Prognostic Factors for Success in Treating Kidney Stones by Extracorporeal Shock Wave Lithotripsy

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Background: *Extracorporeal shock wave lithotripsy (ESWL) is widely used worldwide to treat kidney stone because it is without invasive and can be done on an outpatient basis. However, not all patients are treated successfully. The success of kidney stone treatment by ESWL depends on several factors.*
Objective*: To investigate prognostic factors for the successful treatment of kidney stones by ESWL.*
Material and Method*: A prospective cohort study was made of 394 patients with kidney stone who underwent ESWL using Storz SLX-20 Lithotripter at Chiang Mai University Hospital between June 2008 and October 2009. All patients were followed up for three months after treatment to evaluate treatment success. Success was defined as the presence of clinically insignificant residual fragments less than or equal to 4 mm or complete clearance of the stones. Data were analyzed using exponential risk regression to determine the prognostic factors of ESWL treatment success.*
Results*: The ESWL treatment success rate was 81.2%. The stone free (SF) rate was 56.4%. The clinically insignificant residual fragment (CIRF) rate was 24.8%. The median number of ESWL treatment sessions was two (IQR = 2-4). Multivariable exponential risk regression analysis demonstrated that the statistically significant prognostic factors for ESWL treatment were stone size < 15 mm (IRR = 1.52, 95% CI = 1.13-2.05, p = 0.005), stone location (renal pelvis had a higher success rate than lower calyx; IRR = 1.32, 95% CI = 1.01-1.72, p = 0.028) and a single stone (IRR = 1.35, 95% CI = 1.02-1.79, p = 0.035).*
Conclusion: *Stone size, stone location, and stone number were prognostic factors in determining the success of ESWL treatment.*

Keywords: *Extracorporeal shock wave lithotripsy, Kidney stones, Prognostic factors*

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Kidney stone disease, or nephrolithiasis, is a common disorder, with a prevalence ranging from 4-15% in different parts of the world[1]. Its prevalence in Thailand is 10%[2]. Methods of kidney stone management include drug therapy, extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), ureteroscopy and open surgery.

ESWL is an acceptable technique and widely used because it is a non-invasive treatment and does not require anesthesia and it can be done on an outpatient basis[3,4]. It can disintegrate a stone into particles of less than 2 mm by shock wave energy, so the particles can then pass down to the ureter[5,6]. Generally, ESWL is the best treatment for kidney stones smaller than 2 cm[7,8]. However, not all ESWL treatments are successful[8,9]. The success rate has been reported to be between 50%-90%[10,11], depending on stone size, stone location, stone number, renal morphology, congenital anomalies[5,12] and stone composition[12,13].

There are few reports on ESWL treatment success rates including prognostic factors for success rates in Thailand. Therefore, the present study aimed to investigate factors for successful ESWL treatment

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of kidney stones. Determining these factors will increase the efficiency of kidney stone treatment by ESWL.

Material and Method

Study design

A prospective cohort study recruited 394 patients diagnosed with nephrolithiasis and treated by ESWL in the Surgery Department, Chiang Mai University Hospital, between June 2008 and October 2009. All patients were treated with Storz Medical Lithotripsy (MODULITH® SLX-20). Inclusion criteria were patients age>18 years with kidney stones who underwent ESWL. Exclusion criteria were patients with kidney stones who were candidates for ESWL but had residual stones after treatment with open surgery or PCNL and/or non-functioning kidneys.

Data including age, sex, body mass index (BMI), kidney morphology, congenital anomalies, stone size, stone number, stone location and complications after ESWL were collected and evaluated according to the success rate of treatment.

Measurements and definitions

Stone free is defined as complete clearance of the stones.

Clinically insignificant residual fragment is defined as fragments of stone smaller than or equal to 4 mm.

Success of ESWL is defined as the presence of clinically insignificant residual fragments less than or equal to 4 mm, complete clearance of the stones, or being stone free after ESWL.

All patients were investigated with pre-treatment urinalysis, plain kidney urinary bladder (KUB) x-ray and/or intravenous pyelogram (IVP) if kidney function was present. Patients were followed-up for 3 months to evaluate the success of treatment using plain KUB. The Faculty of Medicine, Chiang Mai University's ethics committee approved the present study.

Statistical analysis

The exponential risk regression was used to determine the prognostic factors of success after treatment. The analysis was divided into two steps. The first step was a univariable analysis to determine the prognostic factors for treatment success. Factors with p-value less than 0.2 were then selected to the multivariable analysis using the stepwise method. Risk ratios (Incidence risk ratio (IRR)) with 95% CI were presented for the results. A p-value less than 0.05 was used for statistical significance.

In order to detect a difference of at least 16.5% success rate between number of stone (s)[13,14], a sample size of 186 would be required, based on a significance level of 5% and a power of 90%. A dropout rate of 15% was included in the calculation, giving a total sample size of at least 214 patients to be recruited in the present study.

Results

A cohort study was made of 394 patients. The success rate after ESWL was 320 cases (81.2%). Of these, 222 cases (56.4%) were stone free. Ninety-eight cases (24.8%) had CIRF or stone size < 4 mm. Stone free rate of stones < 15 mm was 65.4% and of stones > 15 mm was 15.5%. Seventy-four cases were treated unsuccessfully (18.8%). Of these, 50 cases (12.7%) had significant residual fragments (SRF) or size of stone > 4 mm and 22 cases (5.6%) showed no response to ESWL or change after other methods of treatment. Re-treatment was needed in 238 cases (60.4%). The median number of ESWL sessions was two (IQR = 2-4) to reach stone free status or complete stone clearance. The average number of shock waves was 1000-3500. The duration of ESWL was between 25 and 100 minutes.

Treatment success, classified by demographic characteristics of patients and characteristics of stones by univariable exponential risk regression, shows that BMI 18.5-24.9 kg/m^2 (IRR = 1.36, 95% CI = 1.05-1.77, p = 0.021), stone size < 15 mm (IRR = 1.66, 95% CI = 1.25-2.21, p < 0.001), stone location (renal pelvis had a higher success rate than lower calyx; IRR = 1.32, 95% CI = 1.02-1.71, p = 0.033), a single stone (IRR = 1.59, 95% CI = 1.23-2.07, p < 0.001) were prognostic factors for successful treatment by ESWL (Table 1).

After controlling for variables with p-value less than 0.2 from univariable analysis, such as BMI, stone number, stone size and stone location, multivariable exponential risk analysis showed that stone size < 15 mm (IRR = 1.52, 95% CI = 1.13-2.05, p = 0.005), stone location (renal pelvis had a higher success rate than lower calyx; IRR = 1.32, 95% CI = 1.01-1.72, p = 0.028) and a single stone (IRR = 1.35, 95% CI = 1.02-1.79, p = 0.035) were statistically significant prognostic factors of ESWL (Table 2).

Complications after ESWL occurred in 13 cases (3.4%), with steinstrasse in 10 cases (2.5%) and one each of massive hematuria, septicemia and anuria (0.2%).

Table 1. Treatment success classified by demographic and baseline characteristics of patients and stone

Characteristics	Success (n = 320) n (%)	Failure (n = 74) n (%)	Crude IRR (95% CI)	p-value
Age (years)				
≤ 40	60 (81.1)	14 (18.9)	Reference	
> 40	260 (81.3)	60 (18.7)	1.01 (0.75-1.34)	0.988
Mean (SD)	50.9 (11.6)	49.1 (9.8)		
Sex				
Female	146 (80.2)	36 (19.8)	Reference	
Male	174 (82.1)	38 (17.9)	1.02 (0.81-1.27)	0.839
BMI (kgs/m^2)				
≤ 18.5	11 (84.6)	2 (15.4)	1.31 (0.70-2.48)	0.391
18.5-24.9	202 (87.5)	29 (12.5)	1.36 (1.05-1.77)	0.021
> 25.0	77 (64.2)	43 (35.8)	Reference	
Mean (SD)	23.7 (3.4)	24.3 (3.2)		
Kidney morphology				
Perfect	246 (81.7)	55 (18.3)	1.36 (1.05-1.77)	0.356
Obstructed	67 (80.7)	16 (19.3)	Reference	
Congenital anomalies				
No	310 (81.8)	69 (18.2)	1.22 (0.65-2.29)	0.524
Yes	10 (66.7)	5 (33.3)	Reference	
Stone size (mm)				
≤ 15	259 (91.6)	24 (8.4)	1.66 (1.25-2.21)	<0.001
> 15	61 (54.9)	50 (45.1)	Reference	
Mean (SD)	12.7 (4.3)	16.8 (4.8)		
Stone location				
Lower calyx	145 (72.5)	55 (27.5)	Reference	
Middle calyx	29 (90.6)	3 (9.4)	1.25 (0.84-1.86)	0.237
Upper calyx	40 (93.0)	3 (7.0)	1.28 (0.90-1.82)	0.163
Renal pelvis	96 (96.0)	4 (4.0)	1.32 (1.02-1.71)	0.033
Multiple sites	10 (52.6)	9 (47.4)	0.72 (0.38-1.37)	0.327
Stone number				
Single	246 (92.5)	20 (7.5)	1.59 (1.23-2.07)	<0.001
Multiple	74 (57.8)	54 (42.2)	Reference	

IRR = incidence risk ratio

Discussion

ESWL is the treatment of choice for patients with kidney stones[14]. The mechanism of ESWL is disintegration of the stone into particles by producing mechanical compressive, tensile forces, and transient cavitation at the stone's surface with shock wave energy, followed by the particles passing down through the ureter[5,6,16]. The success rate of ESWL depends on several factors, such as stone size, stone composition, and stone number[13,14].

The present study shows that the success rate of ESWL treatment was 81.2% (stone free and CIRF). The results are consistent with those from previous studies by Abdel-Khalek (86.7%), Al-Ansari (78%) and Politis (74%)[12,13,20]. The overall stone free rate in the present study was 56.6%, which compares to studies from the USA[19]. However, the rate is lower than that of Qatar (63.4%) and in Egypt (86.7%)[13,14]. Stone free rates ranged between 70% and 90% for upper and middle calyceal stones, while those for stones located in the lower calyces ranged from 50% to 70%[21,22]. It was difficult to directly compare the stone free rates to other studies due to the use of different types of ESWL machine and cutoff points of stone size. The original HM3 lithotriptor was more effective than the newer lithotripters, and the different cutoff points for stone size may have affected the treatment outcome[23].

In the present study, the prognostic factors for success rate following ESWL were studied, such as sex, age, BMI, kidney morphology, congenital

Table 2. Factors associated to treatment success in kidney stone patients (multivariable analysis)

Factors	Adjusted IRR (95%CI)	p-value
Stone size		
≤ 15 mm	1.52 (1.13-2.05)	0.005
> 15 mm	Reference	
Stone location		
Upper calyx	1.23 (0.86-1.74)	0.246
Middle calyx	1.22 (0.82-1.81)	0.327
Renal pelvis	1.32 (1.01-1.72)	0.028
Multiple sites	0.92 (0.45-1.84)	0.911
Lower calyx	Reference	
Stone number		
Single	1.35 (1.02-1.79)	0.035
Multiple	Reference	

After adjusted for BMI, stone number, stone size, stone location
IRR = incidence risk ratio

anomalies, stone size, stone location, and stone number. By multivariable analysis, the results also showed that stone size, stone location and stone number were significant prognostic factors of successful ESWL outcome. The results were consistent with Abdel-Khalek et al's and Al-Ansari et al's studies[12,13]. In contrast, previous studies found that age, kidney morphology, and congenital kidney anomalies had a significant impact on the success rate[13,14].

Several studies indicated that the stone size strongly predicted ESWL success[12,13]. ESWL was the best treatment for stones less than 2 cm in size[7,8]. In the present study, small stone size was the strongest factor, with an adjusted relative risk ratio of 1.52. Small stones (size < 15 mm) had higher success rates than large stones (size > 15 mm) because shock wave energy more easily fragmented the smaller stones than the large stones. Previous studies reported that small stones had a success rate of 91% with stone size of 2 cm or smaller[16] and large stones had success rates ranging from 50% to 70% with a stone size of 2-3 cm[15]. Sorensen et al concluded that stone size could predict outcome of ESWL, rather than lower pole caliceal anatomy[17].

The location of stone is one of the most common factors for success following ESWL. Several studies concluded that stone location was a predictor of ESWL success rate[12,13]. Stone location in the renal pelvis had the highest treatment success compared to other locations. In addition, the results of the present study by multivariable analysis showed that the stone location was a significant prognostic factor. Thus, ESWL is the most efficient treatment for stone in the renal pelvis. Nevertheless, the success rate of ESWL usually decreases according to location, starting with the upper calyx, the middle calyx and the lower calyx, respectively. In particular, the success rate is the lowest when treating stones in the lower calyx because there are often fragments of stones remaining in this location after ESWL, which pass with much more difficulty down the ureter[18,19].

In the present study, stone number was a significant factor of ESWL success rate. A single stone was a strong factor with an adjusted relative risk ratio of 1.35 and had a higher success rate than multiple stones since the energy of the shock waves compress the surface of a single stone, leading to easy fragmentation. On the contrary, multiple stones have multiple surfaces, making it more difficult to cause fragmentation. Similarly, Abdel-Khalek et al's study showed that stone number was a significant predictor of ESWL outcome[13]. Some studies concluded that the number of stones can predict a better ESWL success rate than the stone size[19].

Complications of ESWL were steinstrasse, hematuria, septicemia, and adjustment open surgery. In the present study the rate of complications was low (3.4%), compared with other studies[12,19]. Complications included steinstrasse (2.5%), massive hematuria (0.2%), septicemia (0.2%) and anuria (0.2%). Steinstrasse is a column of stone fragments within the ureter that may cause partial or complete obstruction after ESWL[14,19]. However, the steinstrasse could be prevented by insertion of a ureteral stent prior to treatment[7]. Hematuria is virtually universal after ESWL because ESWL affects the kidneys and nearby organs. Most patients after ESWL may have slightly pink or dark red urine[24], which will usually disappear within 24 hours after treatment.

Finally, there were some limitations to the present study. First, some factors predicting the success rate of ESWL in the present study may not be consistent with the factors in previous studies due to the small number of patients in the failure group in the present study. This might cause lower power to detect some factors. Second, the present study did not include stone composition which may be a potential factor affecting the success rates following ESWL. Some types of kidney stones have higher levels of density, leading to more difficult stone fragmentation.

The expense of stone composition analysis was an obstacle to study this factor in the present study.

Conclusion

ESWL will have a high success rate for kidney stone patients with stone size (< 15 mm), stone location in the renal pelvis and a single stone. The results of the present study can provide information for urologists to treat kidney stones effectively with ESWL.

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Potential conflicts of interest

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ปัจจัยทำนายความสำเร็จของผู้ป่วยนิ่วในไตด้วยการสลายนิ่ว

วิไลวรรณ จงรักษ์สัตย์, บรรณกิจ โลจนาภิวัฒน์, วรวัฒน์ ชุมสาย ณ อยุธยา, ชไมพร ทวิชศรี, ชยันตร์ธร ปทุมานนท์, สมบูรณ์ ไพจิตรวิเชียร

ภูมิหลัง: *การสลายนิ่ว (extracorporeal shock wave lithotripsy-ESWL) เป็นการรักษานิ่วในไตที่ใช้ กว้างขวางทั่วโลก เพราะไม่ล่วงล้ำทั้งยังสามารถรักษาแบบผู้ป่วยนอก อย่างไรก็ตามการรักษาไม่ประสบความสำเร็จในผู้ป่วยทุกราย ความสำเร็จของการสลายนิ่วขึ้นกับหลายปัจจัย*

วัตถุประสงค์: *ประเมินปัจจัยที่มีผลต่อความสำเร็จของการรักษานิ่วในไตด้วยการสลายนิ่ว*

วัสดุและวิธีการ: *การศึกษาแบบ Prospective cohort study ในผู้ป่วยที่ได้รับการวินิจฉัยเป็นโรคนิ่วในไต และได้รับการสลายนิ่วโดยใช้เครื่องรุ่น Storz Medical Lithotripsy (MODULITH® SLX-20) จำนวน 394 ราย ณ โรงพยาบาลมหาวิทยาลัยเชียงใหม่ ตั้งแต่เดือนเมษายน พ.ศ. 2551 ถึงตุลาคม พ.ศ. 2552 ติดตามผู้ป่วยทุกรายหลังการสลายนิ่วเป็นเวลา 3 เดือน เพื่อประเมินความสำเร็จของการรักษา ซึ่งหมายถึงการไม่พบนิ่วเหลืออยู่ (stone free-SF) หรือนิ่วเหลือขนาด ≤ 4 มม. (clinically insignificant residual fragment-CIRF) วิเคราะห์ข้อมูล ด้วยสถิติ exponential risk regression*

ผลการศึกษา: *อัตราความสำเร็จของการสลายนิ่ว 81.2% ไม่พบนิ่วเหลืออยู่ 56.4% และนิ่วเหลือขนาด ≤ 4 มม. 24.8% จำนวนครั้งของการสลายนิ่วที่สำเร็จเท่ากับ 2 ครั้ง (พิสัยควอไทล์เท่ากับ 2-4) ผลการวิเคราะห์แบบ multivariable exponential risk regression analysis พบว่าปัจจัยที่มีผลต่อความสำเร็จของการสลายนิ่วอย่างมีนัยสำคัญทางสถิติได้แก่ นิ่วที่มีขนาด ≤ 15 มม. (IRR = 1.52, 95% CI = 1.13-2.05, p = 0.005) ตำแหน่งของนิ่ว (นิ่วที่อยู่ตำแหน่ง renal pelvis มีอัตราความสำเร็จสูงกว่า lower calyx; IRR = 1.32, 95% CI = 1.01-1.72, p = 0.028) และนิ่วก้อนเดียว (IRR = 1.35, 95% CI = 1.02-1.79, p = 0.035)*

สรุป: *ขนาด ตำแหน่ง และจำนวนของนิ่ว เป็นปัจจัยที่มีนัยสำคัญทางสถิติต่อความสำเร็จของการรักษาด้วยวิธีสลายนิ่ว*