IN VITRO ASSESSMENT OF ULTRASONIC LITHOTRIPTORS

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ABSTRACT

Purpose: Ultrasonic lithotriptors are commonly used to fragment and remove stones during percutaneous nephrolithotomy. To date a comparative assessment of current units has not been accomplished without potential operator bias. An objective testing environment is required for optimal appraisal of the efficiency of ultrasonic lithotriptors.

Materials and Methods: An in vitro test system was devised to evaluate the ability of ultrasonic lithotriptors to core through artificial stones. The system consisted of an irrigation sheath (Cook Urological, Spencer, Indiana) through which ultrasonic probes were placed. Ultrasonic hand pieces and probes were secured in an upright position. An Ultracal-30 (U.S. Gypsum, Chicago, Illinois) stone cylinder (mean length 12.8 ± 0.6 mm, mean diameter 7.6 ± 0.07 mm) was centered on the probe tip. A weight (62.7 gm) was placed atop the stone to provide a constant force. We evaluated the Olympus LUS-1 and LUS-2 (Olympus, Melville, New York), Circon-ACMI USL-2000 (Circon-ACMI, Southborough, Massachusetts), Karl Storz Calcuson (Karl Storz, Culver City, California) and Richard Wolf model 2271.004 (Richard Wolf, Vernon Hills, Illinois). All probes had outer diameters of 3.4 mm except for the Circon-ACMI unit (3.8 mm). Using 100% power settings times for complete stone penetration were assessed for all units. Differences in mean stone penetration times were compared using ANOVA.

Results: The Olympus LUS-2 had the fastest mean stone penetration time (28.8 ± 2.7 seconds). This value was used to normalize the data into efficiency ratios, where other unit times were expressed as multiples of the LUS-2 time: Olympus LUS-2 (1.0 ± 0.1) equals Circon-ACMI USL-2000 (1.1 ± 0.3) greater than Karl Storz Calcuson (1.4 ± 0.3) greater than Olympus LUS-1 (2.1 ± 0.5) greater than Richard Wolf (3.6 ± 0.8). Efficiencies of the LUS-2 and USL-2000 units were essentially equivalent, with all others significantly less efficient (p <0.05).

Conclusions: This new in vitro testing model provides an objective, reproducible method for evaluating the efficiency of intracorporeal lithotriptors. Of the units tested the Olympus LUS-2 and Circon-ACMI USL-2000 were the most efficient.

Key Words: lithotripsy, ultrasonography; nephrostomy, percutaneous

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METHODS

Percutaneous nephrolithotomy (PNL) has become the accepted surgical standard for large renal stone burdens, virtually replacing open surgery. Once access into the collecting system has been successfully obtained, ultrasonic lithotriptors are commonly used to fragment calculi.1,2 These devices typically consist of a generator unit that powers a piezoelectric crystal array within an attached hand piece. When the generator is activated the crystals vibrate at frequencies of up to 27,000 Hz.1,3 This vibrational energy is transmitted directly onto the stone surface via a hollow probe secured to the hand piece.

Numerous ultrasonic lithotripter units are in use worldwide, and with ongoing research and development new models have become available for clinical use. The efficiency of these units is difficult to assess and compare in the clinical setting because of multiple factors, including the skill of the operator, variation in stone size and composition, and anatomical variability. The purpose of this study was to design an in vitro testing system that would provide objective, reproducible results in evaluating ultrasonic lithotriptors, and to use this system to assess the efficiency of available clinical devices.

Our in vitro testing system was designed to minimize the variables present during the clinical use of ultrasonic lithotriptors. We devised a stationary framework to maintain the probe and hand piece of each ultrasonic unit in a secure, fixed position (fig. 1). The probe/hand piece combination was placed in a vertical orientation with the probe superior to the hand piece. This orientation permitted a test stone to be positioned above the probe tip, thus eliminating the variability in contact pressures created by hand piece differences, and enabling a weight to be placed atop the stone/probe tip interface to provide a constant force through gravity. To retain fluid around the distal portion of the probe, we used a specially designed irrigation sheath (Cook Urological) with a water seal at its inferior end. Irrigant was instilled into the system through a sheath port. A fluted stabilizer was inserted snugly within the distal portion of the irrigation
sheath. This device ensured targeting of the probe tip at the stone center during treatment while enabling vibrational energy transmission through the probe. Irrigant flow around the stabilizer was facilitated by the outer fluted channels. A translucent acrylic sheath was fashioned to insert over the superior end of the irrigation sheath. This accessory sheath enabled visualization of the probe tip so that its progress through a stone could be monitored. It also steadied the weighted rod placed atop the stone, which consisted of a fluted stainless steel cylinder and rubber stopper combination (62.7 gm).

Natural kidney stones are highly variable in structure and mineral composition, and this heterogeneity could influence the response to treatment with an ultrasonic lithotriptor. To avoid stone heterogeneity as a potential source of variability we used homogeneous artificial stones.\(^4\)–\(^6\) The stones were prepared from Ultracal-30 (U-30) gypsum cement (U.S. Gypsum). U-30 powder was mixed 1:1 with deionized water and the slurry was poured into molds fashioned from 1 ml segments cut from 10 ml polystyrene pipettes, in turn glued with methylene chloride to a flat plastic plate. The slurry was allowed to cure overnight under water, then the plastic was dissolved away with multiple changes of chloroform. The stones were stored in water until use. Stones prepared in this way measured 12.8 ± 0.6 mm in length, by 7.6 ± 0.07 mm in diameter (fig. 2).

We evaluated 5 ultrasonic lithotriptors: the LUS-1 and LUS-2 (Olympus) the USL-2000 (Circon-ACMI), the Calculson (Karl Storz) and the Wolf 2271.004 (Richard Wolf). Each unit was operated at 100% power. Ultrasonic probe diameters were 3.4 mm for all devices except the USL-2000, which came standard with a 3.8 mm probe. The hand pieces of the units were draped with an ultrasound probe cover to protect them from irrigant during testing.

For each test a U-30 stone cylinder was centered on the probe tip and the weighted rod was placed atop the stone. The interface between the probe tip and stone was easily visible through the acrylic sheath. Tap water was used as the irrigant and was instilled via cystoscopic tubing from a 3 l bag suspended 60 cm above the level of the irrigation sheath. All ultrasonic hand pieces were connected via tubing to a portable vacuum pump (EMS Medical, Dallas, Texas), which produced a constant level of suction (432 cm H\(_2\)O) monitored by a vacuum gauge.

The efficiency of each generator was assessed by determining the time in seconds needed for the probe tip to core entirely through artificial stones (see table and fig. 2). Irrigant flow through the sheath was adjusted manually to ensure that fluid surrounded the probe and stone during treatment. After treating each stone irrigant was suctioned through the system to dislodge stone particles, and ensure that the hand piece and probe channels were clear. Data were analyzed with ANOVA using the Tukey-Kramer HSD test to compare individual means. Differences were considered significant at \(p < 0.05\), and data are expressed as mean ± standard deviation.

RESULTS

The Olympus LUS-2 unit gave the fastest mean penetration time (28.8 ± 2.8 seconds). This value was used to normalize the data for the other ultrasonic generators. These data, expressed as the efficiency ratio for each device, are listed in the table. When the efficiency ratios were compared the Olympus LUS-2 and Circon-ACMI USL-2000 units were not different, and the efficiency of these units was significantly better than that of the other ultrasonic lithotriptors.
This study examined the time required for complete stone fragmentation and clearance of particles using each unit. The measured times included the time required to clear the probes and tubing of obstructing fragments. Stone phantoms in this study were placed in a plastic container and manually held against the container wall with the ultrasonic probe. Although this manual testing mimics the use of an ultrasonic lithotriptor during PNL, such a method has the drawback of being subject to operator bias.

Our apparatus provided a stable testing environment which allowed an objective determination of penetration times through U-30 stones. By clearing the ultrasonic probe, hand piece channels and tubing after each trial, we ensured that each ultrasonic device was able to perform under optimal conditions. As a result we did not experience episodes of probe or tubing clogging over time, which tended to occur in some devices tested in the Liatsikos et al study.20

Several design features may have affected the performance of the devices we tested. For example, the larger probe diameter of the Circon-ACMI unit may allow a greater degree of suction to be applied to the stone surface. In the case of the Storz Calcuson unit, the probe has a serrated tip as opposed to the smooth ends of the other devices. As a result the amount of probe surface area in contact with the stone at any given time is decreased and this factor may have decreased the efficiency of the unit.

CONCLUSIONS

Our in vitro testing system provides an impartial means of evaluating the efficiency of ultrasonic lithotripsy devices. This hands-free testing method eliminates operator bias so that the efficiency of stone penetration is dependent only on the performance of the device. Using this system we demonstrated that the Olympus LUS-2 and Circon-ACMI USL-2000 ultrasonic lithotripsy units were comparable in performance, followed by the Storz Calcuson, Olympus LUS-1 and Wolf 2271.004 devices, respectively. Although further clinical evaluation of the devices tested in this study will be required to substantiate overall performance, to our knowledge this model provides the most objective data on these units to date.

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