Comparison of Treatment Efficacy of Extracorporeal Shock Wave Lithotripsy Verses Ureteroscopy in Patients Presenting with Upper Ureteric Stone: A Randomized Controlled Trial.

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ABSTRACT:

Objective: Upper ureteric stones cause pain, hematuria, obstruction, and renal complications. Extracorporeal shock-wave lithotripsy (ESWL) is non-invasive but may require repeated sessions. Ureteroscopy (URS) permits direct stone fragmentation and removal. To compare the treatment efficacy of extracorporeal shock wave lithotripsy (ESWL) and ureteroscopy (URS) in patients with upper ureteric stones.

Methodology: This comparative study included 100 patients from 01 December 2025 to 01 June 2026 aged 18–75 years with a single upper ureteric stone smaller than 10 mm and density not exceeding 1000 Hounsfield units. Patients were allocated by lottery into ESWL and URS groups, with 50 patients in each group. ESWL was performed with a MODULITH SLX-F2 lithotripter for up to three sessions. URS was performed under general anesthesia using a semirigid ureteroscope and pneumatic lithotripsy. Stone clearance was assessed by non-contrast computed tomography after four weeks. Data were analyzed using IBM SPSS Statistics version 21.

Results: Complete stone clearance at four weeks occurred in 40 of 50 patients (80.0%) after ESWL and 47 of 50 patients (94.0%) after URS (p=0.037). Treatment failure occurred in 20.0% and 6.0% of patients, respectively. Immediate procedural complications occurred in 4.0% of the ESWL group and 6.0% of the URS group. Post-treatment complications occurred in 18.0% and 20.0% of patients, respectively (p=0.799).

Conclusion: URS achieved a higher four-week stone-clearance rate than ESWL. Both treatments had comparable short-term complication rates.

Keywords: Extracorporeal shock-wave lithotripsy, Hounsfield unit, Stone clearance, Upper ureteric stone.

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Introduction:

Urolithiasis is a common urological disorder and remains a major healthcare burden. More than 115 million incident cases were estimated worldwide in 2019. The total number of cases, disability-adjusted life years, and deaths increased between 1990 and 2019, despite a reduction in age-standardized rates. South Asia continues to carry a substantial burden of the disease.[1]

Upper ureteric stones can cause severe colic, hematuria, urinary obstruction, infection, and progressive impairment of renal function. Their management has shifted from open surgery towards minimally invasive procedures. Extracorporeal shock-wave lithotripsy (ESWL) fragments the stone without ureteric instrumentation. It can usually be performed as an outpatient procedure. Ureteroscopy (URS) permits direct visualization, fragmentation, and removal of the stone. ESWL is less invasive but may require repeated sessions. URS usually provides earlier clearance but requires anesthesia and ureteric instrumentation. A randomized prospective study found high final stone-free rates (SFRs) with both treatments for stones smaller than 1 cm. However, retreatment was more frequently required after ESWL.[2] Evidence from Pakistan has mainly involved larger proximal ureteric stones. A cross-sectional study of 60 patients with stones measuring 10–15 mm reported treatment efficacy of 93.3% after URS and 60.0% after ESWL.[3] A subsequent Pakistani study of 168 patients with stones measuring 10–15 mm also found a higher clearance rate after URS than ESWL. The reported rates were 83.3% and 64.2%, respectively.[4] These studies support the use of URS for larger stones. However, their findings cannot be directly applied to upper ureteric stones measuring less than 10 mm. Recent evidence indicates that the timing of treatment and stone-related characteristics can influence the success of ESWL. An observational study of patients with 5–10 mm upper ureteric stones found that early ESWL provided better outcomes than delayed ESWL. However, that study did not compare ESWL directly with URS.[5] Stone size, location, and attenuation on computed tomography also influence fragmentation and the need for retreatment. A recent study found that stone attenuation was significantly associated with further intervention after ESWL.[6]

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A prospective comparative study of 100 patients with upper ureteric stones smaller than 10 mm reported an initial stone free rate (SFR) of 80% after URS and 62% after ESWL. Repeated ESWL sessions increased the final clearance rate.[7] The difference between the treatments diminished at three months. However, heterogeneity across published studies persists, particularly in patient allocation strategies, follow-up duration, imaging modalities, stone-density thresholds, and definitions of treatment success. These methodological variations limit direct comparability and may partly explain the variability in reported outcomes. Evidence from randomized studies using a uniform four-week assessment and complete stone absence on non-contrast computed tomography (NCCT) remains limited, particularly in Pakistan.

It was hypothesized that URS would produce a higher four-week SFR than ESWL among patients with upper ureteric stones smaller than 10 mm and a density of not more than 1000 Hounsfield units (HU). A direct comparison in this defined population may improve treatment selection. It may also reduce treatment failure and repeated procedures. The objective of this study was to compare the treatment efficacy of ESWL and URS in patients presenting with upper ureteric stones.

Methodology:

This comparative study was conducted in the Department of Urology, Federal Postgraduate Medical Institute, Shaikh Zayed Hospital, Lahore, Pakistan. The study was completed over six months from 01 December 2025 to 01 June 2026. Each participant was followed for four weeks after completion of treatment. Ethical approval was granted by the Technical and Ethical Review Committee of the Institutional Review and Research Advisory Board, Shaikh Zayed Medical Complex, Lahore, on 29 November 2025. The approval number was TERC/SC/INT/2025/570. Written informed consent was obtained from all participants before enrolment. Patient identity and clinical information were kept confidential.

The sample size was calculated to compare two independent proportions. Salem et al.[8] reported initial stone-free rates of 80% following shock-wave lithotripsy and 100% following ureteroscopy among patients with proximal ureteric stones measuring less than 1 cm. Using these anticipated efficacy rates, a two-sided significance level of 5%, statistical power of 80%, and an allocation ratio of 1:1, the minimum required sample size was 39 patients per group, based on a two-sided Fisher's exact test. Allowing for a 20% loss to follow-up or non-evaluable outcome assessment, the adjusted sample size was 48.75 patients per group. This was rounded to 50 patients in each group, yielding a total of 100 patients, with 50 allocated to the ESWL arm and 50 to the ureteroscopy arm.

Patients of either sex, aged 18–75 years, with a single unilateral upper ureteric stone located above the sacroiliac joint were included. The stone was confirmed on non-contrast computed tomography of the kidneys, ureters and bladder and measured less than 10 mm, with a density not exceeding 1000 Hounsfield units. Only patients who provided written informed consent and agreed to complete the assigned treatment and four-week follow-up were enrolled. Patients with a solitary functioning kidney, bilateral ureteric stones, active urinary tract infection, deranged renal function, a stone measuring 10 mm or more, or stone density greater than 1000 Hounsfield units were excluded. Active urinary tract infection was defined as a positive urine culture requiring antimicrobial treatment. Patients who were unable or unwilling to complete the assigned treatment or four-week follow-up were also excluded. All eligible patients underwent a detailed history and clinical examination. Age, gender, body mass index, symptoms, relevant comorbidities, stone size and stone density were recorded. Pain, hematuria and evidence of infection were documented. Baseline serum creatinine was measured. Urine was sent for culture and sensitivity. Non-contrast CT KUB was performed in all patients. It was used to confirm the stone location, maximum diameter and density in Hounsfield units. All information was entered into a predefined proforma.

The enrolled patients were allocated into two equal groups by the lottery method. Group A included 50 patients who underwent extracorporeal shock-wave lithotripsy. Group B included 50 patients who underwent semirigid ureteroscopy. All procedures were performed under the supervision of consultant urologists according to standard departmental practice.

Patients in Group A underwent extracorporeal shock-wave lithotripsy using a MODULITH® SLX-F2 lithotripter. The stone was localized and shock waves were focused on it. Shock waves were delivered at a rate of 60–120 per minute. The energy was adjusted within a range of 1–9 kV according to patient tolerance and stone fragmentation. Approximately 2500–3000 shock waves were delivered during each session. Each session lasted 30–60 minutes. A maximum of three sessions was performed when clearance remained incomplete. A minimum interval of 48 hours was maintained between successive sessions. The number of sessions, energy level, shocks delivered, stone clearance and complications were recorded. Patients in Group B underwent semirigid URS under general anesthesia in the lithotomy position. A 6.5–7.5 Fr semirigid ureteroscope was introduced through the urethra and urinary bladder into the affected ureter. The stone was fragmented using the pneumatic, or ballistic, mode of the Swiss LithoClast® Master lithotripter (EMS Electro Medical Systems S.A., Nyon, Switzerland) with a 1-1.2 Fr pneumatic probe. The pneumatic energy was adjusted according to stone hardness, fragmentation response and the risk of proximal migration. Stone fragments were removed using a Dormia basket or grasping forceps when required. A double-J ureteric stent was inserted in all patients in the URS group. The stent was removed after two weeks or, when prolonged drainage was considered necessary, after four weeks.

The primary outcome was complete stone clearance, assessed by non-contrast computed tomography of the kidneys, ureters, and bladder at four weeks following completion of the assigned treatment. Complete clearance, or stone-free status, was defined as the absence of any residual stone or fragment in the ipsilateral kidney or ureter. Treatment failure was defined as the presence of any residual stone or fragment at the four-week assessment. For ESWL, completion of treatment referred to the final required session, with a maximum of three sessions. For URS, completion referred to the index ureteroscopic procedure. Patients requiring an additional stone-removal procedure before the four-week assessment were also classified as treatment failures. Secondary outcomes included the number of ESWL sessions, pain relief, immediate procedural complications, and complications recorded during the four-week follow-up. Pain relief was categorized as complete, partial, or absent. ESWL-related complications included hematuria, urinary tract infection, and hematoma,

while URS-related complications included fever and hematuria.

Data were entered and analyzed using IBM SPSS Statistics version 21.0. The Shapiro-Wilk test was applied to assess the normality of continuous variables. Normally distributed variables were summarized as mean ± standard deviation (SD), while non-normally distributed variables were expressed as median and interquartile range (IQR). Categorical variables were reported as frequencies and percentages. Between-group comparisons of normally distributed continuous variables were performed using independent-samples t-tests. The primary outcome was compared using Pearson's Chi-square test, with Fisher's Exact test applied when any expected cell frequency was less than five. Exploratory stratified analyses were conducted according to age, gender, stone size, and Hounsfield units (HU). All statistical tests were two-sided, and a p-value ≤0.05 was considered statistically significant.

Results:

Baseline demographic, clinical, and stone characteristics were comparable between the ESWL and URS groups. No statistically significant differences were observed in age, gender, BMI, serum creatinine, presenting symptoms, stone size, or stone density as shown in table 1.

Table No 1: Comparison of baseline characteristics between the ESWL and ureteroscopy groups.

Characteristics	ESWL, n=50	URS, n=50	p-value
Age, years	45.00 ±11.40	42.28 ±9.21	0.193
Male	37 (74.0)	32 (64.0)	0.280
Female	13 (26.0)	18 (36.0)	–
BMI, kg/m²	24.99 ±3.60	26.11 ±3.80	0.136
Baseline serum creatinine, mg/dL	0.96 ±0.15	0.94 ±0.14	0.491
Pain at presentation	48 (96.0)	47 (94.0)	1.000
Hematuria at presentation	19 (38.0)	21 (42.0)	0.683
Stone size, mm	5.25 ±1.70	5.62 ±1.72	0.275
Stone density, HU	823.96 ±90.63	849.98 ±88.13	0.149

Values are presented as mean ± standard deviation or frequency (%). Independent-samples t-test was used for quantitative variables; chi-square or Fisher's exact test was used for categorical variables. HU: Hounsfield units; BMI: body mass index; ESWL: extracorporeal shock-wave lithotripsy; URS: ureteroscopy.

Complete stone clearance on four-week NCCT KUB was achieved in 40 of 50 patients (80.0%) treated with ESWL and 47 of 50 patients (94.0%) treated with URS. The difference was statistically significant (p=0.037). Immediate and short-term post-treatment complication rates were comparable between the groups as shown in table 2.

In exploratory stratified analyses, no statistically significant differences between treatments were observed within the age or gender subgroups. Ureteroscopy demonstrated higher clearance rates than ESWL among patients with stones measuring 5-<10 mm and among those with stone densities of 600-1000 HU. These subgroup findings should be interpreted with caution, as formal interaction tests were not performed and several strata contained small patient numbers (Table III).

Table No 2: Comparison of four-week treatment efficacy and short-term complications between the ESWL and URS groups.

Treatment variable or outcome	ESWL, n=50	URS, n=50	p-value
Treatment exposure			
One ESWL session	31 (62.0)	Not applicable	–
Two ESWL sessions	7 (14.0)	Not applicable	–
Three ESWL sessions	12 (24.0)	Not applicable	–
Ureteric stent placed	Not applicable	50 (100.0)	–
Dormia basket used	Not applicable	47 (94.0)	–
Stone-clearance response			
Complete clearance on four-week NCCT KUB	40 (80.0)	47 (94.0)	0.037
Failed clearance on four-week NCCT KUB	10 (20.0)	3 (6.0)	–
Clinical response			
Complete pain relief	42 (84.0)	46 (92.0)	
Partial pain relief	7 (14.0)	3 (6.0)	0.410*
No pain relief	1 (2.0)	1 (2.0)	
Treatment complications			
Any immediate treatment complication	2 (4.0)	3 (6.0)	1.000
Bleeding	2 (4.0)	2 (4.0)	–
Post-treatment complications			
Any post-treatment complication	9 (18.0)	10 (20.0)	0.799
Hematuria	6 (12.0)	5 (10.0)	–
Urinary tract infection	2 (4.0)	0	–
Perirenal hematoma	1 (2.0)	0	–
Fever	0	4 (8.0)	–

*Values are frequency (%) or mean ± standard deviation. The primary outcome was complete stone clearance on NCCT KUB four weeks after completion of treatment. *The p-value applies to the overall three-category pain-relief comparison. Time to clearance was calculated only among patients achieving complete clearance.*

Table No 3: Treatment efficacy stratified according to age, gender, stone size and stone density.

Effect modifier	Category	ESWL effective/total (%)	URS effective/total (%)	p-value
Age	18-40 years	12/17 (70.6)	19/21 (90.5)	0.207
	41-75 years	28/33 (84.8)	28/29 (96.6)	0.201
Gender	Male	29/37 (78.4)	29/32 (90.6)	0.166
	Female	11/13 (84.6)	18/18(100.0)	0.168
Stone size	<5 mm	22/22(100.0)	17/17(100.0)	1.000
	5-<10 mm	18/28 (64.3)	30/33 (90.9)	0.011
Stone density	300-599 HU	4/4 (100.0)	3/3 (100.0)	1.000
	600-1000 HU	36/46 (78.3)	44/47 (93.6)	0.033

Efficacy was defined as complete stone clearance on NCCT KUB at four weeks. The p-value compares ESWL and URS within each stratum. Fisher's exact test was used when expected cell counts were small.

Discussion:

The demographic, clinical and stone characteristics were comparable between the two treatment groups. No significant difference was found in age, gender, body mass index, serum creatinine, presenting symptoms, stone size or stone density. A local clinical trial conducted at Services Hospital, Lahore, also reported a mean age of 44.01 years and a male predominance of 75.6% among patients with upper ureteric stones. The treatment groups in that study were also comparable at baseline. The similar demographic pattern supports the internal comparability of the current treatment groups.[9]

Complete stone clearance on four-week non-contrast computed tomography was achieved in 80% of patients treated with ESWL and 94% treated with URS. The difference was statistically significant. A randomized study from Bahawalpur reported complete clearance in 84.62% of patients treated with URS and 57.69% treated with ESWL. The direction of that finding was consistent with the current result. However, the lower ESWL rate in the Bahawalpur study may be explained by its inclusion of stones measuring 8–15 mm and assessment after only two weeks. Larger stones require greater fragmentation and may pass more slowly. These findings support URS when early and complete clearance is the main treatment goal.[10]

URS produced complete clearance after the initial procedure in 94% of patients. Direct visualization allows controlled fragmentation and active removal of stone fragments. A study from Peshawar found 100% radiological clearance when a stone cone was used during ureteroscopic lithotripsy, compared with 70% without it. Proximal migration occurred in none of the patients treated with a stone cone but occurred in 30.4% without the device. The frequent use of a Dormia basket in the current study may similarly have supported fragment retrieval and limited residual stone burden. Therefore, control of stone migration appears important for achieving high initial URS clearance.[11]

Complete clearance after the first ESWL session was 62%. It increased to 76% after the second session and 80% after the third session. This gradual improvement shows that the outcome of ESWL should not be judged after one session alone. A Pakistani study assessing the Triple-D score reported an overall ESWL success rate of 68.7%. Success increased from 26.7% in patients with the lowest score to 96.7% in those with the highest score. Although that study evaluated renal stones, it showed that repeated shockwave treatment works best when stone dimensions, density and anatomical factors are favorable. The final ESWL response therefore depends on both retreatment and appropriate patient selection.[12]

In exploratory stratified analysis, the difference in efficacy between URS and ESWL was more apparent among patients with stones measuring 5-<10 mm. Both ESWL and URS achieved complete clearance in patients with stones smaller than 5 mm. Among stones measuring 5 to less than 10 mm, clearance was 64.3% with ESWL and 90.9% with URS. An Indian comparative study reported clearance in 93% of patients with stones measuring 6–10 mm, compared with 73.7% for stones measuring 11–15 mm. It also found higher overall clearance with ureteroscopic lithotripsy than with ESWL. Smaller stones require less fragmentation and their fragments pass more easily through the ureter. These findings suggest that URS may provide a greater clearance advantage as stone size approaches 10 mm, although confirmation through an interaction analysis is required.[13]

Complete pain relief was observed in 84% of the ESWL group and 92% of the URS group. The difference in the overall distribution of pain relief was not statistically significant. URS produced faster clearance, which may explain its numerically higher rate of complete pain relief. ESWL also provided substantial symptomatic improvement after successful fragmentation and passage of the stone. Therefore, both treatments relieved symptoms, although URS achieved stone clearance more quickly.

The final ESWL success rate of 80% was consistent with regional evidence. A prospective Indian study of renal and upper ureteric stones reported successful ESWL treatment in 81.5% of patients. Surgical intervention was required in 18.5% because of incomplete fragmentation or significant residual stones. These findings closely resemble the 80% clearance and 20% failure rates observed in the current ESWL group. This consistency supports ESWL as an effective option for carefully selected upper ureteric stones smaller than 10 mm.[14]

The greater four-week efficacy of URS was not reproduced in every international study. A large prospective study of proximal ureteric stones reported one-month clearance rates of 88.7% after ultrasound-guided SWL and 83.6% after URS. The difference was not significant. That study used an early second-session SWL protocol, which allowed incomplete fragmentation to be treated promptly. It also used a propensity-matched observational design rather than randomized allocation. In contrast, the current study used complete absence of stone on four-week NCCT as a strict endpoint. Optimized and rapidly repeated SWL may therefore reduce the efficacy difference between the two treatments.[15]

Immediate and post-treatment complications were low and comparable between the groups. Post-treatment complications occurred in 18% of ESWL patients and 20% of URS patients. Most were minor and were managed conservatively. A large prospective study of distal ureteric stones similarly found comparable complication rates of 6.0% after SWL and 5.9% after URS. Ureteric injury occurred only in the URS group. The lower absolute complication rates in that study may reflect its distal-stone population and differences in complication definitions. The present findings nevertheless indicate that both procedures were acceptably safe when performed in appropriately selected patients.[16]

ESWL failed to achieve complete four-week clearance in 20% of patients. URS may be used as a secondary treatment in such cases. A prospective comparative study found stone-free rates of 83.3% for URS performed after failed SWL and 81.3% for primary URS without previous SWL. Previous unsuccessful SWL did not meaningfully reduce subsequent URS success. Therefore, an ESWL-first strategy remains reasonable for selected patients who prefer a non-invasive procedure, provided that timely URS is available when ESWL fails.[17]

Ureteral wall thickness was not measured in the current study. This unmeasured factor may explain some failures despite similar stone size and density. An Italian study of 5-10 mm ureteric stones found that increased maximum ureteral wall thickness was associated with incomplete clearance, longer procedures, greater stent use and more postoperative complications after primary URS. A wall thickness greater than 2 mm was particularly associated with adverse findings. Ureteral wall thickness may reflect oede-

ma and stone impaction. Its omission limits a complete explanation of the few URS failures.[18]

In exploratory stratified analysis, URS showed higher clearance than ESWL among patients with stone density of 600-1000 HU. Among stones measuring 600-1000 HU, complete clearance was achieved in 78.3% after ESWL and 93.6% after URS. Higher-density stones are more resistant to shock-wave fragmentation, whereas intracorporeal lithotripsy permits direct application of energy. A large international ureteroscopy registry also identified HU as a relevant parameter for predicting residual fragments after endoscopic laser treatment, although stone size, location and laser type remained important. That study involved intrarenal stones, so its findings cannot be transferred directly to upper ureteric stones. Stone density may therefore assist treatment selection when considered together with stone size, although the subgroup result requires confirmation in a larger sample.[19]

Age and gender did not significantly alter the difference in efficacy between ESWL and URS. Both treatments remained effective across the predefined age groups and in both genders. A study of primary URS also found that age did not predict the number of procedures. However, male gender was associated with greater primary clearance in that study. The difference may be related to its mixed population of proximal, middle and distal stones and its inclusion of emergency procedures. The subgroup sizes in the current study were also small. Age and gender alone should therefore not determine the choice between ESWL and URS.[20]

ESWL success depends partly on the amount and delivery of shock-wave energy. The current protocol delivered 2500–3000 shocks per session, with energy adjusted to patient tolerance. Keskin and colleagues found that stone size, number of sessions, number of shocks, pain tolerance and the Storz Medical Lithotripsy Index relative to stone size were associated with SWL success. Their study used a Storz lithotripter and showed that machine-related parameters can influence clearance independently of patient characteristics. Standardized energy escalation and accurate stone targeting are therefore important for achieving reproducible ESWL outcomes.[21]

Stone size and HU were assessed in the current study, but stone volume and skin-to-stone distance were not recorded. A prospective study evaluating an adjusted Triple-D system reported an ESWL success rate of 66.2%. Stone size, density and the amount of energy delivered relative to stone volume were among the most important predictors. These variables provide more information than maximum diameter alone. A wider set of NCCT measurements could improve the identification of patients likely to benefit from ESWL.[22]

The present findings favor URS for patients who require rapid and complete clearance, particularly when stone size approaches 10 mm or density is high. ESWL remains a useful non-invasive option for smaller and less dense stones when repeated sessions are acceptable. A cohort study of ESWL found that smaller stone size and lower age were the strongest predictors of successful treatment, while only 46.7% were stone-free after the first session. The need for repeated treatment in that study agrees with the progressive clearance observed in the current ESWL group. Treatment selection should therefore be individualized rather than based on one characteristic alone.[23]

Taken together, the findings indicate that both ESWL and URS are effective for upper ureteric stones smaller than 10 mm, with comparable short-term complication rates. URS achieves higher initial and four-week clearance rates and shortens the time to complete clearance. ESWL avoids ureteric instrumentation but often requires multiple sessions. The relative advantage of URS becomes more pronounced for stones measuring 5-<10 mm and for stones with higher density. These results support the use of URS when prompt clearance is clinically desirable, while ESWL remains a suitable option for carefully selected patients.

Conclusion:

URS achieved a higher four-week stone-clearance rate than ESWL in patients with upper ureteric stones smaller than 10 mm. Both treatments had comparable short-term complication rates.

Limitations:

This study had several limitations. It was conducted at a single center and included only 100 patients. The follow-up period was limited to four weeks. Late complications, stone recurrence and long-term ureteric stricture could not be assessed. Blinding was not possible because the treatments were clearly different. Ureteral wall thickness, hydronephrosis grade, skin-to-stone distance, stone volume and chemical composition were not recorded. These variables may influence treatment success. Pain relief was based on clinical assessment and may have been affected by patient perception. Cost, quality of life and patient preference were also not evaluated. The subgroup analyses contained small numbers and should therefore be interpreted cautiously.

Future directions:

Future studies should adopt a multicenter randomized design with larger sample sizes to enhance generalizability.

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Abdul Rauf	Supervision, methodology, interpretation of results, and critical revision of the manuscript.
Fazal Ur Rehman Khan	Literature review, data collection, and manuscript writing.
Muhammad Hamza Azhar	Patient recruitment, data collection, and manuscript review.
Abdullah Ilyas	Data interpretation, literature review, and manuscript editing.
Muhammad Labeed Khan	Data collection, data organization, and final manuscript review