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Facilitated Clearance of Small, Asymptomatic Renal Stones With Burst Wave Lithotripsy and Ultrasonic Propulsion

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Study Need and Importance: Recent studies suggest that new technologies may tilt the risk-benefit ratio toward intervention for asymptomatic stones to prevent future stone events. In the present paper, we test an investigational device that is an alternative to surgery for fragmenting and facilitating clearance of small (2-7 mm), asymptomatic renal stones in awake patients. Our office-based device images, breaks, and repositions stone fragments to facilitate their natural clearance using burst wave lithotripsy to fragment stones and ultrasonic propulsion to reposition fragments.

What We Found: Twenty participants with 31 stones received the research procedure with 7 undergoing a single repeat procedure. Twenty-two of 31 stones (71%) met the primary effectiveness outcome of no fragment > 2 mm on CT follow-up, with 17 of 31 stones (55%) reported as stone free (Table). Median stone volume reduction (IQR) was 100% (88%-100%).

Table. *Stone Outcomes*

	Stones (N = 31)
Primary end point: no fragments >2 mm on CT, No. (%)	22 (71.0)[a]
Lower pole stones	12 (60)
Interpolar stones	5 (100)
Upper pole stones	5 (83.3)
Stone free, No. (%)	17 (54.8)[a]
Reduction in stone volume, median (IQR), %	100 (88-100)

[a] Another participant was found to be stone free on annual follow-up imaging.

Limitations: Small calcifications that were treated and did not pass were likely small parenchymal or interstitial calcifications and plaques, which were demonstrated on ultrasound or CT but were not at immediate risk of a stone event. The study is small, which limits information related to generalizability of the data. For now, this ultrasound-based technology is not recommended where treatment has to penetrate ribs, as this diminishes the focal pressure. There is currently no restriction on patient BMI or stone density. Multiple transducers can be introduced to target stones over a range of skin-to-stone depths.

Interpretation for Patient Care: Burst wave lithotripsy followed by ultrasonic propulsion was used in a clinic setting to clear 71% of small renal stones targeted with minimal risk or discomfort to the awake study participants. Ultrasonic propulsion has been cleared by the Food and Drug Administration to facilitate passage of residual fragments, and burst wave lithotripsy is being tested in a pivotal trial.

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Facilitated Clearance of Small, Asymptomatic Renal Stones With Burst Wave Lithotripsy and Ultrasonic Propulsion

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Purpose: We tested feasibility of burst wave lithotripsy and ultrasonic propulsion to noninvasively fragment and expel small, asymptomatic renal stones in awake participants.

Materials and Methods: Adult patients suspected of having 2- to 7-mm stones were consented and screened for eligibility. Burst wave lithotripsy and ultrasonic propulsion were applied to up to 3 stones in 1 kidney of qualifying participants for a 30-minute total exposure. Participants completed a CT scan and the Wisconsin Stone Quality-of-Life (WISQOL) questionnaire within 90 days before and 120 days after the procedure. Participants were contacted weekly for 3 weeks after the procedure to assess adverse events (AEs). Outcomes included

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Conflict of Interest Disclosures: Drs Sorensen, Maxwell, Dunmire, and Bailey reported having equity in and consulting agreements with SonoMotion, Inc. No other disclosures were reported.

Ethics Statement: This trial received WCG Institutional Review Board approval (IRB No. 20210905).

Author Contributions:

Conception and design: Maxwell, Holmes, Dunmire, Levchak, Yang, Lingeman, Harper, Hall, Bailey.

Data analysis and interpretation: Desai, Holmes, Dunmire, Levchak, Yang, Thiel, Harper, Dighe, Bailey, Sweet, Wang.

Data acquisition: Desai, Holmes, Burke, Levchak, Popchoi, Yang, Thiel, Kucewicz, Harper, Hall, Sorensen, Bailey, Sweet, Totten, Wang.

Drafting the manuscript: Holmes, Levchak, Yang, Harper, Bailey, Totten.

Critical revision of the manuscript for scientific and factual content: Maxwell, Desai, Holmes, Burke, Dunmire, Popchoi, Yang, Lingeman, Thiel, Kucewicz, Harper, Hall, Dighe, Sorensen, Bailey, Sweet, Wang.

Statistical analysis: Holmes, Bailey.

Supervision: Maxwell, Desai, Holmes, Burke, Dunmire, Levchak, Popchoi, Yang, Lingeman, Thiel, Harper, Hall, Dighe, Sorensen, Bailey, Sweet.

Clinical training and overseeing new users: Thiel.

Data aquisition through ultrasound imaging: Thiel.

Hardware/software development: Kucewicz.

Technical support: Totten.

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(1) no fragment > 2 mm, (2) unanticipated health care visits, (3) change in stone volume, (4) reported AEs, and (5) WISQOL score.

Results: Forty-one participants were enrolled between April 2023 and October 2024. Twenty-one participants failed screening because no stones were seen, stones were too large or small, stone visibility was too deep or obstructed, or they declined to participate. Twenty participants with 31 stones received the research procedure with 7 undergoing a single repeat procedure. Twenty-two of 31 stones (71%) met the primary effectiveness outcome of no fragment > 2 mm, with 17 of 31 stones (55%) reported as stone free. Median stone volume reduction (IQR) was 100% (88%-100%). No participants returned unexpectedly for care related to the procedure. AEs were all grade I by modified Clavien classification. WISQOL scores improved on 10 of 15 completed questionnaires.

Conclusions: Small, asymptomatic renal stones were effectively and safely removed in awake participants in a clinic setting.

Key Words: kidney stones, ultrasound, lithotripsy

US and European guidelines recommend active monitoring instead of surgery for small, asymptomatic renal stones.[1-3] However, US and European guidelines cite several studies that asymptomatic renal stones and stone fragments have about a 50% potential to result in a stone-related event within 5 years.[2,3] In addition, many patients have significant anxiety in observing small stones that would likely be symptomatic when they pass.

Recent studies suggest that new technologies may tilt the risk-benefit ratio toward intervention for asymptomatic stones to prevent future stone events. A previous randomized controlled trial (RCT) reported that removal of secondary, small, asymptomatic renal stones during surgery for a primary stone reduced stone-related relapse events by 82%.[4] Another previous RCT reported that ultrasonic propulsion to facilitate passage of residual stone fragments < 5 mm reduced relapse by 70% with only nonsignificant transient AEs reported.[5]

In this study, we test an investigational device that is an alternative to surgery for fragmenting and facilitating clearance of small (2-7 mm), asymptomatic renal stones. Our office-based ultrasound system images, breaks, and repositions stone fragments to facilitate their natural clearance using burst wave lithotripsy (BWL) to fragment stones and ultrasonic propulsion to reposition fragments.[6,7] Both technologies have been tested in a series of preclinical and clinical studies and are well tolerated by awake study participants, without anesthesia.[4,8-16] An ultrasonic urinary stone propulsion device has recently been cleared by the FDA (US Food and Drug Administration) for the repositioning of residual stone fragments after lithotripsy.[17] This study reports on the first human feasibility study of using both technologies together to clear small, asymptomatic renal stones.

MATERIALS AND METHODS

This study was a prospective, investigator-initiated, open-label, feasibility study (ClinicalTrials.gov, NCT04796792). The trial was approved by the WCG-IRB Institutional Review Board (#20210905). The investigational device was made by the University of Washington team, and the investigational device exemption, approved by the FDA, was sponsored by a University of Washington investigator.

Eligibility Criteria

We enrolled ambulatory, English-speaking participants older than 18 years with small stones identified on any imaging. Stone characteristics were confirmed by CT within 90 days before the investigational procedure, if not obtained already, and participants were excluded if their stone was ≤ 2.0 mm or > 7.0 mm. We excluded participants with a bleeding disorder or coagulopathy or who could not pause anticoagulant medications, those with an untreated UTI, solitary kidney, current pregnancy, participants with a calcified abdominal aortic aneurysm or ipsilateral calcified renal artery aneurysm, or physician exclusion because of comorbidity risk that would make them a poor candidate for the investigational procedure.

Procedures

We performed a screening ultrasound examination with the investigational device on all participants to confirm an ultrasonic view of stones within the target depth (4-9 cm from skin surface) unobstructed by the rib or bowel. Participants without stone visualization were excluded. A urinalysis was obtained within 30 days of the investigational procedure, and any infections were treated. When appropriate, pregnancy tests were also conducted before use of the investigational device. The Wisconsin Stone Quality-of-Life (WISQOL) examination was administered online or in person within 90 days of the investigational procedure.

On the treatment day, participants were encouraged to drink fluids before and after the study. Pain was assessed from 0 (no pain) to 10 (maximum pain) before and after the investigational procedure, and the participants' skin at the ultrasound transducer site was observed before and after the procedure. During the procedure, participants underwent continuous cardiac monitoring. Participants were engaged to modulate their breathing pattern to maintain the stone in the ultrasound focus, during which time therapy was delivered and then repeated. All participants voided during the session to measure for hematuria.

We contacted participants weekly for 3 weeks after the procedure to assess for adverse events (AEs). AEs were queried using a script of 10 common surgery and stone-related symptoms, along with any other reported events.[18] CT imaging was obtained within 120 days after the procedure to detect hydronephrosis or hematoma and to measure residual fragment size. A second WISQOL questionnaire was obtained at approximately 120 days after the procedure. Participants could undergo a single re-treatment of any residual fragments $>$ 2 mm.

Stone volume before and after was calculated from the 3-axis measurement of stone size from the CT examinations assuming an ellipsoid. CT stone density, which was based on the average Hounsfield units, was measured in the axial plane by a circle or oval filling the stone. Hematuria was graded by color on a 0-10 scale.[19] An independent radiologist blinded to the treatment parameters adjudicated the imaging data, and an independent data safety monitoring board of 3 urologists and a statistician adjudicated the safety data blinded to patient identification. A stopping rule was in place if any device-related significant AEs were detected. As part of their standard clinical care, all participants were offered metabolic evaluation and education on appropriate dietary, medical, and fluid consumption interventions for stone prevention.

Intervention

The investigational device included a central, in-line commercial imaging transducer coaxially aligned with a surrounding, 65-mm diameter, annular therapy transducer.[7] The entire assembly was hand-held. The device operated similarly to a diagnostic ultrasound instrument. Gel and transducer were placed against the participant's skin, and the target was visualized with conventional ultrasound imaging techniques and positioned within the target zone. Separate transducers were available depending on the stone depth and stone size.

When triggered by an operator-controlled switch, BWL or ultrasonic propulsion pulses were applied. BWL pulses were at a nominal frequency of 380 kHz or 650 kHz, at a pulse repetition rate of 10 Hz, and contained 20 to 50 cycles. The pulse amplitude ranged from 4 to 8 MPa in situ. The higher, 650-kHz, frequency transducers were used on stones or fragments estimated to be 3 mm or smaller.[20] Ultrasonic propulsion pulses were at a nominal frequency of 380 or 650 kHz, at a pulse duration up to 25 ms, and at a duty factor of 25% or 50%. The pulse amplitude ranged from 1.2 to 2.4 MPa in situ (50-200 W/cm^2 in intensity). A single ultrasonic propulsion pulse ensemble could be delivered up to 3 seconds. The combination of BWL and ultrasonic propulsion pulses could be delivered up to a total exposure of 30 minutes.

The therapy pulses were interleaved with imaging pulses for real-time image guidance. Ultrasonic propulsion pulses at the lower settings were delivered approximately every 5 minutes of BWL delivery with the intent to stir-up but not displace fragments. Once the BWL portion of treatment was felt to be complete, a final series of ultrasonic propulsion pulses at higher settings were delivered to push the fragments toward and into the ureter to facilitate passage and to assist with end point determination.

Up to 3 stones in 1 kidney could be targeted in a single 30-minute session. Participants were most often positioned in a lateral decubitus position and the transducer on their abdomen under the ribs; however, several participant and transducer positions were used during the study. Toward the end of the treatment session, the participant often was positioned in mild Trendelenburg (head down) while delivering ultrasonic propulsion pulses to aid in fragment clearance from lower pole calyces.[21]

Outcomes

The primary effectiveness end point was the number of stones absent or $\leq$ 2 mm on postprocedure CT imaging. Other outcomes included (1) occurrence of unanticipated health care visits related to the procedure, (2) change in stone volume between pre- and post-CT imaging, (3) all reported AEs, and (4) change in WISQOL score after vs before the procedure. Hematuria score, pain level before and after the procedure, tolerance and completion of the procedure, and cardiac arrythmias correlated with BWL pulses were also noted.

Statistical Analysis

Sample size was duplicated from previous feasibility studies; no formal power analysis was conducted. Descriptive statistics were used to tabulate the results.

RESULTS

Participant Disposition and Baseline Characteristics

The trial was conducted from April 3, 2023, through October 21, 2024. A total of 41 participants were enrolled (Figure). Twenty-one participants were withdrawn from the study for the reasons listed. Complete end point data were available from all participants except for 3 participants who failed to complete either the preprocedure or postprocedure WISQOL questionnaire.

Twenty participants and 31 stones received the research procedure (Table 1). There were no Hispanic participants. Otherwise, the group was representative of the population following up from

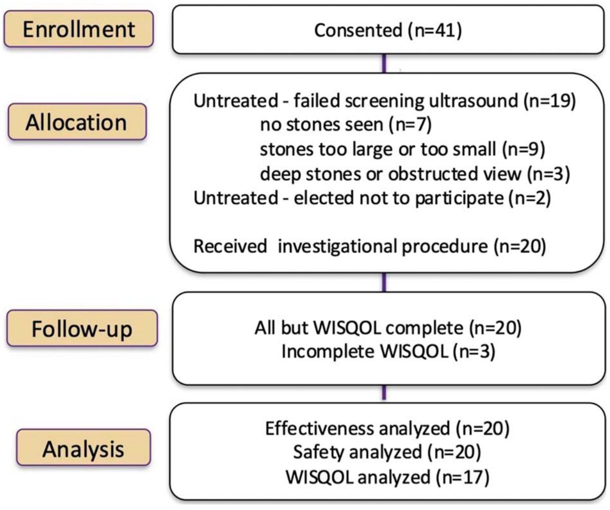

Figure. Enrollment. WISQOL indicates Wisconsin Stone Quality-of-Life.

Table 1. *Baseline Clinical Characteristics*

	Participants (N = 20)	
Age, median (IQR), y	47	(35-60)
Female sex, No. (%)	9	(45)
Left side, No. (%)	11	(55)
Race, No. (%)		
White	15	(75)
Black/African American	2	(10)
Asian	3	(15)
BMI, median (IQR), kg/m^2	25.2 (22.7-26.4)	
Stone composition, No. (%)		
Calcium oxalate	7	(35)
Calcium phosphate	2	(10)
Unknown	11	(55)
CT density, median (IQR)[a], HU	538	(437-748)
Stone dimension, median (IQR)[a], mm	5.5	(4.5-6.1)
	Stones (N = 31)	
Lower pole location, No. (%)	20	(64.5)
Interpolar location, No. (%)	5	(16.1)
Upper pole location, No. (%)	6	(19.4)
CT density, median (IQR)[b], HU	455	(341-730)
Stone dimension, median (IQR)[b], mm	4.7	(3.5-5.7)

Abbreviations: HU, Hounsfield units.
Data were obtained from the participants' medical records.
[a] Largest stone per participant.
[b] Every treated stone.

stone surgery (Supplementary Material: Table S1, https://www.jurology.com).

Outcomes

The primary effectiveness end point was met in 22 of 31 stones (71.0%; Table 2) and 12 of 20 participants (60%). These primary results include 6 of 8 participants (75%) with multiple stones achieving success, and of the 7 re-treated participants, 3 (43%) achieved the primary end point. All stones showed a reduction in volume. Stone fragmentation and repositioning could be observed with the real-time ultrasound imaging, as shown in the Supplementary (recorded) Video.

No participants returned for care because of the device or procedure. All AEs were self-resolving and classified as Clavien-Dindo grade I (Table 3). No treatments were stopped early, and no cardiac arrythmias related to the procedure were observed. There were no emergency department visits due to any stone-related symptoms. One participant with a history of UTIs was given antibiotics after the procedure despite a negative urinalysis. Four participants reported mild increase in pain from 0 to 0.5, 2, 2, and 3 (on a scale of 10) after the procedure and 1 participant reported a decrease in pain from 5 to 4. No cases of hydronephrosis or hematoma were identified in the follow-up imaging.

Table 2. *Stone Outcomes*

	Stones (N = 31)	
Primary end point: no fragments >2 mm, No. (%)	22	(71.0)[a]
Lower pole stones	12	(60)
Interpolar stones	5	(100)
Upper pole stones	5	(83.3)
Stone free, No. (%)	17	(54.8)[a]
Reduction in stone volume, median (IQR), %	100 (88-100)	

[a] Another participant was found to be stone free on annual follow-up imaging.

Table 3. *Participant Outcomes*

	Participants (N = 20)	
Primary safety end point: return for care, No. (%)	0	
Significant adverse events or Clavien-Dindo grade >I, No. (%)	0	
AEs (Clavien-Dindo grade I), No.[a] (%)[b]	18	(90)
Potentially device-related AEs (mild, grade I), No.[a] (%)[b]		
Hematuria	16	(80)
Pain	11	(55)
Nausea	2	(10)
Skin bruise	2	(10)
Vomiting	1	(5)
Urinary frequency	1	(5)
Constipation	1	(5)
Hematuria score, median (IQR)	2 (0.75-4)	
Improvement on WISQOL, No. (%)	10[c]	(66.7)[a]

Abbreviations: AEs, adverse events; WISQOL, Wisconsin Stone Quality-of-Life.
[a] Seventeen participants completed both the preprocedure and postprocedure Wisconsin Stone Quality-of-Life questionnaire.
[b] Participants could have more than 1 adverse event.
[c] One participant showed no change and 4 showed worse scores.

DISCUSSION

BWL and ultrasonic propulsion were successful in fragmenting and clearing small kidney stones, in awake participants in a clinic setting. Seventy-one percent of treated stones were comminuted to ≤ 2 mm fragments or to stone free as demonstrated on postprocedure CT. Three of 7 re-treatments met the outcome, which may indicate that a longer treatment or a shift in dose parameters could lead to even higher success rates. In addition, the procedure was tolerated by all participants without anesthesia or medication. There were no serious AEs, and all AEs were transient Clavien grade I events. Only 4 of these generally asymptomatic participants reported any increase in discomfort immediately after treatment. One participant reported discomfort for shorter than 48 hours with fragment passage but did not present to the emergency department.

There is no direct comparison of effectiveness outcome to the standard of care because this study included stones not typically indicated for stone surgery. The median stone size at the participant level was slightly below 6 mm, which is commonly the threshold size for surgery because smaller stones are more likely to spontaneously pass. As noted in the Introduction though, US and European guidelines report that asymptomatic renal stones and stone fragments not indicated for surgery have approximately a 50% potential to relapse within 5 years. The end point of ≤ 2.0 mm residual fragments on CT is a stringent standard not commonly used but potentially appropriate for small stones. The risk is that the apparent small stones are actually small parenchymal or interstitial calcifications and plaques, which are demonstrated on ultrasound but are not at immediate risk of a stone event. Finally, 65% of the stones treated were lower pole, and not surprisingly, the success in this group was lower, similar to standard-of-care procedures. Given these qualifiers, in comparison, the reported success rate for shock wave lithotripsy measured by varying metrics is 30% to 70% for kidney stones of various sizes.[1,3]

The trial was constructed as a short-term feasibility study, in anticipation of a larger efficacy trial. There was no control group, and we do not know whether treated or untreated participants would have gone on to require additional care or surgery or would have spontaneously passed their stones. The study is small, but for its size, had good demographic representation. The safety data added to a database of now over 200 study participants who have undergone a procedure with these investigational technologies without a serious AE. Although arrythmias are associated with up to 20% of shockwave lithotripsy procedures,[18] none have been reported with BWL. In addition, although not a focus of this study, the technologies have been tested by several users including sonographers, urologists, and emergency medicine doctors. The results suggest there is a potential to prophylactically treat asymptomatic small renal stones with little risk and reasonable expectations of success. The next phase of testing will include an RCT and a separate study of treating small, asymptomatic renal stones in a spinal cord injury population. If ultimately demonstrated to be effective in a larger cohort, the combined therapies of BWL and ultrasonic propulsion could be a safe and noninvasive treatment option to minimize the morbidity of kidney stones.

CONCLUSIONS

BWL followed by ultrasonic propulsion was used in a clinic setting to clear 71% of small renal stones targeted with minimal risk or discomfort to the awake study participants.

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