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Invasive Cardiologists Are Exposed to Greater Left Sided Cranial Radiation

The BRAIN Study (Brain Radiation Exposure and Attenuation During Invasive Cardiology Procedures)

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ABSTRACT

OBJECTIVES This study sought to determine radiation exposure across the cranium of cardiologists and the protective ability of a nonlead, XPF (barium sulfate/bismuth oxide) layered cap (BLOXR, Salt Lake City, Utah) during fluoroscopically guided, invasive cardiovascular (CV) procedures.

BACKGROUND Cranial radiation exposure and potential for protection during contemporary invasive CV procedures is unclear.

METHODS Invasive cardiologists wore an XPF cap with radiation attenuation ability. Six dosimeters were fixed across the outside and inside of the cap (left, center, and right), and 3 dosimeters were placed outside the catheterization lab to measure ambient exposure.

RESULTS Seven cardiology fellows and 4 attending physicians (38.4 ± 7.2 years of age; all male) performed diagnostic and interventional CV procedures ($n = 66.2 \pm 27$ cases/operator; fluoroscopy time: 14.9 ± 5.0 min). There was significantly greater total radiation exposure at the outside left and outside center (106.1 ± 33.6 mrad and 83.1 ± 18.9 mrad) versus outside right (50.2 ± 16.2 mrad; $p < 0.001$ for both) locations of the cranium. The XPF cap attenuated radiation exposure (42.3 ± 3.5 mrad, 42.0 ± 3.0 mrad, and 41.8 ± 2.9 mrad at the inside left, inside center, and inside right locations, respectively) to a level slightly higher than that of the ambient control (38.3 ± 1.2 mrad, $p = 0.046$). After subtracting ambient radiation, exposure at the outside left was 16 times higher than the inside left ($p < 0.001$) and 4.7 times higher than the outside right ($p < 0.001$). Exposure at the outside center location was 11 times higher than the inside center ($p < 0.001$), whereas no difference was observed on the right side.

CONCLUSIONS Radiation exposure to invasive cardiologists is significantly higher on the left and center compared with the right side of the cranium. Exposure may be reduced similar to an ambient control level by wearing a nonlead XPF cap. (Brain Radiation Exposure and Attenuation During Invasive Cardiology Procedures [BRAIN]; NCT01910272) (J Am Coll Cardiol Intv 2015;8:1197–206) © 2015 by the American College of Cardiology Foundation.

Radiation exposure is a proven hazard to patients and a potential hazard for staff and physicians during fluoroscopically guided invasive medical procedures. Although the potential deterministic and stochastic effects of direct exposure to high-dose, ionizing radiation are well described, the effects of long-term, low-dose radiation exposure are less well known. Long-term exposure increases the risk of cataract development, whereas the long-term use of lead aprons may predispose operators to orthopedic injuries (1). Previous analyses have estimated that there may be an increased risk of malignancy for cardiac catheterization staff (2,3). Further, since an initial report detailing 9 cases of brain and neck tumors affecting interventional physicians was published in 2012 (4), additional

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ABBREVIATIONS AND ACRONYMS

BMI = body mass index

DAP = dose area product

IC = inside center

IL = inside left

IR = inside right

OC = outside center

OL = outside left

OR = outside right

reports tallying 35 head and neck malignancies have been published (5,6). The majority of physicians have been diagnosed with malignant glioblastoma multiforme, with the left side of the brain disproportionately involved (5). Although a direct link between operator radiation exposure and brain cancer has not been established, these reports have heightened awareness of a potential association.

Operator exposure to radiation is dependent on shielding, positioning, distance from radiation source, and patient factors (7). Technological advancements in fluoroscopic equipment (8–10) and the use of lead-based shields (7) have helped reduce operator exposure to radiation scatter, but dedicated cranial protection has been limited, possibly due to reduced awareness and poorly tolerated cranial protection devices.

The differential exposure and potential for protection across the head of primary and secondary operators during fluoroscopically guided, invasive cardiology procedures is not well known in contemporary practice. We undertook this study to investigate the cranial exposure of cardiologists and trainees to ionizing radiation during invasive cardiovascular procedures. We also sought to determine the differential exposure and the attenuation ability of a nonlead cap at specific cranial locations.

METHODS

STUDY DESIGN. The BRAIN (Brain Radiation Exposure and Attenuation During Invasive Cardiology Procedures) study was a single-center, prospective evaluation of ionizing radiation exposure to operators of invasive cardiovascular procedures. The study protocol was designed and written by the primary investigators (R.R., E.M.). The sponsor (BLOXR Corp., Salt Lake City, Utah) provided nonlead-based caps for the study but did not participate in the writing of the protocol or data analysis. All authors take complete responsibility for the integrity of the data and have participated in the writing of the paper. The study protocol was approved by the University of California, San Diego Human Subjects Protections Program, and all subjects provided written informed consent before participation.

STUDY PROTOCOL. Cardiology fellows-in-training and invasive cardiology faculty at an academic medical center were prospectively enrolled. Radiation safety training is provided on an annual basis and protective measures of shielding, the distance from radiation source, and the principle of “as low as reasonably achievable” are continuously stressed by supervising physicians and staff. Attending physicians and interventional cardiology fellows-in-training maintain a State of California Fluoroscopy operator permit that requires a written examination and biannual renewal. At the beginning of each fellow’s rotation, training in the use of fluoroscopic and protective equipment is provided.

Each operator wore an XPF attenuating cap (BLOXR Corp.) with 6 InLight nanoDot dosimeters (Landauer Inc., Glenwood, Illinois) inserted in small pockets on the outside and inside surfaces of the cap. The XPF cap is composed of a flexible strip of a bilayer of barium sulfate and bismuth oxide constructed into a semidisposable surgical cap with lightweight cloth. The material has been shown to significantly attenuate radiation equivalent to a 0.5-mm thick lead barrier (11,12). The cap is available in multiple sizes that all weigh ~144 g. Nonoverlapping pairs of dosimeters were positioned outside and inside the cap at locations corresponding to the left, center, and right sides of the head. Each dosimeter was secured in custom-made pockets fabricated from lightweight cloth material similar to the outside layer of the cap fabric. The paired dosimeters at each location were positioned within 1 cm of each other, whereas the outside pockets did not directly overlay the inside pockets. Each operator used the same cap throughout the study, and the individual dosimeters were not removed from the original pocket position. Ambient control dosimeters were placed in the physician workroom outside the individual catheterization laboratories. Each dosimeter was labeled with a unique alphanumeric identifier to distinguish operator and location. At the conclusion of the study period, all dosimeters were sent in a blinded fashion via standard protocol to Landauer, Inc. for reporting of exposure. The procedures were performed using multiple catheterization rooms equipped with the following imaging systems: GE Innova (GE Healthcare, Little Chalfont, United Kingdom), Phillips Allura Xper FD 20, and 1 of 2 Phillips Allura Xper FD 10 systems (Phillips Healthcare, Amsterdam, the Netherlands).

After providing informed consent, demographic characteristics and level of training of each operator were recorded. The operators recorded each case number that they scrubbed in a log book located in a secured office in the cardiac catheterization laboratory workroom. Attending physicians generally occupied the secondary position standing to the right of the fellow and were scrubbed for the entirety of the case. Specific factors potentially related to operator radiation exposure for each procedure were recorded including patient weight and body mass index (BMI), dose area product (DAP), fluoroscopy time, length of procedure, and type of procedure. The operators were asked to evaluate the comfort of the cap using a semiquantitative scale (very uncomfortable, uncomfortable, comfortable but noticeable, minimally noticeable).

STATISTICAL ANALYSES. Power analysis of the number of cases to demonstrate an exposure difference between the left side and right side of the cranium was performed for a 2-tailed hypothesis with a desired statistical power of 80% and Cohen's *d* effect size of 0.5. It was determined that 128 cases would be required for comparison of exposure between the left and right sides of the head. A moderate estimate of 0.5 for Cohen's *d* effect size was chosen because a clear precedent for total exposure and the distribution of values across multiple operators participating in widely different cases in a contemporary cardiac catheterization laboratory could not be approximated. We therefore chose a high, but attainable, target of 50 cases for each operator to decrease the effect that outlying cases may have on the final results.

TABLE 1 **Baseline Subject Characteristics**

Operator	Age, yrs	Weight, kg	Height, cm	Level of Training
1	35	75.3	173	F
2	37	88.5	193	F
3	33	77.1	178	F
4	35	72.6	175	F
5	48	81.7	178	A
6	33	60.8	163	F
7	31	70.3	173	F
8	50	77.1	183	A
9	35	74.4	173	A
10	35	72.6	175	F
11	50	87	184	A
	38.4 ± 7.2*	76.1 ± 7.8*	177 ± 7.7*	

*Mean ± SD.

A = attending physician; F = fellow in training.

Planned analyses included comparison of the radiation exposure between dosimeters positioned externally at the left, center, and right sides of the head, between internal dosimeters at the same locations, and between the external and internal dosimeters at each location. A separate analysis of the total exposure between each dosimeter location compared with that of ambient controls was also performed. Statistical analysis was performed using SPSS software, Version 21 (IBM Corp., Armonk, New York). The Student *t* test and analysis of variance were used to compare continuous data and simple linear regression analyses were performed to evaluate for the presence of possible measurable predictors of exposure in this study. The following were identified as potential predictors of the degree of radiation exposure: level of training (fellow in training or attending cardiologist), patient weight, patient BMI, operator height, operator weight, percentage of radial cases, fluoroscopy time, and DAP. For the inside dosimeters, the corresponding outside dosimeter measurements were included in the linear regression analyses. All predictors with a measured p value <0.2 were included in a multiple linear regression. Significance was set at a probability level of $p < 0.05$.

TABLE 2 **Procedural and Patient Characteristics Potentially Associated With Operator Exposure**

Operator	No. of Cases	Coronary (No. of Cases)	Coronary Interventions (No. of Cases)	Peripheral (No. of Cases)	Peripheral Interventions (No. of Cases)	Fluoroscopy/Case, min	DAP/case, cGy cm^2	Patient Weight/ Case, kg	Patient BMI/ Case, kg/m^2
1 (F)	115	108	65	7	6	15.6 ± 16.3	13,003 ± 9,003	83.2 ± 20.6	29.4 ± 8.9
2 (F)	55	51	11	3	0	8.6 ± 8.0	7,431 ± 6,135	87.8 ± 21.0	29.2 ± 5.9
3 (F)	49	46	13	2	1	9.7 ± 6.0	6,264 ± 4,436	83.4 ± 18.4	28.1 ± 5.9
4 (F)	52	43	30	12	9	20.8 ± 16.6	10,421 ± 9,358	81.3 ± 23.1	28.8 ± 7.8
5 (A)	51	42	34	12	6	24.4 ± 16.7	12,983 ± 8,410	86.6 ± 17.8	29.7 ± 6.3
6 (F)	81	73	23	5	2	12.3 ± 10.0	8,248 ± 6,990	83.9 ± 21.5	28.6 ± 6.5
7 (F)	61	59	24	2	1	13.5 ± 11.3	6,752 ± 4,890	84.1 ± 20.9	28.5 ± 7.1
8 (A)	26	25	6	2	0	8.68 ± 7.1	7,086 ± 4,422	94.6 ± 24.8	31.7 ± 7.0
9 (A)	80	69	44	11	11	18.4 ± 18.0	10,365 ± 8,454	84.7 ± 18.5	29.4 ± 5.4
10 (F)	108	101	54	11	6	15.8 ± 14.6	9,216 ± 7,029	84.3 ± 18.1	29.2 ± 5.9
11 (A)	50	47	33	2	2	15.7 ± 13.5	9,367 ± 9,707	78.9 ± 21.3	27.6 ± 6.8
Average per operator	66.2 ± 27.0	60.4 ± 25.5	30.6 ± 18.2	6.3 ± 4.4	4.0 ± 3.8	14.9 ± 5.03	9,194 ± 2,340	84.8 ± 4.0	29.1 ± 1.1

Values are mean ± SD unless otherwise indicated.

BMI = body mass index; DAP = dose area product; other abbreviations as in Table 1.

TABLE 3 Total Radiation Exposure

Operator	No. of Cases	Outside Left, mrad	Outside Center, mrad	Outside Right, mrad	Inside Left, mrad	Inside Center, mrad	Inside Right, mrad
1 (F)	115	143	N/A	96	45	48	46
2 (F)	55	98	81	43	40	41	41
3 (F)	49	N/A	63	40	39	41	N/A
4 (F)	52	59	60	44	37	38	37
5 (A)	51	95	83	47	44	42	40
6 (F)	81	124	93	44	45	45	44
7 (F)	61	87	75	47	39	43	42
8 (A)	26	58	65	38	41	38	38
9 (A)	80	157	121	53	49	42	44
10 (F)	108	134	100	58	44	44	42
11 (A)	50	106	90	42	42	40	44
Mean ± SD	66.2 ± 27	106.1 ± 33.6*	83.1 ± 18.9†	50.2 ± 16.2	42.3 ± 3.5	42.0 ± 3.0	41.8 ± 2.9

*$p < 0.001$ vs. outside right and inside left. †$p < 0.001$ vs. outside right and inside center.

N/A = not available, dosimeters were not in the cloth pockets on final examination of the cap; other abbreviations as in Table 1.

RESULTS

Eleven operators, including 4 attending physicians, 3 interventional cardiology fellows, and 4 general cardiology fellows, were recruited for the study. All subjects were male, and relevant physical characteristics that affect head positioning, and therefore potential cranial radiation exposure, are presented in Table 1. The Phillips Allura Xper FD 10 systems were used in 61% of cases, the Phillips Allura Xper FD 20 in 29% of cases, and the GE Innova in 10% of cases.

The operators participated in a large volume of cases (66.2 ± 26.8) with a variation in the number of coronary angiograms relative to peripheral angiograms for each operator (3.5% to 29.5%). Radial access was the primary access route in 13.5 ± 9.3% of reported cases. Other procedural and patient characteristics relevant to operator exposure are listed in Table 2. The cap was not removed during any procedure, the same cap was worn by each operator throughout the study period, and no subjects dropped out of the study. All operators (100%) graded the cap as minimally noticeable on the semiquantitative scale.

The regional total exposure and adjusted per-case exposure for the operators are presented in Tables 3 and 4. The total exposure on the outside left (OL) was slightly higher than exposure on the outside center (OC) location (106.1 ± 33.6 mrad and 83.1 ± 18.9 mrad, respectively, $p = 0.075$), and exposure at both locations was significantly higher than that at the outside right (OR) location (50.2 ± 16.2 mrad,

TABLE 4 Radiation Exposure per Case

Operator	No. of Cases	Outside Left, mrad/case	Outside Center, mrad/case	Outside Right, mrad/Case	Inside Left, mrad/Case	Inside Center, mrad/Case	Inside Right, mrad/Case
1 (F)	115	1.24	N/A	0.83	0.39	0.42	0.4
2 (F)	55	1.78	1.47	0.78	0.73	0.75	0.75
3 (F)	49	N/A	1.29	0.82	0.8	0.84	N/A
4 (F)	52	1.13	1.15	0.85	0.71	0.73	0.71
5 (A)	51	1.86	1.63	0.92	0.86	0.82	0.78
6 (F)	81	1.53	1.15	0.54	0.56	0.56	0.54
7 (F)	61	1.43	1.23	0.77	0.64	0.7	0.69
8 (A)	26	2.23	2.5	1.46	1.58	1.46	1.46
9 (A)	80	1.96	1.51	0.66	0.61	0.53	0.55
10 (F)	108	1.24	0.93	0.54	0.41	0.41	0.39
11 (A)	50	2.12	1.8	0.84	0.84	0.8	0.88
Mean ± SD	66.2 ± 27	1.65 ± 0.39*	1.47 ± 0.45†‡	0.82 ± 0.25	0.74 ± 0.32	0.73 ± 0.29	0.72 ± 0.31

*$p < 0.001$ vs. outside right and inside left. †$p = 0.001$ vs. outside right. ‡$p < 0.001$ vs. inside center.

N/A = not available, dosimeters were not in the cloth pockets on final examination of the cap; other abbreviations as in Table 1.

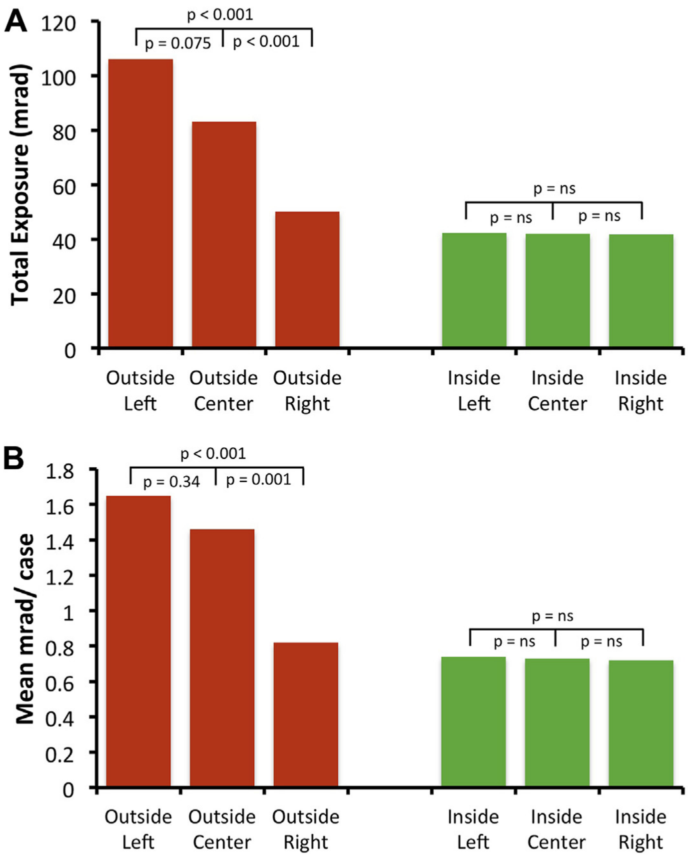
$p < 0.001$ for both) (**Figure 1A**). The total exposure at the inside left (IL), inside center (IC), and inside right (IR) locations (42.3 ± 3.5 mrad, 42.0 ± 3.0 mrad, 41.8 ± 2.9 mrad, respectively) was similar (analysis of variance, $p = 0.94$). The exposure per case did not differ between the OL and OC locations (1.65 ± 0.39 mrad/case and 1.47 ± 0.45 mrad/case, respectively, $p = 0.34$), but exposure at both locations was significantly higher than at the OR location (0.82 ± 0.25 mrad/case, $p < 0.001$ and $p = 0.001$, respectively) (**Figure 1B**). The exposure per case at the IL, IC, and IR locations (0.74 ± 0.32 mrad/case, 0.73 ± 0.29 mrad/case, and 0.72 ± 0.31 mrad/case, respectively, $p = 0.984$) was not significantly different.

The IL and IC total exposures were significantly lower than the corresponding outside locations (IL, 42.3 ± 3.5 mrad vs. OL, 106.1 ± 33.6 mrad, $p < 0.001$; IC, 42.0 ± 3.0 mrad vs. OC, 83.1 ± 18.9 mrad, $p < 0.001$) (**Figure 2A**). The IR and OR exposure levels were similar (41.8 ± 2.9 mrad vs. 50.2 ± 6.2 mrad, $p = 0.125$). Corresponding to the total exposure, the exposure per case recorded at the IL dosimeters was lower than at the OL dosimeters (0.74 ± 0.32 mrad/case vs. 1.65 ± 0.39 mrad/case, $p < 0.001$) (**Figure 2B**). Similarly, the IC location was associated with a significantly lower exposure than the OC location (0.73 ± 0.29 mrad/case vs. 1.47 ± 0.45 mrad/case, $p < 0.001$). There was no significant difference between the outside and inside locations on the right side of the head (0.82 ± 0.25 mrad/case vs. 0.72 ± 0.31 mrad/case, respectively, $p = 0.4$).

The average of the total exposure at each location was compared with the average of 3 control dosimeters located outside the cardiac catheterization laboratory (**Figure 3A**). The measured total exposure at the OL location was 177% higher than the average of the ambient controls (106.1 ± 33.6 mrad vs. 38.3 ± 1.2 mrad, $p = 0.006$). Similarly, the total exposure at the OC location (83.1 ± 18.9 mrad) was 117% higher than that of the ambient controls ($p = 0.002$). Total exposure at the OR location (50.2 ± 16.2 mrad) was 31% higher than that of controls but did not reach statistical significance ($p = 0.24$). The mean exposures at each inside location were nonstatistically higher than that of the 3 control dosimeters. However, when the inside dosimeters were grouped together, the exposure within the cap was 10% higher than that measured by the ambient controls ($p = 0.046$) (**Figure 3B**).

Controlling for the ambient exposure by subtracting the average of the control dosimeter measurements from the study dosimeter measurements, the OL exposure was 16 times higher than the IL exposure ($p < 0.001$) and 4.7 times higher than the OR exposure ($p < 0.001$) (**Figure 4**). The OC exposure was 11 times higher than the IC exposure ($p < 0.001$), whereas the OR exposure was 2.4 times higher than the IR exposure ($p = 0.13$).

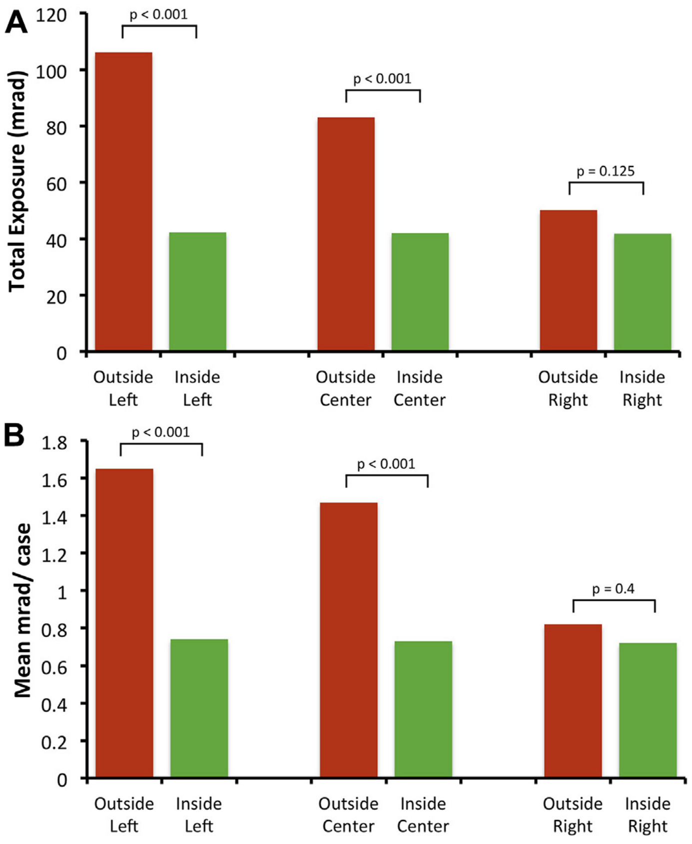
FIGURE 1 **Comparison of the Radiation Exposure Across Locations Outside and Inside the Protective Cap**



The means of the total exposure **(A)** and the means indexed to the number of cases performed by each operator **(B)** are shown. The exposure outside the cap was significantly higher at the left and center locations relative to the right side, whereas there was no significant exposure difference at the locations inside the cap.

The only factor that predicted the extent of exposure at the OL and OC locations was the operator level of training ($p = 0.002$ and $p = 0.01$, respectively), with the highest level of training, attending cardiologist status, associated with increased cranial exposure (**Figure 5**). The inclusion of the other possible predictors with p values <0.2 in the multiple linear regression models did not alter the findings and level of training remained the only significant variable (OL, $p = 0.016$; OC, $p = 0.012$). The statistically significant predictors of exposure at the OR location include patient weight/case ($p = 0.03$), patient BMI/case ($p = 0.02$), and percentage of radial cases ($p = 0.04$).

FIGURE 2 **Comparison of the Radiation Exposure Between the Pair of Outside and Inside Dosimeters at Each Location Across the Cap**



The means of the total exposure **(A)** and the means indexed to the number of cases performed by each operator **(B)** are shown. Exposure at the left and center locations was significantly higher outside the cap compared with the inside. There was no significant difference between the outside and inside locations on the right side.

None of these variables remained significant on the multiple regression analysis.

DISCUSSION

This prospectively designed study has 2 unique findings: invasive cardiologists and fellows-in-training are exposed to substantially greater ionizing radiation to the left side of the brain and a lightweight, nonlead-based cranial cap can attenuate the exposure of the brain during invasive cardiovascular procedures to a level comparable to that of ambient radiation.

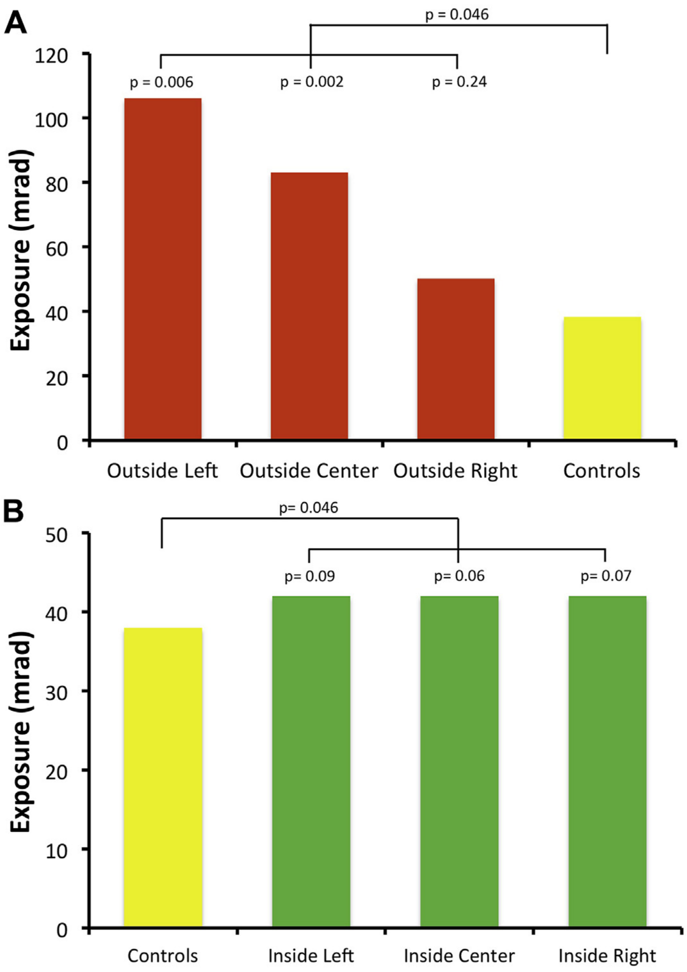
The recent reports of left-sided brain cancer in operators of fluoroscopically guided procedures are alarming given the location and aggressive nature of these malignancies. Invasive cardiologists are exposed to some of the highest levels of radiation in the medical field (3,13-15) and constitute the majority of subjects in the reported cases. Investigation into the reports estimates that the mean time of practicing invasive cardiology before diagnosis is 23 ± 5 years (5). Despite substantial technological advancements that have decreased potential operator exposure, increasingly complex procedures and higher volume further increase radiation exposure (16-22). The association between medical radiation exposure and the risk of brain malignancy is difficult to study and define given the relatively long period of exposure in the referenced cases, differing practice patterns, and technological advances. There is no evidence that long-term exposure to medical radiation increases the risk of brain cancer, and although a direct causal link between operator exposure and the risk of brain cancer may be impossible to establish, further studies are required to investigate this potential.

It is well known that the major source of operator exposure is scatter radiation originating from the patient's body within the primary beam. Cardiovascular catheterization procedures are predominantly performed from the right side of the patient, regardless of access site; therefore, the major scatter source is most often to the left side of the operator. The left and center regions of the head are closer to the radiation source and more exposed than the right-sided structures, which are farther away and shielded by left-sided structures. The finding that radiation exposure decreases moving from left to right across the head is consistent with local shielding from left-sided structures and with the inverse square law; radiation intensity is inversely proportional to the square of the distance from the radiation source. Directly studying the risk of the development of left-sided brain cancer in invasive cardiologists with a longitudinal study would be extremely difficult due to the number of subjects and the extended time period required to reach a definitive conclusion for a low probability event. The effect of long-term, low-dose ionizing radiation on small groups of medical professionals has been studied and may alter multiple biological pathways (23-25). Therefore, this study adds to the theoretical validity that long-term, low-dose exposure from cardiovascular catheterization procedures increases the risk of the development of left-sided brain malignancy.

To further examine exposure on a per-case basis, the total exposure of each operator was indexed to the number of procedures performed. The comparative results between each location remained significant, similar to the total exposure comparisons. Further statistical analysis suggested that level of training may be associated with the degree of radiation exposure at each measured site, with attending physicians receiving greater exposure than trainees. Although procedures with trainees typically result in higher radiation doses, differences between operators have not been fully defined (26). Although this finding is not conclusive, one possible explanation is that the second operator position is most often occupied by the attending physician to provide both supervision and instruction, whereas the trainee controls the protective shield and the fluoroscopy pedal from the primary operator position. Despite the decreased exposure to the second operator as explained by the inverse square law, the optimal use of shielding in favor of the primary operator may overcome the protection offered by the increased distance. Effective shield management is essential in providing optimal protection (7,21,27,28). Operator positioning in this study was not constant, and a different study design would be required to test exposure at different positions and validate this finding.

Protective measures from the occupational hazard of radiation exposure include distance, shielding, and time, which, to some extent, are all operator dependent, and exposure may be reduced with reinforcement of these principles (29–34). The concept of "as low as reasonably achievable" is a cornerstone in radiation safety that is endorsed by multiple cardiology societies and should be stressed before any operator enters a cardiac catheterization laboratory and be frequently reinforced (35). Lead-based shields located in the procedure room and lead aprons worn by operators are commonplace in modern catheterization laboratories. However, with its high atomic number and density, lead is a relatively heavy substance and not ideally suited for cranial protection. Previous investigations have evaluated the feasibility of cranial protection with lead-based caps, but despite the potential to reduce exposure, weight and poor tolerability have likely hindered widespread acceptance (36). The cap used in the current study consists of a bilayer of barium sulfate and bismuth oxide, which constitutes the attenuating material secured within an adjustable cloth covering. It was well tolerated and significantly reduced cranial radiation exposure, especially in the region that received the highest level of radiation. The left side of the head was protected to the greatest magnitude, resulting in exposure similar to that at the other two locations inside the cap and only marginally greater than ambient control dosimeters far removed from medical radiation.

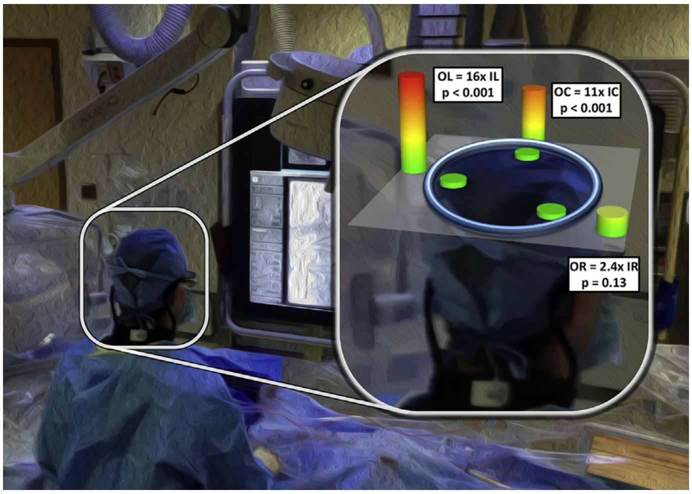
FIGURE 3 **Comparison of the Radiation Exposure Between Each Dosimeter Location and Ambient Control Dosimeters**



Comparison of the means of the total exposure at the outside **(A)** and inside **(B)** locations to the mean of 3 ambient control dosimeters located outside of the catheterization laboratory. The exposure at the outside left and outside center locations was 177% and 117% higher than the ambient controls, respectively. The exposure at the outside right and each inside location was not significantly higher than the mean of the ambient controls.

Total fluoroscopy time and DAP were included in the analysis because they predict patient and operator exposure (8,9). These measurable factors did not predict operator exposure in this study. Despite a wide case-by-case variation, the large case number allowed for adequate control for these factors (8). Variable use of room shielding and constantly varying distances from the radiation source by the different operators could not be controlled and might explain the lack of impact on operator exposure. Operator positioning has been postulated to affect operator exposure when predictors such as fluoroscopy time and DAP are similar (37). In the recently reported RadiCure study, fluoroscopy time and DAP were also

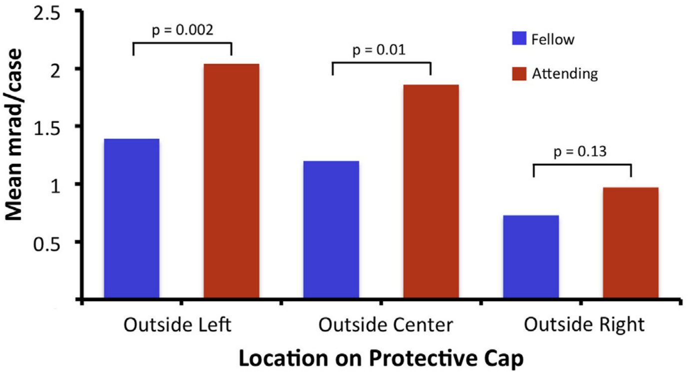
FIGURE 4 **Comparison of the Radiation Exposure Between the Pair of Inside and Outside Dosimeters After Controlling for Ambient Exposure**



Controlling for ambient exposure was performed by subtracting the mean of the ambient dosimeters from the mean of the exposure at each location. Exposure outside the cap was 16 times ($p < 0.001$) and 11 times ($p < 0.001$) times higher at the left and center locations, respectively, relative to the corresponding inside location.

not significantly reduced in the group using the real-time radiation detection device despite a reduction in operator exposure (38). It is likely that increased shielding use and distance optimization blunt the impact that fluoroscopy time and DAP have on operator exposure. Although increased patient weight and BMI also affect scatter dose (10), these factors did not predict operator exposure in the BRAIN study. There is an inherent relationship between DAP and patient habitus, and it is likely that the shielding use and distance optimization also protected operators from the increased scatter produced by larger patients. Operator height and weight may alter operator exposure due to varying distances and angles of an operator's head from the radiation source. We did not detect any differences on the basis of physical characteristics of the operators. Previous investigations into the use of the radial approach suggest an increased risk of exposure (37,39). The use of the radial artery was relatively low compared with femoral access in this study, and no differences were observed on the basis of the percentage of procedures completed using the radial approach.

FIGURE 5 **Comparison of the Radiation Exposure Outside the Cap Between Cardiology Fellows in Training and Attending Cardiologists**



On simple linear regression, the only factor that predicted the extent of exposure at the outside left (OL) and outside center (OC) locations was the level of training ($p = 0.002$ and $p = 0.01$, respectively), with the highest level of training and attending cardiologist status resulting in increased cranial exposure. Level of training remained significant after multivariable linear regression including factors with p value <0.2 on the simple linear regression analyses (OL, $p = 0.016$ and OC, $p = 0.012$).

STUDY LIMITATIONS. The wide range of cases may be considered both a strength and limitation of this study. Although the results are applicable to real-world cardiovascular catheterization laboratories at academic institutions, facilities with different laboratory characteristics and staffing structures may not have the same findings. Operator and hospital factors (e.g., tube angulation, frames per second, filtration) are known to cause significant variations in fluoroscopy times (40–43) and were not controlled for in this study. Although confounding may exist in the subgroup analyses, each operator served as both study subject and control in evaluating regional cranial exposure and the protective ability of the cap in the primary analyses. The radiation absorption and attenuation ability of the skull and the brain is unknown, and it is conceivable that the left side of the head and brain may limit right-sided exposure, similar to the findings in this study if the cap was not worn during the procedures.

CONCLUSIONS

In the BRAIN study, we demonstrate differences in cranial radiation exposure during fluoroscopically guided, invasive cardiology procedures. The left side and center of the cranium are exposed to significantly higher levels of radiation than the right side of the head. A lightweight, nonlead-based cap has the potential to reduce exposure across the head to nearly ambient levels.

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PERSPECTIVES

WHAT IS KNOWN? Radiation exposure is a potential occupational hazard for staff and physicians during fluoroscopically guided invasive medical procedures, and recent reports of left-sided brain malignancies have heightened awareness among invasive cardiologists.

WHAT IS NEW? This study shows that compared with the right side of the head, the left side is exposed to substantially greater levels of ionizing radiation during invasive cardiovascular procedures. Further, a lightweight, nonlead-based cranial cap can attenuate this exposure to a level comparable to ambient radiation.

WHAT IS NEXT? Future studies are required to evaluate additional strategies to reduce occupational hazards for invasive cardiologists.

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