Efficiency of novel shielding curtains combined with pulsed irradiation for reducing radiation exposure in an operating room; Human Renal Collecting System Phantom Study.

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Key Words:	novel shielding curtains, pulsed irradiation, radiation exposure, radiological protection, ureteroscopy
Abstract:	Purpose: To evaluate the impact of novel shielding curtains (NSC) combined with pulsed irradiation mode to protect medical radiation workers from radiation exposure during ureteroscopy (URS). Methods: 0.25mm Pb equivalent NSC were mounted to the caudal and bilateral sides of the operating table in URS setting. C-arm was positioned as per normal in the operating room with the X-ray tube under the patient table. A water-filled anthropomorphic renal collecting system phantom was positioned in the standard position on the operating table that was set at a height of 100cm. The ionization chambers were also positioned at a height of 100cm and set in eight positions. We took measurements at distances of 50cm, 100cm, 150cm, and 200cm from the phantom with the focus directed towards the X-ray tube. We measured the spatial distribution of the scattered radiation dose in four combinations: 1. Continuous irradiation mode without NSC. 2. Pulsed irradiation mode (11 films per second) without NSC. 3. Continuous irradiation mode with NSC. 4. Pulsed irradiation mode with NSC. Continuous or pulsed irradiation was activated for 30 seconds each time. Results: Pulsed irradiation mode with NSC was significantly more efficient method than other combinations to reduce scattered radiation exposure in this study (P<0.001). There was approximately 95% reduction in scattered radiation exposure with the pulsed irradiation mode with NSC setup as compared with continuous irradiation mode

	without NSC. Conclusion: Combining a Novel Shielding Curtain and using a low pulse radiation setting can greatly reduce radiation exposure during ureteroscopic procedures.

(Title)

Efficiency of novel shielding curtains combined with pulsed irradiation for reducing radiation exposure in an operating room; Human Renal Collecting System Phantom Study.

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(Abstract)

Purpose: To evaluate the impact of novel shielding curtains (NSC) combined with pulsed irradiation mode to protect medical radiation workers from radiation exposure during ureteroscopy (URS).

Methods: 0.25mm Pb equivalent NSC were mounted to the caudal and bilateral sides of the operating table in URS setting. C-arm was positioned as per normal in the operating room with the X-ray tube under the patient table. A water-filled anthropomorphic-renal collecting system phantom was positioned in the standard position on the operating table that was set at a height of 100cm. The ionization chambers were also positioned at a height of 100cm and set in eight positions. We took measurements at distances of 50cm, 100cm, 150cm, and 200cm from the phantom with the focus directed towards the X-ray tube. We measured the spatial distribution of the scattered radiation dose in four combinations:

1. Continuous irradiation mode without NSC.
2. Pulsed irradiation mode (11 films per second) without NSC.
3. Continuous irradiation mode with NSC.
4. Pulsed irradiation mode with NSC.

Continuous or pulsed irradiation was activated for 30 seconds each time.

Results: Pulsed irradiation mode with NSC was significantly more efficient method than other combinations to reduce scattered radiation exposure in this study ($P<0.001$). There was approximately 95% reduction in scattered radiation exposure with the pulsed irradiation mode with NSC setup as compared with continuous irradiation mode without NSC.

Conclusion: Combining a Novel Shielding Curtain and using a low pulse radiation setting can greatly reduce radiation exposure during ureteroscopic procedures.

(Key words)
novel shielding curtains, pulsed irradiation, radiation exposure, radiological protection, ureteroscopy

(Introduction)

Recent technological developments with surgical equipment and endoscopy have led to remarkable advancements in ureteroscopy (URS) for stone management and expanded the indications. These procedures are commonly performed under fluoroscopy. The mean fluoroscopic time during URS for stone treatment is 1 to 2 minutes [(1), (2), (3)].

When performing these surgeries, there is a risk of radiation exposure to the patient, surgeon and other medical staff. The International Commission on Radiological Protection (ICRP) states that all physicians should adopt the principle of limiting radiation exposure to "as low as reasonably achievable" (ALARA) [(4)]. Radiation exposure may come in the form of direct exposure from the X-ray tube or as a result of scattered radiation from the patient and other objects such as the surgical table. Most occupational radiation exposure of medical staff is caused by scattered radiation. In order to comply with ALARA, we must do more to reduce scatter radiation and protect medical personnel.

Generally, a lead apron, thyroid shield, and lead glasses are used to protect oneself from radiation exposure during procedures. In addition, depending on the features of the imaging machine, pulsed irradiation mode can be used to reduce the radiation dose. However, these may still not be enough to completely protect healthcare professionals from scattered radiation exposure.

Our goal in this study was to evaluate the efficacy of a novel shielding curtains (NSC) to protect against scattered radiation exposure and also to determine the best combination to reduce radiation dose during URS in the operating room.

(Materials and Methods)

1, Measurement setting for spatial dosimetry in operation room

The measurement of the spatial scattered radiation dose was performed in an operating room for simulated URS management of urolithiasis. A water-filled anthropomorphic renal collecting system phantom was placed on the operating table as per our normal patient setup. The X-ray tube was positioned as far as possible from the phantom and was oriented under the patient table while the image intensifier was positioned over the phantom. The C-arm we tested was "Cios Select TM (Siemens, Munich, Germany)". We have set C-arm dose mode to standard mode which was comfortable for surgeons. The height of the operating table was set at 100 cm as in the case of ordinary surgeries which is a comfortable height for our surgeons. NSC (Radprotection Co., Ltd.) which were made from a mixture of Antimony and Bismuth elements were mounted to the caudal and bilateral sides of the operating table in URS setting. By attaching NSC using radiotranslucent Velcro, they can be used with many types of operating tables (Figure 1a). Figure 1b shows a picture of an actual surgery in use. The operating table we tested was manufactured by Getinge and the model was Maquet Alphamaxx. The ionization chambers

(HITACHI "ICS-1323") were placed in eight positions at distances of 50 cm, 100 cm, 150 cm, and 200 cm from the phantom. They were positioned at a height of 100 cm which correlated with the waist level of the surgeon, and the chambers were directed towards the X-ray tube (Figure 1c, 1d).

We measured the spatial distribution of the scattered radiation dose while simulating the use of an ureteroscope for stone management testing four different setups.

Group A: Continuous irradiation mode without NSC.

Group B: Pulsed irradiation mode (11 films per second) without NSC.

Group C: Continuous irradiation mode with NSC.

Group D: Pulsed irradiation mode with NSC.

The scattered radiation dose inside the NSC was also measured (Figure 1e).

Continuous or pulsed irradiation from the X-ray tube to the phantom was activated for 30 seconds each time, and the ionization chambers measured the resulting scattered radiation dose per hour (μSv/h).

2, Measurement items

We compared the total spatial scattered radiation dose among the 4 groups and measured the radiation dose in 8 directions (The head side of the phantom was designated as "Anesthesiologist", the left side as "Monitor", the caudal side as "Operator", and the right side as "C-arm". "A-M" was set between Anesthesiologist and Monitor, "M-O" was set between Monitor and Operator, "O-C" was set between Operator and C-arm, and "C-A" was set between C-arm and Anesthesiologist (Figure 2a)) among the 4 groups.

Additionally, The directions of M-O～Operator～O-C in 50 cm to 150 cm were set as operator's field (Figure 2b), the directions of C-A～Anesthesiologist～A-M in 150 cm to 200 cm set as anesthesiologist's field (Figure 2c). We compared each fields' scattered radiation dose under the 4 conditions.

3, Statistical analysis

The average value of the collected data for each of the 8 directions and each distance (50 cm, 100 cm, 150 cm, 200 cm) were compared among 4 groups. In addition, post-hoc analysis was performed to compare each of the 8 directions. We also evaluated the reduction rate of radiation dose at operator's field and anesthesiologist's field with and without NSC.

All statistical analyses were performed with EZR [5], which is for R. More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics. Distribution-free test was performed by Friedman test, and post-hoc analysis performed by Bonferroni correction. P value of <0.05 was considered statistically significant.

(Results)

The measured data are shown in supplemental figure S1(Group A), S2(Group B), S3(Group C), and S4(Group D).

1, Comparison among 4 groups

The scattered radiation dose between 4 groups are shown in Figure 3. Group D was significantly more efficient method than the other Groups to reduce scattered radiation exposure in this experiment ($P<0.001$). Post-hoc analysis showed that Group A had significantly higher scattered radiation dose than any other settings ($P<0.05$) and that Group D had significantly lower dose than Group B and Group C ($P<0.05$). However, there was not a significant difference between Group B and Group C ($P=0.089$). There was a 93% reduction in the average scattered radiation exposure in all directions during an URS setting with Group D as compared to Group A.

2, Comparison among 8 directions

Mean dose of radioactivity of 8 directions were shown in Figure 4a. Group D configuration reduce scattered radiation dose significantly in all directions ($P<0.05$).

2a, Operator's field

Radiation dose in operator's field is shown in Figure 4b. There was a 96% reduction of scattered radiation exposure between Group A and D ($P<0.05$). There was 84% reduction of scattered radiation exposure between Group A and C ($P<0.05$), and 91% reduction between Group C and D as well ($P<0.05$).

2b, Anesthesiologist's field

Radiation dose in anesthesiologist's field is shown in Figure 4c. Group D was significantly more efficient than the other settings with an 80% reduction of scattered radiation exposure compared with Group A ($P<0.05$). However, no significant difference was found in the reduction of scattered radiation exposure in the comparison between Group A and Group C, Group B and Group D.

3, Comparison inside NSC among 4 groups

Figure 5 shows the radiation dose inside NSC. There was no difference between with and without NSC, and the dose was reduced to about 1/3 when using the pulsed irradiation mode.

(Discussion)

In the present study, pulsed irradiation in combination with NSC was able to reduce the dose of spatially scattered radiation by approximately 93% when compared to continuous irradiation without NSC during URS setting in the operating room. The typical URS setting in Japan is with the continuous irradiation mode (standard mode) and the X-ray tube not covered by protective curtains. By using pulsed irradiation mode with NSC, the spatially scattered radiation was reduced significantly compared with the other settings. In addition, the radiation dose inside the curtain was measured to see if there was any increase in the phantom's exposure by shielding the X-ray tube. We found no change in the radiation dose with or without NSC. Therefore, we do not anticipate that the use of NSC will cause an increase in radiation dose to the patient.

Occupational radiation exposure in URS is caused by both direct radiation generated between the X-ray tube and image intensifier, and the scattered radiation resulting from the interaction of the primary radiation with the operating table and the patient's body. For urologic surgeries, the main source of radiation is due to scattered radiation [(6)] because there is almost no need for the surgeon to put his or her hands directly into the direct irradiated area during URS that will be exposed to direct radiation. There are two types of scattered radiation: Backward scatter and forward scatter. Depending on the energy of the photons, as well as the density of the material, backward scattering radiation may be as much as 20 times higher than forward scattering radiation [(7)]. Therefore, back scatter radiation from under the table is a major source of radiation exposure to medical personnel.

ICRP guidelines states that the annual occupational radiation exposure dose limit be less than 100 mSv per year, averaged over 5 years with a maximum of 50 mSv in any one year [(4)]. Physicians must also adopt the ALARA principles that limits radiation exposure to "as low as reasonably achievable" due to the known adverse effects of radiation exposure.

In particular leukemia, thyroid cancer, and breast cancer in women are known to be likely malignancies caused by excessive radiation exposure dose [(8), (9)]. A common misconception assumes the brain to be insensitive to radiation. However, recent research demonstrates a plethora of neurological effects including double the brain cancer mortality rate for those who worked with fluoroscopy compared to those who did not [10]. Radiation exposure is also a known risk factor for cataracts. Historically, the ICRP has considered bone marrow, gonads, and lens of the eye to be among the most radiosensitive tissues. In 2011, ICRP reduced the annual dose limit for the eye by more than seven-fold; from 150 to 20 mSv/year [11]. Cardiovascular risk has also been reported, and low to moderate radiation exposure is suspected to increase cardiovascular mortality [12]. There are also reports of radiation effects even with low-dose exposures. In a study of radiation workers, risk of induction of total chromosome-type aberrations and micronuclei in peripheral blood lymphocytes was more frequent although the radiation exposure was low-level [13].

Despite the known risks of radiation exposure, radiation protection is often ignored by medical staff. A 2015 survey found only 54% of medical staff used an adequate level of protective clothing [14]. In a study of 531 surgeons, most were worried about their radiation exposure, but lacked the knowledge and the practical implementation of radiological protection [15]. In a 2020 survey of urologists, 89.6% of them wore lead aprons and 84.4% used thyroid shields, while only 14.7% and 8.1% used glasses and gloves, respectively [16].

With advances in URS surgery, the use of radiation has increased [17]. In the United States, the number of young urologists and female urologists has also risen in the last 10 years. As a result, it is even more important for us to develop practices that will reduce long term, low dose radiation exposure for medical personnel [18]. Studies to reduce radiation exposure to health care workers have been previously reported. There are published reports of radiation shielding in angiography and orthopedic surgery [19], [20], [21], [22]. In our previous study, Inoue et al previously reported the benefit of lead curtains during URS [7]. They hand-made an operative table curtain made from lead and used it to protect against scattered radiation exposure. They found that lead curtains led to a reduction of 75%-80% in the scattered radiation dose in operation room of URS setting. In this current study, we utilized a novel curtain containing two metals antimony (Sb) and bismuth (Bi) instead of lead. For radiation shielding, higher densities are important, and lead is a known high density metal and has been used for many years in radiation protection [23]. Antimony and bismuth are also suitable for radiation protection because of their high density and in addition, may have potential weight savings when compared to lead. Bismuth and antimony are also less damaging to the environment with much lower toxicity when compared to lead. The energy of the X-rays used in diagnostic imaging is typically from 60-120 kVp [24], [25]. In reality, however, it is not possible to generate only a single energy, and lower energy X-ray are also generated at the same time. These two metals were combined to make NSC and may provide a broader range of protection than from a single metal like lead because Antimony is strongly protective at the lower kV energies, and bismuth has similar higher kV protection to lead.

Contemporary C-arms have a pulsed irradiation mode which can reduce radiation exposure while still providing adequate image quality [26), (27]. It has been reported that pulsed irradiation mode can reduce radiation exposure by approximately 70% when compared with continuous irradiation mode.

In this study, we evaluated the combination of novel shielding curtains and pulsed irradiation mode, and the result was remarkable as described above. To the best of our knowledge, this is the first report to examine the combination of NSC and pulsed irradiation mode in the field of urology.

This study demonstrated the radiation dose in all eight directions that were measured to be significantly reduced. According to our result, the dose was reduced by 96% in the surgeon's field and 80% in the anesthesiologist's field during URS. Anesthesiologists are commonly sitting in chairs cephalad of the patient's head during surgery. A reduction in radiation dose at the Anesthesiologist's eye level will decrease the risk of cataracts. The anesthesiologists are often stationed in a position that does not have shielding against scatter radiation. Although the NSC were mounted to the caudal and bilateral sides of the phantom, a decrease in radiation dose was also observed in the cephalad direction of Anesthesia area. We hypothesize that this is because the use of the pulsed irradiation mode was found to be the main factor in reducing the radiation dose when comparing 150 cm and 200 cm in the direction of the patient's head. Therefore, this study demonstrated that pulsed irradiation mode could reduce the radiation dose in the anesthesiologist's field and help protect their eyes.

In addition, since there was no significant difference in total spatial scattered radiation dose between Group B and Group C. For those medical facilities that lack a C-arm with pulse mode feature, the use of NSC may provide a similar reduction in the scattered radiation dose.

Limitations in present study:

First of all, we used a renal collecting system phantom to evaluate the efficacy of NSC in this study. The actual radiation dose generated during URS surgery in clinical practice may be higher or lower depending on the body habitus of the patient. Secondly, we took the measurement height at the surgeon's waist level of 100 cm to quantify scattered radiation dose. However, the amount of radiation dose to the feet **and lens** were not measured in this study. Thirdly, we measured the radiation dose without moving the C-arm. During procedure, the C-arm is moved, which may take a difference compared to the actual radiation dose. **Fourthly, we have not been able to evaluate the use of flatpanel detectors because this was a phantom study using a C-arm in the operating room.** Finally, it has been reported that with the low-dose mode the exposure is reduced [28], however, we have set the C-arm dose mode to the standard mode because the image quality deteriorates at low. Future studies taking measurements at different heights and low dose mode are being planned.

In this present study, the combination of NSC and using the pulsed irradiation mode was able to significantly reduce the scattered radiation in the URS setting. This combination should decrease future radiation induced health risks and may also reduce the weight of protective clothing needed by surgeons.

The NSC was quite useful instrument to reduce scattered radiation exposure in operation room of URS setting. Pulsed radiation mode with NSC is most beneficial prevention method. URS surgeons should adopt this combination to decrease the health risks of occupational radiation exposure.

(Introduction to conclusion; 2674words)

(Abbreviations)

NSC; novel shielding curtains

URS; ureteroscopy

(Acknowledgements)

Employees of MEDICAL LEADERS co. were asked to help with measurement and experimentation.

(Disclosure)

Conflict of interest: None decleared

Approval of the research protocol by an Institutional Reviewer Board: N/A

Informed Consent: N/A

Registry and the Registration No. of the study/trial: N/A

Animal Studies:N/A

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(Figure legends)

Figure 1. Setting of measuring equipment and spatial dosimetry in operating room. a) Attaching the novel shielding curtains (NSC) to the operating table by using Velcro. b) Actual surgical setting and surgeon. c) Measuring equipment: The C-arm, the water-filled anthropomorphic renal collecting system phantom, the ionization chambers, the NSC which were mounted to the caudal and bilateral sides of the operating table. d) Equipment layout during ureteroscopy (URS) and measurement range of measurement of scattered radiation. e) Setting of ionization chamber inside NSC.

Figure 2. a) 8 direction names; A-M: between Anesthesiologist and Monitor, M-O: between Monitor and Operator, O-C: between Operator and C-arm, C-A: between C-arm and Anesthesiologist. b) The directions of M-O～Operator～O-C in 50cm to 150cm (dot) set as Operator’s field. c) The directions of C-A～Anesthesiologist～A-M in 150cm to 200cm(dot) set as Anesthesiologist’s field.

Figure 3. Mean dose of radioactivity among 4 groups.

Figure 4. a) Mean dose of radioactivity among 8 directions. b) Mean dose of Operator’s field. c) Mean dose of Anesthesiologist’s field.

Figure 5. Dose of inside the NSC among 4 groups.

Supplemental Figure S1, S2, S3, S4. The measurement data. S1: Group A, S2: Group B, S3: Group C, S4: Group D.

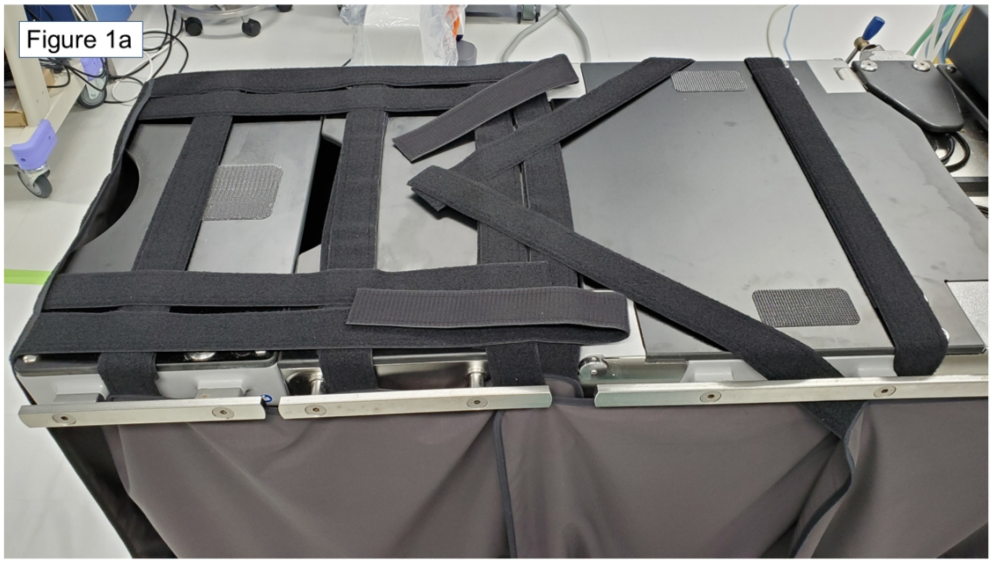

Figure 1a
Attaching the novel shielding curtains (NSC) to the operating table.

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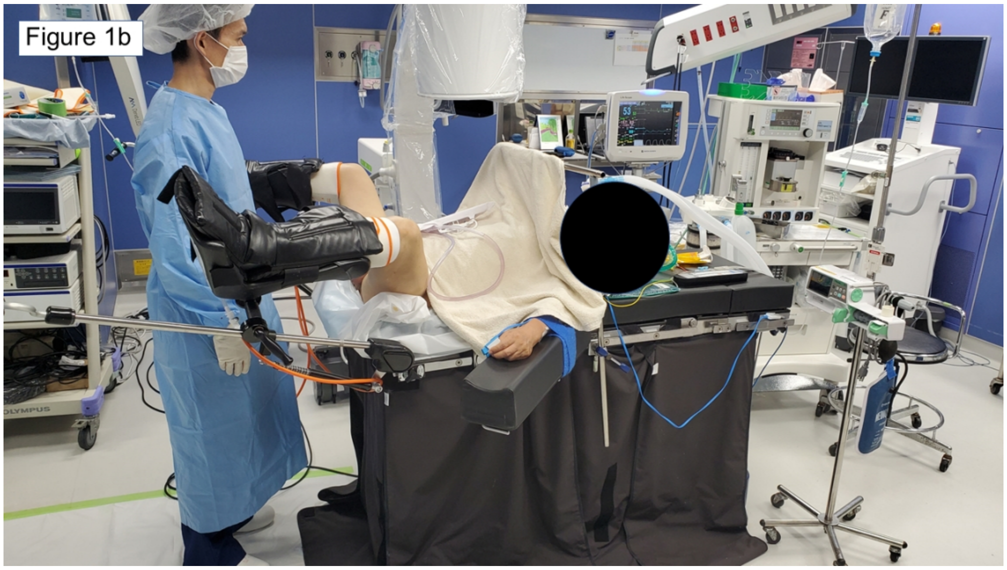


Figure 1b
Actual surgical setting and surgeon.

338x190mm (96 x 96 DPI)

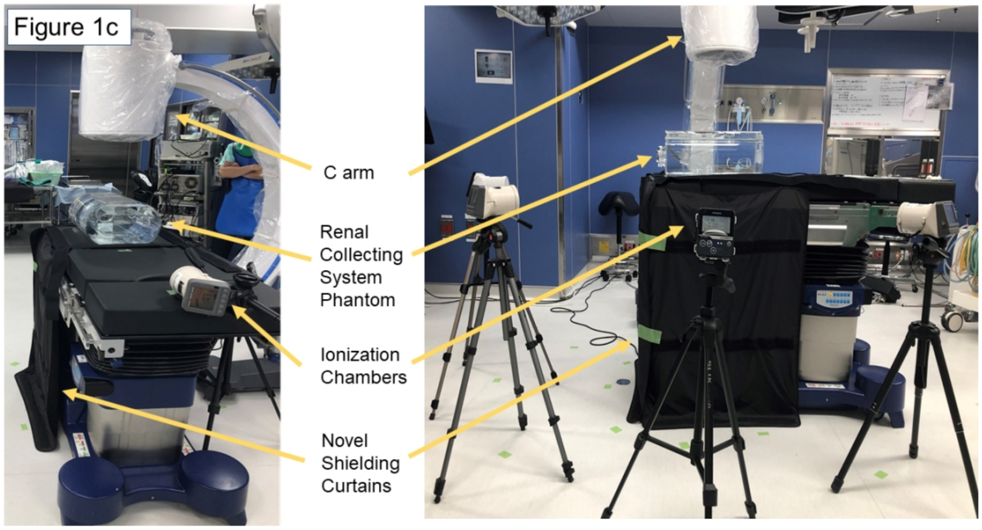
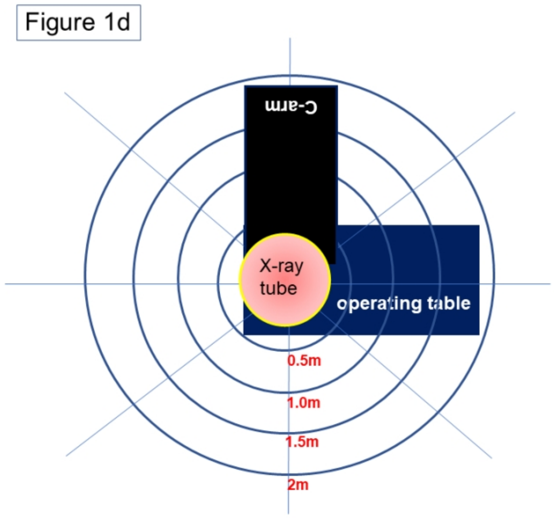


Figure 1c
Measuring equipment.

338x190mm (96 x 96 DPI)



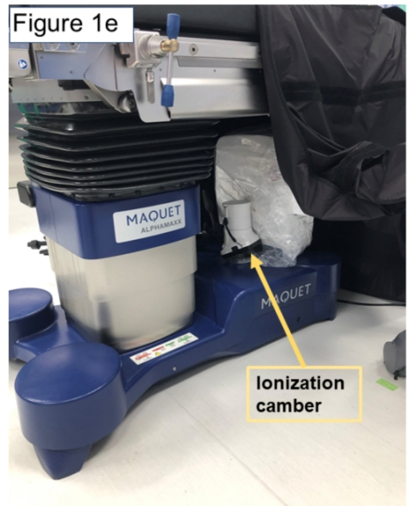


Figure 1d,e
d) Equipment layout during URS and measurement range of measurement of scattered radiation. e) Setting of ionization chamber inside NSC.

338x190mm (96 x 96 DPI)

Figure 2a

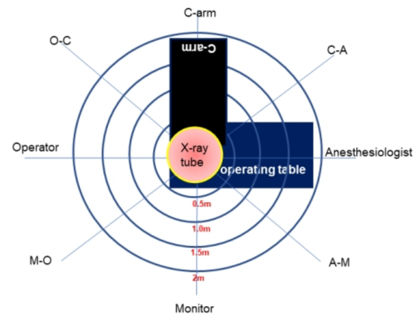


Figure 2b

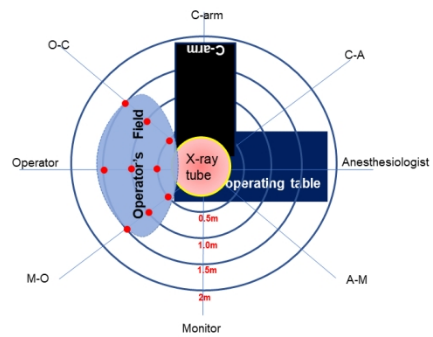


Figure 2c

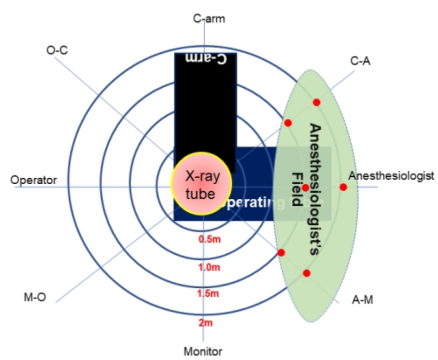


Figure 2a,b,c
a) 8 direction names. b) Operator's field. c) Anesthesiologist's field.

200x510mm (96 x 96 DPI)

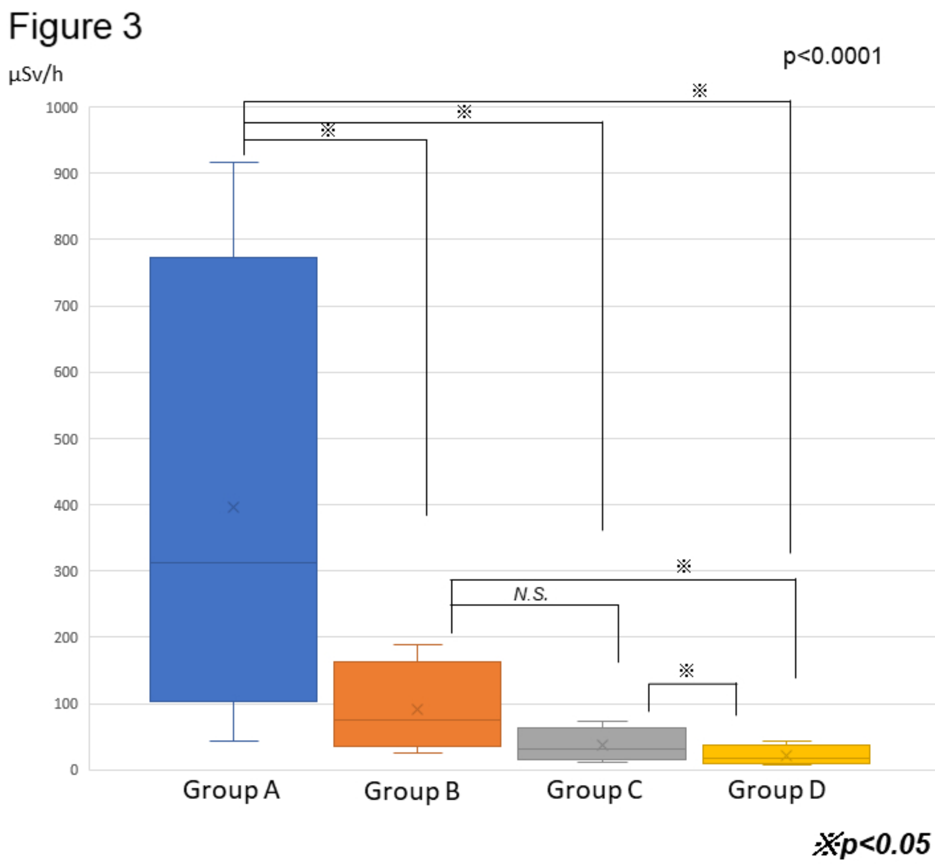


Figure 3
Mean dose of radioactivity among 4 groups.

200x179mm (96 x 96 DPI)

Figure 4a

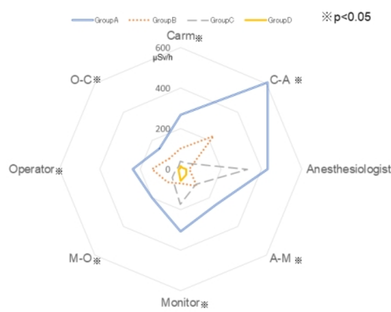


Figure 4b

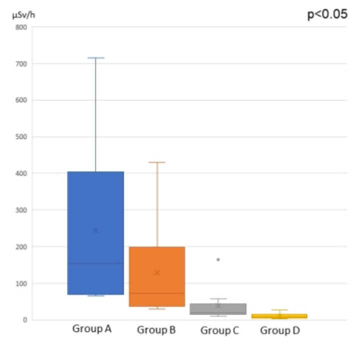


Figure 4c

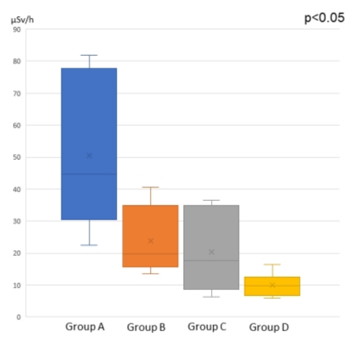


Figure 4a,b,c

a) Mean dose of radioactivity among 8 directions. b) Mean dose of Operator's field. c) Mean dose of Anesthesiologist's field.

200x510mm (96 x 96 DPI)

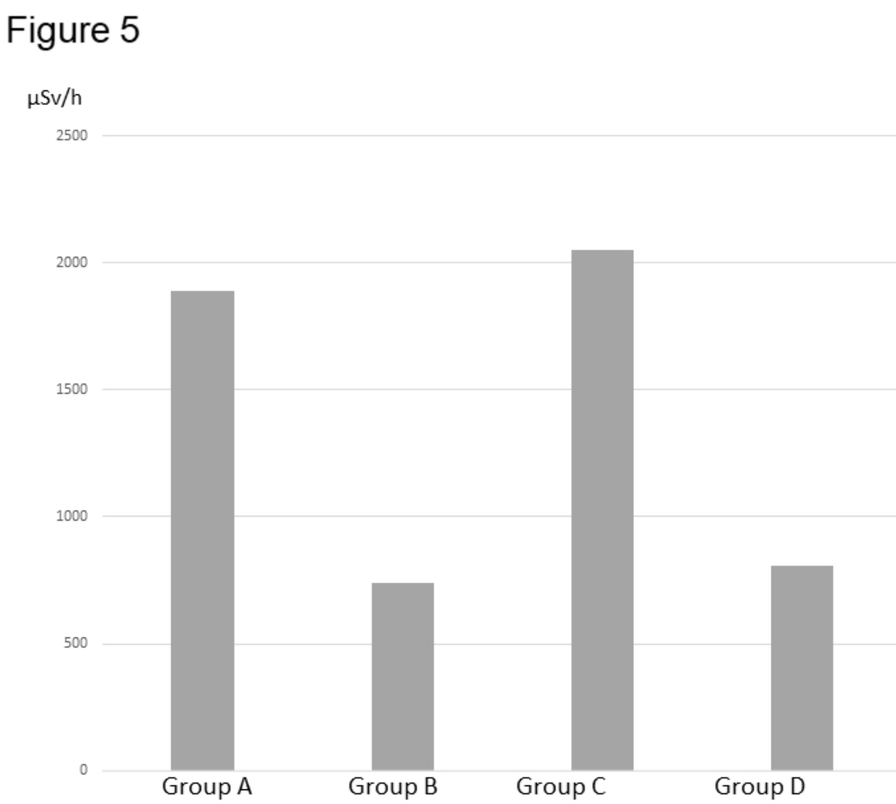


Figure 5
Dose of inside the NSC among 4 groups.

200x179mm (96 x 96 DPI)

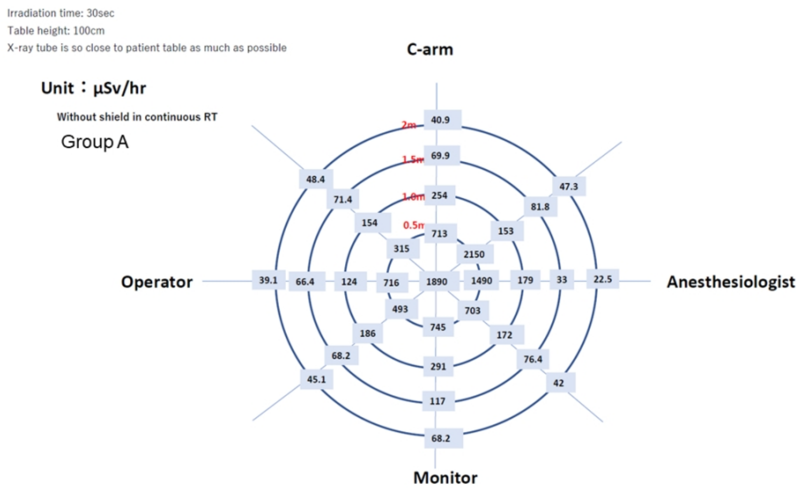


Figure S1

338x190mm (96 x 96 DPI)

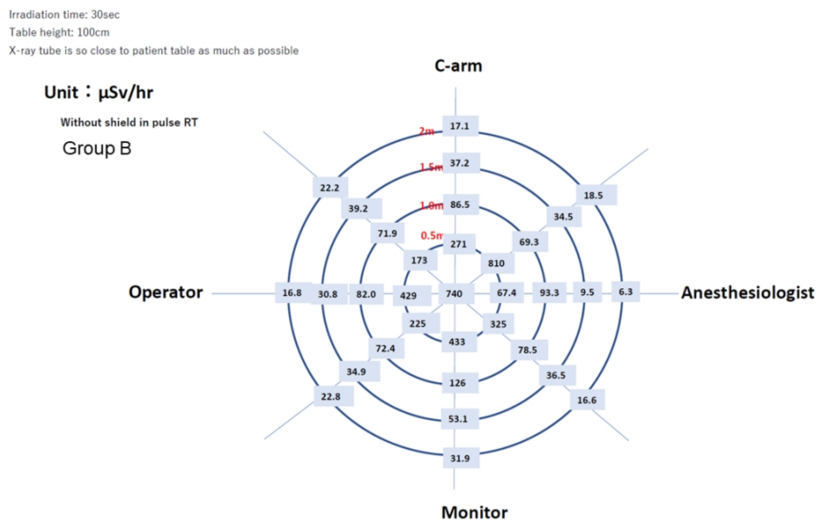


Figure S2

338x190mm (96 x 96 DPI)

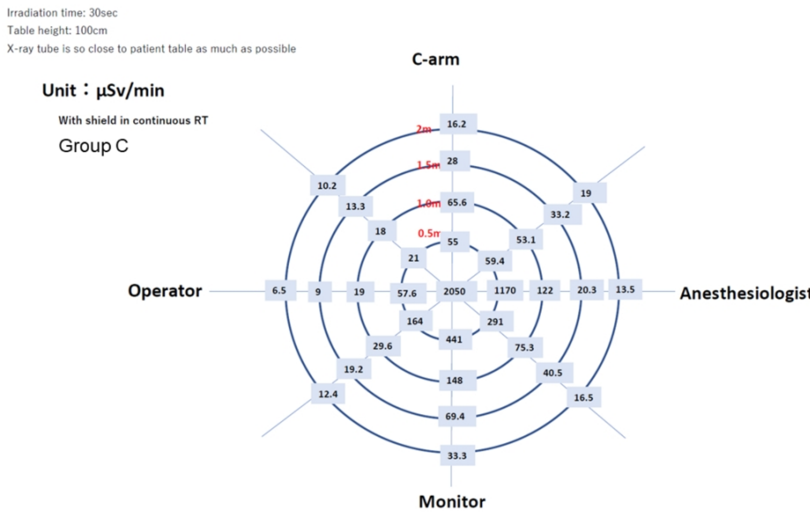


Figure S3

338x190mm (96 x 96 DPI)

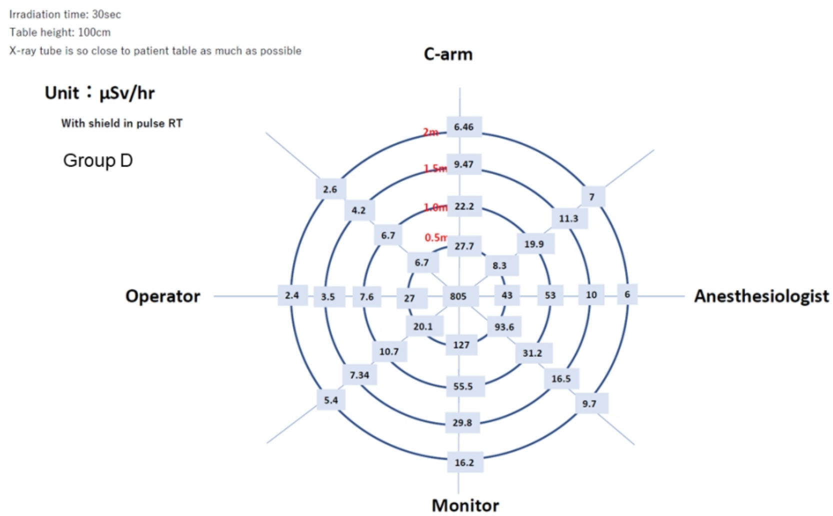


Figure S4

338x190mm (96 x 96 DPI)