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Sterile Radiation Protective Sheet Placed on the Patient's Abdomen during Hepatic Arterial Chemoembolization Reduces Radiation Dose to the Operator's Eyes

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Purpose: To evaluate efficacy of a sterile radiation protective sheet for reduction of operator's eye dose during hepatic transarterial chemoembolization (TACE).

Materials and Methods: As an experiment, a protective sheet was placed on a RANDO phantom. Scatter radiation during fluoroscopy and angiography were measured with and without the sheet. As a clinical study, the sheet was placed over the patient's lower abdomen. Forty consecutive TACE were randomly assigned to be performed either with or without use of the sheet. Radiation by fluoroscopy and angiography was measured with a dosimeter beside the operator's left eye.

Results: The phantom study showed reduction of radiation distributed to the area corresponding to the upper body of the operator with use of the sheet by the maximum of 63.2% on fluoroscopy and 56.3% on angiography. In the clinical study, the median dose rate by fluoroscopy at the operator's eye was 1.3 μSv/min with use of the sheet; being significantly smaller than the controls at 2.9 μSv/min ($p < 0.0001$). The median eye doses by one series of DSA with manual contrast injection with and without the protective sheet were 4.1 μSv and 5.0 μSv, respectively ($p = 0.049$). The mean total eye dose was 70.7 μSv per procedure with use of the sheet and 148.8 μSv in the controls ($p = 0.0019$).

Conclusion: The radiation protective sheet is effective for reduction of operator's eye dose during TACE.

Key words: Scatter radiation, Radiation protection, Hepatocellular carcinoma, Radiation-induced cataract, Transarterial chemoembolization (TACE)

INTRODUCTION

During fluoroscopy-guided interventional radiological procedures, operators may receive a significant dose from scatter radiation. The harmful effects of ionizing radiation are well documented, and one of these effects is radiation-induced cataract[1]. Radiation-induced lens opacity or cataract is a tissue reaction effect, and it may occur when the radiation dose is above the threshold. Recently the International Commission on Radiological Protection (ICRP) has lowered the threshold dose of the lens opacity to be 0.5 Gy as the absorbed dose, and they recommend, for occupational ex-

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posure in planned exposure situations, an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv[2]. It is therefore extremely important to make attempts to reduce the dose to the eyes of the operators wherever possible.

Among a number of methods devised to reduce the radiation dose to operators, some studies have shown the effectiveness of a sterile protective sheet placed over the patient in certain fluoroscopy-guided procedures[3)~6)]. However, to our knowledge, no clinical study has yet evaluated the efficacy of this method for reduction of scatter radiation during transarterial chemoembolization (TACE) for hepatic tumors, which is one of the common interventional radiological procedures.

The purpose of this study was to evaluate the efficacy of a sterile radiation protective sheet for reduction of scatter radiation to the eyes of the operator in phantom experiments and a clinical randomized study of TACE procedures.

MATERIALS AND METHODS

Sterile radiation protective sheet

The protective sheet was a commercially available sterile drape composed of tungsten and antimony (0.20 to 0.25 mm lead equivalency) covered with non-woven polyester fabric (Radpad™, Worldwide Innovations & Technologies, Inc., Kansas City, Kansas, USA). The sheet measured 32×42.5 cm.

Phantom experiment

Phantom experiments were carried out with a floor-mounted C-arm digital angiographic device (DFP-2000A; Toshiba, Tokyo, Japan). The phantom used for the experiment was an anthropomorphic RANDO phantom (Alderson Research Laboratories, Stanford, CT), which is equivalent to the human body in terms of X-ray absorption and scattering. Thickness of the abdomen of the phantom was 18 cm. A protective sheet was placed at the site corresponding to the right lower abdomen on the phantom (Fig. 1). Scatter radiation during fluoroscopy and image acquisition were measured at different distances (50 cm, 100 cm and 150 cm from the center of the X-ray beam), and heights (30, 60, 90, 120, 150, 180 cm from the floor) with and without the protective sheet. Dosimetric measurements were obtained using a real-time semiconductor dosimeter (Unfors EDD-30, Unfors Instruments AB, Billdal, Sweden) and an ionization chamber survey meter (Aloka ICS-311, Hitachi Aloka Medical LTD. Tokyo, Japan). The source-to-image distance of the C arm was set to be 100 cm, the table-to-image distance 30 cm, and the floor-to-table distance 103 cm. Fluoroscopic images were acquired with 80-kV tube voltage, 40-mA tube current, with normal mode and pulse rate of 15 per second. Digital subtraction angiography (DSA) was acquired with 70-kV tube voltage, 400-mA tube current and with 2 image acquisitions per second. Field size was 9 inch (22.5 cm) for both

Fig. 1. RANDO phantom with a protective sheet.
A protective sheet was placed at the site corresponding to the right lower abdomen on the phantom.

fluoroscopy and DSA. Under each condition, scatter radiation for one-minute fluoroscopy and 5-second DSA were measured.

Clinical study

This prospective study was approved by the institutional review board, and informed consent was obtained from all participants. Forty consecutive segmental or subsegmental TACE for unresectable hepatocellular carcinoma (HCC) were performed by four interventional radiologists with more than 8 years' experience, respectively. Before the start of this study, a randomization table was generated using a computer program by the simple randomization method. Each procedure was assigned to be with or without use of the protective sheet to the operators in numerical order.

A probe of the real-time dosimeter (Unfors EDD-30) was attached near the operator's left eye, and the radiation doses by fluoroscopy and DSA acquisitions were separately measured (Fig. 2). Gafchromic film (Type R, ISP Technologies, Inc., Wayne, NJ, USA) placed under the patient's back was used to measure the entrance skin dose and dose-area product (DAP) during the procedure. After the procedure, the film was scanned with a flatbed scanner (Epson Offirio ES-10000G, Seiko Epson, Suwa, Japan), and the data were processed using the software (DD-IVR ver 3.0, R-Tech Japan, Tokyo, Japan). Another real-time dosimeter with a radiolucent optic-fiber cable (Skin Dose Monitor, McMahon Medical, Inc., San Diego, CA, USA) was placed as the reference of the entrance skin dose at the patient's back behind the liver.

Fig. 2. A probe of the real-time dosimeter (Unfors EDD-30) was attached near the operator's left eye.

All TACE procedures were performed with local anesthesia via the right femoral artery. First, a 4-French sheath (Terumo, Tokyo, Japan) was inserted in the right femoral artery. Celiac and superior mesenteric arteriography was performed using a 4-French catheter (Terumo). Then, a 2.0- or 2.3-French and 130 or 135-cm long microcatheter (Progreat α; Terumo, or Transit; Johnson and Johnson, New Brunswick, NJ, USA) was inserted into the distal portion of the tumor-feeding segmental or sub-segmental artery. After an emulsion of iodized oil (Lipiodol; Andre Guerbet, Aulaysous Bois, France) and 30–40 mg of epirubicin (Farmorubicin; Kyowa-Hakko, Tokyo, Japan) was injected into the feeding artery, embolization was performed with porous gelatin particles 1 mm in diameter (Gelpart; Nippon-kayaku, Tokyo, Japan)[7]. When a patient was assigned to use the protective sheet, a sterile sheet was placed over the surgical drape at the right lower abdomen of the patient after the sheath was inserted and catheter passed the pelvic region. The semicircular cutout of the sheet was positioned at the access site of the right femoral artery (Fig. 1). The protective sheet was placed not to overlap the irradiation field. The position of the sheet was not changed throughout the procedures. When a patient was assigned to be without use of the protective sheet, no sheet was placed over the surgical drape.

The same C-arm digital angiographic device was used as the phantom study with use of automatic exposure control (AEC) in all procedures. The source-to-image distance was set to be 100 cm, and the patient table was positioned as high as possible. Normal mode fluoroscopy with the pulse rate of 15 per second was used. In principle, DSA acquisition was performed using a power injector. DSA by manual contrast injection was only taken at the peripheral small branches, with the operator standing as far as possible from the X-ray source. Magnified or oblique DSA studies were performed according to the location of the target tumor. Fluoroscopy time, number of DSA acquisitions, number of DSA with manual contrast injection and number of embolized arteries were recorded. Body weight, height and body mass index (BMI) were recorded for all patients. Antero-posterior abdominal diameter at the level of hepatic hilum was measured on preoperative CT images in all patients.

Statistical Analysis

Commercially available software (SPSS for Windows, version 11; Aspire Software International, Leesburg, VA) was used for data analysis. The Mann-Whitney U test was used to test differences between two groups (with vs. without the protective sheet group) for continuous variables, and the Fisher exact test for categorical variables. P values <0.05 were considered to indicate statistically significant.

RESULTS

Phantom experiment

The scatter radiation dose and reduction rate with use of the protective sheet during fluoroscopy are shown in Table 1. And their distributions are shown in Figure 3. The maximum scatter radiation dose without the sheet during

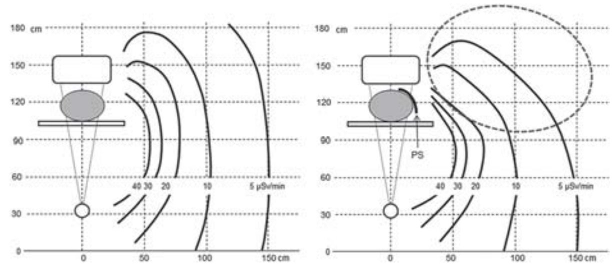

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Fig. 3. Distributions of scatter radiation on fluoroscopy.
a. Distribution without the protective sheet.
b. Distribution with the protective sheet. A dot circle shows the area with more than 25% reduction of the scatter radiation.
PS: Protective sheet

Table 1. Scatter radiation dose and reduction rate on fluoroscopy in the phantom study

	Distance from center of the X-ray beam																	
	50 cm						100 cm						150 cm					
	SD			ICS			SD			ICS			SD			ICS		
Height from floor	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction
30 cm	22.9	23.4	2.1	28.2	28.8	2.1	9.9	10.3	3.9	12.8	13.2	3.0	4.7	4.9	4.1	5.8	6.2	6.5
60 cm	39.8	40.0	0.5	49.2	49.2	0.0	10.5	11.1	5.4	12.4	13.0	4.6	4.7	5.1	7.8	5.6	6.2	9.7
90 cm	40.8	44.3	7.9	55.2	58.8	6.1	9.4	10.7	12.1	11.8	13.0	9.2	4.3	5.0	14.0	5.2	6.0	13.3
120 cm	19.4	34.9	44.4	16.8	45.6	63.2	5.8	8.1	28.4	8.4	13.6	38.2	2.7	3.8	28.9	3.8	5.2	26.9
150 cm	10.1	19.3	47.7	11.4	23.4	51.3	4.6	6.4	28.1	7.6	11.6	34.5	2.9	4.2	31.0	3.6	5.4	33.3
180 cm	3.6	7.9	54.4	4.8	11.4	57.9	4.5	6.2	27.4	5.8	8.0	27.5	2.7	3.9	30.8	3.8	5.0	24.0

(μSv/min)

SD: Semiconductor dosimeter ICS: Ionization chamber survey meter wo: Without PS: Protective sheet

Table 2. Scatter radiation dose and reduction rate on DSA in the phantom study

	Distance from center of the X-ray beam															
	50 cm					100 cm					150 cm					
	SD			ICS		SD			ICS		SD			ICS		
Height from floor	with PS	wo PS	% Reduction	with PS	wo PS	with PS	wo PS	% Reduction	with PS	wo PS	with PS	wo PS	% Reduction	with PS	wo PS	% Reduction
30 cm	36.0	36.2	0.6	OOR	OOR	16.7	17.1	2.3	OOR	OOR	7.7	8.1	4.9	9.5	10.0	5.0
60 cm	62.1	63.0	1.4	OOR	OOR	18.3	19.2	4.7	OOR	OOR	7.3	7.9	7.6	8.6	9.2	6.5
90 cm	59.5	64.4	7.6	OOR	OOR	13.2	15.8	16.5	OOR	OOR	5.5	6.8	19.1	7.0	9.0	22.2
120 cm	40.8	64.2	36.4	OOR	OOR	10.8	14.7	26.5	OOR	OOR	4.8	6.6	27.3	6.0	8.2	26.8
150 cm	16.2	27.2	40.4	OOR	OOR	8.3	12.6	34.1	OOR	OOR	4.4	6.6	33.3	5.5	8.2	32.9
180 cm	5.2	11.9	56.3	OOR	OOR	6.6	9.4	29.8	OOR	OOR	4.1	6.1	32.8	5.1	7.6	32.9

(μSv/5 sec)

SD: Semiconductor dosimeter ICS: Ionization chamber survey meter wo: Without PS: Protective sheet
OOR: Out of range

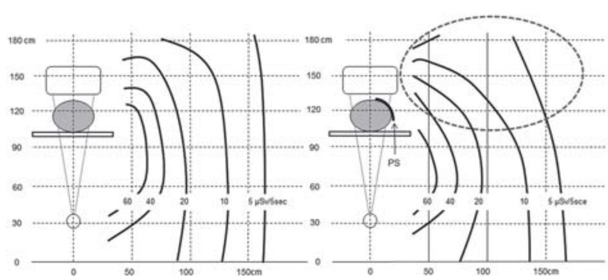

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Fig. 4. Distributions of scatter radiation dose on DSA.
a. Distribution without the protective sheet.
b. Distribution with the protective sheet. A dot circle shows the area with more than 25% reduction of the scatter radiation.
PS: Protective sheet

fluoroscopy was recorded as 58.8 μSv/min by ionization chamber at 50 cm distant from the center of the X-ray and 90 cm above the floor. At the position of 120, 150 and 180 cm above the floor corresponding to the upper half of the body of the operator, the doses were reduced by placing the sheet, with the maximum of 63.2% reduction (from 45.6 to 16.8 μSv/min) at 50 cm distant from the center of the X-ray and 120 cm above the floor (Table 1).

The corresponding results for DSA are shown in Table 2 and Figure 4. The dose at 50

Table 3. Background of TACE-treated Patients

	With protective sheet	Without protective sheet	p
No. of patients (male, female)	20 (15, 5)	20 (17, 3)	
Age (years)	69.5±10.1 (39–83)	68.7±8.5 (54–89)	0.79
Height (cm)	158.4±8.5 (139–178)	160.6±8.5 (141.1–176.1)	0.42
Weight (kg)	58.5±12.2 (37.0–86.7)	58.4±10.9 (39.2–74.4)	0.97
BMI	23.2±3.9 (16.4–31.2)	22.7±4.3 (18.0–34.9)	0.47
AP diameter of abdomen (cm) **	21.6±3.0 (16.9–29.2)	21.6±2.1 (16.7–25.1)	0.87
Fluoroscopy time (min.)	30.1±16.4 (11.8–69.9)	28.8±13.5 (11.4–59.9)	0.94
No. of DSA acquisitions	13.0±3.8 (8–22)	13.4±4.1 (8–25)	0.72
No. of manual contrast injections	3.1±2.8 (0–12)	3.0±3.4 (0–15)	0.75
No. of embolized arteries	2.3±1.1 (1–4)	2.0±0.8 (1–4)	0.33

* Data are given as mean±SD. Numbers in parentheses are range.
TACE: transarterial chemoembolization
BMI: body mass index
** Antero-posterior abdominal diameter at the level of hepatic hilum on preoperative CT images.

Table 4. Comparison between groups with and without the protective sheet

	With protective sheet (n=20)	Without protective sheet (n=20)	p
Median eye dose rate by fluoroscopy (μSv/min)	1.3 (0.5–4.3)	2.9 (1.7–6.7)	<0.0001
Median eye doses by one series of angiography with manual contrast injection (μSv)	4.1 (1.2–11.9)	5.0 (3.4–25.4)	0.049
Total eye dose per procedure (μSv)			
Mean±SD	70.7±40.7 (22.9–162.4)	148.8±92.2 (29.5–340.2)	0.0019
Median	57.7	130.8	
3rd quartile	91.9	199.4	
Max	162.4	340.2	
DAP ($Gycm^2$)			
Mean±SD	353.9±285.4 (75.4–1060.7)	339.4±260.9 (91.2–1105.4)	0.87
Median	269.5	269.5	
3rd quartile	350.6	357.0	
Entrance skin dose (mGy)			
Mean±SD	934.5±555.5 (29.6–1766.8)	962.7±581.0 (114.8–2231.9)	0.88
Median	979.4	864.6	
3rd quartile	1429.5	1187.7	

* Data are given as mean±SD. Numbers in parentheses are range. DAP: dose-area product

cm and 100 cm distant could not be assessed by the ionization chamber because of overdose. The measurement by real-time dosimeter showed reduction of the dose by placing the sheet at 120, 150 and 180 cm above the floor, like the results of fluoroscopy, with a maximum 56.3% reduction (from 11.9 to 5.2 μSv/5 sec) achieved at 50 cm from the center of the X-ray and 180 cm above the floor (Table 2).

Clinical study

All TACE procedures were performed successfully. No technical problems were caused by the presence of the protective sheet. No patient complained of any uncomfortable feeling by the use of the sheet. The patient's background and procedural data are shown in Table 3 and 4, respectively. No statistical difference

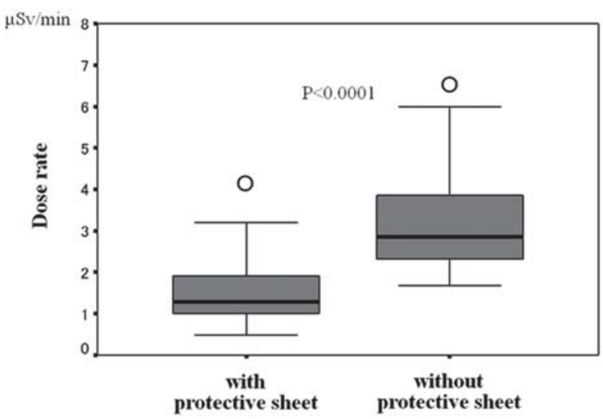

Fig. 5. Dose rate by fluoroscopy at the operator's eye.
The median dose rate by fluoroscopy at the operator's eye was 1.3 μSv/min with use of the protective sheet. This was significantly smaller than that of the controls with a median value of 2.9 μSv/min (p<0.0001).

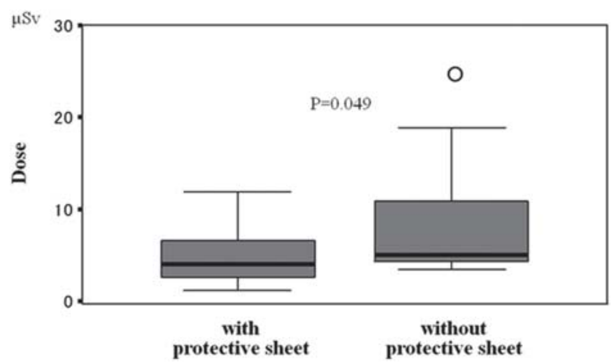

Fig. 6. Dose by one series of angiography with manual contrast injection at the operator's eye.
The median eye doses by one series of angiography with manual contrast injection with and without the protective sheet were 4.1 μSv and 5.0 μSv, respectively (p=0.049).

in the patient's background was seen between the two groups. The median eye dose rate by fluoroscopy was 1.3 μSv/min with use of the sheet. This was significantly smaller than that of the controls at a median value of 2.9 μSv/min ($p < 0.0001$) (Fig. 5). The median eye doses by one series of DSA with manual contrast injection with and without the sheet were 4.1 μSv and 5.0 μSv, respectively ($p = 0.049$) (Fig. 6). The mean total radiation dose at the operator's eye was 70.7 μSv per procedure with use of the sheet. This was significantly smaller than that of the controls at a mean value of 148.8 μSv per procedure ($p = 0.0019$).

DISCUSSION

Several studies have shown that using a sterile protective sheet during particular interventional procedures can significantly reduce the dose to operators[3)~6)]. Sharma et al. reported that use of this protective sheet during transcatheter aortic valve implantation achieved a significant dose reduction at the left eye of the primary operator (14.8 mSv vs. 24.3 mSv, $P = 0.008$)[3)]. King et al. found that use of the device during percutaneous nephrostomy led to a significant reduction in the dose to the eyes (12-fold reduction), thyroid (25-fold reduction) and hands (29-fold reduction) of operators[4)]. Jones et al. reported that not only the exposure dose to the eyes was reduced, but the hands and body doses were also significantly reduced during cardiac resynchronization device implantation[5)]. Kherad et al. reported that total radiation exposure to primary operators was reduced using the device by 59%, and the exposure rate by 47% during diagnostic coronary angiography[6)].

Our phantom study simulating abdominal interventions demonstrated reduction of scatter radiation distributed to the area corresponding to the upper half of the body of the operator with use of the protective sheet. In addition, a clinical study confirmed the reduction of scatter radiation to the eyes of the operator during TACE. Our study showed that the mean radiation dose to the eyes of the operator is about 0.15 mSv per procedure without the protective sheet. This value corresponds to about 133 TACE procedures when the dose limit is 20 mSv/year for the lens of the eyes. In more prolonged and complicated procedures, radiation exposure to the eyes will increase. This estimation shows that the new ICRP-recommended dose limit of 20 mSv/year for the lens of the eyes can be easily exceeded in the case of a primary operator who performs many procedures.

The mean maximum entrance skin doses to the patients with and without the protective sheet were 935±556 mGy and 963±581 mGy, respectively. Previously, some investigators evaluated the entrance skin dose during TACE. Suzuki et al. reported that the maximal skin dose was 1,068±439 mGy[8)]. Ishiguchi et al. reported that the entrance skin dose was 973±681 mGy[9)]. There were no significant differences between our results and theirs. It is considered that all the procedures in the present study were performed within the normal range of radiation exposure.

In our clinical study, the effectiveness of other radiation-protective devices including protective glasses or a ceiling-suspended screen was not evaluated. The usefulness of protective glasses has been widely recognized, but depending on the design and size of the glasses and angles of the X-ray beam, the scattered radiation may still pass through the gap between the skin and the glasses and irradiate the eyes directly[10)]. The widely used 0.07-mm Pb equivalent protective glasses shield approximately 60% of eye dose[11)]. A ceiling-suspended screen provides good shielding; in practice however, it may not always be well placed to protect the eyes depending on the position of the operator. The efficiency of the protective sheet is independent of the above-mentioned factors and can be easily used in combination with the routine protective means including radiation protective glasses and ceiling-suspended screen. The protective sheet was placed not to overlap the irradiation field. However, in case the protective sheet overlaps in radiation field for some reason, the sheet has to be changed its position or removed because AEC of the angiography system will increase X-ray output. Though we used an I.I-angiography system in the present study, the results would be applied to a flat-panel-detector angiography system.

There are some limitations to the present study. First, the cohort size of this study is too small. Second, a non-protective dummy sheet was not placed in the control group. The operators had known whether the patients were assigned to be with or without the protective sheet. Thus, the operators may had been biased against the study.

In conclusion, use of a protective sheet is a simple and effective method to reduce scatter radiation to the upper body, especially to the eye, of the operator during TACE for HCCs.

OFFICIAL STATEMENTS

a) Conflict of Interest Statement

On behalf of all authors, the corresponding author states that there is no conflict of interest.

b) Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

c) Informed Consent

Informed consent was obtained from all individual participants included in the study.

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