The Efficacy of Early Extracorporeal Shockwave Lithotripsy for the Treatment of Ureteral Stones

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Purpose: To determine the efficacy of early extracorporeal shockwave lithotripsy (e-ESWL) in colic patients with ureteral stones and the patient criteria for the most effective e-ESWL.

Materials and Methods: 335 patients who received ESWL due to ureteral stone, were divide in two groups: e-ESWL and d-ESWL by the critical cut-off point. we performed the sensitivity and specificity cut-off analyses to identified the critical cut off point. To assess the difference in the factors affecting ESWL success, univariate and multivariate logistic analyses were implemented with using variables: ESWL success; age; gender; BMI; comorbidity; serum creatinine; stone size; stone location; stone laterality; Hounsfield unit (HU); presence of hydronephrosis; and presence of tissue rim. The subgroup analysis for the screened variables was conducted.

Result: Optimal e-ESWL was defined to occur within a 24-hour critical cut-off time. Multivariate regression analysis concluded with screened variables: age, stone size, stone location, and HU, that ESWL success was 1.85-fold higher in the e-ESWL patient group. The subgroup analyses the following conditions: ≤ 65 years old by 1.784-fold; □10 mm stone size by 1.866-fold; mid to distal stone location by 2.234-fold; and ≤ 815 HU by 2.130-fold. When all the conditions were met, the e-ESWL success was 3.22-fold higher.

Conclusion: In case of colic due to ureteral stones, the patient is recommended to receive a lithotripsy within the first 24 hours. E-ESWL is recommended especially in patients who are ≤ 65 years, or with a ureteral stone HU ≤ 815, sized ≤ 10 mm, or in a mid to distal location.

Keywords: Extracorporeal shock wave lithotripsy; ureteral stones; colic

INTRODUCTION

Ureteral obstruction from ureteral stones often results in colic-like pain and is one of the most common conditions in the field of urology[1]. For the treatment of acute colic caused by ureteral stones, methods such as extracorporeal shockwave lithotripsy (ESWL), ureteroscopic (URS) lithotripsy, and conservative drug therapy are used. The treatment method is determined through consideration of factors such as the ureteral stone status; size, location, degree of obstruction, technical facilities, possible complications, surgeon and patient preference, and comorbidities. Conservative drug therapy often leads to complications like recurrent pain, and URS lithotripsy shares the advantages of a more rapid stone clearance but requires a longer hospital stay with an increased rate of complications [2,3]. Recently, ESWL is the treatment method of choice for ureteral stone patients because it is noninvasive compared to the surgical method, meaning there are fewer risks associated with general anesthesia and a lower morbidity due to the advancements in equipment[4,5].

Performing ESWL before a mucosal edema develops around the ureteral stones is expected to help with reducing the stone free time; many studies have since proceeded with ESWL and have found that early treatment after the development of colic-like pain leads to fast stone break up and effective relief of the pain from obstruction[2,6-9]. However, studies regarding the use of ESWL in an emergency setting to conduct the most effective early ESWL (e-ESWL) are still insufficient[10]. There is a requirement for e-ESWL in order to effectively treat ureteral stones; therefore, the purpose of this study was to determine the efficacy of e-ESWL and the patient criteria for the most effective e-ESWL.

MATERIALS AND METHODS

Study design and ESWL procedure

This retrospective study conducted a single center, the

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Table 1. Comparison of characteristics between the early ESWL and the deferred ESWL groups.

Variables	early ESWL a (N=215)	deferred ESWL a (N=120)	*p*-value
Demographics			
Age (yr)	46.71 ± 12.97	49.12 ± 15.35	0.1481[b]
Gender (Male)	131 (60.93%)	79 (65.83%)	0.3736[c]
BMI (kg/m^2)	24.59 ± 3.13	24.11 ± 3.94	0.4918[b]
Hypertension	23 (10.70%)	29 (24.17%)	0.0011[c]
Serum creatinine (mg/dl)	0.8 (0-1.5)	0.8 (0-2.2)	0.6713[d]
Radiologic parameters			
Stone size (mm)	6.93 ± 2.40	7.91 ± 2.99	0.5653[d]
Stone location (mid-to-distal)	127 (59.07%)	54 (45.00%)	0.0132[c]
Stone laterality (left)	102 (47.44%)	63 (52.50%)	0.3746[c]
Hounsfield unit	612.22 ± 360.05	647.00 ± 316.08	0.3769[b]
Hydronephrosis	171 (79.53%)	92 (76.67%)	0.5400[c]
Tissue rim sign	46 (22.12%)	44 (39.29%)	0.0011[c]
ESWL treatment			
Time to ESWL (hr)	15.64 ± 7.74	120 ± 167.08	<.0001[d]
Number of ESWL	1.75 ± 1.63	2.31 ± 1.74	0.0149[d]
Post ESWL treatment (URS lithotripsy)	7 (3.93%)	4 (4.49%)	1.0000[e]
Time to stone free (day)	14.0 ± 26.82	18.5 ± 51.30	0.0303[d]
Stone free within 1 month	171 (79.53%)	78 (66.00%)	0.0035[c]
Adverse events			
Asymptomatic Steinstrasse	0 (0.00%)	1 (0.83%)	
Pain	5 (2.31%)	2 (1.67%)	
other	2 (0.93%)	1 (0.83%)	

Abbreviations: ESWL, extracorporeal shockwave lithotripsy; BMI, body mass index; URS lithotripsy, Ureteroscopic lithotripsy
aMean ± SD or median (range) for continuous variables, N (%) for categorical variables; bt-test; cChi-square test; d. Mann-Whitney *U* test; e. Fisher's exact test.

Gachon University Gil Medical Center. This study included 378 patients who were admitted to the Gachon University Gil Medical Center Emergency Room, or to the Urology Department as an outpatient, due to colic-like pain caused by a solitary radio opaque ureteral stone resulting in treatment with ESWL from January 2016 to December 2016. Among the patients included in this study, the 43 patients were dropped out and the 335 patients completed follow up. The study patients did not have conditions which were contraindicative to ESW: acute urinary tract infection or urosepsis; uncorrected bleeding disorders or coagulopathies; pregnancy; uncorrected obstruction distal to the stone, and did not receive any other procedures except until the end of treatment for the ureteral stone. Before patients received ESWL, their medical history was collected, and the patients underwent a physical examination, routine blood or urine tests, plain radiography of the kidney-ureter-bladder (KUB), and non-contrast enhanced computed tomography (NCCT). Based on the radiological findings, stone factors including size, location, presence or absence of hydronephrosis, tissue rim sign, and mean Hounsfield units (HU) were investigated. HU, a parameter generated from standard CT, are related to the density of the stone or structure of interest. Prior to ESWL, patients received an analgesic (Dichlofenac, 30 mg, intra-muscular injection or pethidine, 50 mg, intravenous injection), after ESWL, all patients were given pain medication. Patients did not receive pain medication during the ESWL procedure. ESWL was conducted using a Modulith SLX-F2 Urological workstation (Storz Medical, Switzerland). In all cases, ESWL procedures were conducted at 3000 shocks were performed per session, at a frequency of 90 shocks per minute (1.5Hz) and the same power per shock wave. One week after the ESWL session, plain radiography of the KUB was used to check for the presence of residual ureteral stones. If residual stones could not be determined with plain radiography of the KUB, NCCT was used. When a residual stone was identified, the next ESWL session was carried out. Stone frees status was defined as no identification of any residual stones upon imaging. The time to ESWL (from the start of the pain to the first ESWL session), total number of ESWL sessions, time to stone free status, and stone free status within 1 month of the first ESWL session was defined as ESWL success; the ESWL success rate and complications after ESWL were investigated.

Variables that affect ESWL success rate in early ESWL and statistics

To determine the time to ESWL in order to perform the most effective ESWL (the critical point of the most effective ESWL), the sensitivity and specificity depending on the cut-off time to ESWL were analyzed. In a Receiver Operating Characteristic (ROC) curve, the true positive rate (Sensitivity) is plotted in function of the false positive rate (100-Specificity) for different cut-off time points to ESWL. Each point on the ROC curve represents a sensitivity/ specificity pair corresponding to ESWL success (stone-free within a month). We set the closest point to the upper left corner of the ROC curve as a critical cut-off time point. Based on this critical cut-off point, patients were categorized as into the e-ESWL patient group or the deferred ESWL (d-ESWL) patient group to compare the patient characteristics and ESWL success. Univariate logistic regression was conducted on the ESWL success with variables such as age, gender, BMI, comorbidity, serum creatinine, stone size, stone location, stone laterality, HU, presence of hydronephrosis, and presence of a tissue rim. Those variables with a *p*-value < 0.1 were screened further with multivariate logistic regression analysis. In addition, to determine the patient criteria for the most effective e-ESWL, further subgroup analysis was performed for those screened variables through univariate logistic analysis.
Ethical approval was obtained by the Institutional Re-

Table 2. Variables that affect early ESWL success using univariate and multivariate logistic regression analyses.

Variables	Unit	Odds Ratio (95% C.I.) [a]	*p*-value
All patients (N=335)[b]			
Age	10	0.789 (0.659-0.944)	0.0213
Hypertension		0.487 (0.261-0.907)	0.0234
Stone size	1	0.874 (0.793-0.963)	0.0066
Hounsfield unit	100	0.888 (0.824-0.957)	0.0207
Stone location	'mid to distal' vs 'proximal'	1.873 (1.101-3.186)	0.0018
Early ESWL		1.850 (1.093-3.130)	0.0219
All patients (N=335)[c]			
Age	10	0.804 (0.667-0.968)	0.0213
Hounsfield unit	100	0.888 (0.824-0.957)	0.0207
Stone location	'mid to distal' vs 'proximal'	1.873 (1.101-3.186)	0.0018
Early ESWL		1.850 (1.093-3.130)	0.0219
Patients aged < 65 years (N=297)[c]			
Hounsfield unit	100	0.864 (0.796-0.938)	0.0005
Stone location	'mid to distal' vs 'proximal'	1.912 (1.074-3.402)	0.0276
Early ESWL		1.784 (1.006-3.166)	0.0478
Patients with stone size < 10 mm (N=320)[c]			
Age 10		0.763 (0.627-0.928)	0.0068
Hounsfield unit	100	0.896 (0.827-0.972)	0.0083
Stone location	'mid to distal' vs 'proximal'	1.943 (1.117-3.378)	0.0187
Early ESWL		1.866 (1.080-3.223)	0.0254
Patients with mid-to-distal ureter (N= 181)[c]			
Hounsfield unit	100	0.860 (0.769-0.962)	0.0082
Early ESWL		2.234 (1.029-4.853)	0.0422
Patients with Hounsfield unit < 815 (N=243)[c]			
Hypertension		0.284 (0.131-0.615)	0.0014
Stone location	'mid to distal' vs 'proximal'	2.363 (1.198-4.660)	0.0131
Early ESWL		2.130 (1.084-4.187)	0.0283
Patients favorably treated with early ESWL d (N=128)[c]			
Early ESWL		3.222 (1.038-10.007)	0.0430

Abbreviations: ESWL, extracorporeal shockwave lithotripsy; CI, confidence interval
aOdds ratio for univariate logistic regression and adjusted odds ratio for multivariate logistic regression.
[b]Univariate logistic regression analysis.
[c]Multivariate logistic regression analysis.
dPatients with age < 65 years, Stone size < 10 mm, Stone location = 'Mid-to-distal' ureter and Hounsfield unit < 815.

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RESULTS

The mean age of the 355 patients (210 men, 115 women) was 47.57 ± 13.9 years, the mean body mass index (BMI) was 24.36 ± 3.53 kg/m^2, the mean serum creatinine was 0.72 ± 0.38 mg/dl, and comorbidities included 52 patients with hypertension (15.52%) and 32 patients with diabetes (9.55%). The mean ureteral stone size was 7.42 ± 2.92 mm; a left ureteral stone was found in 165 patients (49.25%), a right ureteral stone in 170 patients (50.75%), an upper ureteral stone in 154 patients (45.97%), and a middle and lower ureteral stone in 181 patients (54.03%). The mean HU of the stone was 624.68 ± 344.9, a tissue rim sign was identified in 90 patients (26.87%). Patients received a mean of 1.95 ± 1.2 sessions of ESWL, and ESWL success was confirmed in 249 patients (74.33%).

Figure 1 showed the results of sensitivity and specificity cut-off analysis. The left diagram was a sensitivity/specificity plot versus time to EWSL and the right diagram was the ROC curve. This ROC curve with area under the curve (AUC) = 0.6434 was significant in contrast to the reference line with AUC = 0.5 ($P <$ 0.0001). The critical point for time to ESWL was determined to be 24 hours (area under the curve = 0.6434) (**Figure 1**). Based on this 24-hour time to ESWL, patients were classified into the e-ESWL patient group (n = 215) and d-ESWL patient group (n = 120)(**Table 1**). The significantly different variables between the patient groups were as follows: In the e-ESWL patient group, the number of patients with signs of a tissue rim were significantly less (46 patients, 22.12% vs 44 patients, 39.23%), as was the number of patients with proximal ureter stones (88 patients, 40.93% vs 66 patients, 55.00%), the mean number of ESWL sessions (1.75 vs 2.31), and the time to stone free status (14 days vs 18.5 days). The ESWL success rate was higher in the e-ESWL patient group when compared to the d-ESWL patient group (171 patients, 79.53% vs 78 patients, 66.00%) (**Table 1**).

The univariate logistic regression analysis showed that age (P = .0098), stone size (P = .0066), stone location (P = .002), and HU (P = .0001) were variables with P-value < 0.1. Results from the multivariate logistic regression analysis indicated that ESWL success was 1.85 times greater in the e-ESWL patient group compared with the d-ESWL patient group (**Table 2**). In order to determine the most effective e-ESWL patient criteria, subgroup analysis was performed for screened variables, which showed that patients aged 65 or younger (n = 297), with stone size 10 mm or smaller (n = 320), a stone location of mid to distal (n = 181), and a HU of 815 or less (n = 243) showed greater ESWL success in e-ESWL than d-ESWL by 1.784 fold, 1.866 fold, 2.234 fold, and 2.130 fold, respectively. When all these variables were met (n = 128), the ESWL success was 3.22 times greater in the e-ESWL group than in the d-ESWL group (**Table 2**).

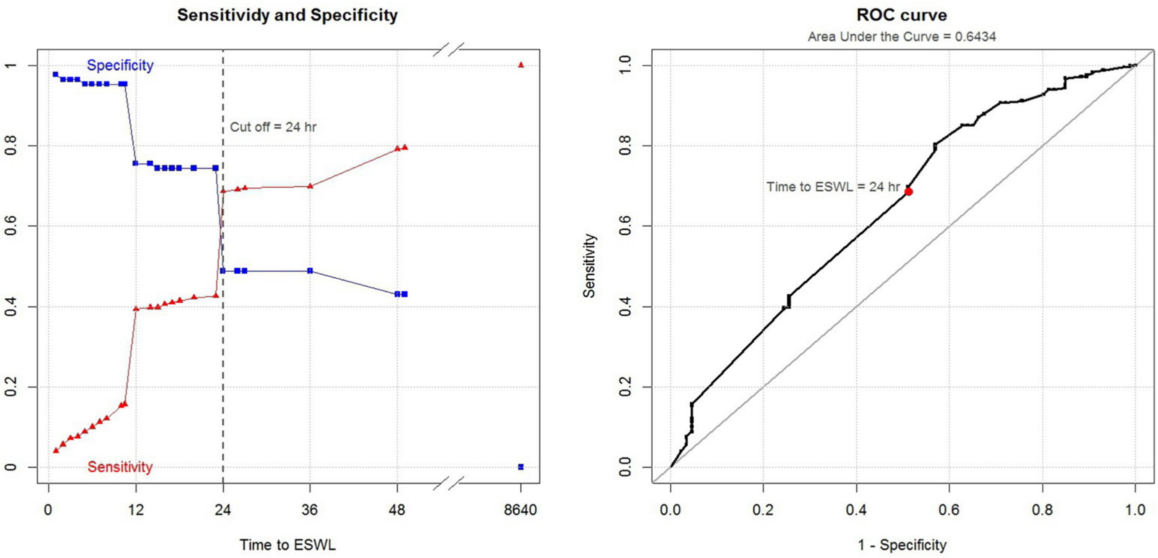

Figure 1. Sensitivity and specificity at different 'Time to extracorporeal shock wave lithotripsy (ESWL)' (left); Receiver operating characteristic (ROC) curve of 'Time to ESWL' (right).

DISCUSSION

In this study, we define optimal e-ESWL to occur within a 24-hour critical cut-off time (area under the curve = 0.6434); e-ESWL had a 1.85 times greater ESWL success rate than d-ESWL (adjusted odds ratio; 1.850). This was especially true in patients aged 65 or younger, with a stone size of 10 mm or smaller, with a stone location of mid to distal, and with a HU of 815 or less, who showed a 3.22-fold greater ESWL success rate with e-ESWL than d-ESWL (adjusted odds ratio; 3.222) (**Table 2**).

Once pain develops due to the ureteral stone, edema of the ureter mucosa occurs within 24-48 hours and inhibits the expansion chamber formation of the ureter; the fluid layer between the stone fragments and tissue disappears, disturbing the removal of stone fragments by ESWL[10-14]. In a study using an artificial neural network, it was suggested that the longer the delay in treatment after the development of pain from a ureteral stone, the longer it takes to remove the stones[12]. As a result, many studies have recommended conducting ESWL at an earlier stage, as soon as the colic-like pain develops; however, the definition of e-ESWL varies between studies (6-72 hours)[15,16]. In this study, sensitivity and specificity cut-off analysis depending on the time to ESWL was conducted to determine the most effective e-ESWL time point; our results suggest that the critical cut-off time to perform ESWL is 24 hours (**Figure 1**). Since there are many factors that affect the ESWL outcome, the patients were classified into e-ESWL or d-ESWL patient groups based on the critical 24-hour cut-off time to ESWL to accurately determine the effectiveness of early lithotripsy. The variables identified in the univariate logistic analysis underwent multivariate logistic analysis to determine ESWL success; it was confirmed that the e-ESWL patient group had a 1.85 times greater success rate than the d-ESWL patient group (adjusted odds ratio 1.850)(**Table 2**).

Many studies to determine the patient criteria for the most effective e-ESWL are also ongoing[16-20]. In this study, we conducted subgroup analysis to identify the patient criteria for the most effective e-ESWL. The results showed that e-ESWL is most effective in patients aged 65 or younger (**Table 2**)[18]. Increasing age is known to decrease the ESWL success rate and increase the chance of side effects[21-23]. Many hypotheses are present for the decreasing success rate with the older age, including that the ureteric motility change with age affects the success rate[21].

In this study, the patient group with a ureteral stone HU of 815 or less (n = 243) showed a higher success rate in e-ESWL. Previous studies have demonstrated that the stone's density evaluation can be accessed via HU value measurement through computed tomography (CT)[24]. Therefore, as the mean HU value of the stone is considered the strongest predictive factor for the removal of a ureteral stone, it plays a critical role in determining the treatment method[17]. In lithotripsy, a higher mean HU value of a stone leads to a lower success rate with a higher probability of residual stones, and thus, it is considered a critical predictive indicator for successful treatment[25]. Many studies have presented various cut-off values of HU for successful ESWL treatment (785-900)[24-28]. A recent study showed that the success rate of lithotripsy was exceptionally higher with stones <815 HU compared to stones > 815 HU, regardless of the stone composition, which is similar to the findings of this study; stones < 815 HU had a 2.213 higher chance of success rate for e-ESWL than d-ESWL[17].

Stone size is also known as an important predictive factor for ESWL success; increasing size of a ureteral stone negatively correlates with the ESWL success rate, which is also associated with e-ESWL[11]. A study by Tligui et al. reported that the success rate of an early lithotripsy is best with 6-10 mm sized stones, while 10-20 mm sized stones had the worst results[8]. In addition, Choi et al. reported that stones sized 10 mm or smaller had the best ESWL success rate[16]. The subgroup analysis of this study also confirmed that the patient group with stones sized 10 mm or smaller had a 1.866 times greater probability (adjusted odds ratio 1.866) of success in e-ESWL than in d-ESWL.

The location of the ureteral stone is another important factor for effective e-ESWL. Uguz et al. reported that e-ESWL of an upper ureteral stone resulted in a higher stone free rate[20]. In addition, Choi et al. reported that during e-ESWL of proximal ureteral stones, the ESWL success rate was high and ESWL sessions were few[16]. On the other hand, Picozzi et al. reported that the location of the stone had no effect on the stone free rate after an early lithotripsy. A study by Choi et al. suggested that although the success rate of e-ESWL for mid to distal ureteral stones is high, it is not statistically significant due to the limitation of a small sample size[16]. In this study, the effectiveness of e-ESWL on mid ureteral stone location was analyzed (adjusted odds ratio 2.234) (**Table 2**). Considering the results of previous studies in our observations, we report that e-ESWL is not only effective in treating proximal ureteral stones, but is also sufficiently effective in treating mid ureteral stones.

Formation of ureteral stone is a common condition that can lead to the development of various side effects, increasing the frequency of the hospital visits, leading to an economic burden on society. Therefore, it is essential that the treatment of ureteral stones is safe and effective. According to the results of this study, conducting ESWL as soon as the stone-associated pain develops can increase the treatment effectiveness. If possible, it is recommended that ESWL is conducted within 24 hours. Moreover, if a ureteral stone patient aged 65 or younger, with a HU of 815 or less than, stone size 10 mm or smaller, and stone location of mid to distal comes in for treatment, then early lithotripsy should be especially considered as priority. In addition, sufficient physical activity, balanced nutrition without excess of any component and sufficient circadian fluid intake of neutral beverages, and ipsilateral position are recommended to augment stone particles passage after ESWL[29].

There a couple of limitations to this study. The presence of residual stones was determined by imaging one week after the ESWL session; thus, the exact time of stone removal cannot be determined if the stone was removed before the imaging. Also, several patients were excluded from the study because they did not attend the follow-up because of reduced pain after ESWL. In addition, stone composition was not included in the variables that affect the success of ESWL. At the medical center where this study was carried out, ESWL was conducted in out-patients; thus, recovering stone fragments was difficult. In this study, the efficacy of e-ESWL is high on stone size 10 mm or smaller or stone location of mid to distal, but the smaller stones located in the distal ureter have a higher likelihood to pass spontaneously, also. And the previous studies have suggested that URS lithotripsy in the emergent setting is recommended for distally located stones[30]. Additional studies should be carried out to supplement these limitations and to accurately identify the criteria by which ureteral stone patients can receive more effective and safe treatment.

CONCLUSIONS

E-ESWL is an effective and safe treatment method for colic caused by a ureteral stone. We recommend conducting ESWL within 24 hours of pain development. In addition, if the patient is 65 or younger, with a HU of 815 or less than, has a stone size 10 mm or smaller, and has a mid to distal stone location then e-ESWL is especially recommended as a more effective lithotripsy result is expected.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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