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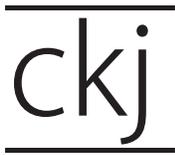


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## ORIGINAL ARTICLE

# Extracorporeal shock wave lithotripsy versus flexible ureterorenoscopy in the treatment of untreated renal calculi

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## Abstract

**Background:** The reported success rates for treatments of kidney stones with either extracorporeal shock wave lithotripsy (ESWL) or flexible ureterorenoscopy (URS) are conflicting. We aimed to compare the efficacy and safety of ESWL and URS for previously untreated renal calculi.

**Methods:** All patients treated with ESWL or URS at our tertiary care centre between 2003 and 2015 were retrospectively identified. Patients with previously untreated kidney stones and a stone diameter of 5–20 mm were included. Stone-free, freedom from reintervention and complication rates were recorded. Independent predictors of stone-free and freedom from reintervention rates were identified by multivariable logistic regression and a propensity score-matched analysis was performed.

**Results:** A total of 1282 patients met the inclusion criteria, of whom 999 (78%) underwent ESWL and 283 (22%) had URS. During post-operative follow-up, only treatment modality and stone size could independently predict stone-free and freedom from reintervention rates. After propensity score matching, ESWL showed significantly lower stone-free rates [ESWL (71%) versus URS (84%)] and fewer patients with freedom from reintervention [ESWL (55%) versus URS (79%)] than URS. Complications were scarce for both treatments and included Clavien Grade 3a in 0.8% versus 0% and Grade 3b in 0.5% versus 0.4% of ESWL and URS treated patients, respectively.

**Conclusions:** Treatment success was mainly dependent on stone size and treatment modality. URS might be the better treatment option for previously untreated kidney stones 5–20 mm, with similar morbidity but higher stone-free rates and fewer reinterventions than ESWL.

**Key words:** adverse effects, kidney calculi, lithotripsy, minimally invasive surgery, treatment outcome

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## Introduction

Urolithiasis is a common disease, representing a relevant public health problem worldwide with a prevalence of 8.8% in the USA and annual health care costs of USD 3.8 billion [1–3]. Although kidney stones initially often remain asymptomatic, treatment is frequently performed to prevent future problems associated with the disease (e.g. renal colic, urinary tract infections and impairment of kidney function) [4]. Treatment for kidney stones should achieve both high stone-free rates and low complication rates. Extracorporeal shock wave lithotripsy (ESWL) and flexible ureterorenoscopy (URS) are nowadays the most commonly used treatment options for kidney stones <20 mm. ESWL was introduced in the 1980s [5] and quickly became the gold standard for the treatment of kidney stones [6, 7]. In the 1990s, URS emerged with the advantages of direct visualization and extraction of kidney calculi [8–10]. Currently, the American Urological Association guideline recommends ESWL or URS as equivalent first-line interventions for the treatment of kidney stones < 20 mm [11]. The guidelines of the European Association of Urology (EAU) additionally distinguish between lower pole and non-lower pole kidney stones. They recommend both treatments as equivalent options for kidney stones of 10–20 mm, but favour URS for lower pole stones if adverse factors (such as anatomy and stone composition) argue against ESWL [4].

A recent meta-analysis including several randomized controlled trials (RCTs) demonstrated a superior treatment success of URS over ESWL when treating lower pole kidney stones [10]. However, evidence regarding optimal treatment of non-lower pole kidney stones is scarce. In this study, we aimed to compare success and complication rates of ESWL and URS in a large cohort of patients with previously untreated lower or non-lower pole kidney stones of 5–20 mm in size.

## Materials and methods

We retrospectively identified patients with kidney stones treated with ESWL or URS at our tertiary care centre between 2003 and 2014. Treatment method was chosen according to the surgeon's and patient's preferences. Patients with previously untreated kidney stones and a stone diameter of 5–20 mm were included. Patients with further untreated kidney stones on the contralateral side were included a second time if a treatment was performed. Patients with new onset of nephrolithiasis but with a previous history of kidney stones were only included if they were stone-free for at least 12 months. The study was approved by the local ethics committee (STV KEK-ZH 2014-0198).

Pretreatment stone size and location were generally assessed by ultrasonography (US) and radiological examination [X-ray and or non-contrast computed tomography (CT) of the abdomen]. The following preoperative parameters for each patient were noted: age, gender, body mass index (BMI), stone size, number of stones and stone location (upper calyx, middle calyx, lower calyx, pelvis or multiple locations). All perioperative complications until discharge were assessed using the Clavien–Dindo grading system [12].

Success rate after intervention was assessed by stone-free and freedom from reintervention rates. As primary endpoint, we assessed stone-free rates for each treatment method during follow-up using X-ray, US or CT. Stone-free was defined as stone clearance during postinterventional follow-up without any residual fragments >2 mm in the kidney. Retreatment for residual stones was recorded during follow-up and freedom from reintervention was chosen as secondary endpoint. Freedom

from reintervention was defined as no need of secondary intervention for residual stone(s) after primary treatment.

ESWL was performed under general or regional anaesthesia depending on patient's preference. The exact stone location was identified by X-ray and/or US at baseline and verified regularly during ESWL treatment. In general, a maximum of 3000 shock waves were applied to the kidney stone(s) or fewer if complete stone disintegration was observed before. In case of double J ureter stenting during ESWL, the stent normally remained for 4–6 weeks or longer depending on the clinical course. Two different lithotripters were used during the study period: from the start of the study until September 2007, the ESWL treatments were performed on a Dornier DL50 lithotripter (Dornier MedTech, Wessling, Germany). Subsequently, a Dornier DLS II (Dornier MedTech) was in operation from September 2007 until the end of this study.

URS was conducted under general or regional anaesthesia depending on patient's preference. The choice between primary and secondary URS (double J ureter stent 7–14 days before surgery) was based on the surgeon's preference. A flexible URS was introduced for direct vision of the collecting kidney system after insertion of a ureteral access sheath. Irrigation was performed using a roller-pump mechanical irrigation device (Uromat; Karl Storz, Culver City, CA, USA) and intrarenal pressure levels ranging from 100 to 200 mmHg, depending on the individual intrarenal anatomy and visibility.

Stone fragmentation, if required, was performed using a holmium: YAG laser. Calculi and fragmented stones were extracted using a stone basket. At the end of the procedure, the ureteral mucosa was reinspected to identify any potential damage or perforation and all patients received a double J ureter stent for 3–10 days.

Independent predictors of stone-free and freedom from reintervention rates were identified by multivariable analysis using logistic regression including the following covariates: age, gender, BMI, largest stone size and number of stones. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. To assess whether one of the two lithotripters showed relevant differences in stone-free and freedom from reintervention rates, we compared both endpoints for each lithotripter in a sensitivity analysis.

We analysed a propensity score-matched sample from all included patients to limit the observational character of the study. For the computation of the propensity score, the following variables were included into a non-parsimonious logistic regression with ESWL/URS as dependent variable: age, gender, BMI, stone size and number of stones. Missing values were replaced by multiple regression imputation for the respective analysis. The validity of the logistic regression was assessed using the Hosmer–Lemeshow test.

Statistical analysis was performed with IBM SPSS Statistics (Version 21.0; IBM Corp., Armonk, New York, USA). Propensity score matching was performed using R programming language and software environment version 3.1.3 (R Foundation for Statistical Computing, Vienna, Austria) using the package Matching in R [13]. The results for continuous normally distributed variables are expressed as means  $\pm$  standard deviation (SD) and differences in patient characteristics between two groups were compared using Student's unpaired t-test. Continuous non-normally distributed variables are presented as median and interquartile ranges (IQR) and analysed using the Mann–Whitney U test. The results for categorical variables are presented as percentage analysed using Fisher's exact test

**Table 1.** Patient characteristics of all patients and the propensity score-matched cohort

	All (n = 1282)		P-value	Propensity score 2:1 matched (n = 735)		P-value
	ESWL	URS		ESWL	URS	
Number of patients (%)	999 (78)	283 (22)		490 (67)	245 (33)	
Age, years ( $\pm$ SD)	49 (15.0)	51 (14.4)	0.124	50 (15.0)	51 (14.2)	0.685
Female (%)	274 (27.4)	74 (26.1)	0.669	126 (25.7)	71 (29.0)	0.346
Male (%)	725 (72.6)	209 (73.9)		364 (74.3)	174 (71.0)	
BMI, kg/m <sup>2</sup> ( $\pm$ SD)	27 (4.75)	27 (4.64)	0.596	27 (4.4)	27 (4.9)	0.790
Size of biggest stone, mm (IQR)	9 (7–11)	8 (6–11)	<b>&lt;0.001</b>	8 (6–10)	8 (6–12)	0.988
Number of stones (%)			<b>&lt;0.001</b>			0.722
1	49	51		57	58	
2	15	25		26	22	
3	7	13		11	11	
>3	4	11		5	9	
Complications (%)						
Clavien II	24 (2.4)	20 (7.1)	<b>&lt;0.001</b>	17 (3.5)	17 (6.9)	<b>&lt;0.001</b>
Clavien IIIa	8 (0.8)	0 (0)	0.21	3 (0.6)	0 (0)	
Clavien IIIb	5 (0.5)	1 (0.4)	0.30	3 (0.6)	1 (0.4)	
Clavien IV	0	0		0 (0)	0 (0)	

Bold P-values indicate statistical significance.

**Table 2.** Multivariable logistic regression analysis evaluating predictors for (A) stone-free and (B) freedom from reintervention rates after primary treatment for nephrolithiasis

	OR (95% CI)		P-value
<b>(A) Stone-free rate</b>			
ESWL versus URS	0.421 (0.267–0.662)		<b>&lt;0.001</b>
Age, years	0.982 (0.971–0.993)		<b>0.002</b>
Female versus male	1.190 (0.812–1.746)		0.372
BMI, kg/m <sup>2</sup>	0.976 (0.942–1.012)		0.194
Stone size, mm	0.850 (0.840–0.920)		<b>&lt;0.001</b>
Number of stones	0.9329 (0.828–1.065)		0.326
<b>(B) Freedom from reintervention rate</b>			
ESWL versus URS	0.340 (0.203–0.571)		<b>&lt;0.001</b>
Age	0.987 (0.975–1.000)		<b>0.043</b>
Female versus male	1.134 (0.868–1.988)		0.197
BMI	1.000 (0.961–1.041)		0.996
Stone size, mm	0.797 (0.751–0.845)		<b>&lt;0.001</b>
Number of stones	0.945 (0.823–1.0836)		0.426

Bold P-values indicate statistical significance.

or chi-square test whenever appropriate. A P-value of  $<0.05$  was considered significant. All statistical tests were two-sided.

## Results

Of the 1282 patients included in our study, 999 (78%) underwent ESWL and 283 (22%) had URS for primary treatment of kidney stones. A primary URS was conducted in 154/283 patients (54.4%), whereas in 129/283 cases (45.6%), a secondary URS was performed. Patient baseline characteristics partitioned into ESWL and URS patients as well as the propensity score-matched populations are shown in Table 1.

Patients treated with ESWL and URS showed comparable characteristics for age, BMI and gender, but significantly differed regarding median stone size [ESWL versus URS, 9 (IQR 7–11) versus 8 (IQR 6–11),  $P < 0.001$ ] and number of stones ( $P < 0.001$ ) (Table 1).

The only independent predictors for stone-free rate as defined by multivariable regression analysis were the treatment modality [ESWL versus URS; OR 0.421 (95% CI 0.267–0.662),  $P < 0.001$ ] and the stone size [OR 0.850 (95% CI 0.840–0.920),  $P < 0.001$ ] (Table 2). The same parameters were also independent predictors for lower freedom from reintervention [choice of treatment: ESWL versus URS; OR 0.340 (95% CI 0.203–0.571),  $P < 0.001$ ; and stone size; OR 0.797 (95% CI 0.751–0.845),  $P < 0.001$ ]. Our sensitivity analysis for the two different ESWL lithotripters revealed no significant difference in stone-free (–4.2%, 95% CI –1.0 to 1.6,  $P = 0.16$ ) and freedom from reintervention rates (–4.3%, 95% CI –11.5 to 2.9,  $P = 0.26$ ). A visual analysis of stone-free rate over the whole study period confirmed similar results for both lithotripters (Supplementary data, Figure S1).

A 2:1 propensity score matching showed an adequate level of calibration (Hosmer–Lemeshow test:  $P = 0.322$ ). After propensity

score matching, the ESWL group consisted of 490 and the URS group of 245 patients. The matching successfully eliminated the significant differences in median stone size ( $P=0.988$ ) and in number of stones ( $P=0.722$ ) (Table 1). However, the two treatment modalities still showed significant differences regarding stone-free [ESWL 350/490 (71%) versus URS 206/245 (84%),  $P<0.001$ ] and freedom from reintervention rates [ESWL 199/361 (55%) versus URS 133/168 (79%), versus  $P<0.001$ ] (Figure 1).

In a subgroup analysis, the patients with non-lower pole stones treated with ESWL showed a significantly lower stone-free rate [ESWL 251/368 (68.2%) versus URS 131/159 (82.4%),  $P<0.001$ ] as well as a lower freedom from reintervention rate [ESWL 145/276 (52.5%) versus URS 98/127 (77.2%),  $P<0.001$ ] compared with the patients treated with URS. The subgroup analysis of lower pole stones revealed nonsignificantly lower stone-free rates after ESWL treatments [ESWL 89/111 (80.2%) versus URS 40/45 (88.9%),  $P=0.246$ ] but a significantly lower freedom from reintervention rate [ESWL 53/84 (61.1%) versus URS 33/36 (91.7%),  $P=0.002$ ] than after URS treatments.

Only very few relevant perioperative complications for both treatment modalities were recorded. After ESWL, 24 (2.4%) Grade II complications including 22 urinary tract infections (UTIs), one patient with urinary retention and one patient with strong urge to void was recorded. Additionally, 13 out of 999 (1.3%) patients had a Grade IIIa or IIIb complication. Among these, 12 patients were diagnosed with painful ureteral obstructions due to passing fragments and subsequently underwent transurethral stent insertion. Angiography was performed in one patient with a renal haematoma after ESWL. No active bleeding was observed and the angiography was terminated without coiling placement. In the URS group, 20 (7.1%) Grade II complications including 18 UTIs and 2 atrial fibrillations were observed. One patient (0.4%) needed a transurethral stent reposition because of stent migration (Grade IIIb complication). We did not observe any Grade 4 (life-threatening) complication for either intervention (Table 1).

## Discussion

The present study aimed to investigate and compare the treatment success of ESWL and URS in a large cohort of patients with untreated renal stones of 5–20mm in size. Our study revealed that ESWL was less effective than URS for the treatment of kidney calculi. Treatment modality (in favour of URS) and stone size were the only independent predictors for stone-free and freedom from reintervention rates. After propensity score matching, ESWL showed significantly lower stone-free rates and fewer patients with freedom from reintervention compared with URS.

Our findings are consistent with, and extend those of, prior reports. To date, the efficacy and safety of URS compared with ESWL has been evaluated in a few RCTs and several cohort studies. Recently, five RCTs and two out of three meta-analyses confirmed the superiority of URS in patients with lower pole kidney stones [8–10, 14–17]. For non-lower pole kidney stones, however, only limited evidence exists. Only two RCTs included non-lower pole stones. The first study failed to accrue a sufficient number of patients [18]. The second RCT included only 46 obese patients and showed a significantly higher stone-free rate in the URS group (90.4% versus 68%) [19]. The low number of patients and/or patient selection limits the validity for both studies. Thus, the available RCTs are inconclusive regarding treatment of non-lower pole stones.

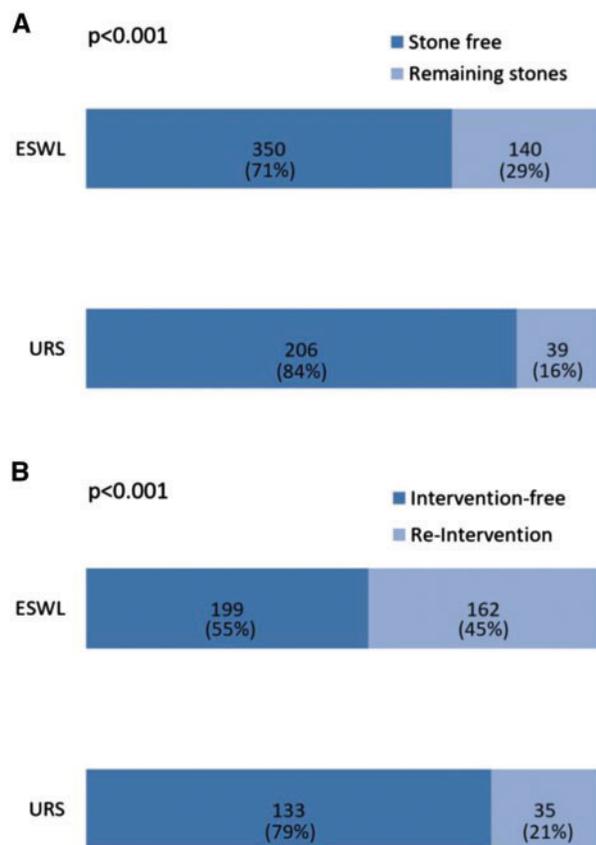


Fig. 1. (A) Stone-free and (B) intervention-free rates for ESWL and URS in the propensity score-matched cohort.

Additionally, several cohort studies proposed the superiority of URS; however, they showed some evident limitations due to the nature of their study design [20–27]. Most of these retrospective cohort studies were small (with a mean of 162 patients) and no statistical methods to control for confounders were applied. To the best of our knowledge, our study including over 1200 patients is the largest retrospective study comparing the success rates of ESWL and URS for untreated renal calculi. Moreover, it is the first non-randomized cohort study that factors in known confounders such as age, sex, BMI, stone size and number of stones.

In our study, URS showed significantly better treatment success, which is reflected by higher stone-free and freedom from reintervention rate in comparison with ESWL. However, the higher stone-free rate after URS would be less game-changing if associated with distinctly higher rates of morbidity. As URS is considered as more invasive than ESWL, the assessment of treatment morbidity is crucial for further comparison of both interventions. In our large cohort study, we found a similarly low perioperative morbidity with very few relevant complications (Clavien Grade IIIa or IIIb complications) in both intervention groups. Our data confirmed that both interventions (ESWL and URS) are safe procedures, which is in line with previously published work [8–10, 14–17, 20–27].

The most common complications in our cohort were UTIs. In our cohort, 2.2% of all patients undergoing ESWL were diagnosed with a UTI, which is comparable to other series ranging from 0.5 to 2.5% [28–30]. Similarly, UTIs were found in 6.4% of all URS patients, which is comparable to previously published cohorts

reporting UTI rates ranging from around 7.4 to 7.7% [31, 32]. This highlights the importance of preoperative urine cultures, which should be performed several days ahead of the procedure. Whereas for ESWL, the EAU guidelines recommend to prescribe perioperative antibiotics only in patients with infected stones or bacteriuria, it is recommended to give perioperative antibiotics to every patient before undergoing URS [4]. However, it remains challenging to choose the right antibiotic and to identify patients at risk for postoperative UTIs because of the poor correlation between voided urine and stone cultures [33].

The second most common complication in the ESWL group represented ureter obstruction caused by passing stones and the need for stent placement. In our cohort, 12 (1.2%) patients needed a stent placement due to obstructing ureter stones, which is slightly lower compared with previously described cohorts ranging from 4 to 8% [34, 35]. A potential explanation may include the inpatient management at our institution allowing an intensified pain management. Our most severe complication included a haemodynamically relevant renal haematoma post ESWL for which the patient underwent angiography. At the time of angiography, no active bleeding was identified and thus no coiling was performed. Symptomatic haematoma represents a feared complication but has been reported in <1% of all patients [36, 37].

Our results must be interpreted in the context of the retrospective study design. Because of the observational study design potential selection, misclassification and information bias may have occurred. Although the study was controlled for known confounders, residual confounding by disregarded or unknown variables may still have occurred. US and X-ray have limited accuracy in detecting residual stones after treatment, which might have resulted in an overestimation of stone-free rate in the current study. As even clinically insignificant residual stones affect recurrence rates [38], freedom from reintervention might be a superior endpoint for the assessment of efficacy in stone treatment. In our study, URS resulted in distinctly more patients with freedom from reintervention compared with ESWL. Another limitation is that we are not able to report long-term complications.

The varying stone-free rate observed after ESWL during our study period indicates that additional factors (i.e. detailed and specific settings of the lithotripter, experience of treating physician) are important for successful ESWL treatments. The importance of a comprehensive understanding not only of the pathophysiology, but also of shock wave physics in order to facilitate a successful ESWL treatment has already been demonstrated in previous work [39].

In this study, we present one of the largest reported cohorts for comparison of ESWL and URS for primary stone treatment. Besides the assessment of efficacy of treatment, we also analysed the complication rates and found them to be equally low for both treatment groups. This observation is of importance, as large cohort studies are more likely to detect differences in complication rates between treatments than smaller cohorts or even RCTs. In the absence of RCTs for non-lower pole kidney stones, this study is the largest comparative study of treatment efficacy and safety between ESWL and URS, providing evidence that URS might be the better treatment option in untreated kidney stones up to 20 mm in size.

## Supplementary data

Supplementary data are available at [ckj online](http://ckjonline.com).

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## Conflict of interest statement

None declared.

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