Extracorporeal Shock Wave Lithotripsy (ESWL) vs. Ureterorenoscopic (URS) Manipulation in Proximal Ureteric Stone

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ABSTRACT

Objective: To compare the stone free rate at one week after extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation for proximal ureteric stone (10 - 15 mm size).

Study Design: Randomized controlled trial.

Place and Duration of Study: Sindh Institute of Urology and Transplantation (SIUT), Karachi, from August 2010 to February 2011.

Methodology: One hundred and ninety patients with 10 - 15 mm proximal urteric stone, in each group were treated with ESWL and ureterorenoscopic manipulation by using an 8.0 or 8.5 Fr semi rigid ureteroscope. Intracorporeal lithotripsy was performed by using pneumatic lithoclast. The stone free rate were compared between groups by considering size of stone at one week after procedure. The success rate, retreatment rate, auxiliary procedure and complication rate were compared in each group.

Results: Success rate was 49.2% for ESWL and 57.8% for URS (p = 0.008). The re-treatment rate was significantly higher in ESWL group than in URS group (40% vs. 11 and 18% in URS group).

Conclusion: Although ESWL is regarded as the preferred choice of treatment for proximal ureteric stone, the present results suggest that ureterorenoscopic manipulation with intracorporeal lithotripsy is a safe alternative, with an advantage of obtaining an earlier or immediate stone-free status. Laparoscopic approaches are reasonable alternatives in cases, where ESWL and URS have failed.

Key Words: Ureteral calculi. Laser. Stents. Intracorporeal lithotripsy. Ureterorenoscopic manipulation (URS).

INTRODUCTION

Urolithiasis is the worldwide health problem.¹ Pakistan falls into Afro-Asian stone Belt (stretching from Egypt, Iran, India, and Thailand to Indonesia and the Philippines) which has consistently reported a high incidence of urolithiasis.²

Approximately 12% of the population suffers from urinary stone disease in their life time and recurrence rate approaches 50%.³ In Pakistan, stone diseases constitute the major work load in adult and paediatric papulations.⁴ For the purpose of determining the site of impacted stone, ureter is divided into different sections. Section-1 extends from UPJ (uretero-pelvic junction) to the lower border of kidney; section-2 extends 2.5 cm below; section-3 extends upto the upper border of sacroiliac joint; section-4 is parallel to the sacroiliac joint, section-5 is upto the ischial spine and section-6 is upto the vesico-ureteric junction.⁵ Section 1, 2 and 3 constitute proximal ureter, section-4 constitute middle and section 5 and 6 lower ureter.

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It is estimated that 68% stone of about 5 mm size and 47% stone of over 5 mm to under 10 mm size may pass spontaneously and stones of over 10 mm size need intervention.⁶

A variety of treatment options are available for ureteric calculi but there is increasing trend towards minimally invasive procedures. The introduction of extracorporeal shock wave lithotripsy (ESWL) revolutionized the management of urinary calculus.⁷ It is the treatment of choice for renal and ureteric calculi. The technology is easy to use, non-invasive and effective, while patient recovery time remains short.⁸ All shock waves, despite their source are capable of fragmenting stones when focused. The most popular management for proximal ureteric stone is ESWL, with low morbidity and acceptable efficacy.⁹

The introduction of small caliber semi-rigid ureteroscope, as well as development of intracorporeal lithotripsy method has substantially improved the ureteroreno-scopic (URS) manipulated stone free rate (71 - 78%) and significantly decreased the complication rate.⁹ A combination of ureterorenoscopy and intracorporeal lithotripsy has proven to be a viable alternative to ESWL.¹

ESWL remains the primary treatment modality for proximal ureteric calculi in many centres. However, some urologists have recommended ureterorenoscopic manipulation as first line treatment. Despite the prescribed guidelines of EUA and AUA (European and American Urologic Associations) for proximal ureteric stone,⁸ the debate still continues whether ESWL or ureterorenoscopic manipulation should be the first line treatment for proximal ureteric stone.

The aim of this study was to compare the stone free rate at one week after extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation in the treatment of proximal ureteric stone (10 - 15 mm size).

METHODOLOGY

A total of 398 patients were included in the study from August 2010 to February 2011 from clinic at SIUT. Diagnosis was based on history, clinical examination, plain X-ray KUB and ultrasound kidneys ureter and bladder. Inclusion criteria comprised patients over 16 years of age of either gender with solitary proximal ureteric stone of 10 - 15 mm size with normal renal function (serum creatinine 0.7 - 1.5 mg/dl). Patients with renal failure, pregnancy, sepsis, co-morbid cardiac or respiratory diseases, coagulation disorder (INR 1 - 1.4), severe hydronephrosis (renal pelvis > 6 mm diameter and cortex < 1 cm on ultrasound KUB) and multiple ureteric stones were excluded from the study.

Haematological investigation like total leukocyte count, haemoglobin, coagulation profile, biochemical investigation like serum urea / creatinine, urine routine examination, culture and sensitivity performed. Proximal ureteric stone was assessed at the time of admission and the selected patients were randomly divided into two groups by draw method. One hundred and ninety nine patients each were placed in group-A treated with ESWL, in group-B treated with ureterorenoscopic (URS) manipulation. Informed written consent was taken, after full explanation of the study.

ESWL was performed by using the electromagnetic generator as an energy source. Stone was targeted with the help of fluoroscopy and 3000 shock waves were given with a rate of 60 – 90 shock waves per minute. The level of shock wave energy was progressively stepped up till satisfactory stone fragmentation within the comfort of patients. All patients were previously well hydrated to improve the efficacy of ESWL. Fluoroscopy was used time to time during the procedure to see the cleavage of stone and re-targeting if required. The procedure was done as a daycare procedure. All patients were treated in supine position and had received analgesia according to their body weight. All patients were advised an oral analgesic and selective alpha-1 D adrenergic inhibitor agents on discharge to improve stone clearance. Ureterorenoscopic manipulation was performed in the operating theater under full general anaesthesia in modified lithotomy position with ipsilateral leg kept somewhat straight to facilitate the handling of semi-rigid

ureteroscope with continuous irrigation, using 8 or 8.5 Fr semi-rigid ureteroscope (Richard Wolf, Knittlingen, Germany). Intracorporeal lithotripsy was performed by pneumatic (Swiss) Lithoclast. Fluoroscopy was used if required seeing the slippage of stone and for remaining stones. A 4.8 Fr Double J stent was placed to prevent ureteric obstruction if required and in the last, Foley catheter was placed. Patient were treated as a daycare procedure until required admission. Follow-up was done after one week in stone clinic. The stones were assessed postoperatively using plain X-ray KUB (kidneys, ureter, and bladder). Treatment outcome was assessed by the post-procedure stone size.

Re-treatment was performed if inadequate fragmentation of stone observed in plain X-ray KUB after ESWL. If no disintegration of stone occurred after 2 sessions then the case was considered as ESWL failure and the patient underwent ureterorenoscopic manipulation/open ureterolithotomy. For residual stone after ureterorenoscopic manipulation, ancillary procedures included like ESWL/ Double J stent.

Data was entered and analyzed in statistical software Statistical Package for Social Sciences (SPSS) version 12. Frequency and percentage were computed for categorical variables like age groups, gender, socioeconomic status, presenting complaint, past history, comorbid condition and stone free status. Mean values and standard deviation, were computed for quantitative measurement like age, stone size. Chi-square test was applied to compare proportion of gender, socioeconomic status and stone free rate between groups. Independent sample t-test was applied to compare mean difference between groups for age and stone size. P < 0.05 was considered as a level of significance.

RESULTS

The average age of the patients was 42.54 ± 14.07 years. There were 289 (72.6%) males and 109 (27.4%) females. The commonest presenting complaint was colic i.e. 80%, followed by vomiting and nausea (50%), fever (22.6%), haematuria (19%) and burning micturation (10%). Age and stone size among the groups is described in Table I.

The success rate of URS was high than ESWL but insignificant difference was not observed between groups (49.2% vs. 57.8%; p = 0.088). Stone free status at 1 week was 49.2% in ESWL group. In total, 40% patients required second session of ESWL for disintegration. Out of them, 22% patients required ancillary treatment like URS. Regarding the complications, steinstrasse was observed in 7%, UTI in 5% and haematuria was found in 5%. In the URS group, stone free status was 57.8%, and 11% patients required repeated ureteroscopy. Ancillary treatment, like ESWL/ Ureteric stenting / Double J stent was done in 18%. Proximal ureteric stone migration was observed in 10%, UTI 5% and fever was observed in 20%. Stone free rate was significantly higher in URS group than ESWL group (p = 0.020) for stone size > 12 mm as presented in Table II.

| Table I. | | -1-1-1 | - 4 | . ام . بار م | |
|----------|-------------|------------|-----|--------------|--------------|
| Table I: | Descriptive | statistics | OT | stuay | / variables. |

| Variables | Group A (ESWL) n = 199 | Group B (URS) n = 199 | p-values | | | |
|-----------------|------------------------------|-----------------------------|----------|--|--|--|
| Age (years) | 44.32 ± 10.07 | 45.41± 13.21 | 0.35 | | | |
| Stone size (mm) | 10.84 ± 4.25 | 11.32 ± 3.74 | 0.23 | | | |

 Table II: Comparison of frequency of stone clearance between groups at one week with respect to size of stone.

| Stone size | Stone status at 1 week | Group A (ESWL) n = 199 | Group B (URS) n = 199 | p-values | |
|------------|---------------------------|------------------------------|-----------------------------|----------|--|
| ≤ 12 mm | Free | 33 | 35 | 0.88 | |
| | Not Free | 41 | 44 | 0.00 | |
| > 12 mm | Free | 65 | 80 | 0.04.0* | |
| | Not Free | 60 | 40 | 0.019* | |

DISCUSSION

With the development of advanced instruments and techniques, minimally invasive surgical procedures have gradually replaced open surgery for treating proximal ureteric stones.¹⁰ To choose between active stone removal and conservative treatment, it is important to take into account all individual circumstances that may affect treatment decisions.

Stone removal is indicated in the presence of persistent obstruction, failure of stone regression, or in the presence of increasing or unremitting colic.11 For proximal ureteric calculi, the chance of spontaneous passage is lower than that of mid and distal ureteric calculi. According to guidelines on urolithiasis 2013, the Panel performed a meta-analysis of studies in which spontaneous ureteral stone passage was assessed. The median probability of stone passage was 68% for stones < 5 mm (n = 224) and 47% for those > 5 and< 10 mm (n = 104) in size. The Panel recognized that these studies had certain limitations including nonstandardization of the stone size measurement, and lack of analysis of stone position, stone-passage history, and time to stone passage. Although patients with ureteral stones > 10 mm could be observed or treated with MET, in most cases, such stones will require surgical treatment.12 Shock wave lithotripsy does not assure complete relieve of obstruction and is associated with prolonged attacks of pain during stone passage.

Ureteric stones are often more difficult to locate and, therefore, more difficult to target with the shock wave. However, several studies have demonstrated stone-free rate close to 100% for the treatment of proximal ureteral stone with ESWL.¹³ However, stone free rate appears to decline to 70% for mid-ureteral stone for many lithotripters.¹⁴

The number of previous randomized trials of URS vs. ESWL for proximal ureteric stone is very limited.¹⁵ Most of them were retrospective in design. These retrospective reviews have been the only evidence based for advocating the merits of one treatment over the other. Wu et al. suggested that URS achieved excellent result and should be considered first-line therapy for proximal ureteric stones greater than 1 cm.¹⁶ Fong et al. experienced an overall stone free rate of 50% in ESWL and 80% in URS.7 Kawano et al. found that 83.6% of patients with proximal ureteric stone became stone free after one session of ESWL.¹⁷ Singh *et al.* achieved an overall stone free rate of 83.3% but with high retreatment rate of about 60% after ESWL.18 Tawfick achieved the 92% stone free rate with ureteroscopic lithotripsy of proximal ureteric stone, and initial stone free rate for in situ SWL was 58%.19 Saleem achieved stone free rate of 88% with URS and 60% with ESWL for stone size greater than or equal to 1 cm size.²⁰ In this study, stone free rate at 1 week was 49.2% in ESWL and 57.8% in URS. The follow-up of patients was done upto 1 month and performed re-treatment/ secondary treatment to make them stone free if required. In group-A (patients treated with ESWL) second session was done in 40% of patients and out of them 22% underwent URS / DJ stenting. Double J stent is used to prevent complication after ESWL like ureteric obstruction, especially in cases of large stone burden. However, DJ stents themselves can cause complications. After all efforts, a stone free rate of 59% after ESWL and 68% after URS was achieved in one month follow-up.

Andreoni *et al.*,²¹ treated patients by URS with stone size less than 15 mm, they reached an initial stone free rate of 70%. While shock wave application is contraindicated during pregnancy, Lifshitz *et al.* successfully treated 10 pregnant women by ureteroscopy and intracorporeal lithotripsy and did not note obstetric or urological complication.²²

In group-B (patients treated with URS) re-treatment was required in 11% of the patients and ancillary treatment like Double J stent / ESWL / ureteric stenting in 18% of patients. Stone migration was observed in 10% of patients while Kelly *et al.* experienced 8% rate of stone migration.²³

Tamsulosin (selective alpha-1 D adrenergic inhibitor) used as an adjunct to ESWL for renal and ureteric stone improves stone clearance rate, and reduce the symptom of ureteric colic and analgesic requirement.

Finally, each treatment modality has its own advantages and disadvantages, and several factors influence the choice of treatment. Studies have reported overall complication rate after ureteroscopy of 10 - 20%.²⁴ Accumulation of peri-renal fluid and sub-capsular bleed has been reported in 15 - 32% of patients treated with shock wave lithotripsy. This risk is even more problematic since the re-treatment rate for shock wave lithotripsy ranges from 4 - 50%.²⁵ The observed overall complications were 14% after URS and 6% after ESWL.

ESWL was less invasive and was performed as an outpatient procedure with adequate pain management; it did not need hospital admission or an operating theater. Although the re-treatment rate was very high because of larger stone (> 10 mm) and those causing hydroureteronephrosis, usually required more treatment session.²⁵ The practice of keeping the patient hospitalized for 1 or 2 days after URS is not universal and URS can be done as an outpatient procedure in many centres around the world. Several groups have demonstrated that out-patient treatment is safe with less than 1% unplanned readmission, if patients were selected properly.²⁶

With increasing restraints being placed on the cost of healthcare, it is important to consider the cost effectiveness of treatment. Those Urologists who prefer ESWL have based their decision on its non-invasiveness, minimal anaesthetic requirements, low morbidity and acceptable efficacy. ESWL treatment is less invasive than ureteroscopy, but has some limitation such as high retreatment rate, and is not available in all centres.²⁷

Urologists who favour URS claim that although it is an invasive procedure, it has, in contrast to ESWL, a greater success rate at the first treatment session. Patient preference should always be a great concern. Some patients might have certain fears regarding the anaesthesia required and invasiveness of URS. Others might prefer to have the stone removed and the pain alleviated more rapidly without the possibility of multiple treatment sessions and prolonged stone clearance period such as can occur with ESWL. The availability of the equipments, experience of the surgeon with both modalities, and the patient preference will determine the choice.

CONCLUSION

Although ESWL is regarded by many urologists as the preferred choice of treatment for proximal ureteric stone, the present results suggest that ureterorenoscopic manipulation (URS) with intracorporeal lithotripsy is a viable and safe alternative, with an advantage of obtaining an earlier or immediate stone-free status. Laparoscopic approaches are reasonable alternatives in rare cases where ESWL and URS have failed.

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