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Comparison of radiation exposure to physicians between anteroposterior and lateral real-time fluoroscopy when performing lumbar transforaminal epidural steroid injections

A randomized controlled trial

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Abstract

Background: Lumbar transforaminal epidural steroid injections are used widely to alleviate low back radicular pain, but it requires real-time fluoroscopy, which can increase the risk of radiation exposure. Anteroposterior or lateral real-time fluoroscopy can be used during lumbar transforaminal epidural steroid injections, but there have been no comparative studies on the exposure of physicians to radiation from anteroposterior or lateral real-time fluoroscopy. The aim of this study was to compare the cumulative radiation exposure to each body part of the physician according to the method of real-time fluoroscopy when performing lumbar transforaminal epidural steroid injections.

Methods: A single physician performed lumbar transforaminal epidural steroid injections, and 2 groups of patients were formed based on the method used: group A (anteroposterior real-time fluoroscopy) and group L (lateral real-time fluoroscopy). Dosimeters were placed outside the chest, inside the chest, outside the thyroid collar, inside the thyroid collar, outside the groin, inside the groin, outside the lead gloves, and left rim of the glasses.

Results: A total of 200 lumbar transforaminal epidural steroid injections were analyzed, and the radiation exposure was measured by cumulative dose equivalents in mSv. The dose equivalents were lower at every level in group A compared with group L except for outside the groin.

Conclusions: The cumulative radiation exposure at all the measurement sites was lower for anteroposterior real-time fluoroscopy compared with lateral real-time fluoroscopy when performing lumbar transforaminal epidural steroid injections, except for outside the groin.

Abbreviations: AP = anteroposterior; BMI = body mass index, DAP = dose area product, DE = dose equivalent, L-TFESIs = lumbar transforaminal epidural steroid injections, SIS = International Spine Intervention Society.

Keywords: body part, groin, radiation exposure, real-time fluoroscopy, scattered radiation, transforaminal epidural steroid injections

1. Introduction

Spine interventionists frequently employ fluoroscopy to guide injection procedures. Fluoroscopy ensures the accuracy of therapeutic injections with a sufficient percentage of injectates reaching the target site and thus affects treatment outcomes.[1] This technique may reduce complications such as intravascular injections, dural punctures, paraplegia secondary to spinal cord infarctions, cerebellar infarctions, and even death.[2] However, the increase in fluoroscopically-guided procedures in recent years has led to a growing concern about radiation exposure. Lumbar transforaminal epidural steroid injections (L-TFESIs) are one of the most common procedures for patients suffering from low back radicular pain,[3] and fluoroscopic imaging is also mandatory.[4,5]

There are 2 main types of radiation exposure. One is primary radiation, direct exposure to the body where the useful X-ray beam enters the body.[6] The other is secondary radiation, indirect exposure related to leakage and scattered radiation. Leakage radiation is defined as radiation that escapes

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from the shielding of the X-ray tube. This is usually a small quantity, which is not a significant concern.[7] Scattered radiation is defined as radiation that travels in all directions after interacting with objects (body of a patient or physician, operating table)[8] and is a critical route of radiation exposure to physicians.[5,9–11]

Real-time (continuous) fluoroscopy is necessary to determine where and how far the injectate spreads and to detect intravascular or intrathecal injections during L-TFESIs.[12] However, real-time fluoroscopy is thought to increase radiation exposure[13] and scattered radiation is higher with steep oblique and lateral fluoroscopy.[9] However, when performing real-time fluoroscopy in L-TFESIs, anteroposterior (AP) real-time fluoroscopy is implemented, but lateral real-time fluoroscopy has also been used depending on the physicians' preference.[14,15]

To the best of our knowledge, there is still no standard for whether real-time fluoroscopy should be performed during AP or lateral monitoring, and there has been no comparative study on the radiation exposure of physicians (especially, according to each body part of the physician) between AP and lateral real-time fluoroscopy during L-TFESIs. We hypothesized that are differences in the cumulative radiation exposure for each body part between AP and lateral real-time fluoroscopy when performing L-TFESIs. Therefore, the aim of this study was to compare the cumulative radiation exposure to the body parts of physicians according to the method of real-time fluoroscopy in L-TFESIs.

2. Methods

This study was a prospective, randomized controlled clinical trial. This study received full approval from the institutional review board of Ewha Womans University Hospital (EUMC 2020-09-024-006) and was conducted according to the ethical principles of the Declaration of Helsinki. This study was registered with the Clinical Research Information Service (registration number: KCT 0006494, https://cris.nih.go.kr/cris/search/detailSearch.do/19015). The period of this study began in January 2021 and ended in July 2021. All patients provided written informed consent. A single physician (Y.S.H.: specialist in pain medicine, 6 years of experience) carried out 200 L-TFESIs, and she also provided written informed consent.

The inclusion criteria consisted of patients treated with fluoroscopically-guided L-TFESIs with low back radicular pain from a herniated nucleus pulpous or spinal stenosis. The injection level varied by the patient's symptoms and the location of nerve root compression. The exclusion criteria included allergy to iodine dye, pregnancy, a history of surgery with surgical instruments implanted, and history of compression fractures.

We divided the patients into 2 groups: group A (AP real-time fluoroscopy) and group L (lateral real-time fluoroscopy). Patients were randomly allocated to 1 of the 2 groups using a randomizing table generated using Random allocation software version 1.0.0. Block randomization with a block size of 4 was used in order to obtain equal group numbers. The randomization sequence was designated by a statistician not involved in this study, and the given group was determined by the physician who opened the sealed envelopes just before the procedure.

One of the authors (Y.S.H.) was provided with 8 dosimeters before the procedures. The dosimeters were marked in accordance with group A or group L, respectively. In groups A and L, the dosimeter badges were displayed outside the chest, inside the chest, outside the thyroid collar, inside the thyroid collar, outside the groin, inside the groin, on the left rim of glasses, and finger (outside lead gloves; Fig. 1A–H). The thickness of the lead apron worn by the physician was 0.5 mm. The dosimeter badges outside and inside the chest were attached at the shirt-pocket level of the apron. The dosimeter badges outside and inside the thyroid collar were placed anteriorly and posteriorly over the neck. The dosimeter badges outside and inside the groin area were placed at the front and back of the apron at the level of the physician's groin. The dosimeter badges were optically stimulated luminescence dosimeters. The ring dosimeters were put on the index finger of the physician's dominant hand (outside the lead glove) and the rim of lead glasses. The ring dosimeters were thermoluminescent dosimeters. The C-arm fluoroscopy machine performed in the study was a Siremobil Compact L (Siemens, Mountain View, CA), and the automatic exposure control mode was used.

Figure 1. Allocation of dosimeters. (A) Outside the chest, (B) inside the chest, (C) outside the thyroid collar, (D) inside the thyroid collar, (E) outside the groin, (F) inside the groin, (G) on glasses, and (H) finger.

2.1. Procedure setting

L-TFESIs were performed in a sterile and lead-shielded operating room. The blood pressure, electrocardiogram, and pulse oximetry of all patients were monitored throughout the procedure. Each patient was in a prone position on the operating table and supported by pillows under the abdomen and knees to reduce lordosis. The injection site in the lumbar region was prepared and draped using a sterilized technique. The procedure was as follows according to the International Spine Intervention Society (SIS) Guidelines[12]: (1) the C-arm was tilted to a cephalic or caudal direction to adjust the superior and inferior endplates of the intervertebral body (Fig. 2A); (2) and it was rotated in an ipsilateral (right or left) direction about 15 to 25° degrees for optimizing the Scotty dog shadow in the oblique projection. The spinal needle entry point was checked using an indicator. A 22-gauge 5-inch spinal needle was guided to this point and advanced into the intervertebral foramen, subpedicular location superolateral to the exiting spinal nerve, the so-called "safe triangle," by accurately checking the needle tip location. When the needle tip was adjacent to the "safe triangle," and the inferolateral border of the vertebral body in the oblique projection (Fig. 2B); (3) the C-arm was rotated to a lateral projection and the needle was cautiously advanced to approximately 1 to 2 mm dorsal to the posterolateral vertebral body. When the needle was at the appropriate location, aspirations were performed. If there was no blood or cerebrospinal fluid, 0.2 to 0.3 mL of a test dose of contrast media was injected through the extended tubing to confirm the epidural flow of the injectate and to confirm the inadvertent intravascular or intrathecal injection (Fig. 2C); and (4) a repeat AP projection was performed to confirm the epidurogram (Fig. 2D). All the procedures from (1) to (4) were performed with intermittent fluoroscopy, and the numbers of AP, oblique, or lateral intermittent fluoroscopic monitoring were recorded respectively. Last, further injection contrast media was injected through the extended tubing for 3 seconds with AP real-time fluoroscopy in group A (Fig. 2E) or with lateral real-time fluoroscopy in group L (Fig. 2F). Then, the treatment drug (a total of 4 mL of 0.1875% ropivacaine with 5 mg dexamethasone disodium phosphate) was injected, and patients stayed still for 30 minutes in the recovery room while checking for adverse events.

2.2. Assessments

Information about patient sex, age, height, weight, body mass index (BMI), level of procedure, side of procedure, numbers of AP, oblique or lateral intermittent fluoroscopy before real-time fluoroscopy (i.e., number of intermittent fluoroscopy taken during the procedure in Fig. 2A–D), procedure time, and fluoroscopy time were collected. The procedure time was measured using a timer from the beginning to the end of each procedure. The start and end points were defined as when the needle first went through the skin and when it was removed from the skin, respectively. Fluoroscopy time was automatically measured by the C-arm. The radiation dosimetry included the cumulative dose equivalent (DE) in mSv (Sievert) for the period during which 100 TFESIs were performed in each group. The radiation dosimetry was reported from Hanil Nuclear.

2.3. Statistical analysis

This study aimed to compare cumulative radiation exposure (mSv). The sample size could not be calculated because the cumulative dose is a value for which variation (e.g., standard deviation) is not available. Therefore, we referred to similar existing studies that measured radiation exposure during spinal procedures.[6,16,17] In each article, the cumulative radiation exposure over 100 procedures was measured, and the number of L-TFESIs was determined.

The normal distribution of continuous variables was evaluated by the Shapiro–Wilk test. Continuous variables are expressed as the mean ± standard deviation, and ordinal data are expressed as a number. Parametric data were analyzed by independent the *t* test and descriptive variables were evaluated by the χ^2 test. Values of $P < .05$ were considered statistically significant. All statistical analyses were performed using SPSS 18 software (Chicago, IL).

3. Results

A total of 200 L-TFESIs (100 L-TFESIs per group) were performed in this study and there were no exclusions (Fig. 3).

Table 1 shows the demographic characteristics that can affect scattered radiation including sex, age, height, weight, BMI, level and side of procedures, the numbers of AP, oblique or lateral intermittent fluoroscopy monitoring, procedure time, and fluoroscopic time. There were no significant differences in demographic characteristics between the 2 groups.

Table 2 shows the cumulative DEs in mSv among both groups in accordance with various body levels. As expected, the cumulative DEs were higher outside the apron at the level of the chest, thyroid collar, and groin compared with inside the apron (fingers and eyes were only measured at outside sites). In group A, the DEs at all levels inside the apron were all 0.01 mSv, which was reduced by more 99% compared with outside the apron. In addition, the DEs were lower at every level in group A compared with group L except for outside the groin; the DE of group A was 97% outside the chest, 25% inside the chest, 60% outside the thyroid, 13% inside the thyroid, 81% at the fingers, and 91% at the eyes. Therefore, the DEs at all sites outside and inside the apron in group A were lower than in group L except for outside the groin. The DE outside the groin in group L was 87% compared to group A (Fig. 4).

4. Discussion

Our results showed that the cumulative DEs, in mSv, in all the measurement sites were lower in group A compared with group L, except for outside the groin.

Radiation exposure is defined as the quantity of X-ray or gamma radiation required to produce an amount of ionization in air at standard temperature and pressure. When patients and physicians are exposed to radiation, some of this will be absorbed into the body (radiation absorbed dose). DE is used in radiation safety to measure biologic "harmfulness" and is defined in Sv.[10]

During L-TFESIs procedures, real-time fluoroscopy is mandatory and helps confirm the needle position and target site, as well as recognizing inadvertent injection such as intravascular injection and dura punctures that can cause life-threatening adverse side effects such as cerebral infarction, paraplegia, and even death.[18] According to SIS guidelines, Bogduk described that a test dose of contrast medium indicated that the injection was not intrathecal or intravascular and that a further injection of contrast medium should be performed. This further injection should be performed under real-time fluoroscopic monitoring to determine where and how far the injectate spreads and further exclude intrathecal or intravascular injection.[12] For this reason, even if the physician uses an extension tube, it should be positioned close to the C-arm when injecting the contrast medium during real-time fluoroscopy (Fig. 2E, F).

Most radiation exposure to physicians is associated with secondary radiation, which includes leakage and scattered radiation. Leakage radiation is defined as radiation that escapes from the shielding of the X-ray tube, and the radiation exposure rate can be reduced to 0.1% at a distance of 1 m from the X-ray tube. Therefore, leakage radiation is small and not a significant concern.[7] Scattered radiation has lower energy than primary

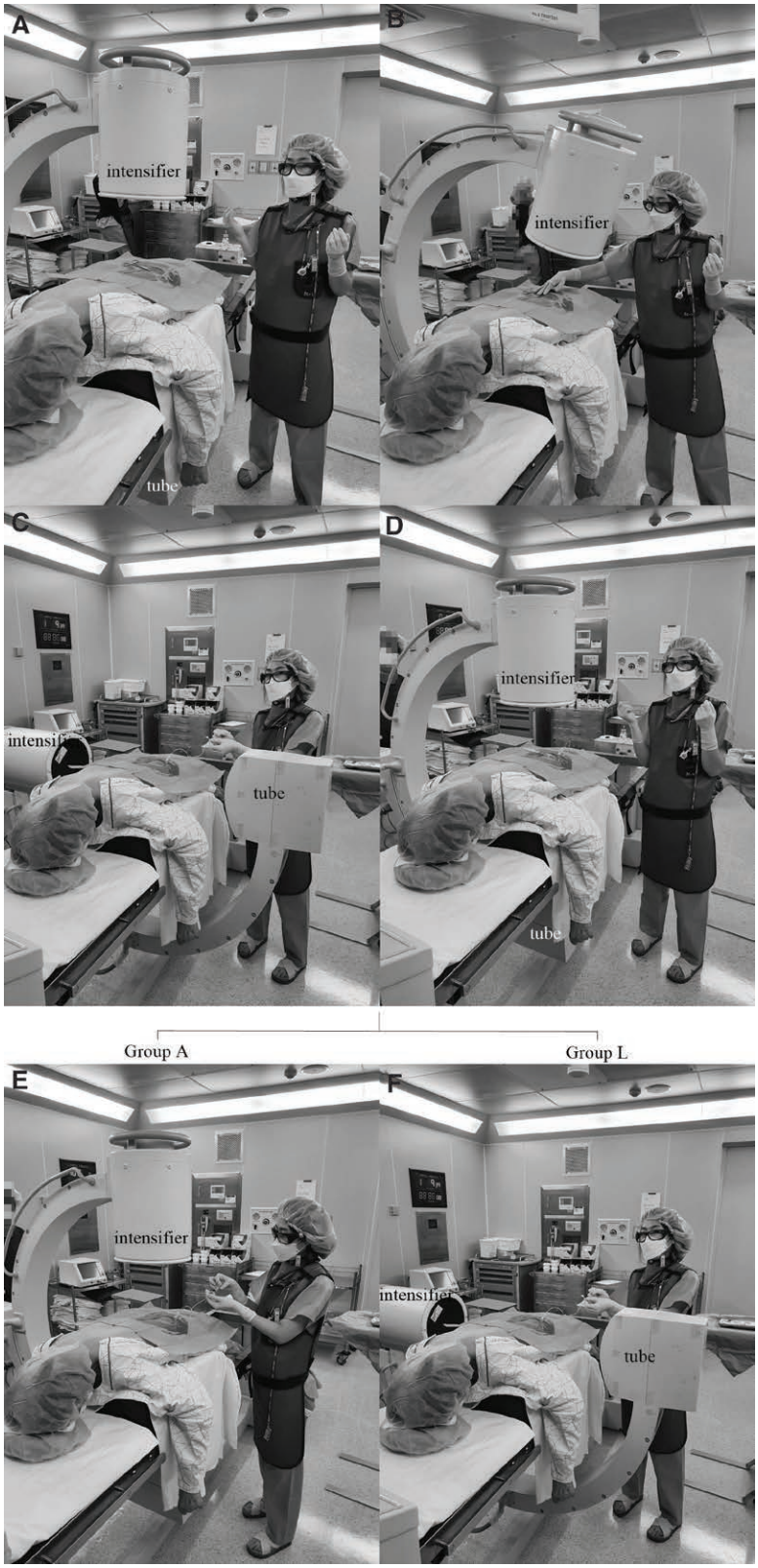

Figure 2. The procedure setting for lumbar transforaminal epidural steroid injections. (A) AP fluoroscopy, (B) oblique fluoroscopy, (C) lateral fluoroscopy, (D) AP fluoroscopy, (E) AP real-time fluoroscopy in group A, and (F) lateral real-time fluoroscopy in group L. AP = anteroposterior.

energy and deflected radiation occurs with increasing proportionally from primary radiation that has interacted with objects such as patients, floor, or X-ray tube in its path and comes from any direction, which is critical for radiation exposure to physicians.[5,9–11]

Several factors can affect the physicians' exposure to scattered radiation, including the distance, backscattered radiation, collimation, mode, and beam-on time.[11] First, the X-ray tube should be positioned beneath the operating table to reduce backscattered radiation, and the physician should stand as

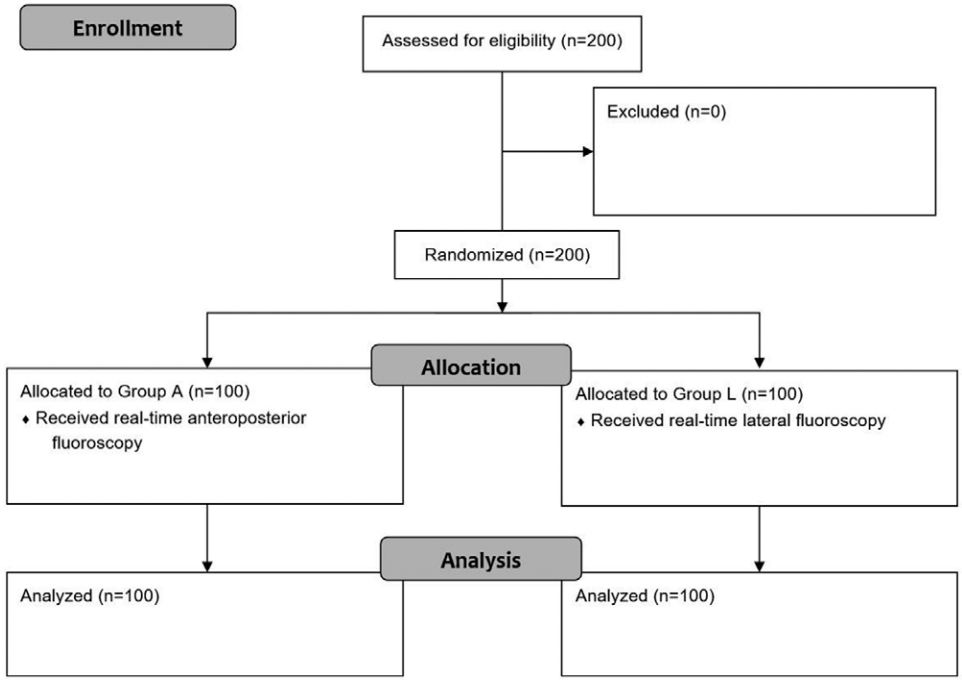

Figure 3. CONSORT flow diagram. A total of 200 L-TFESIs were performed and there were no exclusions. Consequently, 100 L-TFESIs remained in group A, and 100 L-TFESIs remained in group L. L-TFESIs = Lumbar transforaminal epidural steroid injections.

Table 1

Demographic data.

Valuables	Group A (n = 100)	Group L (n = 100)	*P* value
Sex (M/F)	48/52	39/61	.199
Age (yr)	59.0 ± 14.2	63.9 ± 14.1	.085
Height (cm)	162.9 ± 10.9	161.9 ± 9.4	.524
Weight (kg)	67.2 ± 13.9	64.8 ± 11.9	.414
BMI	25.2 ± 3.7	24.6 ± 2.9	.335
Level of procedure (L1/L2/L3/L4/L5)	0/1/10/41/48	0/1/6/31/62	.244
Side of procedure (right/left)	45/55	46/54	.887
Number of intermittent fluoroscopic monitoring before real-time fluoroscopy			
Anteroposterior	3.7 ± 2.0	3.4 ± 1.3	.570
Oblique	8.2 ± 3.5	7.9 ± 3.8	.276
Lateral	6.2 ± 2.3	6.6 ± 2.8	.486
Procedure time (s)	172.5 ± 71.4	176.6 ± 74.7	.380
Fluoroscopic time (min)	0.27 ± 0.12	0.27 ± 0.12	.931

Values are expressed as a number or the mean ± standard deviation.
BMI = body mass index, F = female, M= male.

Table 2

Illustration of cumulative dose equivalent in mSv.

Valuables	Group A (n = 100)	Group L (n = 100)
Chest (outside)	2.08	2.14
Chest (inside)	0.01	0.04
Thyroid (outside)	1.39	2.31
Thyroid (inside)	0.01	0.08
Groin (outside)	1.74	1.51
Groin (inside)	0.01	0.01
Fingers	0.55	0.68
Eyes	0.73	0.80

far away as possible from the X-ray tube during AP fluoroscopy.[6,8,10,19,20] The same applies to lateral fluoroscopy, that is, the scattered radiation on the side of X-ray tube is 2 to 3 times higher than the side of image intensifier.[21] Therefore, physicians are recommended to stand on the side of the image intensifier or stay at least >1 m away from the X-ray tube.[22] However, as mentioned above, physicians cannot avoid being positioned close to the X-ray for real-time fluoroscopic imaging and they must stand on the X-ray tube side during lateral fluoroscopy while performing L-TFESIs (Fig. 2F). In addition, scattered radiation is higher with steep oblique and lateral positions.[9] Therefore, the cumulative DEs of all measurement sites may be higher in group L than in group A, except for the groin. The results showing that the DEs in the groin were higher in group A could be explained by the closer location of the lower part of the body to the X-ray tube, which can increase backscattered radiation during AP fluoroscopy. We confirmed that the distance from the X-ray tube is one of the major factors affecting the radiation exposure of physicians. Because this is a factor that can be corrected, physicians should be as far away from the X-ray tube as possible. Second, collimation enhances image contrast by decreasing the amount of scattered radiation. However,

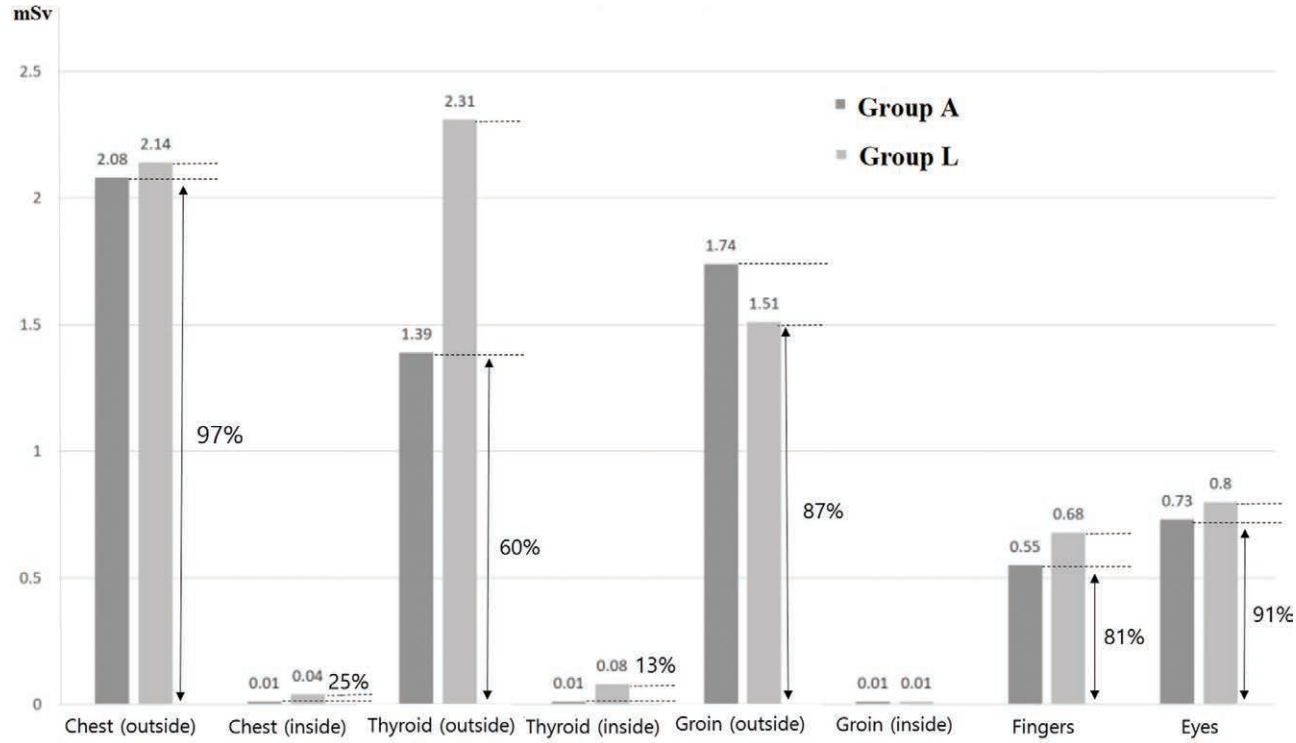

Figure 4. Cumulative dose equivalent in mSv.

it appears as if this protective effect may not be as pronounced for the physician[23] and an inconsistent size of collimation can affect the results; therefore, we did not use collimation in this study. Third, pulsed-mode fluoroscopy may minimize the scattered radiation by decreasing the total beam-on time.[11] However, the pulsed mode may not be accurate for monitoring injectate spreads and intrathecal or intravascular injection compared with real-time fluoroscopy; therefore, we did not use pulsed-mode fluoroscopy. Fourth, radiation exposure is proportional to the duration of beam-on time. However, our results showed that the total fluoroscopic time and number of intermittent fluoroscopic monitoring were not statistically different between the 2 groups. In addition, thicker and heavier patients generate a greater amount of scattered radiation because higher values of kVp and mA are required for better visualization[24]; however, our results showed that there was no difference in height, weight, and BMI between the 2 groups.

Although several studies have reported the cumulative radiation exposure of physicians for each body part in spine interventions,[16,17] most of them have focused on the radiation exposure of physicians in the upper part of the body, and the lower part of the body has been neglected.[9] To the best of our knowledge, there are only 2 studies on radiation exposure to the lower part in spine interventions.[5,9] Moreover, although these studies have measured scattered radiation exposure to the lower part of the body, cumulative radiation exposure was measured with a range of inclusion criteria, including different procedures (facet joint nerve blocks, epidural blocks, percutaneous adhesiolysis, intercostal nerve blocks, and sympathetic blocks), modes (from pulsed imaging to continuous fluoroscopic imaging), and postures (prone or supine position).[5,9] However, we focused on comparing the cumulative radiation exposure to each body part (including the groin) of the physician according to the method of real-time fluoroscopy in L-TFESIs.

The dose area product (DAP) value is used to assess the radiation dose (entrance surface dose multiplied by the field size) and is commonly used for fluoroscopy in moving fields.[25] The DAP value is an independent parameter of distance from the source and does not include scattered radiation. It requires calibration using conversion factors for measuring the skin entrance dose and it is measured in real time. Although DAP has been used in several studies of radiation exposure to physicians,[18,25–27] we measured cumulative DEs to examine differences in the exposure of body parts of a physician and to monitor radiation exposure doses to skin considering scattered radiation.

The International Council on Radiation Protection regulates the annual permissible radiation dose to reduce the amount of scattered radiation. The recommended annual limited radiation exposure level varies depending on the body part: 500 mSv for the thyroid, extremities, and gonads; 150 mSv for the lens of the eye and 50 mSv for the whole body.[28] Considering the annual limited value, the DEs inside the apron appeared to be well within the maximum safe allowable exposure limits when performing L-TFESIs. Even with the DEs measured at the rim of the glasses, approximately 18,000 cases per year can be performed. However, establishing reference levels in the area of fluoroscopic intervention is difficult due to the variability of the duration and complexity of each intervention. Therefore, radiation exposure should be minimized in keeping with the as low as reasonably achievable philosophy in spine intervention.

Our study had several limitations. First, only 1 physician at a single center was involved as the subject in this study to minimize other variables. Accordingly, there may be personnel differences in the distance between the X-rays and the physician, fluoroscopy time, and the physician's skills, which might have affected the results. This may have decreased the generalizability of our findings. Second, we performed the TFESIs according to the SIS guidelines in order to implement procedures as consistently as possible; however, there might be some differences between the procedures, including the distance of the physician in relation to the X-ray. Third, we did not place a control dosimeter inside the operating room, and background radiation was not checked. However, the goal of our study was to compare the radiation exposure between the 2 groups and both groups were investigated under the same conditions by leaving the dosimeter outside the operating room during times other than the

procedure. Fourth, when the efficiency of the C-arm declines beyond a certain point, the automatic exposure control function compensates for the poorer quality of the images by boosting the intensity of the incipient beam, which gives rise to higher exposure rates. The C-arm we used is not a new model, and the radiation exposure may be different depending on each model.

In conclusion, the cumulative radiation exposure of all the measurement sites was lower for AP real-time fluoroscopy compared with lateral real-time fluoroscopy when performing L-TFESIs, except for outside the groin. Therefore, in L-TFESIs, AP real-time fluoroscopy may be recommended to reduce the radiation exposure of physicians; however, it should be noted that radiation exposure to the groin may be higher with AP real-time fluoroscopy.

Author contributions

Conceptualization: Won-joong Kim
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Formal analysis: Seung Hee Yoo
Funding acquisition: Won-joong Kim.
Methodology: Won-joong Kim
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Visualization: Won-joong Kim.
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