In situ Piezoelectric ESWL for Ureteric Calculi

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Objective: To assess in situ Piezoelectric ESWL for ureteric calculi, avoiding false positive results arising from the spontaneous passage of small stones and also to evaluate the efficiency of the EDAP LT02 Lithotriptor for insitu ESWL treatment of ureteric calculi. **Study Design:** A prospective evaluation of patients with ureteric calculi treated with Piezoelectric ESWL using EDAP LT O2 Lithotriptor. **Place & Duration of Study:** patients with ureteric calculi treated with Piezoelectric ESWL using EDAP LT O2 Lithotriptor for a period of twelve months, coming to Urology department of Pakistan Institute of Medical Sciences (PIMS), Islamabad, as out door patients. **Patients and methods:** A prospective evaluation of patients with ureteric calculi treated with Piezoelectric ESWL using EDAP LT O2 Lithotriptor for a period of twelve months, Seventy two patients, 60 males and 12 females, with mean age of 39.6 years, presenting with solitary ureteric calculus were treated using EDAP LT 02 Piezoelectric Lithotriptor, localization with fluoroscopy. No regional or general anesthesia given. **Results:** After 3 months follow-up, of the 72 ureteric calculi cases, 60(83.3%) were successfully fragmented and ureter was stone free in 54 patients (75.1%) after insitu ESWL alone. The mean duration of stone clearance was 50 days (SD +11.58). Sixteen patients required one session only, 28 patients required 2 sessions and twelve patients required three and more than three sessions. Stone location was 28 upper ureteric, 18 middle and 26 in lower ureter. Stone size varied from 7mm.to 17mm. in longest diameter. The average number of session, 1.5 for upper ureteric stone, 1.8 for mid and lower ureteric stones. Stone clearance for upper ureteric calculus was 85.7%, for mid ureteric 66.7% & for lower ureteric 69%, the overall stone clearance was 75%. **Conclusion:** In situ piezoelectric ESWL is safe, simple and effective technique for treating ureteric calculi. The site and size of the stone affects the success rate.

Key words: Stones, Ureteric stones, ESWL, Lithotriptor, Piezoelectric

Urolithiasis affliction is common among the world population. Of all the diseases in the world, its prevalence is second to malaria and shistosomiasis[1]. Morbidity rate of the urinary calculus is 2% to 4% of total population, which is similar to that of diabetes[2,3,4]. Pakistan comes within the geographical distribution of stone disease because of high temperature and humidity. Urolithiasis is the common urological ailment in Pakistan[5].

Surgery has been most important treatment modality for stone disease but its association with long surgical incision, significant blood loss, post operative pain, prolonged convalescence (4-6 weeks), wound dehiscence, ugly scars and incisional hernias could not be separated. Surgical procedure also requires prolonged hospitalization and patient experiences discomfort for several months.

The Extracorporeal piezoelectric shock wave lithotripsy is an effective non-invasive method for treating a variety of urinary tract calculi[6]. The efficiency of extracorporeal shock wave lithotripsy and ureteroscopy now frequently satisfies intervention for small ureteric calculi even when spontaneous passage is likely[7].

Previous reports have advocated in situ ESWL, as treatment of choice in the management of ureteric calculi[8,9]. This concept is based on the principal of minimal morbidity without invasiveness. In the past, the success of this method has been limited by difficulties in stone localization particularly for calculi in the mid ureter.[10]

Patients and methods:

This is a prospective evaluation of patients with ureteric calculi treated with Piezoelectric ESWL using EDAP LT O_2 Lithotriptor for a period of twelve months extending from June 1999 to May 2000, coming to Urology department of Pakistan Institute of Medical Sciences (PIMS), Islamabad, as out door patients.

Between June 1999 to May 2000, 72 consecutive patients (60 males, 12 females), with mean age 39.6 years ranging from 18 to 90 years presenting with solitary ureteric calculus, were treated using EDAP LT O2 Lithotriptor.

Each patient was evaluated with detailed history and thorough physical examination. Pre ESWL investigation included complete blood count, blood urea, serum creatinine, blood sugar, urine analysis, ultrasound and IVP as out-door patient.

Patients were prepared with laxative, the night before, to eliminate bowel gas and to achieve proper focusing of the stone with fluoroscope and ultrasound. Prophylactic antibiotics were used in few patients with history of UTI. Patients with completely obstructing infective stones, having very large stones of >2 cm. size, patients with bleeding diathesis, pregnant ladies, patients with serum creatinine of >2 mg/dl., and with previous ureteric surgery on the same side were excluded from the study. 48(70%) patients had a mild hydronephrosis, 20(27.8%) were with moderate hydronephrosis and 4(5.6%) patients had gross hydronephrosis. All calculi were treated insitu but in one case double-J stent was already inserted before referred to lithotripsy unit and stent was left in position during ESWL procedure.

Lithotriptor: EDAP LT O_2 Lithotriptor is a third generation piezoelectric Lithotriptor equipped with iso-

centric ultrasonographic and radiographic systems for localizing stones, thus allowing in situ ESWL under real time ultrasonic or fluoroscopic guidance at various ureteric levels. Energy required was adjusted by firing rate that ranged from 1, 2, 4 & 8 Hz. For ureteric calculi most of the time 8 Hz. firing rate was used. Shockwave energy time was expressed as total energy storage.

The mean duration of ESWL for ureteric calculi was 80 minutes, SD ± 16.25 (ranging from 40 min. to 110 min.) with a mode of 80. The session was terminated either if the stone has broken down earlier or the required energy has been delivered. Patient's complain of pain, nausea and vomiting were also noted during the procedure. Firing rate and shock wave intensity were adjusted according to the patient's compliance during the procedure.

No anesthesia was required in any of the patient, 60 patients were required analgesia, 50 were given simple analgesia (inj. Diclofenac sodium), 10 patients required narcotic analgesia (inj. Pentazocin) during ESWL procedure. No epidural or general anesthesia required.
Three patients (4%) with history of UTI received prophylactic antibiotic according to the urine culture and sensitivity. In the absence of fever (temp. >38°C) or severe flank pain, patients were discharged from the hospital on the same day.

Follow up after treatment consisted of a plain radiograph after 15 days. When spontaneous passage was likely, residual fragments were managed conservatively, with a further plain radiograph one month latter. Second or complimentary session of ESWL was however scheduled if stones were symptomatic or fragments were huge >4mm.or stone remained unchanged. Treatment failure was labeled after stone remained unchanged after 2 sessions of ESWL. The results were analyzed using student's t-test and SPSS software program.

Results:

The localization of calculi was assessed as very easy in 50 cases (69.4%) and difficult in 22(30.6%). 46 patients (63.9%) were treated with supine position and 26 patients (36.1%) were treated in prone position to avoid pelvic and sacral bone interposition. Localization of the calculus was mainly by fluoroscope but some calculi in the upper third allowed constant real time ultrasonic monitoring during ESWL. The intra-operative administration of I/V contrast was required only in one case. Intra-abdominal gas and interposition of bone caused some difficulty in eight patients with upper ureteric, six with mid ureteric and sixteen with lower ureteric stones. The size of the calculi ranged from 7mm to 17mm with longest diameter with a mean size of 9.8mm.

The number of ESWL sessions per patient varied from 1 to 4 with average of 1.77 per patient (median 2). For upper ureteric calculi, the number of session varied from 1 to 3 (average of 1.5 per patient), for mid ureteric calculi the number of session varied from 1 to 4(average of 1.8 per patient, median of 2), and for lower ureteric calculi the number of session varied from 1-4(average of 2 per patient, median of 2). Multiple sessions were needed in 40 patients, 28 patients required 2 sessions, 8 required 3 sessions and 4 patients required 4 sessions while 32 patients required only a single session for fragmentation of the stone till the clearance of the stone. There were 54 stone free patients (75.1%) after in situ piezoelectric ESWL treatment alone.

Table I: Success rate according to the level of stone in the ureter.

Location	No	Stone Size	Stone free	Residual	Failure
Upper ureter	28	9.76(±2.9)	24 (85%)	2 (7.1%)	2 (7.1%)
Mid ureter	18	9.2(±3.7)	12 (66.7%)	2 (11.1%)	4 (22.2%)
Lower ureter	26	10.3(±2.8)	18 (69%)	2 (7.7%)	6 (15.4%)
Total	72	9.8	54 (75%)	6 (8.3%)	12 (16.6%)

P <0.001(Largest mean diameter) (mm.)(SD)*

Table II: Comparison of stone clearance at different centers.

Author	Lithotriptor	Stone Clearance
Robert M et al15, 1995.	EDAP LT O2	76%
Rotriguez N92, 1990.	Lithostar	87%
Umeyama93, 1990.	Dornier HM3	92%
Cole, Shuttle W94, 1988.	Dornier HM3	80%
Tung KH, 95 1990.	EDAP LT O1	75%
Present Study, (PIMS) 2000.	EDAP LT O2	75%

The duration of stone clearance ranged from ten days to ninety days, mean 50 days, S.D±11.58 and mode of 30 days. For upper ureteric calculus, the stone clearance was 85.7%[24], for mid ureteric 66.7%[12] and for lower ureteric 69%[18]. Table I. Six patients have partial clearance with fragmented residual stones.

Endoscopic extraction using Dormia basket was performed in 1 symptomatic patient while the stone was fragmented. In situ ESWL failed in twelve cases with no change in stone size after repeated two sessions of ESWL. The abandoning of ESWL session depended on the stone fragmentation result, the patient's compliance and referring Urologist. Partial fragmentation suggested repeated ESWL but symptomatic patients and doubtful urologist often choose other treatment modalities. Ureterolithotomy was performed in six patients, two patients spontaneously voided intact stone and four patients lost to follow-up.

The largest diameter of stone resisting to ESWL was 14mm. significantly higher than successfully treated calculi, mean diameter of 9.8mm.

Complications after in situ ESWL included haematuria in 64 patients, only transient, severe renal colic in 3 patients, acute pyelonephritis in one patient. All complications were managed conservatively.

Discussion:

The natural history of ureteric stones favors spontaneous elimination, the incidence of which depends essentially on the size of the stone and to a lesser degree on their topography and timing of clinical observation. The incidence varies between 59 and 69 percent for stones with a diameter less than or equal to 4mm. and decreases beyond that with increase in size.[7] This natural migration however is frequently accompanied by pain and very often by serious complications, notably obstructive and infective[11].

Modern options for urological treatment of stones in the upper urinary tract tend, with an immediately reduced morbidity, to palliate these potential discomforts. With the small ureteric calculi, it may be significantly dubious to credit stone clearance within several weeks of ESWL to the treatment as may such a stone would have passed spontaneously. To avoid this ambiguity to evaluate rigorously the ESWL with EDAP LT O2, sufficiently large ureteric calculi were selected that most unlikely to pass spontaneously.

The EDAP LT O2 extrácorporeal Lithotriptor is characterized by remarkable maneuverability, which permits easy localization of most stones in the ureter. The quality of the fluoroscope and ultrasonographic equipment limit the need to use other techniques of localization such as preliminary introduction of ureteric stent or the opacification of the urinary tract. Beyond placing the patients in the supine or prone position, the mobility of the treatment table in relation to the shock-head helps to avoid obstruction by the bony structures, which can block the shock waves. Lateral or longitudinal tilting of the patient allows the upper ureteric calculi to be localized despite obstructive transverse spinal process. Moreover the maximum power of this lithotriptor can be used with no anesthesia for upper or lower ureteric calculi.

The overall success rate for in situ ESWL of ureteric calculi varies from 64% to 95%. In our study it varies from 61 % to 85 %. The lower performances were frequently obtained using 1st. generation piezoelectric lithotriptors that had only an ultrasonographic system for stone localization and which had a low fragmentation potential. The better results were obtained with electro-hydraulic or electromagnetic lithotriptor[12-31].

Despite the relatively few sessions per patients, the present study illustrates the notable improvement in the performance of piezoelectric ESWL related not only to the improvement in the localization system, but also to the increase in the fragmentation power. Thus two ESWL sessions might be performed before other forms of treatment were indicated.

With the stone in the upper ureter, the yield of ESWL can be significantly increased by first pushing them back to the kidney, but the endoscopic manipulation fails in 20 - 80 percent of the cases.[21, 22, 31-34]

Technological progress has reduced the previously recommended use of catheterization of the ureter before in situ ESWL for ureteric stones. This manipulation, whose morbidity was not negligible and that routinely required general anesthesia or local-regional anesthesia was intended to facilitate localization of the calculus and to create interface, theoretically favourable to better fragmentation. With modern localization techniques it is difficult to recommend a procedure whose clinical benefits were unproven[16, 19, 21, 32, 33, 35, 36].

Ureteroscopy is the main alternative to ESWL for ureteric calculi. Beside the miniaturization of endoscopic equipment, this technique has benefited from the development of high performance less traumatic endocorpreal lithotriptor such as various pulsed lasers and lithoclast. The success rate varies from 50 to 90 percent, is directly affected by the calculus topography, and the best result are obtained with the calculus in the lower ureter.[36, 38] Difficulties in access, or pushing stone back into the kidney, often means that an additional ESWL is required during such a treatment of upper ureteric calculi. The morbidity of such a treatment varies from 4 to 30 percent, most of the complications treatable by internal ureteric stents[7].

In contrast to ureterolithotomy and ureteroscopy, patients treated with ESWL often require a repeat therapy and the end point of the treatment is generally reached much latter. In open ureterolithotomy and in some cases of ureteroscopy, however stone clearance is achieved on the day of procedure. On the other hand, ESWL has a lower potential of hospitalization or none at all and that usually because of ancillary procedures or recurrent colic[34].

In our study, the overall stone clearance rate after in situ ESWL (75%) compare favorably with those of M.Robert (76% using the EDAP LT O2).[7], Rodriguez Netto (87% using Lithostar) [37], Umeyama (92% using a Dornier HM3) [38], Cole & Shuttleworth (80% using Dornier HM3) [39], Tung (75% using the EDAP LT O1) [40]. (Table II) ESWL provides a non-invasive, simple and safe option for the management of upper, mid and lower ureteric calculi, provided that the stone burden is less than 50sq.mm., larger calculi are better treated with URS.[41] The stone free rates were affected by the level of the ureter with statistically significance ($p<0.001$) as shown in the table I, between upper and middle ureter.

Conclusion:

In situ Piezoelectric ESWL wit the EDAP LT O2 lithotriptor represents an outstanding method of treatment for most ureteric calculi. The success rate is more for upper ureteric calculi as compare to middle and lower ureteric calculi. However for calculi greater than 15mm. size or with stone burden of more than 150 sq.mm. , impacted, obstructing or infected calculi (particularly in the lower ureter), ureteroscopy is the treatment of choice.

Although academic centers in the developing countries should push for technologically advanced equipment to be centered in the tertiary care hospital, surgeons should be trained simultaneously to carry out open ureterolithotomy that can be performed quickly, with minimal support and in any hospital setting. The procedure is effective, especially for large mid ureteric stones.

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