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ORIGINAL ARTICLE

Extended Protective Shield Under Table to Reduce Operator Radiation Dose in Percutaneous Coronary Procedures

The EXTRA-RAD Study

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BACKGROUND: Different tools and devices are effective to reduce operator radiation exposure at thorax level during percutaneous coronary procedures, but the operator radiation dose received at pelvic region still remains high. Our aim was to evaluate the efficacy of under-the-table adjunctive shields to reduce operator radiation exposure during percutaneous coronary procedures

METHODS AND RESULTS: The EXTRA-RAD study (Extended Protective Shield Under Table to Reduce Operator Radiation Dose in Percutaneous Coronary Procedures) is a prospective, single-center, randomized study. Patients who underwent transradial coronary procedures were randomized into 2 groups: group 1 (standard arrangement) and group 2 (adjunctive anti-rx shield under the angiographic table). In group 2, a further randomization was performed to compare 2 different under-the-table shields (a small curtain and a drape). A total of 205 procedures (122 diagnostic coronary angiographies and 83 percutaneous coronary interventions) performed in 157 patients by 4 different operators were included without significant differences in clinical and procedural characteristics between groups. The use of adjunctive shields was associated with lower radiation dose compared with no shield at pelvic region (42 μSv [14–98] in group 1, 13 μSv [5–27] in group 2; $P<0.0001$) and also at thorax level (4 μSv [1–13] in group 1, 2 μSv [1–4] in group 2; $P=0.001$). The reduction in dose was observed in all the operators. No significant differences were observed in pelvic dose using the 2 different shields ($P=0.183$).

CONCLUSIONS: The use of adjunctive anti-rx shields under the angiographic table during transradial coronary procedures is associated with a significant lower radiation dose to operators at pelvic and thorax level.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT03259126.

Key Words: coronary angiography ■ humans ■ pelvis ■ protective devices ■ radiation exposure ■ random allocation

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WHAT IS KNOWN

- Interventional cardiologists are chronically exposed to radiation during their activity.
- Despite the use of different protective devices, the radiation operator radiation exposure still remain high in particular at pelvic level.

WHAT THE STUDY ADDS

- The use of an adjunctive protective shield placed under the angiographic table is associated with a significant reduction in operator radiation exposure in particular at pelvic level.
- The operators exposed to the higher doses receive the higher benefit.
- The adjunctive shield does not limit operator movement during the procedure.

In recent years, among interventional cardiologists, the knowledge of deterministic[1] and stochastic[2] risks associated with their chronic exposure to radiographs has been increased. Many procedural advices (as the use of a reduction in radiographs pulse rate or the use of fluoro rather than cine mode acquisition)[3,4] or different protective devices (as the use of adjunctive protective drapes or dedicated protective boards and structures)[5–8] have been tested with a significant reduction in radiation exposure for the operator. In particular, the use of adjunctive protective drapes placed over the pelvic region of the patient is a simple and highly effective measure to reduce the operator radiation dose at thorax level with a reduction in dose ≤84%.[9]

Generally, in most studies, radiation exposure has been measured at thorax or left wrist or eye and head level missing the opportunity to evaluate the radiation dose on the lower parts of the interventional cardiologists' bodies. At the same time, the use of adjunctive protective pelvic drapes or dedicated boards is highly effective in the control of the operator radiation exposure at the upper parts of the operator body, but the reduction in radiation exposure at operator pelvic level is small compared with the thorax level accounting for <40% reduction[10] leaving this part of the body exposed to high doses of radiation. The reason for this high dose at pelvic region is because of the closer position of this part of the operator body to the radiation source and to the role of the protective drapes placed on the patient that mainly block the scattered radiation coming from the patient and directed upward.

The radiation exposure to the pelvic region could be an important issue for women, in particular for young women, because of the radiation exposure to gonads and the possible future pregnancy. These concerns have been confirmed in a large European survey showing that radiation exposure is a main factor that prevents physicians from pursuing the interventional cardiologist career in particular for women.[11]

We decided to perform a randomized study using 2 different homemade protective shields placed under the angiographic table to evaluate the possible reduction in operator radiation exposure at pelvic level during percutaneous diagnostic or interventional coronary procedures using these shields.

METHODS

The authors declare that all supporting data are available within the article and its Data Supplement.

Study Design and Population

The EXTRA-RAD study (Extended Protective Shield Under Table to Reduce Operator Radiation Dose in Percutaneous Coronary Procedures; NCT03259126) is a single-centre, prospective, randomized, open-label, 2 arms study designed to evaluate the radiation dose absorbed by operators at pelvic level during transradial percutaneous coronary procedures using 2 different adjunctive protective shields placed under the angiographic table and on top of the standard protective measures routinely used.

All patients who underwent diagnostic or interventional percutaneous coronary procedures through transradial access and aged >18 years old were eligible for the study. Exclusion criteria were acute ST-segment–elevation myocardial infarction, hemodynamic instability, previous coronary artery bypass, necessity of femoral approach or impossibility to perform transradial access, lack of written informed consent. Moreover, after the enrolment, all patients requiring a switch of vascular access were excluded.

Before the procedure, all patients enrolled were initially randomized into 2 groups: standard protective measures (no adjunctive shields under table, group 1) or adjunctive protective shields (group 2). Allocation to 1 of the 2 groups was made by mean of a computer-generated random sequence available on the web (http://www.randomization.com) without stratification for clinical or procedural characteristics. Moreover, after the allocation in the 2 groups, a second-order randomization according to a 1:1 scheme in group 2 was performed to allocate patients in 2 groups based on the 2 different shields utilized (Figure 1). The randomization list was managed by the nursing staff, who informed the interventional cardiologist of the assigned approach just before the procedure.

The Institutional Ethics Committee approved the protocol, and all patients signed a written informed consent before participation.

Transradial Coronary Procedure and Standard Protective Measures

All procedures were performed using an angiographic flat panel system (IGS 520; General Electrics Healthcare, Buckinghamshire, United Kingdom). The system was set using a field of view of 15 cm, a fluoroscopic speed of 7.5 frames/s and cine acquisition speed of 15 frames/s. The use of fluoro

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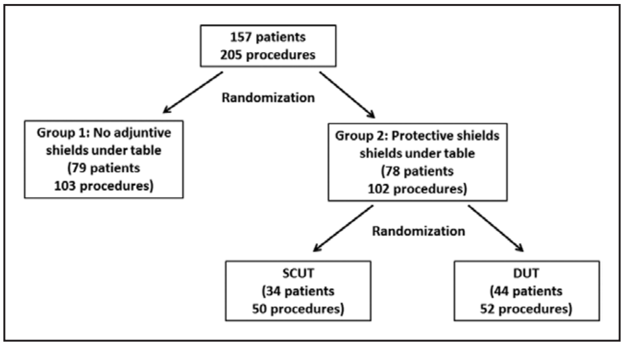

Figure 1. Flowchart of randomization.
Patients were initially randomized into 2 groups according to the standard arrangement (group 1) or to the use of an adjunctive protective drape placed under the angiographic table (group 2). Patients in group 2 were subsequently randomized into 2 other groups to test the small curtain under table (SCUT) and the drape under table (DUT).

storing rather than cine acquisition was encouraged during percutaneous coronary interventions (PCIs).

In all procedures, standard operator radioprotection was ensured using a lead apron, a thyroid lead collar, lower body radiograph curtain fixed on the angiographic table, suspended protective lead shield, and leaded glasses. Moreover, according to a previous study that showed a significant reduction in operator radiation exposure with the use of adjunctive anti-rx drapes placed on the patient,[7] in all procedures, 2 adjunctive protective drapes of 0.5 mm lead equivalent (dimensions 80×60 cm) were placed on the patient's pelvic region and on the legs (Dear Composites, Rivarolo Canavese, Turin, Italy; Figure 2). The 2 shields were placed on the angiographic table and under the mattress (Figure 2).

Four different operators (A.S., S.R., R.P., and L.Z.) performed all the procedures: 3 operators were seniors and 1 (L.Z.) a fellow. The senior cardiologists were high-volume transradial operators (>250 transradial procedures per year), of similar height, and performing the procedures using a similar position standing on the right of the table either for right or left transradial procedures.

Two different additional radiation protection shields (curtain or drape) placed under the angiographic table were used in this study. The first shield was a homemade small curtain under the table obtained from an upper mobile ceiling radiograph curtain, 0.5-mm lead equivalent (Mavig, Munich, Germany; Figure 2). The other shield was a homemade small drape under the table obtained from a previous protective skirt, 0.25-mm lead equivalent (Sago Medica, Bologna, Italy; Figure 2).

Radiation Measurement

Radiation measures collected were fluoroscopy time, air kerma (AK), and the dose area product (DAP). The AK is the adsorbed dose in air at a defined distance from the radiograph tube's focal spot, which is generally 15 cm from the isocenter. Differently, the DAP is the product of the AK and the cross-sectional area of the radiograph field for all segments of the procedure. These parameters were measured using specially designed ionization chambers mounted at the collimator system and elaborated by a dedicated software (Innova Dose Report, General Electrics Healthcare).

Operator radiation exposure was measured using wearable personal electronic dosimeters placed at left wrist (RADOS-RAD 60; LAURUS Systems, Inc, Ellicott City), at thorax (outside the pocket of the lead apron), a head level (in the middle front), and at pelvic level on the left hip of the operator (outside the lead apron; PM1610; Polimaster, Austria). These dosimeters have a Geiger-Mueller detector dedicated for radiograph with an energy range of detection between 0.001 μSv and 12.0 Sv. The dose at thorax (outside the apron) was also converted in operator effective dose dividing it by a factor 33 according with an apron thickness of 0.5 mm lead equivalent with a tube voltage under the table.[12] Differently, the equivalent pelvic dose under the lead apron was obtained as the 1.8% of the external dose as documented previously.[13]

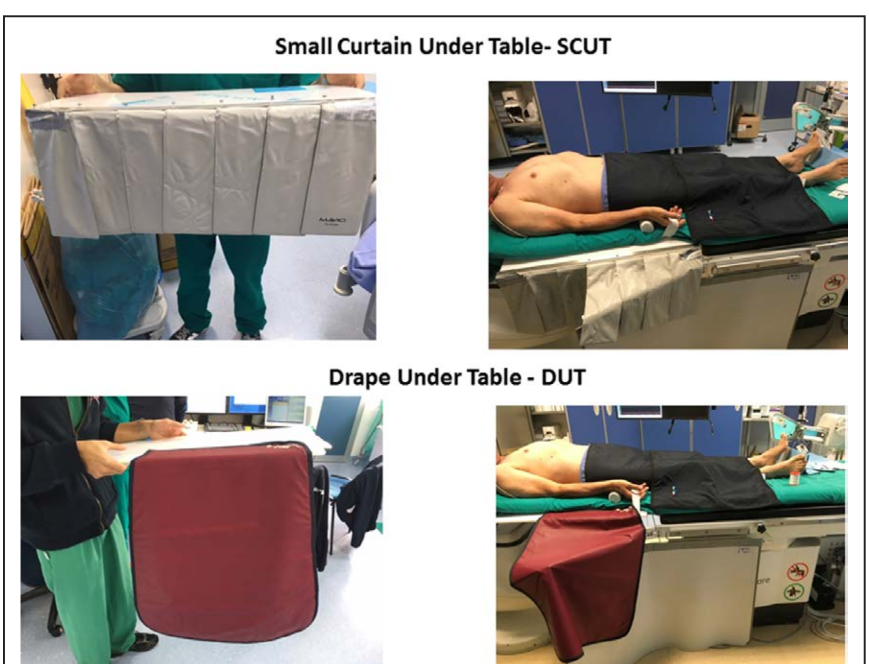

Figure 2. Shields utilized in the study.
In the **top** is presented the small curtain under table (SCUT), whereas in the **bottom**, the drape under table (DUT) when added to the standard patient preparation with the adjunctive pelvic drapes. Neither shield limited the free movement of the interventional cardiologist or those of the radiation tube.

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The radiation and operator measures were recorded at the beginning and the end of each procedure. For those patients who performed a PCI after the diagnostic procedure, the measures of fluoroscopy time, DAP, AK, and dose of the wearable dosimeters were reset after the end of the diagnostic procedure and restarted at the beginning of the PCI.

To take into account possible differences in patient radiation dose affecting the operator exposure, the DAP-normalized and the AK-normalized operator dose was also calculated.

End Point of the Study

The primary end point of the study was the operator radiation dose at pelvic level comparing the use of adjunctive under-table shields versus no under-table shields. We also prespecified a secondary end point comparing the small curtain under the table with the drape under the table. Finally, we also analyzed the operator radiation dose at thorax, head, and wrist level.

Statistical Analysis

The sample size was estimated on the primary end point according to data of a previous study evaluating operator dose at pelvic level.[10] Considering a mean operator dose of 40±25 μS at pelvic level and a 30% reduction with the shields, using the 1-way ANOVA, to detect a 30% reduction of the radiation dose with the under-table shields with a power of 80% and an α-error of 0.05, a total of 138 patients (69 per group) was required.

Continuous variables are reported as mean and SD for variables normally distributed and as median with interquartiles range for those not normally distributed and were compared using *t* test, Mann-Whitney *U* test, or Kruskal-Wallis test as appropriate. Normal distribution of each variable was assessed using the Kolmogorov-Smirnov test. Categorical variables were compared by Pearson χ^2 test or with the Fisher exact test as appropriate.

The clinical characteristics were analyzed at patient level, whereas procedural characteristics and dosimetric data were analyzed at procedural level.

All analyses were performed with SPSS 21.0 software (SPSS, Chicago, IL).

RESULTS

From August 2017 to August 2018, 157 patients and 205 procedures were included in the EXTRA-RAD study (79 patients and 103 procedures in group 1 and 78 patients and 102 procedures in group 2). Clinical and procedural characteristics of the patients are presented in Table 1 and did not differ between the 2 groups. Most of the procedures were performed in male patients with a mean age of 67 years and a body mass index of 27. Almost 40% of the procedures were PCI, and radial access was equally distributed between the right and left access. The high percentage of left radial access compared with the rate all around the world reflects the standard of the enrolling center. Median fluoroscopy time, DAP, and AK did not differ between groups (Table 2).

Table 1. Clinical and Procedural Characteristics

	Group 1 (No Shields)	Group 2 (Adjunctive Shields)
Patients, n	79	78
Procedures, n	103	102
Male sex	61 (77)	52 (67)
Age, y	67±12	67±9
Height, cm	170±10	168±8
Weight, kg	79±15	77±17
Body mass index	27±5	27±5
Smoking habitus	22 (28)	24 (31)
Hypertension	56 (71)	60 (77)
Diabetes mellitus	16 (20)	20 (26)
Dyslipidemia	29 (37)	28 (36)
COPD	5 (6)	9 (12)
Chronic renal disease	3 (4)	4 (5)
Previous stroke	1 (1)	4 (5)
Previous MI	21 (27)	22 (28)
Previous PCI	27 (34)	23 (30)
ACS	62 (79)	61 (78)
PCI	40 (39)	43 (42)
Right radial access	52 (51)	53 (52)

Clinical characteristics are compared at patient level. Results are expressed as mean±SD or absolute number and percentage in bracket. ACS indicates acute coronary syndrome; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PCI, percutaneous coronary intervention.

Operator Radiation Dose With Under-Table Shields

Operator radiation dose at pelvic level was significantly lower in group 2 compared with group 1 with a reduction of 71% (Table 2; Figure 3). After normalization by DAP and AK, the differences between the 2 groups still persisted (Table 2) with a 61% reduction in dose after normalization by DAP and 66% after normalization by AK. The equivalent dose at pelvic level under the lead apron was also significantly reduced (0.75 μSv [0.25–1.77] in group 1 and 0.22 μSv [0.1–0.48] in group 2; $P<0.001$).

Operator dose at thorax level was also significantly lower in group 2 compared with group 1 even after normalization by DAP and AK (Table 2). Differently, there was only a trend to a reduction in radiation exposure at wrist level (3.8 μSv [1–9] in group 1 and 2.7 μSv [1–5.3] in group 2; $P=0.081$) and no significant differences at head level (1.2 μSv [0.7–2.5] in group 1 and 1.1 μSv [0.6–2.1] in group 2; $P=0.482$). The effective dose was low but still significantly reduced with the adjunctive shields (0.11 μSv [0.03–0.38] in group 1 and 0.06 μSv [0.02–0.13] in group 2; $P=0.001$).

The shields were effective during diagnostic coronaroangiography (28.4 μSv [14–61] in group 1 and 8 μSv [4–18] in group 2 at pelvic level; $P<0.001$), as well as in

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Table 2. Operator Radiation Exposure

	Group 1 (No Shields)	Group 2 (Shields)	*P* Value
Procedures, n	103	102	
FT, min	4 (3–8)	4 (2–6)	0.071
DAP, Gy×cm²	16.8 (10.3–28)	15.2 (9.8–24.9)	0.416
AK, mGy	279 (183–472)	278 (176–478)	0.955
Contrast dose, mL*	110±69	104±61	0.492
Operator dose, μSv			
Pelvis	42 (14–98)	12 (5–27)	<0.001
Thorax	3.7 (1–13)	2 (0.8–4)	0.001
Dose/DAP, μSv×Gy⁻¹×cm⁻²			
Pelvis	2.3 (1.3–4.3)	0.9 (0.4–1.7)	<0.001
Thorax	0.2 (0.1–0.6)	0.1 (0.1–0.2)	0.002
Dose/AK, μSv/Gy			
Pelvis	134 (74–266)	47 (22–94)	<0.001
Thorax	11.9 (4–34)	5.8 (3–13)	0.002

Results are expressed as median with interquartile range and compared using the Mann-Whitney *U* test. AK indicates air kerma; DAP, dose area product; and FT, fluoroscopy time.

*Results are expressed as mean±SD and compared with *t* test.

case of PCI (51.7 μSv [22–132] in group 1 and 25.4 μSv [7–45] in group 2 at pelvic level; *P*<0.001).

Both the adjunctive shields were equally effective to reduce operator radiation exposure at pelvic level (41.7 μSv [14–98], no-adjunctive-shields group; 14.6 μSv [7–28], drape-under-the-table group; and 8.3 μSv [5–26], small-curtain-under-the-table group; *P*<0.0001) without significant differences between the 2 shields (*P*=0.183; Table I in the Data Supplement).

Comparison Among Operators

In all operators, we observed a reduction in radiation dose at pelvic level that was statistically significant in three (Figure 4). The lack of significance in the fourth operator was probably because of the low number of procedures performed by this operator (9 procedures with the shields and 13 without). Of note, the highest reduction in the radiation dose at pelvic level was observed in those operators with the highest baseline radiation exposure reaching a reduction of 85% in the fellow.

DISCUSSION

In our study, for the first time, we documented that a simple protective shield placed under the angiographic table is able to significantly reduce the operator radiation exposure at pelvic and thorax level. In particular, the effect is mainly important at pelvic level with a median reduction of 71% in operator dose.

Previously, different tools and devices have been successfully utilized to reduce operator radiation exposure,[14] but these measures, in general, have been tested on the operator exposure at thorax level. Only few studies evaluated the operator radiation dose at pelvic level documenting, despite the use of adjunctive protective drapes placed over the patient abdomen, that the reduction in dose at pelvic level was small.[10] In the current study, the protective effect was observed on top of the best measures known to date to reduce operator radiation exposure (low frame rates, fluoro store, and use of adjunctive protective drapes) increasing the potential role of our devices.

Radiation exposure at pelvic level could be an important issue in particular for young women because of increased radiation exposure to gonads and possible future pregnancies. These concerns have been confirmed in a large European survey showing that radiation exposure is a main factor that prevents physicians from pursuing the career of interventional cardiologist in particular for women[11] preferring a career with minimal radiation exposure as documented by the American College of Cardiology Committee survey on Women in Cardiology.[15]

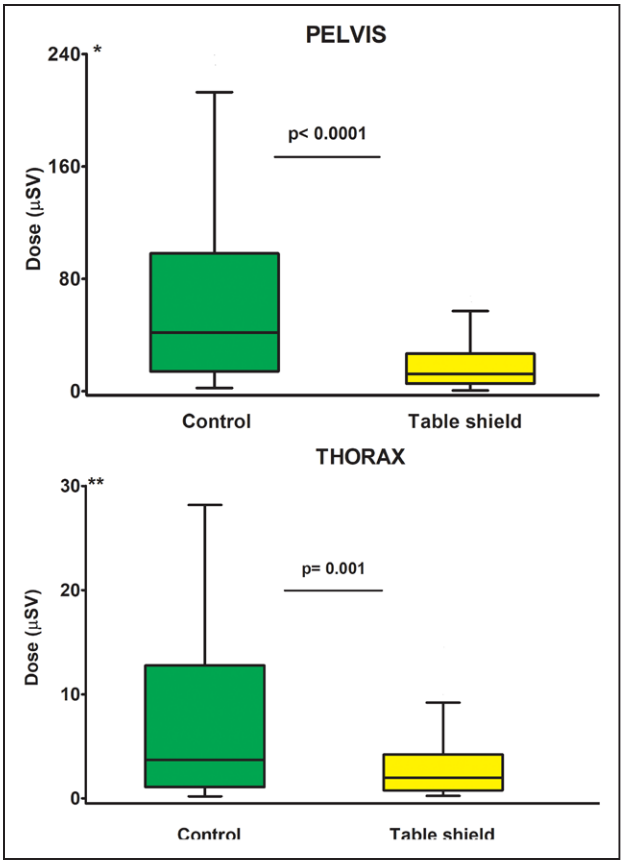

Figure 3. Operator radiation dose at thorax and pelvis with the use of adjunctive anti-rx shields.
The use of adjunctive protective anti-rx under-table shields reduced the operator radiation dose at thorax level (**bottom**), as well as at pelvis level (**top**). Results are presented as median, interquartile range (box), and 1.5×interquartile range (whiskers). *Maximum values for control are 765 and 348 μSv for table shield. **Maximum values for control are 59 and 294 μSv for table shield.

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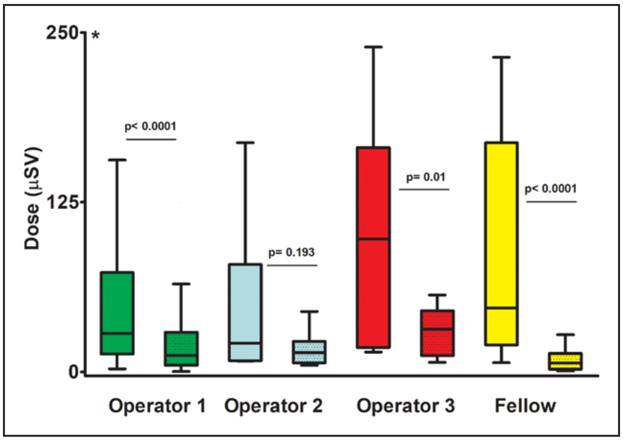

Figure 4. Operator radiation dose with the use of adjunctive anti-rx shields in the 4 operators involved.
The use of adjunctive protective anti-rx under-table shields (dotted boxes) reduced the operator radiation dose in all the operators compared with no shields (plain boxes), and the reduction in dose was higher in those with a baseline higher exposure (operator 3 and fellow). Results are presented as median, interquartile range (box), and 1.5×interquartile range (whiskers). *Maximum values without adjunctive shields are 367 µSv for operator 1, 169 µSv for operator 2, 765 µSv for operator 3, and 404 µSv for fellow, whereas maximum values with the adjunctive shields are 347 µSv for operator 1, 55 µSv for operator 2, 57 µSv for operator 3, and 27 µSv for fellow.

The protection from scatter radiation offered by a variety of shields used alone and in combination was previously measured in different studies performed on a phantom.[16,17] These studies clearly showed that protective drapes and upper mobile ceiling are effective to protect the upper part of the operator body from the scatter radiation coming from the patient, whereas only lower anti-rx curtains are effective on the protection of the lower part of the operator bodies. In our study, performed on patients, we confirmed that standard protective measures are not completely effective on the protection of operator lower parts, whereas our devices are effective in this setting. We also confirmed that the use of adjunctive lower anti-rx curtains is not effective to protect higher part of the body (as the head) or part of the body outside the area covered by these devices (as for the operator wrist).

Another interesting aspect is that the combination of pelvic drapes and under-table shields on top of the standard protective measures of the cath lab reduced the operator radiation exposure at thorax to negligible levels improving the operator safety. The median effective dose obtained with this arrangement is only 0.06 µSv indicating that the operators receive a radiation dose equivalent to 1 chest radiographs after performing >300 procedures.

The effect of our devices is observed in all the operators involved in the study. An interesting point is that the reduction is particularly important in those operators with the higher exposure as the fellows. Because the negative effects of the radiation are inversely related with the age of the operator (the younger the operator, the higher the effect), our devices could be a easy and cheap solution to reduce operator risk in young operators.

One of the more complete shielding device to date is a suspended personal radiation protection system (the Zero Gravity system) that provided a significant reduction in operator radiation exposure ranging from 87% to 100% at the eyes, head, neck, humerus, and tibia.[18] However, the system protects only the primary operators excluding the possible protection of the other personnel of the cath lab. Moreover, and most important, the system is expensive and limits the free movement of the interventional cardiologist as for the other systems tested previously.[5,6,8]

Our study has some limitations. First of all, the study lacks a sham control in group 1. Consequently, we cannot exclude that the presence of the shields made the operators more aware of radiation safety compared with procedures performed without shields. Moreover, our study is a single-center experience, and consequently, a different arrangement of the cath lab or a different preparation of the instrumental patient arm could give different results as documented in previous studies.[19] All procedures were performed through transradial access, and we cannot exclude that the use of a different vascular access as the femoral could give different results. Another limitation is based on the clinical characteristics of patients because a major determinant of scattered radiation dose during percutaneous coronary procedures are the patient weight and body mass index. Consequently, our study could not be replicated in different populations with lower body mass index (as Asians) or higher body mass index (as in the United States). Moreover, the reduction in operator radiation dose in absolute terms is little and seems to be trivial, but according to the linear no threshold principle in radioprotection, no safe doses exist, and the lower the exposure, the lower is the risk.[20] Finally, all the operators involved in the study were of a similar height, and we cannot exclude that our results might not be applicable to shorter operators that generally are exposed to higher doses.[21]

CONCLUSIONS

In our study, the use of adjunctive radiation protection shields placed under the angiographic table during transradial percutaneous coronary procedures is associated with a significant lower radiation dose to operators at pelvic and thorax level. The use of these shields is a simple and cheap measure to reduce the operator radiation exposure and should be implemented as anti-rx protective device in the cath lab.

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Disclosures

None.

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