESWL facility. This is the first lithotripter in the town. The period of this study spans from January 2005 to June 2007.

The prospective observational study was conducted to determine efficacy, efficiency, patient tolerance, satisfaction, and acceptance to this mode of treatment for renal stones. The observation for outcome and number of sessions for total stone clearance were also noted along with total radiation dose given in one session and during whole treatment.

All patients who presented to us with renal stones were explained treatment options after all investigations. Those patients who opted for ESWL were included in this study. A total of 289 patients were included in this study. Four patients opted for open surgery after first session and thirty five patients did not turn up after first session of ESWL. These thirtynine patients were excluded and results were formulated in 250 patients.

Patients below five years of age, hypertensive patients, patients with uncontrolled diabetes, cardiac patients with

pace makers, severe respiratory problem like bronchial asthma and patient whose intravenous urography showed pelviureteric junction obstruction were not included in this study.

About The Equipment Used:
Lithotripter in this private setup is of HM-3 type, hydro-electric with X-Ray focus using C –arm fluoroscopy with vertical as well as side to side tiltable radiolucent table. The mechanics involved per session in this lithotripter are 3-5 MA, 90-98KV and 8-10 EKV. During one sitting 1500-2500 shocks are given with intermittent X-Ray focusing in order to reduce radiation exposure to the patient. Once fluoroscopy exposes the patient to 02 MA/50-60 KV (Max upto 70 KV of radiation) .A gap of 7-10 days given during sessions. Single session to 12 sessions were required in patients to achieve complete clearance.

Few children required sedatives before lithotripsy. Investigations required were ultra sonography abdomen, serum urea, creatinine, X-Ray for KUB. Facilities for retrograde catheterization, endoscopic DJ stenting, Uretero-renoscopy with intra corporeal lithotripsy are also available in the same private setup.

Results

The total number of patients included in this study were 250 .Male to female ratio was 2.5to 1.

Age:
Age of the patients in this study was 5 years to 70 years (Table 1). Majority of patients 168/250 (67.2%) were young adults between 21 to 50 years of age.

Table 1:

Age	No. of Patients	% age
05 – 20 years	51	20.4%
21 – 35	113	45.2%
36 – 50	55	22%
51 – 70	31	12.8%

The number of sessions required depended upon size and site of stone. Staghorn calculi and major burden of stone in lower pole required more sessions. Maximum of 12 sessions were required in one patient with stone size of 56mm.

The total **number of sessions** in this setup was as follows; (Table 2).

Table 2:

No of Sessions	No. of patient	% age
Single session	61	24.4%
01 – 03 sessions	79	31.6%
04 – 06 sessions	99	39.6%
06 – 09 sessions	09	03.6%
09 – 12 sessions	02	0.8%

The single renal unit treatment strategy was exercised during ESWL in this setup, bilateral renal stones were treated as separate units. Simultaneous bilateral treatment with lithotripsy was not done in any patient. Patients with bilateral obstructive stone were treated with prophylactic bilateral endoscopic DJ stenting before embarking on ESWL in 10.8% of patients. The radiolucent stones were given intravenous contrast 05 minutes before ESWL in 43 (17.2%) patients. In remaining 207 (82.8%) patients, stones were radio opaque.

The requirements of auxiliary procedures in post ESWL patients were considered as failure of lithotripsy in 10.8% of patients. Auxiliary procedures, noted in our study were as follows; (Table 3).

Table 3:

S. #	Name of procedure	No of Pts (%)
1.	Prophylactic DJ stenting before ESWL	27 (10.8%)
2.	DJ stenting after ESWL	14 (5.6%)
3.	Uretero-renoscopy and Lithoclasty	13 (5.2%)

The size of stone ranged from 10 mm to 56mm Results obtained in various **sizes of stones** were as follows (Table4).

Table 4:

S. #	Size of Stone	No of Patients	No of patients cleared of stones	%age clearance
1	10 – 15 mm	69	69	100%
2	15 – 30 mm	89	76	85.39.%
3	30 – 45 mm	77	67	87.01%
4	45 – 56 mm	15	11	73.33%
	Total No of patients	250	223	89%

Out of 250 patients, 223 became free of stones, so overall clearance rate was 89%.The patients were advised to maintain sufficient ambulatory lifestyle and increased amounts of oral liquids intake. The use of prophylactic antibiotics (usually ciprofloxacin) and analgesics (usually diclofenac sodium or potassium) were prescribed routinely to adult patients.

Complications

Pain was the major complaint observed during this study. During session of lithotripsy 139 (55.6%) patients had pain, who were managed by giving injectable diclofenac sodium intramuscularly during ESWL. Regular analgesics were advised to patients in between the session so as to facilitate painless passage of stone particles and gravel. Severe colic developed in 07 (2.8%) patients requiring parentral analgesic. Fever developed in 32 (12.8%) patients and high grade fever with rigors developed in 04 (1.6%) patients requiring injectable antibiotics treatment and observation after admission with culture and sensitivity of urine. Nausea occurred in 76 (30.4%) patients and vomiting in 03 (1.2%) patients. One of these three patients needed admission for a day and settled.

The complication of steinstrasse developed in 21 (8.4%) patients. These patients had stone size of 30mm to 45 mm. Steinstrasse developed in those patients who did not have auxiliary treatment with DJ stents before ESWL but required endoscopically manipulation afterwards and settled by clearance of all particle of stone gravel. Two of these patients required surgical intervention by open ureterolithotomy at lower end. While those patients who were stented before ESWL only 3 of them developed steinstrasse but gradually cleared of all gravel without requiring further intervention.

Hematuria observed in 36 (14.4%) patients and this was transient and mild in majority and settled with increased intake of oral liquids while two of these thirty six patients needed admissions and injectable tranexamic acid along with IV fluids.

Retention of urine developed in 02 (0.8%) patients because the stone particles in urinary bladder were larger than 09 mm and these two patients were having urethral stricture hindering the passage of these particles. These were managed by optical internal urethrotomy and litholapexy. Table 5.

Table 5:

Sr #	Complication	No. of pts	% age
1.	Pain	139	55.6%
2.	Colic	07	02.8%
3.	Fever with Rigors	32	12.8%
4.	Nausea &Vomiting	76	30.4%
5.	Haematuria	36	14.4%
6.	Steinstrassee	21	08.4%
7.	Retention of Urine	02	0.8%

Follow-up

All patients who underwent ESWL were followed till the clearance of all stone particles. Minimum of 05 days and maximum of 120 days were required for spontaneous passage of stone particles depending upon stone size and location. The stones in upper ureter and renal pelvis cleared in less time as compared to lower pole stones. The follow up period ranged from 06 weeks to 60 weeks.

Discussion

The age of patients in this study ranged from 05years to 70 years with male to female ratio of 2.5:1.The age range in different studies about ESWL was 04yearsto 82 years[5,6].The male to female ratio in different studies was 1:1 to3:1[6,7].The total number of patients in our study was 250 which is sufficiently large number as compared to few dozen patients in different studies.[1,5,6,8,9.]

The size of stone in our study was 10mm to 56mm.In literature majority of studies had stone size was less than 30 mm while in other studies stone size was larger upto 52 mm.[1,7,10-15] Stone size and number independently increase the probability of treatment failure[8].Best results can be achieved by trained operator, high number of shocks and longer fluoroscopy time and narrow focal zone of 6.5 mm[7]. After ESWL residual fragments 4mm or less are usually considered as clinically insignificant.[16] The anatomy of the kidney collecting system may play a role in the selection of the best method of kidney stone treatment for a specific patient. For stones located in lower pole, the clearance rate after shockwave lithotripsy has been uniformly low relative to that for calculi elsewhere.[17] Renal morphology was the only significant factor affecting stone free rate since stone clearance was significantly less in pyelonephritic kidneys.[18] The frequency of residual stones can be reduced by appropriate indications of ESWL. Once a renal stone has formed, re-treatments with ESWL can not ensure complete elimination of the stones.[19] ESWL was considered a failure if residual stone fragments remained after one month or an auxiliary procedure or retreatment was required.[20] ESWL combined with urinary alkalinization in radiolucent uric acid stones achieves rapid resolution of large calculi.[21] The total amount of ESWL emissions and hyperurecaemia independently affected probability of renal scar formation. Over emission of ESWL (more than 10,000 shocks) must be cared for prevention of renal scarring. After ESWL periodical checkup with ultrasonography will provide useful information.[22] ESWL is highly effective for pediatric urolithiasis with minimal morbidity. Stone clearance is not adversely affected by stone size upto 30mm however lower poler stones and impacted stones at PUJ have relatively poor clearance.[23] ESWL is simple effective and safe primary treatment in children with staghorn calculi.[24]

The complications observed during ESWL in this setup were mainly pain (55.6%), nausea & vomiting (30.4%), Colic (02.8%), Hematuria (14.4%), Steinstrasse (8.4%), Retention of urine (0.8%). These complication rates were significantly higher than mentioned in literarture. Few patients required admissions and treatment, while in different studies similar complications along with development of pyonephrosis, petechial hemorrhages are mentioned. Pyo-

nephrosis required nephrectomy[25]. Other studies mention similar complications as in our study and are at a rate of 8-11%.[6,23,26]

Overall incidence of steinstrasse in literature was 3.97% which significantly correlated with stone size, site, power level used and radiological features of stone. Steinstrasse was more common in renal stones of more than 2cm size. If a patient has high probability of steinstrasse formation ,close follow-up with early intervention or prophylactic pre ESWL ureteral stenting is indicated[3].In the study of AL-Awadi[14], 400 patients with unilateral stone burden of 1.5-3.5 cm were assessed for development of steinstrasse after ESWL with stent and without stents. The development of steinstrasse was 6% in stented and 13% in non stented patients ($p<0.05$). This particular study shows that the incidence of steinstrasse in lower third ureter depend on the size of calculus regardless of J stent presence being 2.6% for a stone of 1.5-2.0 cm and 56% for a stone of 3.1-3.5cm ($p<0.001$) and this resolved spontaneously in majority of both groups. The incidence of steistrasse increased with size of calculus. Presence of stent lowers the incidence of steinstrasse but has no significant effect on subsequent management of this complication of ESWL[14]. Steinstrasse in another study was managed with ureteroscopic manipulation[27]. In our study steinstasse was observed in 21 patients. This correlates with the fact that majority of our patients were with stone burden of 1.5 cm to 4.5 cm. Out of these 21 patients, in 11 patients ureterorenoscopy and intracorporeal lithotripsy was done. In remaining 10 patients steinstrasse resolved spontaneously.

In case of bilateral renal calculi we planned staged fashion of ESWL at interval of 3-20 weeks instead of simultaneous treatment of both kidneys. Traditionally bilateral renal calculi have been managed by staged ESWL due to concern about bilateral obstruction[10]. In some studies bilateral synchronous ESWL was done and it was found to be safe and effective monotherapy for bilateral urolithiasis[8]. The effects of simultaneous versus staged ESWL on renal function as measured by serum creatinine were not statistically different.[10] No patient developed bilateral obstruction or renal failure or deterioration of renal function[8].

Monitoring during ESWL can be done with fluoroscopy or ultrasonography. Dose area product (DAP) measurements with USG 137 $cGycm^2$ equivalent to a mean effective dose of 0.24 mSv while with fluoroscopy mean DAP of 552 $cGycm^2$ with mean effective dose of 1.2mSv.Ultrasound localization is better than fluoroscopic localization but where available pulsed fluoroscopy should be preferable[28]. In our study we have used pulsed fluoroscopic monitoring during the procedure so as to reduce exposure of ionizing radiation to patient. In one session the number of shocks given in our setup are between 1500 to 2500 with intermittent fluoroscopy for target localization thus reducing radiation exposure to 3-5MA, 50-60Kv and 8-10EKv.The target is monitored 03-04 times per session. The number of shocks in other studies are as follows:[10] for stones of 0.70 cm to 1.6 cm^2 are 1386-2094 upto 2500 equivalent to 14.5-17.8 Kv,[30] uses 4000 shocks (10-18.1Kv) with 90 shocks per minute with range of 5300-6295 shocks,[31] used 400-6190 shocks per gram of stone. Over emission of ESWL shocks (more than 10,000 shocks) can affect renal scarring independent of stone size, so must be taken care for prevention of renal scaring[22]. The number of shockwaves for complete communition of per gram of stones can be different with type of chemicals responsible to constitute the particular stone under treatment[31].

The auxiliary treatment was required in 27 (10.8%) patients before ESWL and 9.6% of post ESWL patients during this study. While in literature the requirement of auxiliary treatment in different studies was as 2.85%to 43%.[10-13]

The number of sessions required for complete stone clearance can vary. The single session clearance of less than 1.5 cm stone is 70%[32].Different studies calculate on average 1.5 to 3 sessions per patient.[6,24,30-32] The variation of stone structure could underlie the variation in stone fragility within type.[31] The interval between two sessions was kept 7-10 days apart in this study so as time to pass gravel and stone fragments may be adequate. While in some other studies this interval was kept at 03-20 weeks.[10] The frequency of residual stones can be reduced by appropriate indications of ESWL.Once a renal stone has formed, re treatment with ESWL can not ensure complete elimination of stones.[19] ESWL is initial treatment of choice in patients with lower pole stones ($<2cm^2$ size) and stone free rates are acceptable[15].

The stone clearance in our study is 89%. The stone clearance rates in different studies is as low as 30%to 60% for staghorn stones[16,20] and for stones less than 3 cm it ranges from 60% to 98%.[5,6,9-12,18-20,23-28,30-34] While stone clearance for upper ureteric stones ranges from 87% to 100%.[2,23,33] This rate of stone clearance increases with the use of diuresis and prophylactic insertion of DJ stent along with reduction in the rate of complications especially for lower pole stones.[14,32,33] A stone free state was defined as no radiological evidence of stone fragments 3 mm or less upto at least three months[23]. While in another study, it is declared that ESWL is considered failure if the stone fragments remained as residual after one month or retreatment or auxiliary procedure is required.

The average follow-up period in our study was 08 months (range 04 months to 15 months).In literature the follow-up period varies according to design of study. Different studies reported in national and international literature had follow-up period varying between 06 weeks to 05 years.[15,19,26,32] Majority of the studies has recommended a period of 03-04 months.[18,23,25,27,35] After ESWL periodical follow-up and checkup with ultrasonography will provide useful information.[22] Nevertheless follow-up of stone patients after ESWL is mandatory and ultimate goal for treating stones by whatever means is to get patient free of stone and prevent recurrence.[34,36]

Conclusion

The optimal results of non invasive procedures like ESWL are advantageous for the patients. ESWL is an outdoor based procedure and without anaesthesia.It has lower morbidity and has limited the annual indications for surgery of stone disease. Open surgery is now drastically reducing and endoscopic and extracorporeal methods are increasing. There has been gradual increase in utilization of ESWL due to patient desire to get himself stone free. The stone free rates are significantly influenced by stone size.ESWL is recommendable primary treatment option for renal and ureteric stone patients for being safe, simple and effective. The frequency of residual fragments can be reduced by appropriate indication of ESWL.Best results can be achieved by trained operator, higher number of shocks and longer fluoroscopy time with out deterioration of renal function or scarring. The gadgetry for endoscopic manipulation must be available within the same setup if and when required for stenting or uretero-renoscopy.

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