Comparison of a single center, academic surgeon real-world experience with three percutaneous nephrolithotomy lithotripters

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Introduction: *We compared a single surgeon, single-institution experience with the Wolf Ultrasonic Model #2167.05 (Richard Wolf Medical Instruments Co., Vernon Hills, IL, USA), Lithoclast Ultra (Boston Scientific, Natick, MA, USA), and CyberWand (Gyrus/ACMI, Southborough, MA, USA) lithotripters for percutaneous nephrolithotomy (PCNL). We assessed each lithotripter's performance and durability.*

Materials and methods: *We conducted a retrospective chart review on 70 sequential PCNLs. Treatments were split into three cohorts based on the type of lithotripter used, Wolf (August 2003 to February 2004), Lithoclast (March 2004 to November 2008), or CyberWand (December 2008 to October 2009). Operative time, repeat PCNL procedures, lithotripter efficacy, patient body mass index (BMI), and stone-free rates (defined as < 4 mm fragment on postoperative day one noncontrast CT scan) were compared.*

Results: *Sixty-one patients underwent 70 PCNLs using the Wolf (12), Lithoclast (39) or CyberWand (19). The CyberWand cohort had higher rates of obesity (74% versus 53% for Lithoclast and 45% for Wolf) and staghorn calculi (68% versus 39% for Lithoclast and 36% for Wolf). Operative time were 151 minutes (75-384, Wolf), 190 (55-360, Lithoclast) and 200 (81-387, CyberWand) cohorts. Stone-free rates were 50% (Wolf), 49% (Lithoclast) and 37% (CyberWand). PCNL was repeated within 45 days following 6 (50%) Wolf, 7 (18%) Lithoclast and 1 (5%) CyberWand procedures. Lithotripter malfunction complicated 1 Wolf (8%), 5 (13%) Lithoclast and no CyberWand PCNLs. Intraoperative complications occurred during 1 (8%) Wolf, 9 (23%) Lithoclast, and 2 (11%) CyberWand cases.*

Conclusions: *Despite treating larger stones in more obese patients, the CyberWand lithotripter had a lower malfunction and need for repeat PCNL rates. These findings suggest that the CyberWand may be a more durable lithotripter. However, the overall efficacy of each lithotripter in performing PCNL was similar.*

Key Words: lithotripsy, urolithiasis, percutaneous nephrolithotomy

Introduction

Percutaneous surgery is the first line treatment for large or complex kidney stones.[1] Percutaneous nephrolithotomy (PCNL) uses different energy sources including: the holmium yttrium, aluminum, and garnet (holmium:YAG) laser, ultrasonic lithotripter, pneumatic lithotripter, and a combination ultrasonic-pneumatic lithotripter.[2] The three percutaneous lithotripters utilized by a single academic surgeon in this study use different energy sources. The Wolf Model #2167.05 (Richard Wolf Medical Instruments Co., Vernon Hills, IL, USA) is purely ultrasonic and is a historic gold standard. The combination ultrasonic-pneumatic Lithoclast Ultra (Microvasive, Natick, MA, USA; EMS, Bern, Switzerland) is a second generation machine touted as a more effective tool for PCNL.[2] The dual ultrasonic action of the CyberWand (Gyrus/ACMI, Southborough, MA, USA) lithotripter is a subsequent modification which has gained popularity as an effective PCNL device.

In vitro testing of the CyberWand and the Lithoclast Ultra has shown the CyberWand to be more efficient, with a twofold more rapid stone penetration.[3] Although previous testing has shown excellent clinical results with both devices,[4,5] there is a paucity of clinical data directly comparing the Lithoclast Ultra to the CyberWand. The aim of this study, therefore, is to

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compare a single academic institution, single surgeon experience with the Wolf, Lithoclast and CyberWand lithotripters for PCNL in an effort to gain real world insight as to relative efficacy and durability of each device.

Materials and methods

A retrospective chart review of 61 patients who underwent PCNL at a referral academic medical center between August 2003 and October 2009, by a single surgeon, was conducted. Patient demographics recorded were age, gender, and body mass index (BMI). Preexisting obesity was defined as a BMI ≥ 30 kg/m^2.

We examined stone laterality (unilateral versus bilateral), side (left versus right), location (lower pole, mid/inter pole, upper pole or renal pelvis), size (total burden [mm] or staghorn), and composition. Total stone burden was the sum of the largest measured diameter (mm) of each stone measured from a stone protocol CT scan performed within a month prior to surgery. Stone composition was determined by a single component compromising $\geq 50\%$ of the stone's character.

From August 2003 to March 2004, PCNL was performed using the Wolf lithotripter. From March 2004 until November 2008, PCNL was performed using the Lithoclast Ultra. Starting in December 2008 PCNLs were performed using the CyberWand machine. A comparison of the characteristics of each machine is presented in Table 1. All patients were positioned prone and percutaneous access to the stone was performed by interventional radiologist after discussion or communication with the urologist as to the optimal access location. The radiologist placed percutaneous nephroureteral access to the bladder.

Operative data included treatment date, initial or repeat procedure, operative time, and lithotripter performance. PCNL treatments were considered separately for patients who underwent sequential PCNLs for bilateral calculi. Repeat PCNLs were defined as conducted on the same side of a prior PCNL procedure for a residual stone within 45 days from a primary PCNL procedure. No patient underwent ureteroscopy alone as a secondary procedure. All procedures were performed with a supervised resident physician actively involved as surgeon.

A patient was considered stone free if < 4 mm of residual stone was visible on postoperative day one noncontrast CT scan. We elected to use this, rather than other stricter definitions such as < 2 mm or no residual, as we were interested in comparing each of the three lithotripters ability to fragment calculi into very small fragments. All intraoperative or postoperative complications were noted.

Statistical evaluation of categorical variables was performed using Chi square test, except in cases where the expected frequency was five or less in which case Fisher's exact test was used. P values of < 0.05 were considered statistically significant.

TABLE 1. **Comparison of three percutaneous nephrolithotripters**

	Wolf Ultrasonic	**LithoClast Ultra**	**CyberWand**
Manufacturer	Richard Wolf Vernon Hills, IL	Boston Scientific Natick, MA	Gyrus ACMI Southborough, MA
Mechanism of action	Ultrasonic	Ultrasonic and pneumatic	Ultrasonic and ballistic
Energy source	Piezoelectric elements	Piezoelectric elements, compressed air	Piezoelectric elements
Generator voltage	115 V	100 V-240 V	100 V-240 V
Generator frequency	60 Hz	50 Hz/60 Hz	50 Hz/60 Hz
Ultrasound frequency	23 kHz-27 kHz	23 kHz-26 kHz	21 kHz
Pneumatic frequency		2 Hz-12 Hz	
Ballistic frequency			1000 Hz
Probe diameter	3.5 mm	3.3 mm-3.8 mm	3.75 mm
Suction channel	yes	yes	yes
Dimensions (W x H x D)	340 mm x 120 mm x 260 mm	371 mm x 135 mm x 432 mm	310 mm x 120 mm x 280 mm

TABLE 2. **Patient demographics**

Variable	Wolf	Lithoclast Ultra	CyberWand
Patients	11	33	17
Median age	46 (24-60)	45 (23-78)	45 (23-71)
Average body mass index	31.6 (22-43)	30.3 (16-43)	33.2 (18-52)
Preexisting obesity	5 (45.4%)	18 (54.5%)	12 (70.6%)
Gender			
Male	5 (45.5%)	13 (39.4%)	6 (35.3%)
Female	6 (54.5%)	20 (60.6%)	13 (76.5%)

Results

Sixty-one patients underwent a total of 70 PCNLs using either the Wolf (n = 12), Lithoclast Ultra (n = 39) or CyberWand (n = 19) lithotripter at a referral academic medical center. One Lithoclast Ultra treatment was aborted secondary to severe truncal obesity (BMI = 57) and was subsequently eliminated from the cohort. Table 2 compares patient demographics of the three cohorts.

TABLE 3. **Characteristics of percutaneous nephrolithotomy (PCNL) treatment and calculi**

Variable	Wolf no. (%)	Lithoclast Ultra no. (%)	CyberWand no. (%)
PCNL treatments			
Total PCNL	12	39	19
Primary PCNL	11 (91.7)	34 (87.2)	18 (94.7)
Repeat PCNL	1 (8.3)	5 (12.8)	1 (5.3)
Mean operative time (min)	151 (75-384)	190.6 (55-360)	200 (81-333)
Operative complications	0 (0)	5 (12.8)	1 (5.3)
Lithotripter malfunction	1 (8.3)	5 (12.8)	0 (0)
Stone free outcomes	6 (50)	19 (48.7)	7 (36.8)
Stone side			
Left	7 (58.3)	25 (64.1)	11 (57.9)
Right	4 (33.3)	14 (35.9)	8 (42.1)
Bilateral	1 (8.3)	0 (0)	0 (0)
Stone location			
Upper pole	5	7	4
Middle pole	4	6	1
Lower pole	5	20	10
Renal pelvis	8	23	12
Total stone burden			
Average size (mm)	29.6 (12-91)	29.6 (10-60)	25 (9-35)
Staghorn	4 (33.3)	16 (41)	13 (68.4)
Stone composition			
Calcium oxalate monohydrate	2 (16.7)	9 (23.1)	4 (21.0)
Calcium oxalate dihydrate	1 (8.3)	2 (5.1)	2 (10.5)
Carbonate apatite	6 (50%)	14 (35.9)	8 (42.1)
Uric acid	2 (16.7)	0 (0)	1 (5.3)
Struvite	0 (0)	2 (5.1)	1 (5.3)
Calcium phosphate	0 (0)	1 (2.5)	0 (0)

Table 3 outlines characteristics of the calculi and PCNL procedures for each treatment cohort. The average number of stones treated for the Wolf, Lithoclast Ultra and CyberWand groups were 2.67 (1-13), 1.69 (1-7) and 1.16 (1-3), respectively. Stone composition was obtained for 11 (92%) Wolf, 29 (74%) Lithoclast Ultra and 16 (85%) CyberWand treatments.

Lithotripter malfunction complicated 1 (8%) Wolf, 5 (13%) Lithoclast Ultra and zero CyberWand PCNLs ($p = 0.24$). The Wolf lithotripter malfunction was an inability of the generator to create or transmit energy to the probe. Changing to new probes, adjusting settings, troubleshooting machine and restarting generator were not effective and the case was cancelled and rescheduled. The machine was tested preoperatively and was functional. The five Lithoclast Ultra malfunctions were probe failures and fractures and the solution was changing to new probes. There were no intraoperative complications for patients undergoing surgery using the Wolf machine. Lithoclast procedure intraoperative complications included two hydrothoraces requiring emergent chest tube placement and two blood transfusions (Clavien-Dindo Classification grades 3b, 3b, 2 and 2). One CyberWand PCNL patient became febrile (39.8°C) and hypotensive necessitating case abortion, while another received a blood transfusion (Clavien-Dindo Classification 2 and 2). These intraoperative complications were likely independent of the type of lithotripter used.

Postoperatively, after the first PCNL procedure, 6 (50%) Wolf, 19 (48.7 %) Lithoclast and 7 (36.8%) CyberWand patients were rendered stone free ($p = 0.66$). Wolf patients experienced 3 (25%) postoperative complications (nausea and vomiting, fever and a blood transfusion). Clavien-Dindo classification grades 1, 2 and 2. Lithoclast patients had 8 (21%) postoperative complications (blood transfusion, leukocytosis necessitating antibiotics, 400 cc pleural effusion requiring thoracentesis, fever (2), severe pain (2) and nausea and vomiting Clavien-Dindo classification grades 2, 2, 3a, 2, 2, 1, 1 and 1). CyberWand patients suffered 5 (42%) postoperative complications (severe pain and nausea, febrile illness (2), blood transfusion with transfusion-related fever and ureteral obstruction - Clavien-Dindo classification grades 1, 1, 2, 2 and 3b). No patient had gross hematuria necessitating embolization or required any treatment for postoperative bleeding beyond blood transfusion in three cases. All complications were short term and there were no long term complications. We found no statistically significant difference in complication rate between the three lithotripter cohorts ($p = 0.52$).

Discussion

In a randomized clinical trial of lithotripters, no appreciable difference between the dual-probe CyberWand and the standard single probe ultrasonic Olympus LUS-II (Gyrus/ACMI, Southborough, MA, USA) lithotrites was identified for the treatment of stones greater than 2 cm.[5] No difference ($p > 0.05$) in stone surface area, complications, and clearance rate were observed. Device malfunction occurred in twice as many CyberWand than LUS II procedures (32% versus 16%). In the CyberWand group, the malfunctions included four clogged and four broken probes. These results stands in stark contrast to prior *in vitro* studies[3], emphasizing the importance of comparative clinical trials.

Krambeck and colleagues believed the lack of difference in stone clearance was due to the tendency for the CyberWand probe to plug. We did not observe this in our series. They also commented that their initial production version of the CyberWand probe had a tendency to malfunction or break requiring replacement. We did not observe this in our series using the standard production CyberWand model. In fact, we observed the CyberWand probe to be more dependable and break-free than either the Lithoclast or Wolf lithotripters.

Importantly, the outcomes of Krambeck and colleagues' comparison of the CyberWand to the LUS-II conflicted with the results of Pietrow and associates' comparison of the Lithoclast Ultra to the LUS-II.[4,5] In the latter, the Lithoclast Ultra device was significantly more efficient than the LUS-II with a better stone clearance time (but with similar post-procedure stone free rates). Further, a higher complication rate in the LUS-II group was observed, although the complications could not be directly related to the device.

When comparing Pietrow's Lithoclast Ultra study with Krambeck's CyberWand study, similar stone clearance times (16.3 min versus 21.1 min, respectively) were observed, albeit by different surgical teams. However, continuing this comparison, the two studies reveal that stone clearance rates were lower with the Lithoclast Ultra than the CyberWand (39.5 mm^2/min versus 61.9 mm^2/min, respectively). However, the marked difference in the performance of the LUS-II device in each study well demonstrates the challenges with surgical study comparisons. In Pietrow and colleagues' study, the LUS-II was substantially slower at stone removal, requiring a mean of 43 min compared to the 13.5 min observed in the Krambeck and associates' study.[4,5] Furthermore, LUS-II stone clearance rates were much slower in the former compared to the latter study (16.8 mm^2/min versus 75.85 mm^2/min).

Our study has the known disadvantages of a retrospective, sequential case study. It therefore does not account for the greater BMI and percentage of staghorn calculi present in the CyberWand lithotripter cohort. While it has the limitations of a sequential series, it does have the advantage of being a single institution, single surgeon assessment. Although the senior surgeon's experience was greater in the CyberWand lithotripter cohort, the operative resident surgeons had similar experience in each cohort. This study further compares two different dual probe technologies (CyberWand and Lithoclast Ultra) to a single probe design (Wolf). While similar stone composition was present, the CyberWand cohort had a greater percentage of obese (74% versus 45% and 53%) and staghorn calculi (68% versus 36% and 39%) which while not statistically significant can make stone clearance time and postoperative stone free rate assessment problematic.

The increased obesity and staghorn calculi rates, rather than the type of lithotripter, may explain the increased operative complication rate seen in the CyberWand cohort.

The senior surgeon's opinion, after completing this series, that the CyberWand lithotripter is superior for handling large or staghorn calculi is supported by a lower need for repeat PCNL within 45 days after an initial PCNL using the CyberWand lithotripter (50%, 18% and 5% for the Wolf, Lithoclast and CyberWand, respectively). The decision to proceed with a second PCNL procedure within 45 days was largely subjective and predicated on the presence of significant residual fragments felt to be ineffectively treated by the first PCNL procedure often in a location concerning for obstruction. While the CyberWand cohort did not have a lower stone free rate defined as calculi < 4 mm, the postoperative assessment in this cohort was that the procedure, more often to treat a staghorn calculus, was largely successful, with only one or two residual fragments, typically just over 4 mm is size and in a nonobstructive location. This lower need to proceed with immediate repeat PCNL, we believe support our opinion as well as the findings of prior studies that stone clearance rates are lower with the Lithoclast Ultra than the CyberWand.[4,5]

Regarding lithotripter malfunction, the 8% Wolf and 13% Lithoclast Ultra rates, compared to no CyberWand cases, supports our perception that the CyberWand lithotripter is also the more durable/dependable lithotripter of the three. It is unclear why our malfunction findings are discordant to Krambeck and colleagues' other than that they used an initial production version of the CyberWand probe.

Other newer generation intracorporeal lithotrites have now been introduced, including the Swiss Lithoclast Select (Boston Scientific, Natick, MA, USA) and the Cook-LMA Stone Breaker (LMA Urology, Gland, Switzerland) and there is clear need for additional comparison of currently available lithotripters to further define differences in lithotripter efficacy and durability. □

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