Optimization of Extracorporeal Shock Wave Lithotripsy Delivery Rates Achieves Excellent Outcomes for Ureteral Stones: Results of a Prospective Randomized Trial

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Abbreviations and Acronyms

BMI = body mass index

ECG = electrocardiogram

ESWL = extracorporeal SW lithotripsy

JJ = Double-J

SW = shock wave

URS = ureterorenoscopy

Accepted for publication January 30, 2015.

Study received Canton Bern ethics committee approval.

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Purpose: Management of ureteral stones remains controversial. To determine whether optimizing the extracorporeal shock wave lithotripsy delivery rate would improve the treatment of solitary ureteral stones we compared the outcomes of 2 delivery rates in a prospective randomized trial.

Materials and Methods: From July 2010 to October 2012, 254 consecutive patients were randomized to extracorporeal shock wave lithotripsy at a shock wave delivery rate of 60 and 90 pulses per minute in 130 and 124, respectively. The primary study end point was the stone-free rate at 3-month followup. Secondary end points were stone disintegration, treatment time, complications and the rate of secondary treatments. Descriptive statistics were used to compare end points between the 2 groups. The adjusted OR and 95% CI were calculated to assess predictors of success.

Results: The stone-free rate at 3 months was significantly higher in patients who underwent extracorporeal shock wave lithotripsy at a shock wave delivery rate of 90 pulses per minute than in those who received 60 pulses per minute (91% vs 80%, p = 0.01). Patients with proximal (100% vs 83%, p = 0.005) and mid ureteral stones (96% vs 73%, p = 0.03) accounted for the observed difference but not those with distal ureteral stones (81% vs 80%, p = 0.9, respectively). Treatment time, complications and the rate of secondary treatments were comparable between the 2 groups. On multivariable analysis the shock wave delivery rate of 90 pulses per minute, proximal stone location, stone density, stone size and an absent indwelling Double-J® stent were independent predictors of success.

Conclusions: Optimizing the extracorporeal shock wave lithotripsy delivery rate can achieve excellent results for ureteral stones.

Key Words: ureter, calculi, lithotripsy, high-energy shock waves, outcome and process assessment

Extracorporeal SW lithotripsy for stone disease using the HM-3 lithotripter (Dornier MedTech, Wessling, Germany) was introduced more than 30 years ago.[1] Since then, improvements in SW technology have been minimal and current devices fail to match the efficacy of the HM-3.[2–4] During this time endourological procedures, which offer the possibility of 1-time complete clearance, have become increasingly popular. Nevertheless, ESWL along with URS remains accepted treatment for

0022-5347/15/1942-0418/0
THE JOURNAL OF UROLOGY®
© 2015 by American Urological Association Education and Research, Inc.
http://dx.doi.org/10.1016/j.juro.2015.01.110
Vol. 194, 418-423, August 2015
Printed in U.S.A.

urolithiasis, including stones in the ureter.[5] In fact, depending on stone location and size ESWL may be the better option with the advantage of being a noninvasive procedure.

Recent research has focused on finding ways to make ESWL more effective. Optimizing lithotripter setting parameters, notably the SW delivery rate, may possibly improve treatment outcomes.[6] Several groups evaluated the impact of the SW delivery rate on kidney stone clearance by comparing delivery rates of 60 and 120 pulses per minute.[7–11] Most of these groups reported a better success rate in kidney stones using the lower SW delivery rate of 60 pulses per minute.[7-10] A recent meta-analysis of randomized trials found that SW delivery rates of 60 and 90 pulses per minute yielded better results than higher frequencies but suggested that 90 pulses per minute may be the optimal SW delivery rate because of the shorter treatment duration.[12]

We sought to extend these observations in the setting of ureteral stone disease, especially since data on the impact of SW delivery rates on ESWL efficacy in ureteral stones are sparse and inconsistent.[10,13,14] Therefore, we performed a large, prospective randomized trial comparing ESWL efficacy at 60 vs 90 pulses per minute using the modified HM-3 lithotripter for solitary ureteral stones.

MATERIALS AND METHODS

A total of 207 males and 53 females 18 years old or older with previously untreated, unilateral, radiopaque ureteral stones requiring elective or emergency ESWL were recruited at our department from July 2010 to October 2012. Four patients in whom it was technically impossible to localize the stone due to obesity on the day of intervention and 2 who refused to participate were excluded from study. Upon study entry each patient was randomly assigned by a computer based program without stratification to ESWL at a SW delivery rate of 60 vs 90 pulses per minute (group 1 of 130 patients vs group 2 of 124). Of these patients 14 were excluded from analysis due to loss to followup, including 3 in group 1 and 11 in group 2 (fig. 1). Patient baseline and stone characteristics were comparable in the 2 groups (supplementary table 1, http://jurology.com/). The study protocol was approved by the ethics committee of Canton Bern, Switzerland. The

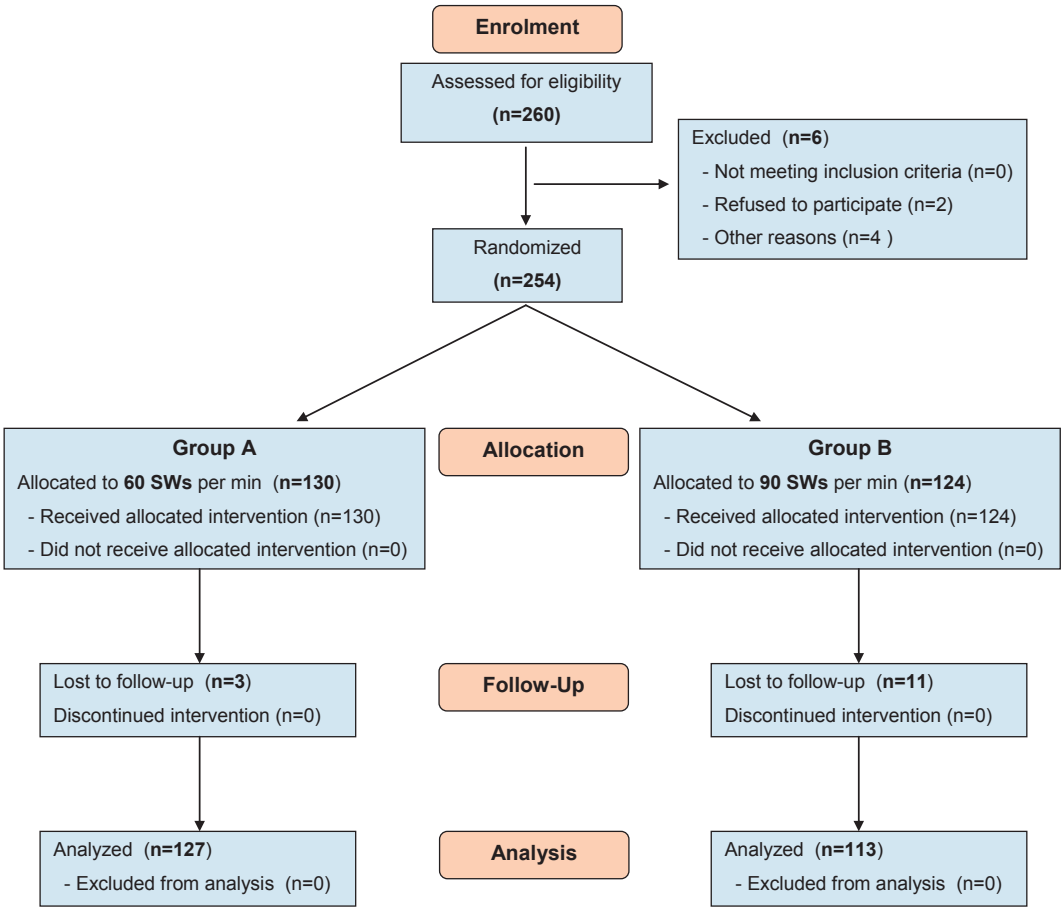

Figure 1. CONSORT diagram shows number of patients screened, randomized, allocated to each treatment arm, lost to followup and included in final analysis.

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