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ORIGINAL PAPER

Outcomes and predictors of success after extracorporeal shock wave lithotripsy for renal stones: A retrospective study

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Summary *Objective: Extracorporeal shock wave lithotripsy (ESWL) is a first-line treatment for renal stones, yet outcomes are variable. This study aimed to identify predictors of stone clearance, complications, and number of treatment sessions in patients undergoing ESWL for kidney stones.*
Patients and methods: We conducted a retrospective cohort study at Aden Affiliated University Hospital (January 2017-May 2024) including 798 adults undergoing ESWL for renal stones. Primary outcome was stone clearance (< 4 mm residuals at three months). Secondary outcomes were complications and number of sessions. Univariate and multivariable logistic and Poisson regression were performed with Bonferroni correction.
Results: The cohort was predominantly male (99.6%) with median age 38 years (IQR 13). Median stone size was 9 mm (IQR 4) and density 1000 HU (IQR 450). Overall stone clearance was 86.8% (672 of 774 evaluable patients).. In univariate analysis, factors associated with clearance were lower BMI (OR 0.95 per kg/m², 95% CI 0.91-1.00, p = 0.05), smaller stone size (OR 0.94 per mm, 95% CI 0.88-1.00, p = 0.06), lower stone density (OR 0.98 per 100 HU, 95% CI 0.97-0.99, p < 0.001), and shorter skin-to-stone distance (OR 0.84 per mm, 95% CI 0.74-0.95, p 0.01). After multivariable adjustment, only stone density remained independently predictive (adjusted OR 0.98 per 100 HU, 95% CI 0.97-0.99, p < 0.001), and middle calyx location predicted better clearance than lower calyx (adjusted OR 2.70, 95% CI 1.09-6.68, p = 0.03). Complications occurred in 14 patients (1.8%) and were associated with low pain tolerance (OR 16.74, 95% CI 4.09-68.54, p < 0.001) and anticoagulation (OR 59.31, 95% CI 3.53-997.2, p = 0.004). Median sessions was 1 (range 1-4); higher number of sessions correlated univariately with power level (ρ = 0.191, p < 0.001), size (ρ = 0.144, p < 0.001), and density (ρ = 0.124, p < 0.001), but none remained significant at multivariable assessment.
Conclusions: Stone density is the strongest independent predictor of ESWL success, with higher density associated with significantly lower clearance. Middle calyx stones have better outcomes than lower calyx. Complications are rare but more frequent with low pain tolerance and anticoagulation. These findings guide patient selection and counseling.

KEY WORDS: Extracorporeal shock wave lithotripsy; ESWL; Kidney stones; Nephrolithiasis; Stone clearance; Complications; Predictors; Hounsfield units; Stone density.

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INTRODUCTION

Urolithiasis is a significant global health issue with increasing prevalence in both developed and developing countries. The lifetime risk of developing kidney stones is approximately 10-15% worldwide, with recurrence rates approaching 50% within five years of the first episode (1). This condition can cause recurrent pain, urinary tract infections, obstruction, and potential long-term kidney damage. The rising incidence, particularly in developing nations, is associated with changing diets, increasing obesity rates, and climate change (2).

Extracorporeal shock wave lithotripsy (ESWL), introduced in the early 1980s, transformed the management of urolithiasis by offering a non-invasive alternative to surgery (3). The procedure uses focused shock waves to fragment stones into small pieces that can pass spontaneously. Due to its minimally invasive nature, low complication rates, and suitability for outpatient care, ESWL has become the first-line treatment for most kidney and upper ureteric stones (3, 4). However, reported success rates vary widely, ranging from 60% to 90% across different studies (3). This variation reflects differences in patient characteristics, stone types, anatomy, treatment protocols, and operator expertise (3, 5).

Stone density, measured in *Hounsfield units* (HU) on non-contrast computed tomography, was one of the predictors of ESWL outcome that received more attention (6). CT scans offer greater sensitivity and specificity for stone diagnosis, offering detailed information about stone composition, size, location, and anatomy (6). Density values correspond to stone hardness; denser stones being generally more resistant to fragmentation (7, 8). Stone location is also important, as stones in the lower calyx have lower clearance rates due to gravity-dependent drainage and unfavourable anatomy (9). Patient-related factors, such as body mass index and skin-to-stone distance, may reduce shock wave energy delivery, potentially decreasing fragmentation success (3). Although less studied, pain tolerance may influence treatment completion and complication risk due to patient movement during procedures (10). Procedural details, including the number of shock waves, power level, and frequency, have been investigated with varying results, and the optimal parameters are not clearly defined (8, 11-

13). Additionally, laboratory results reflecting kidney function or metabolic issues may also affect outcomes, but these have not been thoroughly evaluated in large groups (8, 13). The number of treatment sessions required has significant implications for patient convenience and resource use (14). The factors predicting the need for repeat sessions are still not fully understood. ESWL Complications are rare but can be serious, including perinephric haematoma, infection, and cardiac arrhythmias (15-17). Risk factors for complications have been studied less than those predicting treatment success (18, 19).

In the Middle East and North Africa, the prevalence of stone disease is particularly high due to climate, diet, genetic factors, and metabolic syndrome (20, 21).

However, specific data on ESWL outcomes and locally validated predictive models are not available. This study aims to identify independent predictors of stone clearance, complications, and the number of treatment sessions in a large cohort from Aden, Yemen. We hypothesise that stone density, lower calyx location, greater skin-to-stone distance, and lower pain tolerance will independently predict poorer outcomes and a higher risk of complications.

Patients and methods

Study design and setting

This retrospective cohort study was conducted at the *Department of Urology, Aden Affiliated University Hospital*, between January 3, 2017, and May 12, 2024. The study protocol was reviewed and approved by the *Aden University Ethics Committee* on March 12, 2024, with approval identification number 132. All research procedures were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Study population

The study included all adult patients aged 18 years and older who underwent extracorporeal shock wave lithotripsy for renal stones during the study period. Patients were required to have complete medical records documenting the procedure and follow-up evaluation.

Patients were excluded from the analysis if they had stones located in any ureteral location. Additional exclusion criteria included stones in the bladder, retained DJ stent cases, and patients with incomplete outcome data. Following application of these criteria, the final study cohort comprised 798 patients with renal stones confined to either the right kidney or left kidney.

Data collection

Data were retrospectively extracted from the hospital's electronic medical records and paper charts using a standardized data collection form. Two trained research assistants independently reviewed all records to ensure accuracy and completeness of data abstraction.

Collected variables included patient age at the time of procedure, sex, nationality, body mass index calculated from height and weight measurements, and presence of any significant past medical history. Medication history was reviewed specifically for anticoagulation use at the time of procedure. Stone-related variables included stone side, with classification as right kidney or left kidney. Stone location was categorized according to anatomical position as lower calyx, middle calyx, renal pelvis, or upper calyx. Stone size was measured as the maximum diameter in millimeters on pretreatment non-contrast computed tomography. Stone density was recorded in Hounsfield units from the same imaging studies. The presence of hydronephrosis was documented based on imaging findings. The number of stones treated was recorded for each patient. Skin-to-stone distance was measured on pretreatment computed tomography images as the mean distance from the skin to the stone at three different angles, calculated in millimeters. Pretreatment laboratory evaluation included serum creatinine in micromoles per liter, blood urea nitrogen in millimoles per liter, complete blood count parameters including hemoglobin in grams per deciliter and white blood cell count, and urinalysis findings including red blood cell and white blood cell counts per high power field.

Procedural data included the total number of shock waves delivered, maximum power level used, shock wave frequency in Hertz, total procedure duration in minutes, and number of treatment sessions required. The type of analgesia administered during the procedure was recorded, as was antibiotic administration. Presence of a JJ stent at the time of treatment was documented.

ESWL procedure

All extracorporeal shock wave lithotripsy procedures were performed using a standardized protocol. Patients were positioned on the lithotripsy table, and stone localization was confirmed using fluoroscopy or ultrasound guidance depending on stone radiopacity. Treatment was delivered using an electromagnetic lithotripter with gradual power ramping to achieve optimal stone fragmentation while minimizing patient discomfort. The procedure was continued until adequate stone fragmentation was achieved or until the maximum allowable shock wave number was reached. Pain management was individualized based on patient tolerance and institutional protocols.

Outcome definitions

The primary outcome of the study was stone clearance following ESWL treatment. Stone clearance was assessed at three months post-procedure using non-contrast computed tomography or plain radiography with tomography. Complete clearance was defined as the absence of any residual fragments or the presence of clinically insignificant fragments measuring less than four millimeters. Patients with residual fragments measuring four millimeters or greater were classified as having treatment failure. Patients requiring sandwich therapy or additional interventions were also classified as not achieving complete clearance. Secondary outcomes included the occurrence of procedure-related complications and the number of treatment sessions required to achieve stone clearance. Complications were defined as any adverse event occurring during or within 30 days of the procedure, including hematoma formation, new-onset hypertension, bradycardia, chest pain, or uncontrolled pain requiring intervention. The number of treatment sessions was defined as the total count of ESWL procedures required to achieve stone clearance or until the decision was made to pursue alternative treatment modalities.

Statistical analysis

Descriptive Statistics. Continuous variables were summarized using mean and standard deviation, median and interquartile range, and minimum and maximum values. The normality of distribution for each continuous variable was assessed using the Shapiro-Wilk test. Categorical variables were summarized using frequencies and percentages. Variables with greater than forty percent missing data were excluded from regression analyses. For remaining variables with low missingness, complete case analysis was employed in regression models, with the number of included patients reported for each analysis.

For the primary outcome of stone clearance, comparisons between cleared and not cleared groups were performed using the Mann-Whitney U test for continuous variables due to non-normal distributions, and the chi-square test or Fisher's exact test for categorical variables as appropriate. For the secondary outcome of complications, similar comparisons were performed. For the number of treatment sessions, correlations with continuous variables were assessed using Spearman's rank correlation coefficient, and associations with categorical variables were assessed using the Kruskal-Wallis test.

Univariate logistic regression was performed to calculate unadjusted odds ratios with ninety-five percent confidence intervals for predictors of stone clearance and complications. Variables with a p-value less than 0.2 in univariate analysis or those considered clinically important were entered into multivariate logistic regression models. Multivariate logistic regression using backward stepwise selection was performed to identify independent predictors of stone clearance and complications. For the number of treatment sessions, Poisson regression was employed given the count nature of the outcome, with incidence rate ratios and ninety-five percent confidence intervals reported. Model fit was assessed using the Akaike Information Criterion and examination of overdispersion parameters. All statistical tests were two-sided, and a p-value less than 0.05 was considered statistically significant. Statistical analyses were performed using Python with statsmodels and scipy libraries.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and received ethical approval from the *Ethics Committee/Institutional Review Board of Al-Karama Specialised Clinic in Aden, Yemen*, on January 28, 2026. Due to the retrospective nature of the research and the use of anonymized patient data, the committee granted a waiver of informed consent. Patient confidentiality was strictly maintained throughout the study. All data were handled in compliance with institutional ethical standards to ensure privacy and security.

Results

Patient demographics and baseline characteristics

A total of 798 patients who underwent ESWL for kidney stones were included in the final analysis. The baseline demographic and clinical characteristics are summarized in Table 1. The cohort was predominantly male (99.6%),

Table 1.
Baseline demographic and clinical characteristics of patients undergoing ESWL (n = 798).

Panel A. *Continuous variables.*

Variable	N	Missing N (%)	Mean ± SD	Median (IQR)	Range
Age (years)	798	0 (0)	39.05 ± 9.85	38 (13)	16-74
BMI (kg/m²)	798	0 (0)	26.50 ± 4.07	26 (5)	16.2-41.0
Height (cm)	798	0 (0)	166.83 ± 7.50	167 (10)	106-190
Weight (kg)	798	0 (0)	75.21 ± 14.32	74 (18)	45-145
Shock waves (n)	798	0 (0)	3015.76 ± 493.10	3000 (800)	900-4000
Power level	798	0 (0)	6.22 ± 0.95	6 (1)	3-9
Frequency (Hz)	798	0 (0)	79.82 ± 1.80	80 (0)	70-90
Stone size (mm)	790	8 (1.0)	9.44 ± 4.00	9 (4)	4-45
Stone density (HU)	779	19 (2.4)	974.50 ± 319.32	1000 (450)	200-2045
Serum creatinine (μmol/L)	798	0 (0)	87.54 ± 17.07	86 (17)	50-210
BUN (mmol/L)	775	23 (2.9)	4.28 ± 1.59	4.1 (1.5)	1.7-11.2
Blood WBC (×10^9/L)	798	0 (0)	8.09 ± 3.82	7.8 (2.7)	3.2-98
Hemoglobin (g/dL)	798	0 (0)	14.76 ± 1.44	14.9 (1.6)	4.9-18.4
Urine RBC (/HPF)*	795	3 (0.4)	125.34 ± 458.53	5 (58)	0-4250
Urine WBC (/HPF)*	795	3 (0.4)	28.93 ± 124.57	4 (18)	0-1250
Treatment sessions (n)	797	1 (0.1)	1.25 ± 0.52	1 (0)	1-4
DSS (mm)†	798	0 (0)	8.48 ± 1.62	8 (2)	5-17
Procedure duration (min)	795	3 (0.4)	41.54 ± 5.40	44 (5)	15-65
Number of stones	608	190 (23.8)	1.04 ± 0.27	1 (0)	1-4

Variable	Category	N (%)
Sex	Male Female	795 (99.6) 3 (0.4)
Past medical history	None Missing	600 (75.2) 198 (24.8)
JJ stent	No Yes	688 (86.2) 110 (13.8)
Anticoagulation	No Yes	794 (99.5) 2 (0.3)
Stone side	Left kidney Right kidney	451 (56.5) 347 (43.5)
Stone location	Lower calyx Middle calyx Renal pelvis Upper calyx	475 (59.6) 133 (16.7) 102 (12.8) 87 (10.9)
Hydronephrosis	No Yes	716 (89.7) 82 (10.3)
Pain tolerance§	Good Medium Mild Low	712 (89.2) 46 (5.8) 23 (2.9) 17 (2.1)
****Stone clearance**	Complete (stone-free) Insignificant residuals (< 4 mm) Significant residuals (≥ 4 mm) Sandwich therapy Missing	616 (77.6) 56 (7.1) 94 (11.8) 7 (0.9) 25 (3.1)
Complications ¶	None Hematoma Hypertension Bradycardia Chest pain Pain	784 (98.2) 5 (0.6) 5 (0.6) 2 (0.3) 1 (0.1) 1 (0.1)
Analgesia	Fentanyl Midazolam + Morphine Diclofenac Morphine only	408 (51.2) 378 (47.4) 6 (0.8) 4 (0.5)

** Data winsorized at the 9[th] percentile.*
† DSS, skin-to-stone distance.
§ Ordinal scale: Good (tolerated well, no distress), Medium (mild discomfort), Mild (moderate discomfort), Low (severe distress requiring intervention).
||Classification based on post-ESWL imaging at 3 months.
¶ Some patients experienced more than one complication; only the most severe is tabulated. Percentages may not total 100 due to rounding.
ESWL: extracorporeal shock wave lithotripsy; SD: standard deviation; IQR: interquartile range; BMI: body mass index; HU: Hounsfield unit; BUN: blood urea nitrogen; WBC: white blood cell; RBC: red blood cell; HPF: high-power field.

Panel B.
Categorical variables.

with a median age of 38 years (IQR 13). Following data cleaning, the median BMI was 26 kg/m² (IQR 5). The majority of stones were located in the lower calyx (59.6%), with a median stone size of 9 mm (IQR 4) and a median density of 1000 HU (IQR 450).

A JJ stent was present in 13.8% of patients at the time of treatment. The overall stone clearance rate, defined as stone-free or clinically insignificant residuals (< 4 mm) at three-month follow-up, was 86.8% (672 of 774 patients with complete outcome data).

Factors associated with stone clearance

Univariate analysis (Table 2A) identified several factors associated with stone clearance. Patients who achieved clearance had significantly lower BMI (26.3 ± 3.9 *vs.* 27.4 ± 5.0 kg/m², p = 0.005), smaller stone size (9.1 ± 3.1 *vs.* 9.8 ± 3.2 mm, p = 0.046), lower stone density (951 ± 317 vs. 1088 ± 316 HU, p < 0.001), and a shorter skin-to-stone distance (DSS) (8.4 ± 1.6 *vs.* 8.9 ± 1.8 mm, p = 0.003) compared to those without clearance. However, after applying a conservative Bonferroni correction for multiple testing (significance threshold p < 0.0017), only stone density remained statistically significant in the univariate analysis.

In the multivariable logistic regression model (Table 3A), which controlled for potential confounders, higher stone

Table 2.
Univariate analysis of factors associated with ESWL outcomes.
Panel A. *Factors Associated with Stone Clearance *.*

Variable	Type	Cleared (n = 672) †	Not Cleared (n = 102) ‡	Test	Statistic	p-value
Age (years)	Mean ± SD	38.64 ± 9.60	40.74 ± 11.50	MWU	31221	0.056
BMI (kg/m²)	Mean ± SD	26.29 ± 3.87	27.39 ± 5.02	MWU	32822.5	0.005
Weight (kg)	Mean ± SD	75.14 ± 14.01	75.89 ± 15.98	MWU	29563	0.512
Stone size (mm)	Mean ± SD	9.10 ± 3.09	9.77 ± 3.22	MWU	30955.5	0.046
Stone density (HU)	Mean ± SD	**951.16 ± 316.50**	**1088.02 ± 316.38**	**MWU**	**32617.5**	**< 0.001**
BUN (mmol/L)	Mean ± SD	4.25 ± 1.55	4.43 ± 1.81	MWU	28154	0.361
DSS (mm)	Mean ± SD	8.40 ± 1.57	8.92 ± 1.79	MWU	33053	0.003
Sex	Male/Female	669/3	101/1	Fisher's exact	-	0.475
Stone location	LC/MC/RP/UC	352/108/81/74	63/8/13/10	χ^2 = 6.12	-	0.106
Pain tolerance	Good/Med/Mid/Low	553/30/17/16	79/8/5/2	χ^2 = 4.98	-	0.173

Bolded p-values indicate statistical significance (p < 0.05). After Bonferroni correction (α = 0.0017), only stone density remains significant.
** Cleared includes stone-free and insignificant residuals (< 4 mm).*
† Cleared n includes 616 stone-free + 56 insignificant residuals. ‡Not cleared includes 94 significant residuals + 7 sandwich therapy + 1 missing outcome classification?
LC: Lower Calyx; MC: Middle Calyx; RP: Renal Pelvis; UC: Upper Calyx.

Panel B. *Factors Associated with Complications †.*

Variable	Type	Complication (n = 14)	No Complication (n = 784)	Test	Statistic	p-value
Age (years)	Mean ± SD	43.29 ± 10.40	38.97 ± 9.83	MWU	4184	0.127
Shock waves (n)	Mean ± SD	2542.86 ± 919.63	3024.21 ± 478.94	MWU	7017.5	0.069
DSS (mm)	Mean ± SD	9.29 ± 1.82	8.47 ± 1.61	MWU	3928	0.062
Anticoagulation	Yes/No	1/13	1/771	χ^2=27.11	-	**< 0.001**
Pain tolerance	Low/Med/Good	4/2/8	13/44/704	χ^2=28.11	-	**< 0.001**

Bolded p-values indicate statistical significance (p < 0.05).
† Due to the low number of events (n=14), these results should be interpreted with caution.

Panel C.
Factors associated with number of treatment sessions.

Variable	Type	Test	Statistic	p-value
Power level	Continuous	Spearman ρ	0.191	**< 0.001**
Stone size (mm)	Continuous	Spearman ρ	0.144	**< 0.001**
Stone density (HU)	Continuous	Spearman ρ	0.124	**< 0.001**
Stone side	Categorical	Kruskal-Wallis H	9.16	**0.003**
Pain tolerance	Categorical	Kruskal-Wallis H	8.98	0.030

Bolded p-values indicate statistical significance (p < 0.05). After Bonferroni correction (α = 0.0017), power level, stone size, and stone density remain significant.
MWU: Mann-Whitney U test; χ^2: Chi-square test; DSS: skin-to-stone distance; LC: Lower Calyx; MC: Middle Calyx; RP: Renal Pelvis; UC: Upper Calyx; HU: Hounsfield unit.

density emerged as the most consistent independent predictor of reduced clearance. The odds of clearance decreased by 2% for every 100 HU increase in stone density (adjusted OR 0.98 per 100 HU, 95% CI 0.97-0.99, p < 0.001). Stone location in the middle calyx was associated with significantly better clearance compared to lower calyx stones (adjusted OR 2.70, 95% CI 1.09-6.68, p = 0.03). The full model had an area under the ROC curve (AUC) of 0.70 (95% CI 0.65-0.75), indicating modest predictive ability.

Factors associated with complications

Post-procedural complications were rare, occurring in only 14 patients (1.8%) (Table 1B). Due to this low event rate, multivariable analysis was not performed to avoid model overfitting, and results from the univariate analysis should be interpreted with caution (Table 3B). Factors showing a univariate association with complications included low pain tolerance (OR 16.74, 95% CI 4.09-68.54, p < 0.001) and anticoagulant use (OR 59.31, 95% CI 3.53-997.2, p = 0.004). A paradoxical inverse association was observed between the number of shock waves and complications (p < 0.001), which likely reflects early termination of the procedure due to patient intolerance or pain, rather than a protective effect of fewer shock waves.

Factors associated with number of treatment sessions

The median number of treatment sessions required was one (range 1-4). Univariate analysis (Table 2B) showed

Table 3.
Regression analysis of factors predicting ESWL outcomes.

***Panel A.** Multivariate logistic regression for stone clearance (N = 536) *.*

Variable	Adjusted OR	95% CI	p-value	VIF
Age (years)	1.00	0.97-1.03	0.96	1.21
BMI (kg/m²)	0.92	0.81-1.05	0.23	3.45
Weight (kg)	1.01	0.97-1.05	0.54	3.52
Power level	1.30	0.91-1.86	0.15	1.08
Stone size (mm)	1.00	0.91-1.09	0.91	1.15
Stone density (per 100 HU)	**0.98**	**0.97-0.99**	**< 0.001**	1.09
DSS (mm)	0.87	0.74-1.03	0.10	1.12
Stone location				
- Middle calyx (vs. Lower)	**2.75**	**1.11-6.82**	**0.03**	1.08
- Renal pelvis (vs. Lower)	1.66	0.74-3.73	0.22	1.06
- Upper calyx (vs. Lower)	1.30	0.54-3.12	0.55	1.05

*Bolded p-values indicate statistical significance ($p < 0.05$). * Model fit: Pseudo $R^2 = 0.112$; AIC = 424.3; AUC-ROC = 0.71 (95% CI 0.66-0.76). Adjusted for urine RBC, treatment sessions, number of stones, and pain tolerance (not shown).*

***Panel B.** Univariate associations with complications†.*

Variable	OR	95% CI	p-value
Shock waves (n)	0.998	0.997-0.999	**< 0.001**
DSS (mm)	1.28	0.99-1.67	0.06
Pain tolerance (ref: Good)			
- Low	**16.74**	**4.09-68.54**	**< 0.001**
- Medium	3.55	0.74-16.93	0.11
Anticoagulation	**59.31**	**3.53-997.20**	**0.004**

Bolded p-values indicate statistical significance ($p < 0.05$).
†Multivariate analysis not performed due to low event rate (n = 14).

***Panel C.** Multivariate poisson regression for number of treatment sessions (N = 590) *.*

Variable	IRR	95% CI	p-value
Power level	1.08	0.97-1.19	0.17
Stone size (mm)	1.01	0.99-1.03	0.23
Stone density (per 100 HU)	1.01	0.99-1.03	0.64
DSS (mm)	0.99	0.95-1.04	0.79
JJ stent (Yes vs. No)	0.98	0.79-1.23	0.88
Stone side (RTK vs. LTK)	0.92	0.79-1.07	0.27

Bolded p-values indicate statistical significance ($p < 0.05$).); none reached significance in this model.
**Model fit: AIC = 1348.2; Overdispersion parameter = 0.14. Adjusted for hemoglobin, number of stones, pain tolerance, and antibiotics (not shown).*
OR: odds ratio; CI: confidence interval; VIF: variance inflation factor; IRR: incidence rate ratio;
RTK: right kidney; LTK: left kidney; other abbreviations as in Table 1.

that a higher number of sessions was associated with higher power level (ρ = 0.191, $p < 0.001$), larger stone size (ρ = 0.144, $p < 0.001$), and higher stone density (ρ = 0.124, $p < 0.001$). However, in the multivariable Poisson regression model (Table 3C), none of these factors remained statistically significant predictors of the number of sessions. This suggests that the decision to perform multiple sessions is complex and likely influenced by a combination of clinical factors, physician judgment, and patient preference not fully captured by the variables in this model.

Discussion

This retrospective cohort study of 798 patients who underwent ESWL for kidney stones identified several important predictors of treatment outcomes. The main finding is that stone density, measured in Hounsfield units on pretreatment computed tomography, is the strongest independent predictor of stone clearance. For every 100 HU increase in stone density, the odds of successful clearance decreased by 2%. This relationship remained strong even after adjusting for demographic, clinical, and treatment factors. Additionally, stones located in the middle calyx had a significantly better clearance rate compared to those in the lower calyx, with nearly three times higher odds of success. In univariate analysis, several other factors related to clearance included lower BMI, smaller stone size, and shorter skin-to-stone distance. Complications were rare overall but occurred more frequently in patients with low pain tolerance and those on anticoagulation therapy.

No independent predictors of the number of treatment sessions were identified in our multivariable Poisson regression, despite significant univariate associations between session number and power level, stone size, and stone density. This contrasts with several published studies. *Ergün and Sağır* reported that stone size, density, age, BMI, and location independently predicted single versus multiple sessions (14). *Hevia et al.* developed a risk model showing that density above 864 HU, diameter above 7.5 mm, and pyelocaliceal location predicted retreatment probability ranging from 20.2% to 62.5% (22). *Salah et al.* identified stone density, previous urologic intervention, multiple stones, and skin-to-stone distance as independent predictors of treatment failure requiring repeat sessions (23). The discrepancy may reflect limited statistical power, given that the majority of our patients required only a single session, as well as unmeasured confounders, including physician judgment, patient preferences, scheduling constraints, and institutional protocols,

that inherently influence the decision to repeat ESWL (14, 24). *Muter et al.* noted that the relationship between stone density and session requirements may be nonlinear and better captured by dedicated predictive indices rather than standard regression models (6).
Regarding ESWL success, several key studies and systematic reviews have been investigated predictors of stone clearance after ESWL (15-17). Our finding that higher stone density predicts worse ESWL outcomes aligns with a significant amount of evidence. A recent systematic review by *Garg and colleagues* analyzing 28 studies with 4,206 patients showed that Hounsfield unit values consistently correlate inversely with SWL success. Values below 750 HU were linked to favorable outcomes, while values above 1000 HU were strongly predictive of treatment failure (15). Our finding of a 2% reduction in clearance odds per 100 HU increase provides a precise measurement of this relationship, consistent with the ongoing nature of the association reported in the literature. *Bres-Niewada and colleagues* found that a stone density threshold of 1000 HU provided optimal prediction of ESWL failure with 85% sensitivity and 82% specificity (25). Similarly, Ouzaid and associates reported that average stone density greater than 970 HU was linked to significantly lower stone-free rates (26).
This study builds on these observations by showing that stone density remains an independent predictor even after adjusting for demographic, clinical, and treatment-related factors. This graded relationship indicates that stone density should not be treated as a binary threshold. Instead, it should be viewed as a continuous predictor, with progressively worse outcomes as density rises. Recent analytic techniques, such as CT-based radiomics, have shown promise in improving prediction accuracy (8, 13, 27). *Talyshinskii and colleagues* reported a pooled AUC of 0.883 for radiomics-based models predicting stone-free rates after ESWL, suggesting that machine learning analysis of stone heterogeneity may provide additional predictive insights beyond mean HU alone (28). *Lee and colleagues* similarly demonstrated that the stone heterogeneity index (SHI), defined as the standard deviation of Hounsfield units, was a better predictor for success in larger stones and for predicting clearance in a single session (29).
The mechanisms behind the density-success association are complex and extend beyond simple density measurements. While shock wave lithotripsy breaks stones by generating compressive and tensile stresses that exceed the stone's mechanical strength, the relationship between Hounsfield units and fragility is not always linear. Although high-density stones (e.g., calcium oxalate monohydrate, > 1000 HU) are predictably resistant to fragmentation, certain low-density stones paradoxically exhibit similar resistance. Cystine stones, for example, have mean densities of approximately 600-700 HU but demonstrate poor fragmentation due to their unique internal structure, specifically their microcrystalline architecture and inherent elasticity that dissipates shock wave energy rather than concentrating it at fracture planes (30, 31). In contrast, other low-density stones, such as uric acid or struvite, fragment readily due to their brittle composition and homogeneous internal structure. This complexity underscores that while stone density on CT provides valuable prognostic information, it should be interpreted alongside other characteristics when predicting ESWL outcomes.
Stone location was another independent predictor of clearance in our study. Stones in the middle calyx had significantly better outcomes than those in the lower calyx. This finding is consistent with previous studies. *Ghoneim and colleagues*, in a study of 205 patients with lower pole stones, found that a *lower pole infundibulopelvic angle* (L-IPA) was the most important factor in clearance. Angles of 70 degrees or greater and infundibular lengths under 50 mm predicted favorable outcomes (9). More recently, *Muhammad and colleagues* confirmed these results in 100 patients, showing that average L-IPA was significantly higher in stone-free patients and recommended ESWL as the first-line treatment when L-IPA exceeds 80 degrees (32). *Srisubat and colleagues* noted in a systematic review that lower pole stones had lower clearance rates after ESWL compared to stones in other kidney locations (4). The anatomical reason relates to drainage. After fragmentation, gravity-dependent drainage from the lower calyx is less effective compared to drainage from middle and upper calyces. Small fragments must be expelled against gravity, which may require extra efforts like percussion, diuresis, or inversion therapy (33).
The univariate associations of lower BMI, smaller stone size, and shorter skin-to-stone distance with better clearance in our study deserve attention. These factors did not remain significant after multi-variable adjustment, suggesting their effects may be influenced by stone density and location. A large meta-analysis by *Owen and colleagues*, which included 39 studies with 7,869 patients, confirmed that lower mean stone density, skin-to-stone distance, and stone size are all significantly associated with successful ESWL outcomes (34). *Pareek and colleagues* identified a skin-to-stone distance over 9 cm as a predictor of treatment failure (35). A recent analysis from the Czech Republic also demonstrated that multidimensional measures of stone burden (area and volume) predict stone-free rates with greater accuracy than single linear measurements (AUC 0.71 vs. 0.67, $p < 0.00$), suggesting that assessing volume may refine patient selection further (36).
Composite scoring systems have been created to combine these multiple predictors. *Ichiyanagi and colleagues* and *Saleh et al.* validated the Triple D Score, which includes Density, Distance, and Diameter, along with intrarenal location for predicting SWL success in 10-20 mm kidney stones (7, 8). Such tools may assist clinicians in weighing the importance of various factors when advising patients about expected outcomes.
These findings support using pretreatment CT with density measurement for all patients considered for ESWL, as this information can significantly aid in treatment selection and patient counselling. Patients with stone density over 1000 HU, especially those with unfavorable locations (lower calyx), unfavorable anatomy (narrow infundibulo-pelvic angle), or increased skin-to-stone distance (over 9 cm), should be informed about lower expected success rates and the possibility of needing mul-

tiple sessions or alternative treatments like flexible ureteroscopy or percutaneous nephrolithotomy.

Complications after ESWL were rare in this study, occurring in just 1.8% of patients. This low rate shows how safe modern lithotripsy can be when experienced operators perform the procedure. It is consistent with historical data showing hematoma rates of 0.66% to 3.8% based on patient risk factors (18, 19). However, two factors were strongly linked to complications in our analysis: low pain tolerance (OR 16.74, 95% CI 4.09 to 68.54, $p < 0.001$) and anticoagulation use (OR 59.31, 95% CI 3.53 to 997.2, $p = 0.004$).

The link between anticoagulation and complications is well-known. *Bourdoumis and colleagues* highlighted in a review that anticoagulants should be stopped five days before ESWL, and antiplatelet agents at least seven days prior (37). Bridging therapy is needed for high-risk patients. *Dhar and colleagues* also found anticoagulation as a predictor of hematoma in a multivariate analysis of 318 patients with overall incidence of 4.1% (38). The wide confidence interval around the odds ratio in our study (OR 59.31) reflects the small number of events ($n = 14$) and should be interpreted with caution, but it is consistent with established evidence. Current guidelines recommend ureteroscopy over ESWL if the thrombotic risk is considered too high to safely stop anticoagulation due to higher complications with ESWL (37).

Hypertension, deemed the main modifiable risk factor in the literature, did not reach statistical significance in our univariate analysis. In a landmark study of 3,620 patients, *Knapp and colleagues* reported that poorly controlled hypertension raised hematoma rates from a baseline of 0.66% to 3.8% (39). Similarly, *Kostakopoulos and colleagues* identified hypertension as a primary risk factor in their series of 4,247 patients (40). The lack of this association in our data may be due to the low overall event rate, differences in how blood pressure was recorded, or that our hypertensive patients were well-managed before treatment.

The link between low pain tolerance and complications in our study is noteworthy. Patients experiencing significant discomfort during the procedure may move, which can lead to treatment interruptions or early termination, affecting stone fragmentation. Additionally, pain could suggest inadequate pain control or unrecognized issues like subcapsular hematoma formation (10). The unexpected inverse association between the number of shock waves and complications in our data, where patients who had complications received fewer shock waves, likely indicates reverse causality. Procedures were probably stopped early due to complications or unbearable pain, rather than fewer shock waves being beneficial. This view is supported by the strong link between low pain tolerance and complications.

Other known risk factors from the literature, such as older age, obesity, diabetes, and vascular disease, were not significantly linked to complications in our group. This may again reflect the limited number of events. *Nussberger and colleagues*, using routine post-ESWL CT scans in 868 patients, found that subclinical hematomas happen in 15.4% of patients, which is much higher than the rates that are clinically recognized. They identified extreme BMI as a significant risk factor (41). This implies that the actual rate of ESWL-related kidney injury might be much greater than what is clinically acknowledged, and many hematomas can heal on their own without treatment.

Stepwise voltage ramping has been shown to be an effective protective factor, cutting hematoma rates by over 50% in both experimental and clinical studies (42). This approach, which starts with a small number of lower energy shock waves before giving therapeutic doses, is thought to cause vasoconstriction that limits bleeding injury. Our institutional protocol includes gradual power ramping, likely contributing to our low overall complication rate despite treating anticoagulated patients.

Clinicians should be alert when procedures are interrupted early, as this may indicate an underlying issue rather than just patient discomfort. Focused pain management during the procedure may lower the risk of complications and increase tolerance. Following anticoagulation management guidelines and optimizing blood pressure control before treatment are essential strategies to reduce ESWL complications.

Study limitations

There are some limitations to this study. First, the retrospective design introduces potential for selection bias and information bias, despite our efforts to ensure complete and accurate data gathering. Missing data for some variables, such as stone number (23.8% missing) and stone density (2.4% missing), may have caused bias and reduced statistical power for some analyses. Second, the study took place at one center, which may limit its applicability to other settings with different patient groups, equipment, or treatment methods. Third, we did not have stone composition for analysis since this information is not routinely taken from patients undergoing ESWL. Stone density from CT is used as a proxy, but it does not perfectly predict stone type. Fourth, the low complication rate, while reassuring, limited our ability to conduct multivariable analysis, leading to wide confidence intervals for estimates related to complications. Fifth, the definition of stone clearance at three months, while consistent with clinical practice, may not take into account delayed clearance or late recurrence. Sixth, complete case analysis for regression models reduced the sample size from 798 to 536 for the main analysis, which might introduce bias if missing data were not completely random. Seventh, the overwhelming male representation (99.6%) limits the relevance to female patients, and the specific cultural factors contributing to this imbalance might not be present in other regions. Eighth, we did not collect data on operator experience and specific lithotripter models, limiting our ability to adjust for these potential influences. Finally, factors regarding patient preferences and shared decision-making that impact treatment choices and repeat sessions were not captured due to the retrospective nature of the study.

Conclusions

Stone density is the strongest independent predictor of ESWL success, with a 2% decrease in clearance odds for every 100 HU increase. Stone location in the middle calyx is associated with significantly better outcomes than in the lower calyx. Univariate predictors such as lower BMI, smaller stone size, and shorter distance from skin to stone provide additional useful information for counselling patients, even if they didn't remain significant after multivariable adjustments. Complications are rare but more frequent in patients with low pain tolerance and those on anticoagulation. The significant male predominance in this cohort likely highlights a mix of cultural factors, healthcare-seeking behaviors, and referral patterns, underscoring the importance of culturally sensitive healthcare delivery. These findings support using CT with density measurement before treatment, improve patient counselling about expected outcomes, and help identify patients at higher risk for complications. ESWL continues to be a safe and effective option for well-selected patients with kidney stones.

Declarations

Ethical approval and consent for participate: *All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments. The study protocol was reviewed and approved by the Aden University Ethics Committee on March 12, 2024 (approval number 132).*

Consent for publication: *Given the retrospective nature of the study and the use of de-identified data, the requirement for informed consent was waived by the Aden University Ethics Committee.*

Availability of data and material: *The data supporting the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy and ethical restrictions.*

Competing interests: *The authors declare that they have no conflict of interest, financial or otherwise, relating to the publication of this manuscript. No competing interests exist that could influence the work reported in this paper.*

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- *Editing and language refinement: To improve clarity, grammar, and readability of the manuscript*
- *Formatting assistance: To structure tables and references according to journal guidelines*
- *Literature synthesis: To assist in summarizing and integrating relevant research findings*

After using this tool, the authors thoroughly reviewed and edited the content as needed and take full responsibility for the final content of the manuscript.

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