Efficacy of the RADPAD Protection Drape in Reducing Operators' Radiation Exposure in the Catheterization Laboratory

A Sham-Controlled Randomized Trial

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Background—Interventional cardiologists are increasingly exposed to radiation-induced diseases like cataract and the stochastic risk of left-sided brain tumors. The RADPAD is a sterile, disposable, lead-free shield placed on the patient with the aim to minimize operator-received scatter radiation. The objective of the trial was to examine the RADPAD's efficacy in a real-world situation.

Methods and Results—In the current, double-blind, sham-controlled, all-comer trial, patients undergoing diagnostic catheterization or percutaneous coronary interventions were randomized in a 1:1:1 ratio to a radiation absorbing shield (RADPAD), standard treatment (NOPAD), or a sham shield (SHAMPAD). The sham shield allowed testing for shield-induced radiation behavior. The primary outcome was the difference in relative exposure of the primary operator between the RADPAD and NOPAD arms and was defined as the ratio between operator's exposure (E in µSv) and patient exposure (dose area product in mGy·cm^2), measured per procedure. A total of 766 consecutive coronary procedures were randomized to the use of RADPAD (N=255), NOPAD (N=255), or SHAMPAD (N=256). The use of RADPAD was associated with a 20% reduction in relative operator exposure compared with that of NOPAD (P=0.01) and a 44% relative exposure reduction compared with the use of a SHAMPAD (P<0.001). Use of the SHAMPAD was associated with a 43% higher relative radiation exposure than procedures with NOPAD (P=0.009).

Conclusions—In clinical daily practice, the standard use of the RADPAD radiation shield reduced operator radiation exposure compared with procedures with NOPAD or SHAMPAD. This study supports the routine use of RADPAD in the catheterization laboratory.

Clinical Trial Registration—URL: https://www.clinicaltrials.gov. Unique identifier: NCT03139968.

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Despite technological developments, the profession of an interventional cardiologist is inevitably related to exposure of low-dose radiation. The radiation dose received by the operator is highly variable per procedure and depends on experience level, radiation equipment, procedure type, and patient characteristics.[1,2] An increase in number and complexity of procedures in the catheterization laboratory further increases operators' exposure to scatter radiation. This radiation burden is associated with deterministic tissue reactions such as ocular lens defects[3] and skin injuries. Moreover, exposure to low-dose radiation induces a stochastic risk on various malignancies.[4–6] Case series of left-sided brain tumors in interventional cardiologists raise the question whether new safety measures should be added to conventional safety measures to protect operators.[7,8]

The RADPAD (RADPAD 5100A-O; Worldwide Innovations & Technologies, Inc, Lenexa, KS) is a sterile, disposable, lead-free shield placed on the patient between the image intensifier and the operator (Figure 1), with the aim to minimize operator received scatter radiation. Previous studies are limited by size and the absence of a sham shield.[9–12] The main aim of the study was to examine the effect of a radiation

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WHAT IS KNOWN

- The interventional cardiologist is exposed to chronic low-dose radiation.
- The RADPAD is used to reduce the cardiologists' radiation exposure; however, little is known about the efficacy of such a device in their day-to-day use.

WHAT THE STUDY ADDS

- The cardiologist's radiation exposure during procedures with a RADPAD was substantially lower compared with procedures with no RADPAD or a sham RADPAD.
- Use of the RADPAD was feasible in the majority of the procedures.
- Local interventional centers should consider use of the RADPAD in the catheterization laboratory as one of the possible additional measures to reduce the occupational hazard of radiation exposure.

protective shield (RADPAD) versus conventional safety measures (NOPAD) on the operator's procedural radiation exposure, during coronary angiography (CAG) or percutaneous coronary interventions (PCI) in a large-scale randomized trial. A third arm with a sham protective shield (SHAMPAD) was included in the study, to account for adapted operator's radiation behavior, potentially induced by the presence of a radiation protective device.

Methods

Trial Oversight and Design

The current trial is a single-center, randomized, sham-controlled, double-blind, all-comer trial, initiated and managed by the Heart Center of the Academic Medical Center. The Heart Center of the Academic Medical Center is a high-volume tertiary cardiac care center in Amsterdam, the Netherlands. The sponsor (Worldwide Innovations & Technologies, Inc) provided the protective RADPAD and the SHAM shield but did not participate in the writing of the protocol or data analysis. To resemble clinical practice, all diagnostic CAG's and PCI's during office hours between January and May 2017 were included in the current study. The study consisted of three arms:

- Protective shield group (RADPAD).
- Control group (NOPAD).
- Sham protective shield group (SHAMPAD).

The study protocol was approved by the Institutional Review Boards of the Academic Medical Center. Because the current study does not impose interventions, risks or benefits for the patient, informed consent was not required.

Figure 1. Position of the absorbing shield, placed on the patient, between the image intensifier (**A**), the primary operator (**B**), and occasionally the secondary operator (**C**).

Randomization and Blinding

With the use of a computer-based 1:1:1 block randomization system, procedures were allocated to a RADPAD, NOPAD, or SHAMPAD. Adding the arm with a sham shield allowed for accounting for operator's radiation behavior, potentially induced by the presence of a radiation protective device. The sham protective shield and the real protective shield were tangibly and visually identical (Movie I in the Data Supplement). However, the protective shield consists of bismuth-antimony with radiation protective characteristics whereas the sham shield consists of minimally protective silicone material. In summary, operators, patients, laboratory personnel, and investigators were all blinded to the assigned type of shield. Moreover, during the study period, the operator was blinded to the real-time dosimetry of the Philips DoseAware system.

Study Protocol

In the both the RADPAD and SHAMPAD arm, the disposable, sterile (sham) protective shield, measuring 35×40 cm, weighing 350 g, was positioned on the patient, on the sterile drape, superior, and medial to the sheath insertion point, immediately below the lead shield suspended from the ceiling (Figure 1). Accordingly, the (sham) protective shield was placed outside the direct x-ray bundle and consequently not visible in the image viewer. Placement was performed by the operator, under continuous guidance of a dedicated researcher, to maintain proper placement throughout the procedure and during the study. Because abdominal mass generates the most scatter radiation, the shield was tilted more vertically to cover the abdomen in patients with obesity. Conventional radiation protection measures (lead aprons, lead collar, movable ceiling-suspended lead shield with a long lead skirt attached to its lower margin) were used uniformly in all 3 arms. The procedures were performed using multiple catheterization rooms equipped with the Philips AlluraClarity FD10 or Philips Allura Xper FD10 (Philips Medical Systems, the Netherlands). Dosimetry was performed uniformly at chest height, outside the lead apron, with a Personal Dose Meter (PDM, DoseAware; Philips Medical Systems, the Netherlands) of the first and second operators by a dedicated research nurse. Procedural decisions, including device selection, were all made at the discretion of the operator.

End Points and Definitions

The primary end point of this study was the difference in relative exposure of the primary operator (E/dose area product [DAP]) between the RADPAD and NOPAD arms and was defined as the ratio between radiation dose received by the primary operator because of scatter (effective dose E in μSv) and patient exposure (the DAP) per procedure. The DAP is proportional to the radiation administered to the patient by the operator and is defined as the absorbed skin entrance dose multiplied by the irradiated area (mGy·cm^2). The relative radiation exposure, rather than the actual radiation exposure, is chosen to correct for the interprocedural variance in patient exposure. Our hospital is a training center with staff interventional cardiologists and fellows. The first operator was defined as the operator who received the highest radiation level during the procedure. All clinical and procedural characteristics associated with radiation exposure such as fluoroscopy time, body mass index (BMI) of the patient, location of treated

lesions, and others were collected in a dedicated electronic database. The data will not be made available to other researchers for purposes of reproducing the results or replicating the procedure because substudies are ongoing.

Sample Size Calculation and Statistical Analysis

A reduction of 10% in the relative operator exposure was considered the minimum for a clinically meaningful difference between procedures with a RADPAD and NOPAD. Consequently, a sample size of 250 patients per arm was required to obtain a power of 95% chance of detecting as significant at the 5% level, a reduction of 10% in the primary outcome measure between the study arms. Radiation exposure end points were analyzed based on an intention-to-treat principle. Values were tested for normal distribution and reported as mean±SD or median (25th–75th percentile) for continuous variables (E and DAP) where applicable or frequency for categorical variables. Depending on the distribution of the data, the independent *t* test or Mann–Whitney *U* test was used to compute differences in operator and patient radiation exposure between the 3 study arms. In subgroup analysis, the difference in the primary outcome between RADPAD, NOPAD, and SHAMPAD among various subgroups (obese versus nonobese patients, CAG versus PCI, location of PCI) will be explored. All statistical tests were 2 tailed, and a value of $P<0.05$ was considered statistically significant. Calculations were generated by SPSS software (version 21.0 for Windows, SPSS, Inc, Chicago, IL).

Results

Study Course

Between January and May 2017, 766 consecutive patients undergoing CAG or PCI (Figure 2) were randomly assigned to RADPAD (N=255), NOPAD (N=255), and SHAMPAD (N=256). Eleven procedures assigned to a (sham) shield did not receive the allocated treatment. In these procedures, the (sham) shields were simply not placed (N=3) or dropped on the floor during procedure (N=8). Main reasons were cardiopulmonary resuscitation and restless patients.

Patient Population and Procedure

Patient, procedural, and operator characteristics were similar in the 3 treatment groups (Table 1). Patients had a mean BMI of 28±5 kg/m^2, and 204 (27%) patients presented at the catheterization laboratory with an acute coronary syndrome. Radial access was used in 606 (79%) procedures. A diagnostic coronary angiogram was performed in 372 cases (49%). Diagnostic interventional procedures such as fractional flow reserve and instantaneous wave-free ratio were performed in 131 (17%). Fluoroscopy and procedure times were comparable among all 3 arms.

Radiation Exposure and Outcomes

The per-procedure operator dose (E), the patient exposure (DAP), and the deduced relative operator exposure (E/DAP) are presented in Table 2 and Figure 2. The primary operator dose and patient exposure were not normally distributed, accordingly the data are presented as median (25th–75th percentile). The nonparametric Mann–Whitney *U* test was used to calculate the differences between the 3 arms. Because the relative exposure is a ratio composed of 2 actual outcomes, data on the primary outcome are expressed as means±SD. The primary outcome of the relative operator exposure showed a statistically significant reduction in procedures with the RADPAD (3.2±3.3 E/DAP) compared with both the NOPAD arm (4.0±4.0 E/DAP; $P=0.01$) and the SHAMPAD (5.7±9.3 E/DAP; $P<0.001$). Additionally, the relative exposure was higher in the SHAMPAD group than in the NOPAD group ($P=0.009$). The patient exposure in DAP was comparable in the 3 study arms (RADPAD, 32 774 mGy·cm^2; NOPAD, 32 450 mGy·cm^2; SHAMPAD, 32 456 mGy·cm^2; $P=0.43$ to $P=0.90$). The radiation exposure of the primary operator was slightly lower in the RADPAD arm (7.0 µSv, 3.2–17.2) than in the NOPAD arm (9.5 µSv, 3.4–21.0, $P=0.11$) and significantly lower than the SHAMPAD arm (10.3 µSv, 4.3–27.3, $P=0.001$).

Subgroup Analyses

Subgroup analyses of the relative operator exposure are presented in Figure 3. The primary end point showed similar dispersion among the various subgroups. Relative operator exposure was lowest in procedures with RADPAD compared with procedures in the NOPAD and SHAMPAD arms, both during CAG and PCI as well as for lesion location in case of PCI and patient BMI. The relative operator exposure was 60% lower in patients with BMI >30 in the RADPAD than in the SHAMPAD arm (2.7±2.4 versus 6.7±15.4 E/DAP; $P=0.03$) and, respectively, 33% lower in patients with a BMI <30 (3.4±3.6 versus 5.1±5.0 E/DAP; $P<0.001$). Moreover, during interventional procedures, the relative exposure was 58% lower in procedures with a RADPAD than in those with the SHAMPAD (2.5±3.1 versus 5.9±11.6 E/DAP; $P=0.001$), and

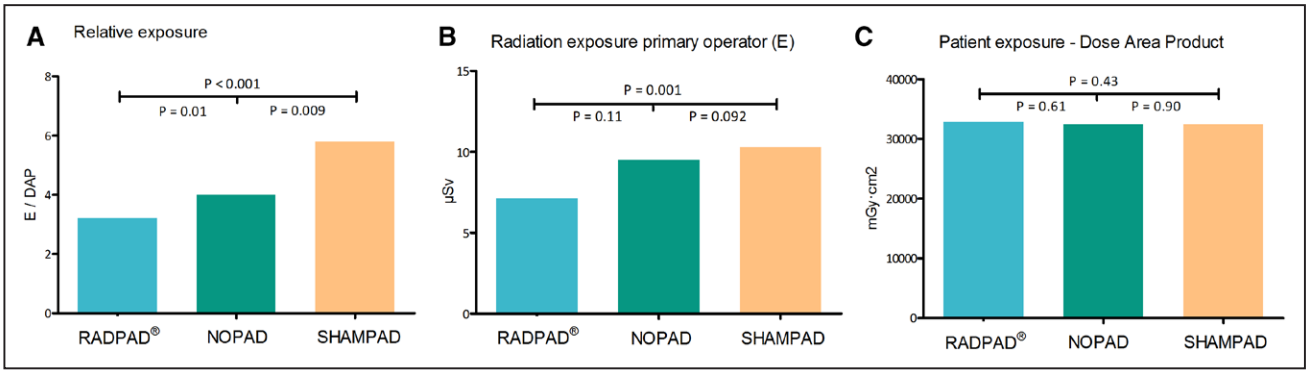

Figure 2. Relative exposure (**A**) (×10^{-4}) is defined as the ratio between the exposure of the primary operator at chest level (**B**) and the patient exposure per procedure (**C**). Data are presented as mean (**A**) or median (**B** and **C**). DAP indicates dose area product; NOPAD, standard treatment; RADPAD, radiation absorbing shield; and SHAMPAD, sham shield.

Table 1. Patient and Procedural Characteristics

	RADPAD (N=255)	NOPAD (N=255)	SHAMPAD (N=256)
Demographics			
Age, y	67±11	67±12	67±12
Male sex	178 (70)	165 (65)	189 (74)
Medical history			
BMI	28±4	28±5	28±5
Previous myocardial infarction	74 (29)	62 (25)	58 (23)
Previous PCI or bypass surgery	99 (39)	99 (39)	90 (35)
Risk factors			
Diabetes mellitus	61 (25)	60 (25)	65 (26)
Known hypertension	157 (64)	137 (56)	136 (55)
Family history of CAD	135 (57)	127 (55)	128 (55)
Hypercholesterolemia	120 (50)	105 (45)	105 (44)
Current cigarette smoking	45 (18)	49 (21)	54 (23)
Presentation			
ACS*	60 (24)	73 (29)	71 (28)
Stable CAD	147 (58)	143 (56)	155 (61)
Other†	48 (19)	39 (15)	30 (12)
Procedural characteristics			
Radial access	201 (79)	202 (79)	203 (79)
CAG‡	136 (53)	116 (46)	120 (47)
IFR/FFR only‡	18 (7)	19 (8)	24 (9)
PCI with stenting	103 (40)	121 (48)	117 (46)
Lesions treated per PCI	1.4±0.7	1.4±0.7	1.4±0.6
Locations of treated lesions			
LM or LAD	61 (59)	59 (49)	70 (59)
CX	35 (34)	38 (31)	26 (22)
RCA	24 (23)	47 (39)	44 (38)
PCI of chronic total occlusion	7 (3)	10 (4)	18 (7)
Primary operator			
Staff operators	168 (66)	175 (69)	177 (69)
Cardiology fellow/trainee	87 (34)	80 (31)	79 (31)
Procedure time, min			
Fluoroscopy time	12.4±11.4	12.9±11.1	13.3±11.2
Skin-to-skin time	45.0±26.7	46.7±25.0	48.9±26.7

Data are number (%) or mean±SD. ACS indicates acute coronary syndrome; BMI, body mass index; CAD, coronary artery disease; CAG, coronary angiography; CX, circumflex artery; FFR, fractional flow reserve; IFR, instantaneous wave-free ratio; LAD, left anterior descending; LM, left main; NOPAD, standard treatment; PCI, percutaneous coronary intervention; RADPAD, radiation absorbing shield; RCA, right coronary artery; and SHAMPAD, sham shield.

*ACS, ST-segment–elevation myocardial infarction/non–ST-segment–elevation myocardial infarction/unstable angina.

†Heart failure, pretransplantation, prevalve replacement.

‡Without any coronary intervention.

31% lower in coronary angiographies (3.8±3.1 versus 5.5±5.6 E/DAP; P=0.005). Furthermore, the relative exposure during femoral access was 35% lower in procedures with a RADPAD than in those with the SHAMPAD (2.9±2.8 versus 4.4±5.7 E/DAP, P=0.09) and, respectively, 45% lower during radial access (3.3±3.3 versus 6.0±10.0 E/DAP; P<0.001).

Discussion

This prospective, large-scale, sham-controlled, randomized study shows that the use of a lightweight, disposable, sterile shield attenuates the relative operators' radiation exposure with 20% compared with conventional safety measures in CAG and PCI. In addition, the use of RADPAD resulted in a 44% reduction of relative operators exposure compared with a sham shield in this study. This effect is consistent during different types of procedures.

Previous Studies

Earlier studies examining the efficacy of the RADPAD during CAG or PCI are limited because of small sample sizes of a maximum of 60 procedures,[9–11] a nonrandomized nature[12] and the lacking of a sham shield group. In contrast, the current study involves a relatively large study population and a sham shield to correct for shield-induced behavior. The reduction of operator received scatter radiation in these earlier studies was between 34% and 59%. The moderately higher reduction rates in these studies may partly be the result of dosimetry performed at left-arm level, in comparison to chest level in the current study. This is confirmed by earlier RADPAD studies that showed that the highest attenuation of scatter radiation is obtained at the sites the closest to the radiation source, such as arms and wrists in comparison to dosimetry at chest and eye level.[11,13,14] The RADPAD was also studied during other interventional procedures in the catheterization laboratory in small randomized, non-sham controlled trials. A 39% operator exposure reduction was observed during transcatheter aortic valve implantation (dosimetry at eye level, N=50),[15] a 54% reduction during resynchronization therapy (dosimetry at hand level, N=22) and a 64% reduction during electrophysiology procedures (dosimetry at arm level, N=20).

Operator Radiation Behavior

Relative operator exposure is strongly variable between procedures because it is the direct consequence of unmeasurable operator behavior characteristics, such as distance to the scatter radiation source. Consequently, there is a large standard deviation of the primary outcome in all 3 study arms. Surprisingly, relative operator exposure was significantly higher in procedures with a SHAMPAD than in procedures with a NOPAD (P=0.009) despite comparable patient exposure (DAP). It is hypothesized that the presence of a radiation protection shield such as the RADPAD induces a sense of security and may reduce the operator's tendency to maintain an appropriate distance from the scatter radiation produced by the patient. This false sense of security in the SHAMPAD arm might explain why the RADPAD is associated with a 2-fold higher relative exposure reduction in the SHAMPAD group compared with the NOPAD group. Because the SHAMPAD accounts for operator behavior, the comparison of the RADPAD versus the

Table 2. Outcomes

	RADPAD (N=255)	NOPAD (N=255)	SHAMPAD (N=256)	RADPAD vs NOPAD	RADPAD vs SHAMPAD	SHAMPAD vs NOPAD
Primary outcome						
Relative exposure (E/DAP)*	3.2±3.3	4.0±4.0	5.7±9.3	*P*=0.01	*P*<0.001	*P*=0.009
Secondary outcomes						
Primary operator dose (E in µSv)	7.0 (3.2–17.2)	9.5 (3.4–21.0)	10.3 (4.3–27.8)	*P*=0.11	*P*=0.001	*P*=0.09
Patient exposure (DAP in mGy·cm^2)	32774 (17 402–64 693)	32450 (16 002–55 584)	32456 (16 633–58 697)	*P*=0.61	*P*=0.43	*P*=0.90

The data of the primary operator dose and the patient exposure were positively skewed, accordingly the operator dose and patient exposure are presented as median (25th–75th percentile). The nonparametric Mann–Whitney *U* test was used to calculate differences between the 3 arms. However, the primary outcome of relative exposure is a ratio, and as such presented as a mean±SD. DAP indicates dose area product; NOPAD, standard treatment; RADPAD, radiation absorbing shield; and SHAMPAD, sham shield.

*$\times 10^{-4}$.

SHAMPAD in this study represents the actual technical qualities of the protective shield. In addition, the SHAMPAD has minimal attenuation characteristics, therefore the actual difference between the RADPAD and a truly nonattenuating pad might be higher than the 44%. On the contrary, the comparison of the RADPAD with the NOPAD arm more likely represents clinical practice. Moreover, the RADPAD was consistently associated with a reduction in relative operator exposure, among various subgroups of procedural and patient characteristics. However, attenuation of the relative exposure was more pronounced in procedures associated with a higher patient exposure, such as procedures in obese patients and coronary interventions. On the contrary, the lower fluoroscopy levels during CAG were associated with smaller benefits of the protective shield. Nevertheless, the current study was not appropriately powered for these subgroup analyses. Finally, the study confirms that the routine use of RADPAD is feasible in almost all procedures aside from cardiopulmonary resuscitations.

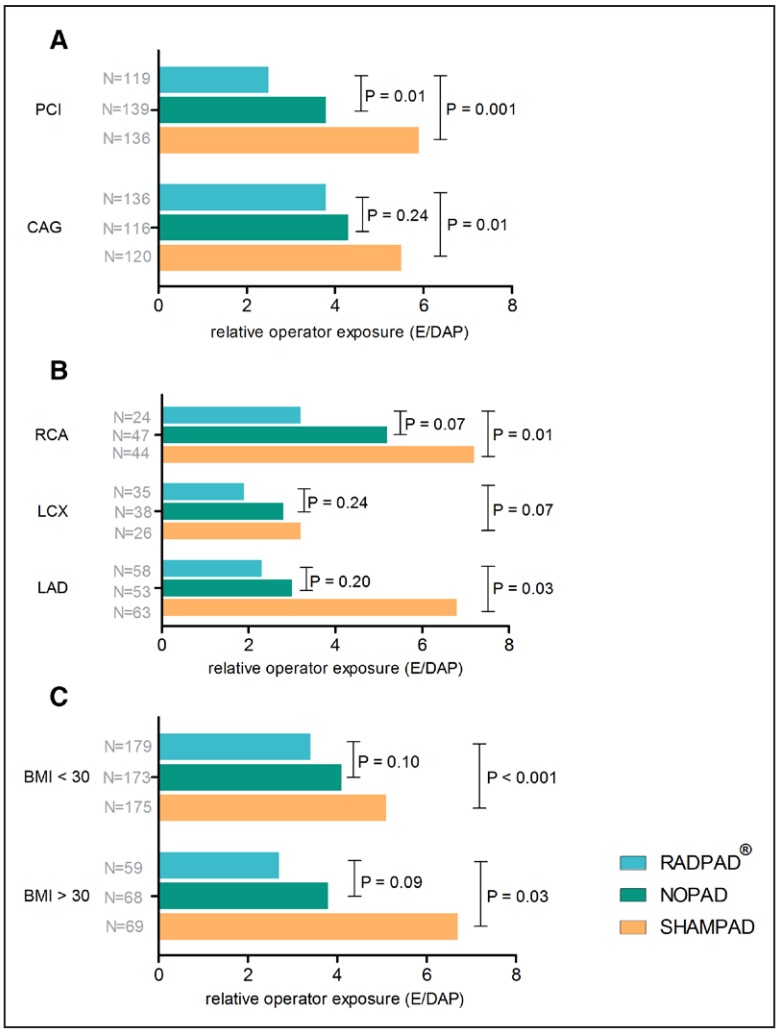

Figure 3. Subgroup analyses of the primary outcome ($\times 10^{-4}$) in procedures with a radiation absorbing shield (RADPAD) vs procedures with standard treatment (NOPAD) or a sham shield (SHAMPAD). **A**, Diagnostic angiogram vs percutaneous coronary interventions (PCI). **B**, Treated vessel in case of PCI. **C**, Procedures in obese vs nonobese patients. BMI indicates body mass index; and CAG, coronary angiography.

Occupational Health Hazards of Radiation Exposure

Procedures in the catheterization laboratory account for almost half of the total cumulative patient dose.[5,16] There are 2 main effects of radiation exposure: tissue reactions (deterministic effects) and stochastic effects (carcinogenic and genetic hazards). Cataract is a deterministic effect associated to the interventional cardiologist's low-level radiation exposure, whereas patients are at risk for skin lesions during high-level radiation exposure. In a recent meta-analysis, the incidence of posterior lens opacities was significantly higher in interventional cardiologists than in control subjects (RR=3.2).[3,17] Moreover, the duration of the professional career in the catheterization laboratory was significantly associated to the risk on radiation-induced lens opacifications.[18] The association between chronic low-dose radiation and the stochastic, long-term risk of malignancies is more difficult to study; currently, there are no good prediction models available. Probabilities for developing radiation-induced malignancies are low, but outcomes can be debilitating and fatal. Therefore, elaborating on the cost-effectiveness of radiation protection devices such as the RADPAD is complex. Nevertheless, the no-threshold stochastic risk on malignancies suggests that there is no such thing as safe radiation exposure. Eventually, all doses accumulate and consequently the risk of malignancies rises. Therefore, the use of extra radiation protection devices deserves sufficient attention and should be included in the appropriate interventional guidelines.

Alternative Radiation Protective Tools

Other personal protective devices besides standard equipment such as mounted shields, aprons and thyroid shields, include gloves and glasses. Leaded glasses, with the presence of side shielding, reduce scatter radiation with a factor of 5 to 10.[19] Nevertheless, the majority of operators reports the glasses as being uncomfortable.[20] Leaded gloves have the ability to reduce hand exposure. However, this is reduced by both forward and backscatter radiation.[21] Therefore, they are not recommended in current guidelines.[22]

Study Limitations

Radiation exposure was measured at chest level (outside the lead apron), exposure at head or eye level was not measured in this study. Nevertheless, current guidelines on the maximum allowed annual operator dose exposure also refer to dosimetry performed outside the lead apron at chest level. Additionally, dosimetry at chest level measures efficacy of the RADPAD and this effect can be extrapolated to other sites of radiation. Moreover, the search for radiation protection devices should never come at the cost of reduced patient safety.[23,24] In this study dosimetry was not performed at patient level. However, we do not expect higher radiation exposure in patients treated with RADPAD because the shield was not placed directly in the radiation beam; this is confirmed by comparable DAP levels among the 3 study arms. Nevertheless, dosimetry at patient level would be of interest in a consecutive trial. Finally, the wide range of procedures is both the strength and a limitation of the current study. The wide range of cases causes a high variability in fluoroscopy use. However, this variation does represent day-to-day clinical practice for interventional cardiologists.

Conclusions

The present large-scale, sham controlled, double-blind, randomized trial resembling real-world clinical practice supports the use of RADPAD, a disposable shield, in addition to conventional radiation protection devices, during diagnostic coronary angiographies and PCIs.

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Disclosures

None.

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