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Primary Choice in the Management of the Ureteral Stones: What is the Factors to a Successful Stone Removal in Primary Extracorporeal Shock Wave Lithotripsy ?

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The aim of the study is to determine the factors that influence a complete ureteral stone fragmentation with a single extracorporeal shock wave lithotripsy (ESWL) session. We analyzed the medical records of 284 patients with ureteral stones who were treated with ESWL as a primary therapy between January 1996 and December 2002. Among them, 265 patients were followed at least 3 months after the ESWL. Patients who had a complete stone-free status in the first session of the ESWL were defined as the successful group and the others were defined as the failure group. We compared the two groups using the multivariate logistic regression analysis. In 265 patients, 244 patients were treated with ESWL alone. Seventy-five percents of the patients were stone-free with a single session of the ESWL. The stone width was the only independent risk factor for ESWL failure. When a stone width was ≧6 mm, more than 20% of the stones would not be removed with a single ESWL. The odds ratio of stone width by 2 mm to the failure rate was 1.71. The stone width of <6 mm was the most important factor influencing the success of a single ESWL session.

Key words: extracorporeal shock wave lithotripsy, ureteral stone, stone-free rate, multivariate logistic regression analysis

Introduction

Extracorporeal shock wave lithotripsy (ESWL) is currently a primary treatment method for upper urinary tract stones. Although it is minimally invasive, the mean stone-free rate of ESWL is 78-89%[1] and sometimes a secondary treatment is required. Recent advances in fiberoptic engineering have enabled the development of functional ureteroscopes that are small enough to allow access to the entire upper urinary tract[2] and ureteroscopic stone removal achieves more immediate stone-free status in a high percentage of patients than the ESWL[1)3)]. To avoid wasteful repetitive treatment, it is useful to determine how a ureteral stone can be disintegrated in a single ESWL session. Therefore, we retrospectively analyzed the stone-free rate of a single ESWL session with the Siemens Lithostar in consecutive series of patients with ureteral stones.

Materials and Methods

Two hundred eighty four patients with ureteral stones underwent shock wave lithotripsy using Lithostar (Siemens Medizinische Technik, Erlangen, Germany) as a primary treatment at the Kurihashi Hospital from January 1996 to December 2002. Of these, 265 (93%) were followed at least 3 months after the ESWL. The patients did not receive any pretreatment procedures such as the placement of a Double-J stent or a percutaneous nephrostomy tube. They were 197 males and 68 females, ranging from 15 to 86 (mean 48) years old.

Table 1 Patient demographics and clinical date (ESWL success group vs ESWL failure group)

Characteristics		Total n = 265	ESWL	
			Success group n = 199	Failure group n = 66
Age (years)	mean ± SD	48 ± 13	47 ± 14	51 ± 12
Gender	male/female	197/68	148/51	49/17
Location	proximal/mid/distal	180/13/72	137/5/57	43/8/15
Stone side	rt/lt	161/104	124/75	37/29
Stone length	mean ± SD	9.8 ± 3.8	9.3 ± 3.4	11.3 ± 4.5
Stone width	mean ± SD	6.1 ± 2.2	5.8 ± 1.9	7.1 ± 2.7
Power	mean ± SD	5.3 ± 1.1	5.3 ± 1.1	5.3 ± 1.2
Shots	mean ± SD	5,154 ± 1,715	4,962 ± 1,702	5,740 ± 1,632
Obstruction	negative/positive	89/176	71/128	18/48

The median length of the stone was 9.8 mm ranging from 3 to 30 mm in diameter and the median width of the stone was 6.1 mm ranging from 2 to 15 mm in diameter. There were 180 patients (68%) with proximal (lumbar), 13 (5%) with mid-ureteral (overlying the bone pelvis) and 72 (27%) with distal (pelvic) stones. Patients were treated with ESWL under intravenous sedation, epidural anesthesia or lumbar anesthesia.

Before the ESWL, all patients underwent plain X-ray of kidneys, ureters and bladder in addition to another radiographic study, such as excretory urography (IVP), ultrasound or computerized tomography. Patients stayed overnight in the hospital on the day of the treatment.

The degree of ureteral obstruction, such as caliceal blunting or clubbing, was classified as negative or positive according to the morphologic findings of the excretory urography and ultrasound. There were no impacted stone.

Crystallographic analysis of stone composition was available in 132 patients in this study (whewellite as the main mineral, n = 50; weddellite as the main mineral, n = 80; calcium phosphate and carbonate, n = 1; and uric acid, n = 1). We analyzed the stone composition which disintegrated with ESWL between the whewellite and the weddellite.

All patients were evaluated at 3 months after the last session of the ESWL. Stone-free status was determined by a plain X-ray of the kidney, ureter, and bladder. Patients who had complete removal of all fragments in the first session of ESWL were defined as the successful group and others who still had residual stone fragments and required an auxiliary procedure or a secondary ESWL were defined as the treatment failure group. We compared these two groups according to the patient and stone characteristics (Table 1).

An appropriate sample size for this research was calculated by nQuery Advisor 5.0. The analyses were performed with the SAS System 8.2 (SAS Institute Inc, Cary, North Carolina, USA). The data were presented as means ± SD. Two-tailed p-values of less than 0.05 as considered indicating statistical significance.

Results

Patient demographics, average stone size, shock wave lithotripsy power, numbers of shot and urinary obstruction are summarized in Table 1. A total of 294 sessions (average: 1.11 sessions/patient) was performed. Of the 265 patients, 244 patients were treated with ESWL alone (single session, n = 229; multiple session, n = 15) and 21 required additional transurethral ureterolithotripsy (TUL) due to the failure of ESWL. The overall stone-free rate for ESWL alone was 79.6% (211/265). 75.1% (199/265) of the patients were stone-free with a single session at the third month after the ESWL. In 199 of the patients with successful single ESWL, there were 137 patients (68.8%) with proximal, 5 (2.5%) with mid-ureteral, and 57 (28.6%) with distal stones. No complications occurred.

No significant differences in gender, existence of obstruction, side (rt/lt) and stone composition were found between the successful single ESWL group and the failure group. In contrast, there were statis-

Table 2 Univariate and multiple logistic regression analysis of stone fragmentation failure in single ESWL session

Predictors	No of patients	No of failure group in single ESWL session	Univariate			Multivariate		
	n = 265	n = 66 (%)	crude odds ratio	95% CI	p value	adjusted* odds ratio	95% CI	p value
Age > 10 years	265	66 (24.9)	1.25	1.01-1.55	0.042			
Gender								
female	68	17 (25.0)	1					
male	197	49 (24.9)	0.99	0.63-1.88	0.983			
Size								
length > 2 mm	265	66 (24.9)	1.29	1.11-1.49	< 0.001			
width > 2 mm	265	66 (24.9)	1.71	1.32-2.22	< 0.001	1.71	1.32-2.22	< 0.001
Obstruction								
negative	88	18 (20.5)	1					
positive	176	48 (27.3)	1.46	0.79-2.70	0.229			
Location								
proximal	180	43 (23.9)	1					
mid	13	8 (61.5)	5.1	1.58-16.40	0.006			
distal	72	15 (20.8)	0.84	0.43-1.63	0.603			
Side								
right	104	29 (27.9)	1					
left	161	37 (23.0)	0.77	0.44-1.36	0.368			
Stone composition								
whewellite	50	13 (26.0)	1					
weddellite	80	16 (19.5)	0.71	0.31-1.64	0.425			

* Adjusted odds ratio was obtained by multiple logistic regression model with best subset variable selection method, 95% CI: denotes 95% confidence interval.

tically significant differences in age, stone location (mid-ureteral), and stone size (length and width) between the groups (Table 2).

The stone width was the only independent risk factor for ESWL failure by the multivariate logistic regression analysis. The odds ratio of stone width by 2 mm to the failure rate was 1.71 (Table 2).

Discussion

ESWL has become a first-line treatment for ureteral stones because of its minimal invasiveness. However, large stones and impacted stones sometimes require a secondary ESWL or additional maneuvers[4]. Hyungkeun et al reported that the stone-free rate after a single ESWL treatment for stones with length < 1.0 cm in diameter was 83.6%. However, the rate for stones with length > 1.0 cm was 42.1%[5]. There are some reports that show the efficiency of ESWL is low (50-60%) for impacted stones[6][7].

In this study, the stone-free rate after a single ESWL session was 75%. Twenty-five percent of the patients needed multiple sessions of ESWL or TUL. Recently, ureteroscopy and intracorporeal lithotripsy has become a safe and highly effective treatment option for ureteral stones. Mario et al[3] reported that stone-free rate in their study was 98%. In treating patients, it is important to achieve a stone-free state as soon as possible. Because repeated ESWL sessions are less cost effective and stressful treatment for the patient, it is useful to distinguish the stones which are successfully removed by a single ESWL session from the stones which are not removed by a single ESWL session.

The aim of this retrospective study, therefore, was to find the factors related to ureteral stones disintegration in a single ESWL session. Our results showed that patient's age, stone size (both length and width) and mid location of a stone were significant predictors of ureteral stones disintegration in a single ESWL in a univariate analysis and stone width was the only independent significant predictor of a successful single ESWL treatment in a mul-

tivariate logistic regression analysis.

Aging as a significant predictor could be speculated by the fact that aging decline the peristaltic action of the ureteral muscle. The decline peristaltic action of the ureteral muscle makes the excretion of stone fragmentations difficult and thus a complete stone clearance after a single ESWL is hardly achieved.

Clearance of stones in the middle ureter was probably more difficult than those in other locations. Hofbauer et al[8] evaluated the treatment outcome of 1,259 ureteral stone and reported that the success rate of ESWL was 98, 71, 84% for stones in the proximal, mid, distal ureter, respectively. With that, it is considered that pelvic bones and/or bowel gas interfered with the delivery of high-energy shock waves and the frequent difficulty of imaging may have influenced the incorrect focusing of the stones.

The American Urological Association guidelines and some previous reports stated the length of the ureteral stone affected stone-free rate but rarely mentioned about the stone width. To our knowledge, this is the first report that shows that stone width is an independent predictor for disintegration in a single ESWL session.

Abdel-Khalek et al[9] evaluated the factors that have a significant impact on the stone-free rate after in situ ESWL monotherapy using a multivariate analysis. The site of the stone, the stone width and the presence of a ureteral stent were factors which had significant impact on the stone-free rate. Similar to our study, the stone length was not a significant predictor of ESWL success. According to their report, 50.4% (473/938) of the cases required a repeat treatment and 24.9% (234/938) had two sessions ESWL and 25.5% (239/938) needed more than two sessions ESWL to ensure complete fragmentations. The overall stone-free rate (88.7%) was very good, but the repeat ESWL rate was higher than other published reports. To promote cost effective treatment, it would be necessary to decide a stricter stone width indication for ESWL.

The mechanisms of stone fragmentation in ESWL are partly explained by the circumferential quasistatic compression or squeezing by evanescent waves in the stone and the cavitation around the stone[10]. Because the pressure waves in ESWL pulses arrive at the side of a stone, ureteral stone width might be the most influential factor in circumferential quasistatic compression or squeezing. The larger the stone width, the less space there is between a stone and the ureteral lumen, making the cavitation around the stone difficult.

Table 3 Estimated probability of failure rate in single ESWL session about stone width

Stone width (mm)	Estimated probability of the failure rate in single ESWL session (%)	95% Confidence interval (%)
2	9.2	4.9－16.6
3	11.7	7.1－18.8
4	14.8	10.0－21.4
5	18.5	13.7－24.6
6	22.9	18.1－28.7
7	28.0	22.5－34.3
8	33.8	26.6－41.7
9	40.0	30.4－50.5
10	46.6	34.0－59.7
11	53.3	37.5－68.4
12	59.9	41.1－76.2
13	66.1	44.7－82.5
14	71.9	48.2－87.5
15	77.0	51.8－91.2

In this study, stone-free rate in a single ESWL session was more than 80% when the stone width was <6.0 mm (Table 3). Literature review for the management of ureteral stones showed that stone-free rate of a single session ureteroscopy was between 74.2 to 97%[11)12)]. Some reported that ureteroscopy achieved a significant earlier stone-free state than the ESWL for distal ureteral stones[13]. In addition, ureteroscopy was more successful than ESWL for the treatment of multiple stones[14]. Except for its invasiveness, ureteroscopy seems to be a more effective treatment method than the ESWL for ureteral stones especially when the stone width $\geqq 6.0$ mm.

Therefore, we recommend using ESWL as a primary treatment if the width of a ureteral stone is <6.0 mm. For stones $\geqq 6.0$ mm, ureteroscopic treatment should be considered as the primary treatment particulary if patients desire an immediate

stone-free status despite all invasiveness caused.

Whewellite is generally considered a risk factor to ESWL failure. In this study, however, there was no significant difference in stone-free rate between the whewellite and the weddellite.

Existence of obstruction is also considered as one of the risk factors affecting the success rate. A lack of a liquid interface surrounding the embedded stone prevents easy fragmentation of the stone. It is reasonable that impacted stones with severe hydronephrosis might be treated less successfully with ESWL[15)16)]. In our analysis, however, existence of an obstruction was not a significant risk factor to the ESWL stone fragmentation.

In conclusion, aging, mid ureteral stone and stone size were the factors of unsuccessfully complete stone fragmentation with a single ESWL session. In addition, stone width is an independent predictor for stone disintegration in a single ESWL session. We therefore suggest that ESWL should be for the primary treatment for ureteral stone when the stone width is less than 6 mm.

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尿管結石に対する初期治療の選択—初回 ESWL において結石治療が成功する要因は何か？—

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今回，我々は尿管結石に対する体外衝撃波結石破砕術（ESWL）の適応を検討するために初回 ESWL による尿管結石完全破砕の要因は何かを評価した．1996 年 1 月から 2002 年 12 月までに尿管結石に対する第一選択治療として ESWL を行った 284 名の患者の治療成績を解析した．これらの症例中，少なくとも ESWL 治療後 3 ヵ月間の治療経過が観察可能であったのは 265 症例であり，初回 ESWL で完全排石した症例を ESWL 成功群，それ以外を ESWL 失敗群と定義し，両群をロジスティック回帰分析で解析を行った．244 例は ESWL 単独で治療されており，その 75% の症例は単回治療で完全砕石された．多変量解析において，結石の短径が唯一の ESWL 不成功の独立因子であった．短径が 6 mm 以上では 20% 以上の症例は ESWL 単回治療では完全砕石されず，短径が 2 mm 増大するごとに結石砕石の不成功のオッズ比は 1.71 倍であった．今回の検討において，尿管結石において短径が 6 mm 未満であることが初回 ESWL での完全破砕率に最も重要な因子であった．