ORIGINAL RESEARCH

The effects of pretreatment oral hydration on extracorporeal shockwave lithotripsy outcomes

A randomized controlled trial

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ABSTRACT

INTRODUCTION: We sought to investigate the effects of pretreatment oral hydration on the outcomes of extracorporeal shockwave lithotripsy (ESWL).

METHODS: Patients who underwent ESWL for a single, radio-opaque, renal or proximal ureteric calculus ≤2 cm in size were randomized into two groups. The oral hydration group (OHG) was administered 600 ml of water before ESWL, while the control group (CG) was not. The urine was held during ESWL to create a full bladder-induced hydronephrosis. Both groups received the same ESWL protocol at four-week intervals and a maximum of three sessions. The primary outcome was stone-free rate (SFR) at 12 weeks and the secondary outcomes were the total number of shockwaves and the number of ESWL sessions.

RESULTS: A total of 154 patients completed the study — 77 patients in each group; both groups were comparable in demographic data and stone characteristics. The SFR was 84.4% in the OHG and 68.8% in the CG group (p=0.036). Stone fragmentation in the OHG was significantly higher than in the CG at 75.3% vs. 58.4% (p=0.040). The OHG had more cases of artificial hydronephrosis (55.8% vs. 27.3%, p=0.001) and higher urine volume (375 [148] ml vs. 230 [110] ml, p<0.001). There were no statistically significant differences in the total number of shockwaves and the number of ESWL sessions. The auxiliary procedures in the OHG were less than in the CG (15.6% vs. 31.2%, p=0.049).

CONCLUSIONS: Pretreatment oral hydration, together with holding urine during ESWL, has increased stone disintegration and SFR. This simple and safe technique improves the ESWL outcomes.

INTRODUCTION

The prevalence of urolithiasis has been increasing globally, posing a significant economic burden on healthcare systems.[1] The mainstay of treatment for upper urinary tract stones are extracorporeal shockwave lithotripsy (ESWL), ureteroscopy, and percutaneous nephrolithotomy. ESWL is considered first-line treatment for small stones because of its advantages as a non-invasive procedure that can be performed in an ambulatory setting, and its low complication rate;[2,3] however, ESWL has the disadvantages of a low stone-free rate (SFR) and repeated procedure may be necessary.

Factors affecting the successful treatment of ESWL, such as stone size, stone density, and skin-to-stone distance (SSD), have been published, but they are non-modifiable.[4] It is generally agreed that the efficacy of ESWL relies on its ability to break the stone into smaller fragments. One of the mechanisms underlying stone fragmentation is acoustic cavitation. Any method of increasing the fluid-stone interface improves the likelihood of the cavitation phenomenon.[5] Therefore, it is possible to enhance stone disintegration by increasing urine flow around the stone.

Previous studies have been reported that diuretics and intravenous fluid, as well as creating artificial hydronephrosis during ESWL enhance stone fragmentation and clearance.[6-16] Nevertheless, the relationship between oral hydration and the efficacy of ESWL has not been well-established. In this study, we aimed to investigate the effects of

KEY MESSAGES

- ESWL is the treatment of choice for small upper urinary tract calculi.
- Increasing urine flow creates a fluid-stone interface that improves the cavitation phenomenon, the main mechanism underlying stone fragmentation.
- Oral hydration and holding urine during ESWL have increased urine volume and induced mild hydronephrosis, resulting in better ESWL outcomes.

pretreatment oral hydration on the outcomes of ESWL in patients with upper urinary tract calculi.

METHODS

Study design and patient selection

A prospective, randomized, controlled trial was conducted between March 2023 and February 2024 at Ratchaburi Hospital, in Ratchaburi, Thailand. The protocol of this research was approved by the Human Research Ethic Committee of Ratchaburi Hospital (COA/COE-RBHEC 013/2023) and registered in the Thai Clinical Trials Registry (TCTR20240319002). Patients who were undergoing ESWL for upper urinary tract calculi were enrolled.

The inclusion criteria included adult aged ≥18 years old; solitary, radio-opaque, renal or proximal ureteric calculus; and stone size ≤2 cm. This study excluded patients with contraindications for ESWL (pregnancy, coagulopathy, untreated urinary tract infection, aortic aneurysm, and severe untreated hypertension), morbid obesity (body mass index ≥40 kg/m^2), kidney anomalies, moderate to severe hydronephrosis, ureteral stenting prior to ESWL, and incontinence.

After obtaining the written informed consent with guarantees of confidentiality, the patients that met the criteria were divided into two groups by stratified-blocked randomization using computer-generated 1:1 ratio (Figure 1).

Study procedures

The patients in the oral hydration group (OHG) were administered 600 ml of water one hour prior to each session of ESWL, while the patients in the control group (CG) were not. All patients were treated in an outpatient setting without anesthesia. The premedication included 1000 mg of paracetamol, 90 mg of etoricoxib (Arcoxia®), and 500 mg of ciprofloxacin or 400 mg of cefixime (Cefspan®) in case of fluoroquinolone allergy. These were taken with 30 ml of water before ESWL. No oral intake was allowed within three hours prior to ESWL except the water in the protocol. The bladder was emptied one hour before ESWL started, and the urine was held until ESWL finished in both groups.

An electromagnetic lithotripter (Lithostar Modularis, Siemens, Munich, Germany) was used for ESWL. The procedure was performed per the standard protocol of stepwise voltage ramping from 8 to 15 kilovolts at a rate of 60–90 shockwaves per minute. ESWL was continued until stone disintegration was seen or 4500 shockwaves were given. Patients whose stones did not fragment and patients who had stone fragments >4 mm were subjected to retreatment at four-week intervals and a maximum of three sessions. All patients in both groups followed the same protocol based on their randomization for the second and third session of ESWL.

Outcome measurements

At the first session of ESWL, renal ultrasound was performed by radiologists to evaluate hydronephrosis before and two hours after taking oral fluid and holding urine. The voided urine volume was recorded after ESWL was completed. A kidney-ureter-bladder radiography (KUB) was obtained and interpreted by radiologists to evaluate the stones at four, eight, and 12 weeks after ESWL. The radiologists involved in this study were blinded. Patient demographic data and stone characteristics were collected. Adverse events during the treatment and auxiliary procedures were also documented. The primary outcome was SFR at 12 weeks after ESWL. Stone-free was defined as a complete clearance of the stones or a presence of clinically insignificant residual fragments ≤4 mm in size on a KUB. The secondary outcome was the total number of shockwaves and the number of ESWL sessions.

Statistical analysis

The SPSS® version 21.0 (SPSS Inc., Chicago, IL, U.S.) was used. Continuous variables were described as mean with standard deviation (SD) or median with interquartile range (IQR), and the two groups were compared using t-test or Mann-Whitney U test. The categorical data were presented as numbers with percentages and were analyzed using Fisher's exact test

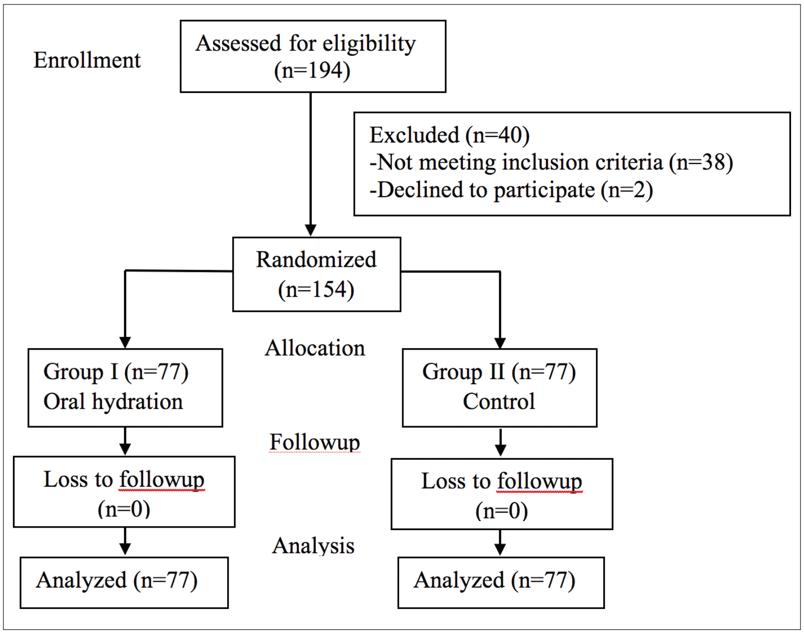

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram for patients flow through the study.

Table 1. Patient demographic data and stone characteristics

	Oral hydration group (N=77)	Control group (N=77)	p*
Age (years), median (IQR)	59.1 (16.6)	52.6 (26.0)	0.188
Sex (male), n (%)	42 (54.5)	44 (57.1)	0.871
BMI (kg/m²), median (IQR)	27.5 (6.9)	26.6 (2.7)	0.140
Stone side (right), n (%)	35 (45.5)	44 (57.1)	0.197
Stone size (mm), median (IQR)	11.0 (4.0)	12.0 (4.0)	0.510
Stone location, n (%)			
Renal pelvic	28 (36.4)	26 (33.8)	0.866
Upper calyx	18 (23.4)	19 (24.7)	1.000
Middle calyx	6 (7.8)	9 (11.7)	0.587
Lower calyx	17 (22.1)	15 (19.5)	0.843
Upper ureter	8 (10.4)	8 (10.4)	1.000
Stone density (HU), median (IQR)	1198.0 (383.0)	1139.0 (270.0)	0.182
SSD (cm), median (IQR)	8.9 (2.5)	8.8 (1.9)	0.187

*p-values are derived from the Mann-Whitney U test for continuous data and the chi-square test for categorical data. BMI: body mass index; HU: Hounsfield unit; IQR: interquartile range; SSD: skin to stone distance.

or Chi-squared test. Logistic regression analysis was performed to identify the independent predictors of treatment success. A two-sided p-value of <0.05 was considered statistically significant, and the confidence interval (CI) was calculated at 95%.

RESULTS

In all, 154 patients underwent ESWL for renal or upper ureteric calculi completed in this study (Figure 1). Table 1 presents demographic data of the patients and stone characteristics. Both groups were comparable in age, sex, body mass index, stone side, stone size (11 [4] mm in OHG vs. 12 [4] mm in CG, p=0.510), stone location, stone density (1198 [383] HU vs. 1139 [270] HU, p=0.182), and SSD (8.9 [2.5] cm vs. 8.8 [1.9] cm, p=0.187).

The outcomes of ESWL treatment are shown in Table 2. There were statistically significant differences between the two groups in stone disintegration (75.3% in the OHG vs. 58.4% in the CG, p=0.040) and size of stone fragments (7 [5] mm vs. 9 [5] mm, p<0.001). The baseline hydronephrosis was not different (23.4% vs. 26%, p=0.852), but the artificial hydronephrosis was developed more in the OHG than in the CG (55.8% vs. 27.3%, p=0.001). All of these were classified as mild degree of hydronephrosis. The urine volume was 375 (148) ml in the OHG and 230 (110) ml in the CG (p<0.001). The number of patients who were not able to tolerate and had to stop the procedure before the stone was broken or before reaching the maximum of 4500 shockwaves during the first session of ESWL was eight (10.4%) in the OHG and 10 (7.8%) in the CG (p=0.779).

The total number of shockwaves (9994±4160 shocks vs. 10024±3800 shocks, p=0.073) and the number of ESWL sessions (2 [2] sessions vs. 2 [2] sessions, p=0.240) were not different between the two groups. The 12-week SFR was significantly higher in the OHG compared to the CG (84.4% vs. 68.8%, p=0.036). The auxiliary procedures in the CG were 31.2%, which was approximately double that of the OHG (p=0.049). Four patients (5.2%) in the OHG and 12 patients (15.6%) in the CG, who had residual stone fragments ≤1 cm in size, proceeded with the fourth session of ESWL. Eight patients (10.4%) in the OHG and 12 patients (15.6%) in the CG, who failed after three sessions of ESWL, underwent retrograde intrarenal surgery (RIRS).

The adverse events in the OHG were rather less than in the CG, but no statistical significance was detected. Hematuria was the most common adverse effect (55.8% in the OHG vs. 59.7% in the CG, p=0.744), followed by renal colic (13.0% vs. 19.5%, p=0.382), and urinary tract infection (5.2% vs 10.4%, p= .367).

The multivariable logistic regression models (Table 3) demonstrated that the following predictive factors were associated with treatment success: stone size (odds ratio [OR] 0.733, 95% confidence interval [CI] 0.603–0.890, p=0.002), lower pole renal stone (OR 0.249, 95% CI 0.081–0.765, p=0.015), stone density (OR 0.994, 95% CI 0.991–0.998, p<0.001), SSD (OR 0.561, 95% CI 0.385–0.818, p=0.003), and mild hydronephrosis (OR 3.178, 95% CI 1.1017–9.931, p=0.047).

DISCUSSION

According to the European Association of Urology guidelines, ESWL is the treatment of choice for small upper urinary tract calculi. The success of ESWL depends on the efficacy of the lithotripter and the following factors: stone size, stone location, stone composition, patient's habitus, and performance of ESWL.[3] The efficacy of ESWL relies on its ability to pulverize stones into smaller fragments. The passage of a shockwave through substances of different acoustic impedance generates the energy that can overcome the tensile strength of the stone resulting in fragmentation.

Several potential mechanisms of stone disintegration have been described, such as tear and shear forces, spall fracture, squeezing-splitting, superfocusing, acoustic cavitation, and dynamic fatigue. Of these, acoustic cavitation plays an important role in stone comminution. It has been reported that increased urinary flow enables a higher possibility of cavitation.[5] Increasing urine flow creates a fluid-film interface between the stone and the collecting system, which facilitates the initial shockwaves to break the outer shell of the stone. Liquid then enters these small cracks and the actual disintegration occurrs later by the violent collapse of cavitation bubbles.[17]

Multiple studies have published the association between diuretics and the outcomes of ESWL. A meta-analysis from six randomized controlled trials (RTC) by Dong et al showed that patients who received diuretics during ESWL had significantly higher successful stone clearance rate, higher stone fragmentation rate, less average number of sessions, and similar average number of shocks per stone.[10] In parallel, Wang et al extracted data from four RTC and revealed that diuretics significantly enhanced stone fragmentation, reduced total numbers of shocks and sessions required, but stone clearance did not significantly differ;[11] however, the use of diuretics may cause undesirable side effects, including electrolyte imbalance, hypotension, and importantly but rarely, furosemide-induced anaphylaxis.

In 2022, Cheng et al retrospectively evaluated patients with ureteric calculi <2 cm in diameter treated with ESWL who received intravenous hydration with 500 ml of normal saline during the procedure. They

Table 2. The outcomes of ESWL treatment

	Oral hydration group (N=77)	Control group (N=77)	p*
The first session of ESWL			
Stone disintegration, n (%)	58 (75.3)	45 (58.4)	**0.040**
Fragmented stone size (mm)**	7 (5)	9 (5)	**<0.001**
Hydronephrosis, n (%)			
Before oral hydration	18 (23.4)	20 (26.0)	0.852
At 2 hours after oral hydration	43 (55.8)	21 (27.3)	**0.001**
Urine volume (ml)**	375 (148)	230 (110)	**<0.001**
ESWL intolerance, n (%)	8 (10.4)	6 (7.8)	0.779
After the third session of ESWL			
Total number of shockwaves, mean ± SD	9994±4160	10024±3800	0.073
Total number of sessions**	2 (2)	2 (2)	0.240
Stone-free rate, n (%)			
4 weeks	22 (28.6)	15 (19.5)	0.258
8 weeks	43 (55.8)	35 (45.5)	0.259
12 weeks	65 (84.4)	53 (68.8)	**0.036**
Auxiliary procedures, n (%)	12 (15.6)	24 (31.2)	**0.049**
ESWL	4 (5.2)	12 (15.6)	0.065
RIRS	8 (10.4)	12 (15.6)	0.472
Adverse events, n (%)			
Hematuria	43 (55.8)	46 (59.7)	0.744
Renal colic	10 (13.0)	15 (19.5)	0.382
Urinary tract infection	4 (5.2)	10 (10.4)	0.367
Stone street	0	0	
Renal hematoma	0	0	

*p-values are derived from the Mann-Whitney U test for continuous data and the Chi-squared test for categorical data. **Values are presented as median (interquartile range). Bold values denote statistical significance at a p<0.05. ESWL: extracorporeal shockwave lithotripsy; SD: standard deviation; RIRS: retrograde intrarenal surgery.

Table 3. Multivariable logistic regression models predicting treatment success

	Odds ratio*	95% CI	p**
Body mass index (kg/m²)	0.982	0.845-1.142	0.817
Stone size (mm)	0.733	0.603-0.890	**0.002**
Stone location: lower pole	0.249	0.081-0.765	**0.015**
Stone density (HU)	0.994	0.991-0.998	**<0.001**
Skin to stone distance (cm)	0.561	0.385-0.818	**0.003**
Mild hydronephrosis	3.178	1.1017-9.931	**0.047**

*Odds ratios for a one-unit change in this factor. **p-values are derived from binary logistic regression analysis. Bold values denote statistical significance at a p<0.05. CI: confidence intervals; HU: Hounsfield unit.

reported treatment success of 66.4%.[14] In comparison, our study found a higher SRF of 84.4% at 12-week followup in the OHG.

Hazar et al conducted a RCT to compare the outcomes in patients undergoing ESWL for lower calyceal stones between standard ESWL and receiving oral hydration before ESWL to induce mild hydronephrosis by a full bladder. The study performed ESWL in prone position and mild hydronephrosis was confirmed by ultrasound in all cases, without mention of the volume of oral fluid intake. They showed statistically significant differences in SFR (88% vs. 67%, p<0.001) and the number of shockwaves between the groups.[15]

Our study treated patients in the supine position and oral hydration was limited to 600 ml so that artificial hydronephrosis did not develop in every case. About half of the patients in the OHG and one-fourth of patients in the CG had mild hydronephrosis. The 12-week SFR was significantly higher in the OHG, but the total number of shockwaves was not significantly different in our study.

AbdelRazek et al assessed the effect of artificial hydronephrosis on the result of ESWL in preschool children with kidney stones. ESWL was performed under general anesthesia and hydronephrosis was created by using a ureteric catheter with fluid irrigation. The SFR was significantly in favor of the hydronephrosis group (94% vs. 86%, p<0.001), while the number of shocks was not statistically different.[16] These results were consistent with the findings from our study. On the other hand, the method we used to induce artificial hydronephrosis was less invasive.

Morse et al conducted a prospective trial in 35 healthy volunteers to determine whether vigorous oral hydration (20 ml/kg) causes hydronephrosis as determined by bedside ultrasound. They found that hydronephrosis occurred in 80% of the subjects.[18] Mann et al performed ultrasound in 72 healthy individuals drank 800 ml of water two hours before the examination. They reported that 13.9% had mild hydronephrosis and 2.8% had moderate hydronephrosis. The average voided urine volume was 834 ml for mild hydronephrosis and 1020 ml for moderate hydronephrosis.[19] These studies confirmed our results that oral hydration influenced the urine volume and induced transient hydronephrosis.

The mechanism of a full bladder causing hydronephrosis can be explained by the principle that bladder distension is associated with increased intravesical pressure and anatomical changes at the ureterovesical junction. Consequently, obstruction of urine flow and alteration of the ureteral peristaltic pattern occur. As a result, urine propulsion is compromised, leading to back pressure and dilatation of the collecting system of the kidney.

In this study, we postulated that oral hydration before ESWL and holding urine improves stone fragmentation and SFR in two ways: 1) by creating artificial hydronephrosis, the fluid-stone interface enhances the cavitation phenomenon; and 2) by expelling the stone fragments mechanically due to increasing urine flow. Multivariable logistic regression analysis supported that treatment success was strongly associated with mild hydronephrosis, which was a modifiable factor induced by a full bladder.

Oral hydration and holding urine technique is a safe, uncomplicated, non-invasive, and inexpensive method. Moreover, there is no risk of diuretic-related side effects, and no intravenous access required. Therefore, we recommend this technique for continent patients with upper urinary tract calculi treated with ESWL.

Limitations

Our study has several limitations. First, hydronephrosis was assessed with ultrasonography by experienced radiologists. Its quality was operator-dependent and subjective to interpretive error. Second, the urine volume was measured by voided volume, which may not represent the whole volume of urine in the bladder in the case of incomplete bladder emptying with high residual urine volume. Third, the procedure was performed without anesthesia, and so optimal pain control may be inadequate. Finally, the SFR was evaluated with a KUB only rather than computed tomography (CT), thus small stone fragments might have been missed.

Further investigation should test the association between the amount of oral fluid intake before ESWL and hydronephrosis to determine how much water patients should be administered. In addition, evaluating the SFR with a non-contrast CT would corroborate the results.

CONCLUSIONS

Pretreatment oral hydration, together with holding urine during ESWL, has increased urine volume and induced mild hydronephrosis, resulting in better stone disintegration and higher SFR in patients with upper urinary tract calculi. Therefore, we recommend this simple and safe technique to improve the ESWL outcomes.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

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This paper has been peer reviewed.

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