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Appropriate management reduces radiation exposure in daily urological practice

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Abbreviations & Acronyms

AK = air kerma

DAP = dose area product

DRL = diagnostic reference level

FPD = flat panel detector

FT = fluoroscopy time

IAEA = International Atomic Energy Agency

ICRP = International Commission on Radiological Protection

PCNL = percutaneous nephrolithotomy

pps = pulses per second

TLD = thermoluminescent dosimeter

TUL = transurethral lithotripsy

Abstract

Objectives: To identify and raise awareness of the radiation exposure of urologists due to X-ray fluoroscopic procedures in daily practice.

Methods: This was a single-center, cohort study of 30 consecutive patients who underwent periodic percutaneous or transurethral replacements of urinary tract catheters. A total of 55 replacements every three months with cases aligned were performed by a single urologist. The urologist's radiation exposure and the incident dose to patients per case were measured with thermoluminescent dosimeters. In the latter three-month period, the pulse fluoroscopy condition was changed from 15 to 7.5 pulses per second, and collimation was added to the field of view.

Results: In the analysis of all patients, the use of a modified pulse rate and collimation did not affect the fluoroscopy time, but it did significantly reduce the air kerma and dose area product; in addition, with respect to the medical exposure dose during percutaneous catheter replacement, fluoroscopy time was longer, but air kerma and dose area product showed significant decreases. As with decreases in medical exposure of patients, the equivalent dose for eye lenses of the urologist decreased from 1.2 mSv in the first three-month period to 0.2 mSv in the second three-month period. Similarly, the exposure dose for the extremities also decreased significantly, from 33.9 mSv to 8.1 mSv.

Conclusions: Urologists are exposed to non-negligible amounts of radiation due to fluoroscopy.

Appropriate management such as Modified pulse fluoroscopy condition and precautions are required.

Key words: radiation exposure, X-ray fluoroscopy, urologist

Introduction

Radiation has become widely used in medicine and is indispensable in the modern world. Whereas use of radiation in medicine has brought great benefits, the radiation exposure associated with medical treatments has been increasing. Against this background, radiation protection has been recognized as an extremely important issue with regard to ensuring the safety and effectiveness of the use of radiation in medicine.

The International Commission on Radiological Protection (ICRP) categorized radiation exposure into three types (“medical exposure,” “occupational exposure,” and “public exposure”) and proposed the concept of radiation protection according to the characteristics of each.¹

Occupational radiation exposure is defined as exposure at work, including hospital work.¹ In addition to the optimization of medical exposure, the ICRP recommends that occupational exposure should be kept as low as possible by specifying the exposure limits for the effective dose and the equivalent dose for individuals, with the aim of preventing radiation injury to healthcare professionals.² In accordance with these recommendations, many studies on occupational exposure have been conducted in the fields of cardiovascular interventional radiology, radiology, and orthopedics.³⁻⁵

In the field of urology, procedures using X-ray fluoroscopy are routine. In urology, fluoroscopy is used not only for endoscopic surgery such as transurethral lithotripsy (TUL), percutaneous

nephrolithotomy (PCNL), and nephrostomy, but also for ureteral stent replacement and catheter replacement for nephrostomy and ureterostomy. Some studies have reported radiation exposure during endoscopic surgeries such as TUL and PCNL,⁶⁻⁸ but there are few reports of occupational exposure due to the use of X-ray fluoroscopy during short and routine procedures such as catheter exchange.^{9,10} There have been some reports of the effects of long-term exposure to low doses of X-ray fluoroscopy on cataract.^{11,12} Therefore, it is important to clarify the actual conditions of radiation exposure in daily practice in the field of urology and to establish measures to reduce radiation exposure.

The present study aimed to clarify the actual radiation exposure and to raise awareness of the radiation exposure of urologists during procedures using X-ray fluoroscopy in daily practice.

Materials and Methods

Study Design and Patient Selection

This was a single-center, cohort study involving 30 consecutive patients who underwent periodic percutaneous or transurethral replacements of urinary tract catheters at Tokushima University Hospital, excluding new cases. The study period was between April and October 2021. Thirty patients who had undergone catheter changes at least twice using X-ray fluoroscopy in the Department of Urology at the University of Tokushima were included in this study. The patients'

background characteristics are shown in Table 1. In total, 55 replacements including 27 transurethral ureteral stent replacements, 25 percutaneous ureteral catheter replacements, and 3 percutaneous nephrostomy catheter replacements were performed by a single urologist in each three-month period. All endourological procedures were performed using pulsed fluoroscopy with the over-tube type of fluoroscopy device, CUREVISTA Open (FUJIFILM Healthcare Corporation, Tokyo, Japan). The ALARA (as low as reasonably achievable) principle was maintained,¹³⁻¹⁵ including the use of thyroid shields, lead aprons, judicious fluoroscopy use, and a maximum operating distance from the radiation source. The last fluoroscopic image was retained without taking X-rays after the exchange.

Measurement of the urologist's radiation exposure and the patient's incident dose

The urologist's radiation exposure was measured with thermoluminescent dosimeters (TLDs) on the neck outside of the thyroid shield, the chest inside of the lead apron, and the exposed left finger. TLDs were analyzed at a central institute each month. The radiation doses detected on the neck and the left finger were counted as representative equivalent doses for the eye lens when not wearing lead glasses and the skin, respectively. In reality, however, the urologist wore lead glasses. The distance from the X-ray tube to the patient's body surface was about 45 cm. A ceiling-mounted shielding panel with a lead equivalent of 0.50 mmPb was used during both three-month

periods, and the distance from the patient and urologist to the panel was 40 cm and 15 cm, respectively. TLDs were also placed on the patient and urologist sides of the shielding panel to compare the exposure doses (Figure 1).

The fluoroscopic conditions were changed in the first and second three-month periods. In the first three-month period, the procedure was performed with pulsed fluoroscopy at 15 pulses per second (pps). In the second three-month period, collimation was added to half of the field of view. Since reduction of the pulse rate to 3.8 pps led to roughness of the image, the reduced pulse rate was decided to be 7.5 pps (Figure 2).

During each three-month period, the air kerma (AK: mGy) and dose area product (DAP: Gy·cm²) as the radiation dose and fluoroscopy time (FT: min) for each procedure were consecutively investigated. The AK did not contain scattered rays and was automatically calculated by the fluoroscopy device, with a reference point 30 cm above the flat panel detector. The DAP was calculated by the product of AK and the incident area. The International Atomic Energy Agency (IAEA) recommends DAP for fluoroscopy and interventional radiology procedures as the primary diagnostic reference level (DRL) quantity for optimizing radiation exposure from medical imaging with ionizing radiation.¹⁶ It also recommends AK and FT as useful additional DRL quantities. Therefore, the DAP, AK, and FT were used as DRL quantities in the present study.¹⁶

In cases of bilateral catheter or stent replacement, the AK, DAP, and FT measurements were each

halved. AK and DAP were set by the incident dose at a 30-cm height from the reference point.

Statistical Analysis

The data for patients' characteristics are expressed as medians and range. Incident doses for each procedure were summarized by medians (25th–75th interquartile range). Continuous variables of incident doses for each procedure were analyzed using the Mann-Whitney U test because the data were non-normally distributed. Linear regression analysis was used to analyze the correlation between cumulative equivalent dose and incident dose. All analyses were performed by SPSS software, version 16.0 (SPSS, Chicago, IL), and $p < 0.05$ was considered significant.

Results

Changes in incident dose

In the analysis of all patients, the use of a modified pulse rate and collimation did not affect the FT, but it did significantly reduce AK from 2.9 to 1.0 mGy and DAP from 1.1 to 0.3 Gy·cm² (Table 2). FT for transurethral stent replacement was halved, whereas, for percutaneous catheter replacement, it was significantly longer in the second three-month period. These were due to patient or technical factors, such as taking time to make adjustments for optimal positioning, because the study population included special cases such as individuals with disabilities or severe obesity, and they were not associated with changes of image smoothness due to collimation or

decreased pulse rate.

For medical exposure during transurethral stent replacement, FT was halved in the second three-month period, but AK and DAP showed an even greater decrease than the decrease in FT. For percutaneous catheter replacement, even with the longer FT, AK and DAP did not increase significantly.

Changes in occupational exposure

The effective dose for the urologist decreased from 0.1 mSv to 0 mSv (Table 3). The equivalent dose for eye lenses decreased from 1.2 mSv in the first period to 0.2 mSv in the second and the exposure dose for extremities decreased significantly from 33.9 mSv to 8.1 mSv. In addition, the exposure at the front of the shield decreased in the second period (from 1.1 mSv to 0.2 mSv), and the shield approximately halved the exposure at its rear in both periods.

Correlation between cumulative equivalent dose and incident dose

On linear regression analysis, there were correlations between the incident dose for patients and the cumulative equivalent doses for both the eyes and fingers of the urologist ($R^2=0.833$ and 0.843 , respectively, Figure 3).

Discussion

The DRL was proposed as a practical tool for promoting optimization of medical exposure of

patients in 1996 in ICRP Publication 73¹⁷ and has been widely used around the world since ICRP Publication 105, which demonstrated its effectiveness, was published.¹⁸ The DRL is not applied directly to individual patients and examinations, but is used to provide feedback for optimizing the exposure at each facility. Though these are approaches for optimization, the ICRP has not applied dose limits to medical exposure, because the dose required to achieve the purpose of medical treatment varies greatly depending on the patient's body shape and the complexity and difficulty of the procedure.¹⁸

The ICRP assesses occupational exposure through personal monitoring using TLDs and recommends that the average equivalent dose of the lenses of the eyes should not exceed 20 mSv/year for 5 years or 50 mSv for any one year.² It is also recommended that the thyroid gland and skin exposures should each not exceed 500 mSv/year.²

In the field of urology, X-ray fluoroscopy is used during endoscopic surgery, nephrostomy, and ureteral stenting. In such surgeries, the difficulty of the procedure varies greatly from case to case, and the exposure dose varies accordingly. There are cases in which ureteral stent replacement and catheter replacement also require confirmation by X-ray fluoroscopy because of the presence of strictures or to ensure proper placement in the indwelling sites. However, since these procedures are performed repeatedly, these procedures become relatively technically stable after multiple exchanges.

Occupational exposure due to fluoroscopy is mainly due to scattered X-rays from the irradiated patient's body and the exposure to the urologist per procedure is much lower than that to the patient. However, since procedures such as catheter exchange need to be performed periodically, cumulative exposure becomes a problem. In addition, unlike fluoroscopic procedures using a C-arm in the operating room, stent/catheter exchange in the fluoroscopy room is often performed using an overhead tube system with the X-ray tube located above the patient. Since using the overhead tube method may cause high exposure to the urologist's fingers and lenses of the eyes, urologists must take care to protect themselves from the radiation exposure.

In the present study, to clarify the actual situation of radiation exposure under fluoroscopy, 30 patients who had already undergone regular urinary catheter exchanges more than twice were selected. The amount of radiation exposure of these patients and the one urologist who performed the procedures were measured. First, the actual exposure with the default settings at our institute was evaluated. The patient exposure by procedure with the default settings was particularly high during transurethral ureteral stent exchange.

To reduce occupational exposure, it is important to control the scattered X-rays from the patient.

The fundamental way to reduce the radiation exposure of the urologist from scattered X-rays involves reduction of exposure time, maintenance of distance, and shielding. In the present study, a shield was placed between the patient and the urologist in all cases, and the exposure on the

patient's side and the urologist's side of the shield was also measured. As expected, there was a clear difference in exposure at the front and at the back of the shield. This result indicated the necessity of thorough shielding in urological procedures, unlike procedures via intravascular approaches, where the distance from the patient's trunk is difficult to maintain. In addition, urological procedures may involve direct radiation exposure of the fingers to X-rays. In fact, the exposure dose of the urologist's fingers was very high in the first three months. Therefore, when there is a possibility of direct exposure to X-rays, efforts should be made to avoid direct dose exposure by shielding with the use of leaded gloves or use of a hands-off technique. Furthermore, sufficient consideration should be given to the irradiation dose and time to be used.

Pulsed fluoroscopy is a simple method for reducing radiation exposure per unit time.^{19,20} In this study, based on the results of the first three months, the pulse rate was changed from 15 pps, which is the default setting at our institute, to 7.5 pps to reduce the irradiation dose. In addition, collimation was used to reduce the irradiation dose to be as low as possible, and the patient's predicted exposure dose and the urologist's exposure dose were measured without changing the other conditions. Though there was no significant difference in fluoroscopy time between the two three-month periods, the patient's exposure dose indicated by AK was clearly reduced. Furthermore, the exposure to the urologist was reduced in all regions, even though the irradiation time was not changed. Regarding the fingers, it is possible that the change in the urologist's

awareness of direct X-ray exposure due to the confirmation of the exposure dose in the first three months may have had an effect, but it is considered that such an effect can be eliminated with respect to the exposure doses to the front and back of the shield and the lenses of the eyes. Therefore, the reduction of patient exposure by changing the pulse rate and using collimation is thought to have led to the reduction of scattered radiation and occupational exposure.

To evaluate whether the safety of the procedure was affected by changing the pulse rate and using collimation, adverse events in patients were also examined; there was no increase in adverse events associated with catheter exchange, suggesting no decrease in the quality of medical care due to the use of the new settings.

The limitations in this study were as follows. First, to eliminate the effect of the skill of the urologist performing the procedure, this study was conducted with a single urologist, and statistical examination was not possible. Second, since it was not blinded, the effects of the urologist's awareness of the study measurements cannot be eliminated. Third, the number of cases of each procedure was small and might not directly reflect the general exposure in the field of urology due to the inclusion of special cases.

The results of this study suggested that, while being aware of the distance based on the three principles of external exposure protection, efforts to reduce radiation exposure using appropriate shielding and low pulse rates could lead to a reduction in occupational exposure while maintaining

the quality of medical care.

In conclusion, although the degree of occupational exposure per procedure is small, the exposure of the urologist in urological procedures using fluoroscopy cannot be ignored, because the procedures must be performed repeatedly. The results of this study help clarify the actual conditions of occupational radiation exposure of urologists in daily practice and will encourage urologists to take measures to reduce their exposure dose.

Disclosure**ETHICAL CONSIDERATIONS****Approval of the research protocol by an Institutional Review Board**

The Ethics Committee of Tokushima University Hospital approved this study (ID: 4063), which was performed in accordance with the tenets of the Declaration of Helsinki.

Informed consent

Since the study design was retrospective and observational, the requirement for obtaining written, informed consent from the patients was waived.

Registry and the Registration No. of the study/trial

N/A

Animal Studies

N/A

Conflict of interest

All authors declare that they have no conflicts of interest.

Data availability

The dataset analyzed in this study is not publicly available but is available from the corresponding author on reasonable request. The corresponding author had full access to all the data in the study and takes responsibility for accuracy of the data analysis.

References

1. ICRP. ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection. *Ann. ICRP.* 1991; 21: 1-201.
2. ICRP. ICRP publication 118: ICRP statement on tissue reactions and early and late effects of radiation in normal tissues and organs—threshold doses for tissue reactions in a radiation protection context. *Ann. ICRP.* 2012; 41: 1–322.
3. Rohlfes F, Spanos K, Debus ES et al. Modern Image Acquisition System Reduces Radiation Exposure to Patients and Staff During Complex Endovascular Aortic Repair. *Eur. J. Vasc. Endovasc. Surg.* 2020; 59: 295-300.
4. Heusch P, Kropil P, Buchbender C et al. Radiation exposure of the radiologist's eye lens during CT-guided interventions. *Acta Radiol.* 2014; 55: 86-90.
5. Yamashita K, Higashino K, Hayashi H et al. Pulsation and collimation during fluoroscopy to decrease radiation: a cadaver study. *JBJS Open Access.* 2017; 2: e0039.
6. Hristova-Popova J, Zagorska A, Saltirov et al. Risk of radiation exposure to medical staff involved in interventional endourology. *Radiat. Prot. Dosim.* 2015; 165: 268–71.
7. Vano E, Fernandez JM, Resel LE et al. Staff lens doses in interventional urology. A comparison with interventional radiology, cardiology and vascular surgery values. *J. Radiol. Prot.* 2016; 36: 37–48.
8. Galonnier F, Traxer O, Rosec M et al. Surgical staff radiation protection during fluoroscopy-

- guided urologic interventions. *J. Endourol.* 2016; 30: 638–43.
9. Ritter M, Krombach P, Martinschek A et al. Radiation exposure during endourologic procedures using over-the-table fluoroscopy sources. *Endourology* 2012; 26: 47–51.
 10. Hartmann J, Distler F, Baumüller M et al. Risk of radiation-induced cataracts: investigation of radiation exposure to the eye lens during endourologic procedures. *J. Endourol.* 2018; 32: 897–903.
 11. Chodick G, Bekiroglu N, Hauptmann M et al. Risk of cataract after exposure to low doses of ionizing radiation: a 20-year prospective cohort study among US radiologic technologists. *Am. J. Epidemiol.* 2008; 168: 620-31.
 12. Milacic S. Risk of occupational radiation-induced cataract in medical workers. *Med. Lav.* 2009; 100: 178-86.
 13. Winkler NT. ALARA concept—now a requirement. *Radiol. Technol.* 1980; 51: 525.
 14. Hendee WR, Edwards FM. ALARA and an integrated approach to radiation protection. *Semin. Nucl. Med.* 1986; 16: 142–50.
 15. Brateman L. Radiation safety considerations for diagnostic radiology personnel. *Radiographics* 1999; 19: 1037–55.
 16. International Atomic Energy Agency. Diagnostic Reference Levels (DRLs). Available at <https://www.iaea.org/resources/rpop/health-professionals/radiology/diagnostic-reference-levels>.

Accessed Feb 13, 2022.

17. ICRP. ICRP Publication 73: Radiological Protection and Safety in Medicine. Ann. ICRP. 1996; 26: 1-47.
18. ICRP. ICRP Publication 105: Radiation protection in medicine. Ann. ICRP. 2007; 37: 1-63.
19. Miller DL, Balter S, Cole PE et al. Radiation doses in interventional radiology procedures: the RAD-IR study: part II: skin dose. J. Vasc. Interv. Radiol. 2003; 14: 977-990.
20. Suzuki S, Furui S, Kobayashi I et al. Radiation dose to patients and radiologists during transcatheter arterial embolization: comparison of a digital flat-panel system and conventional unit. AJR. Am. J. Roentgenol. 2005; 185: 855-859.

Figure legends

Figure 1. Thermoluminescent dosimeter (TLD) arrangement. TLDs a) on the neck outside of a thyroid shield, b) the chest inside of a lead apron, c) the exposed left ring finger, and d) on the patient and e) urologist sides of the shielding panel. Solid arrows and dot arrows demonstrate direct X-rays and scattered X-rays, respectively. FPD: Flat panel detector. Pt: Patient. U:Urologist.

Fig. 2 Fluoroscopic conditions in the first 3-month period and the second 3-month period. Pps: pulses per second.

Figure 3. Correlation between cumulative equivalent dose and dose area product per month.

Table 1 Patients' characteristics

Number of patients	30
Age, years	62.5 (37-90)
Gender (female / male)	19 / 11
BMI, kg/m ²	20.9 (14.1-31.5)
Primary disease	
Malignancy	
Advanced or metastatic disease	14
Postoperative	6
Benign disease	
Retroperitoneal fibrosis	3
Neurogenic bladder	4
Urolithiasis	2
Cystitis glandularis	1

Data are median (IQR), unless otherwise stated.

Table 2 Radiation exposure of patients during stent or catheter replacement

	n	1st	2nd	P
All	55			
AK (mGy)		2.9 (0.9-6.0)	1 (0.6-1.7)	<0.001
DAP (Gy·cm ²)		1.1 (0.4-2.2)	0.3 (0.2-0.4)	<0.001
FT (sec)		33 (9.9-58.9)	26.4 (15.7-47.4)	0.797
Transurethral stent replacement	27			
AK (mGy)		4.4 (3.1-8.8)	0.9 (0.6-1.5)	<0.001
DAP (Gy·cm ²)		2.2 (1.3-3.8)	0.3 (0.2-0.4)	<0.001
FT (sec)		55.5 (45.9-76.1)	27.5 (15.0-42.5)	0.007
Percutaneous catheter replacement	28			
AK (mGy)		0.9 (0.5-2.6)	1.1 (0.6-1.8)	0.403
DAP (Gy·cm ²)		0.4 (0.3-1.0)	0.3 (0.2-0.5)	0.286
FT (sec)		16.9 (9.8-29.1)	28.6 (21.9-53.4)	0.008
Complications	55			
Obstruction, n (%)		2 (36.4)	2 (36.4)	
Febrile urinary infection, n (%)		1 (18.2)		

Data are median (IQR), unless otherwise stated.

Table 3 The single urologist's radiation exposure during the two

	1st	2nd
Effective dose (mSv)	0.1	0
Equivalent dose (mSv)		
Eye lens	1.2	0.2
Extremities	33.9	8.1
Protection by using shield (mSv)		
patient side of the shield	1.1	0.2
surgeon side of the shield	0.6	0.1

Fig. 1

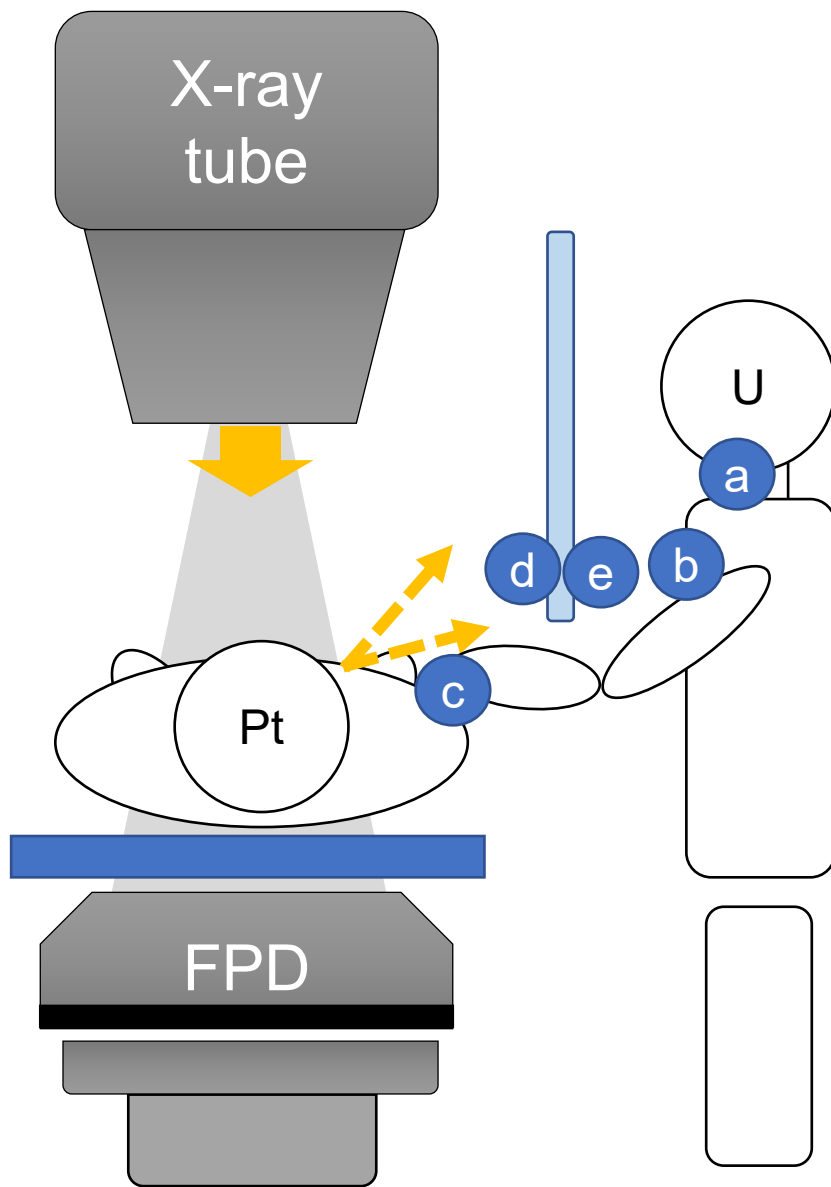


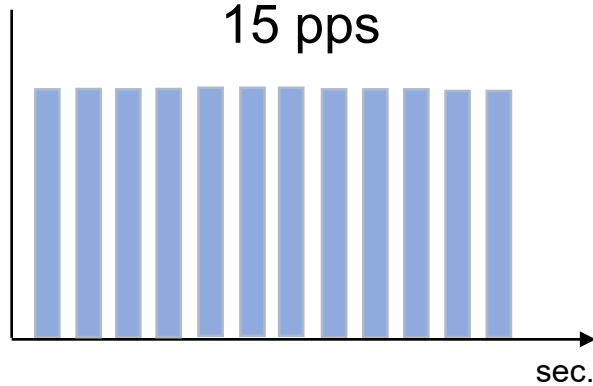
Fig. 2

First Period

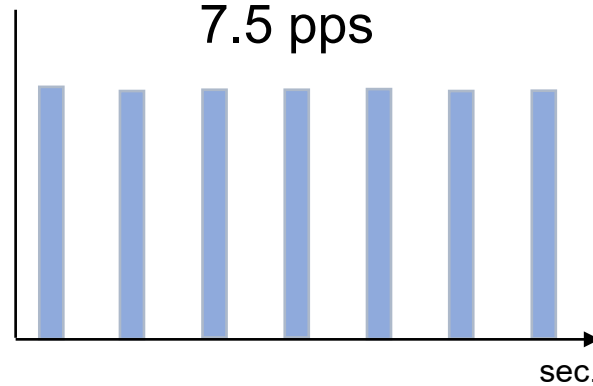
Second Period

Pulsed fluoroscopy

15 pps



7.5 pps



Collimation (+)

Fig. 3

