ORIGINAL ARTICLE

Single Center Experience with Sonolith R Vision Lithotripter for the Treatment of Solitary Urinary Stones in Saudi patients

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ABSTRACT

Objectives: The aim of the study was to evaluate the results of extracorporeal shock wave lithotripsy (ESWL) using the Sonolith R vision Lithotripter for urinary stones.

Patients and methods: From July 2005 to September 2008, 463 patients including 451 Saudi and 12 Non-Saudi patients, 62% males and 38% females aged 18-93 (mean 56.32 years) underwent ESWL treatment for solitary urinary stones at the lithotripsy unit of Arar Central Hospital, Arar City K.S.A. Data was analyzed retrospectively. More than half 250(54%) patients had left sided stones. The most frequent ureteral localization was distal (lower) ureteral 98(52%) patients and most frequent renal localization was renal pelvis 126 (46.49%) patients. The mean stone diameter was 1.41cm (1.02 ureteral and 1.8 cm renal). 56% of patients received ESWL Treatment under sedation with IV Pethidine 50mg diluted.

Results: Our 463 patients required a total of 672 sessions of ESWL. Mean number of sessions per calculi was 1.425 (range 1-6). The percentage of patients who required a single session was 72.3%. The re-treatment rate was 25% for ureteral stones and 32% for renal stones. Treatment was more effective in ureteral stones. 56(12%) patients required other auxiliary procedures like DJ stenting and Ureteroscopy. In conclusion we found Sonolith R vision a safe and effective device for the treatment of urinary stones in selected patients.

Key words: Extracorporeal shockwave lithotripsy, sessions, stone free rate

INTRODUCTION

ESWL is the treatment of choice for majority of urinary stones. The application of shock waves for the treatment of urinary stones was used for the first time in 1982 by Christian Chaussy[1]. Since then there has been a significant advance in ESWL machines with different modifications in the production of shock waves in the size of focal point, in method of terminal adjustment and in methods of location of lithiasis. All these changes have had an effect on the capacity of fragmentation of the lithotripter[2].

There are three primary types of shock wave generators, spark gap (electro hydraulic), electromagnetic and piezoelectric. Spark gap and electromagnetic lithotripters are most common whereas piezoelectric system delivers insufficient power which hampers its ability to effectively fragment urinary stones. Spark gap lithotripters produce shock waves by releasing a high voltage discharge across two electrodes immersed in water.

There are many factors affecting SWL efficacy including shock wave pressure, frequency and size of the target zone. To produce the fragmentation of the stone, the energy must be concentrated on a specific point achieved by focusing the shock waves. When shock waves are unfocussed, fragmentation is only produced by using very high levels of energy which tends to produce lesions in surrounding tissues increasing the risk of secondary damaging effect[3].

Focus of shock waves is achieved through a reflective acoustic lens and depends upon two variables, the size of focus and the focal area. The surface of shock waves depends upon the width of the reflector and the body surface that the shock waves cross before getting to the stone. In general a larger aperture is associated with less pain.

Stone fragmentation by means of shock waves is produced with the combination of the following mechanisms. Tensor stress and spallation stress, cavitations, compression due to the advance of the wave and dynamic fatigue [4].

PATIENTS AND METHODS:

From July 2005 to September 2008: 463 patients including 451 Saudi and 12 Non Saudi patients suffering from solitary renal or ureteral stones were treated by ESWL. ESWL was carried out at Lithotripsy Unit of Arar Central Hospital Arar. This is the only lithotripsy unit in whole Northern region of KSA and patients were referred from the entire Northern region as well as included patients from Arar Central Hospital and Prince Abdul Aziz Bin Musaad Specialist Hospital.

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ESWL was carried out by 3 Urologists supervised by one consultant Urologist. The Lithotripsy device used was Sonolith R Vision (Technomed Medical System Vaulx-en-velin France). This machine generates shock waves by using electro conductive shock wave generator with an elliptical reflector specially designed for maximum concentration of energy on the stone. It has a focal zone of 3.6 x 25 mm peek energy being 20J with aperture angle 80^{o} and aperture diameter being 219 mm[5].

All the patients underwent detailed history and examination and routine investigations including CBC, Blood sugar profile, RFT, LFT, Urine C/E, Urine C/S and coagulation profile.

Patients were diagnosed by means of conventional methods including Plain x-ray KUB, IVU, and Ultrasound and or computed tomography. Stone size was the maximum diameter observed on simple abdominal x-ray before the treatment. Patients with UTI were treated with appropriate antibiotics according to Urine C/S result prior to ESWL. Patients with stone size >2.7 cm were subjected to DJ stenting prior to ESWL.

Exclusion criteria:

- Patients with multiple stones and also with radiolucent stones were excluded (only radio opaque stones were included).
- Patient with stone size 3 cm and above were also excluded. They were subjected to open surgery or referred to higher center for PNL.
- Patients with coagulopathies or on anti – coagulant therapy were excluded.
- All Cardiac patients with active cardiac disease were excluded.

Patients were sedated before or during the treatment procedure with 50 mg IV diluted Pethidine injection according to the circumstances. All patients were treated using C- arm and fragmentation of stone was monitored during the procedure with C – arm. ESWL session was repeated at a minimum interval of two weeks (range 2-4 weeks). One week after the treatment, X-ray KUB and Ultrasound abdomen was done to check the existence of hematoma and evaluation of lithiasis.

The protocol used was to do insitu lithotripsy for the treatment of stones, applying the number of sessions necessary to obtain fragments smaller than 2-3 mm or to obtain elimination of the lithiasis. All treatment sessions were done on OPD basis. Only patients who required DJ stenting or patients with post – ESWL complications were admitted. The energy level used for ESWL sessions ranged from 15k.v to 19k.v, depending upon patient's tolerance. One ESWL session was composed of 3000 to 4000 shock waves.

RESULTS

A total 463 patients were included in the study. 287 (62%) patients were male whereas 176 (38%) patients were female. The age range was 18-93 years (mean 56.32 years).The stone was located on right side in 46% (213) cases and on left side in 54% (250) cases. The mean stone diameter was 1.253 cm (range 0.4 to 3 cm). The location was renal 271 (58.53%) and ureteral 192 (41.46%) cases.

Table I: Stone Size and Percentage of Distributors

Size cm	=n	%age
<0.5	55	12
>0.5 <1	38	8.4
1	2.3	46
>1 <2	98	21.16
2	38	8.3
>2<3	21	4.5

Table II: Stone location and percentage of distribution (n=463)

Location	=n	Total %	Partial %
Renal	271	58.53	
Renal Pelvis	126	27.2	46.49
Inferior Calyx	28	6.04	10.33
Middle Calyx	35	7.55	12.91
Lower Calyx	82	17.71	30.25
Ureteral (on IVP)	192	41.46	
Upper Ureteral Anatomical (from PUJ to lower border of kidney)	59	12.74	30.72
Mid Ureteral (from lower border of kidney to lower border of sacro – iliac joint)	35	7.55	18.22
Lower Ureteral (from Lower border of sacro – iliac joint to ureterovesical junction)	98	21.16	51.04

Our 463 patients required a total of 672 sessions of ESWL .Mean number of session per calculi was 1.425 (range 1-6). The percentage of patients who required a single session was 72.3%. Less than 2 sessions 78.4%, less than 3 sessions 86.04% and only 3 % patients needed 4 or more sessions to fragment the stone. There were differences between the mean number of shock wave lithotripsy sessions according to the stone size. For stones smaller than1 cm. The mean number of session was 1.231 for stones 1 cm it was 1.35, for stones of 2 cm the mean was 2.05 sessions. The greater the stone size the

higher the mean number of sessions. The rate of stone free patients with only one session diminished progressively depending upon the size.

Table III: Average sessions of Lithotripsy and stone free rate at first and second session

Size	=n	Average Session	First Session%	Second Session
<0.5	55	1.12%	92.3%	96.4%
>0.5 <1	38	1.23%	82.5%	91.2%
1	213	1.35%	73.5%	94.3%
>1 <2	98	1.57%	65.3%	83.7%
2	38	2.05%	47%	78.3%
>2 <3	21	2.83%	39%	72.5%

Out of total 463 patients 58.53% (271) stones were renal and about half of these renal stone were in renal pelvis 126(46.49%), 192(41.46%) stones were ureteral and among ureteral stones 98(51.04%) were located in lower ureter. The mean number of the sessions per calculi with ureteral stones was 1.27 and with renal stones 1.58. The re-treatment rate was 25% for ureteral stones and 32% for renal stones. The results show that treatment was more effective in ureteral stones although stone size was also a factor in outcome (the mean size of ureteral stones 1.06 cm as compared to renal stone 1.44 cm).

Table IV: Size, average sessions and percentage of stone free rate with one or two sessions depending upon stone location

Location	Size (in cm)	No	Average Session	First Session	Second Session
Total	1.253	463	1.425%	72.3%	84.45%
Ureteral	1.06	192	1.27%	76.5%	92.4%
Renal	1.44	271	1.58%	68.32%	83.4%

Use of Sedation: 220(47.5%) patients required sedation with 50 mg Pethidine diluted IV during the procedure. Rest of the patients tolerated the treatment well.

Use of other Auxiliary Procedures: 56(12%) patients required other Auxiliary procedures. 12(2.59%) patients with renal stones where stone was approaching 3 cm. (2.7 – 2.9 cm.) were subjected to DJ stenting prior to ESWL. The stents were removed after the patient was stone free .Forty (8.6%) patients underwent ureteroscopy and endoscopic retrieval of stone fragment with basket and forceps in cases of stein stressae and obstructed ureteral fragments (facility of lithoclast was not available at our hospital). Two (0.45%) patients with renal stones size 2.8 and 2.9 cm' each underwent open surgery according to their will as ESWL after DJ stenting was ineffective and facility of PNL was not available.

One (0.215%) patient with lower ureteral stone size 2.3 cm underwent ureterolithotomy due to obstruction and ineffective ESWL. One patient with renal stone developed obstruction and fever after ESWL and underwent percutaneous nephrostomy and subsequent ESWL.

Table V: Auxiliary maneuvers and percentage

Maneuver	=n	%age
Total	56	12
DJ stents	12	2.6
Ureteroscopy	40	8.6
Pyelolithotomy	2	0.43
Ureterolithotomy	1	0.21
PCN (Percutaneous Nephrostomy)	1	0.21

We have obtained a stone free rate with residual post ESWL fragments smaller than 3 mm 90% for ureteral stones and more than 80% for renal stones.

DISCUSSION

Since the first description of the treatment of the urinary stones by ESWL in 1982[1'4'8]. Extracorporeal Lithotripters have gained more effectiveness with less morbidity and less cost. Initially the energy used was electro hydraulic but today electromagnetic shock waves are preferred since energy here is more easily controllable, rate of energy is more constant and produce less pain for the patient due to broader surface of application. Among the disadvantage of electromagnetic waves is the production of a high concentration of energy on a small focal surface increasing the risk of renal injury (hematomas), reaching rate of 4%[6]. In our study none of the patient developed this complication as Sonolith R Vision has increased the focal area to 3.6 x 25mm to reduce this complication [5]. More than half of our patients tolerated the treatment well .Only 270 (47.5%) patients required sedation with IV Pethiidne. Sonolith R Vision seems to strike a good balance between analgesic needs and rate of effectiveness of stone fragmentation[7].

In our study the number of ESWL sessions per calculi to treat urinary stones was 1.425. This is a relatively high percentage regarding the mean stone size compared to other studies [5, 9] whose range is from 1.2 to 1.4 sessions per lithiasis. This difference could be multifactorial. One factor could be the life span of the electrode. It was observed in our study that as the electrode became old, its efficacy was reduced especially after the delivery of 35000 shock waves the efficacy was reduced significantly [10] and we used most of the electrodes beyond this landmark. This factor may be responsible for a relatively high session per lithiasis in our study. In other studies the stone free rate varies between 68%

and 86%.In our study the stone free rate was more than 90%.

In our study the re-treatment percentage was 25% for ureteral stones and 32% for renal stones which is greater than in other studies. The stone free rate is similar to the most effective lithotripter (HM3)[11] but with the inconvenience of more sessions required. This indicates more effectiveness in our work, with smaller number of complications, less anesthetic needs, use of outpatient procedures but with inconvenience of more sessions required. One other factor influencing the re-treatment sessions was non availability of lithoclast and PNL in our hospital and ESWL was the sole modality for the treatment of urinary stones. In the end the high percentage of inferior calyceal stones (30.25% of all renal lithiasis) also contributed to increase the number of sessions per lithiasis and re-treatment rate.

The percentage of patients who required auxiliary procedures in our study was 12 % which is reasonable as we had a careful patient selection and large size renal stones 3 cm and above was not subjected to ESWL [12].

We used DJ stents prior to ESWL in patients with large stone burden >2.7 <3 cm to avoid complications like steinstressae, ureteral obstruction and post ESWL pain [13], although this decreased the efficiency quotient [14], but as the patient's acceptance of complications is relatively low in our population so it is a routine to offer a safe mode of treatment which is relatively costly.

CONCLUSIONS

Our experience with Sonolith R Vision showed that this device is safe and although our session average per lithiasis is slightly higher than other studies as compared swith stone size , we have obtained very good results with a high stone free percentage close to 90% . This leads to conclude that electromagnetic shock move lithotripters will be gold standard for lithotripsy in future.

REFERENCES

1. Chaussy C, Schmiedt E Jockham D, Brendel W, Forssmann B, Walter V. First clinical experience with extracorporeally induced destruction of kidney stones by shock waves. J Urol. 1982; 127(3):417-420.
2. Teichman JM, Portis AJ, Cecconi PP, Bub WL, Endicott RC, Denes B, et al. In Vitro Comparison of Shock Wave Lithotripsy Machines. J Urol. 2000; 164(4):1259-1264.
3. Rassweiler JJ, Taillo GG, Chaussy C. Progress in Lithotriptor Technology EUA Update Series 3. 2005; 17-36.
4. Chaussy C, Schüller J, Schmiedt E, Brandl H, Jocham D, Liedl B. Extracorporeal Shock Wave Lithotripsy (ESWL) For Treatment Of Urolithiasis. Urology. 1984; 23(5 Spec No):59-66.
5. Michael S, Steven J, and David A.Outcomes using a fourth generation lithotripter: a new bench marks for comparison? BJU International Vol 101, Issue 5, April 2008.
6. Streem SB, Bata D, Tornito J, Karafa MT. A Multivariate Análisis Of Risk Factors Associated With Subcapsular Hematoma Formation Following Electromagnetic Shock Wave Lithotripsy. J Urol. 2004; 172:2271-2274.
7. Lingeman JE. Extracorporeal Shock Wave Lithotripsy: What Happened? J Urol. 2003; 169(1):63.
8. Granz B, Lanski M, Nanke B, Mahler M, Rohwedder A, Chausy G, Thüroff S. Lithostar Modularis: A Proven System With New, Innovative Features. Electromedica. 2003; 71:53-57.
9. Egilmez T, Tekin MI, Gonen M, Kilinc F, goren R, Ozkardes H. Efficacy and safety of a new-generation shockwave lithotripsy machine in the treatment of single renal or ureteral stones: Experience with 2670 patients. J.Endourology. 2007; 21(1):23-27.
10. Park BS, Han KS, and Lee CH. Efficacy of the Sonolith Vision R Lithotripter according to the electrode life span: an in vitero study. J.Endourology April 2008; 22(4):735-738.
11. Lingeman JE, Newman D, Mertz JHO, Mosbaugh PG Steele RE, KAhnosski RJ, et al. Extracorporeal Shock Wave Lithotripsy. The Methodist Hospital of Indiana Experience. J Urol. 1986:1134-1137.
12. Gananapragasam,Ramsden,Murthy and Thomes.Primary in situ extra corporeal shock wave lithotripsy in the management of ureteric calculi: Results with a third generation lithotripter.BJU International volume 84,Issue 7 ,pages 770-774.
13. C.Chaussy, T.Bergsdorf, S.Thueroff.Pain during ESWL. Are there any parameters to predict the quantity of analgesic requirement.European Urology Supplements Vol 7 Issue 3, pages 80-80
14. Denstedt JD, Clayman RV, Preminger GM. Efficiency Quotient as a Means of Comparing Lithotripters (Abstract) J Endourology 1990; 4 (suppl): 100.