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Original Article

Clinical outcomes of intravenous urography-assisted shockwave lithotripsy for radiolucent ureteral stones

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Abstract *Objective:* We aimed to compare the clinical outcomes of intravenous urography-assisted fluoroscopy-guided shockwave lithotripsy for radiolucent ureteral stones and standard shockwave lithotripsy for radiopaque ureteral stones.
Methods: We retrospectively reviewed 734 patients with ureteral stones treated by fluoroscopy-guided shockwave lithotripsy between March 2014 and March 2021. The primary outcome was a stone-free rate with one session within 30 days, defined as no residual stones without auxiliary treatment. The multivariate analysis was used to examine whether the intravenous urography use predicted treatment success. Furthermore, we compared the outcomes using propensity score matching.
Results: Ninety-eight patients underwent the intravenous urography use protocol (Group I), and the remaining 636 patients underwent the non-intravenous urography protocol (Group N). Stone-free rates with one session within 30 days were 38% and 32% in groups I and N, respectively ($p=0.3$). No statistical differences were observed in the conversion rate to ureteroscopy ($p=0.3$) or complication rate ($p=0.7$) between Group I and Group N. One patient who developed skin redness was considered a complication of the contrast medium. Propensity score matching examined 88 matched pairs. Treatment success was obtained in 31 (35%) patients in Group I and 33 (38%) patients in Group N ($p=0.9$) within 30 days with one session.
Conclusion: Radiolucent stones can be safely and effectively treated by shockwave lithotripsy with intravenous urography.

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1. Introduction

Shockwave lithotripsy (SWL) is widely used as a treatment modality for ureteral stones. SWL is less invasive than ureteroscopy and an outpatient procedure, which is particularly advantageous during coronavirus disease 2019 pandemic. On the other hand, SWL is challenging when the stone is not visible in the X-ray scan. Since standard fluoroscopy-guided stone targeting is impossible, ultrasonography or intravenous urography (IVU) is used for radiolucent stones [1]. Although IVU-assisted fluoroscopy-guided SWL (IVU-SWL) is a conventional procedure and commonly used, very little has been reported about the procedure's outcomes [2—5]. In addition, most were old and biased in background factors.

Radiolucent stones are more likely than radiopaque stones to show lower CT attenuation, a factor affecting SWL success [1,6]. However, focusing on radiolucent stones is difficult even with IVU since it cannot frequently produce a clear image of stones [7]. We hypothesized that radiolucent stones are difficult to focus on but are broken easily when a shock wave arrives. We believe patients with radiolucent stones can choose IVU-SWL in the same way as patients with radiopaque stones do. We aimed to compare the clinical outcomes of IVU-SWL for radiolucent ureteral stones and non-IVU-SWL for radiopaque ureteral stones. In addition, we used propensity score matching (PSM) to evaluate the technical difficulty of IVU-SWL with radiolucent stones as little influence of background factors as possible, which are quite different in both groups. The subgroup analysis was performed to identify groups for which IVU-SWL should be performed.

2. Patients and methods

We retrospectively reviewed 734 patients with ureteral stones undergoing fluoroscopy-guided SWL between March 2014 and March 2021. The present study protocol was reviewed and approved by the Institutional Review Board of Ijinkai Takeda General Hospital (approval number: 2020005). The informed consent was obtained through an online opt-out form.

Cases wherein stone expulsion could not be confirmed were excluded. Based on our previous report, ureteroscopy was recommended for patients with ureteral and renal stones [8]. SWL or ureteroscopy was recommended for cases with a single ureteral stone. If SWL was selected, ultrasonography-guided SWL was performed on ureteral stones at the ureteropelvic or ureterovesical junction, and fluoroscopy-guided SWL was performed on ureteral stones elsewhere. In principle, ureteroscopy was recommended for radiolucent stones; however, IVU-SWL may be performed at the urologist's discretion if the patient is reluctant to undergo ureteroscopy at the Department of Urology, Ijinkai Takeda General Hospital, Kyoto, Japan.

At the start, the Delta II FarSight and Gemini (Dornier MedTech, Wessling, Germany) with an electromagnetic shockwave emitter were used at shockwave power levels of 10.00 kV and 10.50 kV, respectively. In our protocol, the treatment was started at level 2 and ramped up according to the patient tolerability. There are two protocols for the shock rate and number: reduced (30 shocks/min with 1200 shocks/session) and standard (60 shocks/min with 2400 shocks/session). We previously reported that no particular difference was noted in the outcome between the two protocols [9]. For radiolucent stones, a 300-mL drip infusion of contrast medium was administered over 10 min. Radiographs were taken 10 min and 20 min after injection, respectively, and IVU-SWL was performed if a stone could be identified. If no contrast agent was detected, the patient may wait 1—2 h until the ureter was imaged because obstruction caused by a stone may cause poor urine flow. Diclofenac sodium suppository of 50 mg was rectally inserted 30 min before the treatment; analgesics were administered as appropriate throughout the procedure.

Data, including age, sex, stone size, the stone location (upper, middle, or lower), and attenuation values (Hounsfield unit [HU]) evaluated using CT, were collected from the patient's medical records. Radiolucent stones were defined as undetectable by radiographs of the kidney, ureter, and bladder (KUB). The primary diagnosis of ureteral stones was based on CT. Patients were evaluated using the abdominal ultrasonography and KUB scan within 4 weeks. In doubtful cases or radiolucent stones, CT or IVU was added as needed. If residual stones were detected, SWL was repeated or converted to another modality, such as ureteroscopy. We followed the patients until we confirmed the absence of the stone. In principle, repeat IVU-SWL was not recommended at our institution. Stone free was defined as the absence of residual fragments in any modality without auxiliary treatment.

The primary outcome was the stone-free rate with only one SWL session within 30 days. The secondary outcomes were the stone-free rate within 90 days, conversion rate to ureteroscopy, and complication rate assessed according to the modified Clavien—Dindo classification system.

The statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (R Foundation for Statistical Computing, Vienna, Austria) [10]. The Chi-squared and Mann—Whitney *U* tests were performed for categorical and continuous variables, respectively. The age, sex, stone size, stone location (upper), attenuation values (HU), and the usage of IVU-SWL were considered potential confounding variables [11—17]. Patients were matched based on the age, sex, stone size, stone location (middle), attenuation values, stone side, protocol, and lithotripter machine. One-to-one nearest-neighbor PSM was performed with a caliper width of 0.2 standard deviations of the propensity score. The standardized difference

measured covariate balance and an absolute standardized difference of more than 10% indicated imbalance. Moreover, a subgroup analysis was performed in the IVU-SWL cohort. Continuous variables were divided into binary variables with cutoff values determined according to the receiver operating characteristic analysis. A logistic multivariate regression analysis was used to evaluate predisposing factors. The potential confounding variables were the stone size, location, and attenuation values, which were considered characteristics of radiolucent stones [18]. All statistical tests were two-sided, and *p*-values of less than 0.05 were considered statistically significant.

3. Results

We analyzed 734 patients, including 98 and 636, who underwent IVU-SWL (Group I) and non-IVU-SWL (Group N), respectively. Patients' characteristics are shown in Table 1. The median follow-up period was 19 days in Group I and 22 days in Group N ($p=0.7$), respectively. No significant differences were noted between both groups regarding age ($p=0.9$), sex ($p=0.2$), stone size ($p=0.6$), protocol ($p=0.093$), and lithotripter machine ($p=0.2$). Median attenuation values were 767 HU and 957 HU in groups I and N, respectively ($p<0.001$). The stone location was significantly different in both groups ($p<0.001$), with Group I having more middle ureteral stones.

SWL outcomes are presented in Table 2. The stone-free rates with only one SWL session within 30 days were 38% and 32% in groups I and N, respectively ($p=0.3$). The stone-free rates with any sessions within 30 days were 61% and 63% in groups I and N, respectively ($p=0.7$). The stone-free rates within 90 days were 87% and 91% in groups I and N, respectively ($p=0.2$). Nine (9.2%) and 36 (5.7%) patients in groups I and N ($p=0.3$), respectively, experienced conversion to ureteroscopy. Thirty-four (35%) patients in Group I underwent repeat SWL. Of them, five patients underwent repeat IVU-SWL owing to their strong will, and eight patients underwent ultrasonography-guided SWL because the stones moved to the ureterovesical junction. Twenty-one patients underwent fluoroscopy-guided SWL because stones could be detected. The remaining four patients who had residual ureteral stones at Day 90 achieved stone free spontaneously after Day 90. The outcome of SWL is shown in (Fig. 1). The overall complication rates were 5.1% and 2.8% in groups I and N, respectively; however, they were not significantly different ($p=0.7$). Four (0.63%) patients in Group N were treated with a ureteral stent and antibiotics owing to pyelonephritis, whereas none in Group I. No patients experienced perirenal hematoma. One patient developed skin redness, considered an allergic reaction to the contrast medium and resolved under observation. No patients were diagnosed with acute kidney injury due to the contrast medium.

PSM examined 88 matched pairs from groups I and N (Tables 1 and 3). Treatment success was obtained in 31 (35%) patients in Group I and 33 (38%) patients in Group N within 30 days with one session ($p=0.9$).

Table 2 Treatment outcomes of the patients.

Variable	IVU-SWL ($n=98$)	Non-IVU-SWL ($n=636$)	*p*-Value
Stone free within 30 days with one session	37 (38)	202 (32)	0.3
Stone free within 30 days with any sessions	60 (61)	402 (63)	0.7
Stone free within 90 days with any sessions	85 (87)	578 (91)	0.2
Conversion to ureteroscopy	9 (9.2)	36 (5.7)	0.3
Complication	6 (6.1)	19 (3.0)	0.7
Clavien–Dindo Grade 1	5 (5.1)	15 (2.4)	
Subcutaneous hemorrhage	5 (5.1)	15 (2.4)	
Clavien–Dindo Grade 2	1 (1.0)	4 (0.63)	
Skin redness	1	0	
Fever	0	4	
Clavien–Dindo grades 3–5	0	0	

IVU-SWL, intravenous urography-assisted fluoroscopy-guided shockwave lithotripsy.
Note: values are presented as *n* (%).

Table 1 Background characteristics of the patients.

Variable	Unadjusted cohort			PSM adjusted cohort		
	IVU-SWL ($n=98$)	Non-IVU-SWL ($n=636$)	*p*-Value	IVU-SWL ($n=88$)	Non-IVU-SWL ($n=88$)	*p*-Value
Age, year	54.0 (21.0–83.0)	56.0 (16.0–91.0)	0.9	54.5 (45.0–68.0)	56.5 (46.0–65.0)	0.8
Sex, male	71 (72)	496 (78)	0.2	64 (73)	62 (70)	0.9
Stone side, right	49 (50)	275 (43)	0.2	45 (51)	46 (52)	1
Stone size, mm	7.6 (4.3–15.7)	8.0 (3.2–23.7)	0.6	8.0 (6.2–9.0)	7.1 (6.2–9.0)	0.5
Stone location			<0.001			
Upper	52 (53)	472 (74)		NA	NA	
Middle	33 (34)	46 (7.2)		30 (34)	28 (32)	0.9
Lower	13 (13)	118 (19)		NA	NA	
Reduced protocol	45 (46)	232 (36)	0.093	39 (44)	38 (43)	1
Attenuation value, HU	767 (608–980)	957 (770–1231)	<0.001	772 (610–977)	755 (599–1035)	0.9
Lithotripter machine	94 (96)	585 (92)	0.2	4 (4.5)	6 (6.8)	0.7

HU, Hounsfield unit; PSM, propensity score matching; IVU-SWL, intravenous urography-assisted fluoroscopy-guided shockwave lithotripsy; NA, not available.
Note: values are presented as median (interquartile range) or *n* (%).

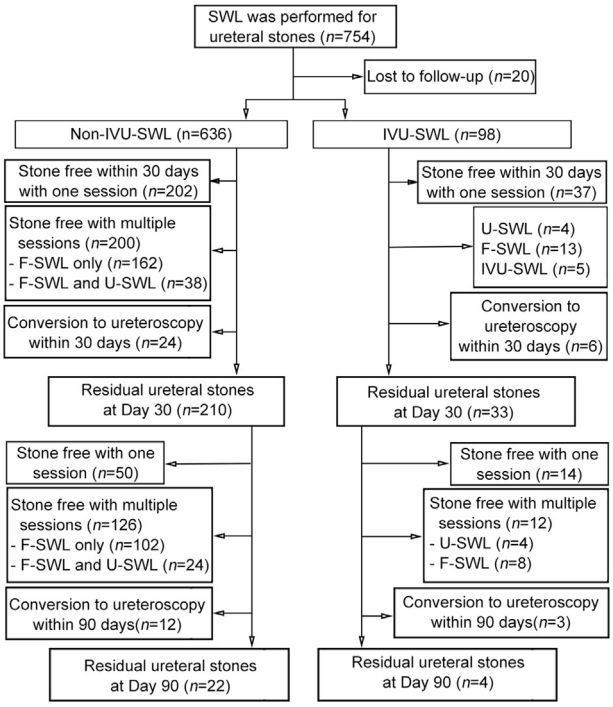

Figure 1 The flow chart for all patients: 98 patients underwent IVU-SWL and 636 patients non-IVU-SWL. SWL, shockwave lithotripsy; U-SWL, ultrasonography-guided SWL; F-SWL, fluoroscopy-guided SWL; IVU-SWL, intravenous urography-assisted fluoroscopy-guided SWL.

In the subgroup analysis, predisposing factors for the stone-free rate with only one IVU-SWL session within 30 days were analyzed in multivariate analyses (Table 4). Continuous variables were dichotomized to determine whether to perform IVU-SWL. According to the receiver operating characteristic analysis, cutoff values were determined as the age of 50 years with a sensitivity of 0.541 and a specificity of 0.656, stone size of 7.1 mm with a sensitivity of 0.526 and a specificity of 0.600, and attenuation value of 694 HU with a sensitivity of 0.491 and a specificity of 0.703 (Fig. 2). An attenuation value of <694 HU was the only predictive factor for treatment success in the multivariate analysis ($p=0.007$). The stone-free rate within 30 days with one session was 52.6% in patients with an attenuation value of <694 HU stones.

Table 3 Treatment outcomes after propensity score matching.

Variable	IVU-SWL ($n=88$)	Non-IVU-SWL ($n=88$)	p-Value
Stone free within 30 days with one session	31 (35)	33 (38)	0.9
Stone free within 30 days	52 (59)	57 (65)	0.5
Stone free within 90 days	76 (86)	80 (91)	0.5
Conversion to ureteroscopy	9 (10)	6 (6.8)	0.6
Complication	5 (5.7)	5 (5.7)	0.5

IVU-SWL, intravenous urography-assisted fluoroscopy-guided shockwave lithotripsy.
Note: values are presented as n (%).

4. Discussion

This is the first study to report that the outcome of IVU-SWL for radiolucent ureteral stones was comparable to that of non-IVU-SWL for radiopaque ones when assessed by PSM. The stone-free rate with only one SWL session within 30 days, stone-free rate within 90 days, conversion rate to other treatment modalities, or complications did not significantly differ. Regarding the allergic reaction to the contrast medium, there was only one skin redness and no serious case. In the subgroup analysis, stones with an attenuation value of <694 HU were associated with the stone-free rate with only one SWL session within 30 days. Our hypothesis, "radiolucent stones were difficult to focus on but were broken easily when a shock wave arrives", was rejected. Focusing on radiolucent stones may be difficult but not a significant problem. Radiolucent stones with lower attenuation values may be broken easily.

To the best of our knowledge, few reports have examined the outcome of IVU-SWL for radiolucent ureteral stones; however, no prospective studies have been conducted. Two studies suggested that the outcome of IVU-SWL for radiolucent ureteral stones was comparable to that of non-IVU-SWL for radiopaque stones in a single session [2,3]. However, Chiang et al. [4] investigated the outcome of SWL for symptomatic ureteral stones and reported that IVU-SWL for radiolucent ureteral stones was a predictor of treatment success in a single session. Buchholz and van Rossum [2] reported a success rate of 66.6%, and Chiang et al. [4] reported 80.0% in a single session within 30 days, which were higher than our report. We believe that this difference is because the auxiliary treatment was performed within 30 days at the discretion of urologists. Furthermore, when the stone location has changed, ultrasound- or fluoroscopy-guided SWL was additionally performed. According to previous reports, such patients may have achieved stone free without the auxiliary treatment, and some of these may be overtreated [2–5].

Fluoroscopically undetectable stones are a heterogeneous group, including truly radiolucent stones and false radiolucent stones masked by other anatomical structures. Sfoungaristos et al. [18] reported that the smaller stone size, lower attenuation value, middle ureter location, longer skin-to-stone distance, and greater fat thickness of the anterior abdomen were significantly associated with stone radiopacity on fluoroscopy. Smaller stone sizes and lower attenuation values are generally associated with better SWL outcomes [19]. They are considered "truly radiolucent stones". Better outcomes would be obtained if stones could be detected through IVU. Chua et al. [6] reported that the mean CT attenuation value of radiolucent stones was 358 (standard deviation: 156) HU because they were likely uric acid stones, whereas that of radioopaque stones was 817 (standard deviation: 274) HU. Conversely, SWL is not recommended in cases with the longer skin-to-stone distance and greater fat thickness of the anterior abdomen [19]. SWL remains not recommended even if stones could be detected by IVU. Regarding middle ureteral stones, several were considered radiopaque stones elsewhere, which might be described as "false radiolucent stones". In this study, attenuation values were lower, and middle ureteral stones

Table 4 Univariate and multivariate analyses of treatment success within 30 days with one session among the patients who underwent intravenous urography-assisted fluoroscopy-guided shock wave lithotripsy.

Valuable	Univariate			Multivariate		
	HR	95% CI	*p*-Value	HR	95% CI	*p*-Value
Age, >50 years	0.46	0.20—1.07	0.071	NA	NA	NA
Sex, male	2.71	0.98—7.53	0.056	NA	NA	NA
Stone size, >7.1 mm	0.66	0.29—1.50	0.3	0.82	0.33—2.05	0.7
Location, middle	0.91	0.38—2.18	0.8	1.77	0.60—5.19	0.3
Attenuation value, >694 HU	0.30	0.13—0.72	0.007	0.25	0.09—0.69	0.007
Reduced protocol	0.99	0.96—1.02	0.4	NA	NA	NA
Lithotripter machine	<0.001	0.00 to infinity	1	NA	NA	NA

CI, confidence interval; HR, hazard ratio; HU, Hounsfield unit; NA, not available.

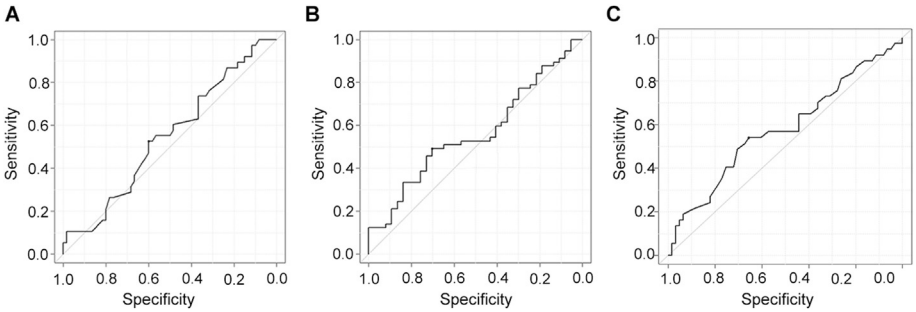

Figure 2 The receiver operating characteristic analysis was used to determine cutoff values and divide continuous variables into binary variables. (A) Stone size; (B) Attenuation values; (C) Age.

were more common in Group I. The subgroup analysis in Group I showed that an attenuation value of <694 HU predicted treatment success, which may be the cutoff point separating the true and false radiolucent stones.

In Group I, the rate of conversion to ureteroscopy was high; however, no statistical difference was observed between both groups. Considering that conversion to ureteroscopy was recommended following one IVU-SWL session, the conversion rate following IVU-SWL was comparable to non-IVU-SWL. Additional ultrasonography-guided SWL could be performed when the stones are moved to the ureterovesical junction, whether radiolucent or not. However, 22 patients underwent additional fluoroscopy-guided SWL, indicating that IVU-SWL was performed on radiopaque stones because the KUB scan could not detect them. The sensitivity of the KUB scan was reported as 44%—77% [20]. Moreover, if stones in the middle ureter are moved to the distal ureter, some of them may be detected by the KUB scan. Taken together, over 90% of radiolucent stones can be treated without conversion to ureteroscopy.

We assessed the stone-free rate within 30 days with only one SWL session; however, whether this was appropriate was not determined. By principle, we recommend a single session IVU-SWL; moreover, previous studies of IVU-SWL reported the outcome of single session SWL within 30 days or 90 days [2—4]. Thus, the stone-free rate within 30 days with only one SWL session may be appropriate to investigate the outcome of IVU-SWL. However, performing additional SWL when stones can be detected is a common strategy in clinical practice. Therefore, there should be a strong bias in this study design. The stone-free rate within 90 days, including multiple sessions, may be appropriate for assessing clinical outcomes for radiolucent stones' beginning treatment with IVU-SWL.

Despite the advantages of IVU-SWL, it also has disadvantages. One is the contrast hypersensitivity reactions to contrast medium, which have been reported to range from 3.8% to 12.7%, with severe reactions occurring in 0.02%—0.04% [21]. The incidence of acute kidney injury was reported to be 4.4%—22.1%; however, the exact number is unknown, depending on the definition used [22]. In our study, no serious complications were observed. This may be because we performed IVU-SWL in patients with good renal function. However, since not all kidney functions were evaluated following the procedure, some patients may have experienced renal injury. The other is a technical issue, indicating that it is difficult to focus on radiolucent stones even with IVU since it cannot frequently produce a clear image of stones. Buchholz and van Rossum [7] reported that the focus should be 5 mm beyond the edge of the column of the contrast medium. The outcome of IVU-SWL itself was shown to be comparable to non-IVU-SWL using PSM in this study, but IVU-SWL was performed by an expert urologist (Higashi Y) in our hospital. It may make a difference for some urologists.

This study had some limitations. First, the selection bias existed owing to the retrospective study design. However, IVU-SWL should be indicated for selected patients. Second, the follow-up schedule was not defined. Within 30 days, several patients underwent additional sessions or were converted to ureteroscopy. This might reduce the stone-free rate within 30 days with only one SWL session. Third, the ultrasonography and KUB scan were used to assess the stone-free rate, and CT was not used for all patients. Some patients, particularly those with radiolucent

stones, were diagnosed as "stone free" only by ultrasonography. However, as previously reported, ultrasonography is useful for detecting ureteral stones [23]. Finally, the long-term effects remain unclear since only acute complications were evaluated.

Despite some limitations, the clinical outcome of IVU-SWL for radiolucent stones is comparable to that of non-IVU-SWL for radiopaque stones, even with PSM. Furthermore, several patients could eventually avoid ureteroscopy, including several additional sessions of non-IVU-SWL. Of course, ureteroscopy remains the first-line modality for radiolucent ureteral stones; however, IVU-SWL can be an alternative for selected patients, especially with lower attenuation value stones.

5. Conclusion

Radiolucent stones can be safely and effectively treated by SWL with IVU. IVU-SWL allows patients to avoid ureteroscopy, especially for stones with low attenuation.

Author contributions

Study concept and design: Shinya Somiya, Katsuhiro Ito, Toru Kanno.
Data acquisition: Shinya Somiya, Shigeki Koterazawa, Takao Haitani, Yuki Makino, Ryuichiro Arakaki, Yoshihito Higashi.
Data analysis: Shinya Somiya.
Drafting of manuscript: Shinya Somiya.
Critical revision of the manuscript: Katsuhiro Ito, Norio Kawase, Toru Kanno.
Software: Hitoshi Yamada.

Conflicts of interest

The authors declare no conflict of interest.

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