# 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 undergoing 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) administered 600 ml of water before ESWL, while the control group (CG) did 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 OHG was significantly higher than CG, 75.3% vs. 58.4% (p=0.040). OHG had more cases of artificial

**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 SWL have increased urine volume and induced mild hydronephrosis, resulting in better SWL outcomes.

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 OHG were less than 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 health care system.[1] The mainstay of treatment for upper urinary tract stones are extracorporeal shock wave lithotripsy (SWL), ureteroscopy, and percutaneous nephrolithotomy. SWL is considered as first-line treatment for small stones because of its advantages in truly non-invasiveness, ambulatory setting, and low complications.[2,3] However, SWL has the disadvantages of a low stone-free rate (SFR) and repeated SWL is necessary.

Factors affecting the successful treatment of SWL, such as stone size, stone density, and skin-to-stone distance (SSD) have been published, but they are nonmodifiable.[4] It is generally agreed that the efficacy of SWL relies on its ability to break the stone into smaller fragments. One of the mechanisms underlying stone fragmentation is acoustic cavitation. By 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.

The previous studies have been reported that diuretics and intravenous fluid as well as creating artificial hydronephrosis during SWL enhanced stone fragmentation and clearance.[6-16] Nevertheless, the relationship between oral hydration and the efficacy of SWL has not been well established. In this study, we aimed to investigate the effects of pretreatment oral hydration on the outcomes of SWL 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, 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 undergoing SWL 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 SWL (pregnancy, coagulopathy, untreated urinary tract infection, aortic aneurysm, and severe untreated hypertension), morbid obesity (BMI, body mass index ≥ 40 kg/m$^2$), kidney anomalies, moderate to severe hydronephrosis, ureteral stenting prior to SWL, 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 in a 1:1 ratio (figure 1).

**Study procedures**

The patients in the oral hydration group (OHG) administered 600 ml of water 1 hour prior to each session of SWL, while the patients in the control group (CG) did 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 SWL. No oral intake was allowed within 3 hours prior to SWL except the water in the protocol. The bladder was emptied 1 hour before SWL started, and the urine was held until SWL finished in both groups.

An electromagnetic lithotripter (Lithostar Modularis, Siemens, Munich, Germany) was used for SWL. The procedure was performed per the standard protocol of stepwise voltage ramping from 8 to 15 kilovolts at a rate of 60 to 90 shock waves per minute. SWL was continued until stone disintegration was seen or 4500 shock waves were given. Patients whose stones did not fragment and patients who had stone fragments > 4 mm were subjected to SWL retreatment at 4-week intervals and a maximum of 3 sessions. All patients in both groups followed the same protocol based on their randomization for the second and third session of SWL.

**Outcome measurements**

At the first session of SWL, 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 SWL was completed. A kidney-ureter-bladder radiography (KUB) was obtained and interpreted by radiologists to evaluate the stones at 4 weeks, 8 weeks, and 12 weeks after SWL. The radiologists who 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 SWL. 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 shock waves and the number of SWL sessions.

**Statistical analysis**

The SPSS® version 21.0 (SPSS Inc., Chicago, IL, USA) 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 or chi-squared test. Logistic regression analysis was performed to identify the independent predictors of treatment success. A two-sided p-value of < .05 was considered statistically significant, and the confidence interval was calculated at 95%.

**RESULTS**
In all, 154 patients underwent SWL for renal or upper ureteric calculi completed in this study (figure 1). The table 1 presents demographic data of the patients and stone characteristics. Both groups were comparable in age, sex, BMI, stone side, stone size [11(4) mm in OHG vs 12(4) mm in CG, p= .510], stone location, stone density [1198(383) HU vs 1139(270) HU, p=.182], and SSD [8.9 (2.5) cm vs 8.8 (1.9) cm, p= .187].

The outcomes of SWL treatment are shown in table 2. There were statistically significant differences between the two groups in stone disintegration (75.3% in OHG vs 58.4% in CG, p= .040) and size of stone fragments [7(5) mm vs 9(5) mm, p <.001]. The baseline hydronephrosis was not different (23.4% vs 26%, p= .852), but the artificial hydronephrosis was developed more in OHG than in CG (55.8% vs 27.3%, p = .001). All of these were classified into mild degree of hydronephrosis. The urine volume was 375(148) ml in OHG and 230(110) ml in CG, p < .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 shock waves during the first session of SWL was 8 (10.4%) in OHG and 10 (7.8%) in CG 9, p= .779.

The total number of shock waves (9994±4160 shocks vs 10024±3800 shocks, p= .073) and the number of SWL sessions (2(2) sessions vs 2(2) sessions, p= .240) were not different between the two groups. The 12-week SFR was significantly higher in OHG compared to CG (84.4% vs 68.8%, p= .036). The auxiliary procedure in CG was 31.2%, which was approximately doubled compared to OHG (p= .049). Four patients (5.2%) in OHG and 12 patients (15.6%) in CG, who had residual stone fragments ≤ 1 cm in size, proceeded with the fourth session of SWL. Eight patients (10.4%) in OHG and 12 patients (15.6%) in CG, who failed after 3 sessions of SWL, undergoing retrograde intrarenal surgery (RIRS). The adverse events in OHG were rather less than CG, but no statistical significance was detected. Hematuria was the most common adverse effect (55.8% in OHG vs 59.7% in CG, p= .744), followed by renal colic (13.0% vs 19.5%, p= .382), and urinary tract infection (5.2% vs 10.4%, p= .367), respectively.

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= .002], lower pole renal stone (OR 0.249, CI 0.081-0.765, p= .015), stone density (OR 0.994, CI 0.991-0.998, p< .001), SSD (OR 0.561, CI 0.385-0.818, p= .003), and mild hydronephrosis (OR 3.178, CI 1.1017-9.931, p= .047).

**DISCUSSION**
According to the European Association of Urology guidelines, SWL is the treatment of choice for small upper urinary tract calculi. The success of SWL depends on the efficacy of the lithotripter and the following factors: stone size, stone location, stone composition, patient's habitus, and performance of SWL.[3] The efficacy of SWL relies on its ability to pulverize stones into smaller fragments. The passage of a shock wave 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 shock waves to break the outer shell of the stone. Liquid then enters these small cracks and the actual disintegration is occurred later by the violent collapse of cavitation bubbles.[17]

Multiple studies have published the association between diuretics and the outcomes of SWL. A meta-analysis from 6 randomized controlled trials (RTC) by Dong et al. showed that patients who received diuretics during SWL 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 Z extracted data from 4 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 W retrospectively evaluated patients with ureteric calculi <2 cm in diameter treated with SWL and received intravenous hydration with 500 mL of normal saline during SWL. They reported treatment success of 66.4%.[14] In comparison, our study found a higher SRF of 84.4% at 12-week follow-up in OHG. Hazar et al. conducted a RCT to compare the outcomes in patients undergoing SWL for lower calyceal stones between standard SWL and receiving oral hydration before SWL to induce mild hydronephrosis by a full bladder. The study performed SWL 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 <.001) and the number of shock waves between the groups.[15] Our study treated differently in supine position and oral hydration was limited to 600 ml so that artificial hydronephrosis did not develop in every case. About half of patients in OHG and one fourth of patients in CG had mild hydronephrosis. The 12-week SFR was significantly higher in OHG, but the total number of shock waves was not significantly different in our study. AbdelRazek M assessed the effect of artificial hydronephrosis on the result of SWL in preschool children with kidney stones. SWL was performed under general anesthesia and hydronephrosis was created by using a ureteric catheter with fluid irrigation. The SFR was significantly in favor of hydronephrosis group (94% vs 86%, p <.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 J 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 M performed ultrasound in 72 healthy individuals who taking 800 ml of water 2 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 SWL 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 SWL.

**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 may be missed. Further investigation should test the associated between the amount of oral fluid intake before SWL and hydronephrosis to determine how much water should patients administer. In addition, the SFR evaluated with a non-contrast CT would corroborate the results.

**CONCLUSIONS**

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

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## FIGURES AND TABLES

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

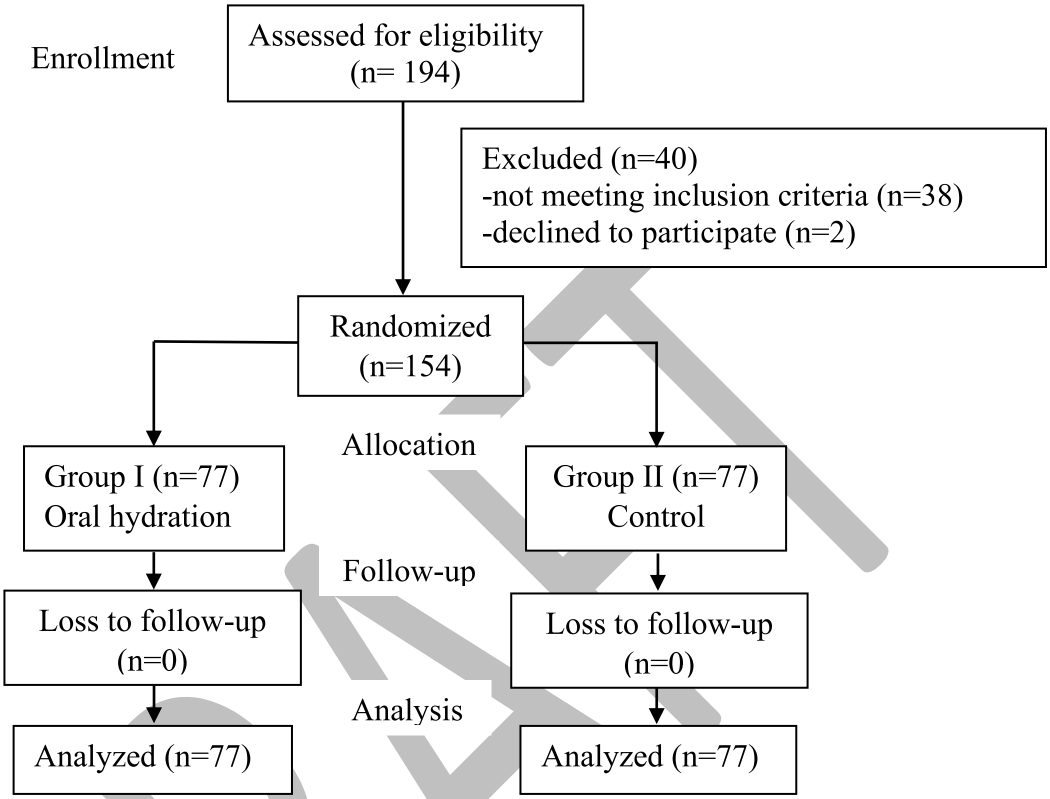


**Table 1. Patient demographic data and stone characteristics**

| | **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/m$^2$), 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.

**Table 2. The outcomes of SWL treatment**

| | **Oral hydration group (N=77)** | **Control group (N=77)** | **p*** |
|---|---|---|---|
| The first session of SWL | | | |
| 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** |
| SWL intolerance, n (%) | 8 (10.4) | 6 (7.8) | 0.779 |
| After the third session of SWL | | | |
| Total number of shock waves, 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** |
| SWL | 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. SWL: shockwave lithotripsy; SD: standard deviation; RIRS: retrograde intrarenal surgery.

**Table 3. Multivariable logistic regression models predicting treatment success**

| | **Odds ratio*** | **CI** | **p**** |
|---|---|---|---|
| Body mass index ($kg/m^2$) | 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.