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*Original Research Article.*

# Comparative Study of Extracorporial Shockwave Lithotripsy Versus Ureterorenoscopic Manipulation for Treatment of Ureteric Calculi

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## ABSTRACT

**Objective:** To compare the efficacy of extracorporeal shock wave lithotripsy (ESWL) and ureterorenoscopic (URS) manipulation for ureteric calculi.

**Method:** Total 50 patients included in study with 25 patients in each group. Patients with ureteric stones less than 15mm, in each group were treated with ESWL and ureterorenoscopic manipulation by using a semi rigid ureteroscope. Intracorporeal lithotripsy was performed by using pneumatic lithoclast. Success rate, retreatment rate, complications and necessity of an additional intervention for both procedures were recorded. The decision about the selection of method was made based on the patients' choice.

**Results:** Success rate was 84% for ESWL and 92% for URS (p = 0.66). The re-treatment rate was significantly higher in ESWL group. (72% vs. none in URS group)

**Conclusion:** ESWL as an outpatient procedure does not require analgesia or anesthesia; it remains the first line therapy for proximal ureteral stones while URS as a surgical procedure requires either general anesthesia or spinal anesthesia and requires hospitalization and should be consider for preferred modality for lower ureteric stones.

**Keywords:** Extracorporial Shockwave Lithotripsy, Ureteric Calculi, Ureteroscope.

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## INTRODUCTION

Urinary stones are the third most common affliction of the urinary tract, exceeded only by urinary tract infections and pathologic conditions of the prostate (BPH and prostate cancer). The disease is both very common among men and women with estimated prevalence among the population of 2–3% and an estimated lifetime risk of 12% for males and 5-6% for females. The life time recurrence rate is approximately 50%.[1-3]

The treatment of urolithiasis varies from simple clinical observation and waiting for spontaneous passage to use of refined endourologic techniques to extract the stone. The therapeutic armamentarium currently available comprises ureteroscopy and extraction of ureteral calculus with or without the need for intracorporeal lithotripsy, percutaneous nephrolithotripsy, open or laparoscopic ureterolithotomy, and ESWL. The choice of treatment depends on the clinical picture, site and size of the stone, associated conditions and availability of material.[4-6]

The treatment strategy of watchful waiting with ultrasound follow-up is an appealing and efficacious approach for ureteral stones with a diameter of less than or equal to 7 mm. Ureteral stones of less than 4 mm in diameter have a chance of over 80% to pass spontaneously.[7]

There is no real debate or rivalry between ESWL and ureteroscopy. Both are accepted as the main therapeutic approaches to ureteral stones. ESWL is a minimally invasive method that requires no anesthesia and in most cases no hospitalization of the patient. On the other hand its success rate for distal ureteral calculi is still somewhat less favorable compared to ureteroscopy and in many cases one single session might not be sufficient. Ureteroscopy is an operative procedure with specific indications, extremely high stone free rate and minimal complication rate. Most of the comparative studies between the two methods are not conclusive and sometimes ambiguous. While some studies are in favor of ESWL, others concluded that ureteroscopy is the preferable approach.[8-11]

Currently both ESWL and URS are preferred treatment for ureteric stonrs but each has its own limitation and drawbacks. The purpose of current study is to identify subgroups of patients in which one modality is better than other.

## MATERIALS AND METHODS

A total of 50 patients were included in the study from November 2015 to October 2016 from the department of General Surgery at

Rama medical college hospital and research centre Hapur, Uttar Pradesh, India. Diagnosis was based on history, clinical examination, plain X-ray KUB and ultrasound kidneys, ureter and bladder. Inclusion criteria comprised of Patients with unilateral or bilateral ureteric calculus of size less then 1.5 cm. 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 divided into two groups by Patients preference after taking written informed consent. Group A included the patients who opted for ESWL and had 25 patients. Group B, which is URS group had 25 patients.

Along with basic investigation patients will be investigated for Ultrasound, intravenous pyelography (I.V.P), renal scan and C.T scan wherever required. Ureteroscopy was performed under General anesthesia in 7 patients and under spinal anaesthesia in 18 patients. ESWL was performed on an outpatient basis with the use sedation and analgesia. For ureterscopy (Richard Wolf, Sheath size 7.5 F and 10 F, Length 34 cm and 43 cm, Field of view 60 degrees, Angle of view 6 degrees), parts were shaved the day before surgery and prepared with asepsis. 2% lignocaine jelly was introduced into the urethra to anaesthetise it. The patient was laid supine on the table with the lower limb of the affected side semi flexed at the knee and the hip. The opposite lower limb was kept supine and abducted for the surgeon to stand between the legs and conduct the procedure. Direct introduction of the rigid ureteroscope after anaesthetising the urethra was done in most patients. Ureteroscope was advanced under direct visual control with irrigation for distension of the urethra. The whole of the urethra and bladder were inspected, the ureteric orifices were identified and assessed for ureteroscopy. The various ways employed for introduction of scope into the ureter were guidewire assisted technique, Hydrostatic dilatation techniques and Ureteric dilatation by balloon dilator. An infant feeding tube passed per urethrally into the bladder was used to prevent bladder over distension and avoid patient discomfort during hydrostatic diatation. Clarity of medium was maintained by continuous irrigation. Normal saline or autoclaved water at room temperature was used for irrigation. Three pronged grasping and retrieval forceps or Dormia baskets were used for the removal of calculi. All manipulations were done under visual control. Intra corporeal pneumatic lithotripsy was used either in a pulsed or continuous mode to deliver shots at a maximum of 12 per second. An impact pressure of 2.5 bas was used per shot to fragment the calculi. Larger fragments were extracted using grasping forceps while smaller fragments were left in situ to be passed spontaneously with urine. Double J stent was inserted in cases of mucosal breech and where obstruction was anticipated.

In ESWL Group, for the sitting, patients were called fasting. Before the start of the procedure an analgesic (Fortwin) and a sedative (Phenargan) was given. The patients were positioned supine on the table for upper ureteric stone and prone for distal ureteric stone. Shock wave therapy was started at low power which was gradually increased to the desired level. During the procedure stone was assessed for fragmentation. A maximum of 3000 shock waves were given to the patient per sitting. If the patient had no response following 2 sittings, it was considered a treatment failure. But if the patient had achieved fragmentation in 2 sittings, he underwent more than 3 sittings to a maximum of five sittings. Following the sitting, patients were advised to maintain a good oral fluid intake. They were prescribed antibiotics and analgesics. They were also advised to observe for passage of stone fragments in urine. Patients in both groups were observed for complications immediately after the procedure and after one week and three weeks. The assessment was made of the time required by the patient to resume the normal activities following both the procedures.

**For URS**: X-ray KUB post procedure for documentary clearance at 3 months.

**For ESWL**: X-ray KUB before every sitting and at 3months.

If there was partial response after one sitting retreatment was advised. Urine routine / microscopy and culture / sensitivity was done at the end of one week. Treatment failure will be based on need for further surgical intervention during follow up or failure to become stone free within 3 months.

Interpretation and analysis of data obtained will be carried out by Standard Statistical test of significance. 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.

**Table 1: Age & Sex Distribution**

| Age(yrs) | Group A-ESWL | | Group B-URS | |
|---|---|---|---|---|
| | Male | Female | Male | Female |
| **10-20** | 3 | 1 | 1 | 1 |
| **21-30** | 4 | 0 | 2 | 3 |
| **31-40** | 5 | 1 | 8 | 1 |
| **41-50** | 2 | 2 | 1 | 2 |
| **51-60** | 2 | 1 | 3 | 0 |
| **61-70** | 2 | 1 | 3 | 0 |
| **71-80** | 1 | 0 | 0 | 0 |
| **Total** | 19 | 6 | 18 | 7 |

**Table 2: Distribution of stones based on Size and Level of stone**

| Size (cm) | ESWL | | URS | |
|---|---|---|---|---|
| | Upper | Lower | Upper | Lower |
| **0-0.5** | 0 | 0 | 0 | 2 |
| **0.6-1.0** | 11 | 5 | 8 | 10 |
| **1.1-1.5** | 4 | 5 | 3 | 2 |
| **TOTAL** | 15 | 10 | 11 | 14 |

**Table 3: Stone clearance rate per sitting**

| Sitting | Stone clearance rate |
|---|---|
| **First sitting** | 28% |
| **Second sitting** | 64% |
| **Third sitting** | 76% |
| **Maximum sitting** | 84% |

**Table 4: Average number of total sitting per size of stone**

| Stone size | Average no. of sitting |
|---|---|
| **0-0.5** | 0 |
| **0.6-1.0** | 1.6 ( 1-2) |
| **1.1-1.5** | 3.1 ( 2-5) |

**Table 5: Stone clearance rate of ESWL**

| | Stone Clearance Rate (%) Of ESWL |
|---|---|
| **Upper Ureteric Stone** | 86.66 |
| **Lower Ureteric Stone** | 80 |
| **Total** | 84 |

## OBSERVATIONS

Out of the 50 patients included in study the mean age of the patient was 40.8 years (18-75 years) in Group A (ESWL Group) while it was 38.9 years (14- 70 years) for Group B (URS Group). Maximum numbers of patients (30 %) were between 31-40 years of age (Table 1). There were 37 males and 13 females in the study with an overall sex ratio 2.8:1 (Male: Female).In the ESWL groups this ratio was 3.1:1 while in URS group it was 2.5:1.

The average size of stone in ESWL group and URS group were 0.92 cm (0.8-1.4cm) and 0.78 cm (0.5 – 1.2) respectively (Table 2). For both groups maximum numbers of stones were between 0.6 – 1.0 cm. In the ESWL group 15 (60%) out of 25 patients had located in upper ureter with 10 (40%) patient having stone in lower ureter. In the URS group, out of total number of 25 patients, 11 patients (44%) had stones in upper ureter and 14 (56%) had stones in Lower ureter. In the ESWL group average size of stone in upper and lower ureter were 0.97 cm (0.8-1.4 cm) and 1.04 cm (0.8-1.2 cm) respectively. In the URS group average size of stone in upper and lower ureter were 0.96 cm (0.75-1.2cm) and 0.85 cm (0.5-1.1cm) respectively.

In Group A, during this period 25 patients underwent extracorporeal shock wave lithotripsy. A total number of 56 sitting of ESWL were undertaken and were discharged following the procedure. An overall stone clearance rate of 84% was observed following upto five sitting of ESWL (Table 3). A total of 7 patients (28%) had stone clearance following one sitting, 9 patients (36%) required 2 sitting, 5 patients (20%) required three or more sitting for clearance and in 4 patients (16%) required auxiliary procedure required for clearance of stones.

While comparing the number of sitting for various sizes of stones it was seen that larger the size of the stones, greater were the number of sittings required for clearance (table 4). Success rates for stone clearance for upper ureter was 13 out of 15 (86%), while for lower ureter it was 8 out of 10 (80%). Total clearance of ESWL for ureteric calculi was 21 out of 25 (84%) (Table 5).

In this study pain was considered as a complication, if either it prevent from resuming his duty or was so significant that it forced hospitalization for patient. Post procedure pain prevented 6 patients from returning to their work. None of the patient required hospitalization because of pain. Hematuria was noticed in 2 patients which persisted of days following the procedure but was never severe enough to warrant transfusions. ESWL group had 4 failures (16%). Failure rate in upper ureteric stone was 13% and for lower ureteric stone was 20%.Two patients of upper ureteric stone had negligible response following 2 sitting and subsequently taken up for URS. Two patients of lower ureteric had no response following 3 and more sitting of ESWL and subsequently taken up for URS. Two patients were having stone size 1.4cm and rest two was having stone size 1.1 and 1.2 cm.

In Group B**,** Out of the total number of patients, in 18 patients (72%) URS was performed under Spinal anesthesia while on 7 patients (28%) procedure was done under general anesthesia. Out of total 25 patients, URS is performed in 14 patients of lower ureteric stones and 11 patients of upper ureteric stones. In all 25 patients, stones were fragmented, large stones were retrieved using either dormia basket or retrieval forceps while small fragments were allowed to pass spontaneously. Post procedure

stents were placed in only 3 patients of upper ureteric stone because all of them had ureteral dilatation with mucosal tear. Average duration of the procedure observed was 48.2 min (25- 90 min). Only in 3 patients, sitting were extended to a period of more than 90 mins. In all of 3 cases stone sizes were 1cm. Stone size significantly affected the duration of the procedure and was more in patients with large stone. Out of 25 patients, 22 (88%) patients were discharged within 24 hours. 3 (12%) patients had hospital stay of more than 24 hours due to causes related to the procedure. Stone clearance rate of lower ureteric stone was 100% and for upper ureteric stone it was 81.8 %. In 2 patients, stone was fragmented and migrated to renal pelvis which could not be retrieved by ureteroscopy and PCNL was done in these patients for removal of stone. These patients also advised for ESWL but they refused because wanted to be stone free as early as possible. Mucosal tear with mild Hematuria was noted in 3 (12%) and was associated with long duration of hospital stay. hematuria was never significant to required blood transfusions.

**Table 6: The Comparision of Effectiveness, Failure, Complication and Treatment Days in ESWL and Ureteroscopy Groups**.

| | ESWL | Ureteroscopy | p |
|---|---|---|---|
| **Effectiveness ( Total)** | 21 (84%) | 23 (92%) | 0.66 |
| **Upper Ureteral Stones** | 13 (86.6%) | 9 (81.8%) | 0.99 |
| **Lower Ureteral Stones** | 8 (80%) | 14 (100%) | 0.32 |
| **Failure** | 4 (16%) | 2 (8%) | 0.66 |
| **Complication** | 10 (40%) | 4(16%) | 0.06 |
| **Treatment Days** | 2.24 | 1.00 | <0.001 |

**Table 7: Baseline Characteristics of Patients**

| Baseline Characteristics of Patients | ESWL | Ureteroscopy | P |
|---|---|---|---|
| **Male/Female** | 19/6 | 18/7 | 0.74 |
| **Age (Years )** | 40.8 | 38.9 | 0.66 |
| **Mean Stone Size (cm )** | 0.92 | 0.78 | 0.15 |
| **Stone Localization ( Upper/Lower)** | 15/10 | 11/14 | 0.25 |
| **Anaesthesia** | | | |
| • **Sedoanalgesia** | 25 | - | |
| • **Spinal Anaesthesia** | - | 18 | |
| • **General Anaesrhesia** | - | 7 | |
| **No. of Sitting (Average Per Patient)** | **2.24** | **1.00** | **<.001** |
| **Mean Sitting Duration** | **35.35 min** | **48.2 min** | **0.002** |
| **Retreatment Rate** | **72%** | **-** | |

## DISCUSSION

Both ESWL and ureteroscopy are minimally invasive treatment options for patients with proximal ureteral stones. The use of ESWL began in the1980s, has stone clearance rate of nearly 90% and has resulted in the fading of open surgical procedures for ureteral stones.[12–14] With subsequent development of ESWL instrument it eliminated the limitations and promoted the efficiencies. Ureteroscopy was first described in 1912, but its use was not widely accepted until the late 1970's, at which time it became a standardized procedure.[15]

The number of previous randomized trials of URS vs. ESWL for proximal ureteric stone is very limited. 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.(16) Fong et al. experienced an overall stone free rate of 50% in ESWL and 80% in URS.[17] Singh et al. achieved an overall stone free rate of 83.3% but with high retreatment rate of about 60% after ESWL.[18] In our study the effectiveness of ESWL and URS on ureteral stones were 80% and 100% respectively (Table 6).

Kawano et al. found that 83.6% of patients with proximal ureteric stone became stone free after one session of ESWL.[19] 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%.[20] Saleem achieved stone free rate of 88% with URS and 60% with ESWL for stone size greater than or equal to 1 cm size.[21] In their study done with 71 patients having upper ureteral stones of 5 to 10 mm, Karlsen and his colleagues[22] have applied ESWL to 33 patients and URS to 38 patients and recorded stone clearance of 58% in ESWL group and 78% in URS group, 3 weeks after the applications. The same patients had 88% stone clearance in ESWL and 89% in URS, after 3 months. The need for analgesics, dysuria, hematuria and lumbar pain has been significantly higher in ESWL group patients.[22] In our study, the complication rate are more in ESWL group and effectiveness of ESWL and URS on proximal ureteral stones were 86.6% and 81.8% respectively (Table 6).

Wu et al. suggested that URS achieved excellent result and should be considered first-line therapy for proximal ureteric stones greater than 1 cm.[23] Depending on the results of our study we have the opinion that URS is a more effective modality for upper ureteral stones. However, in two patients, stone was fragmented and migrated to renal pelvis which could not be retrieved by ureteroscopy and PCNL was done in these patients and duration of surgery increased (Table 6). As the stone size rises, URS

effectiveness rate decreases. The requirement of ureteral stent for an additional intervention after URS can also be regarded as a disadvantage. Increased operation time period for big stones can be regard as another disadvantage.

Honeck and his colleagues[24] had reported stone-free ratio of 84% with ESWL and 98% with URS in a study with 124 patients with distal ureteral calculi. In our study the effectiveness of ESWL and URS on distal ureteral stones were 80% and 100% respectively. The average stone size in our present study was 10 mm while it was 7 mm in the aforementioned studies (Table 7). There are not many studies comparing the effectiveness of these two methods for upper ureteral stones.

In group-A (patients treated with ESWL) second session was done in 36% of patients and out of them 16% 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 84% after ESWL and 92% after URS was achieved in three month follow-up. We compared complications between the two procedures. We didn't have any severe complications such as renal haematoma for ESWL and ureteral perforation or ureteral avulsion for ureteroscopy during both procedures; secondly we found that patients who underwent ESWL experienced a high percentage of hematuria and renal colic than patients who had ureteroscopy. Macroscopic bleeding and renal colic for ESWL were caused by stone fragment movements and ureteral mucosal damage,[25,26] as most stone fragments were cleared during operation fewer hematuria and renal colic were observed after ureteroscopy. Most hematuria and renal colic will vanish after stone passage without special management. Studies have reported overall complication rate after ureteroscopy of 10 – 20%.[27] 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%. We observed overall complications were 16% after URS and 40% after ESWL (Table 7).

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.(28) 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.(29)In our study , treatment days for ESWL and URS are 2.24 days( due to increased no. of sittings) and 1 day respectively ( Table 6).

In conclusion, ESWL as an outpatient procedure does not require analgesia or anesthesia; it remains the first line therapy for proximal ureteral stones while URS as a surgical procedure requires either general anesthesia or spinal anesthesia and requires hospitalization and should be consider for preferred modality for lower ureteric stones .Although Ureterorenoscopic manipulation (URS) with intracorporeal lithotripsy is a viable and safe alternative, with an advantage of obtaining an earlier or immediate stone-free status.

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