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CLINICAL EFFICACY OF A COMBINATION PNEUMATIC AND ULTRASONIC LITHOTRITE

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ABSTRACT

Purpose: A new combination pneumatic/ultrasonic intracorporeal lithotriptor has been developed for percutaneous applications. It combines the stone clearing efficiency of an ultrasonic device with the fragmentation strength of a pneumatic probe into a single handpiece. We present our early clinical experience with this device in a prospective, randomized comparison a combination pneumatic/ultrasound lithotrite and standard ultrasonic lithotripsy.

Materials and Methods: A total of 20 consecutive patients undergoing percutaneous nephrolithotomy for symptomatic calculi were randomized to receive stone fragmentation and removal using a standard ultrasonic device or a new combination pneumatic/ultrasonic unit. Stone location and burden were assessed before the operative procedure. The stone clearance rate in mm.^{2} per minute was calculated for the 2 devices. Complications and stone-free rates were compared in the 2 groups.

Results: There were no significant differences in stone location and composition in the 2 groups of patients. Average time required for complete stone clearance was considerably less for the combination device (21.1 versus 43.7 minutes, $p = 0.036$). The opposite was true for the average rate of stone clearance in mm.^{2} per minute, in that the standard ultrasonic device could clear 16.8 versus 39.5 mm.^{2} per minute for the combination unit ($p = 0.028$). Stone-free and complications rates were slightly superior for the combination device but it was likely attributable to patient factors.

Conclusions: The combination pneumatic/ultrasonic lithotrite is capable of disintegrating and extracting stone material at a more rapid rate than standard ultrasonic devices. Moreover, stone-free and complication rates appear to be slightly superior with the combination unit. This new combination pneumatic/ultrasonic device appears to be efficacious and safe for removing large renal calculi.

KEY WORDS: kidney, kidney calculi, lithotripsy

Percutaneous nephrolithotomy is widely accepted as the procedure of choice for large, complex renal calculi. Ultrasonic lithotrites are commonly used during percutaneous nephrolithotomy because of their ability to disrupt the calculus into small fragments, which can be removed via suction through the central lumen of the ultrasonic probe. However, this fragmentation process can be tedious, especially if the stone is large or dense.

Pneumatic devices have the ability to rapidly fragment large or hard renal calculi. Unfortunately these fragments must then be removed with graspers, which can also be cumbersome. In addition, repeat passage of the nephroscope through the working sheath increases the risk of inadvertently dislodging the safety or working wires, or even the sheath.

A new device has been developed that combines these 2 modalities into a single hand piece. Previous studies at our laboratory have shown the in vitro efficacy of this device and indicated that it is more efficient for stone clearance than either component alone.[1] We present our clinical experience with this new lithotripsy device in a randomized, prospective comparison of combination pneumatic/ultrasonic and standard ultrasonic lithotripsy.

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METHODS

A total of 20 consecutive patients undergoing percutaneous nephrolithotomy for stone extraction were enrolled in our study. Patients were randomized to receive percutaneous nephrolithotomy performed by a standard LUS-2 (Olympus, Inc., Melville, New York) ultrasonic device or a combination Lithoclast Ultra (Microvasive, Natick, Massachusetts and EMS, Bern, Switzerland) pneumatic/ultrasonic unit.

Demographic data, stone sites and stone burden were determined preoperatively. Stone burden was calculated in mm.^{2} using the 2 widest dimensions of each stone, as measured on preoperative plain x-ray of the kidneys, ureters and bladder. After achieving adequate access to the collecting system the total amount of time required to disintegrate the stone burden and clear the collecting system of any residual fragments was measured. The goal was complete clearance of the stone burden in 1 session. Additional percutaneous nephrolithotomy tracts were added as necessary to provide complete extraction of calculi that were difficult to reach but the time needed to acquire this access was not included in total clearance time per instrument. No second look procedures were performed. Stone burden was divided by total clearance time for each procedure to calculate the clearance rate in mm.^{2} per minute.

Stone-free rates were assessed at routine 3-month followup visits using excretory urography with tomography or noncontrast renal computerized tomography. Complications were compiled from inpatient and clinic records. Stone composi-

tion was obtained for all cases. Statistical analysis was performed using commercially available software with $p < 0.05$ considered significant.

RESULTS

Successful percutaneous nephrolithotomy procedures were performed in all cases. The total stone burden was similar in the 2 patient groups. Patients in the ultrasonic group had an average stone burden of 795.5 mm.^{2} (range 110 to 2,925) compared with 809.2 (range 150 to 2,600) in the combination pneumatic/ultrasonic group ($p = 0.49$). Stone location was also similar in the 2 groups. Patients in the combination pneumatic/ultrasonic group required a total of 5 lower pole, 3 interpolar and 2 upper pole access tracts. In the standard ultrasonic cohort 7 lower pole, 3 interpolar and 2 upper pole tracts were required. Two patients required 2 tracts each to clear the total stone burden.

Average time required for complete stone disintegration/extraction was considerably higher in ultrasonic cases (43.7 versus 21.1 minutes, $p = 0.036$). Conversely the average stone clearance rate was less for standard ultrasonic device clearing than for the combination pneumatic/ultrasonic lithotrite (16.8 mm.^{2} per minute, range 2.2 to 41.8 versus 39.5, range 20.8 to 108.3, $p = 0.028$, fig. 1).

The complication rate was slightly higher in the ultrasonic cohort. Two patients sustained hydrothorax, as noted on postoperative chest x-ray. In these cases a supracostal nephrostomy tract was used to access calculi and each was managed successfully by short-term tube thoracostomy. No complications were noted in the combination pneumatic/ultrasonic group. No patient in either cohort required blood transfusion. Stone composition was statistically similar in the 2 sets of patients. About a third of patients per device had uric acid stones, a third had calcium oxalate monohydrate or dihydrate stones and a third had struvite or brushite infection calculi (fig. 2).

The stone-free rate favored the combination device on routine 3-month postoperative imaging. Most patients had no residual stones or a single 2 to 3 mm. fragment. Seven of 10 patients per group were stone-free. Three patients in the combination cohort had residual fragments 3 mm. or less, as did 2 in the ultrasonic group. A single patient in the ultrasonic group had a significant residual calculous burden of 16 × 16 mm. due to stone material in an inaccessible location, increasing the total residual stone burden to 312 mm.^{2} for the ultrasonic device versus 26 mm.^{2} for the combination lithotrite. This difference was not statistically significant ($p = 0.32$). There was no difference in postoperative imaging modalities in the 2 cohorts.

DISCUSSION

In the early 1980s the management of large and complex renal calculi was dramatically improved by the introduction of percutaneous nephrolithotomy.[2–5] The advent of ultrasonic devices and pneumatic lithotriptors further facilitated the destruction and clearance of renal calculi.[6–10] Unfortunately large and/or dense calculi can still require extended operative time with these instruments. Ultrasonic devices may be slow to disintegrate hard or dense stones, while pneumatic devices require significant time to extract all fragments generated by the instrument.

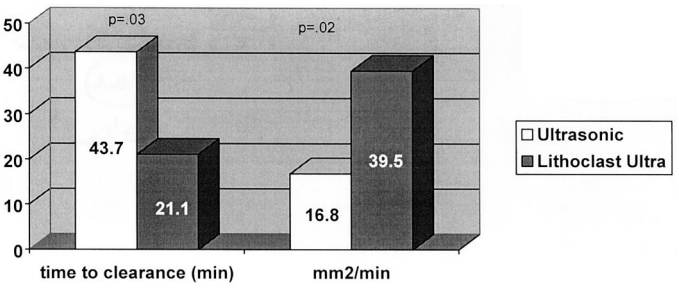

FIG. 1. Stone clearance

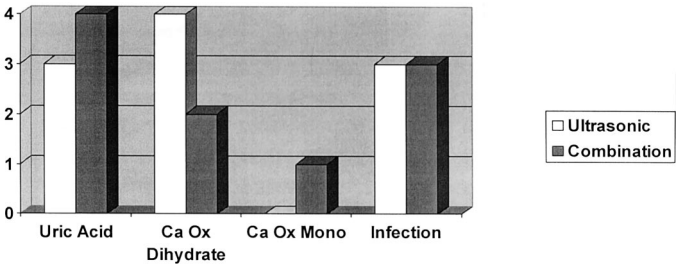

FIG. 2. Stone composition. *Mono*, monohydrate

The ability to combine the strengths of these 2 modalities into a single hand piece should minimize the weakness of each device. Indeed, previous in vitro studies, including that from our institution, have shown that the combination pneumatic/ultrasonic device is capable of disintegrating and clearing phantom stones at a more rapid rate than pneumatic or ultrasonic instruments alone.[1,11] The current prospective study was performed to evaluate the combination pneumatic/ultrasonic lithotrite in a clinical environment.

The combination instrument had speed and efficiency that were superior to those of a standard ultrasonic device with the ability to disintegrate and remove stones almost twice as rapidly. Stone clearance was 39.5 mm.^{2} per minute with the combination lithotrite versus 17.7 mm.^{2} per minute for the ultrasonic device. Most importantly, this added advantage in speed was not achieved at the cost of increased complications or residual stone fragments. In general stone fragments noted on 3-month imaging were small for each device. While a slight advantage in the stone-free rate was noted for the combination device, this finding was mostly due to the result in 1 patient in the ultrasonic cohort, in whom a complex struvite calculus occupied 5 calices. Unfortunately he was not rendered completely stone-free despite the placement of 2 nephrostomy tracts.

The combination pneumatic/ultrasonic device had a lower complication rate than the ultrasonic unit. While this difference was unlikely to have been a direct result of the lithotrite used, we can only speculate that the added operative time associated with the ultrasonic device may have contributed to a larger accumulation of irrigation fluid into the thoracic cavity.

Recent laboratory and clinical trials of the optimal use of the combination pneumatic/ultrasonic device support our initial findings. In 1 study the device decreased the clearance time of soft and hard renal calculi, although the simultaneous use of each component is not always necessary for the full duration of each procedure.[11] In addition, investigations to identify the most effective power settings for the separate components have determined that using the ultrasonic portion at 100% power with the pneumatic component at 8 Hz. provided the best results in an in vitro model.[12]

Although in the current study the 2 devices successfully managed stones of various compositions, the small number of patients in each cohort did not allow us to provide an accurate stone clearance rate for each individual stone subtype. However, as expected, a general trend was observed that the combination pneumatic/ultrasonic unit was more efficacious for removing all calculi. Further clinical experience with the combination device is needed to assess its abilities to fragment and remove stones of all compositions and configurations. Proper use of the device also requires an understanding of when to use each component of the lithotriptor and

when to rely on only 1 modality. These factors can only be determined by expanded clinical exposure.

CONCLUSIONS

The combination pneumatic/ultrasonic lithotrite is capable of disintegrating and clearing stone material at a more rapid rate than standard ultrasonic devices. Complication rates were lower with the combination device, although it was difficult to attribute this difference to the device. Moreover, the stone-free rate is slightly superior with the combination unit. This new combination pneumatic/ultrasonic device appears to be efficacious and safe for removing large or complex renal calculi.

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