

Running Head: Impact of percutaneous nephrostomy on SWL

**Impact of Percutaneous Nephrostomy on the Efficacy of *in Situ* Shock Wave
Lithotripsy for Upper Ureteral Stones**

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ABSTRACT

Purpose: To investigate whether a Percutaneous nephrostomy (PCN) has any impact on the success rate of shock wave lithotripsy (SWL) and to estimate the probability of stone-free in SWL patients with upper ureter stones.

Materials and Methods: Overall, 236 patients who underwent SWL for upper ureter stones between 2015 and 2019 were evaluated. Forty-nine patients who underwent PCN during SWL were identified. Medical data of the patients were retrospectively reviewed, and possible prognostic features were evaluated.

Results: Out of all patients, 147 patients were selected through propensity score matching. There were no significant differences between the PCN and no PCN groups, except for a lower stone-free rate (55.1% vs. 74.5%, $p = .018$) and one-session success rate (24.5% vs. 50.0%, $p = .003$) in the PCN group. In univariate analysis, a younger age, the female sex, a smaller size of stone, lower mean stone density (MSD), and absence of PCN were positive predictive factors of being stone-free in patients who underwent SWL. In multivariate analysis, a smaller size, lower MSD, and absence of PCN were positive predictive factors of being stone-free in patients who underwent SWL.

Conclusion: Stone size, MSD, and PCN were prognostic factors that influence the outcome of SWL. The presence of PCN during SWL is associated with adverse success rates in patients with upper ureter stones.

INTRODUCTION

Urolithiasis is one of the most prevalent problems in patients visiting a department of urology. The commonest risk factors for the progression of urolithiasis include metabolic syndrome, dehydration, lifestyle changes, and rise in ambient temperatures⁽¹⁻³⁾. Usually, upper urinary tract stones pass through the urinary tract without a problem; however, in some cases complications arise, the most frequent being upper urinary tract obstruction and acute renal colic that, often resulting in excruciating pain⁽⁴⁾. If the presence of stones is complicated by acute kidney injury with severe obstruction or infection, either percutaneous nephrostomy (PCN) or a double-J ureteral stent should be attempted as an emergency procedure to allow drainage of urine for decompression before planning further treatment⁽⁵⁾. ~~Several treatment options are available, including watchful waiting for spontaneous expulsion, shock wave lithotripsy (SWL), and percutaneous or retrograde endoscopic surgery.~~ Shock wave lithotripsy (SWL) was introduced in the 1980s for the treatment of urolithiasis and was accepted immediately as a first-line option for treatment⁽⁶⁾. A number of factors, such as position, size, and hardness of the stone determine the efficacy of treatment with

SWL⁽⁷⁾. Retreatment, if required, particularly in the case of large volume stone results in additional expenditure in terms of time and finances⁽⁸⁾. Prior evaluation of whether patients with urolithiasis will respond well to SWL, prevents unnecessary wastage of resources and treatment by procedures likely to be ineffective by selecting more appropriate treatment methods for the management of urolithiasis⁽⁹⁾. Hence, it is advisable to identify in advance patients who can be better served using an alternative modality of treatment. Recently, some studies have demonstrated that double-J ureteral stents reduce the success rate of SWL⁽¹⁰⁻¹²⁾; however, it remains uncertain and debatable whether PCN affects the success rate of SWL. This study aimed to investigate whether PCN affects the success rate of SWL for the treatment of ureteral stones. Additionally, various patient populations and stone characteristics were evaluated using non-contrast computed tomography (NCCT) for predicting the stone-free rate after SWL to counsel patients on the various treatment options available for upper ureteral stones.

MATERIALS AND METHODS

Patient population

A retrospective analysis of the database of patients of our department, who received SWL for a single upper ureteral stone from January 2015 to December 2019, was performed. Overall, 236 patients with previously untreated stones were registered. The inclusion criteria for the current study were a solitary stone measuring 0.5 – 2 cm in diameter, radiopaque, and located within the upper ureter on NCCT. Patients with the following state were excluded: uncontrolled bleeding disorders, uncorrected obstruction inferior to the stone, had a genitourinary tract abnormality, younger than 15 years, double-J ureteral stents inserted state. The medical data of these patients were reviewed to evaluate their suitability as prognostic features. The factors evaluated were age, sex, diabetes mellitus (DM), hypertension (HTN), stone laterality, stone length (X, Y, and Z axes), stone volume, mean stone density (MSD), stone heterogeneity index (SHI), skin to stone distance (SSD), psoas muscle cross-sectional area, colic pain and presence of PCN before SWL. PCN was performed as an emergency procedure in complicated upper ureter stone with severe obstruction and infection. An 8-French tube was introduced in to the obstructed renal pelvis through a PCN puncture. All data analyses were performed according to the relevant regulations and guidelines described in the Declaration of Helsinki; the study was approved by Chungnam National University Hospital institutional ethics committee (Approval No. CNUH 201807047004).

Stone characteristics

The characteristics of the stones were interpreted using NCCT, and maximum stone length was measured on axial and coronal view. The stone volume was calculated using the ellipsoid formula ($\pi/6 \times \text{length} \times \text{width} \times \text{height}$). The MSD was obtained by measuring the mean Hounsfield units (HU) of the defined regions of a circle with a diameter smaller than that of the stone without including the adjacent tissue. The SHI was obtained as the standard deviation of HU. The SSD was obtained by measuring distance from the center of the stone to the skin at 90° in the horizontal axis. Successful SWL outcome was categorized as stone-free and one-session success. Stone-free was defined as an asymptomatic state with residual stone debris of less than 3 mm in the largest diameter or absence of observed stones for four weeks after the first SWL. One-session success was defined as stone-free state after only once SWL.

SWL protocol

The same electromagnetic lithotripter was used for treating all patients under fluoroscopic guidance on an outpatient basis. The lithotripter was an electromagnetic lithotripter made by the DirexGroup (Integra SL, Initia Ltd., Israel). The number of shock waves delivered per session was 2500 to 2800 at a low frequency (sixty times per minute). The voltage of the shock wave started from 10.0 kV and was increased stepwise to a maximum of 18.0 kV in order to reduce the risk of damage to adjacent organs. Additional SWL was carried out at one-week intervals if any evidence of residual stones remained. All patients underwent SWL under opened PCN state. No antibiotics and diuretics were administered during SWL. All patients were instructed to drink sufficient water and continue daily activities with proper exercise.

Statistical analyses with propensity-score matching

The method of propensity-score matching was performed to further clarify patients' characteristics after total group analysis. Combined continuous and categorical factors were evaluated to produce a propensity score for each individual in the surveyed population. Propensity scores were then calculated using a multivariate logistic regression model with a binomial method based on factors that demonstrated significant differences between the PCN and no PCN groups in the total groups. Propensity-score analysis with 1:2 matching was performed with the nearest neighbor matching method. Statistical comparisons of continuous variables were expressed as mean \pm standard deviation and performed using the Student's two-

sample *t*-test. Statistical comparisons of categorical variables were performed using the Pearson's chi-square test. Univariate logistic regression was used to identify factors having an effect on stone-free and one-session success. Significant factors in the univariate logistic regression were further analyzed by multivariate logistic regression. *P*-values ≤ 0.05 were considered statistically significant. All statistical analyses used the IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Characteristics of patients and stone are presented in Tables 1 and 2. Table 1 shows the baseline characteristics of all 236 patients who received SWL for upper ureteral stone. Out of these patients, 20.8% (n=49) had PCN insertion during SWL for upper ureteral stone. Comparisons of the PCN and no PCN groups based on characteristics of patients and stone revealed that age, DM, HTN, stone laterality, size, MSD, SHI, and psoas muscle cross-sectional area were significantly different between the groups. There were no significant differences between the groups in sex, SSD, MSD, and colic pain. Stone-free was significantly less in the PCN group (55.1% vs. 77.5%), as was one-session success (24.5% vs. 51.9%) (Table 1).

After 1:2 propensity-score matching with the nearest neighbor algorithm, stone-free was significantly less in the PCN group (55.1% vs. 74.5%), as was one-session success (24.5% vs. 50.0%) (Table 2).

Univariate logistic regression model proved that the following were significantly related factors of stone-free after SWL for upper ureteral stone: a younger age, the female sex, a smaller stone volume, lower MSD, and no inserted PCN. Multivariate logistic analysis proved that a smaller stone volume, lower MSD, and no inserted PCN were significantly independent predictive factors of stone-free after SWL for upper ureteral stones (Table 3).

Univariate logistic regression model proved that the following were significantly related factors of one-session success after SWL for upper ureteral stone: the female sex, a smaller stone volume, shorter SSD, lower MSD, and no inserted PCN. Multivariate logistic analysis proved that a smaller stone volume, lower MSD, and no inserted PCN were significantly independent predictive factors of one-session success after SWL for upper ureteral stones (Table 4).

DISCUSSION

Since its introduction in the early 1980s, SWL has been recognized as the preferred treatment for ureteral stones because it is non-invasive, has few contraindications, and demonstrates good clinical results⁽¹³⁾.

Over the last 40 years, many scholars have attempted to find out the factors that determined high success and low complication rates in SWL treatment of ureteral stones. In the case of SWL, factors that have been reported to affect success and complication rates contain stone characteristics (size, location, composition, and density), patients' characteristics (age, sex, and obesity), SWL frequency range, lithotripter type, and any hemorrhagic tendency in the patients⁽¹⁴⁻¹⁶⁾. Additionally, pre-SWL PCN has been proposed as an important method of resolving upper urinary tract obstruction. It affords satisfactory drainage, is technically simple, and is associated with fewer complications.

~~In some cases, ureteral stones cause sudden upper urinary tract obstruction, resulting in hydronephrosis.~~ Persistent obstruction may result in subsequent decline of renal function. Elevated pressure above the ureter stone also increases the tension in the wall of the ureter at the stone location and, therefore, the friction between the mucosa and stone of ureter. Moreover, high friction at the stone location injures the mucosal layer of the ureter, leading to bleeding and inflammation around the stone. This leads to swelling that narrows the lumen of the ureter and hinders spontaneous discharge of the stone. On the other hand, severe obstruction with hydronephrosis can be linked to the impaction of a ureteral stone on the ureteral mucosa⁽¹⁷⁾. Chronically impacted ureteral stones can cause edema of the ureteral wall and are often associated with ureteral polyps or strictures⁽¹⁸⁾. These changes can also adversely affect the discharge of the ureteral stone. We consider whether performing PCN to resolve the obstruction could improve the movement of the ureteral stone and increase the success rate of SWL. However, the findings did not support our expectations. Our results indicated that PCN insertions could adversely affect stone-free and one-session success during SWL. In our study, PCN was the only significantly different factor between both groups after 1:2 propensity-score matching. Propensity-score matching was used to reduce the impact of treatment-selection bias for estimating causal treatment effects using observational data⁽¹⁹⁾.

The main rationale for performing decompression stentings (PCN or double-J ureteral stent) was to prevent complications related to upper urinary tract obstruction as stone debris passes through the ureter during SWL. Complete elimination of stones is the supreme goal; however, reducing complications during SWL is another important goal in the management of urolithiasis. In most studies, decompression stents have been shown to be effective in preventing complications. Regrettably, few reports show that decompression stents increase stone-free rates after SWL. Previous studies demonstrated that double-J ureteral stents do not improve the success rate of SWL⁽²⁰⁻²²⁾. Middela et al., reported that the presence of PCN was not a

significant factor in the success rate of SWL ⁽²³⁾. Joshi et al., demonstrated that the outcome of SWL in no decompression stent group was better than that in PCN group and double-J ureteral stent group ⁽²⁴⁾. Although these measures may provide more information to urologists before treatment, the precise meaning of these data in the management of stone remains controversial.

Our assumption was that when the friction between stone and mucosa of ureter was higher than the driving force, the stone will not be dislodged. If PCN was present, it could decompress the dilated renal pelvis and the ureter above the stones and can drain the urine through it. Consequently, it reduces the pressure above the ureteral stone and the friction around the stone, but it also reduces the driving force associated with urine flow, which negatively impacts the success rate of SWL.

Urinary tract obstruction resulting from ureteral stones is a common cause of urinary tract infection (UTI) ⁽²⁵⁾. In patients with acute UTI, the infection should be treated first with appropriate antibiotics before commencing treatment for removal of the stone. In some cases, PCN insertion is inevitable. Until stones are removed, urinary diversions can be performed empirically to prevent deterioration of renal function or aggravation of the UTI. PCN is a well confirmed procedure that allow for temporary or permanent urinary diversion from the renal pelvis in urinary tract obstruction. PCN is mainly performed for patients with severe renal colic, acute kidney injury, and urosepsis caused by urinary tract obstruction ⁽²⁶⁾.

We had several cases of SWL in patients who underwent PCN and observed that PCN could interfere with stone debris migration. As mentioned above, PCN can decrease intrarenal pressures if intrarenal urine and fluid are continuously draining through a PCN, and this may make it difficult for stones to migrate toward the distal ureter and bladder. The results of the current study suggest that physicians may consider stone volume and MSD as factors that influence SWL outcomes when deciding whether to perform PCN prior to SWL. In patients with large upper ureteral stones and a high MSD, the decision to perform PCN should be based on the degree of renal function decline and complications caused by upper urinary tract obstruction. Identifying factors that predict SWL outcomes would help simplify the care of patients with stones. Patients identified to be at high risk of treatment failure may be offered alternative procedures, such as flexible ureteroscopy to manage their urolithiasis. Physicians can determine which types of patients are most likely to benefit from SWL. In an era of limited medical insurance reimbursement, cutting down on medical costs is essential. Thus, we do not recommend routine pre-SWL PCN insertion; PCN insertion should be offered only when there are special indications, such as complicated upper urinary tract obstruction.

The limitation of this study is that it is a retrospective study conducted at a single institution; therefore, our results were derived from a relatively small sample population. A small control group might arouse selection bias in propensity-score matching studies. Also, potential limitation to propensity-score matching studies was that unrecognized risk factors might affect outcomes. Despite this limitation, our study confirmed the effect of PCN on the outcomes of SWL and analysis of stone-free following SWL according to meaningful stone characteristics (stone volume and MSD) in relation to the presence of a PCN. In the future, a well-designed prospective study with a large sample population will be required to prove our observations on the adverse effect of PCN during SWL.

CONCLUSIONS

The presence of PCN during SWL was an adverse predictive factor of stone-free and one-session success in patients with upper ureteral stones. We believe the PCN insertion status can be used to predict the treatment outcomes of SWL, and this may be helpful in selecting the optimal treatment option for patients with upper ureteral stones. PCN should still be used in patients with obstruction, those at risk of sepsis, and in those with unbearable pain or decreased renal function. However, if the underlying problem resolves and the general condition improves, it is suggested that performing SWL after the removal or clamping of the PCN can lead to positive therapeutic effects.

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CONFLICT OF INTEREST

There are no conflicts of interest to declare from all authors.

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Table 1. Demographic data and SWL success rate comparisons between PCN and no PCN groups

Variable	PCN group (n=49)	No PCN group (n=187)	p-value
Age, mean \pm SD	65.31 \pm 12.46	58.08 \pm 14.26	.001
Sex, numbers of female, %	24, 49.0	81, 43.3	.478
Diabetes mellitus, %	21, 42.9	40, 21.4	.002
Hypertension, %	33, 67.3	63, 33.7	<.001
Stone laterality, numbers on right side, %	31, 63.3	86, 46.0	.031
Stone length (mm, X-axis), mean \pm SD	7.01 \pm 1.56	6.41 \pm 1.49	.015
Stone length (mm, Y-axis), mean \pm SD	7.55 \pm 1.21	7.22 \pm 1.75	.123
Stone length (mm, Z-axis), mean \pm SD	10.29 \pm 2.95	9.08 \pm 2.60	.005
Stone volume (mm ³), mean \pm SD	308.15 \pm 167.62	245.62 \pm 173.10	.024
Skin to stone distance (mm), mean \pm SD	109.38 \pm 22.33	107.90 \pm 15.67	.593
Mean stone density, mean \pm SD	707.72 \pm 276.50	790.53 \pm 262.81	.053
Stone heterogeneity index, mean \pm SD	140.81 \pm 88.13	188.47 \pm 79.29	<.001
Psoas muscle cross-sectional area (mm ²), mean \pm SD	965.98 \pm 336.79	1096.98 \pm 362.06	.023
Colic pain, %	41, 83.7	148, 79.1	.480
Stone-free, %	27, 55.1	145, 77.5	.002
One-session success, %	12, 24.5	97, 51.9	.001

Abbreviations: SD = standard deviation; PCN = percutaneous nephrostomy.

Values are presented as mean \pm standard deviation or number (%).

Table 2. Demographic data and SWL success rate comparisons between PCN and no PCN groups for propensity-score matching

Variable	PCN group (n=49)	No PCN group (n=98)	p-value
Age, mean \pm SD	65.31 \pm 12.46	62.70 \pm 13.34	.257
Sex, numbers of female, %	24, 49.0	50, 51.0	.816
Diabetes mellitus, %	21, 42.9	31, 31.6	.180
Hypertension, %	33, 67.3	57, 58.2	.281
Stone laterality, numbers on right side, %	31, 63.3	57, 58.2	.552
Stone length (mm, X-axis), mean \pm SD	7.01 \pm 1.56	6.54 \pm 1.63	.104
Stone length (mm, Y-axis), mean \pm SD	7.55 \pm 1.21	7.32 \pm 1.76	.355
Stone length (mm, Z-axis), mean \pm SD	10.29 \pm 2.95	9.50 \pm 2.69	.105
Stone volume (mm ³), mean \pm SD	308.15 \pm 167.62	264.30 \pm 173.43	.146
Skin to stone distance (mm), mean \pm SD	109.38 \pm 22.33	106.34 \pm 17.32	.366
Mean stone density, mean \pm SD	707.72 \pm 276.50	755.05 \pm 266.15	.317
Stone heterogeneity index, mean \pm SD	140.81 \pm 88.13	157.97 \pm 72.69	.212
Psoas muscle cross-sectional area (mm ²), mean \pm SD	965.98 \pm 336.79	997.98 \pm 368.55	.611
Colic pain, %	41, 83.7	79, 80.6	.651
Stone-free, %	27, 55.1	73, 74.5	.018
One-session success, %	12, 24.5	49, 50.0	.003

Abbreviations: SD = standard deviation; PCN = percutaneous nephrostomy.

Values are presented as mean \pm standard deviation or number (%).

Table 3. Univariate and multivariate logistic regression models for predictive factors of stone-free following shock wave lithotripsy

Parameter	Univariate			Multivariate		
	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value
Age	0.971	0.943-0.999	.046	0.965	0.926-1.006	.093
Sex (female)	2.051	1.010-4.164	.047	1.960	0.728-5.227	.183
Diabetes mellitus	1.253	0.600-2.614	.548			
Hypertension	0.971	0.476-1.979	.935			
Stone laterality (right side)	1.704	0.844-3.440	.137			
Stone length (mm, X-axis)	0.504	0.379-0.671	<.001			
Stone length (mm, Y-axis)	0.546	0.418-0.713	<.001			
Stone length (mm, Z-axis)	0.590	0.489-0.713	<.001			
Stone volume (mm ³)	0.991	0.989-0.994	<.001	0.992	0.988-0.995	<.001
Skin to stone distance (mm)	0.989	0.970-1.008	.244			
Mean stone density	0.996	0.994-0.997	<.001	0.996	0.994-0.998	<.001
Stone heterogeneity index	1.003	0.998-1.007	.254			
Psoas muscle cross-sectional area (mm ²)	1.000	0.999-1.001	.887			
Colic pain	1.943	0.826-4.569	.128			
Percutaneous nephrostomy	0.420	0.204-0.866	.019	0.292	0.104-0.815	.019

Abbreviations: CI = confidence interval.

Table 4. Univariate and multivariate logistic regression models for predictive factors of one-session success following shock wave lithotripsy

Parameter	Univariate			Multivariate		
	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value
Age	1.002	0.977-1.027	.886			
Sex (female)	2.042	1.047-3.982	.036	1.212	0.421-3.487	.721
Diabetes mellitus	1.344	0.678-2.662	.397			
Hypertension	1.371	0.695-2.707	.363			
Stone laterality (right side)	0.838	0.430-1.635	.605			
Stone length (mm, X-axis)	0.402	0.287-0.562	<.001			
Stone length (mm, Y-axis)	0.471	0.351-0.633	<.001			
Stone length (mm, Z-axis)	0.557	0.452-0.686	<.001			
Stone volume (mm ³)	0.988	0.984-0.992	<.001	0.990	0.985-0.994	<.001
Skin to stone distance (mm)	0.978	0.959-0.997	.025	0.979	0.952-1.008	.150
Mean stone density	0.995	0.994-0.997	<.001	0.995	0.992-0.997	<.001
Stone heterogeneity index	0.998	0.994-1.003	.443			
Psoas muscle cross-sectional area (mm ²)	0.999	0.998-1.000	.154			
Colic pain	1.529	0.636-3.679	.128			
Percutaneous nephrostomy	0.324	0.151-0.695	.004	0.168	0.054-0.523	.002

Abbreviations: CI = confidence interval.