The efficacy of the Dornier Doli S lithotripter for renal stones

Christopher C. Hoag, MD, William N. Taylor, MD, Victor A. Rowley, MD

Departments of Urological Sciences and Radiology, University of British Columbia, Vancouver, British Columbia, Canada

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Introduction: *There is little documentation of the efficacy of the Doli-S lithotripter. This study investigated the outcome of ESWL with the Doli-S lithotripter on previously untreated renal calculi.*

Methods: *Over a 12 month period, 105 consecutive patients with renal stones, treated by a single urologist were enrolled in the study. None of the stones were previously treated. Data gathered included stone characteristics and treatment characteristics. Treatment was to an endpoint of either fluoroscopically successful fragmentation or to 2500 shockwaves. Patients were followed with KUBs, ultrasounds, or CT-KUBs to assess residual stone burden. Treatment success was defined as complete clearing of the calculus, or residual fragments of less than 3 mm.*

Results: *One hundred five patients were treated and 16 were lost to follow-up. One hundred nineteen stones in 89 patients were included in our analysis. Mean follow-up was 115 days. The average stone size (expressed as mean of two measured stone dimensions) was 7.8 mm. After a single lithotripsy treatment, the overall treatment success rate was 47.9%. The left kidney accounted for 58% of the treated stones. Treatment success was greater for left renal stones than right-sided stones (55.1% versus 38.0%, p = 0.033). There was no significant difference in treatment success rates for calyceal location of stones. Lower pole stones were treated successfully in 57.9% of cases. Smaller stones (3 mm-10 mm) were more successfully treated than larger stones (10 mm-20 mm) (55.6% versus 24.1%, p = < 0.001).*

Conclusions: *Success rates for the Doli-S lithotripter for a single treatment of previously untreated renal stones ranged from 24%-58%, depending on stone size and location. These rates are lower than success rates reported for other lithotripters. Inferior pole calculi had a higher treatment success rate than previously reported. Factors associated with treatment success included smaller stone size, left-sided stones, and ease of fluoroscopic visualization.*

Key Words: kidney calculi, lithotripsy, prospective studies, treatment outcome, electromagnetics

Introduction

Extracorporeal shockwave lithotripsy (ESWL) was first clinically applied in 1980[1] and since then has become the preferred treatment for small renal and ureteral calculi. The Dornier HM3 was the first commercial lithotripter with reported success rates of 90%.[2,3] Second generation lithotripters were designed to reduce manufacturing and operating costs, to eliminate the water bath used by the HM3, and to make anesthetic-free treatment more feasible by widening the shock-wave source aperture. Despite greater compressive energy with narrower focal points and improved imaging modalities, the reported

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Address correspondence to Dr. William N. Taylor, University of British Columbia, Suite 650, 6091 Gilbert Road, Richmond, BC V7C 5L9 Canada

success rate for stone fragmentation was significantly less with these newer machines.

The Dornier Doli S (DLS) lithotripter, a third generation electromagnetic machine, has only four papers documenting its success, including only one comparative in vitro trial.[4-7] The purpose of this study was to report on a single urologist's experience with the Dornier Doli S machine for the treatment of previously untreated renal stones.

Methods

Over a 12 month period (December 2002 – December 2003), 105 consecutive patients with previously untreated renal stones less than 20 mm in size treated with the Doli S lithotripter by a single urologist (WNT) were enrolled in this study. Stones distal to the ureteropelvic junction were excluded. Data included patient characteristics (age, gender, weight, height, body mass index), stone characteristics (size, location, radio-opacity, ease of visualization), and treatment characteristics (patient position, use of contrast, number of shocks, shock intensity, fluoroscopy time, and the presence or absence of a stent or nephrostomy tube). Radioopacity was judged by VAR based on the pre-operative KUB x-ray. Conscious sedation was used in all patients.

Each stone was treated until successful fragmentation was observed fluoroscopically or to a maximum of 2500 shocks. Of the six possible shock intensities a minimum of level 4 was used and maintained if fragmentation was evident, otherwise the intensity was increased to level 5 or 6 if early fragmentation did not occur. The shock-wave rate was quickly increased to 120 shocks/minute in all patients over the course of the first 500-1000 shocks. IV contrast was required for poorly localized or radiolucent stones.

Patients were followed with plain abdominal x-rays (KUB), ultrasound (US), or non-contrast computed tomography (CT-KUB). The films were all reviewed by the same radiologist (VAR). Pre and post-operative stone size was calculated as the average of the maximum two dimensions measurable on the given imaging modality (stones measured on CT were based on cross-sectional images only). Patients were imaged within 2 weeks following treatment and subsequently as needed. Treatment success was defined as either 'no residual stone fragments' or 'no fragments greater than 3 mm in maximum diameter', in keeping with multiple other ESWL studies.[5,6,8,9] Stone-free rates were also specifically recorded. Stone analysis data was recorded whenever available.

Although we did not specifically track ancillary treatments, lithotripsy failures were managed with ureteroscopy, PCNL, or observation depending on the clinical circumstances.

Statistical analysis

Significance testing was conducted on the continuous variables such as age, body mass index (BMI), stone size, number of shocks and fluoroscopy time, to identify statistically significant differences in these variables for successful versus unsuccessful treatments. The two sample t-test was utilized, with a significance level of $p < 0.05$. In addition, significance testing was conducted on categorical variables using a standard two proportion test to identify statistically significant differences of proportions for successful versus unsuccessful treatments, with a significance level of $p < 0.05$. Categorical variables include gender, stone side, radiolucency, ease of visualization, presence or absence of a stent, presence or absence of a nephrostomy tube, contrast, shock intensity, patient position and location of stones.

Results

Over a 12 month period, 105 patients had ESWL for previously untreated renal stones. Sixteen of these patients were lost to follow-up, leaving 119 treated stones in 98 kidneys of 89 patients for inclusion in the analysis. There were no major complications including perirenal hematomas, sepsis, colic requiring further interventions, or hospitalization. The patient, stone, and treatment characteristics of the analyzed group are detailed in Table 1. The majority of stones (96.6%) were followed-up with KUB x-rays for economic reasons and to minimize radiation exposure (2 with CT; 2 with US). The overall first-treatment success rate, Table 2, was 47.9% (57 stones of 119 stones). Of these, 59.6% (34 of 57) were considered to be stone-free and the remainder had no fragments greater than 3 mm in maximum diameter. Twenty-three stones had repeat ESWL treatments (37% of the first-treatment failures). Of these, eight had a successful outcome, yielding a 34.8% success rate for those with more than one ESWL treatment. Seven of these eight had a successful outcome after a single retreatment, while one required four treatments. Six stones had more than one retreatment and only one of these was successful (a multiple-retreatment success rate of 16.7%). The ultimate success rate (with one or more treatments) was 54.6% (65 stones of 119 stones), 76.9% (50 of 65) of which were stone-free. Ninety stones were < 10 mm in size and 29 were 10 mm -20 mm in size. Stones less than 10 mm were

TABLE 1. **Patient, stone, and treatment characteristics (SD = standard deviation)**

Characteristics	Mean (range or SD)	Percentage (number)
Age	55 yrs (25 yrs-85 yrs)	-
Male patients	-	58.0% (69)
BMI	26.9 (18.4-49.2)	-
Stone size	7.8 mm (2.15 mm-19.25 mm)	-
Radio-opaque	-	92.4% (110)
Easy visualization	-	61.3% (73)
Mod. visualization	-	22.7% (27)
Difficult visualization	-	16.0% (19)
Contrast used	-	10.1% (12)
Supine position	-	98.3% (117)
Max shock intensity	4.8 (4-6)	-
# Shocks administered	2076 (SD = 699)	-
Fluoroscopy time	148 sec (SD = 78 sec)	-
Presence of stent	-	16.8% (20)
Stone location		
Left kidney	-	58.0% (69)
Upper pole	-	19.3% (23)
Middle pole	-	29.4% (35)
Lower pole	-	31.9% (38)
Renal pelvis	-	19.3% (23)

successfully treated on first treatment significantly more often than those 10 mm-20 mm in size (55.6% versus 24.1% respectively, p = 0.002). Left-sided stones were successfully fragmented more often than right-sided stones (55.1% versus 38.0% respectively, p = 0.033). There was no significant difference in treatment success between stones of differing polar locations. Lower pole stones had a success rate of 57.9% which was higher than upper pole stones (39.1%, p = 0.078), although not significant.

TABLE 2. **First-treatment success rates**

Group (number)	Success rate (number)
Stones < 10 mm (90)	55.6% (50)
Stones 10 mm-20 mm (29)	24.1% (7)
Right-sided stones (50)	38.0% (19)
Left-sided stones (69)	55.1% (38)
Upper pole stones (23)	39.1% (9)
Middle pole stones (35)	45.7% (16)
Lower pole stones (38)	57.9% (22)
Renal pelvis stones (23)	43.5% (10)
Overall (119)	**47.9% (57)**

Comparison of the first-treatment success versus non-success groups is detailed in Table 3. There were no significant differences between these groups in terms of gender, BMI, radio-opacity of the stone, ease of visualization of the stone, presence of a stent, number of shocks delivered, or fluoroscopy time. The successfully treated group was approximately 5 years younger than the unsuccessfully treated group. Successfully treated stones were significantly smaller than unsuccessfully treated stones (6.5 mm versus 9.0 mm). Contrast was used significantly less often in the successfully treated group than the unsuccessful group. A significantly higher success rate occurred amongst those stones treated with a shock intensity of 4, as opposed to the maximum intensity of 6 (61.5% versus 26.3%, p = 0.006). The success rate of stones treated with a shock intensity of 5 was intermediary between levels 4 and 6 (45.9%). Despite the obvious pattern, this did not represent a significant difference from either of the other two intensity levels.

Stone analysis data was available for 39 patients (43.8% of those treated). Of these 39 patients, 15 (38.5%) had calcium oxalate stones, 15 (38.5%) had mixed calcium oxalate/calcium phosphate stones, 3 (7.7%) had uric acid stones, 1 (2.5%) had calcium phosphate stones, and 5 (12.8%) had other mixed composition stones.

TABLE 3. **First-treatment success versus non-success group (ns = not significant)**

Factor	Success group	Non-success group	P value
Age (mean)	51.8	56.5	0.028
Gender (% male)	42.0%	58.0%	ns
BMI (mean)	27.2	27.4	ns
Stone size (mean)	6.5 mm	9.0 mm	< 0.001
Radio-opaque	96.5%	88.7%	ns
Easy visualization	59.6%	62.9%	ns
Mod. visualization	24.6%	21.0%	ns
Difficult visualization	15.8%	16.1%	ns
Contrast used	5.3%	14.5%	0.047
Ureteric stent present	19.3%	14.5%	ns
# shocks (mean)	2028	2119	ns
Fluoroscopy time (mean)	141 sec	154 sec	ns

Discussion

The overall first-treatment success rate in our series was 47.9% (59.6% of these were stone free). While first-treatment success rates are often poorly reported in the literature (the tendency being to report ultimate success rates over a course of one or more treatments), our success rate is disappointing. Only one other study clearly reports the first treatment success rates for renal stones with the Dornier Doli S lithotripter (75%)[6] Table 4. Johnson's and Sheir's data for first-time treatment of renal stones had success rates of 81.4% and 65.4% respectively.[4,5] Approximately 20% of Johnson's study subjects were treated under general anesthesia and all of the stones were solitary, while Sheir chose only radio-opaque stones for treatment, making comparison of our results to either of these studies difficult. The pre-cursor machine to the Doli-S, the Dornier Doli/50, reported first-treatment success rates from 55%-87%, with the higher success rates in patients who received a general anesthetic.[10-12] Using the Doli/50, Sorensen found only a 55% first-

TABLE 4. **Reported success rates for electromagnetic lithotripters (success defined as per our definition unless otherwise specified; only comparable studies with clearly reported or easily calculable outcomes for renal stones included)**

Lithotripter	Reference	First-treatment success rate	Ultimate success rate	Stone inclusion criteria
Dornier Doli S	Sheir et al[4]	65.4%*	88.5%	Radioopaque only
	Johnson et al[5]†	81.4%*	87.7%	Solitary stones
	Di Pietro et al[6]	75%	87.5%	5 mm-25 mm, ?solitary
	Authors' findings	47.9%	54.6%	All stones < 20 mm
Dornier Doli/50	Krishnamurthy et al[10]	67.8%*	na	Solitary renal pelvis, < 20 mm
	Sorensen et al[11] (cs)	55.0%	na	Solitary radioopaque < 20 mm
	Sorensen et al[11] (ga)	86.5%	na	Solitary radioopaque < 20 mm
Dornier Compact	Kawano et al[9]	86%	86%	5 mm-80 mm stones
Storz Modulith SL20	Coz et al[19]‡	69.5%	86.2%	Radioopaque, 4 mm-70 mm

* = calculated from data provided in publication; na = not available; cs = conscious sedation; ga = general anesthetic; † = success defined as no fragment > 4 mm and not clear if those with ancillary procedures included in ultimate 'success' group; ‡ = success defined as no fragments on KUB x-ray

treatment success rate when conscious sedation was used instead of general anesthesia.[11] All patients in our series were treated with conscious sedation and our low success rate appears to be concordant with Sorensen's findings. In a separate single-urologist study at our institution, with similar patient/stone inclusion criteria, Perks et al found a 42% first-treatment success rate[13] which is similar to our findings. This range of inter-operator variation in success rates (42% versus 47.9%) is in keeping with other studies of intra-institutional ESWL outcome differences.[14]

Our ultimate success rate (after one or more ESWL treatments) was 54.6% (76.9% of these were stone free). The success rates for several other electromagnetic lithotripters have been studied, Table 4. Few head-to-head trials comparing lithotripsy machines are published. Only two studies have specifically addressed the efficacy of the Doli S lithotripter in comparison to other machines.[4,7] Sheir performed a prospective randomized comparative study of the Doli S machine and the Dornier MFL 5000 (an electrohydraulic lithotripter). He reported that the Doli S machine had higher success rates (88.5% versus 82.4%), shorter treatment times (54 minutes versus 65.7 minutes), and lower retreatment rates (34% versus 51.6%) than the MFL 5000, thereby concluding that the Doli S was the superior lithotripter.[4] An in vitro comparative study of seven commercial lithotripters (Dornier HM3, Dornier Doli S, Storz Modlulith SLX, Siemens Lithostar C, Medstone STS-T, Healthtronics Lithotron 160, and Medispec Econolith), however, found the Doli S and Econolith machines to be the least successful at achieving fragmentation of stones to particles < 2mm in size.[7]

There are multiple factors which may explain our relatively poor success rates in comparison to other published series. First, our goal was to determine the efficacy of this machine for any patient with a previously untreated renal stone. No patient was excluded based on stone radio-opacity, multiplicity, polar location, or size. This differs from many studies in which inclusion criteria are limited based on these factors, "see Table 4". An expected outcome of studies which include small solitary radio-opaque stones would be higher success rates. Second, conscious sedation, used in our series, has demonstrated poorer outcomes than treatments with a general anesthetic[11]. Finally, a potential criticism of our study is that our inclusion criteria were too broad, however similar efficacy results were demonstrated by another urologist in an independent study using the same machine.[13] We feel that the broad inclusion criteria of our study are a strength, as they reflect the spectrum of patients that are referred for ESWL.

Our first-treatment success rate was modest at 47.9% and retreatment success rates were significantly lower. The first retreatment success rate was 30.4% (7 of 23 patients), while further retreatments yielded only a 16.7% success rate. This trend of diminishing returns with repeat ESWL treatments has been well documented in the literature[6, 15] and has led us to conclude that there is little point in persisting beyond a single retreatment in most patients treated on this machine.

Predictors of treatment success were small stones (< 10mm), left-sided stones, easily visualized stones (no contrast used), and low shock-wave power. Success rates based on laterality of stone location are variably reported in the literature. Several authors have reported poorer success rates for ESWL of left-sided stones,[4,16,17] while we found left-sided stones to be treated successfully significantly more often than right-sided stones (55.1% versus 38.0%). In Riedler's study of lower calyceal stones, he found a higher success rate with left-sided stones and he commented on this paradox in the literature.[18]

In this study, significantly higher success rates were also found amongst those treated without the use of contrast and those treated with a lower shock intensity. We believe that these factors are surrogate markers for stones which are easily localized and fragmented under fluoroscopy. Contrast was used only in cases in which localization of the stone was difficult and suggests that targeting in these cases was less accurate. Shock intensity was only increased in cases where poor fragmentation was observed fluoroscopically.

Unsuccessfully treated calculi required a higher number of shock waves than successfully treated stones (2119 versus 2028). We also found no trend to improved outcome with increased fluoroscopy time as has previously been reported[14]. In fact, more fluoroscopic time was used in unsuccessfully treated cases. Finally, our successfully treated group was significantly younger than those who did not achieve a satisfactory outcome, for which there is no explanation. There was no difference in BMI between the two groups which might have otherwise explained the difference.

Conclusions

The first-treatment success rate for renal stones less than 20 mm in size using the Doli-S lithotripter was 47.9% (59.6% of these stone free). A success rate of 54.6% (76.9% of these stone free) was achieved with multiple treatments in this study and compares poorly to the reported success rates with other machines. Comparison with other studies must be interpreted

cautiously, however, as the inclusion criteria of such studies vary widely.

Predictors of success in this study were stones < 10mm in size, easily visualized stones (not requiring contrast administration), lower shock-wave power, and left-sided stones. Retreatment yielded rapidly diminishing returns with a 30.4% success rate for first retreatment, and only 16.7% for all retreatment thereafter. □

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