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Research Article

Role of External Vibratory Lithoclast (Lithecbole) in Improving Lower Pole Stone Clearance After Extracorporeal Shock Wave Lithotripsy (ESWL)

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Abstract

Background and Objective: Extracorporeal shock wave lithotripsy (ESWL) is a widely used non-invasive treatment for renal stones. However, its effectiveness in clearing stones located in the lower pole of the kidney is often limited due to the anatomical challenges that impede the spontaneous passage of fragmented stones. This study evaluate the efficacy and safety of External Physical Vibration Lithecbole (EPVL) when used as an adjunctive therapy following ESWL in patients with lower pole renal stones, with a focus on improving stone clearance rates. **Materials and Methods:** This prospective interventional study was conducted at Al Yarmouk Teaching Hospital over two years and included 100 patients with 10-15 mm lower pole renal stones. Patients were randomized into two groups: The ESWL alone and ESWL plus EPVL. All patients received two ESWL sessions (3000 shocks/session). The treatment group additionally received EPVL therapy using a flank-applied vibration device. Follow-up was performed using ultrasound and KUB radiography. Statistical analysis was conducted using appropriate tests with significance set at $p < 0.05$. **Results:** Baseline characteristics, including age, gender, weight, stone size and location, were statistically comparable between groups. The mean stone size was 12.4 ± 1.7 mm. A significantly higher stone-free rate was observed in the ESWL+EPVL group compared to the ESWL-only group (66% vs. 48%, $p = 0.027$). Although the residual stone size showed a numerical difference favoring EPVL, it was not statistically significant ($p = 0.11$). Complication rates were low, mild and similar in both groups ($p = 0.3$). Logistic regression analysis revealed that smaller stone size ($p < 0.001$) and lower patient weight ($p = 0.030$) were significantly associated with successful stone clearance. Subgroup analysis further confirmed that patients with stones < 11 mm or a weight < 70 kg had the highest stone-free rates. **Conclusion:** In this initial evaluation, EPVL demonstrated a safe and effective adjunct to ESWL in enhancing stone clearance for lower-pole renal stones. Its application was associated with improved treatment outcomes without increasing complication rates. Further studies with extended EPVL sessions and longer follow-up are warranted.

Key words: Lower pole stone, extracorporeal shock wave lithotripsy, external physical vibration Lithecbole, stone clearance, residual stone, renal calculi

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Competing Interest: The authors have declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

Urolithiasis is a common and recurrent condition that affects a large fraction of the world population, with the increase of which causes a significant burden to healthcare systems around the world due to the high rates of recurrence, morbidity and related economic costs¹. Out of the many treatments that exist, Extracorporeal Shock Wave Lithotripsy (ESWL) is one of the most well-established non-invasive primary treatments, designed to target renal calculi not greater than 20 mm in diameter.

The ESWL utilizes externally applied and focused shock waves that target the stone lying in the urinary tract, causing it to break down into smaller fragments that can then be naturally expelled via the urinary tract. Fragmentation is achieved through multiple mechanisms that include the process of direct shearing, cavitation and acoustic erosion²⁻⁴.

The stone-free rates (SFR) after extracorporeal shock wave lithotripsy (ESWL) range between 60 to 98%, depending upon several factors like the size, classification and location of the stone, along with the actual lithotripter machine utilized^{5,6}. Regardless of these encouraging results, ESWL has several disadvantages, one related to the finding of post-procedure residual stone fragments; though these are commonly asymptomatic, the fragments act as a nidus for the creation of future calculi. This is more significant with regard to lower pole stones, where gravity, infundibular anatomy and adverse pelvicalyceal angles prevent the spontaneous passage of the fragments, even after successful fragmentation has been achieved^{7,8}.

To overcome these limitations, several alternative and adjunctive strategies have been explored. Percutaneous Nephrolithotomy (PCNL) and Retrograde Intrarenal Surgery (RIRS) have been shown to have improved stone clearance rates for lower pole calculi, especially for stones greater than 10 mm. However, both are marked by greater invasiveness, increased cost and a higher complication rate compared to Extracorporeal Shock Wave Lithotripsy (ESWL)^{9,10}. A randomized controlled study showed that the stone-free rates seen with PCNL were 92%, compared to only 23% for ESWL in the case of lower pole stones greater than 10 mm⁵.

A wide range of methods has been devised to enhance the removal of stone fragments after extracorporeal shock wave lithotripsy (ESWL). These methods include medical expulsive therapy, hydration regimens, manipulations of the posture of the body (including inversion therapy), magnetic removal with iron oxide microparticles and ultrasonic propulsion¹¹⁻¹³. A further innovative approach is the External Physical Vibration Lithocbole (EPVL), which is an external

mechanical device designed in China. It utilizes vibratory forces targeted towards the flank, along with predetermined positioning of the body, to facilitate the dislodgment and passage of remaining stone fragments from the lower calyceal region to the renal pelvis and ureter^{14,15}.

When applied in conjunction with ESWL, EPVL has demonstrated a significant improvement in stone clearance rates in preliminary studies and systematic reviews, particularly for residual fragments located in anatomically challenging areas. EPVL is easy to apply, repeatable and does not require anesthesia or specialized settings, making it a practical adjunct in clinical practice.

This study evaluates the efficacy and safety of External Physical Vibration Lithocbole (EPVL) when performed after ESWL in enhancing the clearance rate of lower pole renal stones.

MATERIALS AND METHODS

The intended clinical interventional trial was conducted at Al-Yarmouk Teaching Hospital between September 2021 to September 2023, spanning two years' time period. A total of 100 individuals participated, including 62 males and 38 females, who all presented with diagnosed radio-opaque renal calculi at the lower poles of the kidneys. Varying dimensions of the calculi ranged between 10 mm to 15 mm.

Patient evaluation: Each patient underwent a thorough clinical assessment, including detailed history-taking and physical examination, with documentation of body weight. Laboratory evaluations included urinalysis, urine culture and sensitivity, complete blood count (CBC), coagulation profile and renal function tests. Imaging assessments comprised abdominal ultrasound, kidney-ureter-bladder (KUB) X-ray and non-contrast computed tomography (CT).

Following a comprehensive explanation of the procedure, informed consent was obtained from all participants. The patients were then randomized into two equal groups:

- **Group A (treatment group):** Received two sessions of ESWL followed by EPVL
- **Group B (control group):** Received ESWL only, without EPVL

ESWL protocol: All patients underwent two sessions of ESWL using the Siemens Modularis Uro 3 machine. The machine was set at a frequency of 70 shocks per minute and a power of up to 7 joules, delivering a total of 3000 shockwaves per session.

EPVL protocol (Group A): The patients allocated to the intervention group received their first EPVL session one hour after the ESWL procedure, which was performed under no anaesthesia. Participants were instructed to ingest 1500 mL of fluid before the EPVL was started. After one hour of hydration, the EPVL procedure was started. Patients were placed in the chest-knee position on the instrument table. Afterwards, the EPVL oscillator device was placed at the flank area, moving at the rate of 3000 oscillations per minute and with an amplitude of 4 mm. Pressure was applied to the renal area along with the application of vibrations, which continued for 20 min.

A follow-up EPVL session was administered after the second ESWL treatment, using the same protocol. Ultrasound was utilized to monitor the location and size of residual stones after each treatment.

Control group (Group B): Patients in the control group were instructed to drink 1500 mL of fluid following each ESWL session, similar to the treatment group, but did not undergo EPVL.

Post-treatment monitoring: All patients were advised to maintain high fluid intake over the subsequent days and to monitor their urine for visible stone fragments. They were also instructed to document any adverse events experienced following treatment.

Outcomes and definitions: Key outcomes measured included:

- **Stone-free rate (SFR):** Defined as complete stone clearance based on follow-up ultrasound and KUB imaging
- **Residual stone size:** Measurement of remaining fragments post-treatment
- **Treatment-related complications:** Including pain, hematuria and any other side effects

Statistical analysis: Continuous variables were reported as Mean $\pm$ Standard Deviation or as medians with ranges, as appropriate. Categorical variables were described as counts and percentages. Welch's t-test was used to compare means between groups for normally distributed variables. For categorical comparisons, the Chi-square test with Yates' correction or Fisher's exact test was applied depending on the data characteristics. A p-value <0.05 was considered statistically significant.

All data analysis and visualizations were performed using R software (version 4.2.2, R Foundation for Statistical Computing, Vienna, Austria), with the assistance of the 'dplyr', 'gtsummary' and 'ggplot2' packages.

Ethical approval and consent to participate: This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Ethical approval for the study protocol was obtained from the Institutional Review Board (IRB) / Ethics Committee of Al-Yarmouk Teaching Hospital and Mustansiriyah College of Medicine, Baghdad, Iraq, before patient enrollment.

All participants were informed about the purpose and procedures of the study and written informed consent was obtained from all patients before inclusion in the study. Patient confidentiality and data privacy were strictly maintained throughout the research process.

RESULTS

The baseline demographic characteristics were statistically similar between the two study groups, confirming the effectiveness of randomization. No significant differences were found in age, gender, or weight ($p>0.05$). The average stone size was 12.4 ± 1.7 mm in both groups. Similarly, stone location (right or left kidney) showed no significant difference ($p = 0.2$), supporting the homogeneity of both study arms shown in Table 1.

After intervention, the stone-free rate was significantly higher in the ESWL+EPVL group (66%) compared to the ESWL-only group (48%) with a p-value of 0.027. This demonstrates a marked improvement in stone clearance when EPVL is added to the treatment protocol. Although the residual stone size was smaller in the EPVL group (3.1 ± 1.2 mm) compared to the ESWL group (3.6 ± 1.4 mm), the difference did not reach statistical significance ($p = 0.11$) shown in Table 2.

Figure 1 illustrates the predictive capacity of our regression model. The ROC curve achieved an Area Under the Curve (AUC) of 0.67, reflecting fair discriminatory ability in predicting stone-free outcomes.

Analysis of factors associated with being stone-free showed that while age and gender did not differ significantly between groups, both body weight and initial stone size were strongly associated with treatment success. Patients with smaller stones and lower weight had higher clearance rates shown in Table 3.

Similarly, stone size stratification showed that patients with stones <11 mm had the highest clearance (68.4%), followed by those with 11-13 mm (61.5%), while patients with stones >13 mm had the lowest clearance rate (40.0%), Fig. 3.

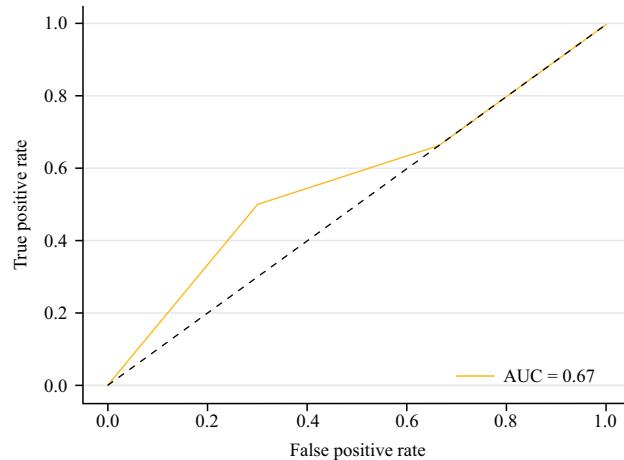


Fig. 1: ROC curve for predicting stone-free status (AUC = 0.67)

Table 1: Baseline characteristics of study participants

Parameter	ESWL only group (n = 50)	ESWL+EPVL group (n = 50)	p-value
Age (years)	Comparable	Comparable	>0.05
Weight (kg)	Comparable	Comparable	>0.05
Gender (M/F)	Comparable	Comparable	>0.05
Stone size (mm)	12.4±1.7	12.4±1.7	0.3
Side (R/L)	Comparable	Comparable	0.2

ESWL: Extracorporeal shock wave lithotripsy, EPVL: External physical vibration lithotripsy. M: Male, F: Female, R: Right and L: Left

Table 2: Treatment outcomes and complications

Outcome	ESWL only group	ESWL+EPVL group	p-value
Stone-free rate (%)	48	66	0.027
Residual stone size (mm)	3.6±1.4	3.1±1.2	0.11
Complications (overall)	Mild/Comparable	Mild/Comparable	0.3
Pain (%)	12	10	0.5
Hematuria (%)	6	4	>0.9

ESWL: Extracorporeal shock wave lithotripsy, EPVL: External physical vibration lithotripsy

To visualize relationships between all continuous parameters and the stone-free outcome, a heatmap was generated. The heatmap revealed strong negative correlations between stone size and stone-free status and between body weight and stone-free outcome, confirming the statistical findings in Fig. 4.

These visual and statistical results collectively reinforce the role of EPVL in improving lower pole stone clearance when added to ESWL, especially among patients with smaller stones and lower body weight.

DISCUSSION

Management of lower-pole renal stones remains a clinical challenge due to the anatomical complexity of the calyceal system. Extracorporeal Shock Wave Lithotripsy (ESWL) has long been favored for its non-invasive nature and absence of the need for anesthesia, particularly for renal stones measuring 10-20 mm. However, a critical limitation of ESWL is the unpredictable clearance of stone fragments, especially in the gravity-dependent lower pole.

The spontaneous passage of stone fragments post-ESWL can be influenced by multiple variables, including stone size and density, the anatomical location of the stone, infundibulo-pelvic angle, urine flow and the contractile dynamics of the ureter¹⁵. The lower calyx poses specific challenges, as its angle and position impede fragment migration. To address this, various adjunctive therapies have been explored.

This study assessed the efficacy and safety of External Physical Vibration Lithotripsy (EPVL), a device newly introduced in Iraq, applied after ESWL to promote the expulsion of residual fragments from the lower pole. Patients were randomized into two groups: Group A received ESWL followed by EPVL and Group B received ESWL only. The study included only patients with lower pole stones, minimizing anatomical variability and improving internal validity.

Demographic characteristics such as age, gender, weight, stone size and laterality were statistically comparable between the two groups (Table 1), ensuring baseline equivalence.

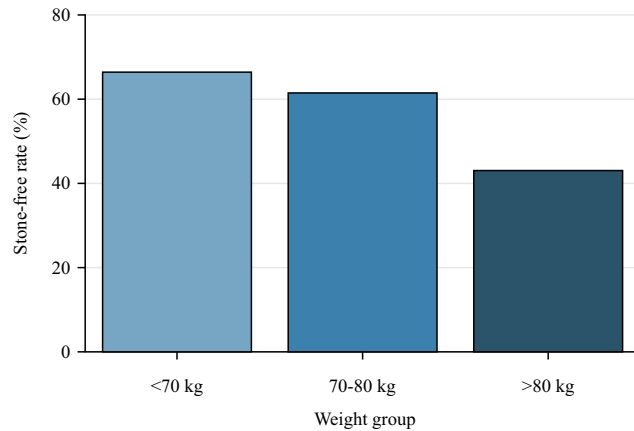


Fig. 2: Stone-free rate by weight group

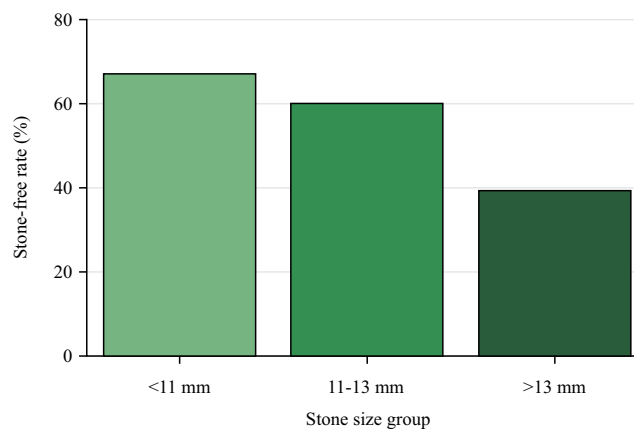


Fig. 3: Stone-free rate by stone size group

Analysis of treatment outcomes demonstrated a significantly higher stone-free rate in the EPVL group compared to the ESWL-only group (66% vs. 48%, $p = 0.027$), suggesting a synergistic effect of the combined treatment approach. Although the difference in residual stone size between the groups was not statistically significant (3.1 ± 1.2 mm vs. 3.6 ± 1.4 mm, $p = 0.11$), the observed trend favors EPVL and warrants further investigation into its potential impact on fragment displacement dynamics.

Our findings are broadly consistent with earlier studies showing that adjunctive physical therapy can improve fragment clearance after ESWL. D'A Honey *et al.*¹⁵ first demonstrated that mechanical percussion combined with diuresis and inversion could mobilize retained lower-pole fragments and facilitate their passage after shock wave lithotripsy. More recently, Peng *et al.*¹³ reported in a meta-analysis of eight prospective studies involving 1,065 patients that post-lithotripsy physical therapy significantly improved stone-free rates overall, with particular benefit for lower calyceal stones; both EPVL and PDI were effective and complication rates were not significantly increased.

Nevertheless, the stone-free rate in the present study was somewhat lower than that reported in some prior EPVL series and this difference is likely multifactorial rather than being explained by the smaller number of EPVL sessions alone. First, population characteristics may have influenced outcomes. In our cohort, higher body weight was independently associated with lower clearance, which is biologically plausible because greater soft-tissue thickness can reduce effective energy transmission during ESWL and may also make fragment migration less efficient. This interpretation is supported by a 2023 randomized trial in obese patients with lower-pole stones <15 mm, in which EPVL remained beneficial, but outcomes still varied according to patient habitus and study selection criteria.

Second, procedural and technical differences between studies may also explain the variation in results. These include the timing of EPVL after ESWL, the number and duration of EPVL sessions, hydration protocols, patient positioning and the exact vibration device parameters used. In addition, ESWL outcomes themselves are known to depend on factors such as stone size, stone hardness or density and lower-pole anatomy,

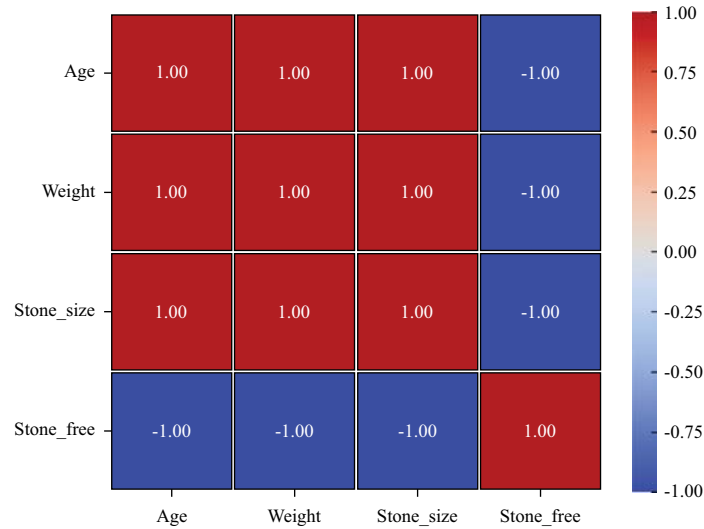


Fig. 4: Heatmap of correlation between age, weight, stone size, and stone-free status

Table 3: Factors associated with stone-free rate

Factor	Stone-free group	Residual stone group	p-value
Age (years)	45.6±7.9	45.9±8.3	0.63
Weight (kg)	72.2±8.7	77.9±10.1	0.030
Gender (M/F)	32/18	30/20	0.77
Stone size (mm)	11.4±1.2	13.2±1.3	<0.001

A multivariate logistic regression confirmed that the use of EPVL significantly increased the odds of being stone-free (OR = 2.91; 95% CI: 1.11-7.62; p = 0.031). Stone size and weight remained independent predictors, negatively impacting clearance outcomes (p<0.001 and p = 0.029, respectively) shown in Table 4

Table 4: Multivariate logistic regression analysis

Variable	OR	95% CI	p-value
EPVL treatment	2.91	1.11-7.62	0.031
Stone size (mm)	0.52	0.37-0.74	<0.001
Weight (kg)	0.89	0.81-0.98	0.029

Stone-free rates varied by body weight, with lower rates observed in heavier patients. Specifically, patients <70 kg had a 68.4% stone-free rate, while those in the 70-80 kg range had 63.3% and those >80 kg had only 44.4% Fig. 2

including infundibular length, width and infundibulopelvic angle. Therefore, differences in baseline stone burden, calyceal anatomy and lithotripter settings across studies may reasonably lead to lower or higher stone-free rates even when the same adjunctive concept is used.

Recent evidence also strengthens the rationale for discussing EPVL within the broader treatment landscape for lower-pole stones. A 2021 systematic review and meta-analysis concluded that EPVL can improve stone-free rates after ESWL and RIRS without a significant increase in adverse events, supporting its role as a practical, repeatable adjunct rather than a replacement for definitive endourologic options. At the same time, more recent comparative evidence continues to show that for lower-pole stones, especially as stone burden or hardness increases, flexible ureteroscopy and mini-PCNL often achieve higher stone-free rates than ESWL, although at the cost of greater invasiveness. Thus, the present results support EPVL as a useful strategy for improving ESWL

outcomes in selected patients, particularly those with smaller stones and lower body weight, rather than as a universal solution for all lower-pole calculi¹³.

However, the stone-free rates in our study were lower than those reported in other EPVL studies. This discrepancy likely stems from our limited use of only two EPVL sessions, in contrast to protocols that employed 3-6 sessions to maximize clearance. The current study assesses the feasibility, safety and preliminary efficacy of EPVL in an Iraqi population rather than achieving maximum clearance. Additionally, to ensure patient compliance and minimize dropout, only two sessions were conducted.

Complication rates were low and statistically similar between both groups (p = 0.3), with no significant differences in the occurrence of pain (p = 0.5) or hematuria (p>0.9). This supports the safety of EPVL, consistent with the findings of the Hospital of Guangzhou Medical University and other studies¹³.

Multivariate logistic regression further supported the efficacy of EPVL, revealing that its use significantly increased the odds of being stone-free (OR = 2.91, $p = 0.031$). In addition, both stone size and patient weight emerged as significant negative predictors of treatment success ($p < 0.001$ and $p = 0.029$, respectively), reinforcing the notion that smaller stones and lower body mass favor better clearance.

Subgroup analyses illustrated the influence of these variables. Stone-free rates were highest among patients weighing less than 70 kg (68.4%) and among those with stones smaller than 11 mm (68.4%). As body weight and stone size increased, the success rate decreased (Fig. 2 and 3). The heatmap correlation analysis (Fig. 4) visually confirmed these associations, with stone size and weight showing inverse correlations with stone-free outcomes.

Hence, the study demonstrates that EPVL is a safe and promising adjunct to ESWL, capable of enhancing lower pole stone clearance with minimal risk. While our findings support its clinical utility, future studies with larger sample sizes and extended EPVL treatment protocols are recommended to validate and optimize its effectiveness.

Despite the benefits, the present study comes with several limitations that deserve mention. To begin with, the sample was modest in size and limited to one institution, which could impact the external validity of the findings to the broader patient population. Secondly, the study participants received up to two EPVL sessions at best. This limitation to treatment duration may be suboptimal to best illustrate the potential efficacy of EPVL, specifically compared to studies using 3-6 sessions. Thirdly, due to resource limitations and the priority given to initial assessments, the follow-up period was fairly limited, thus limiting the potential to assess delayed complications such as recurrences or late complications. Additionally, though randomization was built into the study design, the lack of blinding could introduce detection or performance biases. Lastly, compliance with post-treatment protocols such as hydration and stone monitoring was based on patient report alone, which may negatively impact the precision of the reported stone-clearance rates. Future studies must include a greater-scale, multi-institutional and blinded design, prolonged follow-up time and greater EPVL session frequency to prove and strengthen these observations.

CONCLUSION

This study illuminates the possible therapeutic benefit of External Physical Vibration Lithotripsy (EPVL) as an adjuvant to Extracorporeal Shock Wave Lithotripsy (ESWL) for the management of lower pole renal calculi. This enhanced

stone-clearance rate seen with the ESWL+EPVL cohort suggests that this effect is likely due to the synergistic interaction between the two treatments, thus establishing an effective method to maximize clinical results. Of particular note is the low incidence of adverse effects with the treatments, which included discomfort, that was statistically equivalent between the two cohorts, thus supporting not only the safety but the practicality of combining EPVL with routine ESWL therapy. Lastly, this study clarified that initial stone size and patient body weight are two determinants of successful treatment, with smaller stone size and lower body mass correlating with higher stone-clearance rates. These findings support the imperative of individualized treatment approaches to specific anatomy- and physiology-based characteristics of individual patients. Overall, EPVL is revealed to be an efficient, minimally invasive and safe adjuvant that can enhance stone-clearance rates for lower-pole renal calculi. Further studies with large patient populations with extended duration of EPVL application are needed to confirm these findings and inform practice.

SIGNIFICANCE STATEMENT

This study demonstrates that External Physical Vibration Lithotripsy (EPVL) is a safe and effective adjunct to ESWL, significantly improving stone clearance rates for lower pole renal stones without increasing complications, highlighting its potential to enhance non-invasive management of challenging kidney stones.

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