

Optimum Time for Extracorporeal Shock Wave Lithotripsy for Residual Stones after Percutaneous Nephrolithotomy: A Prospective Comparative Randomized Study

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Introduction

Percutaneous nephrolithotomy (PCNL) is considered the gold standard for the treatment of large renal stones (1). However, residual fragments (RFs) are not uncommon, occurring in 10–30% of cases (2). Management of these fragments is essential, as they may serve as a nidus for recurrent stone formation, infection, or obstruction (3).

Extracorporeal shock wave lithotripsy (ESWL) is often used for treating such residual stones, yet there is no consensus regarding the optimal timing of ESWL following PCNL (4,5). Early ESWL may facilitate stone clearance before fragments become embedded or encrusted but might increase the risk of bleeding or infection due to incomplete renal healing. Conversely, delayed ESWL allows for better renal recovery but may permit stone growth or recurrent symptoms (4,6).

This study aims to determine the optimal timing of ESWL after PCNL to achieve the highest stone-free rate with minimal complications.

Aim of the Work

Primary Objective:

To compare stone-free rates between early and delayed ESWL after PCNL.

Secondary Objectives:

To compare complication rates between the two groups.

Methodology

Type of the Study:

Prospective, randomized, comparative clinical study.

Site of the Study:

Urology Department, Beni-Suef University Hospital.

Duration of the Study:

From December 2025 till December 2026.

Study Population:

Patients who underwent PCNL and were found to have residual renal stones ≤ 15 mm on postoperative imaging (CT or ultrasound).

Sample Size Technique:

Random consecutive sampling based on eligibility.

Sample Size Calculation:

Using Chi-square test to detect a 10% difference in stone-free rate (SFR) between groups.

Based on prior data showing $\text{SFR} \approx 93\text{--}95\%$.

Required sample:

214 patients per group at 90% power, $\alpha = 0.05$.

After adding 10% dropout:

238 patients per group \rightarrow Total sample size = 476 patients.

Inclusion Criteria:

- Age 18–70 years.
- Single or multiple residual renal stones ≤ 15 mm after PCNL.
- Normal renal function (serum creatinine < 1.5 mg/dL).
- No active UTI.

Exclusion Criteria:

- Bleeding disorders or anticoagulant therapy.
- Obstructed drainage or active sepsis.
- Stones > 15 mm or requiring secondary PCNL.

Study Procedures / Tools:

Randomization:

Patients will be assigned into two equal groups: Total number of patients 476 patients and will be randomized to 238 patients per group →

Group A (Early ESWL): ESWL within 7–14 days after PCNL.

Group B (Delayed ESWL): ESWL after 3–4 weeks.

ESWL Protocol:

Same lithotripter model for all patients.

Sedation as needed.

Standardized energy and frequency according to EAU guidelines.

Maximum of 3 sessions.

Follow-Up:

Ultrasound or CT 2 weeks after final ESWL session.

Stone-free status = no fragments >2 mm.

Outcome Measures:

Primary:

Stone-free rate at 3 months.

Secondary:

Complications (hematuria, fever, infection).

Pain score (VAS).

Need for secondary intervention (URS or PCNL).

Statistical Analysis:

SPSS version 26.

Continuous variables: mean \pm SD, Student's t-test.

Categorical variables: percentages, Chi-square test.

$P < 0.05$ considered significant.

Ethical Consideration:

The study protocol will be reviewed and approved by the Research Ethics Committee, Faculty of Medicine, Beni-Suef University before conducting the study.

Sufficient time will be allocated to each patient and their family to explain the procedure in detail, including discussions with other patients who have previously undergone the same procedure.

A comprehensive explanation of the research project will be provided to all participants prior to enrolment.

Written informed consent will be taken from all study participants before enrolment in the study.

The study followed the Declaration of Helsinki for research ethics standards.

References:

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