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Comprehensive radiation shield minimizes operator radiation exposure in coronary and structural heart procedures

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ABSTRACT

Objectives: This study evaluated the efficacy of a novel comprehensive shield designed to minimize radiation exposure (RE) to Physicians performing coronary and structural heart procedures.
Background: The Protego™ radiation shielding system (Image Diagnostics Inc., Fitchburg, Ma) is designed to provide comprehensive protection from RE and has been State certified sufficient to allow operators to perform procedures without orthopedically burdensome lead aprons.
Methods: This single center two-group cohort study assessed the efficacy of this shield in a large number of cardiac procedures (coronary and structural), comparing operator RE compared to standard protection methods (personal lead apparel and "drop down" shield).
Results: The Protego™ system reduced operator RE by 99 % compared to Standard Protection. RE was significantly lower at both "Head" level by thyroid median dose 0.0 (0.0, 0,0) vs 5.7 (2.9, 8.2) μSv ($p < 0.001$), as well as waist dose 0.0 (0.0, 0.0) vs 10.0 (5.0, 16.6) μSv ($p < 0.001$). ("Zero" Total RE was documented by Raysafe™ in 64 % ($n = 32$) of TAVR cases and 73.2 % ($n = 183$) of the coronary cases utilizing Protego™. In contrast, standard protection did not achieve "Zero" exposure in a single case. These dramatic differences in RE were achieved despite higher fluoroscopy times in the Protego™ arm (11.9 ± 8.6 vs 14.3 ± 12.5 min, $p = 0.015$). Per case procedural exposure measured by Dose Area Product was higher in the Protego™ group compared to standard protection (115.4 ± 139.2 vs 74.9 ± 69.3, $p < 0.001$).
Conclusion: The Protego™ shield provides total body RE protection for operators performing both coronary and structural heart procedures. This shield allows procedural performance without the need for personal lead aprons and has potential to reduce catheterization laboratory occupational health hazards.

1. 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 [1–15]. Societies representing Interventional Physicians have emphasized the need for workplace innovations with the goal of achieving as close to a zero RE work environment as possible, and thereby ultimately eliminating the need for personal protective apparel and thereby mitigate its orthopedic consequences [1,2].

A novel comprehensive shielding system (Protego™, Image Diagnostics Inc., Fitchburg, Ma, Fig. 1) was designed to provide comprehensive total body protection to the entire Catheterization Laboratory staff [16]. Prior studies have documented that this Shield offers unprecedented protection to Physician operators performing cardiac procedures, achieving up to >99 % reductions in RE [17–19]. Similar magnitude of reduced RE has been documented in our crucial and jeopardized allied Catheterization Laboratory staff including Nurses and Technicians [20]. 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 [21]. Given the importance of further validation in a large number of cardiac procedures, the present study was designed to assess and compare the efficacy of RE reduction by this shield compared to standard protection methods in a large case cohort spanning a breadth of cardiac procedures (diagnostic, coronary interventions including complex cases and structural).

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Fig. 1. Protego set up.

2. Methods

2.1. Study design

This single center two-group cohort study compared Physician RE to the primary operator utilizing the Protego™ shield ($n = 300$ cases) or standard protection alone (personal lead apron 0.5 mm, thyroid collar and leaded glasses, together with ceiling drop-down shield, $n = 150$ cases). There were multiple operators who performed the Protego™ cases, which were consecutive. The standard protection "control" cohort represented consecutive cases by multiple operators who similarly wore dosimeters at waist and thyroid levels. Use of Protego™, was at the discretion of the physician operator. Overall, the study analyzed 350 coronary procedures including 4 chronic total occlusions, 8 cases involving unprotected left main intervention, as well as 100 transcatheter aortic valve (TAVR) cases. Procedures were performed in a single cardiac catheterization laboratory equipped with a floor-based single plane C-arm (Axiom Artis, Siemens, Munich, Germany). Employing prior established methods [17–20] RE to both thyroid and waist were measured by a real-time dosimetry system (Raysafe™, Billdal, Sweden). All operators by State mandate wore personal leaded apparel (0.5 mm lead aprons, glasses, thyroid collars), both in the controls (which also utilized a "drop-down" shield) and in the Protego™ shield groups. Therefore, the present study deployed the dosimeters outside of the lead apron at waist and thyroid levels, the purpose to analyze total body exposure, including protection to the trunk and extremities assessed by the waist dosimeter and exposure to the head (brain and eyes) measured by the thyroid dosimeter. RE in micro-sieverts (μSv) measured by the RaySafe dosimeters was expressed on mean per case basis at the waist and thyroid levels. Recognizing that some prior studies report median RE data, in the present study we provide both reporting mean and median, thereby facilitating comparison to prior observations. "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 site.

2.1.1. Protego™ radiation protection system

The Protego™ radiation shielding system has previously been described [16–20] Briefly, it consists of a combination of rigid shields above and below the table, integrated with inter-connecting flexible radiation resistant drapes (Fig. 1), designed to in aggregate achieve a comprehensive radiation barrier that minimizes RE from the 1^{O} X-ray source as well as patient scatter, thereby affording protection to personnel "downstream" of the protective umbrella it casts. Components include: (1) Upper shield with angulated configuration which passively accommodates unimpeded C-arm motion; this component is reversibly connected to the table to facilitate unified motion during table movements (e.g. panning); This shield is connected to and floats with an articulated support arm suspended from either a mobile pedestal platform or the ceiling; (2) Lower shield attached to the table to reduce scatter along the lower length of the table; (3) Operator side Accessory shield; (4) Flexible radiation drape extending from the lower abdomen to the lower thighs, designed with dual apertures for bilateral femoral vascular access; (5) Arm board with in-built radiation drapes for radial access; (6) Disposable sterile drapes that cover the fixed and flexible components.; (7) the system is equipped with 2 cameras focused on the patient, with real time video monitor (s) placed on the operator side of the shield. The System is designed to achieve >40 LAO-30 Caudal C-arm angulation without shield manipulation. The system easily facilitates right and left femoral as well as radial approaches.

2.1.2. Primary measures of interest

The primary outcome was Physician operator RE measured in μSv. For each cohort, RE was measured at the Head level thyroid dosimeter) and at the waist. Also recorded were per case fluoroscopy time and dose area product (DAP). Additional data collected included procedure type, access site and patient factors including body mass index (BMI).

2.2. Statistical analysis

Descriptive statistics were used to summarize 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 ± standard deviation. Categorical variables are shown as count (% frequency). Comparisons were conducted using Mann-Whitney *U* tests with an alpha of 0.05.

Of note, prior investigations in the field vary with regard to reporting of RE data, both with respect to units of exposure (mrems vs μSv) as well as statistical expression (median vs means). In the present paper, we report results as μSv consistent with prior investigations of this and other devices. Further, we report RE data as median doses (with 25th and 75th percentiles), based on the statistical concpet that non-normally distributed data such as in the present study are most appropriately expressed in this format. This related to concern that mean radiation dose from such a data set may be skewed by a small number of cases with non-zero radiaiton doses, artificially giving the impression that the operator receives a small amount of radiaiton in the average case. Therefore, for the purposes of comparison to previous reports, we provide RE in both, μSv, expressed as median doses with 25th and 75th percentiles (Table 2).

3. Results

Demographic and procedural data for both groups are illustrated in Table 1. In the coronary cohort, the Protego™ shield facilitated ease of access for radial cases (76 % of total procedures) as well as femoral access (24 % of total cases). In the TAVR cohort in which Protego™ was used, 96 % of the cases involved both radial and femoral access and 4 % of cases involved bi-femoral access. The full range of C-arm angulations 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.

3.1. Operator radiation exposure: Protego™ shield vs standard protection

Protection with Protego™ was superior to Standard Protection, reducing operator RE by 99 % (Tables 1 and 2, Fig. 2). Overall, Protego™ was associated with significantly lower RE at the "Head" level by thyroid median dose 0.0 (0.0, 0.0) vs 5.7 (2.9, 8.2) μSv, ($p < 0.001$) as well as waist dose 0.0 (0.0, 0.0) vs 10.0 (5.0, 16.6) μSv, ($p < 0.001$). These statistically significant reductions in RE in the aggregate population of coronary and structural cases (Fig. 2) were also independently seen in both the coronary only cases as well as the TAVR cases (Fig. 3, Table 2). Remarkably, utilizing Protego™ was associated with Zero" Total RE in 215 cases overall, including 64 % of TAVR cases ($n = 32$) and 73 % of coronary procedures ($n = 183$). In contrast, standard protection did not achieve "Zero" exposure in a single case. These marked reductions in RE were achieved despite significantly higher fluoroscopy times in the Protego™ arm (mean 14.3 ± 12.5 vs 11.9 ± 8.6 min, $p = 0.015$). It also merits discussion that the per case procedural exposure measured by Dose Area Product was significantly higher in the Protego™ group compared to standard protection (115.4 ± 139.2 vs 74.9 ± 69.3, $p < 0.001$).

4. Discussion

Observations from the present study document that the Protego™ radiation shielding system provides excellent RE protection to the Physician operator, a level of protection markedly lower compared to standard methods and achieving "Zero" RE in over 70 % of all structural and coronary cases. The present findings based on a large number of patients undergoing a

Table 1
Patient and procedural characteristics.

	Control Group	Protego™ Group	
Total Cases	n = 150	n = 300	
LHC/PCI Cases	n = 100	n = 250	
TAVR Cases	n = 50	n = 50	
Patient Characteristics			
Age (years)	72.6 years	69.9 years	p = ns
Female Gender	n = 60 (40 %)	n = 87 (29 %)	p = 0.019
Male Gender	n = 90 (60 %)	n = 213 (71 %)	p = 0.019
Body mass index (kg/m^2)	28.5 (SD 4.69)	28.6 (SD 5.18)	p = ns
Procedural Characteristics: Coronary Cases			
Diagnostic	n = 54 (54 %)	n = 87 (34.8)	
Intervention	n = 46 (46 %)	n = 163 (65.2)	p = 0.009
Access Site – Radial	n = 74 (74 %)	n = 190 (76 %)	p = ns
Access Site – Femoral	n = 26 (26 %)	n = 60 (24 %)	p = ns
Procedural Characteristics: TAVR			
Dual Access Site: Radial and Femoral	n = 50 (100 %)	n = 48 (96 %)	p = ns
Radiation Exposure: Aggregate of Coronary & TAVR Cases			
Fluoroscopy Time (min)	11.9 (SD 8.6)	14.3 (SD 12.5)	p = 0.015
Air Kerma (mGy)	683.1 (SD 575.7)	930.9 (SD 958.7)	p = 0.004
DAP (Gy•cm^2)	74.9 (SD 69.3)	115.4 (SD 139.2)	p < 0.001
Dose/DAP (1/cm^2)	0.0091	0.0080	

broad spectrum of procedures (diagnostic catheterizations, percutaneous coronary interventions and structural heart procedures) are consistent with and extend those of prior studies in smaller patient cohorts [16–20] documenting that the Protego™ radiation shielding system provides unprecedented RE protection, reduced >99 % compared to standard methods. From an ergonomic perspective, the system is practical and user-friendly, can be deployed in<5 min, allows the operator full procedural performance including radial and femoral vascular access and accommodates the full range of C-arm angulations. Independent testing by the State of Michigan has documented the level of protection sufficient to certify the Protego™ shield for use in lieu of and without need for orthopedically burdensome personal lead aprons [21].

4.1. Catheterization laboratory occupational health risks

The present observations suggest that this shield system has potential to reduce the concerning incidence of the direct and indirect occupational health hazards associated with working in the fluoroscopic laboratory [1–16].

4.1.1. Direct radiation injuries: cataracts and cancers

Ionizing radiation induces adverse tissue effects, categorized as "Deterministic" injury defined as those occurring when exposure exceeds a certain threshold, versus "Stochastic" effects which occur in proportion to cumulative radiation dose over time with a long latency period and there for which there is no threshold dose below which genetic damage will not occur (e.g. cancers). Chronic accumulated occupational RE is associated with adverse health consequences, particularly cataracts and alarmingly cancers [1–12]. Occupational RE has been associated with premature cataracts in 50 % of interventional physicians, a frequency 3-fold greater than the general population, with a strong dose–response relationship to occupational exposure [6]. Forebodingly, increasing reports signal a link between occupational RE and cancer induction [7–13], concerns first highlighted by reports of a cluster of predominantly left-sided brain cancers in interventionists [8,9]. Further, there is growing anxiety regarding RE to women working in the fluoroscopic environment, based on an increased incidence of breast cancer in female Interventionists [3] and Radiology technicians [9], as well as female orthopedic surgeons who routinely perform fluoroscopically guided procedures [10]. The direct impact of RE is supported by evidence documenting disproportionate anatomic injury closet in proximity to the X-ray source, evidenced by findings of a preponderance of "left-sided" brain cancers [8,9], carotid atherosclerosis [13] and cutaneous malignancies in exposed and unprotected zones [11,12].

4.2. RE indirect injuries: orthopedic afflictions

Orthopedic maladies plague 50 % of Interventional Cardiologists, as well as Cath Lab Nurses and Technicians [1–4,14,15,22]. RE is "indirectly" implicated as a factor responsible for this "endemic" of orthopedic injuries, indisputably related to and aggravated by the physical burden of lead aprons (which are only partially protective). These ailments may result in missed days of work, corrective surgeries and, in some cases, abbreviated professional careers.

4.3. Importance of radiation exposure to women in the field

Occupational health hazards are of particular relevance to women performing fluoroscopic procedures. The signals of disproportionate cancer risk, particularly breast cancer is of great concern [23–25]. RE during child-bearing years and the orthopedic burden of wearing heavy lead pose further practical and logistical challenges. 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.

4.4. Protego™ shield: comprehensive radiation protection

The ultimate goal in mitigating occupational risk is obtaining a RE work environment sufficiently low 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 support those of prior studies demonstrating that the Protego™ radiation shield was associated with exceptional protection to the Physician operator performing diagnostic and interventional coronary [18] as well as TAVR procedures [19]. These occupational health concerns apply to the entire catheterization laboratory team including Nurses and Technicians [20]). Of note, the Protego™ shield was designed to cast a broad geographic "umbrella" of protection. Recent studies now document that this shielding system affords comprehensive RE protection to all "tableside" personnel as well circulating catheterization laboratory staff during the times in which they are "downstream" to the shield, levels measured as "Zero" [20].

In the aggregate group of coronary and structural procedures, the overwhelming majority of cases done with Protego™, was associated with a RE to the primary operator of "zero". As shown in Table 2, the median radiation exposure to the primary operator is "zero" with 25th and 75th percentiles of

Table 2
Comparison of Aggregate LHC/PCI/TAVR Cases (n = 450), Coronary Only Cases (n = 350), and Structural Only Cases (n = 100).
Shown are the Median and Interquartile Ranges for Microsieverts (μSv) of Radiation Exposure by Group and Site of Measurement (Waist and Thyroid).

		Waist		Thyroid	
Aggregate Coronary & Structural Cases (LHC/PCI/TAVR)		Protego™	Standard Protection	Protego™	Standard Protection
N	Valid	300	150	300	150
	Missing	0	0	0	0
Median		0.00	10.00	0.00	5.70
Percentiles	25	0.00	5.00	0.00	2.90
	50	0.00	10.00	0.00	5.70
	75	0.00	16.60	0.00	8.20
		Waist		Thyroid	
Coronary Only Cases: LHC/PCI		Protego™	Standard Protection	Protego™	Standard Protection
N	Valid	250	100	250	100
	Missing	0	0	0	0
Median		0.00	5.85	0.00	5.50
Percentiles	25	0.00	4.70	0.000	2.30
	50	0.00	5.85	0.000	5.50
	75	1.00	11.60	0.000	6.00
		Waist		Thyroid	
Structural Only Cases: TAVR		Protego™	Standard Protection	Protego™	Standard Protection
N	Valid	50	50	50	50
	Missing	0	0	0	0
Median		0.00	14.40	0.00	7.30
Percentiles	25	0.00	10.65	0.000	3.70
	50	0.00	14.40	0.000	7.30
	75	1.00	17.00	0.000	10.50

Data were entered and analyzed using IBM SPSS Version 28 (IBM Corp. Released 2022.). The alpha level was set at 0.05. The Bonferroni correction (α/k) was applied to adjust for experimenter-wise error with multiple comparison test on the same participants resulting in an adjusted alpha of 0.025 (0.05/2).
Data were screened for parametric statistical test assumptions. Kolmogorov-Smirnov tests were conducted to assess normality on radiation exposure (μSv) by condition (standard protection vs Protego™) at waist and thyroid. Results indicated that μSv did not follow normal distributions for both the waist, $D(450) = 9.93$, $p < 0.001$, and thyroid, $D(450) = 9.87$, $p < 0.001$.
Results of the Mann-Whitney U tests indicated significantly less radiation exposure for the Protego™ group compared to the standard protection group at the waist ($z = -19.15$, $p < 0.001$) and thyroid ($z = -18.72$, $p < 0.001$).
Similar levels of reduced radiation exposure were seen in the Coronary only cases and Structural only cases, with achieved p values for both comparisons at < 0.001.

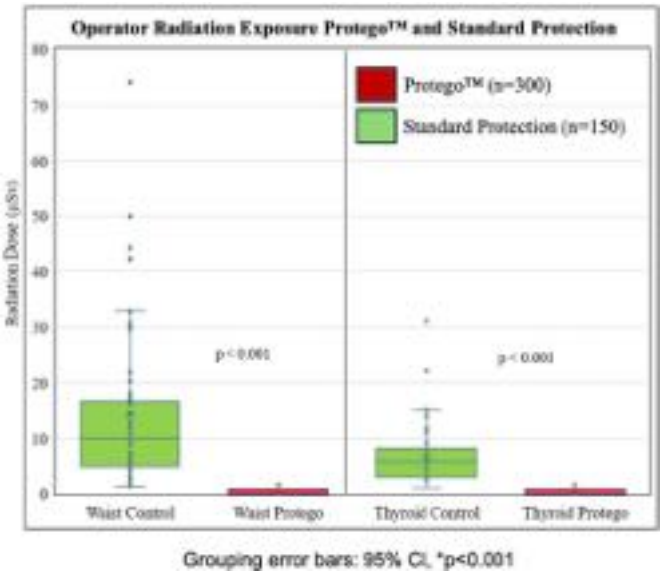

Fig. 2. In the aggregate group of coronary and structural heart procedures, Protego™ was associated with superior operator protection, with a median exposure of "zero" taken at the waist and thyroid compared to Standard Protection. This represents a > 99% reduction in median radiation exposure in the Protego™ arm.

zero; these are levels as close to perfect protection as any radiation device studied has ever achieved. Occupational Safety and Health Administration (OSHA) Federal standards [26] 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 0.5 % of the allowable limit, whereas a "high volume" Interventionist performing 1000 cases/annum would receive 1.26 % of the recommended annual allowable. Performing procedures with the present comprehensive total body shielding has the promise to reduce these "direct" injury related maladies. Getting "the Lead off our Backs" will hopefully mitigate orthopedic afflictions and promote longer and healthier careers.

4.5. Limitations

It is important to emphasize the limitations of this observational study. All operators in both Protego™ and traditional protection groups wore personal leaded aprons (a requirement not yet exempted by the State of Arizona); RE measurements beneath the aprons were not expected to yield informative data. Therefore, dosimeters were deployed outside of the lead aprons, the goal to analyze total body exposure, including protection to the trunk and extremities assessed by the waist dosimeter, and exposure to the head (Brain and Eyes) measured by the thyroid dosimeter. As so measured, the present findings emphasize the benefits of the more comprehensive shielding afforded by the Protego™ shield.

It is noteworthy that in the present study, patient radiation doses (i.e. total fluoroscopy time and DAP) were significantly higher in the Protego™ group. These differences, not seen in the TAVR comparisons between Protego™ and Standard Protection, were noted only in the coronary case comparisons. Specifically, there were more coronary interventions performed in the Protego™ arm of the coronary cohort than in the Standard Protection arm (65.2 % vs 46 %). We speculate this may be due to the sense that over the course of the study, the protective benefits of the shield led operators to preferentially seek to use Protego™ for more complex (and thus RE intensive) percutaneous coronary interventions. Most importantly, the higher procedure based RE in the coronary group serves to emphasize the protective capabilities of the Protego™ shield, for the reductions in operator RE were dramatically lower than coronary cases in the control arm which had lower procedure based (DAP) exposure.

Further testing and technological developments are needed to establish protective capabilities for peripheral vascular and electrophysiologic procedures; similarly, shielding adaptations are needed to protect Echocardiography and Anesthesia colleagues collaborating on Structural heart procedures. Finally, whether routine use of the present shield system will reduce occupational maladies requires further study.

5. Conclusions

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

CRediT authorship contribution statement

David G. Rizik: Methodology. **Kevin P. Gosselin:** Data curation. **Robert F. Burke:** Methodology. **James A. Goldstein:** Conceptualization.

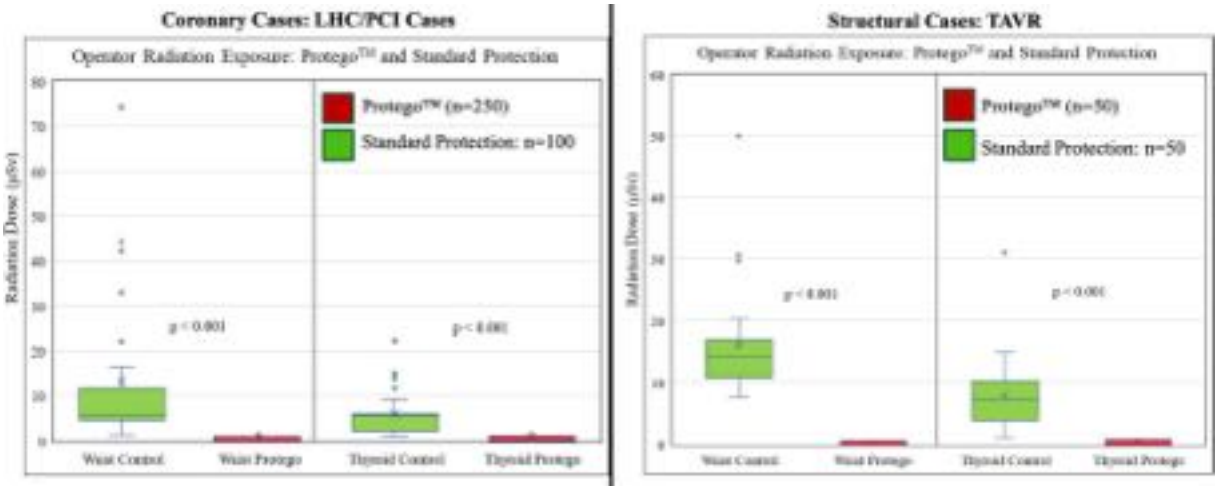

Fig. 3. The significant reductions in operator radiation exposure at the waist and thyroid in the overall population were also independently seen in the Coronary only cases (left panel) and Structural only cases (right panel) in the Protego™ arm compared to Standard Protection. This represents a > 99% reduction in median radiation exposure in the Protego™ arm.

Declaration of competing interest

*JG 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. No funding for this study was provided.

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