Original Article

# Treatment outcomes and factors affecting the success of extracorporeal shockwave lithotripsy in urinary stone treatment: a study of ten years of data from Mahasarakham Hospital

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**Keywords:**
Extracorporeal shock wave lithotripsy, factors affecting success, MK ESWL Score

## Abstract

**Objective:** To explore the outcomes and factors affecting the success of extracorporeal shockwave lithotripsy (ESWL) in upper urinary stone treatment.

**Materials and Methods:** A retrospective review of 4,293 patients with renal or ureteric stones treated with ESWL using Siemens Modularis Vario lithotripter at Mahasarakham Hospital between October 2011 and September 2020. Non-contrast computed tomography or intravenous urography were used to determine stone characteristics. All patients were followed up at week 12 after treatment to evaluate treatment outcome. Success was defined by the presence of clinically insignificant residual ≤ 4 mm or complete clearance of the stones. Data were tested with multivariate logistic regression analysis to determine the predictors of ESWL success.

**Results:** The overall success rate was 70.1 %. The success rate of patients aged ≤ 40 years was 78.2% The lowest success rate was associated with lower calyceal stones with 54.6%, for stones ≤ 10 mm the success rate was 76.3% and the success rate of stones with a surface area ≤ 50 $mm^2$ was 77.0%. The complication rate was 5.2%, and auxiliary procedures were 4%. The mean number of ESWL sessions was 2.1. Multivariable logistic regression analysis demonstrated that age, stone size, stone surface area and stone location were significant predictors of ESWL success.

**Conclusions:** Treatment of renal and ureteric stones with ESWL showed good results. MK ESWL Scoring is a good predictive system for the success of ESWL treatment.

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## Introduction

Since its introduction in the 1980s, extracorporeal shock wave lithotripsy (ESWL), a convenient noninvasive standard outpatient procedure, has been used for the treatment of renal and proximal ureteric calculi.[1] Since its introduction it has become a preferred treatment modality for uncomplicated renal and ureteral stone of < 20 mm in diameter as it was found to be safe and non-invasive.[2-5] The success rate of ESWL has a wide variation ranging from 46% to 91%.[6-11] The results of ESWL are measured with regard to stone fragmentation and clearance, which have been found to be influenced by some predicting factors such as stone size, stone location, skin-to-stone distance (SSD), stone composition, severity of obstruction, urinary tract anatomy, obesity, and ESWL machine type.[12-20] ESWL had been one of the mainstays in the management of renal and ureteric calculi since its inception in 1984, and it is currently one of the most recommended treatment options for small- and medium-sized stones. The use of ESWL increased up until 2006 but then started to decline because many urologists switched to endoscopic surgical treatments especially ureteroscopy and laser fragmentation.[21]

Nevertheless, ESWL was shown to be a cost-effective treatment for small- and medium-sized stones. It was recommended as the preferred treatment for various types of stones in many countries. In the recent coronavirus disease 2019 (COVID-19) outbreak there was a new increase in ESWL use as it avoided the need for a general anesthetic (GA) and its potential complications in patients with COVID-19 infection.[22-26] Therefore, during the pandemic period, many hospitals tended to avoid the use of GA in less urgent cases.

This retrospective review aimed to explore the outcome and factors affecting the success of Extracorporeal Shockwave Lithotripsy in upper urinary stone treatment.

## Materials and Methods

This retrospective review was conducted in adult patients with renal or ureteric stones, treated with ESWL between October 2011 and September 2020 at Mahasarakham Hospital, Thailand. The research protocol was approved by the Ethical Committee of Mahasarakham Hospital (Protocol Number: MSKH_REC 64-01-049). The inclusion criteria were radiopaque stone size of > 4 mm on a pretreatment plain abdominal x-ray of the kidney, ureter, and bladder (KUB). Pregnant women and patients with uncontrolled coagulopathy, ongoing urinary tract infection, uncontrolled hypertension, and stone with distal obstruction were excluded from the study. The case summary, hematological, biochemical, radiological investigations, and follow-up data were analyzed. All patients underwent X-ray KUB and ultrasound, non-contrast computed tomography (NCCT) or intravenous urography for initial diagnosis. Patient data, and treatment data were collected from Mahasarakham Hospital Information System (MKHIS). The radiological findings were evaluated by radiologists from the Picture Archiving Communication System (PACs) at the hospital.

Out of the 4,484 patients being treated, 191 were excluded from the study due to non-availability of patient electronic medical data, radiologic data or failed follow-ups. Therefore, the final analysis, results, and conclusions were based on 4,293 patients. NCCT or intravenous urography (IVU) were used to determine stone characteristics; namely, size, surface area, location and laterality. The largest dimension of the stone with soft tissue window in coronal view was used to represent the stone size. The stone surface area (SA) was estimated from the length (L) and width (W) of the stone by using the formula: $SA = (L) \times (W) \times \pi \times 0.25$ ($\pi$=3.14159).[9]

The patients in the study were subjected to ESWL. The Siemens Modularis Vario lithotripter, a third generation of lithotripter with electromagnetic shockwave source, was implemented after collection of written informed consent. All treatments were carried out using intravenous analgesia in the form of Fentanyl IV (1 μg/kg/dose) and Midazolam IV (0.05-0.1 mg/kg) when needed. The procedure was performed under intermittent fluoroscopic guidance. The targeted stone was struck by a maximum of 4,000 shocks per session for renal stones and 4,500 shocks per session for ureteric stones; all of which were at the rate of 60-90 shocks per minute with gradually increasing energy level to maximal level of 3, or 4 for renal stones; and 4 for ureteric stones. Stone localization was achieved by fluoroscopy or a combination of ultrasound and fluoroscopy. Patients were followed up at the outpatient department at week 4 and 12 after ESWL with a

plain film KUB. ESWL was repeated if no stone fragmentation occurred, or if the residual stone fragments were larger or equal to 5 mm in size. A maximum of 4 sessions of ESWL were carried out with a time lag of 4 weeks between sessions.

After the ESWL sessions, patients were followed-up for three months for the outcome of stone clearance. At the endpoint, patients were evaluated with X-ray plain KUB. Stone clearance, stone fragmentation, stone surface area, number of ESWL sessions, requirement of auxiliary procedure, and complications were recorded. Treatment was defined as being successful in cases of complete clearance (stone free) or the presence of asymptomatic, non-infectious, and non-obstructive fragments of ≤ 4 mm Treatment failure was considered in cases with no fragmentation, or residual stone fragments of > 4 mm after four sessions of ESWL; or if the patient required other modes of treatment.

At the end-point evaluation, patients were categorized into success and failure groups. Data were described using frequency, percentage, mean and standard deviation. To test the statistical significance of the relationship between ESWL outcome and the factors affecting it, data were analyzed using chi-squared test, independent samples t-test, and correlation. Thereafter, the significant associated variables were tested with multivariate logistic regression analysis to identify the independent predictors of treatment failure. The level of significance for the two-tailed test was set at 0.05. All statistical analysis was carried out using SPSS Statistics (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

## Results

Data from a total of 4,293 patients: 2,628 males and 1,665 females; with renal or ureteric stones (3,470 RC and 823 UC) who received ESWL treatment from October 2011 to September 2020 were analyzed. Out of all patients, ESWL was 70.1% successful with therefore a 29.9% failure rate. The baseline demographic characteristics are presented in Table 1. The multivariate analysis showed there was no statistically significant difference between the two groups as regards patient gender, BMI and stone laterality. However, differences in age, stone size, stone location and stone surface area were statistically significant.

**Table 1.** Demographic characteristics (N = 4,484)

| Parameters | |
|---|---|
| Patients n | 4,293 |
| Gender n (%) | |
| Male | 2,628 (61.2) |
| Female | 1,665 (38.8) |
| Age (years) | |
| Mean±SD | 55.4±11.7 |
| Range | 18-94 |
| BMI (kg/m$^2$) | |
| Mean±SD | 24.5±4.9 |
| Range | 11.8-47.6 |
| Stone laterality n (%) | |
| Right | 2,292 (532.4) |
| Left | 2,001 (46.6) |
| Stone location n (%) | |
| Renal calculi | 3,470 (80.8) |
| Ureteric calculi | 823 (19.2) |
| Size (mm) | |
| Mean±SD | 11.9±6.3 |
| Range | 6-70 |
| ESWL session (episode) | 2.1±1.6 |

SD = standard deviationl, BMI = body mass index, ESWL = extracorporeal shockwave lithotripsy

The success rate of ESWL for lower calyceal stones was the lowest (54.6%) compared to stones in the upper, middle calyx and pelvis (86.0, 75.2, and 75.3%). Patients with lower calyceal stones of ≤ 10 mm in size had a success rate of 60.0% in comparison to stones of > 10 mm in size where the success rate was noted to be 46.7%.

The overall rate of significant complications was 5.2%. This included 2.7% of severe pain that required inpatient care for pain control, 0.2% of gross hematuria with required blood transfusion, 0.3% of sepsis with a requirement of parenteral antibiotics, 1.9% of stein Strasse with failed conservative treatment and 0.1% of perirenal hematoma. Post-interventional auxiliary procedures were required in 4.0% of the patients.

In the multivariate logistic regression analysis, four variables were found to be statistically significant in predicting the success of ESWL, specifically age, stone size, stone location, and stone surface area as shown in Table 2.

## Discussion

Since the introduction of ESWL in 1980, it had become an established and preferred treatment for uncomplicated renal and ureteral

**Table 2.** Multivariate analysis of the factors affecting outcome of ESWL

| Variables | Success (n = 3,009) n (%) | Failure (n = 1,284) n (%) | OR | 95% CI | P-value |
|---|---|---|---|---|---|
| Gender | | | | | |
| Male | 1,842 (70.1) | 786 (29.9) | Ref | | |
| Female | 1,167 (70.1) | 498 (29.9) | 0.959 | 0.831-1.107 | 0.566 |
| Age (years) | | | | | |
| ≤ 40 | 338 (78.2) | 94 (21.8) | 1.475 | 1.113-1.954 | 0.007* |
| 41-60 | 1,712 (71.2) | 692 (28.8) | 1.228 | 1.056-1.428 | 0.007* |
| > 60 | 959 (65.8) | 498 (34.2) | Ref | | |
| BMI (kg/m$^2$) | | | | | |
| < 18.5 | 280 (71.3) | 113 (28.7) | Ref | | |
| 18.5-22.9 | 953 (72.0) | 371 (28.0) | 1.037 | 0.808-1.330 | 0.777 |
| 23-24.9 | 562 (70.4) | 236 (29.6) | 0.961 | 0.736-1.254 | 0.770 |
| ≥ 25 | 1,214 (68.3) | 564 (31.7) | 0.869 | 0.683-1.105 | 0.251 |
| Stone laterality | | | | | |
| Right | 1,591 (69.4) | 701 (30.6) | 1.037 | 0.901-1.192 | 0.614 |
| Left | 1,418 (70.9) | 583 (29.1) | Ref | | |
| Stone size (mm) | | | | | |
| ≤ 10 | 1,922 (76.3) | 596 (23.7) | Ref | | |
| 11-20 | 842 (60.7) | 545 (39.3) | 0.540 | 0.434-0.673 | < 0.001* |
| > 20 | 245 (63.1) | 143 (36.9) | 0.584 | 0.434-0.785 | < 0.001* |
| Stone location | | | | | |
| Upper calyx | 745 (86.0) | 121 (14.0) | Ref | | |
| Middle calyx | 487 (75.2) | 161 (24.8) | 0.488 | 0.372-0.640 | < 0.001* |
| Lower calyx | 705 (54.6) | 587 (45.4) | 0.176 | 0.139-0.221 | < 0.001* |
| Pelvis | 500 (75.3) | 164 (24.7) | 0.568 | 0.433-0.746 | < 0.001* |
| Upper ureter | 356 (72.2) | 137 (27.8) | 0.285 | 0.212-0.382 | < 0.001* |
| Middle ureter | 58 (59.8) | 39 (40.2) | 0.153 | 0.096-0.246 | < 0.001* |
| Lower ureter | 158 (67.8) | 75 (32.2) | 0.225 | 0.158-0.321 | < 0.001* |
| Stone surface area (mm2) | | | | | |
| ≤ 50 | 1,562 (77.0) | 467 (23.0) | Ref | | |
| > 50 | 1,447 (63.9) | 817 (36.1) | 0.634 | 0.509-0.789 | < 0.001* |
| Mean ± SD | 91.2±86.9 | 140.6±194 | | | |

*Statistically significant
SD = standard deviation, OR = odds ratio, 95% CI = 95% confidence interval of the difference, Ref = reference, BMI = body mass index, ESWL = extracorporeal shockwave lithotripsy

stone (< 20 mm in diameter) as it was safe and non-invasive.[1-5] The success rate of ESWL varied from 46% to 91% and was measured in terms of stone fragmentation and clearance.[6,7] Previous studies had demonstrated that predicting factors such as stone size, stone location, stone density, severity of obstruction, urinary tract anatomy, obesity, SSD, type of ESWL machine and use of diuretics could have an influence on the success rate of ESWL.[13-19]

Many studies discussed factors affecting outcome of ESWL, but only a few considered age as being a significant factor. One study of 3,023 patients with renal and ureteric calculi treated with ESWL revealed that older patients had a significant poorer stone-free rate.[6] Another multivariate analysis of 2,954 patients with renal stones treated with ESWL revealed that patients aged > 40 years a had significant poorer stone-free rate.[11] However, another study was conducted on patients with ureteric stones within the same age range but found that age did not affect outcome of ESWL.[23]

In our study, age was found to be a significant factor affecting the outcome of ESWL. Success rate of the treatment in patients in the age group of ≤ 40 years was 78.2% (338/432) compared to that of only 71.2% (1712/2404) in those aged between 41-60 years and 65.8% (959/1457) in those aged > 60 years. Multivariate logistic regression

**Table 3.** Point system for MK ESWL Score

| Factors | Point |
|---|---|
| Age (years) | |
| ≤ 40 | 1 |
| > 40 | 0 |
| Size (mm) | 1 |
| ≤ 10 | 0 |
| > 10 | |
| Surface area ($mm^2$) | 1 |
| ≤ 50 | 0 |
| > 50 | |
| Stone location | |
| Upper calyx | 2 |
| Middle calyx | 1 |
| Lower calyx | 0 |
| Pelvic | 2 |
| Upper ureter | 1 |
| Middle ureter | 0 |
| Lower ureter | 1 |

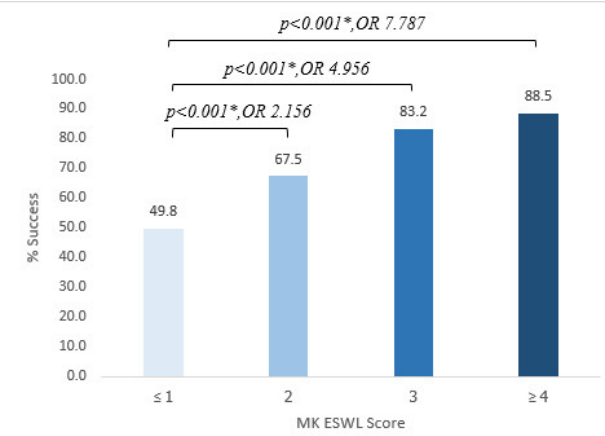


**Figure 1.** Success rate of ESWL treatment in each area of MK ESWL Score

analysis revealed that age was an independent predictor of failure of ESWL. The success rate in the age group of > 60 years was significantly lower when compared to the age group of ≤ 40 years. (OR = 1.475; 95% C.I.: 1.113-1.954; p = 0.007) and age group of 41-60 years. (OR = 1.228; 95% C.I.: 1.056-1.428; p = 0.007). The reason for the possible poorer stone-free rate of renal calculi in elderly patients is unknown. However, age-related sclerosis of the kidney may affect the acoustic impedance and lower the efficacy of ESWL. Many studies have shown that gender is not a significant predictor of ESWL outcome.[24] This was found to be similar, in our study, as the success rate of ESWL in males was 70.1% which was equal to a 70.1% rate of success in females. This result was not statistically significant.

Additionally, previous studies have shown that stone size was a significant predictor of ESWL treatment success. The larger the size of stone, the higher the risk of ESWL failure became. In a study of 2,954 patients with renal stones, the authors observed a success rate of 89.7% for stones of < 15 mm and of 78% for stones of >15 mm (p < 0.001).[11] In another study of 427 patients with renal stones, the success rate of ESWL for stones of ≤ 10 mm was 90% and 70% for stones of > 10 mm (p < 0.050).[12,24] Similarly, in our study, stone size was one of the most important factors determining ESWL success. Success rate of treatment in stones of ≤ 10 mm was 76.3% (1922/2518) compared to that of only 60.7% (842/1387) in stones of 11-20 mm and 63.1% in stones of > 20 mm. Multivariate analysis revealed that stone size was an independent predictor of failure of ESWL in each group when compared to stone size of ≤ 10 mm (stone size 11-20 mm; OR = 0.540; 95% CI: 0.434-0.673; p < 0.001; stone size > 20 mm; OR = 0.584; 95% CI: 0.434-0.785; p < 0.001).

Next, stone location was a significant predictor of ESWL outcome. Various studies had observed a lower success rate in treating lower calyceal stones other than stones in other sites. One study showed that the success of ESWL treatment was only 47% in the treatment of lower calyceal stones compared to that of 79% for stones in other sites (chi-squared = 6.3, df = 1, p = 0.012).[17] A recent study revealed a stone-free rate of 75% for treatment of lower calyceal stone (size ranging from 10-20 mm) with ESWL.[25] In our study, we found that the stone location was a significant predictor of ESWL outcome in the univariate analysis. We compared the success rate of lower calyceal stones with stones from other sites. The success rate of ESWL for lower calyceal stones was 54.6% compared to 86.0, 75.2, 75.3% for stones located in the upper, middle calyx and pelvis (chi-squared value = 276.517, df = 6, p < 0.001)

The multivariate analysis revealed that stone location was a strong independent predictor of ESWL failure. In each location, in comparison to upper calyceal stones, the result from the logistic regression analysis showed significant differences in comparison to other locations: middle calyceal stone: OR = 0.586; 95% CI: 0.448-0.767; p < 0.001; lower calyceal stone: OR = 0.196; 95% CI: 0.156-

0.246; p < 0.001; pelvic stone: OR = 0.738; 95% CI: 0.557-0.977; p = 0.034; upper ureteric stone: OR = 0.340; 95% CI: 0.256-0.452; p < 0.001; middle ureteric stone: OR = 0.205; 95% CI: 0.130-0.324; p < 0.001; and lower ureteric stone: OR = 0.284; 95% CI: 0.202-0.401; p < 0.001. There was a success rate of 60% in patients with lower calyceal stones of ≤ 10 mm in size in comparison to stones of > 10 mm in size, the success rate of which was 46.7% (OR 1.712; 95% CI: 1.369-2.143; p < 0.001). The stone free rate of patients with lower calyceal stones of ≤ 10 mm in size was 38.9% in comparison to stones of > 10 mm in size of which the stone free rate was 8.2% (OR 7.122; 95% CI: 5.049-10.047; p < 0.001). The clearance of the fragments was lower due to the unfavorable spatial anatomy of the lower pole collecting system. Another study of 66 patients revealed that none of the anatomic factors had a statistically significant effect in predicting the success of ESWL in patients with lower pole stones.[28] As ESWL is a non-invasive modality, it could be offered for lower calyceal stones with low burden and favorable anatomy.

One study of 109 patients with renal stone disease who underwent ESWL had shown that stone surface area was a significant predictor of ESWL treatment success. A univariate logistic regression analysis revealed the high prognostic power of stone surface area for ESWL treatment failure (OR = 1.03, 95% CI: 1.01-1.06, p = 0.02).[27] Similarly, in our study, we found from the multivariate logistic regression analysis that stone surface area was one of the significant predictors of ESWL treatment success (OR = 0.991, 95% CI: 0.989-0.993, p < 0.001). The larger the surface area of the stone, the higher the risk of ESWL failure became. A group-variate logistic regression analysis also revealed that the stone surface area was a strong significant predictor of ESWL outcome. The success rate of ESWL for stones of ≤ 50 $mm^2$ in surface area was 77.0% compared to 63.9% for stones of > 50 $mm^2$ in surface area (OR = 0.634, 95% CI: 0.509-0.789, p < 0.001).

A series of minor complications can occur after ESWL.[25,26] In this study, the overall complication rate was 5.2%. However, all complications were managed successfully with conservative treatment. Among 4.0% of the patients, post-interventional auxiliary procedures were necessary.

Finally, we developed a predictive system for the success of ESWL treatment, specifically "MK ESWL Scoring". We defined the cut-off points from four predictive factors and summarized them into an overall MK ESWL score (Table 3). The score was group and analyzed using logistic regression. We found that the MK ESWL score shows a strong correlation to the probability of ESWL treatment success (Figure 1).

This study had several limitations. It was conducted as a retrospective review which introduces variation into the various data sets. Also plain radiography was used instead of NCCT for the follow-up protocol to confirm treatment success. Stone composition, stone density and stone to skin distance which had significant influence on outcome of ESWL were not evaluated and also analysis of the retrieved fragments was not completed. However, the study provides strong evidence that patient age, stone size, stone location and stone surface area affected the ESWL outcome. In additional, the MK ESWL score could be extremely useful informing patient selection for the improvement of ESWL outcomes to save time and treatment costs.

## Conclusion

This single institution study showed good results of treatment of renal and ureteric stones with ESWL. Greater success of ESWL was observed in cases of patients aged ≤ 40 years, with a stone size of ≤ 10 mm, a stone surface area of ≤ 50 $mm^2$ and a location in the upper calyx. MK ESWL Scoring is a good predictive system for the success of ESWL treatment.

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## Conflict of Interest

The authors declare no conflict of interest.

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