

Preoperative use of alpha-1 receptor blockers in male patients undergoing extracorporeal shock wave lithotripsy for a ureteral calculus: a retrospective cohort study

Takashi Yoshioka

Fukushima Medical University

Kenji Omae (✉ omae416@fmu.ac.jp)

Fukushima Medical University <https://orcid.org/0000-0003-0109-7425>

Tatsushi Kawada

Hiroshima City Hiroshima Citizens Hospital

Yosuke Inoue

Onomichi Municipal Hospital

Morito Sugimoto

Onomichi Municipal Hospital

Tadashi Oeda

Onomichi Municipal Hospital

Shinya Uehara

Kawasaki Medical School General Medical Center

Motoo Araki

Okayama University

Shunichi Fukuhara

Kyoto University

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Abstract

Purpose To characterize the preoperative use of alpha-1 adrenergic receptor (AR) blockers and investigate its impact on the outcome of single-session extracorporeal shock wave lithotripsy (SWL) for a ureteral calculus in male patients.

Methods We conducted a retrospective single-center cohort study involving 193 patients who underwent SWL for a single ureteral calculus between 2006 and 2016. We reviewed their medical records to obtain the data on the preoperative use of alpha-1 AR blocker and, if any, the reason for the prescription. The primary outcome was treatment success after single-session SWL, defined as complete stone clearance or residual fragments <4 mm in size by X-ray imaging. We performed a multivariable logistic regression analysis adjusting for clinically important confounders to examine the association between preoperative use of alpha-1 AR blockers and the treatment success of SWL. We further analyzed this association according to the reason for the prescription.

Results Among the 193 patients, 15 (7.8%) were taking an alpha-1 AR blocker preoperatively with 8 (4.1%) for medical expulsive therapy (MET) and 7 (3.7%) for the treatment of benign prostatic hypertrophy (BPH). A multivariate analysis showed that the preoperative use of alpha-1 AR blocker was a significant negative predictor for treatment success of SWL (adjusted odds ratio [aOR] 0.17; 95% confidence intervals [CI], 0.04–0.74). Moreover, the use of alpha-1 AR blocker for MET, but not for BPH, was associated with lower rate of successful treatment (aOR 0.14 and 0.23; 95% CI, 0.02-0.90 and 0.03-1.97, respectively).

Conclusions Our findings suggest that the preoperative use of alpha-1 AR blocker, especially for MET, was a negative predictor for treatment success of SWL in male patients with a single ureteral calculus. Clinicians should pay more attention to the preoperative drug use in determining an appropriate stone therapy modality.

Introduction

Upper urinary tract calculi is a common disorder with a prevalence of 5.2% in the United States (between 1988 and 1994) and showing an increasing trend all over the world [1]. The patients present with varied symptoms, and the condition may sometimes prove fatal [2,3]. Once patients are diagnosed with upper urinary tract calculi, urologists determine the most suitable type of surgical treatment from among various modalities, such as extracorporeal shock wave lithotripsy (SWL), ureteroscopic lithotripsy (URSL), and percutaneous nephrolithotomy (PCNL), based on the size and localization of the calculus in the urinary system [4–6]. In Japan, about 60% of the patients with upper urinary tract calculi were treated surgically in 2015, 60% and 39% of whom underwent SWL and URSL or PCNL, respectively [7]. Of the aforementioned treatments, SWL is a good alternative modality that may have clinical advantage over URSL in patients with solitary upper urinary tract calculi ≤ 20 mm [4–6]. The guidelines issued by the European Association of Urology (EAU) and American Urological Association (AUA) /Endourological

Society have provided a grade B recommendation for both SWL and endourology (URSL) in the management of solitary non-lower pole calculi ≤ 20 mm in size [5,6].

Some meta-analyses have reported the beneficial effects of alpha-1 adrenergic receptor (AR) blockers, which could cause an earlier expulsion of the stone and decrease the requirement for analgesics following SWL for ureteral calculi [8,9]. The current EAU guidelines also recommend postoperative medical expulsive therapy (MET) with alpha-1 AR blockers after SWL in cases of residual fragments [5]. On the other hand, alpha-1 AR blockers are prescribed for benign prostatic hyperplasia (BPH) as well as for MET in men in the clinical practice. Only one study has revealed beneficial SWL outcomes with preoperative administration of alpha-1 AR blockers for BPH [10]. However, preoperative alpha-1 AR blockers for those who failed MET and underwent subsequent SWL is still unknown. Therefore, in this study, we aimed to characterize the preoperative use of alpha-1 AR blockers based on the purpose of prescription in male patients who underwent SWL for ureteral calculi and to evaluate the impact of the preoperative administration of alpha-1 AR blockers on their outcomes of a subsequent SWL procedure.

Methods

Study design

We performed a retrospective single-center cohort study.

Research Setting

The study was conducted at the Onomichi Municipal Hospital in Japan. We included patients diagnosed with ureteral calculi from 1 January, 2006 to 31 December, 2016.

Inclusion and exclusion criteria

We included patients who had been diagnosed with solitary upper urinary tract calculi on non-contrast computed tomography (NCCT) within the study period. To evaluate the association of alpha-1 AR blockers with SWL outcomes, only male patients with a solitary ureteral calculus were included. We excluded the patients with multiple calculi, for whom other surgical modalities such as URSL or PCNL were more suitable rather than SWL. We also excluded patients with indwelling ureteral stents, those for whom we did not have follow-up data, and those with missing outcome-data.

Measurement of exposure

For this study, we reviewed the registration forms filled by the patients at the first visit from their medical records. The registration forms had been recorded by well-trained nurses and contained the details of

every prescription drug that the patient was on. We utilized this data to determine whether the patient was taking any alpha-1 AR blocker (e.g. tamsulosin, naftopidil, silodosin, and urapidil) preoperatively. It is important to note that all patients who underwent SWL in Onomichi Municipal Hospital did not have postoperative MET (post-MET) done in case of residual fragments. The patients who were on preoperative alpha-1 AR blockers (both for BPH and for preoperative MET (pre-MET)) had continued to receive them till the completion of SWL.

Main outcome measures

Our primary outcome measure was the proportion of cases in which treatment was successfully completed in a single session. We defined a successful treatment as one where the patient needed no additional treatment for the ureteral stone after completion of a single session of SWL. We evaluated the outcome of the procedure based on abdominal X-ray KUB (kidney, ureter, and bladder) film taken at the patient's next visit to the outpatient clinic. If the size of the targeted calculus had been <4 mm, the SWL was deemed successful only when the calculus had passed completely and was undetectable on the KUB film. If the size of the targeted calculus had been ≥ 4 mm, the procedure was labelled successful either if the calculus had completely passed and was undetectable on KUB, or if the size of renal residual fragments after the SWL was <4 mm, which are defined as clinically insignificant residual fragments (CIRF) [11]. Also, we defined patients who required further treatment with modalities such as URSL or PCNL (instead of a second session of SWL) as treatment failures (NOT successful treatment).

SWL method

The SWL was performed with the Dornier Lithotripter D (Dornier MedTech, Wessling, Germany) at the hospital. All the patients were administered transrectal diclofenac as an analgesic, prior to the procedure. For targeting upper ureteric calculi, patients were placed in the supine position. For targeting mid-to-lower ureteric calculi, patients were placed in the prone position. The shock-waves were applied at a rate of 60 per minute. The shock wave energy was gradually increased according to patient tolerance. Maximum 3000 shocks were administered to almost all the patients. The first postoperative follow-up was conducted within 1 month.

Data collection

We collated the relevant data from the patients' medical records. A standardized protocol was formulated to collect data of exposure and outcome. The protocol provided instruction on how to measure exposure and outcome in each patient.

Statistical analysis

We analyzed the group-wise patient demographics of those who were receiving alpha-1 AR blockers and those who were not, using the Wilcoxon rank sum test for the continuous variables and the Fisher's exact test for the categorical variables. To evaluate the effectiveness of alpha-1 AR blockers, we mainly applied a multivariable logistic regression analysis. We selected 6 variables (age, location of the calculus, stone length, mean stone density (MSD), and skin-to-stone distance (SSD)) as the most important confounders, based on published guidelines [4–6]. The selected confounders were converted to dichotomous variables, with reference to social factors, anatomical factors, and previous studies: age (cut-off value: 65 years), localization of the calculus (upper or mid-to-lower ureter), stone length (cut-off value: 5 mm) [12], MSD (cut-off value: 600 Hounsfield units (HU)) [13], and skin-to-stone distance (cut-off value: 120 mm) [13]. Furthermore, we included information regarding whether the administered alpha-1 AR blocker had effectively served the purpose for which it had been prescribed. We performed an additional analysis of the reason for which the alpha-1 AR blocker had been prescribed and also carried out a multivariable logistic regression analysis of the dichotomously classified confounders to estimate their influence on the outcome of the SWL. Thus, we performed a complete-case analysis. The data were analyzed using STATA ver. 15.1 (Stata Corp., College Station, Texas).

Results

A flowchart with study participant information is presented in Fig. 1. We reviewed medical records of all the patients who underwent SWL at the hospital between January 2006 and December 2016 and found 193 eligible participants. Of these, 15 participants (7.8%) had been on some alpha-1 AR blocker before the procedure.

Table 1 shows the characteristics of the included patients. The median age was 57 years and the median body mass index (BMI) was 23.8 kg/m². The median stone length was 5.6 mm, and the median MSD was 882 HU. An upper ureteral calculus was diagnosed in 135 (69.9%) of the 193 patients. The patients taking alpha-1 AR blockers were found to be older than those who were not (62 years vs. 56 years). In addition, the calculi in the treated group were smaller in diameter (4.9 vs. 5.6 mm), had lower MSD (870 vs. 893.5 HU), and a lower proportion of occurrence in the upper ureter (60.0% vs. 67.0%), respectively. However, these differences were not found to be statistically significant. A successful treatment outcome was seen in 136 (70.5%) of the 193 patients. The patients taking the alpha-1 AR blockers achieved a significantly lower treatment success rate compared to those who were not on the medications (46.7% (7 of the 15 patients) vs. 72.5% (129 of the 178 patients), $P = 0.043$).

Table 2 shows the results of the multivariable logistic regression analysis estimating the treatment success of a single session of SWL. After making necessary adjustments, the administration of alpha-1 AR blocker was found to be negatively associated with a successful treatment outcome (adjusted odds ratio (aOR) 0.17; 95% confidence intervals (CI) 0.04 to 0.74; $P = 0.018$). A significant association of treatment success was also seen with physical and anatomical characteristics such as age <65 years (aOR 2.16; 95% CI: 1.02 to 4.60; $P = 0.045$), stone length <5 mm (aOR 4.51; 95% CI 1.64 to 12.42; $P = 0.004$), and MSD <600 HU (OR 6.82; 95% CI 1.44 to 32.20; $P = 0.015$).

Table 3 shows the description of preoperative administration of alpha-1 AR blocker. Of the included patients, an alpha-1 AR blocker was preoperatively administered for BPH and pre-MET to 7 and 8 patients, respectively. The median duration of administration for BPH and pre-MET was 90 days (range: 10 to 1460), and 22 days (range: 7 to 90 days), respectively. Multivariable logistic regression model was applied as additional analysis, as shown in Table 4, which indicated that SWL for pre-MET, but not for BPH was a negative predictor for SWL success (aOR 0.14, 95% CI 0.02–0.90, $P = 0.038$; and aOR 0.23, 95% CI 0.03–1.97, $P = 0.180$, respectively).

Discussion

In this study, we described the preoperative use of alpha-1 AR blockers and evaluated its association with the outcome of a subsequently performed SWL for ureteral calculi. Among the patients, about 8% were taking an alpha-1 AR blocker preoperatively with about 4% for pre-MET. We achieved an overall treatment success rate of 70.1% in our study, which was comparable or superior to those attained in previous studies (49.6% to 69.9%) [13–15]. Furthermore, we evaluated the association based on the purpose of prescription. We found that the preoperative administration of alpha-1 AR blocker was a statistically significant negative predictor for the success of SWL.

Medical expulsive therapy (MET) using alpha-1 AR blockers is widely utilized for ureteral stones as the drugs are localized in the ureter and the blockade of alpha-1 AR can relax the ureteric smooth muscle [16]. The EAU guidelines recommended alpha-1 AR blockers for spontaneous passage of both ureteral stones and fragments created after SWL [5]. However, studies that evaluated the effectiveness of preoperative alpha-1 AR blockers use were scarce. Only one study from 2013 showed that preoperative alpha-1 AR blockers administered for BPH patients improved stone-free rate after SWL [10]. The results of this study were not adjusted sufficiently for confounding factors (e.g. patient age, stone size, stone location, number of SWL sessions and shockwaves administered per session). In contrast, we adjusted for sufficient confounding factors including NCCT factors, and we found that preoperative alpha-1 AR blocker use for BPH had no association with SWL success. We do not think our findings were contrary to the ones from previous studies, as we might not detect the possible association between alpha-1 AR blocker use for BPH and SWL success because of insufficient sample size. On the other hand, we found a negative association between alpha-1 AR blocker use for pre-MET patients and SWL success in spite of such a small sample size. We speculate that patients who underwent SWL after pre-MET represented those who were resistant to SWL, especially to stone passage. One possible mechanistic explanation is that such patients might have decreased ureteral peristalsis due to low expression of alpha-1 AR in their ureters [17], and /or have impacted stone, to which the effect of SWL is limited [18].

Our study has two important strengths. Firstly, we adjusted for all the known and important confounding factors including the ones detected on NCCT (patient age, stone length, localization of the calculus, MSD, and SSD). In addition, we had no missing data with respect to the confounders due to rigorous data collection. Secondly, the prescribed dose of tamsulosin was lower than the standard one (0.4 mg/day) because only 0.2 mg/day for benign prostatic hyperplasia is covered by the Japanese health insurance

system. Third, we investigated the purpose of the prescribed alpha-1 AR blockers in an additional analysis. To our knowledge, this is the first study to reveal the negative impact of preoperatively administered alpha-1 AR blocker on pre-MET patients with the success of a subsequent SWL. Despite these strengths, our study has some limitations. Firstly, our study is a single-center study. All the patients included were of the Asian ethnicity, and were from a rural city (Onomichi). Therefore, further study is required to be able to generalize our findings for application to patients of different races or social backgrounds. Secondly, our study cannot help us identify the mechanism of how preoperative alpha-1 AR blockers decrease the treatment success rate of SWL. We need further studies to clarify the mechanism of our findings.

Our study has a significant clinical implication. The negative influence of the alpha-1 AR blockers is so prominent (aOR 0.17 for SWL success) that based on our findings, we recommend urologists to pay more attention to preoperative alpha-1 AR blockers use when selecting treatment modalities. Subsequently, doing a URSL might be preferred to SWL. As mentioned above, future studies should focus on verifying our findings and discerning the mechanism behind this occurrence.

Conclusions

Our findings suggest that the preoperative use of alpha-1 AR blocker, especially for MET, was a negative predictor for treatment success of SWL in male patients with a single ureteral calculus. Therefore, urologists should pay more attention to the use of alpha-1 AR blockers when selecting a treatment modality in patients with a single ureteral calculus. Further studies are needed to validate and generalize our findings as well as to elicit the mechanism of action of the alpha-1 AR blockers in this scenario.

(2,346 words)

Abbreviations

SWLshock wave lithotripsy

URSLureteroscopic lithotripsy

PCNLpercutaneous nephrolithotomy

EAUthe European Urological Association

AUAAmerical Urological Association

ARadrenergic receptor

METmedical expulsive therapy

BPHbenign prostatic hyperplasia

NCCTnon-contrast enhanced computed tomography

KUBkidney ureter, and bladder

CIRFclinically insignificant residual fragments

MSDmean stone density

SSDskin-to-stone distance

HUHounsfield units

BMIbody mass index

aORadjusted odds ratio

CIconfidence intervals

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of Onomichi Municipal Hospital. The approval number was 17–23. The data were scrubbed of all identifying markers and anonymised before the statistical analysis. This is a retrospective observational study, therefore consents were obtained by opting out.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

We have no conflict of interests to declare.

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This study did not receive any financial supports.

Authors' contributions

All authors contributed to the study conception and design. Conceptualization was performed by TY, KO, SU, MA, and SF. Material preparation, data collection were performed by TY, YK, YI, MS, and TO. Analysis was performed by TY. Supervision was performed by KO, SU, MA, and SF. All authors commented on previous versions of the manuscript, and all authors read and approved the final manuscript.

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Tables

Table 1. Patients characteristics of the study

Characteristic	Total, n = 193		Patients without alpha-1 AR blocker, n = 178		Patients with alpha-1 AR blocker, n = 15		Number of missing value (%)		P-value
	Median [IQR]		Median [IQR]		Median [IQR]		n	%	
Age (years)	57 [43 - 65]		56 [42 - 65]		62 [51 - 68]		0	0	0.076
BMI (kg/m ²)	23.8 [22.2 - 26.2]		23.9 [22.1 - 26.2]		23.5 [23.3 - 25.4]		21	10.9	0.982
Stone length (mm)	5.6 [4.7 - 7.3]		5.6 [4.7 - 7.3]		4.9 [4.6 - 9]		0	0	0.613
Mean stone density (HU)	882 [661 - 1117]		893.5 [662 - 1125.5]		870 [509 - 1154]		0	0	0.946
SSD (mm)	115.7 [104.7 - 124]		115.7 [103.7 - 123.7]		119 [108.7 - 125]		0	0	0.313
Localization of calculus (n, %)							0	0	0.581
Upper ureter	135	69.9	126	70.8	9	60.0			
Middle ureter	23	11.9	21	11.8	2	13.3			
Lower ureter	35	18.1	31	17.4	4	26.7			

AR; adrenergic receptor, IQR; interquartile range, BMI; body mass index, AR; adrenergic receptor, HU; Hounsfield units SSD; skin-to-stone distance

Table 2. Multivariable logistic regression analysis estimating treatment success of SWL

	aOR	95% CI	P-value
Medication of alpha-1 AR blocker (ref. absent)			
present	0.17	(0.04 to 0.74)	0.018
Age (ref. 65 years or more)			
less than 65years	2.16	(1.02 to 4.60)	0.045
Localization of calculus (ref. mid-to-lower ureter)			
upper ureter	1.96	(0.91 to 4.23)	0.087
Stone length (ref. 5 mm or more)			
less than 5 mm	4.51	(1.64 to 12.42)	0.004
Mean stone density (ref. 600 HU or more)			
less than 600 HU	6.82	(1.44 to 32.20)	0.015
SSD (ref. 120 mm or more)			
less than 120 mm	1.11	(0.54 to 2.28)	0.776

SWL; Shock Wave Lithotripsy, aOR; adjusted odds ratio, CI; confidence intervals, AR; adrenergic receptor, HU; Hounsfield units, SSD; skin-to-stone distance

Table 3. Description of detailed information for taking alpha-1 AR blocker

Purpose of prescription	Drugs	Dosage	n	Median administration period (days [range])
For BPH	Tamsulosin	0.2 mg	4	90 [10 to 1460]*
	Silodosin	8 mg	2	
	Naftopidil	25 mg	1	
For pre-MET	Tamsulosin	0.2 mg	8	22 [7 to 90]

AR; adrenergic receptor, BPH; benign prostatic hypertrophy, pre-MET; preoperative medical expulsive therapy

* 2 out of 7 were missing data

Table 4. Multivariable logistic regression estimating treatment success of SWL according to the purpose of prescription for alpha-1 AR blocker

	aOR	95% CI	P-value
Medication of alpha-1 AR blocker (ref. absent)			
present for BPH	0.23	(0.03 to 1.97)	0.180
present for pre-MET	0.14	(0.02 to 0.90)	0.038
Age (ref. 65 years or more)			
less than 65 years	2.19	(1.03 to 4.67)	0.042
Localization of calculus (ref. mid-to-lower ureter)			
upper ureter	2.00	(0.92 to 4.35)	0.082
Stone length (ref. 5 mm or more)			
less than 5 mm	4.60	(1.65 to 12.79)	0.003
Mean stone density (ref. 600 HU or more)			
less than 600 HU	6.83	(1.44 to 32.30)	0.015
SSD (ref. 120 mm or more)			
less than 120 mm	1.13	(0.55 to 2.32)	0.748

SWL; Shock Wave Lithotripsy, AR; adrenergic receptor, aOR; adjusted odds ratio, CI; confidence intervals, BPH; benign prostatic hypertrophy, pre-MET; preoperative medical expulsive therapy, HU; Hounsfield units, SSD; skin-to-stone distance

Figures

Figure 1.

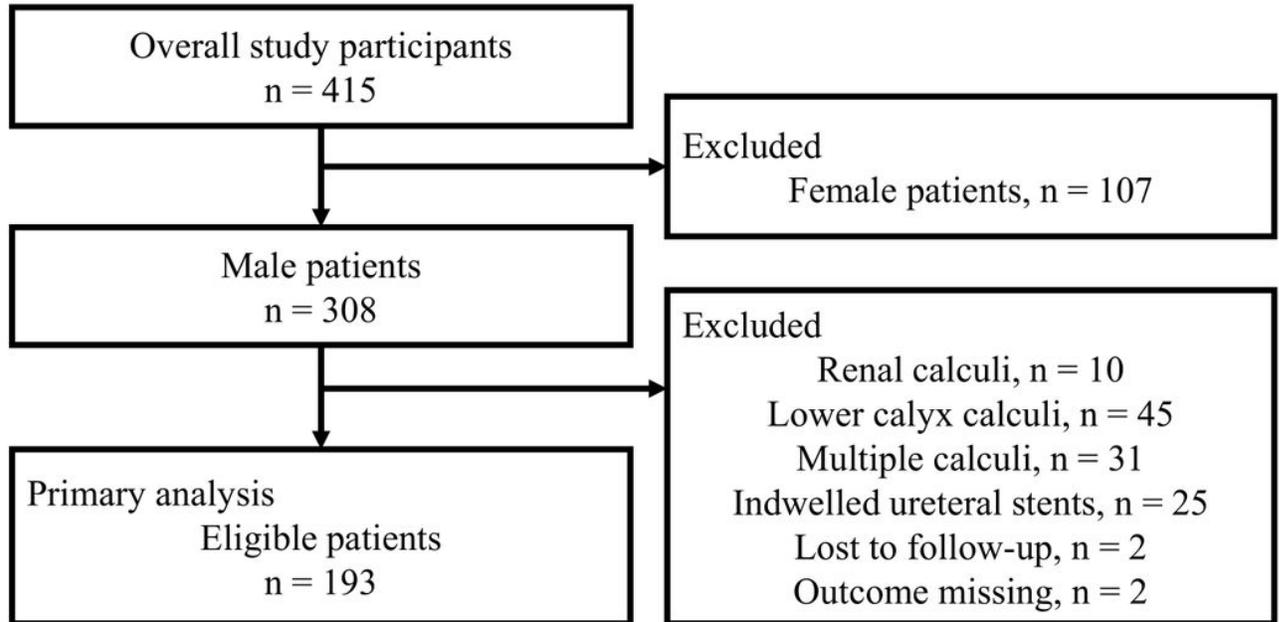


Figure 1

Flow-diagram of this study. A total of 415 patients underwent SWL in the hospital. Of these, female patients, patients with renal, lower calyceal or multiple calculi, those with indwelling ureteral stents, and those lost-to-follow-up were excluded. Consequently, a total of 193 patients were eligible.