Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 100603

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Original Research

Comprehensive Radiation Shield Minimizes Operator Radiation Exposure and Obviates Need for Lead Aprons

David G. Rizik, MD [a,*], Robert D. Riley, MD [a], Robert F. Burke, MD [a], Sabrina R. Klassen [a], Ariana M. Nigoghosian [b], Kevin P. Gosselin, PhD [a], James A. Goldstein, MD [c]

[a] Department of Cardiovascular Medicine, Honor Health, Scottsdale, Arizona; [b] University of Michigan, Ann Arbor, Michigan; [c] Beaumont Hospital, Royal Oak, Michigan

ABSTRACT

Background: The catheterization laboratory predisposes to occupational health hazards. Chronic radiation exposure (RE) direct injuries include a predilection to cataracts and concerns for cancers. Indirectly adverse effects underly the prevalence of orthopedic maladies in interventionists, linked to the burden of mandatory protective lead aprons. A novel comprehensive shielding system (Protego, Image Diagnostics Inc) has been validated in early studies to provide excellent radiation protection. The system is designed to reduce operator RE sufficient to eliminate the need for personal lead aprons. Recent system refinements offer potentially even greater degrees of protection. This clinical study evaluated the efficacy of this system.

Methods: This single-center 2-group cohort study compared physician operator RE utilizing the latest iteration of the Protego shield (n = 25 cases) or standard protection (personal leaded apparel and drop-down shield, n = 25 cases) during routine cardiac catheterization procedures. RE at both thyroid and waist levels were measured with a real-time dosimetry system (Raysafe) and calculated on a mean per case basis at both thyroid and waist levels. Additional parameters collected included procedure type, access site, per case fluoroscopy time, and patient factors including body mass index. Between-group comparisons were conducted to evaluate RE by group and measurement sites.

Results: Protection with Protego was superior to standard methods. Protego showed markedly lower RE at both the thyroid level (0.36 $\pm$ 0.86 vs 58.5 $\pm$ 50.2 μSv; $P < .001$) and the waist level (0.84 $\pm$ 2.99 vs 121.4 $\pm$ 171.2 μSv; $P < .001$. "Zero" total RE was documented in 68% (n = 17) of Protego cases; in contrast, standard protection did not achieve "zero" exposure in a single case.

Conclusions: The Protego shield system provides excellent RE protection to the physician operator, achieving "zero" RE in two-thirds of cases. RE was superior to standard protection methods. The magnitude of protection achieves state regulatory standards sufficient to allow operators to perform procedures without orthopedically burdensome lead aprons. This shield system has the potential to reduce occupational health hazards.

Introduction

Chronic occupational radiation exposure (RE) from working in the fluoroscopic laboratory poses health hazards to physicians and staff owing to risks of direct radiation-induced injuries, including cataracts and cancers, as well as indirect adverse consequences of orthopedic afflictions related to the cumulative burden of bearing the weight of mandatory personal lead aprons.[1–16] Societies representing interventional physicians have emphasized the need for workplace innovations with the ultimate goal to achieve as close to a zero RE work environment as possible, ultimately eliminating the need for personal protective apparel and thereby mitigating its orthopedic consequences.[1,2]

A novel comprehensive shielding system (Protego, Image Diagnostics Inc; Figure 1) was designed to provide comprehensive total body protection to physician operators (as well as the laboratory staff including nurses and technicians). Early data demonstrated excellent levels of radiation protection with the first iteration of the device[17,18]; the State of Michigan has validated and certified that the magnitude of protection provided is sufficient to allow operators to perform procedures without personal lead aprons.[19] Recent refinements to the shield system were implemented to achieve even greater degrees of protection and ease of use. This study was designed to assess the protective capabilities of the present iteration of the Protego shield.

Abbreviations: DAP, dose area product; RE, radiation exposure.

Keywords: occupational hazard; occupational health; radiation safety.

* Corresponding author: DavidRizik@aol.com (D.G. Rizik).

https://doi.org/10.1016/j.jscai.2023.100603

Received 2 October 2022; Received in revised form 1 February 2023; Accepted 3 February 2023

Available online 21 March 2023

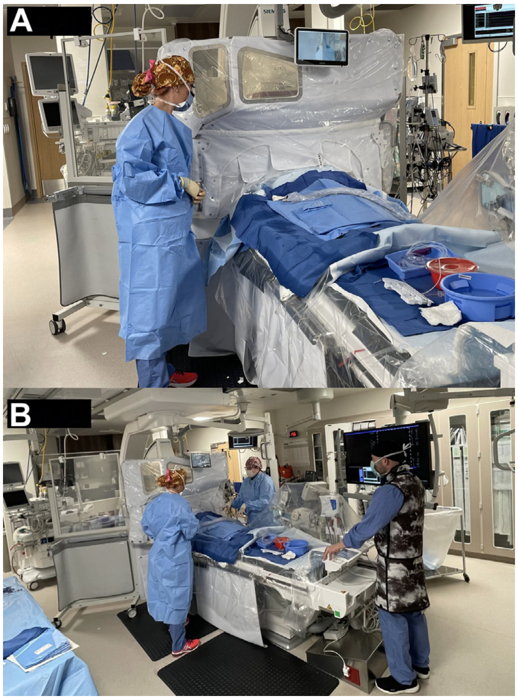


Figure 1.
The Protego shield in clinical operation. (**A**) Protego shield set up. (**B**) In clinical use. Note that the shield casts a broad umbrella of protection that may benefit all catheterization laboratory personnel.

Methods

Study design

This single-center 2-group cohort study compared physician RE to the primary operator utilizing the Protego shield (n = 25 cases) or standard protection alone (personal lead apron, 0.5 mm, thyroid collar and leaded glasses, together with ceiling drop-down shield, n = 25 cases) during routine cardiac catheterization procedures performed in a single catheterization laboratory equipped with a floor-based single plane C-arm (Axiom Artis, Siemens). Employing prior established methods,[17,20] RE to both the thyroid and waist were measured by a real-time dosimetry system (Raysafe). In both groups, operators wore lead aprons and thyroid shields and dosimeters were deployed at the waist and thyroid level external to the lead apron/thyroid collar. RE in microsieverts (μSv) was calculated on mean per case basis at the waist and thyroid levels. "Zero" RE was defined as individual cases in which both thyroid and waist badges showed no detectable RE. Additional parameters collected included procedure type, access site, per case fluoroscopy time, and patient factors including body mass index. Between-group comparisons were conducted to evaluate RE by group and measurement sites.

Protego radiation protection system

The Protego radiation shielding system consists of a combination of rigid shields above and below the table, integrated with interconnecting flexible radiation-resistant drapes (Figure 1), designed to in aggregate achieve a comprehensive radiation barrier that minimizes RE from the 1° x-ray source as well as patient scatter,[19] thereby affording protection to personnel "downstream" of the protective umbrella it casts. Components include the following: (1) upper shield above the table which features an angulated configuration that passively accommodates unimpeded C-arm motion. This component is connected to an articulated support arm that can be suspended from a mobile pedestal platform or the ceiling. This upper shield is mounted on a spring arm and is attached to the table via 2 passive pivoting magnets; this mechanism facilitates quick deployment and release; (2) lower shield attached to the table to reduce scatter down the lower length of the table; (3) operator side accessory shield; and (4) patient visualization enhancements; the upper shield has built-in windows. Furthermore, the system is equipped with left and right cameras on the front side of the shield that project images of the patient's head on monitors mounted for display on the operator side of the shield; (5) flexible radiation drape extending from the lower abdomen to the lower thighs, designed with dual apertures for bilateral femoral vascular access; (6) arm board with in-built radiation drapes for radial access; and (7) disposable sterile drapes that cover the fixed and flexible components. Recent refinements novel to the present iteration employed include a radial arm board shielded vertically (32″ of side scatter protection) and horizontally (table up scatter 32″) and augmented patient-side facing shield to enhance scatter reduction.

The system is designed to achieve 40 LAO-30 caudal C-arm angulation without shield manipulation. To accommodate steeper angles, the shield can be maneuvered via a "sliding" mechanism, whereby the mounting magnets connected to the table rail facilitate further 8 degrees of caudal angulation. Regarding accommodation for vascular access, the system was designed to, and when fully deployed, easily facilitate right and left femoral as well as right radial approaches, thereby allowing access in a "protected mode." Left radial access with the present iteration of the system is less facile but can be accomplished with additional maneuvering of the shield components: During set up, the upper shield is slid caudally along the rail system; alternatively, access can be obtained without the upper shield in place but with the operator wearing a lead apron, then subsequently deploying the upper shield (and if desired, removing the personal lead apron and regowning).

The system, while fully deployed, provides personnel (nurse, technician, physician) access to the patient for routine medical needs (eg, medication administration via intravenous lines and O_2 adjustments), as well as access to the chest and head for emergencies (defibrillation, chest compressions, ventilator management, etc). In scenarios in which greater patient access is deemed necessary, the upper shield can be rapidly released and moved out of the field by unlocking the passive pivoting magnets attaching it to the table. Furthermore, as part of in-service training and manual for use, it is emphasized that all catheterization laboratory personnel must at all times have lead aprons readily available in scenarios in which they must cross to the unprotected (patient head) side of the shield during the procedure.

Primary measures of interest

The primary outcome was the physician operator RE measured in μSv. For each cohort, RE was calculated at the waist and thyroid levels. Also, recorded were per case fluoroscopy time and dose area product. Additional data collected included procedure type (diagnostic, interventional, chronic total occlusion), access site, and patient factors including body mass index.

Statistical analysis

Descriptive statistics were used to summarize the study variables. Shapiro-Wilk test for normality was performed to determine the presence of a normal distribution. Normally, distributed continuous variables are shown as mean ± SD. Categorical variables are shown as count (% frequency). Comparisons were conducted using Mann-Whitney *U* tests with an alpha of 0.05.

Table 1. Patient and procedural characteristics.

	Control group (n = 25)	Protego group (n = 25)
Patient characteristics		
Age, y	70.2	66.9
Female sex	8 (32%)	9 (36%)
Male sex	17 (68%)	16 (64%)
Body mass index, kg/m^2	28.2 ± 4.91	29.1 ± 4.82
Procedural characteristics		
Diagnostic	16 (64%)	13 (52%)
Intervention	9 (36%)	12 (48%)
Chronic total occlusion	1 (4%)	1 (4%)
Access site—radial	18 (72%)	19 (76%)
Access site—femoral	7 (28%)	6 (24%)
Access site—both	0 (0%)	0 (0%)
Fluoroscopy time, min	10.5 ± 10.1	12.0 ± 11.6
Air kerma, mGy	716.8 ± 660.4	766.3 ± 716.9
DAP, Gy·cm^2	44.6 ± 40.4	49.5 ± 41.5
Dose/DAP (1/cm^2)	0.0161	0.0155
Raysafe badge dose		
Waist badge, mrem	12.14 ± 17.12	0.084 ± 0.29
Thyroid, mrem	5.85 ± 5.02	0.036 ± 0.08
Waist badge, μSv	121.4 ± 171.2	0.84 ± 2.9
Thyroid, μSv	58.5 ± 50.2	0.36 ± 0.86

Values are expressed as n (%) or mean ± SD.
DAP, dose area product.

Of note, prior investigations in the field vary with regard to reporting of RE data. Some reports express RE in mrem units and others in μSv; similarly, some report data as median whereas others as mean. Throughout the body of the present paper, we report results as μSv (mean, SD). However, for the purposes of comparison to previous reports, we provide RE in both μSv and mrem (Table 1), as well as expressed as mean vs median (Table 2).

Results

Demographic and procedural data for both groups are illustrated in Table 1. The Protego shield system facilitated the ease of access for radial cases (76% of procedures) as well as femoral access (24% of cases). The full range of C-arm angulation was easily accommodated and in no case did the shield system impair procedural performance with respect to vascular access, utilization, and manipulation of catheter equipment or observation and communication with the patient or staff.

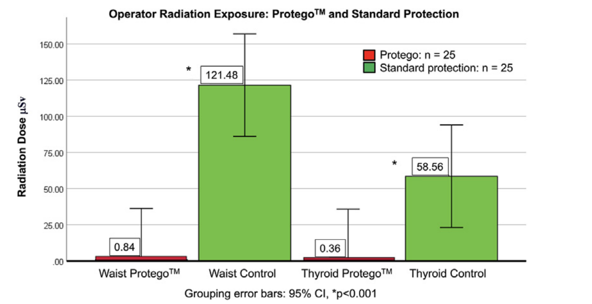
Operator radiation exposure: Protego shield vs standard protection

Protection with Protego was superior to standard methods (Table 2). Protego showed markedly lower RE at both the thyroid level (0.36 ± 0.86 vs 58.5 ± 50.2 μSv; $P < .001$) and at the waist (0.84 ± 2.99 vs 121.4 ± 171.2 μSv; $P < .001$). Remarkably, there was "zero" RE in 17 (68%) Protego cases. In contrast, standard protection did not achieve "zero" exposure in a single case. Comparisons of mean RE levels in Protego and standard cohorts are presented in Central Illustration. Mean fluoroscopy time/case was similar in both groups (Protego 12.0 ± 11.6 vs standard protection 10.5 ± 10.1 minutes), as was mean dose area product/case (Protego 49.5 ± 41.5 vs standard protection 44.6 ± 40.4 Gy·cm^2; P = not significant).

It should be noted that in one Protego femoral-based procedure, the RaySafe system detected a brief intraprocedural RE "leak" (waist RE = 15.0 μSv). Intraprocedural assessment revealed a gap between shield components, which was rapidly rectified by readjustment. This observation emphasizes the importance of the "on-line" personal radiation detector mandated to instantaneously identify radiation "leaks" and thereby assure optimal operator safety.

Table 2. Mean, median, standard deviation, and interquartile ranges for microsieverts (μSv) of radiation exposure by group and access site.

	Waist		Thyroid	
	Protego	Standard protection	Protego	Standard protection
N				
Valid	25	25	25	25
Missing	0	0	0	0
Mean	0.840	121.480	0.360	58.560
Median	0.000	54.000	0.000	56.000
Standard deviation	2.996	171.238	0.860	50.284
Percentiles				
25	0.000	36.500	0.000	18.000
50	0.000	54.000	0.000	56.000
75	0.500	107.500	0.000	62.000



Central Illustration.
Real-time Raysafe dosimetry comparison between Protego and standard protection. Operator mean radiation exposure/case is described in μSv measured at the waist and thyroid for both groups.

Discussion

Observations from the present study document that the Protego radiation shielding system provides excellent RE protection to the physician operator, superior to protection compared with standard methods and achieving "zero" RE in two-thirds of cases. This system allows the operator full procedural performance, including radial and femoral vascular access, and accommodates the full range of C-arm angulation. These findings support the concept that this comprehensive radiation shielding system provides exceptional operator protection sufficient to obviate the need for orthopedically burdensome lead aprons and has the potential to reduce catheterization laboratory occupational health hazards.

Catheterization laboratory occupational health risks

Increasing attention has been drawn to occupational health hazards associated with working in the fluoroscopic laboratory.[1–6] Chronic occupational RE has been associated with posterior subcapsular cataracts evident in over 50% of interventional physicians, with a strong dose–response relationship to occupational exposure.[7–9] There are also growing concerns for cancer induction,[4,11–16] first highlighted by reports of a cluster of predominantly left-sided brain cancers in interventionists.[10] There are growing concerns regarding RE to women working in the fluoroscopic environment, with an increased incidence of breast cancer in female interventionists[4] and radiology technicians,[11,12] as well as female orthopedic surgeons who routinely perform fluoroscopically guided procedures.[13] Considerations of cancer, together with RE during pregnancy, orthopedic burdens, and lower extremity venous disease, have been cited as contributors for the disproportionately low representation of women in the interventional field.[21–23]

Data implicating RE and organ injury is supported by observations demonstrating the disproportionate vulnerability of anatomic regions unprotected by traditional shielding, a notion emphasized by interventionists suffering predominantly "left-sided" brain cancers,[10] carotid atherosclerosis,[5] and cutaneous malignancies in exposed zones.[14–16] The protective benefits of the present shield system in reducing RE at the head, neck, and eye levels above and beyond standard shielding have promise to reduce these maladies. The alarming 50% rate of orthopedic afflictions in interventional cardiologists, most prevalent in the cervical and lumbar spine, has been inextricably linked to the cumulative effects of bearing the weight of mandatory leaded aprons that provide only partial protection.[1–4] These occupational health concerns apply to the entire catheterization laboratory team including nurses and technicians,[20] as well as to the fields of electrophysiology and interventional radiology.

Comprehensive radiation protection

The ultimate goal in mitigating occupational risk is obtaining a sufficiently low radiation exposure work environment to eliminate the need for personal lead apparel in order to prevent its unfavorable orthopedic consequences.[1] The Protego shield was designed to provide comprehensive "whole-body" operator protection, protecting the brain and extremities, which traditional shielding leaves not fully covered. The present findings are consistent with and extend those of prior studies demonstrating that the Protego radiation shield provides exceptional protection to the physician operator.[17,18] The State of Michigan has been deemed the level of protection sufficient to certify the Protego shield for use in lieu of and without the need for personal leaded apparel.[19] The present observations documenting that two-thirds of cases were performed with "zero" RE reflects the efficacy afforded by further shield refinements and the benefit of experience from earlier initial studies pioneering the not unexpected "learning curve" for deployment and operation intrinsic to any novel technology.

Occupational Safety and Health Administration federal standards[24] set the maximum annual allowable occupational radiation exposure at 5 rem/annum (5000 mrem/annum). Extrapolating from the present mean waist/case RE data (employing the standard mathematical conversion of μSv to mrem/case), a "busy" interventionist could perform 400 cases/year and be exposed to approximately only 0.67% of the allowable limit, whereas a "high-volume" interventionist performing 1000 cases/annum would receive 1.68% of the recommended annual allowable.

Limitations

It is important to emphasize the limitations of this observational study. The Protego shield was designed to cast a broad geographic "umbrella" of protection. Although it is anticipated to afford RE protection to all "tableside" personnel as well circulating catheterization laboratory staff during the times in which they are "downstream" to the shield, the present study measured primary operator RE only; therefore, future studies will be necessary to establish the broadness of protection. Protective capabilities for peripheral vascular and structural procedures also require further evaluation. Whether routine use of this shield system will reduce occupational maladies requires further study.

Conclusions

The Protego radiation shielding system provides comprehensive physician operator RE protection while allowing the operator complete procedural performance. This shielding approach can eliminate the need for orthopedically burdensome personal leaded apparel and has the potential to reduce catheterization laboratory occupational health hazards.

Peer review statement

Section Editor David G. Rizik had no involvement in the peer review of this article and have no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Associate Editor Sahil A. Parikh.

Declaration of competing interest

James A. Goldstein is an owner of equity and Board Member of ECLS, Inc, which licenses technology to Image Diagnostics Inc, which manufactures and sells the Protego shield. David G. Rizik, Robert D. Riley, Robert F. Burke, Sabrina R. Klassen, Ariana M. Nigoghosian, and Kevin P. Gosselin reported no financial interests.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics statement and patient consent

The research reported has adhered to the relevant ethical guidelines; patient consent has been obtained, if needed.

References

1. Klein LW, Goldstein JA, Haines D, et al. SCAI multi-society position statement on occupational health hazards of the catheterization laboratory: shifting the paradigm for healthcare workers' protection. *Catheter Cardiovasc Interv*. 2020;95(7):1327–1333.
2. Klein LW, Tra Y, Garratt KN, et al. Occupational health hazards of interventional cardiologists in the current decade: results of the 2014 SCAI membership survey. *Catheter Cardiovasc Interv*. 2015;86(5):913–924.
3. Orme NM, Rihal CS, Gulati R, et al. Occupational health hazards of working in the interventional laboratory: a multisite case control study of physicians and allied staff. *J Am Coll Cardiol*. 2015;65(8):820–826.
4. Andreassi MG, Piccaluga E, Guagliumi G, Del Greco M, Gaita F, Picano E. Occupational health risks in cardiac catheterization laboratory workers. *Circ Cardiovasc Interv*. 2016;9(4):e003273.
5. Andreassi MG, Piccaluga E, Gargani L, et al. Subclinical carotid atherosclerosis and early vascular aging from long-term low-dose ionizing radiation exposure: a genetic, telomere, and vascular ultrasound study in cardiac catheterization laboratory staff. *JACC Cardiovasc Interv*. 2015;8(4):616–627.
6. Sciahbasi A, Frigoli E, Sarandrea A, et al. Radiation exposure and vascular access in acute coronary syndromes: the RAD-matrix trial. *J Am Coll Cardiol*. 2017;69(20):2530–2537.
7. Ciraj-Bijelac O, Rehani MM, Sim KH, Liew HB, Vano E, Kleiman NJ. Risk for radiation-induced cataract for staff in interventional cardiology: is there reason for concern? *Catheter Cardiovasc Interv*. 2010;76(6):826–834.
8. Elmaraezy A, Ebraheem Morra M, Tarek Mohammed A, et al. Risk of cataract among interventional cardiologists and catheterization lab staff: a systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2017;90(1):1–9.
9. Karatasakis A, Brilakis HS, Danek BA, et al. Radiation-associated lens changes in the cardiac catheterization laboratory: results from the IC-CATARACT (CATaracts Attributed to Radiation in the CaTH lab) study. *Catheter Cardiovasc Interv*. 2018;91(4):647–654.
10. Roguin A, Goldstein J, Bar O, Goldstein JA. Brain and neck tumors among physicians performing interventional procedures. *Am J Cardiol*. 2013;111(9):1368–1372.
11. Rajaraman P, Doody MM, Yu CL, et al. Cancer risks in U.S. radiologic technologists working with fluoroscopically guided interventional procedures, 1994-2008. *AJR Am J Roentgenol*. 2016;206(5):1101–1108.
12. Preston DL, Kitahara CM, Freedman DM, et al. Breast cancer risk and protracted low-to-moderate dose occupational radiation exposure in the US Radiologic Technologists Cohort, 1983-2008. *Br J Cancer*. 2016;115(9):1105–1112.
13. Chou LB, Johnson B, Shapiro LM, et al. Increased prevalence of breast and all-cause cancer in female orthopaedic surgeons. *J Am Acad Orthop Surg Glob Res Rev*. 2022;6(5), e22.00031.
14. Yoshinaga S, Hauptmann M, Sigurdson AJ, et al. Nonmelanoma skin cancer in relation to ionizing radiation exposure among U.S. radiologic technologists. *Int J Cancer*. 2005;115(5):828–834.

15. Eagan JT, Jones CT, Roubin GS. Interventional cardiologists: beware and be aware: an updated report of radiation-induced cutaneous cancers. *Catheter Cardiovasc Interv*. 2018;91(3):475–477.
16. Purohit E, Karimipour D, Madder RD. Multiple cutaneous cancers in an interventional cardiologist: predominance in unprotected skin nearest the radiation source. *Cardiovasc Revasc Med*. 2021;28S:206–207.
17. Dixon SR, Rabah M, Emerson S, Schultz C, Madder RD. A novel catheterization laboratory radiation shielding system: results of pre-clinical testing. *Cardiovasc Revasc Med*. 2022;36:51–55.
18. Rabah M, Allen S, Abbas AE, Dixon SR. A novel comprehensive radiation shielding system eliminates need for personal lead aprons in the catheterization laboratory. *Catheter Cardiovasc Interv*. 2023;101(1):79–86.
19. Michigan Occupational Safety and Health Administration. *MIOSHA RSS-0037 February 2021 Code of Federal Regulations (10 CFR Part 20)*; 2022. Accessed March 13, 2023. https://www.michigan.gov/leo/bureaus-agencies/miosha; 2022
20. Madder RD, LaCombe A, VanOosterhout S, et al. Radiation exposure among scrub technologists and nurse circulators during cardiac catheterization: the impact of accessory lead shields. *JACC Cardiovasc Interv*. 2018;11(2): 206–212.
21. Best PJ, Skelding KA, Mehran R, et al. SCAI consensus document on occupational radiation exposure to the pregnant cardiologist and technical personnel. *Catheter Cardiovasc Interv*. 2011;77(2):232–241.
22. Wang TY, Grines CL, Ortega R, et al. Women in interventional cardiology: update in percutaneous coronary intervention practice patterns and outcomes of female operators from the National Cardiovascular Data Registry. *Catheter Cardiovasc Interv*. 2016;87(4):663–668.
23. Grines CL, Voeltz M, Dupont A, Tukaye D. Society for Cardiovascular Angiography and Interventions Women in Innovations. A paucity of female interventional cardiologists: what are the issues and how can we increase recruitment and retention of women? *J Am Heart Assoc*. 2021;10(5): e019431.
24. US Department of Labor. Code of Federal Regulations, Title 29, Occupational Safety and Health Administration, Part 1910.1096. Ionizing Radiation Standard. December 2003.