Decreased Radiation Exposure and Increased Efficacy in Extracorporeal Lithotripsy Using a New Ultrasound Stone Locking System

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Abstract

Purpose: To compare fluoroscopy duration, radiation dose, and efficacy of two ultrasound stone localization systems during extracorporeal shockwave lithotripsy (SWL) treatment.

Patients and Methods: Monocentric prospective data were obtained from patients consecutively treated for renal stones using the Sonolith[®] i-sys (EDAP TMS) lithotripter, with fluoroscopy combined with ultrasound localization using an “outline” Automatic Ultrasound Positioning Support (AUPS) (group A), or the “free-line” Visio-Track (VT) (EDAP-TMS) hand-held three-dimensional ultrasound stone locking system (group B). Efficacy rate was defined as the within-groups proportion stone free or with partial stone fragmentation not needing additional procedures. Statistical analysis used Pearson chi-square tests for categorical variables, non-parametric Mann-Whitney tests for continuous variables, and linear regression for operator learning curve with VT. Continuous variables were reported as median (range) values.

Results: Patients in group A (n=73) and group B (n=81) were comparable in baseline characteristics (age, kidney stone size, others) and in SWL application (duration, number of shocks, energy [Joules]). During SWL, the median (range) duration (seconds) of radiation exposure was 159.5 (0–690) in group A and 3.5 (0–478) in group B ($P<0.001$) and irradiation dose (mGy.cm²), 10598 (0–54843) in group A and 163 (0–13926) in group B ($P<0.001$). Fluoroscopy time significantly decreased with operator experience using VT. The efficacy rate was 54.5% in group A and 79.5% in group B ($P=0.001$).

Conclusion: VT significantly reduced fluoroscopy use during SWL and the duration and dose of patient exposure to ionizing radiation. Stone treatment efficacy was significantly greater with VT mainly because of a better real-time monitoring of the stone.

Introduction

SHOCKWAVE LITHOTRIPSY (SWL) is the most widely used treatment for patients with uncomplicated urinary stones <20 mm.¹ Introduced into clinical use in the early 1980s, SWL dramatically altered the management of urinary tract stones by eliminating the need for open surgery in most cases, along with the morbidity, complications, and convalescent period associated with invasive interventions of stones.² As a noninvasive intervention with few side effects and excellent stone clearance efficacy, SWL has broad patient and urologist acceptance.^{3,4}

SWL necessitates the use of imaging technologies for precise stone localization and targeting of shockwave delivery. While fluoroscopy and ultrasonography can both be used as imaging modalities, fluoroscopy is most frequently employed. Widely used since the introduction of urolithiasis

management and easy to operate and interpret, fluoroscopy remains the standard stone localization modality. Fluoroscopic imaging emits ionizing radiation, and efforts to reduce radiation exposure resulted in combining ultrasonography with fluoroscopy for imaging during SWL.

Ultrasonography is conventionally performed using an ultrasound probe attached to the lithotripter. The limited movement of the conventional ultrasound probe renders its use cumbersome and difficult, thus ultrasonographic imaging is generally limited to SWL in nonradiopaque stones.

Given the concerns over patient and medical staff exposure to radiation during fluoroscopy, and the limitations of conventional ultrasonographic imaging, we assessed the utility of a new three-dimensional ultrasound stone locking system in reducing fluoroscopy duration, decreasing radiation dose, and increasing stone fragmentation efficacy as an imaging and stone localization modality during SWL.

Patients and Methods

The objective of this study was to compare two different kinds of combined localization systems in terms of fluoroscopy duration, radiation dose, and efficacy rate. Patients were treated using the Sonolith[®] i-sys (EDAP TMS) lithotripter with fluoroscopy combined with two different ultrasound localization means: An “outline” Automatic Ultrasound Positioning Support (AUPS) versus the “free-line” Visio-Track (VT, EDAP-TMS), a hand-held three-dimensional (3D) ultrasound stone locking system (Fig. 1).

Prospective data were obtained from patients consecutively treated with SWL for renal stones in a university hospital by eight different operators on the same lithotripter system. This study is naturalistic, because it captures real world patient care

in a urologic clinic before and after the introduction of a new imaging technology. Thus, analysis was performed comparing patients treated with SWL from September 2009 to March 2012 using fluoroscopic + AUPS imaging (group A), and patients treated with SWL from April 2012 to January 2014 using fluoroscopy + VT imaging (group B).

Stone localization systems and procedure

All study patients received SWL using the Sonolith i-sys lithotripter. The Sonolith i-sys incorporates electroconductive technology, the most recent advance in shockwave generation.

In group A, fluoroscopy and ultrasonography with AUPS were used for imaging and stone localization during SWL (Fig. 1a). After patient scanning by robotized radiography,

FIG. 1. Stone localization systems: Automatic Ultrasound Positioning Support (AUPS) and Visio-Track. (a) AUPS configuration; (b) Visio-Track configuration.

the physician pointed the localized stone shown on the touch screen display of the fluoroscopic image. The motorized patient support table automatically positioned the stone to the focal point, with automatic alignment between patient, stone, and focal point designed to reduce fluoroscopy duration. Ultrasonographic stone localization was performed with an AUPS, attached to the lithotripter.

Movement of the system is isocentric with F2 focal point, motorized and instrumented, and allows the ultrasound probe to directly contact the skin. Requirement of a motorized system to adjust the ultrasound probe location imposes substantial limitations in mobility and movement on the imaging system and have restricted its use to nonradiopaque stones. With direct skin contact but a fixed-position ultrasound system, the AUPS is termed outline.

In group B, imaging and stone localization during SWL were performed by fluoroscopy and the VT ultrasound localization system. Components of the VT include an ultrasound system, a fixed stereotactic camera on the lithotripter, optical landmarks on patient support, SWL generator, and also on the ultrasound probe (Fig. 1b). The camera locates each component with guidance from all optical landmarks.

With unrestrained movement, the probe is held by the physician to localize the kidney and stone. When the stone is detected, the ultrasonographic image is frozen, and the exact 3D position of the transducer is memorized. The physician points on the localized stone image shown by the touch screen display, and the motorized patient support table automatically positions the patient for optimal alignment of

stone and focal point. The ultrasound transducer is then fixed on a support, and placed in direct contact with patient skin to facilitate treatment monitoring in real time. With fragmentation monitored throughout treatment, patient position can be readjusted at any point. If needed, simultaneous imaging with fluoroscopy and ultrasonography can be performed without stopping treatment.

Statistical analyses

Fluoroscopy duration and radiation dose during SWL were quantified with built-in measures of time and radioisotope output. Success rate was defined as stone free or partial stone fragmentation without the need for additional procedures.

Statistical analysis of categorical variables was performed using the Pearson chi-square test to compare distributions between the two groups (AUPS vs VT). Except for age (normal distribution), analysis of continuous variables was performed using nonparametric Mann-Whitney tests, because these variables were not assumed to follow normal distribution. Median (range) was presented for these variables. A linear regression was used to model the operator learning curve for the VT group. A *P* value of <0.05 was considered statistically significant. Statistical analysis was performed using SPSS statistical software.

Results

A total of 154 patients received SWL with either AUPS (group A; *n*=73) or VT (group B; *n*=81). Median (range)

TABLE 1. PATIENT DEMOGRAPHIC AND STONE CHARACTERISTICS

Variable (as mean $\pm$ SD [median; range] unless otherwise stated)	Group A (AUPS; <i>n</i> =73)	Group B (VT; <i>n</i> =81)	Mean A + B	P value
Age	53.8 $\pm$ 14.9 (53.7; 22–82)	52.2 $\pm$ 14.9 (55.4; 15–78)	53.1 $\pm$ 14.9 (54.9; 15–82)	0.541
Sex (<i>n</i> , percent)				
Male	38 (52.1%)	45 (55.6%)	53.9%	0.663
Female	35 (47.9%)	36 (44.4%)	46.1%	
Side of stone (<i>n</i> , percent)				
Right	44 (45.8%)	39 (40.6%)	83 (43.2%)	0.466
Left	52 (54.2%)	57 (59.4%)	109 (56.8%)	
Stone location, anatomy (<i>n</i> , percent)				
Upper calix	15 (15.6%)	9 (9.4%)	24 (12.5%)	0.049
Middle calix	18 (18.8%)	28 (29.2%)	46 (24.0%)	
Low calix	37 (38.5%)	43 (44.8%)	80 (41.7%)	
Renal pelvis	14 (14.6%)	13 (13.5%)	27 (14.1%)	
Pyeloureteral junction	12 (12.5%)	3 (3.1%)	15 (7.8%)	
Stone size pre-SWL #1 (mm)	10.3 $\pm$ 4.0 (10; 4–25)	9.9 $\pm$ 3.5 (10; 4–20)	10.1 $\pm$ 3.8 (10; 4–25)	0.660
Stone size post-SWL #2 (mm)	9.1 $\pm$ 2.9 (8; 5–15)	11.1 $\pm$ 3.4 (10; 6–160)	10.0 $\pm$ 3.2 (10; 5–16)	0.133
SWL duration (min)	63.1 $\pm$ 16.6 (60.3; 11.1–143.3)	60.5 $\pm$ 15.1 (59.1; 20.7–97.6)	61.8 $\pm$ 15.8 (59.5; 11.1–143.3)	0.223
Number of shocks	2901 $\pm$ 610 (3000; 275–4262)	2799 $\pm$ 633 (3000; 763–4000)	2850 $\pm$ 622 (3000; 275–4262)	0.396
Energy (joules)	800 $\pm$ 185 (827; 50–1001)	781 $\pm$ 223 (850; 125–1000)	791 $\pm$ 205 (834; 50–1001)	0.897
Irradiation dose (mGy.cm ²)	13082 $\pm$ 9812 (10597; 0–54843)	1354 $\pm$ 2505 (163; 0–13926)	7218 $\pm$ 9250 (3595; 0–54843)	<0.0001
Time of fluoroscopy (sec)	176.0 $\pm$ 107.7 (159.5; 0–690)	46.1 $\pm$ 84.8 (3.5; 0–478)	111.0 $\pm$ 116.6 (94.0; 0–690)	<0.0001

SD=standard deviation; AUPS=Automatic Ultrasound Positioning Support; VT=Visio-Track; SWL=shockwave lithotripsy.

FIG. 2. Learning curve.

patient age in groups A and B were 53.8 (22–82) and 52.2 (15–78) years, respectively ($P=0.541$). The median (range) pre-SWL kidney stone size (mm) in group A and group B was 10.3 (4–25) and 9.9 (4–20), respectively ($P=0.660$). Patient characteristics, as the percentage of underweight, normal, and obese patients, were comparable between the two groups (Table 1).

The application of SWL was similar in both groups, including median (range) duration (min) of SWL, 60.3 (11.1–143.3) in group A versus 59.1 (20.7–97.6) in group B ($P=0.223$); number of shocks 3000 (275–4262) in group A versus 3000 (763–4000) in group B ($P=0.396$); and energy (joules) 827 (50–1001) in group A versus 850 (125–1000) in group B ($P=0.897$) (Table 1).

During SWL, the median (range) duration (seconds) of radiation exposure was 159.5 (0–690) in group A versus 3.5 (0–478) in group B ($P<0.001$). The median (range) irradiation dose ($\text{mGy}\cdot\text{cm}^2$) was 10597 (0–54843) in group A versus 163 (0–13926) in group B ($P<0.001$) (Table 1). Although operators lacked familiarity with Visio-Track, proficient use was evident after a learning curve process. The regression curve in Figure 2 shows significant reduction in median fluoroscopy time immediately at the installation of VT and with cumulative experience (slope = -2.13 sec/treatment; $P=0.013$).

With SWL outcome, success rates were 54.5% in group A versus 79.5% in group B ($P=0.001$) (Fig. 3). The proportions of patients with partial stone fragmentation not necessitating an additional procedure and patients with complete stone fragmentation were 11.7% and 42.9% in group A, and 15.7% and 63.9% in group B. The re-treatment rate was 23.4% in group A versus 16.9% in group B (Fig. 3).

Discussion

Procedural interventions for symptomatic stones should ideally alleviate pain and prevent renal dysfunction from chronic obstruction with the least harm and greatest efficacy possible. Thus, we compared the radiation exposure and efficacy of two imaging combinations, fluoroscopy and outline ultrasound versus fluoroscopy and a 3D free-line ultrasound stone locking system, during SWL treatment of renal stones.

FIG. 3. Treatment efficacy.

Renal stones impose a significant disease burden to patients and health care resources, making it essential to use effective interventions with the greatest safety profile.

In the United States, renal stones account for more than 1 million healthcare provider visits and more than 300,000 emergency department visits annually.⁵ The lifetime prevalence in the United States is 13% for men and 7% for women,⁶ nearly identical to the prevalence in France of 13.6% in men and 7.6% in women.⁷ Renal stones represent one of the most costly urologic conditions in annual medical expenditures, which a 2006 estimate placed at greater than \$10 billion in the United States.^{8,9} With renal stones primarily affecting working-age adults, important contributions to overall disease burden come from indirect costs such as work loss and temporary disability.¹⁰

SWL was introduced as a prototype device in 1980 and as a commercial product with the Dornier HM3 in 1984. The HM3 became the first widely distributed lithotripter in clinical use, and its rapid market entrance and success dramatically changed the management of stone disease. Open and laparoscopic surgical procedures, widely used for stone removal before SWL, are now indicated in fewer than 1% of cases.¹¹ Acceptance of this noninvasive treatment alternative for renal and ureteral stones coincided with a broader shift away from open operations in favor of minimally invasive approaches,¹ and while several other interventions have entered clinical use, SWL and ureteroscopy (URS) remain the two principal modalities.^{12,13}

Stone fragmentation sufficient for expulsion necessitates effective targeting of shockwave delivery to the stone. Fluoroscopy has been the first choice standard, because of simplicity of imaging and interpretation.¹⁴

In appropriately selected patients, the overall stone clearance success rate with SWL is greater than 90%, with patients remaining stone free up to 2 years. The stone-free rate drops significantly with stones exceeding 20 mm, and the stone-free rate is typically approximately 50% in stones 20 to 30 mm^{3,15} because of fragment size exceeding the ability for ureteral discharge.¹ This variable efficacy relative to stone size may contribute to the 60% to 90% efficacy range reported in the literature.^{16,17} While other factors influence SWL outcome, such as lithotripter efficacy, obesity, and stone location and composition, the greatest contribution to the quality of treatment outcome is the imaging control of localization and operator skill.¹²

Numerous urologic organizations have recommended the use of SWL in stones. The Lithiasis Committee of the French Association of Urology concluded in 2004 and confirmed in 2013 that SWL was the first-line treatment for kidney or ureteral stones less than 20 mm in all age groups.^{11,18} The most recent practice guidelines for stone management were published by the European Association of Urology (EAU) in 2014. They also recommended SWL as first-line treatment for patients with stones <2 cm within the renal pelvis and upper or middle calices.

The American Urological Association/EAU stated the limitation in ultrasonographic imaging during SWL of some stones in the proximal and distal ureter can be offset by combining ultrasonography with fluoroscopy, which can also reduce radiation exposure.^{12,13} Ultrasonography was recommended by the EAU as the first choice in diagnostic imaging in stones of unknown composition.¹²

Flexible URS has become an increasingly used technique in stone removal. Compared with URS stone removal, SWL results in less morbidity and shorter hospital stays¹⁵ and remains prominent among treatment options as a noninvasive intervention with proven efficacy and few side effects.⁴ Patients who undergo URS stone removal are exposed to ionizing radiation, ranging from 0.67 mSv to 2.23 mSv.¹⁹

Removal of kidney stones with SWL has long been considered a safe and effective therapy. Fluoroscopy is the standard modality for guidance, image formation, and localization of renal calculi during SWL but exposes patients and medical staff to ionizing radiation.²⁰ Although risk associated with a radiologic procedure is considered low, it is increasingly recognized that needless exposure to radiation and added risk is unacceptable in the absence of patient benefit, especially when safer effective alternatives are available.²¹

The primary risk associated with exposure to ionizing radiation is cancer. It is estimated that approximately cancer will develop in 1 in 1000 persons from an exposure of 10 mSv/year.²² Patients who are younger or possess genetic vulnerability have greater risk of long-term harm from radiation exposure. Given the long latency period of radiation-induced cancer mortality risk, the risk in children is three to five times higher than adults, and risk to those 80 years old is three to four times less than to those 40 years old.²³

To help reduce cumulative radiation exposure, the European Atomic Energy Community enacted Council Directive 2013/59 Euratom in December 2013.²⁴ This reaffirmed previous European Union-wide statutes, which placed the annual regulatory limit of exposure to ionizing radiation at 1 mSv per year for the public. The radiation exposure from imaging modalities in stone evaluation include 0.7 mSv with kidney, ureter, and bladder radiography, 1.3–3.5 mSv with intravenous urography and with abdomen and pelvis CT imaging, 10 mSv with noncontrast and 20 mSv with three-phase contrast.^{12,25} The minimal effective dose in fluoroscopic examinations is higher than conventional radiography,²¹ and actual dose delivery is widely variable because of the influence of examination type, patient size, equipment, technique, and other factors.²⁶

The importance of minimizing or eliminating radiation exposure during SWL is underscored by the natural history of stone disease, which can exhibit the characteristics of a chronic, relapsing condition; additional stones develop in up to 50% of patients within 5 years of the initial stone.²⁷ Each stone

recurrence and treatment can expose patients to radiation from fluoroscopic imaging during SWL: CT, radiography, or radiographic intravenous urography during diagnosis,²⁸ and CT or radiography during post-treatment stone status assessment.²⁹

With some patients needing additional or multiple re-treatments after the first stone event, concerns over procedural radiation exposure shift from single to cumulative exposure. Especially concerning are younger patients with chronic recurring stones.³⁰ A multicenter study evaluated patient exposure to radiation during their initial acute stone episode and during 1-year follow-up. In 108 patients, the median radiation dose was 29.7 mSv, with 20% receiving >50 mSv. All exposures came from diagnostic imaging alone, which were repeated for some patients with stone recurrence.³¹

With ultrasonography devoid of radiation exposure, ultrasound systems were attached to lithotripters to reduce the duration of fluoroscopic imaging during SWL. While earlier inline and outline ultrasound systems were found beneficial in controlling the coupling quality and providing procedural imaging in real time, poor visualization specifically with obese patients limited its use.¹⁴

In our clinical experience using an outline ultrasound system during SWL, the device was found cumbersome to use and nonintuitive to operate. With the ultrasound probe attached laterally to the lithotripsy generator, adjusting the probe location to improve the image necessitated mechanical manipulation to adjust the stone location on the ultrasound probe. These drawbacks made the procedure much longer and more difficult compared with fluoroscopic imaging. The free-line VT ultrasound stone locking system was developed to overcome the limitations of currently used inline and outline ultrasound stone localization systems.

In our earlier patient cohort (group A), imaging guidance of SWL treatment of stones used fluoroscopy and the outline AUPS. In these 73 patients, the mean duration of fluoroscopic imaging was 176 seconds and the mean irradiation dose (mGy.cm²) was 13,082, which is equivalent to an effective dose of 2.35 mSv. Duration of fluoroscopic imaging is an important variable because it strongly correlates with the level of radiation exposure.³⁰ The average fluoroscopy duration in group A was similar to the mean fluoroscopy durations reported by Carter and colleagues³² of 160 seconds and by Sandilos and associates³³ of 204 seconds. The mean irradiation dose in group A of 2.35 mSv was higher than the mean effective radiation dose during fluoroscopic imaging, ranging from 0.75 mSv to 1.82 mSv.^{34,35}

After introduction into patient care in our clinic, the use of the Visio-Track system resulted in substantial decreases in exposure time to fluoroscopy and level of radiation exposure during SWL. In the latter cohort of 81 patients (group B) receiving SWL treatment using fluoroscopy and VT imaging, the mean length of fluoroscopy exposure was 46 seconds (vs 176 seconds group A, $P < 0.0001$), and the mean dose of fluoroscopic radiation exposure (mGy.cm²) was 1354 (vs 13,082 in group A, $P < 0.0001$), which corresponds to an efficacy dose of 0.24 mSv. Both exposure time and efficacy dose of radiation exposure are below the ranges of 160 to 204 seconds and of 0.75 to 1.82 mSv presented in the literature for an SWL treatment.^{32–35}

Because standard management of urolithiasis typically involves several radiologic examinations, reducing the radiation exposure from fluoroscopy use during SWL treatment

to fall within the 10 mSv/year safety limit diminishes patient health hazards from cumulative irradiation exposure.²² The average 0.24 mSv in kidney radiography dramatically reduces radiation exposure during VT, and led to EAU guidelines on urolithiasis¹² placement of VT among imaging modalities with the lowest patient exposure to ionizing radiation during stone evaluation.

We began recording patient outcomes in group B immediately after obtaining the VT system. Early in the operator experience using VT, ultrasonography was used for stone localization and real-time treatment follow-up (enabling immediate focus point readjustment and treatment efficacy monitoring), whereas fluoroscopy was used only to assess stone localization and end of treatment validation.

VT use was a novel experience involving a learning curve to achieve proficiency. Figure 2 illustrates the significant interaction between operator experience and fluoroscopy time. Calculation of the regression curve found that with each treatment, fluoroscopy time was reduced by 2.13 seconds (slope = $-2.13 \text{ sec/treatment\#}$; $P=0.013$). These data show that after sufficient operator familiarity and comfort achieved with VT, fluoroscopy use was negligible, with a median of 3.5 (vs 159.5 in group A) seconds per treatment.

Medical staff members involved in the treatment of patients with renal stones are also exposed to ionizing radiation, and despite considerably lower exposure levels per procedure relative to the patient, the chronicity of exposure can be worrisome. The absence of radiation during VT imaging of SWL permits staff to move freely in the operating suite and allows closer contact to be maintained with patients, which can be comforting and reassuring.³⁶

In some patients treated by SWL, stones do not fully break apart sufficiently for urinary expulsion, and subsequent management of the stone fragments may be needed. This problem is not unique to SWL. Detectable stone fragments after treatment occur in as many as 38% of patients receiving ureteroscopic stone removal.³⁷

We found the improved localization and stone monitoring in real time with VT reduced the frequency of residual stone fragments necessitating additional procedures, resulting in higher efficacy rates. Efficacy was defined in our study as patients with complete stone fragmentation or with partial stone fragmentation without necessitating additional procedure. Use of VT led to 79.5% efficacy versus 54.5% in SWL without VT ($P=0.001$). Significant differences favoring VT were also found in patients with total fragmentation, and patients with no fragmentation. Rates of re-treatment were comparable.

A limitation of our study was the lack of standardized fragmentation control. The post-SWL evaluation was dependent of each physician (ultrasonographic imaging, radiography, CT scan).

Continuous ultrasonographic monitoring in real time allows the operator to deliver shockwaves solely when the stone aligns to the target zone. Operator ability to halt shockwave delivery during patient coughing, sighing, deep breathing, or restlessness enhances safety by sparing adjacent normal renal tissue from shockwave exposure that would otherwise occur with localization and targeting by intermittent fluoroscopic control.³⁶ Real-time monitoring enhances efficacy by enabling immediate position readjustments to maintain stone alignment to the target zone.

We have described our experience before and after the installation of the free-line ultrasound stone-locking system. We obtained very satisfactory results in reducing radiation exposure and increasing efficacy. The mobile stereotaxic ultrasound probe greatly improved the operational ergonomics over the previous ultrasound system, and operators found this device highly satisfying to use. The medical staff gained freedom in movement with radiation-protective aprons and shields no longer necessary.

Despite the potential advantages of ultrasound, it has not been widely used because of practical limitations, the time savings and ease of use with fluoroscopy, and has been primarily limited for use in low-radiopaque stones that are difficult to visualize with fluoroscopy. The new VT system eliminates the practical limitations and most of the imaging shortcomings, and we believe the use of ultrasonography during SWL can be greatly expanded.

Conclusion

During SWL treatment of patients with renal stones, imaging and stone localization using a free-line ultrasound stone locking system led to substantial reductions in duration of fluoroscopy exposure and fluoroscopy radiation dose, and to significant improvement in efficacy because of real-time monitoring of the stone. The VT system is easy to use and frees the medical team from cumbersome radiation protection.

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Author Disclosure Statement

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Abbreviations Used

AUPS = automatic ultrasound positioning support
CT = computed tomography
EAU = European Association of Urology
SWL = shockwave lithotripsy
3D = three-dimensional
URS = ureteroscopy
VT = Visio-Track