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Platinum Priority – Stone Disease

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## Does Stepwise Voltage Ramping Protect the Kidney from Injury During Extracorporeal Shockwave Lithotripsy? Results of a Prospective Randomized Trial

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### Abstract

**Background:** Renal damage is more frequent with new-generation lithotripters. However, animal studies suggest that voltage ramping minimizes the risk of complications following extracorporeal shock wave lithotripsy (SWL). In the clinical setting, the optimal voltage strategy remains unclear.

**Objective:** To evaluate whether stepwise voltage ramping can protect the kidney from damage during SWL.

**Design, setting, and participants:** A total of 418 patients with solitary or multiple unilateral kidney stones were randomized to receive SWL using a Modulith SLX-F2 lithotripter with either stepwise voltage ramping ( $n = 213$ ) or a fixed maximal voltage ( $n = 205$ ).

**Intervention:** SWL.

**Outcomes measurements and statistical analysis:** The primary outcome was sonographic evidence of renal hematomas. Secondary outcomes included levels of urinary markers of renal damage, stone disintegration, stone-free rate, and rates of secondary interventions within 3 mo of SWL. Descriptive statistics were used to compare clinical outcomes between the two groups. A logistic regression model was generated to assess predictors of hematomas.

**Results and limitations:** Significantly fewer hematomas occurred in the ramping group (12/213, 5.6%) than in the fixed group (27/205, 13%;  $p = 0.008$ ). There was some evidence that the fixed group had higher urinary  $\beta_2$ -microglobulin levels after SWL compared to the ramping group ( $p = 0.06$ ). Urinary microalbumin levels, stone disintegration, stone-free rate, and rates of secondary interventions did not significantly differ between the groups. The logistic regression model showed a significantly higher risk of renal hematomas in older patients (odds ratio [OR] 1.03, 95% confidence interval [CI] 1.00–1.05;  $p = 0.04$ ). Stepwise voltage ramping was associated with a lower risk of hematomas (OR 0.39, 95% CI 0.19–0.80;  $p = 0.01$ ). The study was limited by the use of ultrasound to detect hematomas.

**Conclusions:** In this prospective randomized study, stepwise voltage ramping during SWL was associated with a lower risk of renal damage compared to a fixed maximal voltage without compromising treatment effectiveness.

**Patient summary:** Lithotripsy is a noninvasive technique for urinary stone disintegration using ultrasonic energy. In this study, two voltage strategies are compared. The results show that a progressive increase in voltage during lithotripsy decreases the risk of renal hematomas while maintaining excellent outcomes.

**Trial registration:** ISRCTN95762080

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## 1. Introduction

Introduction of the Dornier HM-3 lithotripter in the early 1980s for extracorporeal shockwave lithotripsy (SWL) revolutionized the treatment of urolithiasis [1]. Major urologic associations currently recommend SWL as first-line treatment for kidney stones <2 cm located in the pelvis or upper or middle calices [2,3]. In recent years, several new-generation lithotripters have been introduced, many of which are being used in clinical practice. Although SWL is generally considered a safe procedure, it is associated with postintervention renal hematomas in 0.5–13% of all cases according to prospective data [4–7]. Severe hematomas can initiate an inflammatory response, resulting in scar formation and damage to tubules with subsequent loss of functional renal mass [8].

Against this background, current research is dedicated to improving SWL treatment strategies to minimize the risk of hematomas while maintaining or improving clinical effectiveness. Porcine models have shown that stepwise voltage ramping can significantly reduce the extent of renal parenchymal hemorrhagic lesions [9]. To date, clinical evidence has come only from trials with a small number of participants and/or suboptimal study design [10–12].

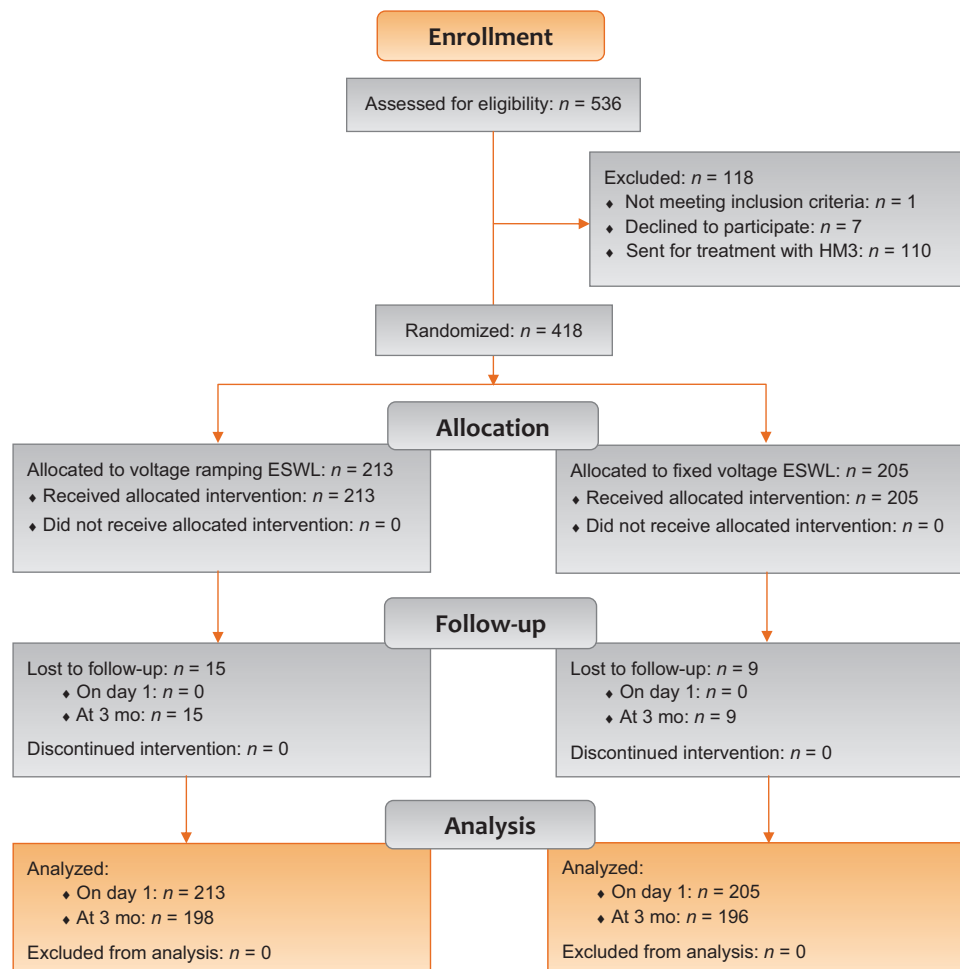
Notwithstanding their shortcomings, these studies suggest that voltage ramping is safe and may even confer a protective effect compared to fixed voltage treatment. However, data on the impact of voltage application on clinical effectiveness are conflicting [10–12].

To redress the deficiencies of previous studies, we conducted a well-powered, single-blinded, prospective randomized trial to evaluate the effect of stepwise voltage ramping on renal damage during SWL of kidney stones.

## 2. Patients and methods

### 2.1. Patients and randomization

From July 2010 to March 2013, 418 patients (296 males and 122 females)  $\geq 16$  yr of age requiring elective or emergency SWL were randomized without stratification by a software program to treatment using the Modulith SLX-F2 lithotripter (Storz Medical AG, Tragerwilen, Switzerland) with either stepwise voltage ramping or a fixed maximal voltage (Fig. 1). Unrestricted randomization was chosen because of the high number of patients to be recruited. Use of a password-protected computer database ensured allocation concealment until the intervention. Inclusion criteria were solitary or multiple unilateral radiopaque kidney stones <3 cm in diameter, ability to receive neuroaxial regional or general anesthesia, and informed consent. Exclusion criteria were a



**Fig. 1** – Consolidated Standards of Reporting Trials diagram enumerating the patients screened, randomized, allocated to each treatment arm, lost to follow-up, and included in the final analysis. HM3 = Dornier HM-3 lithotripter; ESWL = extracorporeal shockwave lithotripsy.

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