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Prospective Randomized Comparison of a Combined Ultrasonic and Pneumatic Lithotrite with a Standard Ultrasonic Lithotrite for Percutaneous Nephrolithotomy

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ABSTRACT

***Purpose*: To compare the efficiency and cost effectiveness of a combined pneumatic and ultrasonic lithotrite (Lithoclast Ultra) and a standard ultrasonic lithotrite, (LUS-1) during percutaneous nephrolithotomy.**

***Materials and Methods*: In a prospective randomized trial, 30 patients undergoing percutaneous nephrolithotomy (PCNL) were randomized to PCNL with either the combined pneumatic and ultrasonic lithotrite (PUL) or a standard ultrasonic lithotrite (SUL). Patient demographics, stone composition, location, pre- and postoperative stone burden, fragmentation rates, and device failures were compared.**

***Results*: There were 13 patients in the PUL group and 17 patients in the SUL group. Stone burden and location were equal. Overall, 64% of the PUL group had hard stones (defined as stones that were either pure or a mixture of cystine [3], calcium oxalate monohydrate [CaOxMono; 2], and calcium phosphate [$CaPO_4$; 2]), and four had soft stones (3 struvite and 1 uric acid [UA]). In the SUL group, there were eight hard stones (5 CaOxMono and 3 $CaPO_4$), and six soft stones (4 calcium oxalate dihydrate [CaOxDi] and 2 UA) ($P = 0.51$). Stone composition data were unavailable for five patients. Fragmentation time for the PAL was 37 minutes versus 31.5 minutes for the SUL ($P = 0.22$). Stone retrieval and mean operative times were similar for both groups. There were a total of three (23.1%) device-related problems in the PUL group, and eight (47%) in the SUL group. There was one (7.7%) device malfunction in the PUL group due to probe fracture. There were two (11.7%) device failures in the SUL group; one failure required the device to be reset every 30 minutes, and the second was an electrical failure. Suction tubing obstruction occurred twice (15.3%) in the PUL group and 35.3% in the SU group ($P = 0.35$). The stone-free rates for the PUL and SUL were 46% and 66.7%, respectively ($P = 0.26$).**

***Conclusion*: Although the PUL was more costly, stone ablation and clearance rates were similar for both the combined pneumatic and ultrasonic device and the standard ultrasonic device. When stratified with respect to stone composition, the PUL was more efficient for harder stones, and the SUL was more efficient for softer stones.**

INTRODUCTION

THE MANAGEMENT OF UROLITHIASIS has evolved significantly over the last 20 years. Open stone surgery has become a procedure of last resort, and most training urologists have never performed open stone surgery. The description of successful percutaneous renal stone removal in a series of 25 patients by Castenada-Zuniga and colleagues[1] heralded a new era in minimally-invasive stone management. The original recommendations for this procedure were limited to high-risk surgical candidates, recurrent stone formers after previous open renal surgery, or patients with retained or missed stone fragments. Since this landmark study was published, the efficacy of percutaneous nephrolithotomy (PCNL) has become well estab-

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lished.[2] Currently, the recommendations for PCNL have expanded, and although extracorporeal shockwave lithotripsy (SWL) and ureteroscopy have roles in the management of upper tract calculi, PCNL remains the procedure of choice for most stones that are more than 2 cm in size, complex staghorn calculi, some lower-pole stones, stones in caliceal diverticuli, and larger renal stones that are refractory to SWL.

The technology associated with percutaneous stone surgery has also undergone significant advancement. Refinements in rigid and flexible nephroscopes have improved visualization and allowed access to more stones without the need for additional percutaneous tracts. Above all, improvements in the technology available for stone fragmentation have provided the greatest positive impact on percutaneous stone surgery. The original uses of Randall forceps and electrohydraulic lithotripsy, which causes bleeding and urothelial damage, have been largely replaced by laser, pneumatic, and ultrasonic lithotripsy devices. Advantages of holmium laser energy include efficacy in fragmenting all types of urinary calculi, including calcium oxalate monophosphate and cystine stones, and the fact that the fibers are small enough to be passed through flexible endoscopes.[3] However, in the management of large calculi, application of laser energy can be time consuming. Ultrasonic energy devices fragment calculi into small pieces and have the ability to aspirate these small particles through the hollow bore of the transducer, which eliminates manual stone extraction.[4] Relatively hard stones may limit the efficacy of ultrasonic lithotripsy. Pneumatic lithotrites use compressed air to propel a metal rod against the stone at a rate of 12 cycles per second.[5] Pneumatic lithotrites are effective in fragmenting even the hardest of stones, but subsequent extraction of the stone fragments is required.

Often with large, hard stones, the ultrasonic device can be used to fragment and aspirate the stone particles produced by the pneumatic device, or alternatively, the pneumatic device may be used to fragment hard stones refractory to ultrasound.[5] More recently, the two technologies of ultrasound and pneumatic lithotripsy have been combined into one device. *In vitro* comparison of the combined pneumatic and ultrasonic device revealed a statistically significant increase in efficacy (stone disintegration) and increase in efficiency (stone fragmentation and clearance) in favor of the combined device over the ultrasonic-only device.[6,7] Initial clinical experience with the combined device is encouraging, with overall stone-free rates of 86.9% (in 68 patients) and 85.7% (in 14 patients) in two series.[7,8] However, despite these encouraging data, the new combination device is significantly more costly than existing technology, and prospective randomized comparison for PCNL has not been performed. The objective of this study is to compare the *in vivo* efficacy of the new combination pneumatic and ultrasonic lithotripter with that of a standard ultrasound lithotripter.

MATERIALS AND METHODS

Permission for the study was gained from the institutional review boards of both medical centers participating in the trial. Between November 2003 and November 2004, 30 patients requiring percutaneous nephrolithotomy were incorporated into this multi-institution randomized prospective study comparing PCNL stone fragmentation with either a combined pneumatic and ultrasonic device (Swiss Lithoclast Ultra [PUL]; EMS Co., Dallas, TX) or a standard ultrasonic lithotripter (LUS-1 [SUL]; Olympus, Center Valley, PA). Patients who required PCNL for their stone management were incorporated into this study. Inclusion criteria included patients with large (>2 cm) renal stones, lower-pole stones, and large stone burden. Exclusion criteria included patients under the age of 18, patients who were unable to give consent for study, patients with coagulopathies, and pregnant women. All PCNL procedures were performed in the standard clinical manner by two fellowship-trained endourologists with high-volume stone practices. Stone fragments smaller than 10 mm were extracted per surgeon preference. Larger stones were removed with a three-pronged grasper, and smaller fragments were removed with a two-pronged grasper.

Preoperatively, stone burden and location were documented. We categorized stones as either hard or soft based on postoperative stone analysis. Hard stones were defined as stones that were mostly composed of calcium oxalate monohydrate, cystine, or calcium phosphate. Similarly we defined soft stones as struvite, uric acid, or calcium oxalate dehydrate.[14] All 30 patients underwent percutaneous access for PCNL by deployment of a 30F sheath over a dilating balloon. The initial ultrasound fragmentation setting for the PUL was 80%; this setting was increased if required during the procedures. The pneumatic component was set at level 8 and was similarly increased to level 12 if required. Incremental increases in settings were documented, as were the reasons for the increases. The SUL device was initially set between 1 and 2, per the manufacturer's recommended specifications, and was increased as clinically indicated up to 3. Additional data collected included fragmentation time, stone removal/retrieval time, effectiveness of fragmentation of the device, overall operative time, need for additional modalities (e.g., laser), estimated blood loss, stone-free rate, requirement for a second-look procedure, and complications. Operative time was defined as the duration of the surgical procedure, beginning with percutaneous access. Blood loss was calculated in conjunction with anesthesia by the amount and color of irrigating fluid, and by the number and degree of saturation of the used lap pads. A standard t-test was used to compare the averages for all continuous data and data comparing stone types and time required to fragment stones.

RESULTS

Thirteen patients were randomized to the PUL group, and 17 patients were randomized to the SUL group. Tables 1 and 2 show the demographic distribution of the PUL group and the SUL group, respectively. The percutaneous nephrolithotomy procedures were successfully performed in all cases. Stone burden was similar in both groups. Patients in the PUL group had an average stone burden of 21 mm, compared to 18.5 mm for the SUL group ($P = 0.52$). In each group, two patients had complete staghorn calculi. Stone location was also similar.

Stone composition was documented in all but five patients. The PUL group had a total of seven hard stones (64%; three cystine, two calcium oxalate monohydrate, and two calcium phosphate) and four softer stones (three struvite stones and one

Table 1. Data for the Stones Fragmented by the Combination Pneumatic and Ultrasonic Device

Patient	*Gender*	*Side*	*Preoperative stone burden (mm)*	*Stone composition*	*Fragmentation time (min)*
1	F	L	15	Cystine	45
2	F	R	21	Struvite	30
3	M	L	17	NA	8
4	F	L	23	$CaPO_4$	20
5	F	L	42	$CaPO_4$	72
6	F	R	10	CaOxMono	16
7	M	R	15	Struvite	17
8	F	R	50	CaOxMono	22
9	M	R	12	Cystine	12
10	M	L	9	Cystine	12
11	F	L	21	Uric acid	90
12	M	L	18	NA	50
13	F	R	20	Struvite	87
Total	5 M, 8 F	7 L, 6 R	Mean = 21	7 hard, 4 soft, 2 NA	Mean = 37

CaOxMono = calcium oxalate monohydrate; $CaPO_4$ = calcium phosphate; NA = not available.

uric acid stone) (Table 1). The SUL group had eight hard stones (57%; five calcium oxalate monohydrate stones and three calcium phosphate stones), and six soft stones (four calcium oxalate dihydrate stones and two uric acid stones) (*P* = 0.51). (Table 2).

Mean fragmentation time for the PUL cohort was 37 minutes *v* 31.5 minutes for the SUL group (*P* = 0.22). A side-by-side comparison shows that the PUL fragmented hard stones faster than the SUL, but the SUL fragmented soft stones faster. The PUL group needed an average of 28.4 minutes to break up the hard stones, and the SUL needed an average of 41.12 minutes to break them up (*P* = 0.4323). The PUL needed an average of 56 minutes to break up soft stones, and the SU group needed an average of only 15.8 minutes to break them up (*P* = 0.0323).

The stone retrieval times were similar: 10 minutes in the PUL cohort and 9 minutes in the SUL cohort. The mean operative time was also similar, at 129 minutes for the PUL group and 130 minutes for the SUL group (*P* = 0.98). All patients had postoperative CT scan follow-up evaluations. The mean residual stone burden was 5.3 mm for the PUL cohort and 3.2 mm for the SUL cohort. With respect to stone-free rates (defined as residual stone burden less than 3 mm in diameter), six patients (46%) in the PUL group had no evidence of stone disease, compared to 10 patients (66.7%) in the SUL group (*P* = 0.26). There was a mean estimated blood loss of 193 mL for the com-

Table 2. Data for the Stones Fragmented by the Standard Ultrasonic Device

Patient	*Gender*	*Side*	*Preoperative stone burden (mm)*	*Stone composition*	*Fragmentation time (min)*
1	M	R	30	CaOxMono	120
2	M	R	15	$CaPO_4$	14
3	F	L	18	CaOxDi	21
4	F	R	20	CaOxDi	21
5	F	R	10	Uric acid	25
6	F	L	20	CaOxMono	60
7	F	L	17	$CaPO_4$	60
8	M	L	15	Uric acid	8
9	F	L	10	$CaPO_4$	25
10	F	R	12	CaOxDi	15
11	F	L	9	CaOxDi	5
12	M	R	25	NA	2
13	F	L	28	NA	5
14	F	L	8	CaOxMono	21
15	F	L	45	NA	105
16	M	L	14	CaOxMono	5
17	M	R	18	CaOxMono	24
Totals	6 M, 11 F	7 R, 10 L	Mean = 18.5	8 hard, 6 soft, 3 NA	Mean = 31.5

CaOxDi = calcium oxalate dihydrate; CaOxMono = calcium oxalate monohydrate; $CaPO_4$ = calcium phosphate.

bined pneumatic and ultrasonic group, and 203 mL for the ultrasonic group ($P = 0.71$). The total mean fluoroscopy time was 11 minutes for the PUL group and 8 minutes for the SUL group ($P = 0.38$).

There were a total of three (23.1%) mechanical failures in the PUL group, and eight (47%) in the SUL group ($P = 0.18$). Two of the three mechanical failures in the PUL group were from suction tube obstruction, as compared to six of the eight cases in the SUL group. There was one malfunction in the PUL group, which was due to the lithoclast probe fracturing, and there were two episodes of suction tube obstruction. There was one episode of suction tube kinking in the SUL group, and there were two device failures in the SUL group in which the machine needed to be reset every 30 minutes. Only one malfunction in the SUL group led to a significant increase in operative time (Table 3).

Postoperative pain requirements were similar for the two cohorts. The PUL group required an average of 37 mg of morphine sulfate *v* 48 mg for the SUL group ($P = 0.38$). (Table 2)

Cost comparison

The Lithoclast Ultra's retail price is $39,000 US, with each probe costing $200 US. The probes can be reused up to five times. The cost of one air tank for the pneumatic device is $65 US, and it supplies enough gas 200 procedures, for a cost of approximately $0.35 per procedure. In comparison the Olympus LUS-1 ultrasonic device has a retail price of $18,000 US, with each probe costing $250 US, which could also be used up to five times. A pneumatic-only machine costs approximately $20,000 US, and the probes are reusable.

DISCUSSION

By the mid-1980s percutaneous nephrolithotomy had become the standard of care for removal of larger stones or smaller stones in dependent calices. As fragmentation technologies improved with the introduction of electrohydraulic, and then the pneumatic and ultrasonic lithotripters, the indications for PCNL expanded. In the mid-1980s the addition of combination therapy with SWL further expanded the indications for PCNL.[9,10] Currently, with recent advances in ureteroscopy, lasers, and lithotripters, and refinement of techniques, PCNL has virtually eliminated open stone surgery.[11]

Pneumatic lithotripters fragment stones effectively and decrease ablation time; however, with harder stones, pneumatic lithotripsy results in larger stone fragments and longer extraction times. Recently, pneumatic lithotripsy and ultrasonic probes were combined into a single device known as the Swiss Lithoclast, and it was intended to improve the efficiency of stone fragmentation for harder stones. Indeed, benefits of the combined pneumatic and ultrasonic device have been demonstrated for harder calcium oxalate monohydrate and brushite stones.[12] Furthermore, clinical evaluation has demonstrated that the combined pneumatic and ultrasonic device has significantly increased the efficiency of stone fragmentation compared to the ultrasonic-only device.[7,13]

We compared the efficiency and cost effectiveness of the combined pneumatic and ultrasonic device with those of a standard ultrasonic device. There was no significant difference in the mean operative times between the two cohorts. In contrast to prior data, our study suggests that the PUL device did not fragment stones noticeably faster than the SUL device. In fact for soft stones, the SUL probe was faster.

Prior studies also demonstrated improved stone retrieval time for the PUL device compared to that of the SUL device. In our study, however, we found no difference in stone retrieval time between the two devices. Additionally, there was a higher percentage of stone-free patients in the SUL group than in the PUL group. For insignificant stones, defined as stones less than 3 mm in size, 10 patients (66.7%) in the SUL group had no evidence of stone disease, compared to only six patients (46%) in the PUL group. Kuo and associates, using stone fragments seen on CT as an end point, had a similar stone-free rate of 66.7%.[15]

As stone composition is a strong determinant of outcome, we were also able to stratify efficacy with respect to stone composition. It is well established that in descending order, cystine, calcium oxalate monohydrate, and apatite stones are the hardest to fragment, and calcium oxalate dihydrate, struvite, and uric acid stones are the easiest to fragment.[15] Indeed for harder stones, the PUL seems to fragment them more efficiently, but the SUL is more efficient in fragmenting softer stones. Nakada

TABLE 3. RESULTS OF THE COMPARISON

	Lithoclast Ultra (PUL)	*LUS-1 (SUL)*	P *value*
Number of patients	13	17	—
Mean cumulative preoperative stone burden (mm)	21	18.5	0.52
Stone composition (% hard)[a]	64%	54%	0.51
Mean fragmentation time (minutes)	37	31.5	0.22
Mean stone retrieval time (minutes)	10	9	0.91
Mean operative time (minutes)	129	130	0.98
Mean cumulative postoperative stone burden (mm)	5.3	3.2	0.21
Number of stone-free patients[b]	6 (46%)	10 (66.7%)	0.26
Total technical problems	3 (23.1%)	8 (47%)	0.18
Number of suction tubing obstruction	2 (15.4%)	6 (35.3%)	0.35
Number of lithotrite malfunctions	1 (7.7%)	2 (11.8%)	0.53

[a] Hard stones are defined as calcium oxalate monohydrate, cystine, and calcium phosphate; soft stones defined as calcium oxalate monohydrate, struvite, and uric acid.

[b] Defined as stone fragments less than 3 mm in size.

and colleagues reported that treatment modalities can be selected by calculating the attenuation:size ratio. Stones can be differentiated as primarily calcium oxalate or uric acid on the basis of a cutoff of 80 Hounsfield units per millimeter.[16] Preoperative CT scans to determine stone composition can be a useful adjunct to help choose the most effective PCNL device.

CONCLUSION

Despite earlier studies suggesting improved efficacy of the combined pneumatic and ultrasonic probes in shortening overall operative time during PCNL, our study data suggest that ultrasonic probes are better able to fragment and completely remove staghorn calculi. This is especially true for softer stones composed of uric acid, calcium oxalate dihydrate, and struvite. Finally, with its significantly lower price, the ultrasonic LUS and the newer LUS-1 are considerably more cost effective than the Lithoclast Ultra.

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ABBREVIATIONS USED

CaOxDi = calcium oxalate dihydrate; CaOxMono = calcium oxalate monohydrate; $CaPO_4$ = calcium phosphate; CT = computed tomography; PCNL = percutaneous nephrolithotomy; PUL = pneumatic and ultrasonic lithotrite; SUL = standard ultrasonic lithotrite; SWL = extracorporeal shockwave lithotripsy.