Clinical Trial/Experimental Study

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Evaluation of protective equipment for the reduction of radiation exposure to physicians performing fluoroscopically guided lumbar transforaminal epidural steroid injections

A randomized controlled trial

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Abstract

Background: Spine interventionists frequently employ fluoroscopy to guide injection procedures. The increase in fluoroscopically guided procedures in recent years has led to a growing concern about radiation exposure. A new method of covering the C-arm tube with a lead apron has been suggested to reduce radiation exposure. This study aimed to compare the radiation exposure when performing lumbar transforaminal epidural steroid injections (TFESIs) using this new method to a control group.

Methods: A total of 200 patients who underwent lumbar TFESIs by a single physician were recruited. Patients were divided into 2 groups, the new method group (group A) and the control group (group C), and the amount of radiation exposure was compared. The dosimetry badge locations were marked as outside of apron, inside of apron, outside of thyroid collar, inside of thyroid collar, ring, and glasses.

Results: The cumulative dose equivalents of all the measurement sites were reduced in group A compared with group C, and the most reduced site was inside the thyroid collar.

Conclusions: Covering the C-arm tube with a lead apron can be effective in reducing the cumulative radiation exposure when performing fluoroscopically guided TFESIs.

Abbreviations: DE = dose equivalent, RAD = radiation absorbed dose.

Keywords: analgesia, epidural, fluoroscopy, injections, radiation, radiation equipment and supplies, radiation protection, scattering

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. To mitigate potential radiation hazards, multiple techniques have been introduced, including physical protection, decreased duration of the intervention, very low-frame-rate-pulsed fluoroscopy, removal of the grid, "last image hold" feature on equipment, electronic collimation, and intermittent fluoroscopy.[3]

Radiation exposure is defined as the amount of X-rays or gamma radiation required to produce a specific unit of ionization in the air at standard temperature and pressure. Patients and physicians are exposed to radiation, and only a portion of it will be absorbed into the body, called the radiation absorbed dose (RAD). Dose equivalent (DE) is used in radiation safety to measure the biologic "harmfulness" of any RAD. DE is defined in REM or Sv (1 mREM = 0.01 mSv).[4]

Radiation exposure to the physician typically comes from primary radiation or scatter.[5] Another source is leakage of

Editor: Eric Bush.

This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korean government (MSIT) (NRF-2019R1G1A1100523).

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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How to cite this article: Kim Wj, Yoo SH, Park HS. Evaluation of protective equipment for the reduction of radiation exposure to physicians performing fluoroscopically guided lumbar transforaminal epidural steroid injections: A randomized controlled trial.. Medicine 2020;99:31(e21424).

Received: 22 March 2020 / Received in final form: 3 June 2020 / Accepted: 24 June 2020

http://dx.doi.org/10.1097/MD.0000000000021424

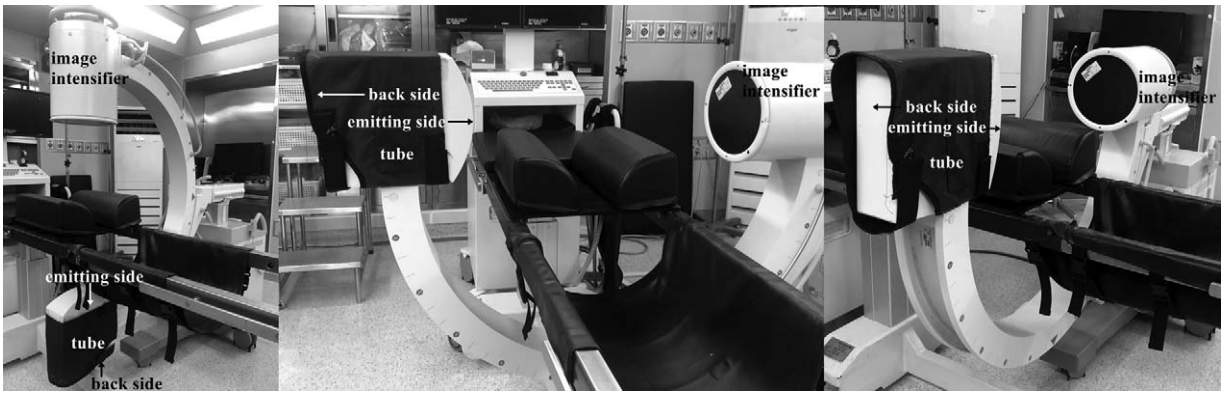

Figure 1. C-arm tube covered with an apron.

radiation from the C-arm unit, but this is of a lesser concern.[3] Lumbar transforaminal epidural steroid injections (TFESIs) are one of the most common procedures in spine intervention. TFESIs under fluoroscopy have been advocated as a means to assure proper localization within the epidural space.[6,7] However, in performing TFESI, physicians often stand on the exit side of the image intensifier, use monitoring in the lateral projection of fluoroscopy, and perform the procedure closer to the X-ray tube for convenience. These can increase radiation exposure to the physician.

A new method of covering the C-arm tube with a lead apron has been suggested to reduce leakage radiation[8] (Fig. 1). Lee et al[8] investigated the dose rate according to the distance of the radiation leaked from the C-arm tube in the lateral view and demonstrated a shielding effect. However, there currently have not been any clinical studies investigating the possible reduction in radiation exposure when using this new method for TFESIs. Therefore, the purpose of our study was to compare the cumulative DE between a group of TFESIs performed under the new method of covering the C-arm tube with an apron and a control group.

2. Methods

A total of 200 patients who underwent lumbar TFESIs by a single physician for radicular pain were recruited. This study was conducted with the full approval of the Institutional Review Board (EUMC 2018-07-063-001) and by the ethical principles of the Declaration of Helsinki. A subject is one of the authors, and we only used the existing data of patients (sex, age, height, weight, and diagnosis) rather than the new data of patients. Therefore, our IRB waived the requirement for procuring written informed consent. This study was registered with the Clinical Research Information Service (CRIS, registration number: KCT0003394). Inclusion criteria consisted of patients with radicular pain from a herniated nucleus pulposus or spinal stenosis, which was treated with fluoroscopically guided lumbar TFESIs. The level of injection varied according to the patient's symptoms and the location of nerve root compression. Exclusion criteria included an allergy to iodine dye, a history of surgery, and a history of compression fractures.

We divided the patients into 2 groups, group A (C-arm tube covered with a 0.35 mm lead apron) and group C (control group). The patients were randomly assigned to one of the 2 groups using a randomizing table generated using Excel 2016 (Microsoft Corporation, Redmond, WA). Block randomization with a block size of 4 was used to prevent imbalances in treatment assignments. The randomization sequence was generated by a statistician who was not involved in this study. The assigned group was revealed to the physician just before the procedure via numbered sealed envelopes. One radiography technologist allocated 6 badges to the physician before the procedures. The badges were marked as outside of apron (Fig. 2A), inside of apron (Fig. 2B), outside of thyroid collar (Fig. 2C), inside of thyroid collar (Fig. 2D), ring (Fig. 2E), and glasses (Fig. 2F). The apron was 0.5 mm lead. The badge of the apron was placed at the shirt-pocket level. The thyroid badge was placed anteriorly over the neck. The ring badge was placed on the ring finger of the physician's dominant hand (outside of the lead glove). The glasses badge was placed on the frame of the lead glasses. When the badges were not in use, they were all placed together 10 m outside of the operating room. The C-arm used in this study was Siremobil Compact L (Siemens, Mountain View, CA), and the height of the procedure table and C-arm was fixed.

2.1. Procedure setting

TFESIs were performed in a sterile operating room. All patients were monitored by pulse oximetry, blood pressure, and electrocardiogram before, during, and after the procedure. Each patient was placed in the prone position, prepared for the injection, and draped using sterile technique. The procedure was as follows: the cephalo-caudal angle of the C-arm was adjusted, allowing the incident X-ray beam to be parallel to the inferior and superior endplates of the intervertebral disc (Fig. 3A); the right and left angles of the C-arm were rotated toward the lesion site by 15° to 25°. A 22-gauge 5-inch spinal needle was guided inferior to the pars interarticularis and into the intervertebral foramen. The needle was advanced into the "safe triangle," which was inferior to the pedicle and superolateral to the exiting spinal nerve (Fig. 3B); in the lateral projection, needle placement was confirmed with the needle tip approximately 1 to 2 mm dorsal to the posterolateral vertebral body. Aspirations were routinely performed. If no blood or cerebrospinal fluid was aspirated, 0.5 to 2 mL of contrast media was injected through the extended tubing to confirm the epidural flow of the injectate and to provide our intravascular, intrathecal, and soft tissue infiltration with continuous monitoring (Fig. 3C); repeat anteroposterior (AP) projection was performed to confirm the epidurogram (Fig. 3D); a total of 4 mL of 0.1875% ropivacaine with 5 mg dexamethasone disodium phosphate was injected; patients then spent

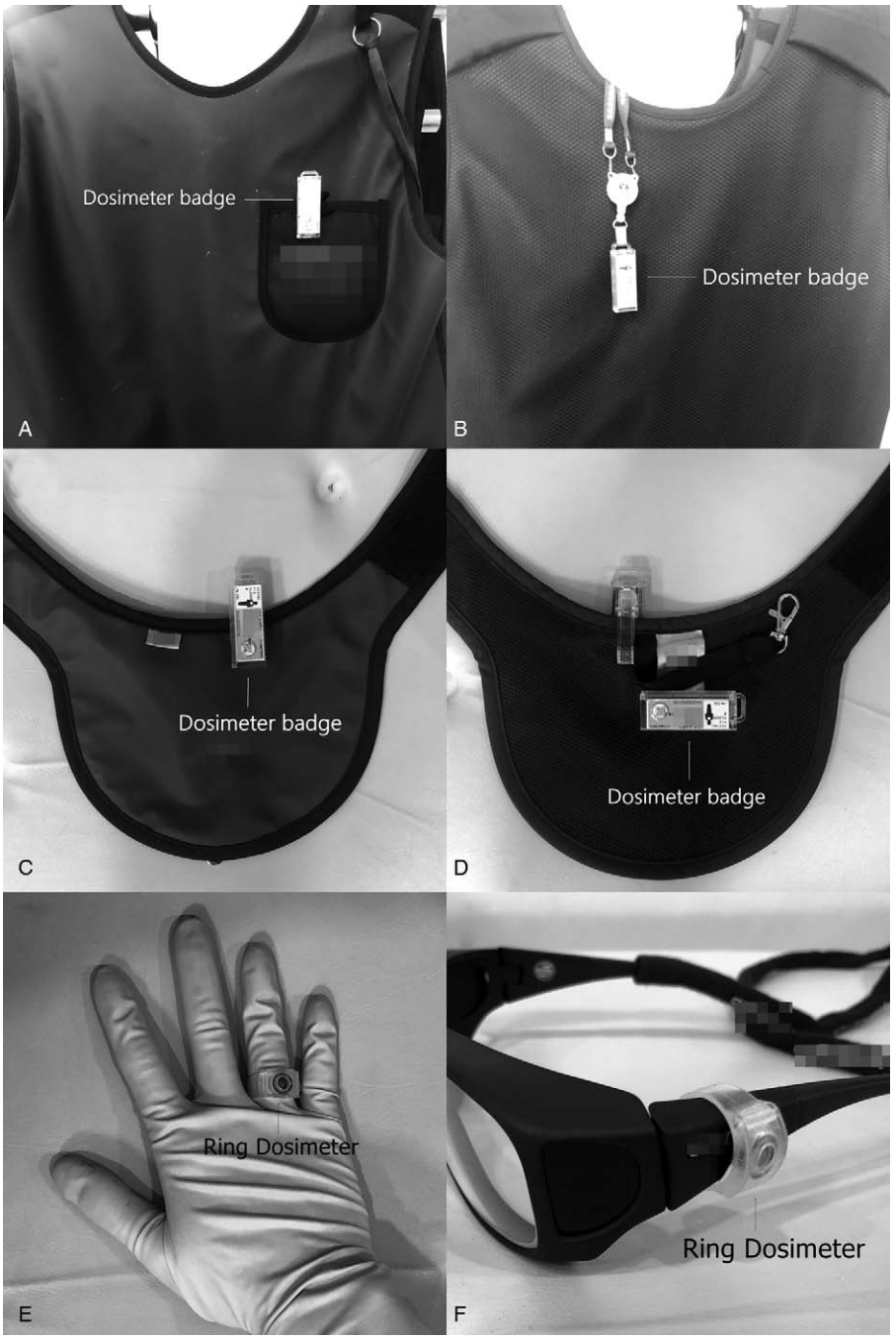

Figure 2. Allocation of dosimeter badges. (A) Outside of apron, (B) inside of apron, (C) outside of thyroid collar, (D) inside of thyroid collar, (E) ring, and (F) glasses.

30 x0200A;minutes in the recovery unit. Intermittent fluoroscopy with "last image hold" features was used. An auto exposure control mode was used, which manipulates the peak X-ray energy and the current of the fluoroscopic X-ray beam that provides the appropriate image contrast and brightness on the viewing monitor.

2.2. Assessments

Patient sex, age, height, weight, BMI, level of TFESIs, location of TFESIs, total procedure time, total fluoroscopy time, the voltage in kV (p), and amperage in mA were collected. Total procedure time was documented manually from the beginning to the end for each intervention. The beginning and endpoints were defined when the needle first penetrated the skin and first exited the skin, respectively. Our fluoroscopic unit could document peak skin dose and fluoroscopy time, so total fluoroscopy time, the voltage in kV (p), and amperage in mA were obtained. The radiation dosimetry included the cumulative DE in mSv for the period during which 100 TFESIs were performed in each group. Separate readings were obtained for all badges. The radiation dosimetry was reported from Hanil-Nuclear.

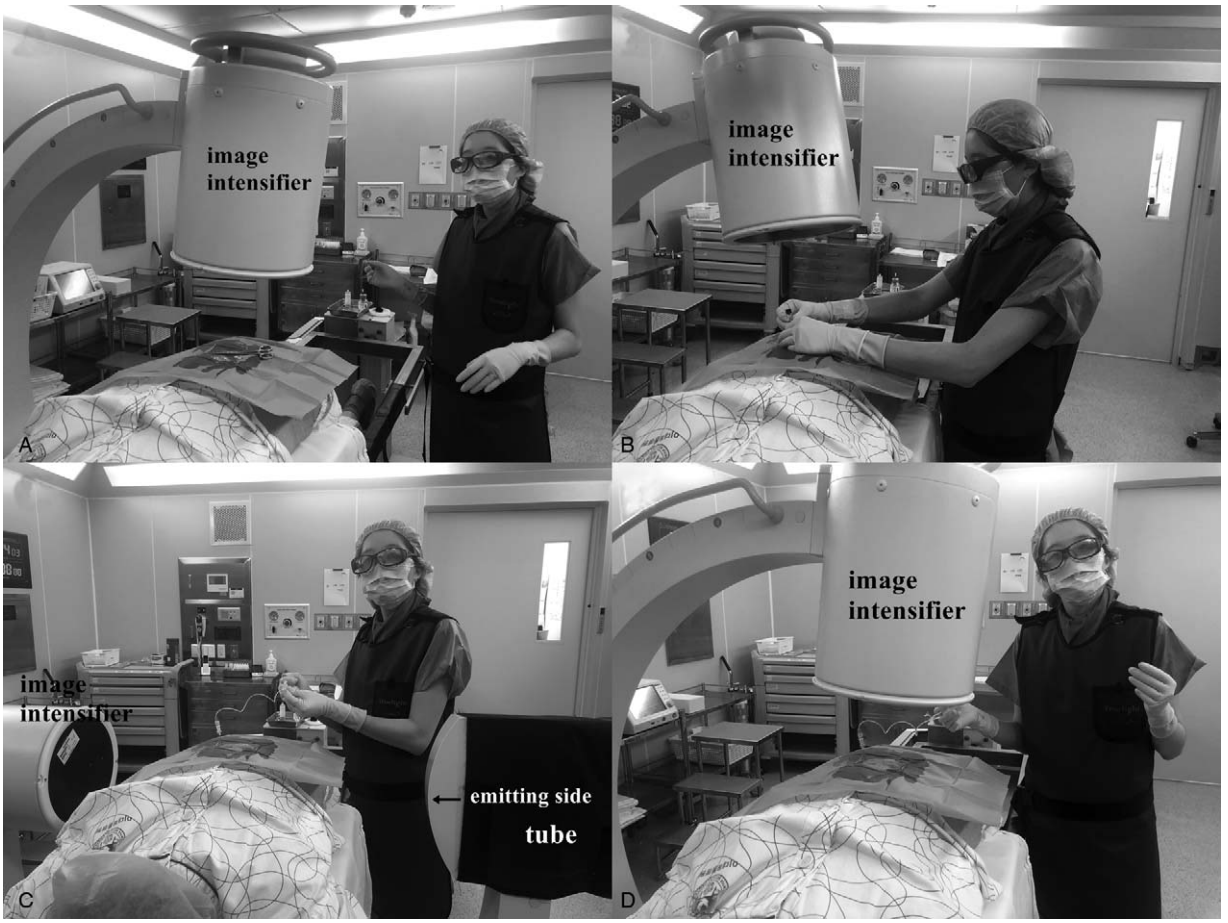

Figure 3. The procedure for lumbar transforaminal epidural steroid injections. (A) Anteroposterior view, (B) oblique view, (C) lateral view, and (D) anteroposterior view.

2.3. Statistical analysis

This study aimed to compare the cumulative DE in mSv, but 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.[9,10] In each article, the cumulative radiation exposure over 100 procedures was measured, and the number of patients was determined. Continuous variables were reported as a mean ± SD, and categorical variables were reported as numbers. Demographics were compared between the 2 groups using Student *t* test or χ^2 test, as appropriate. All statistical analyses were performed using the Statistical Package for the Social Sciences, version 18.0 (IBM Corporation, Armonk, NY).

3. Results

Two hundred patients (100 patients per group) were included in this study. There were no exclusions.

Table 1 illustrates the demographic data. Several factors that can affect radiation exposure were analyzed, including patient sex, age, height, weight, and BMI. We found no significant differences between the 2 groups in any of these parameters.

Table 2 illustrates the cumulative DEs in both the groups. As expected, the DEs were higher outside the apron and thyroid collar than inside the apron and thyroid collar in both the groups. In addition, the DEs of every badge were lower in group A than in group C; the DE of group A was 83% at the outside chest, 81% at the inside chest, 85% at the outside thyroid, 20% at the inside thyroid, 53% at the eyes, and 83% at the fingers.

4. Discussion

Our results showed that the cumulative DEs, in mSv, of all the measurement sites were reduced in group A compared with group C, and the most reduced site was inside the thyroid collar.

Calculation of the radiation field consisted of 3 parameters: primary radiation, scatter radiation, and leakage radiation. Radiation exposure to the physician typically comes from primary radiation or scatter.[5] Primary refers to radiation in the path between the X-ray generator and the image intensifier. Scatter is the radiation produced from interactions between the primary beam and objects in its paths such as the patient, the operating table, and instruments.[3]

Leakage radiation is the radiation that escapes through the shielded head of the C-arm unit. The magnitude of leakage radiation is essentially a function of the shielding efficiency of the wall of the C-arm tube. The adequacy of this shielding must be verified during acceptance testing.[11] Most shielding designs limit the leakage radiation to 0.1% of the useful beam at 1 m from the source.[12] O'Brien et al[13] demonstrated that the maximum leakage rate at 1 m from the accelerator was 0.075% Sv per peak

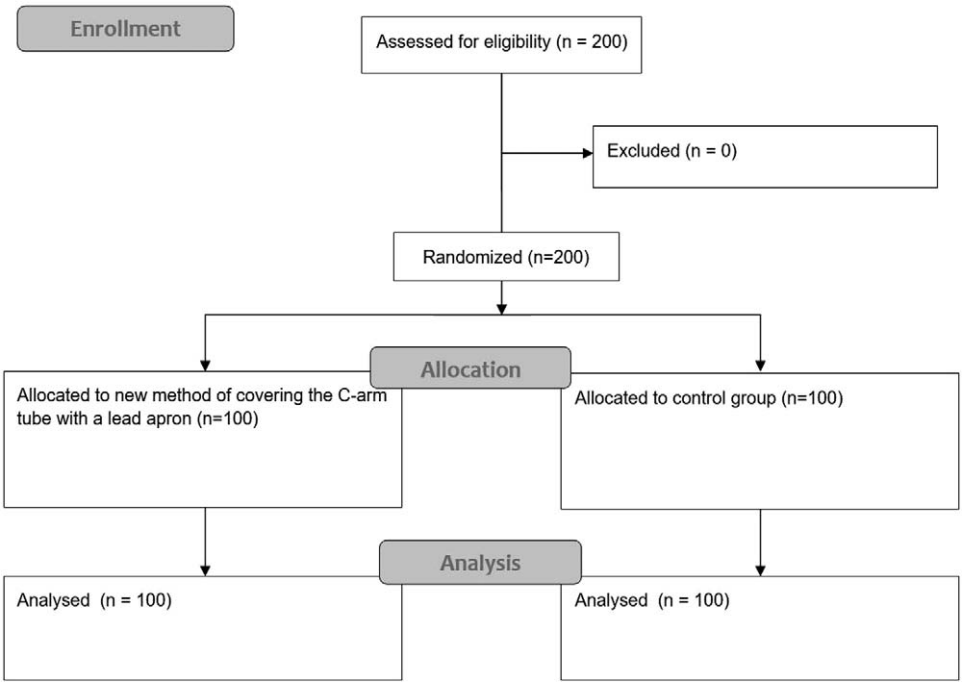

Figure 4. Xxxxx.

photon Gy. Therefore, leakage radiation is of lesser concern and has not been studied in spine intervention.

However, in performing TFESI, physicians usually stand on the X-ray tube side, use monitoring in the lateral projection of fluoroscopy, and often perform the procedure within 1 m of the X-ray tube side (Fig. 3C). When the efficiency of C-arm declines beyond a certain point, the automatic brightness 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. Similarly, any deterioration of the insulation that lines the X-ray tube may result in greater leakage of radiation from the housing apparatus.[14] Therefore, leakage radiation may be problematic in TFESIs, especially when using old C-arm equipment. It may be difficult to clearly explain the decrease in the cumulative DEs in group A, but we suggest that the new method of using the covering apron on the C-arm tube would have the most impact on reducing leakage radiation from the tube housing.

Compared with other sites, there was a large difference in the DE at the inside of the thyroid collar (decreased by 80%). Though it may be difficult to determine, a physician may sometimes wear a thyroid collar loosely, causing the badge inside the thyroid collar to be directly exposed to radiation, which might have affected our results. Otherwise, our protection method can prevent radiation exposure more effectively at the thyroid gland.

Several studies have investigated the radiation exposure of various procedures, but there has been only 1 study on TFESIs. Botwin et al[10] reported that the DE for TFESIs for all 100 procedures was 70 mREM at the ring badge, 40 mREM at the glasses badge, and 30 mREM at the outside apron badge, which differs from our results. However, they used a pulsed mode and did not use continuous monitoring in the fluoroscopy. The same

Table 1

Demographic data.

Valuables	Group A (n=100)	Group C (n=100)	*P* value
Sex (M/F)	37/63	43/57	.39
Age (y)	64.5±12.7	64.3±13.1	.95
Height (cm)	159.4±8.7	158.9±9.0	.76
Weight (kg)	63.6±10.8	64.3±11.4	.67
BMI (<20/20–24/25–29/30–40/>40)	2/7/39/46/6	1/12/31/51/5	.57
Level (L1/L2/L3/L4/L5)	1/7/7/19/66	2/9/4/22/63	.79
Location (right/left)	46/54	45/55	.89
HNP/SS/both	40/48/12	33/58/9	.36
procedure time (s)	127.8±61.4	126.1±59.2	.84
Fluoroscopic time (min)	0.25±0.11	0.26±0.14	.44
Voltage (kVp)			
Anteroposterior	101.7±11.0	102.0±10.9	.44
Oblique	101.9±9.9	101.9±9.9	.98
Lateral	109.6±1.8	109.0±5.1	.86
Amperage (mA)			
Anteroposterior	5.4±0.6	5.4±0.7	.95
Oblique	5.4±0.6	5.4±0.5	.97
Lateral	5.0±0.1	5.1±0.3	.22

HNP = herniated nucleus pulposus, SS = spinal stenosis.

Table 2

Illustration of cumulative dose equivalent in mSv.

Valuables	Group A (n=100)	Group C (n=100)
Chest (outside)	3	3.62
Chest (inside)	0.09	0.11
Thyroid (outside)	1.87	2.18
Thyroid (inside)	0.07	0.35
Eyes	0.43	0.8
Fingers	6.12	7.34

researcher reported radiation exposure for caudal epidural steroid injections,[9] where the DEs for all 100 procedures were 398 mREM at the outside apron, 15 mREM at the inside apron, 247 mREM at the glasses, and 410 mREM at the ring. DEs can vary prominently depending on the type and details of a procedure, which may provide an explanation for our differing results.

When we extrapolated our data to 1000 fluoroscopically guided TFESIs, which could conceivably be performed annually per physician, a total DE of 1.1 mSv at the inside of the apron and 3.5 mSv at the inside of the thyroid collar were calculated, even in group C. In evaluating our data, the radiation exposure appears to be well within the maximum safe allowable exposure limits, which have been established by the National Council on Radiation Protection and Measuring as a maximum permissible dose.[15] However, establishing the 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.[16]

Several factors can affect scattered radiation. Large patients generate a greater amount of scattered radiation because higher values of kVp and mA are required for better visualization.[17] In addition, when employing lateral monitoring with a C-arm unit, the amount of scattered radiation may be higher at the X-ray tube than at the image intensifier.[18] Our results can be affected by scattered radiation, but there was no statistical difference in demographic data such as height and weight between the 2 groups.

Our study had several limitations. First, only 1 physician was included as the subject and 1 C-arm equipment was used in order to minimize the effect of other variables. However, by doing so, we may have decreased the generalizability of our findings. Second, we set the procedure guideline (Fig. 3) to perform TFESIs as consistently as possible; however, there may be some differences between the procedures, including the distance of the physician in relation to the tube and fluoroscopy time for the oblique and lateral views, which may have affected the results. Third, unavoidable radiation occurs all around us (background radiation), and we did not place the control badge inside the operating room. Despite this, the goal of our study was to compare the radiation exposure between the 2 groups under the same conditions; thus, keeping the control badge outside of the operating room was justifiable. Fourth, it is necessary to investigate whether covering the C-arm tube with an apron adversely affects the machine, perhaps from thermal injury to determine if this is a feasible method that can be applied clinically.

In conclusion, our method of covering the C-arm tube with an apron can effectively reduce radiation exposure during fluoroscopically guided TFESIs. Future, larger studies that include other procedures should be conducted to investigate the effect of this protective equipment on the effective reduction of radiation exposure to physicians.

Acknowledgments

The authors thank Yeon Sil Lee, Yu Jin Choi for their assistance in the preparation of this manuscript.

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