# **ORIGINAL ARTICLE**

# Effect of intra-institutional standardization of using intraoperative fluoroscopy in ureteroscopy

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# Abstract :

**Introduction:** This study aimed to examine the efficacy of intra-institutional standardization of fluoroscopy use to reduce X-ray exposure and identify factors that predict reduced fluoroscopy time.

**Methods:** We recruited 231 patients who underwent ureteroscopy at our institution between April 2017 and March 2019. The patients were divided into two groups, group A (ureteroscopy after standardization) and group B (ureteroscopy before standardization). The clinical factors that reduced fluoroscopy time were identified using a multivariate regression model.

**Results:** Fluoroscopy time was significantly shorter in group A (0.22 min) than in group B (1.11 min; p = 0.012); however, no significant difference in surgical outcomes including stone free status and postoperative complications was found between the groups. The multivariate regression model identified ureteroscopy with standardizing the fluoroscopic use (odds ratio: 23.90, 10.59–50.98; p < 0.001) and ureteroscopy without postoperative ureter stent placement (odds ratio: 4.38, 1.98–9.68; p < 0.001) as independent contributors to reduced fluoroscopy time.

**Conclusion:** The proposed standardization succeeded to minimized fluoroscopy time without compromising surgical outcomes.

Key words: fluoroscopy time, ureteral access sheath, ureteroscopy, urinary stone, X-ray exposure

# INTRODUCTION

Ureteroscopy (URS) has been performed as a treatment for urinary stones for more than 30 years, and various clinical practice guidelines have recently recommended it as a standard therapy for upper urinary stones.<sup>1-3)</sup> Complications are generally minor, and serious complications, such as postoperative sepsis and ureteral rupture, have been reported in only 2.39% of cases.<sup>4)</sup> Cases of solitary kidney<sup>5)</sup> or bilateral intervention performed in a single session<sup>6)</sup> have been reported owing to fewer complications. URS is typically performed under fluoroscopy to facilitate the safe use of a rigid or flexible ureteroscope, ureteral access sheath (UAS), and guide wire (GW). Exposure to fluoroscopy causes various adverse changes to the human body, such as cataract,<sup>71</sup> infertility<sup>8,9)</sup> and some malignant neoplasms.<sup>10)</sup> Therefore, surgeons should reduce the X-ray exposure during surgery, not only for the patients but also for medical staff including themselves. Based on the recommendations of the International Commission on Radiological Protection (ICRP), the maximum effective dose for medical workers is 100 mSv for five years and 50 mSv for one year; the annual exposure threshold for the public is within 1 mSv. Although the effective dose due to medical exposure is not limited, X-ray exposure to patients undergoing

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URS has been reported to be 1.13 mSv at a fluoroscopy duration of 47s,<sup>11)</sup> which exceeds the public dose limit. The intraoperative exposure dose to surgeons and assistants in URS is 11.6  $\mu$ Gy for the lower limbs and 1.9  $\mu$ Gy for the eyes, with a fluoroscopy duration of 78 s.<sup>12)</sup> The ICRP advocates the principle of radiation protection (as low as possible), and urologists should try to reduce X-ray exposure during URS by reducing fluoroscopy time and using appropriate protection.<sup>13)</sup>

Many reports have addressed the factors that contribute to the extension of fluoroscopy time<sup>12,14)</sup> and investigated measures to reduce X-ray use and their efficacy. At our hospital, intraoperative fluoroscopy was previously used at the discretion of each operator until May 2018 when we started to standardize fluoroscopy usage to minimize fluoroscopy time during URS. Since cases have accumulated after intra-institutional standardization, we investigated the efficacy of standardization on fluoroscopy time and surgical outcome of URS by performing a retrospective single institution comparative study.

# MATERIALS AND METHODS

We analyzed 231 patients with URS who were treated at our hospital between April 2017 and March 2019. In all, 36 URS cases involving simultaneous bilateral URS or other simultaneous operations were excluded. The clinical criteria for the selection of shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL), and URS for the treatment of urinary stones at our institution were as follows. For urinary stones > 20 mm in diameter, PCNL is offered as the first-line treatment, with URS offered as the second choice.

The final selection of the treatment modality is based on the patient's preference.

Intra-institutional standardization for fluoroscopic use was initiated after May 2018. The patients were divided into two groups: group A, URS after standardization, which was performed after May 2018 (n = 118); group B, URS before standardization, which was performed before April 2018 as a historical control (n = 113). The following patient data for both groups were collected from medical records: age, sex, height, weight, body mass index (BMI), affected side, number of stones, position of stone, stone at low calyx, number of stones at the calyx, stone volume, cumulative stone distance (CSD), maximum value of computer tomography (CT), average value of CT, preoperative hydronephrosis, pre-stent, history of SWL, surgeon experience, and assistant experience and surgical results including stone free status, postoperative complications, and fluoroscopic time.

The 231 URS cases were further divided into two groups as

follows based on the median fluoroscopy time (33.9 s): lowdose group ( < 33.9 s, n = 116) and high-dose group ( > 33.9 s, n = 115). Factors contributing to reduce the fluoroscopy time were identified using logistic regression analysis.

Statistical calculations were performed using SPSS version 19 (IBM Corporation, Armonk, NY, USA).

#### Surgical technique

The patients were intravenously administered a preoperative antibiotic and then placed in the lithotomy position under anesthesia. At our institution, either the surgeon or assistant has URS experience more than 50 cases to ensure safety. Subsequently, the urethra and urinary bladder were observed using a 22.5 Fr cystoscope. An 8.6 Fr rigid ureteroscope (Olympus, Tokyo, Japan) was inserted under the GW until it reached the stone or renal pelvis. A hydrophilic UAS (10/12 Fr)Bi-Flex, Edap Technomed) was inserted with the GW under fluoroscopic guidance. A flexible ureteroscope (4.9/7.95 Fr URF-P6, Olympus, Tokyo, Japan) was utilized to crush stones using a holmium yttrium aluminum garnet laser (Ho-YAG 200 μm, Luminous, or 270 μm, Dornier) and to extract fragments with a stone basket (1.5 Fr Dormia No-Tip, Coloplast) until absence of fragments except minute dust, could be confirmed with both endoscopy and fluoroscopy. Postoperative stents were inserted for patients with a surgical duration > 60 min, >70 years, female sex, solitary kidney cases, and other cases for whom the surgeon judged to require stents. In other cases, a 6 Fr overnight urethral catheter was placed in the ureter. Stonefree status was defined as the absence of visible fragments in the kidney-ureter-bladder film (KUB) two weeks after removal of ureteral stents or overnight catheter.

#### Standardization of using intraoperative fluoroscopy

It was recommended that surgeons used fluoroscopic guidance at five situations, namely to confirm the position of the rigid ureteroscopy at the level of the stone or renal pelvis, immediately before insertion of the UAS, during adjustment of the tip of the UAS, during residual stone evaluation, and during postoperative ureteral stent placement.

The C-arm position was set preoperatively by the surgeon without fluoroscopic guidance, considering the position of the pelvic urinary tract or target calculus. Intermittent output was recommended when fluoroscopy was necessary.

# RESULTS

Stone volume (0.26 mL vs. 0.48 mL; p = 0.001) and CSD (11.1 mm vs. 14.7 mm; p < 0.001) were smaller in group A

	Group A		Group B			
	median / No.	range (%)	median / No.	range (%)	P value	
Age	62	20 - 94	60	22 - 85	0.555	
sex female	34	(28.8)	36	(31.9)	0.615	
height [cm]	165	140 - 183.5	165	140 - 178	0.434	
weight [kg]	65.7	33.7 - 114.5	64.0	35.9 - 97.2	0.212	
BMI	24.1	14.2-39.8	23.5	15.5 - 33.6	0.333	
Affected side right	50	(42.4)	48	(42.5)	0.987	
Number of stone	1	1 - 10	1	1 - 16	0.185	
Stone at low calyx	39	(33.3)	40	(35.4)	0.742	
Number of stone at calyx	0	0 - 3	0	0 - 7	0.081	
Stone volume [ml]	0.26	0.04 - 2.11	0.48	0.03 - 3.18	0.001*	
CSD [mm]	11.1	0.78 - 118	14.7	1.06 - 73.4	< 0.001*	
Maximum value of CT [HU]	1292	435 - 1940	1137	233 - 1882	0.029*	
Average value of CT [HU]	801	277 - 1476	824	226 - 1732	0.721	
Preoperative hydronephrosis	45	(38.1)	72	(63.7)	< 0.001*	
Pre-stent	55	(47.4)	69	(61.6)	0.031*	
History of SWL	9	(7.6)	5	(3.5)	0.178	
Using UAS	89	(75.4)	94	(83.2)	0.146	
Surgeon experience < 50 cases	64	(54.2)	43	(38.1)	0.014*	

(19.5)

## Table 1. patient background

Assistant experience < 50 cases

CSD : cumulative stone distance UAS : ureteral access sheath

SWL: shock wave lithotripsy

\* significant difference

than in group B (Table 1). There were fewer patients with hydronephrosis (38.1% vs. 63.7%; p < 0.001) and preoperative stent placement (47.4% vs. 61.6%; p = 0.031) in group A than in group B. Surgeon experience was lower in group A (less than 50 URS experience: 54.2% vs. 38.1%; p =

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0.014). UAS was used frequently in both groups.

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Surgical (70 min vs. 78 min; p = 0.012) and fluoroscopy (0.22 min vs. 1.11 min; p = 0.012) times and fluoroscopy dose (0.97 mGy vs. 3.51 mGy; p < 0.001) were lower in group A than group B (Table 2). However, no significant differences

(14.2)

0.279

### Table 2. surgical results

		Group A		Group B		D 1	
	-	median / No.	range (%)	median / No.	range (%)	P value	
f-URS		94	(79.7)	100	(88.5)	0.067	
Operation time	[min]	70	17 - 144	78	26 - 143	0.012*	
postoperative s	tent placement	53	(55.1)	69	(61.1)	0.358	
Stone free		101	(85.6)	96	(85.0)	0.891	
Fluoroscopy tir	me [min]	0.22	0 - 2.4	1.11	0.2 - 11.14	0.012*	
fluoroscopy [m	nGy]	0.97	0 - 18.4	3.51	0.66 - 99.9	< 0. 001*	
Postoperative fever $(> 38^{\circ}C)$		10	(8.5)	12	(10.6)	0.579	
Using catecholamine		0	(0)	1	(0.9)	0.306	
Injury of ureter	or renal pelvis	4	(3.4)	4	(3.5)	0.950	
Length of postoperative stay		2	2 - 12	2	2 - 11	0.891	
	Calcium oxalate	85	(72.6)	63	(55.8)		
	Calcium phosphate	2	(1.7)	10	(8.8)		
	Uric acid	2	(1.7)	6	(5.3)		
Stone analysis	Struvite	1	(0.9)	3	(2.7)	0.008*	
-	Mix	24	(20.5)	22	(19.5)		
	Others	2	(1.7)	1	(0.9)		
	unknown	1	(0.9)	8	(7.1)		

\* significant difference

	Full model			Reduced model		
	P value	Odds	95% CI	P value	Odds	95% CI
CSD	0.584	0.79	0.33-1.87			
Stone volume	0.905	1.06	0.43 - 2.58			
Preoperative hydronephrosis	0.957	1.07	0.52 - 2.18			
Without reduction technique	< 0.001	23.90	10.59 - 50.98	< 0.001*	22.03	10.67 - 45.49
UAS	0.439	0.70	0.28 - 1.73			
Postoperative stent placement	< 0.001	4.38	1.98 - 9.68	< 0.001*	3.91	1.88-8.16

Table 3. multivariate analysis of factors contributing to fluoroscopy time extension

\* significant difference

 Table 4. influence on fluoroscopy time by using ureteral access sheath

		Fluoroscopy time [min]	Range	P value
Group A	Without UAS	0.10	0 - 2.4	0.067
	With UAS	0.25	0.035-1.9	0.067
Group B	Without UAS	0.76	0.2 - 3.0	0.045*
	With UAS	1.16	0.28-11.14	0.045*

\* significant difference

were observed between the two groups in terms of stone-free rate, complications (postoperative fever, use of catecholamines and injury of ureter or renal pelvis), or cases in which flexible URS (f-URS) was used. In group B, one patient had a ureteral perforation during UAS insertion; however, no serious complications occurred in group A. Other complications were minor, such as ureteral mucosal contusions.

Multivariate analysis revealed that URS after standardization (odds ratio, 22.03; p < 0.001) and postoperative stent placement (odds ratio, 3.91; p < 0.001) were independent predictors of reduced fluoroscopy time (Table 3). In contrast, CSD, stone volume, preoperative hydronephrosis, and UAS use were not significant contributing factors to fluoroscopy time.

UAS use significantly increased fluoroscopy time in group B (p = 0.045) compared to group A (Table 4).

# DISCUSSION

The standardization described in the present report aimed to minimize fluoroscopic time during URS. This standardization resulted in a notable decrease in fluoroscopic time, which indicates that excessive and unnecessary fluoroscopy was used during the URS.

In Japan, in the manual on upper urinary tract stone endoscopy,<sup>15)</sup> use of X-ray fluoroscopy is recommended during UAS insertion. Although the fluoroscopy duration associated with URS insertion can be significantly reduced (Table 4), the results of the multivariate analysis (Table 3) indicated that the use of UAS was not a significant factor associated with fluoroscopic time. Based on previous reports, the average fluoroscopy time for URS was 0.73– 2.74 min<sup>12,14,16–18)</sup>. Our fluoroscopic time was relatively short before standardization (1.11 min). We speculate that this is the reason that the UAS was not a significant factor associated with fluoroscopic time in the multivariate analysis.

Multivariate analysis revealed that stone volume and CSD were not independent factors associated with prolonged fluoroscopy time, since fluoroscopy was not used in the stone crushing and extraction processes even prior to standardization.

Postoperative stent placement was a significant factor prolonging fluoroscopy time. Khoury et al.<sup>19)</sup> reported that URS, including postoperative stent placement, can be performed safely without fluoroscopy in children, and Aboutaleb et al.<sup>20)</sup> reported the same results for adult URS procedures. However, in 9-18% of cases, operators were unable to insert a stent, and complications of stent intrusion or dropout have been reported. In order to reduce bladder irritation symptoms, direct measurement of ureter length using a ureteral catheter was adopted in our hospital; therefore, postoperative stent placement prolonged the fluoroscopic time at our hospital.

Tepeler et al.<sup>21)</sup> reported that postoperative stent placement was not necessary in case of URS with lower ureteral stones, accounting for more than one-half of cases, and surgery duration within 60 min, except in patients with anatomical abnormalities and ureteral strictures. The average fluoroscopy time was reported to be 0.15 min. In our study, approximately 80% of patients had kidney stones and upper ureteral stones, 75% used UAS, and > 50% underwent postoperative ureteral stent placement, with a median fluoroscopy time of 0.22 min.

Ngo et al.<sup>14)</sup> reported that the average fluoroscopy time could be reduced by 24% by consciously reducing the use of intraoperative fluoroscopy by the surgeon. Greene et al.<sup>16)</sup>

could reduce intraoperative fluoroscopy time by 82% by limiting fluoroscopy in 60 simple cases without additional procedures such as balloon dilatation, without compromising surgical outcome. In this study, we examined 231 cases including high-difficulty cases such as multiple stones and lower renal calyx stones, and achieved a reduction in fluoroscopy time of about 80% without compromising surgical outcomes.

The URS procedure is equivalent to 1.13 mSv at a fluoroscopy time of 47s.<sup>11)</sup> According to Meltter et al.,<sup>22)</sup> the effective dose is equivalent to approximately one abdominal KUB radiograph. After standardization, URS could be performed with approximately one-quarter of the dose required for a KUB radiograph. Reduced fluoroscopy time may provide more benefits not only to patients, but also to medical staff, surgeons, assistants, and anesthesia personnel who participate in or perform many URSs in their lifetimes. In high-volume centers, the cumulative difference is likely to be large. There is no doubt reducing fluoroscopic time; however, fluoroscopy time should be reduced only when possible without affecting surgical safety. Therefore, more sophisticated standardization is warranted to maintain the balance between surgical safety and fluoroscopy time.

As the present investigation was a single-institution study, institutional bias was difficult to eliminate. Minor differences between institutions with respect to surgical techniques may be associated with different outcomes and require different standardization.

In our study, although patient backgrounds (stone volume, and CSD, among others) significantly differed between groups A and B, the multivariate analysis revealed that these factors did not have a significant impact independently. As this was a retrospective analysis, the influence of a conscientious reduction in fluoroscopy time by the operators and assistants cannot be eliminated. However, we assume that this may be due to the essential effect of standardization, since awareness of fluoroscopy use under intra-institutional standardization resulted in a remarkable reduction in fluoroscopy time. In conclusion, we successfully reduced fluoroscopy time during URS by introducing an intra-institutional standardization for fluoroscopic use. Urologists should pay attention to the amount of X-ray exposure, for patients and medical staff while ensuring a safe procedure.

This study was conducted with the approval of the ethics committee at our hospital, and patient data was collected only after obtaining written consent.

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