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Different failure rates of insertion of 10/12-Fr ureteral access sheaths during retrograde intrarenal surgery in patients with and without stones

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Purpose: The aim of this study was to compare the failure rates of insertion of a 10/12-Fr ureteral access sheath (UAS) during retrograde intrarenal surgery (RIRS) in cases with and without stones and to analyze the risk factors for UAS insertion failure.

Materials and Methods: A total of 640 RIRS cases (538 with and 102 without stones) were evaluated. The primary outcome of interest was the failure rate of insertion of a 10/12-Fr UAS. Associated risk factors were assessed using univariate and multivariate logistic regression analyses. Propensity score (PS) matching and inverse probability of treatment weighting (IPTW) were used to ensure the robustness of the results.

Results: The overall failure rate of 10/12-Fr UAS insertion in the cases without stones was significantly higher than that in the cases with stones (39.2% vs. 7.2%; p<0.001), and was approximately 2.5 to 4 times higher after PS matching and IPTW. Multivariate logistic analyses showed that being in the group without stones and younger age were independent significant risk factors for insertion failure in both the PS-matched cohort (odds ratio [OR], 5.43; 95% confidence interval [CI], 2.16–13.6; and OR, 1.04; 95% CI, 1.01–1.07) and the IPTW-adjusted cohort (OR, 1.82; 95% CI, 1.14–2.90; and OR, 1.03; 95% CI, 1.01–1.04).

Conclusions: The incidence of 10/12-Fr UAS insertion failure during RIRS was higher in cases without stones than in those with stones. These results provide valuable information for surgeons to use during informed consent discussions with patients undergoing RIRS, especially patients without stones.

Keywords: Hematuria; Kidney calculi; Risk factors; Ureter; Ureteroscopy

INTRODUCTION

Thanks to advances in endoscopic technology, retrograde intrarenal surgery (RIRS) has become an essential procedure for patients with stone disease and for patients with non-stone diseases such as chronic unilateral hematuria and urothelial carcinoma. Compared with the insertion of a flexible ureterorenoscope directly into the ureter, the use of a ureteral access sheath (UAS) has great advantages, such as repeated insertion of a flexible ureterorenoscope, decreased intrarenal pressure, and improved visibility [1,2]. However, we sometimes encounter cases in which a UAS cannot be in-

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serted. The failure rates of UAS insertion for patients with stones are reported to be 8.8% for 10/12-Fr UASs and 13% to 20% for 12/14-Fr UASs [3-7].

Failure rates in patients without stones have not been reported to date. Thus, in this study, we compared the failure rates of insertion of a 10/12-Fr UAS in patients with and without stones and analyzed the risk factors for UAS insertion failure.

MATERIALS AND METHODS

1. Patient selection and data collection

We retrospectively reviewed all consecutive RIRS procedures performed in patients with and without stones at our institution between February 2009 and April 2021. For patients who underwent bilateral procedures, each renal unit was analyzed separately. Patients with a preoperative ureteral stent or nephrostomy were excluded. Patients with only ureteral stones were also excluded to ensure that the same surgical procedures were performed. In cases without stones, patients with urothelial carcinoma were excluded because of their potential risk for a narrow ureter. Thus, in non-stone cases, RIRS was mainly performed for the evaluation of gross hematuria and treatment of chronic unilateral hematuria.

Among the 1,259 RIRS procedures performed for stone and non-stone cases, 551 cases with ureteral stents and 68 cases with nephrostomy were excluded. A total of 640 RIRS procedures for 538 stone cases (449 patients) and 102 non-stone cases (86 patients) were included in the analysis. Thereafter, data regarding patients' clinical characteristics, including age, sex, body mass index (BMI), laterality of surgery, history of ureteroscopic surgeries, history of stone treatment or spontaneous stone passage, maximum stone diameter, and operation duration were collected. Written informed consent was obtained from all patients or their surrogates. The study protocol was reviewed and approved by the Institutional Ethics Committee of Tokyo Metropolitan Ohtsuka Hospital (approval no. 2020-63) and conformed to the provisions of the Declaration of Helsinki.

2. Technique of retrograde intrarenal surgery

All surgeries were performed with patients under general anesthesia in the lithotomy position. The surgery was performed using a flexible ureterorenoscope (URF-P5, URF-P6, URF-P7, and URF-V2, Olympus, Tokyo, Japan; or Flex-X2s, Karl Storz, Tuttlingen, Germany) after insertion of an appropriately sized UAS. We routinely used 8- to 14-Fr ureteral dilators and chose a 10/12-Fr or 12/14-Fr UAS (ReTrace®, Coloplast, Humlebaek, Denmark; or Biflex®, Rocamed, Monaco) that could be inserted smoothly into the ureter. If there was any difficulty in insertion of the 12 Fr dilator, we gave up the placement of the UAS and attempted to insert the flexible ureterorenoscope directly over a guidewire. If the ureter was still non-accommodating, we stopped the surgery and placed a 6-Fr double-J ureteral stent. Secondary surgery was performed at least 7 days after the primary surgery.

Table 1. Characteristics of 640 cases undergoing retrograde intrarenal surgery

Variable	All (n=640)	Stone group (n=538)	Non-stone group (n=102)	p-value	SD
Age (y)	57.5 (13–93)	59 (18–93)	48 (13-81)	<0.001*	0.80
Sex				0.047*	
Male	395 (61.7%)	341 (63.4%)	54 (52.9%)		0.21
Female	245 (38.3%)	197 (36.6%)	48 (47.1%)		-0.21
Body mass index (kg/m^2)	23.0 (12.8–41.9)	23.6 (12.8–41.9)	20.0 (14.5–27.9)	<0.001*	1.12
Laterality of surgery				0.397	
Right	283 (44.2%)	233 (43.5%)	49 (48.0%)		-0.09
Left	357 (55.8%)	304 (56.5%)	53 (52.0%)		0.09
Maximum stone diameter (mm)	13 (2–80)	13 (2–80)	-	-	-
Prior ipsilateral intervention	118 (18.4%)	118 (21.9%)	0 (0%)	<0.001*	0.75
Stone history	242 (37.8%)	242 (45.0%)	0 (0%)	<0.001*	1.28
Alpha-blocker	10 (1.6%)	10 (1.9%)	0 (0%)	0.376	0.19
Operation duration (min)	77 (12–191)	85 (12–191)	49 (15–116)	<0.001*	1.24
UAS insertion failure	79 (12.3%)	39 (7.2%)	40 (39.2%)	<0.001*	-0.82
Needed pre-stenting	60 (9.4%)	38 (7.1%)	22 (21.6%)	<0.001*	-0.42

Categorical variables are shown as the number (%) of participants. Continuous variables are presented as median (full range).
UAS, ureteral access sheath; SD, standardized difference.
*Statistically significant at p<0.05.

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3. Outcome assessment

The primary outcome was the failure rate of UAS insertion, which was defined as an inability to insert the 10/12-Fr UAS because of an intrinsically tight narrow ureter. The narrowed part of the ureter that resulted in UAS insertion failure was recorded.

4. Statistical analyses

The differences between the characteristics of the patients in the two groups (stone group and non-stone group) were analyzed by using the Mann–Whitney test for continuous variables and the chi-square test (or Fisher's exact test, if necessary) for categorical variables. Using unadjusted data, the risk factors for UAS insertion failure were assessed using univariate and multivariate logistic regression analyses. Risk factors identified in the univariate analysis (p-value <0.10) were further included in the multivariate analysis.

To reduce selection bias and potential confounding factors, covariates were adjusted using a propensity score (PS), which was estimated using a logistic regression model. Two matching methods, PS matching and inverse probability of treatment weighting (IPTW) [8], were used to ensure the robustness of the results. The post-weighting balance in covariates between the two groups was evaluated using the standardized differences approach. An imbalance was defined as a standardized difference greater than 10%. Different PS distributions were visualized using kernel density estimation.

In PS matching, one participant of the stone group was matched with one participant from the non-stone group with a PS within the caliper value set at 20% of the standard deviation of PSs. In IPTW, we restricted the analysis to patients excluding the nonoverlapping portions of the PS distribution [9]. IPTW was performed using a weight; participants in the stone group were assigned a weight of one, whereas those in the non-stone group were allotted a weight defined as PS/(1-PS) [10]. Thus, the stone group served as the reference population, to which the non-stone group was standardized. The risk factors for UAS insertion failure in the matched cohorts were examined using logistic regres-

Table 2. Part of the ureter with narrowing in the case of ureteral access sheath insertion failure

Narrowed part of ureter	All (n=79)	Stone group (n=39)	Non-stone group (n=40)
Proximal	9 (11.4%)	5 (12.8%)	4 (10.0%)
Mid	20 (25.3%)	14 (35.9%)	6 (15.0%)
Distal	50 (63.3%)	20 (51.3%)	30 (75.0%)

Table 3. Results of logistic regression analyses of risk factors for ureteral access sheath insertion failure in the unadjusted cohort

Variable	Univariable			Multivariable (full model)			Multivariable (reduced model)		
	OR	95%CI	p-value	OR	95%CI	p-value	OR	95%CI	p-value
Younger age	1.05	1.04–1.07	<0.001*	1.03	1.02–1.05	<0.001*	1.03	1.02–1.05	<0.001*
Female (ref. male)	0.99	0.70–1.81	0.952						
Lower body mass index	1.17	1.09–1.25	<0.001*	1.07	0.99–1.15	0.087			
Left side (ref. right)	1.12	0.70–1.81	0.640						
Non-stone case (ref. stone case)	8.26	4.94–13.8	<0.001*	2.76	1.48–5.14	0.001*	3.48	1.96–6.16	<0.001*
Absence of prior ipsilateral intervention	6.53	2.02–21.1	0.002*	0.55	0.09–3.38	0.519			
Absence of stone history	10.8	4.31–27.2	<0.001*	8.32	1.96–35.4	0.004*	6.13	2.35–16.0	<0.001*

OR, odds ratio; CI, confidence interval.
*Statistically significant at p<0.05.

sion analyses after PS matching and by weighted logistic regression analyses after IPTW. Statistical analyses were performed using SPSS statistical software, version 20 (IBM Corp., Armonk, NY, USA) and R v.3.3.1 (R Foundation for Statistical Computing, Vienna, Austria) with the MASS package v.7.3.45 and the Matching package v.4.9.2. Statistical significance was set at a $p<0.05$.

RESULTS

The characteristics of the 640 RIRS cases included in this study are summarized in Table 1. The patients without stones were significantly younger (mean age 48 vs. 59 years; $p<0.001$), included a higher proportion of females (47.1% vs. 36.6%; $p=0.047$), and had a lower BMI (20.0 vs. 23.6; $p<0.001$) compared with patients in the stone group. In the unadjusted data, the overall failure rate of 10/12-Fr UAS insertion was 12.3%, with a higher incidence in the non-stone group than in the stone group (39.2% vs. 7.2%; $p<0.001$). In the cases of UAS insertion failure, narrowing occurred most frequently in the distal ureter, followed by the mid ureter, and least frequently in the upper ureter (only 10%) in both groups (Table 2). In the cases of UAS insertion failure, we could complete the surgery by direct insertion of a ureteroscope in 18 patients (17.6%) in the non-stone group and 1 patient (0.2%) in the stone group. In all other cases of failure (21.6% in the non-stone group and 7.1% in the stone group), we placed 6 Fr double-J ureteral stents. Secondary surgeries were successfully performed in all cases.

In the multivariate logistic regression analysis of the unadjusted data, being in the non-stone group (odds ratio [OR], 3.48; 95% confidence interval [CI], 1.96–6.16; $p<0.001$), younger age (OR, 1.03; 95% CI, 1.02–1.05; $p<0.001$), and an absence of stone history (OR, 6.13; 95% CI, 2.35–16.0; $p<0.001$) were independent significant risk factors for UAS insertion failure (Table 3). In both groups, the incidence of UAS insertion failure when evaluated according to age was higher in patients in their 10s and 20s (Fig. 1).

The PS for allocation to the stone group was calculated as a function of age, sex, and BMI. After PS matching, the standardized differences in the matched cohort were generally within a range of -0.1 to 0.1 for these three variables (Table 4, Fig. 2). A comparison of 80 pairs after PS matching showed that the rate of UAS insertion failure was about 4 times higher in the non-stone group than in the stone group (33.8% vs. 8.8%; $p<0.001$). In the multivariate logistic regression analysis for the matched cohort, being in the non-stone group (OR, 5.43; 95% CI, 2.16–13.6; $p<0.001$) and younger age (OR, 1.04; 95% CI, 1.01–1.07; $p=0.010$) were significant risk factors for UAS insertion failure (Table 5).

Using the IPTW method, pseudo-cohorts were created using 567 cases: 477 and 90 cases in the stone and non-stone groups, respectively. The two pseudo-cohorts were well-balanced (Table 4, Fig. 2). After IPTW was applied, the rate of UAS insertion failure was approximately 2.5 times higher in the non-stone group than in the stone group (19.9% vs. 8.0%; $p=0.005$). In the multivariate weighted logistic regression analysis of the pseudo-cohorts, being in the non-stone group (OR, 1.82; 95% CI, 1.14–2.90; $p=0.012$), younger age (OR, 1.03; 95% CI, 1.01–1.04; $p=0.001$), absence of stone history (OR, 7.45; 95% CI, 2.58–21.5; $p<0.001$), and a lower BMI (OR, 1.13; 95% CI, 1.04–1.22; $p=0.003$) were revealed as significant risk factors for UAS insertion failure (Table 5).

DISCUSSION

The present study was performed to investigate the rate of 10/12-Fr UAS insertion failure in patients undergoing

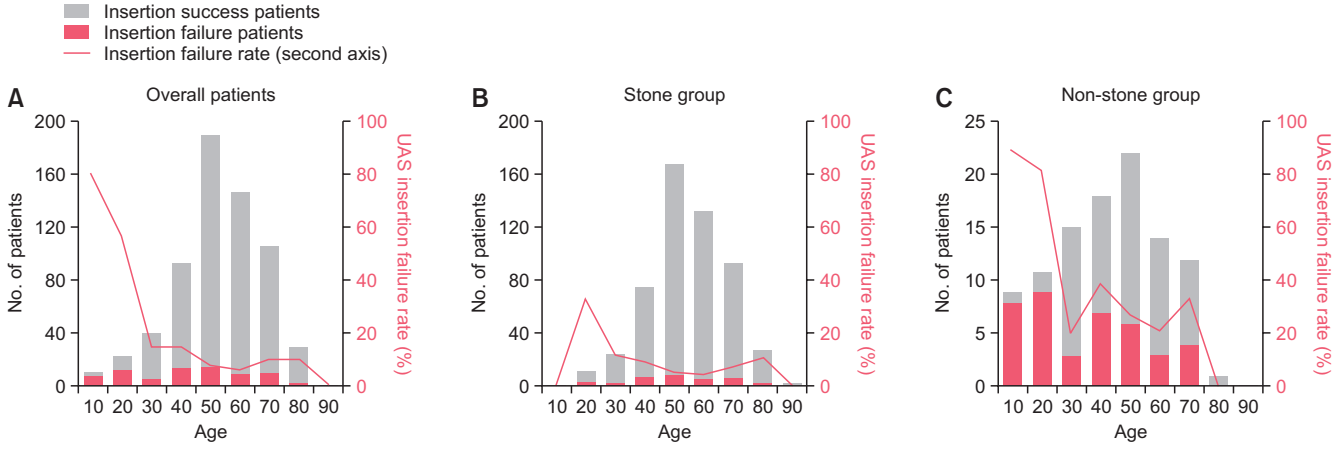

Fig. 1. The failure rate of insertion of a ureteral access sheath (UAS) by age in overall patients (A), the stone group (B), and the non-stone group (C).

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Table 4. Characteristics of the stone and non-stone groups after adjustment by PS matching and IPTW

Variable	PS matching				IPTW-adjusted pseudo-cohort			
	Stone group (n=80)	Non-stone group (n=80)	p-value	SD	Stone group (n=477)	Non-stone group (n=90)	p-value	SD
Age (y)	53.5 (16–86)	52 (16–81)	0.688	0.06	58.4 (57.2–59.6)	60.3 (57.4–63.3)	0.232	-0.08
Sex, female	39 (48.8%)	36 (45.0%)	0.751	0.08	35.2% (30.9–39.5)	43.1% (33.2–53.0)	0.148	-0.10
Body mass index (kg/m^2)	19.7 (12.8–29.8)	20.4 (16.0–27.9)	0.461	-0.11	23.1 (22.8–23.4)	23.1 (22.8–23.8)	0.983	0
Left side	39 (48.8%)	38 (47.5%)	0.874	0.03	56.4% (51.9–60.9)	44.2% (34.2–54.1)	0.027*	0.15
UAS insertion failure	7 (8.8%)	27 (33.8%)	<0.001*	-0.64	8.0% (5.6–10.5)	19.9% (11.9–28.0)	0.005*	-0.18
Needed pre-stenting	7 (8.8%)	14 (17.5%)	0.101	-0.26	8.0% (5.6–10.5)	14.0% (7.0–20.9)	0.105	-0.11
Prior ipsilateral intervention	19 (23.8%)	0 (0%)	<0.001*	0.79	16.2% (13.5–18.8)	0	<0.001*	0.84
Stone history	40 (50.0%)	0 (0%)	<0.001*	1.41	35.3% (31.8–38.8)	0	<0.001*	1.45

For PS matching, categorical variables are expressed as the number (%) of participants, and continuous variables are shown as median (full range). For IPTW, all variables are shown as an average with a 95% confidence interval.
PS, propensity score; IPTW, inverse probability of treatment weighting; SD, standardized difference; UAS, ureteral access sheath.
*Statistically significant at p<0.05.

RIRS and to compare the rate between patients with and without stones. To the best of our knowledge, this is the first report to show that the failure rate of 10/12-Fr UAS insertion is higher in patients without stones than in those with stones. Furthermore, in almost half of the failed cases in the non-stone group (21.6%), we could not directly insert a flexible ureterorenoscope. These results provide valuable information for surgeons to use during informed consent discussions with patients without stones who require RIRS.

Our study endpoint was failure of insertion of a 10/12-Fr UAS. Some experimental studies have shown that a 9.5/11.5-Fr UAS permits the entry of some flexible ureterorenoscopes but cannot maintain sufficient irrigation flow and intrarenal pressure [11,12]. A 10/12-Fr UAS has the potential to maintain irrigation flow and intrarenal pressure within acceptable levels during surgery, although not as well as a 12/14-Fr or 14/16-Fr UAS. Compatibility of the size of the ureterorenoscope and that of the UAS should be considered during RIRS. In the cases of failed UAS insertion in our study, if a flexible ureterorenoscope could be inserted directly, the endoscopic evaluation was achieved in the patients without stones. In the patients with stones, however, we chose to perform pre-stenting and an additional session to avoid postoperative complications such as ureteral wall injury and febrile urinary tract infection. Thus, it is informative to recognize that the failure rate for UAS insertion varies depending on the purpose for which RIRS is performed.

Previous analyses reported a failure rate of 8.8% for 10/12-Fr UAS insertion [4] and a requirement for pre-stenting in 6% to 16% of stone treatment cases [5-7]. In our unadjusted data, the rate of 10/12-Fr UAS insertion failure was 7.2% and pre-stenting was required in 7.1% of patients in the stone group, which is comparable to the previous reports. Additionally, in our study, the success rate of UAS insertion during the second surgery was 100%, which is consistent with previous reports showing good outcomes [4,13]. In patients without stones, who underwent treatment primarily for the evaluation of gross hematuria, the higher rate of UAS insertion failure and need for pre-stenting make a definitive diagnosis more difficult; however, as we have previously reported, the success rate of endoscopic hemostasis in the second surgery was equally good [14]. The multivariate analysis in our study showed an absence of stone history to be a powerful risk factor for UAS insertion failure. Current or past stone impaction causes ureteral dilation, which may have caused the lower failure rate of UAS insertion in the stone group. In fact, we recently reported that patients with a history of stone events are less likely to require pre-stenting during retrograde ureteroscopic lithotripsy [15]. Ad-

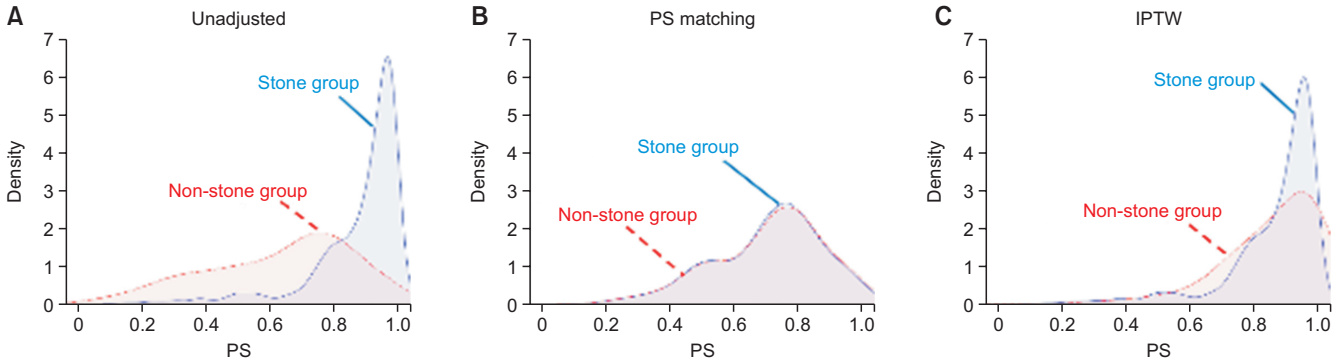

Fig. 2. Kernel density plot comparing the stone and non-stone groups in the unadjusted cohort (A), after propensity score (PS) matching (B), and with inverse probability of treatment weighting (IPTW) (C).

ditionally, younger patients, especially those in their 10s and 20s, had a higher risk for UAS insertion failure irrespective of stone events. It has been reported that 30% to 40% of children without preoperative stenting require pre-stenting at the time of primary ureteroscopy [16,17], which suggests that ureteral diameter increases with age.

Previous experimental studies have shown that the human ureter contains alpha-adrenergic receptors along its entire length, with the highest concentration in the distal ureter. Alpha-blockers are commonly used for medical expulsion therapy for ureteral stones. Alpha-blockers act by decreasing intraureteral pressure and increasing fluid passage [18]. Koo et al. [19] reported that preoperative alpha-blockers could reduce resistance during insertion of a UAS. In the present study, only 10 patients (1.9%) in the stone group were taking an alpha-blocker for benign prostatic hyperplasia, and the failure rate of UAS insertion in this small subset was 10%. On the other hand, none of the patients in the non-stone group were taking alpha-blockers. Although we did not address the efficacy of the alpha-blockers in this study, interestingly, we showed that narrowing occurred most frequently in the distal ureter, which is consistent with the distribution of alpha-adrenergic receptors. Further study should address this point.

Although our results revealed that patients without stones and younger patients are at higher risk for UAS insertion failure, it remains difficult to predict insertion failure before surgery. Active ureteral balloon dilation and pre-stenting are sometimes performed to complete ureterorenoscope surgery in a primary session; however, each procedure has its disadvantages. Forceful manipulation of an intrinsically tight narrow ureter may cause ureteral shear injury [20,21]. Additionally, after pre-stenting, 80% of patients reportedly experience bothersome symptoms, such as bladder wall irritability, pain, bleeding, and infection [22,23]. Thus, we recommend explaining the possibility of a second session to patients at high risk for UAS insertion failure and to plan the date in advance as a backup.

The present study had several limitations. First, this study was limited by its retrospective nature, which makes it susceptible to baseline confounding factors. Applying multiple matching methods is recommended to improve intergroup comparability [24], and the results of the two matching methods in the present study were comparable. Second, this was a single-center study. Further multicenter studies are necessary to verify these results, although uniformity of technique is required for greater reliability of this kind of study.

CONCLUSIONS

The incidence of 10/12-Fr UAS insertion failure during RIRS was higher in patients without stones than in those with stones. In almost half of the failed cases in patients without stones, a flexible ureterorenoscope could not be inserted directly and pre-stenting was required. These results are valuable for surgeons for facilitating informed consent discussions with patients, especially patients without stones, who require RIRS.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Yuma Waseda and Ryoji Takazawa. Data acquisition: all authors. Data analysis and

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Table 5. Results of logistic regression analyses after PS matching and of weighted logistic analysis after IPTW of risk factors for ureteral access sheath insertion failure

Variable	PS matching						IPTW-adjusted pseudo-cohort					
	Univariable			Multivariable (reduced model)			Univariable			Multivariable (reduced model)		
	OR	95%CI	p-value	OR	95%CI	p-value	OR	95%CI	p-value	OR	95%CI	p-value
Younger age	1.04	1.01–1.06	0.008*	1.04	1.01–1.07	0.010*	1.03	1.01–1.04	<0.001*	1.03	1.01–1.04	0.001*
Female (ref. male)	1.01	0.47–2.16	0.981				0.79	0.51–1.21	0.285			
Lower body mass index	0.98	0.85–1.12	0.761				1.16	1.08–1.24	<0.001*	1.13	1.04–1.22	0.003*
Left side (ref. right)	0.82	0.38–1.75	0.599				0.85	0.57–1.27	0.429			
Non-stone case (ref. stone case)	5.31	2.15–13.1	<0.001*	5.43	2.16–13.6	<0.001*	3.80	2.48–5.83	<0.001*	1.82	1.14–2.90	0.012*
Absence of prior ipsilateral intervention	5.50	0.71–42.8	0.103				9.42	2.29–38.8	0.002*			
Absence of stone history	4.30	1.24–14.9	0.022*				12.3	4.47–33.8	<0.001*	7.45	2.58–21.5	<0.001*

PS, propensity score; IPTW, inverse probability of treatment weighting; OR, odds ratio; CI, confidence interval.
*Statistically significant at p<0.05.

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