

Can operator-controlled imaging reduce fluoroscopy time during flexible ureterorenoscopy?

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Introduction Fluoroscopy is routinely used during ureterorenoscopy. According to the 'As Low As Reasonably Achievable' (ALARA) principle, radiation exposure should be kept as low as reasonably achievable to decrease the risk of negative long-term effects of radiation for patients and medical staff. This study aims to assess if operator-controlled imaging during flexible ureterorenoscopy for nephrolithiasis could reduce fluoroscopy time when compared to radiographer-controlled imaging.

Material and methods This study was a bicentric, retrospective comparison between patients treated for nephrolithiasis with flexible ureterorenoscopy with either operator-controlled imaging or radiographer-controlled imaging. A total of 100 patients were included, 50 were treated with operator-controlled imaging and 50 with radiographer-controlled imaging. Patients undergoing flexible ureterorenoscopy with a total stone burden <20 mm and data on radiation exposure were included. Patient characteristics, stone characteristics, surgical details and fluoroscopy time were recorded for each patient and both groups were compared. Patient data were expressed as median. A 2-sided p-value <0.005 was considered statistically significant.

Results This study found no significant differences between both groups regarding the patient and stone characteristics. However, it found a significant shorter fluoroscopy time in the operator-controlled imaging group of 33.5 seconds (IQR 16.0–70.0) compared to 57.0 seconds (IQR 36.8–95.3) in the radiographer-controlled imaging group (p = 0.001).

Conclusions This study shows that operator-controlled imaging in flexible ureterorenoscopy could reduce fluoroscopy time when compared to radiographer-controlled imaging. Operator-controlled imaging might therefore allow urologists to perform ureterorenoscopy with greater independence while additionally reducing fluoroscopy time and its consequent negative effects for medical staff and patients.

Key Words: ALARA-principle ◊ endourology ◊ fluoroscopy ◊ radiation exposure ◊ ureterorenoscopy

INTRODUCTION

Over the last two decades, minimally invasive surgery for nephrolithiasis has gained in popularity [1]. Fluoroscopy is routinely used during these procedures and as a result radiation exposure for patients and medical staff increased consequently. Literature shows that radiation exposure can result

in DNA and tissue damage when a certain cumulative radiation threshold is crossed, which then can lead to an increased risk of cataract, malignancies, skin reactions, sterility or congenital anomalies [2–6]. According to the ALARA-principle, radiation exposure should be kept 'As Low As Reasonably Achievable' to decrease the risk of negative long-term effects of radiation for patients and medical staff [7].

A previous study by our group showed that there is still a wide variety in the use of fluoroscopy during ureteroscopy (URS) [8]. Different variables of endourologic procedures, such as surgeon's experience and the use of a ureteral access sheath (UAS), are known to lead to an increase in radiation exposure [9]. This variety might lead to a difference in cumulative dose area product and fluoroscopy time (FT) [10]. Furthermore, a study by Peach et al. has shown that operator-controlled imaging (OCI) during endovascular aneurysm repair (EVAR) can reduce radiation exposure when compared to radiographer-controlled imaging (RCI) [11]. However, this has, to the best of our knowledge, not yet been evaluated in a urologic setting. Therefore, this study aims to evaluate if OCI during flexible URS for nephrolithiasis reduces FT when compared to RCI.

MATERIAL AND METHODS

Study design and population

This study was a bicentric, non-randomized, retrospective comparison between patients treated for nephrolithiasis with flexible URS with either OCI or RCI. Data of consecutive patients undergoing flexible URS with a total stone burden <20 mm with data on radiation exposure was collected at two university hospitals (Amsterdam UMC, the Netherlands and Antwerp University Hospital, Belgium) until both centers included 50 patients. Fifty were treated using OCI (Antwerp University Hospital) and 50 using RCI (Amsterdam UMC).

Ethics

This study was performed according to the ethical standards described in the 1964 Declarations of Helsinki and its later amendments and was approved by the local ethics committee (W20_277 #20.312 on 11-06-2020).

Procedures

All procedures were performed by a certified urologist or by a resident, under direct supervision. All patients were positioned in the dorsal lithotomy position. Both centers had the same standard approach for flexible URS. An X-ray was taken at the start of the procedure. Afterwards a retrograde contrast study of the ureter and pyelogram was performed with a semirigid ureterorenoscope or ureter catheter to assess the upper urinary tract. Then, if applicable, a UAS was placed under fluoroscopy guidance. The flexible URS was inserted, the stones

were located and subsequently treated with a laser VersaPulse® PowerSuite™ 100W laser (Lumenis Ltd., Borehamwood, UK) at Amsterdam UMC and Rhapsody® H-30® (Cook medical, Bloomington, Indiana, USA) at the Antwerp University Hospital if necessary and fragments were retrieved with a basket. Fluoroscopy was used to check endoscopic stone-free status at the urologist's discretion. If the placement of a double-J stent was needed at the end of the procedure, it was placed under fluoroscopy guidance.

Both urologists and radiographers had additional training regarding radiation safety and were certified to operate a C-arm. Imaging was carried out using a Veradius Unity mobile C-arm with flat detector (Philips Electronics, Eindhoven, the Netherlands) or OEC 9900 Elite C-arm (GE Healthcare, Wisconsin, USA) with a standard static, radiolucent theatre table. FT was recorded automatically by the software in the C-arms. Collimation, pulsation, magnification, and other C-arm settings were at the image-controller's (radiographer or operator) discretion. In the OCI group, the operator had to push on a foot pedal to use fluoroscopy, whereas fluoroscopy was started and stopped on vocal command by the operator to the radiographer in the RCI group.

Statistical analysis

Patient and stone characteristics, surgical details, outcome, and radiation characteristics were recorded for each patient. All stone characteristics were based on a preoperative computed tomography (CT) scan. A descriptive analysis was conducted for patient [age, sex and body mass index (BMI)] and stone (side, number of stones, total stone burden defined as the sum of the maximal diameters and location of the stones) characteristics, surgical details (operation time, pre-stenting, use of a UAS, laser-setting, peri-operative complications according to the modified Satava-classification by Tepeler et al. [12], post-stenting, surgeon's experience (≤ 100 and > 100 procedures), modified Clavien-Dindo classification (CDC) [13] and the need for secondary treatment within three months and FT.

SPSS V.26 (IBM Corp, Armonk, NY, USA) was used to perform the statistical analysis. Figures and tables were created with Microsoft® Excel for Mac V.2016 (Microsoft Corp, Redmond, WA, USA). Normality of the different continuous variables was checked with the Shapiro-Wilk test. As all continuous variables were non-parametric, medians and interquartile ranges (IQR) were reported for these continuous variables. Frequencies were reported for categorical variables. A Mann-Whitney U-test and two-tailed

χ^2 -test was applied to determine statistical significance between the various variables of the study group. A 2-sided p-value ≤ 0.05 was considered statistically significant.

RESULTS

Patient and stone characteristics are presented in Table 1. Patient and stone characteristics did not differ significantly between both groups. The mean age for the OCI cohort was 56.0 years (IQR 51.8–62.5), consisting of 58.0% men and 42.0% women with a median BMI of 26.7 kg/m² (IQR 23.2–30.9). Whereas the RCI cohort had a median age of 55.5 years (IQR 44.3–63.5), consisting of 58.0% men and 42.0% women with a median BMI of 24.9 kg/m² (IQR 22.5–29.8). The mean number of stones was 1.0 (IQR 1.0–1.0) and 1.0 (IQR 1.0–2.0) for OCI and RCI respectively. The stones were localized in the left kidney in 74.0% (60.0%) and in the right kidney in 26.0% (40.0%) in the OCI group (RCI group). The mean stone burden was 9.8 mm \pm 3.0 in the OCI-group and 10.1 mm \pm 3.0 for the RCI-group. Forty-two percent (54.0%) of the stones were localized in the lower pole, whereas 18.0% (22.0%) were found in renal pelvis, 16.0% (10.0%) interpolar, 8.0% (8.0%) in the upper pole and 16.0% (6.0%) had stones in multiple locations in the OCI group (RCI group).

Table 2 shows the perioperative variables. The mean operation time was 60.5 minutes (IQR 43.0–79.0)

in the OCI cohort and 57.0 minutes (IQR 40.0–81.0) for the RCI cohort. The OCI group tended to be pre-stented, 70.0% versus 26.0% in the RCI group. No significant difference was found concerning post-stenting, with 90.0% receiving a double-J stent at the end of the procedure in the OCI group and 92.0% in the RCI cohort. A UAS was used in 60.0% of the OCI population and 66.0% of the RCI population. We found peri-operative complications according to the modified Satava-classification in 44.0% of the cases in the OCI group compared to 26.0% in the RCI group. Peri-operative complications were maximal Satava class 2a. Post-operative complications according to the modified CDC were seen in only 6.0% in the OCI-group and 2.0% in the RCI group and no major complications (CDC ≥ 3) were

Table 1. Patient and stone characteristics

Variable	OCI	RCI	p-value
Age (years)	56.0	55.5	0.456
Median (IQR)	(51.8–62.5)	(44.3–63.5)	
Sex			1.000
Female	42.0%	42.0%	
Male	58.0%	58.0%	
BMI (kg/m ²)	26.7	24.9	0.350
Median (IQR)	(23.2–30.9)	(22.5–29.8)	
Side			0.137
Left	74.0%	60.0%	
Right	26.0%	40.0%	
Number of stones	1.0	1.0	0.641
Median (IQR)	(1.0–1.0)	(1.0–2.0)	
Stone load (mm)	9.0	10.5	0.337
Median (IQR)	(8.0–11.6)	(7.8–12.3)	
Stone location			0.283
Renal pelvis	18.0%	22.0%	
Lower pole	42.0%	54.0%	
Middle pole	16.0%	10.0%	
Upper pole	8.0%	8.0%	
Multiple	16.0%	6.0%	

OCI – operator-controlled imaging; RCI – radiographer-controlled imaging; IQR – interquartile range; mm – millimeter

Table 2. Perioperative characteristics

Variable	OCI	RCI	p-value
Operation time (minutes)	60.5	57.0	0.997
Median (IQR)	(43.0–79.0)	(40.0–81.0)	
Surgeon's experience			0.799
<100 procedures	20.0%	18.0%	
>100 procedures	80.0%	82.0%	
Pre-stenting			0.000
No	30.0%	74.0%	
Yes	70.0%	26.0%	
Ureteral access sheath			0.534
No	40.0%	34.0%	
Yes	60.0%	66.0%	
Post-stenting			0.727
No	10.0%	8.0%	
Yes	90.0%	92.0%	
Satava-classification			0.120
0. No incidents	56.0%	74.0%	
1. Incidents without consequences	36.0%	24.0%	
2a. Incidents treated intraoperatively with endoscopic surgery	8.0%	2.0%	
2b. Incidents requiring endoscopic re-treatment	0.0%	0.0%	
3. Incidents requiring open or laparoscopic surgery	0.0%	0.0%	
Clavien-Dindo classification			0.360
0	94.0%	98.0%	
1	4.0%	2.0%	
2	2.0%	0.0%	
3a	0.0%	0.0%	
3b	0.0%	0.0%	
4a	0.0%	0.0%	0.360
4b	0.0%	0.0%	
5	0.0%	0.0%	
Secondary treatment within 3 months			0.360
No	88.0%	92.0%	
Yes	12.0%	8.0%	

OCI – operator-controlled imaging; RCI – radiographer-controlled imaging; IQR – interquartile range; CDC – modified Clavien-Dindo classification

Table 3. Fluoroscopy time

Variable	OCI	RCI	p-value
Fluoroscopy time (seconds)	33.5	57.0	0.001
Median (IQR)	(16.0–70.0)	(36.8–95.3)	

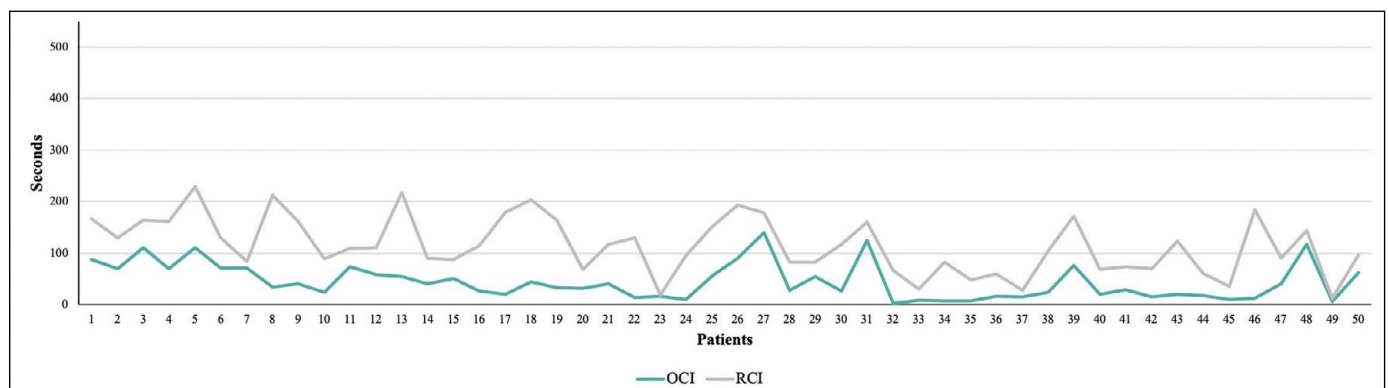
OCI – operator-controlled imaging; RCI – radiographer-controlled imaging;
IQR – interquartile range

described. The majority of the procedures were performed by experienced urologists (OCI 80.0% vs RCI 82.0%). Twelve percent (OCI) and 8.0% (RCI) required secondary treatment within three months. No statistical significant difference was found between both groups concerning the duration of the procedure, the use of a UAS, post-stenting at the end of the procedure and surgeon's experience, four variables that are known to influence FT [9, 14]. Furthermore, no difference was found concerning pre-operative and post-operative complications (Satava and CDC). However, there was a significant difference between both groups concerning pre-stenting. Finally, we calculated FT as presented in Table 3. We found a significantly shorter fluoroscopy time in the OCI group of 33.5 seconds (IQR 16.0–70.0) vs 57 seconds (IQR 36.8–95.3) ($p = 0.001$). Figure 1 show the difference in FT between both groups.

DISCUSSION

Radiation exposure is an undesirable, yet inevitable consequence of the use of fluoroscopy during procedures [11]. However, a review by Emiliani et al. described the possibility of fluoroless endourological surgery for stone disease. They found that low radiation or completely fluoroless procedures are feasible and safe and that a specific preoperative checklist should be used to reduce radiation exposure [15]. A study by Mohey et al. confirms these findings

in a randomized controlled trial for endourological management of distal stones. They compared 80 standard procedures with 74 fluoroless procedures and found no significant difference between both groups for FT. However, they still recommend that fluoroscopy should always be available during a fluoroless procedure [16]. In 2019, Manzo et al. did a similar study for kidney stones, where they retrospectively compared 33 flexible URS performed under fluoroscopy with 67 procedures and found that a fluoroless approach was feasible and safe. Still they recommend to start by gradually reducing the use of fluoroscopy until one develops the expertise and feels comfortable to perform a fluoroless procedure [17]. So, even though this technique is possible in the majority of cases in experienced hands, fluoroscopy will still be a part of endourology. Therefore, we should keep aiming to reduce radiation exposure as much as possible and OCI can help to achieve this. Several studies have investigated the variables of URS that might influence radiation exposure. A study by Violette et al. in 2011 identified predictors of radiation exposure during URS in 76 patients. They found that a longer operation time and male gender were predictors for a longer FT [18]. Our study groups did not differ in operation time, nor gender. Furthermore, Violette et al. stated that stone characteristics, such as a difference in stone load, did not influence FT either [18]. Weld et al. found that the use of a flexible scope led to an increase in fluoroscopy time [9]. As all of our procedures were flexible URS, this variable had no influence on our results. Surgeon's experience is another variable that might influence FT [9, 11, 14]. The same is true for the use of a UAS, the use of ureteral balloon dilatation or insertion of a double-J stent at the end of the procedure [9]. Experience, use of a UAS and post-stenting did not differ significantly between our two study groups and balloon dilatation was not per-

**Figure 1.** Fluoroscopy time.

OCI – operator-controlled imaging; RCI – radiographer-controlled imaging

formed in any of the cases. Therefore, none of the patient, stone or perioperative variables in our study cohort, should interfere with radiation exposure and the only possible influence was the difference in the operator of the perioperative imaging.

This study aimed to evaluate if OCI could lower FT during flexible URS when compared to RCI in a study population with otherwise similar groups treated according to the same procedure-protocol but in different centers. To the best of our knowledge, this is the first study comparing RCI with OCI in a urological setting. We found that OCI during flexible URS for the treatment of nephrolithiasis significantly reduces FT [33.5 seconds (IQR 16.0–70.0)] compared to RCI [57 seconds (IQR 36.8–95.3)]. As patients with kidney stone disease tend to relapse with a recurrence rate of 35–50% after five years and thus have a high chance of requiring repeat surgery with the associated radiation, maximal efforts should be made to reduce radiation exposure as much as possible [19]. Furthermore, patients with kidney stones tend to undergo repeated imaging studies before and after treatment, which increases the cumulative radiation dose even more [6].

This study found a lower FT during procedures with OCI and thus one could assume that a urologist can reduce radiation exposure during flexible URS by operating the fluoroscopy themselves. A possible explanation for this difference in radiation exposure is that OCI removes the middleman in the fluoroscopy process. When the operator must give a vocal command to start but also stop fluoroscopy, there will automatically be a delay in this process. All those small delays could add up to a significant higher FT. Another possible reason for the lower exposure could be the operator's awareness of the radiation when he/she has to operate fluoroscopy him/herself. We believe that this knowledge can help reduce radiation exposure and its negative long-term effects for both patients and medical staff during URS. An additional beneficial consequence of OCI is that fewer medical staff is required to perform this procedure, however it will demand greater awareness of the surgeon who will also have to monitor radiation levels during the procedure.

The major limitation of these results lies within the retrospective nature of the study design. Furthermore, it is a non-randomized study design, in which selection bias in the study population may be the case as not only two different imaging operator techniques (OCI and RCI), but also patients from two different centers were compared. However, we believe selection bias was minimal as both study groups did

not differ in patient and stone characteristics or in variables known to influence radiation exposure. Nevertheless, there was a significant difference between both groups concerning pre-stenting. This difference might be due to differences in patient population, standard practice procedures or training specific to each study-center. Although this variable is not known to be directly related with an increase in radiation exposure, as it is not an action requiring the use of fluoroscopy during URS, it might have an influence on the use of fluoroscopy. A future single-center randomized study comparing OCI and RCI is needed to omit all forms of bias and confirm our findings.

CONCLUSIONS

This study was conducted to evaluate if operator-controlled imaging could lower FT during flexible URS. We found that OCI during flexible URS for the treatment of nephrolithiasis can significantly reduce FT when compared to RCI.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

COMPLIANCE WITH ETHICAL STANDARDS

Research involving Human Participants and / or Animals: This study was reviewed by and approved by the ethical commission of our hospital under reference W20_277 #20.312 on 11-06-2020.

Informed consent: Informed consent was not obtained from individual participants included in the study as consent is not required as long as information is anonymized and the submission does not include images that may identify the person. Therefore, our institution waived the need for an informed consent.

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AUTHORS CONTRIBUTION

M.M.E.L. Henderickx: Protocol/project development, data collection or management, data analysis, manuscript writing/editing

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