

Comparing Efficacy of Extracorporeal Shock Wave Lithotripsy in Patients of Renal Calculi with Ureteric Pre-stenting and without Ureteric Stents

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ABSTRACT

Objective: To study effects of extracorporeal shock wave lithotripsy on patients of renal calculi who have previous ureteric stents and between the patients who don't have previous ureteric stents.

Study Design: Quasi Experimental Study.

Place and Duration of Study: Department of Urology, Armed Forces Institute of Urology Rawalpindi, Pakistan from Jul 2023 to Jun 2024.

Methodology: A cohort of 150 patients presenting with solitary renal or ureteral calculi. Participants were randomly allocated into two groups: Group-A: (non-stented, n=75) and Group-B (stented, n=75). Both groups underwent Extracorporeal Shock Wave Lithotripsy (ESWL), and outcomes were evaluated. Patients were prospectively followed for 3 months after stone clearance to assess for any recurrence.

Results: Group-A achieved a significantly higher complete stone clearance rate (84%) compared to Group B (72%) ($p=0.04$). Patients in Group-A also required fewer ESWL sessions (1.6 ± 0.7 vs. 2.1 ± 0.9 , $p=0.02$). Minor complications were more frequent in the stented group (22.6% vs. 12%), though not statistically significant ($p=0.11$). No major complications were observed. Stone recurrence at 3 months was low and comparable (5.3% vs. 6.6%, $p=0.71$), indicating no significant difference in recurrence between the groups.

Conclusions: Non-stented patients showed significantly better stone clearance rates and required fewer Extracorporeal Shock Wave Lithotripsy (ESWL) sessions compared to stented patients.

Keywords: Double-J stent, Extracorporeal shockwave lithotripsy, Lower urinary tract symptoms, Renal Calculus.

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INTRODUCTION

Urolithiasis is a prevalent condition affecting individuals across all age groups and socioeconomic strata globally. The lifetime risk of developing urinary stones is estimated to be 12% in men and 5% in women, with recurrence rates as high as 50% within ten years of the first episode.¹ In South Asia, including Pakistan, the prevalence of renal calculi is increasing, with reported rates ranging between 12% and 15%.² The disease burden is more pronounced in regions with hot climates, dietary imbalances, and limited access to clean water, and is attributed to poor hydration practices, high oxalate intake, and insufficient public awareness regarding preventive strategies.^{2,3}

Extracorporeal shock wave lithotripsy (ESWL) is a recognized and effective treatment technique for ureteral calculi.⁴ ESWL is minimally invasive and outpatient feasibility has made it a preferred modality

over more invasive techniques like percutaneous nephrolithotomy (PCNL).⁴ Nevertheless, stone-free rates vary significantly among treated patients.⁵ It is hypothesized that pre-stenting ureter may improve stone clearance by facilitating fragment passage thus, reducing ureteral edema.⁶ However, ureteral pre-stenting remains controversial due to associated discomfort, cost, and potential morbidity.^{7,8}

Studies conducted in the past have shown mixed reports with some showing better outcomes with pre-stenting and others showing no significant improvements.^{4,7-9} In Pakistan, little to no well-designed comparative studies are available to evaluate the results of ESWL in patients with ureteric stents and patients without them.¹⁰ Thus, this research was carried out to evaluate the effectiveness of ESWL between patients who had ureteric pre-stenting and those who did not have.

METHODOLOGY

This Quasi-experimental Interventional study was conducted in Department of Urology Armed

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Forces Institute of Urology Rawalpindi, Pakistan, from 01 July 2023 to 30 June 2024, after obtaining permission from the Institutional Ethical Review Board of AFIU (permission no: URO-TRG-1/IRB/2024025 dated: 10 Oct 2024).

These patients were having renal and upper ureteric calculi that underwent extracorporeal shock wave lithotripsy.

Inclusion Criteria: Individuals of either gender aged 15 to 60 years, with presence of a single renal or ureteral calculus confirmed by computed tomography (CT) scan, located in the renal pelvis, upper or middle calyx, or upper ureter, with a size ranging between 5 mm and 2 cm., or in the lower calyx, size ranging between to 5 mm to 1 cm were included.

Exclusion Criteria: Patients with stones larger than 1 cm in the inferior calyx or exceeding 2 cm in the upper calyx, mid calyx, or renal pelvis, those who had multiple stones or staghorn calculi, those with Distal ureteric obstruction, pregnancy, untreated urinary tract infections (UTIs), coagulopathy, or arrhythmia were excluded.

Sample size was calculated using WHO calculator, taking prevalence of renal calculi, as 10% came to 139.¹¹ We increased it to 150 for better generalizability of results.

Written informed consent was obtained from all participants, and non-probability consecutive sampling was used to collect data. Patients were informed of their right to withdraw from the study at any time without consequence. Participants were randomized into two groups using computer-generated random numbers, which were sealed in envelopes. These were opened by a nurse, not involved in the study. Seventy-five patients in Group-A underwent ESWL following the placement of a 5Fr DJ stent, while 75 patients in Group-B underwent ESWL without the insertion of a DJ stent. Patients were randomized by selecting slips from a mixed pool containing equal numbers of Group-A and Group-B assignments.

Before undergoing ESWL, detailed history and examination of every patient was done. Ultrasound KUB as initial investigation followed by CT scan KUB (plain) was done. Apart from imaging, blood complete picture, renal function test and Urine R/E was done.

Group-A (ESWL without Ureteric Stenting): In this group, patients underwent ESWL directly without prior ureteric stenting. The procedure was similarly

performed under fluoroscopic guidance using the same lithotripsy equipment and protocol, by the same consultant with 15 years of clinical experience in ESWL. Each session also lasted approximately 45–60 minutes, with up to 3,000 shock waves administered as needed. One to two sessions were typically required, depending on stone size, location, and response to treatment. Post-treatment evaluation was done using imaging at 2 and 4 weeks to assess the stone-free rate and detect any complications such as steinstrasse or incomplete fragmentation.

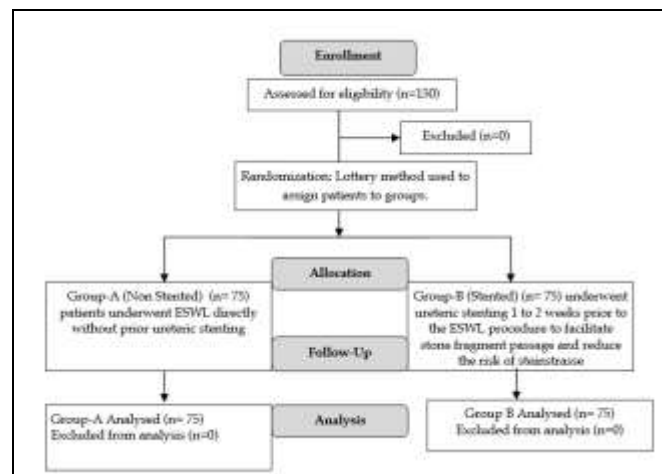


Figure: Patient Flow Diagram (n= 150)

Group-B (ESWL with Ureteric Pre-stenting): Patients in this group underwent ureteric stenting 1 to 2 weeks prior to the ESWL procedure to facilitate stone fragment passage and reduce the risk of steinstrasse. The ESWL was performed using a standard electrohydraulic lithotripter under fluoroscopic guidance. Each session lasted approximately 45–60 minutes and was conducted by a senior urology consultant with over 15 years of experience in stone management. Most patients required one to two ESWL sessions, with up to 3,000 shock waves per session delivered at gradually increasing energy levels. Stents were removed 2–3 weeks after the final session, once radiological imaging confirmed adequate stone clearance.

All procedures were performed by a single surgeon with a minimum of three years of post-fellowship experience. Preoperative antibiotics and analgesics were administered to all participants. Repeat ESWL sessions were conducted at two-week intervals, and patients were monitored regularly. Treatment success was defined as complete stone clearance, confirmed by the absence of radio-opaque

shadows on X-ray KUB and ultrasonography one month post-ESWL. Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 23. Mean±SD were calculated for age, BMI, and stone size. Frequency and percentages were determined for gender, residual stone presence, and treatment success. The success rates between the two groups were associated using the chi-square test, for age and ESWL, independent samples *t* test was applied. A *p*-value of ≤0.05 considered statistically significant.

RESULTS

The mean age of the study participants was 35.8 years, with Group-A having a mean age of 30.5±2.2 years and Group-B a mean age of 40.2±2.3 years. Group-A comprised 47(62.66%) male and 28(37.33%) female patients, while Group-B included 41(54.66%) males and 34 (45.33%) females. A total of 150 patients with solitary renal or ureteric calculi were enrolled and randomly allocated into two groups: Group-A (non-stented, n=75) and Group-B (stented, n=75).

Regarding number of ESWL Sessions, Group-A required an average of 1.6±0.7 sessions., Group- B required an average of 2.1±0.9 sessions. This difference was statistically significant (*p*=0.02), as shown in Table-I.

Table-I: Demographics Characteristics of Patients (n=150)

Variables	Group-A (n=75) n (%)	Group-B (n=75) n (%)	<i>p</i> -value
Male	47(62.6%)	41(54.6%)	0.08
Female	28(37.4%)	34(45.4%)	0.23
Age (years)	30.5±2.2	40.2±2.3	0.22
ESWL Sessions (Minutes)	1.6±0.7	2.1±0.9	0.02

Group-A (non-stented) demonstrated a higher rate of successful outcomes when it came to stone clearance rates. Specifically, 63(84%) of patients in the non-stented group achieved complete stone clearance within three months following the procedure. In contrast, Group-B (stented) exhibited a lower clearance rate, with 54(72%) achieving the same outcome, which was statistically significant (*p*=0.04), indicating a clear advantage for patients who did not receive stents.

Regarding complications, minor adverse events such as hematuria and flank pain occurred more frequently in the stented group (n=17, 22.6%) compared to the non-stented group 9 (12%). However, this difference did not reach statistical significance

(*p*=0.11). Importantly, no major complications such as sepsis or ureteric perforation were reported in either group, underscoring the overall safety of both approaches. At the 3-month follow-up, stone recurrence was low and comparable between groups, with 4(5.3%) in Group-A and 5(6.6%) in Group-B experiencing recurrence (Table-II). This difference was not statistically significant (*p*=0.71).

Table-II: Outcome of variables of Patients across Groups (n=150)

Variables	Group-A (n=75) n (%)	Group-B (n=75) n (%)	<i>p</i> -value
Complete Clearance	63(84.0%)	54(72.0%)	0.04
Complications	17(22.6%)	9(12.0%)	0.11
Stone Clearance	4(5.3%)	5(6.6%)	0.71

DISCUSSION

In our study, we compared the effectiveness of ESWL in patients who had and those who did not have ureteric stenting. Ureterscopy (URS) is the initial treatment of mid and distal ureteric stones particularly in the cases where an urgent stone clearance is necessary. However, extracorporeal shock wave lithotripsy (ESWL) has been employed as an alternative that is not invasive and has been applied especially on patients who do not want their surgery or are not fit to receive it. The size of the stone, location, patient preference and institutional expertise is the deciding factor as to whether to go with one or the other.^{12,13}

The results of our analysis revealed that patients who were not stented had much better outcome regarding stone clearance and fewer sessions of ESWL, compared to stented patients. In particular, complete clearance was 84 percent in Group-A, as compared with 72 percent in Group-B (*p*=0.04). Also, Group-A patients had a mean of 1.6 +/- 0.7 sessions which was much less than the 2.1+/-0.9 sessions that the stented group needed (*p*=0.02). The results indicate that prophylactic ureteric stenting before ESWL does not confer a clinical benefit and could in fact be linked to inferior results. This is consistent with an analysis of 474 patients treated with Storz Modulith SLX-F2 lithotripter. Their work showed a stone-free rate of 77%, which was much better in patients who were not exposed to ureteric stents (78.7% vs 64.3%, *p*=0.001). During multivariate analysis, the lack of stent, smaller stone size, younger age, and the location of the stone on the right side were all independent predictors of success in treatment.¹⁴ Our findings are also in line

with a study by Abouelgreed *et al.*, They did not find any statistically significant difference between the stone-free rates between the pre-stented and non-pre-stented groups at 4 weeks (67.5% vs 58.1%, $p=0.89$) or at 6 months (85% vs 76.7%, $p=0.081$). Moreover, there were no major differences observed in perioperative complications.¹⁵

Conversely, Falahatkar *et al.*, investigated pharmacological adjuncts and reported that the timing of stone passage was better with use of tamsulosin but not the ultimate clearance rate (71.4% vs 60.5%, $p=0.116$).¹⁶ The non-stented group experienced higher clearance in our cohort, where there was no medical expulsive therapy, which shows that the mechanical interference caused by stents can negate its possible benefits.

Of the participants in the present study, 62.6% and 54.6% of Group-A and Group-B, respectively, were men, which is also in line with past statistics in Pakistan. The same gender distribution in renal stone patients has been reported in Peshawar, and it was found that the prevalence was higher in males, which may be linked to the socio-environmental and dietary factors in this area.² The age structure of our study (mean 35.8 years) corresponds to local previous studies indicating the highest incidence in people aged 20 to 40 years, as reported by a study conducted in Punjab, Pakistan.¹⁷

In terms of complications, we found a higher incidence of minor adverse events in the stented group (22.6%) compared to non-stented group (12%) and this was not statistically significant ($p=0.11$). This pattern is similar to the results reported by Reddy *et al.*, whose study demonstrated the prevalence of postoperative flank pain and hematuria in patients with ureteric stents.¹⁸ Nevertheless, there were no significant complications, including ureteral injury or sepsis, in either of the groups in our study, which highlights the safety of ESWL with or without stenting.

Notably, the short-term recurrence rates were low and comparable in both groups (5.3% in Group-A and 6.6% in Group-B, $p=0.71$). Another study that provides a comparative understanding is the one by Kulsoom *et al.*, who compared the effectiveness of pneumatic ureteroscopic lithotripsy and ESWL in the treatment of proximal ureteric calculi in 150 patients. This study showed a significant difference in the stone-free rate with URS group stone-free rate of 86.7%, 92%, and 100% following the first, second, and third sessions respectively, compared to 64%, 77.3%

and 94.7% in the ESWL group ($p<0.001$).²⁰ Nonetheless, ESWL had been linked to the following advantages: decreasing procedure duration, less hospitalization, and lower total treatment expenses. Even though the direct effect of ureteric stenting was not studied, such results underline the importance of making individual decisions about treatment, based on clinical efficacy, economical and logistic factors.

LIMITATIONS OF STUDY

Being a study conducted at a single center, with a relatively small sample size and a short follow-up duration were the main limitations of our study.

CONCLUSION

Non-stented patients showed significantly better stone clearance rates and required fewer Extracorporeal Shock Wave Lithotripsy (ESWL) sessions compared to stented patients.

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AYK & BM: Data acquisition, data analysis, critical review, approval of the final version to be published.

MFS & GA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MTA & SSK: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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