Ionizing Radiation in Cardiac Imaging

A Science Advisory From the American Heart Association Committee on Cardiac Imaging of the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention

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A preliminary report on medical radiation exposures to the US population based on publicly available sources of data estimated that the collective dose received from medical uses of radiation has increased by >700% between 1980 and 2006. Computed tomography (CT) has had an annual growth rate of >10% per year and accounted for ~50% of the collective dose in 2006. Approximately 65% of the collective CT dose is from studies of chest, abdomen, and pelvis. In 2006, cardiac CT accounted for 1.5% of the collective CT dose; however, utilization of cardiac CT is expected to rise, with the potential to further increase exposure to the population. Nuclear medicine studies in the United States have increased by 5% annually to 20 million in 2006 and accounted for ~25% of the 2006 collective medical radiation dose. Among nuclear medicine studies, cardiac imaging represented 57% of the number of studies and ~85% of the radiation dose.

A number of publications on imaging with CT, fluoroscopy, or radioisotopes have emphasized the risks that may be associated with exposure to ionizing radiation. To make informed decisions concerning the use of medical radiation in imaging procedures, the following are important components: (1) A working knowledge of the principles and uncertainties of the estimation of patient dose and biological risk; (2) a comparison of the risks of radiation exposure with the risks of activities in daily life; and (3) recognition of the potential risk of failing to make important diagnoses or treatment decisions if imaging is not performed because of safety concerns.

There is no federal regulation of patient radiation dose, with the exception of mammography. Most federal and state regulations are aimed at equipment performance or the handling of nuclear materials. Therefore, appropriate utilization of the equipment or nuclear material in cardiac imaging, to maintain the dose as low as reasonably achievable, is the responsibility of the imaging physician and facility. The purpose of this Science Advisory is to provide a conceptual framework and make general recommendations for the safe use of cardiac imaging that relies on ionizing radiation.

Parameters of Dosimetry

CT and Fluoroscopy

The parameters by which ionizing radiation is quantified differ among imaging modalities. The amount of radiation produced by an imaging device can be described using exposure, expressed in International System of Units (SI) units of coulombs per kilogram (C/kg), or air kerma, expressed in SI units of milligrays (mGy). This document will use the term exposure, which refers to the amount of ionization produced in air by photon irradiation. Exposure can be measured for CT and fluoroscopy with ionization chambers within test objects (phantoms) or at body surfaces with minimal difficulty. Measurable or easily derived parameters, such as entrance skin exposure in radiography and fluoroscopy and the weighted CT dose index (CTDIw) in CT, are useful to establish diagnostic reference levels for radio-
Absorbed radiation dose, expressed in SI units of mGy, is a measure of the energy absorbed per unit of mass by some portion of a patient’s body as a result of an exposure to ionizing radiation. For a given exposure (or radionuclide activity; see below), the absorbed dose depends on the absorbing material and the energy of the photons (or particles). Radiation dose to internal organs cannot be quantified easily. For fluoroscopy and CT, organ doses can be estimated from exposures measured in air or in phantoms.

The effective dose (E), expressed in SI units of millisieverts (mSv), is a parameter meant to reflect the risk of the biological effects of ionizing radiation. It represents the amount of whole-body irradiation that would yield a biological risk equivalent to that of an irradiation to only a portion of the body, such as that which occurs during a diagnostic or therapeutic medical procedure. The E is widely used in the medical imaging literature despite the fact that it is defined expressly for use in the field of radiation protection. E is a concept that is pertinent to an exposure to a broad population and is derived from organ risk data in the Japanese atomic bomb survivor cohort. It is important to recognize the limitations of the concept of E, because effective dose is often misunderstood as a parameter that can be measured directly and quantified precisely and that is patient-specific.

In contradistinction to this perception, however, E is estimated with the use of 3 pieces of information. First, the radiation doses received by individual organs (organ dose) are estimated with Monte Carlo simulations, which model the interaction of ionizing radiation with tissue in standardized mathematical models of the human body with the characteristics of a man or woman. Second, the relative biological effectiveness of ionizing radiation is represented by a radiation weighting factor that differs depending on the type and energy of radiation. Third, the radiation sensitivity of each organ or tissue is represented by tissue-specific weighting factors. These tissue-specific factors determine how much each organ’s dose contributes to the E. The factors are determined from population averages over age and gender from the atomic bomb survivors cohort. The E for a given procedure is the sum of the products obtained by multiplying organ doses with radiation- and tissue-specific weighting factors.

The tissue-specific weighting factors defined by the International Commission on Radiation Protection (ICRP) have been revised twice since their introduction in 1977. For example, the ICRP tissue-weighting coefficient for the breast, which is relevant in cardiac imaging, was 0.15 in 1977 but was reduced to 0.05 in 1991 and increased to 0.12 in 2007. As a consequence, estimates for the E of coronary CT angiograms based on the new 2007 weighting factors may be approximately 30% to 50% higher than estimates based on 1991 weighting factors. In addition, methodological differences in the calculations exist between the 3 ICRP recommendations. Thus, estimates for E can differ substantially on the basis of definitional changes alone, even if the actual radiation exposure was identical.

It is important to know that although the correct unit for organ dose is mGy, the equivalent organ dose (which takes into account the type of radiation), expressed in units of mSv, is sometimes reported. This may result in mistaking values of equivalent organ dose for values of E. For example, in cardiac CT, the numerical value for equivalent organ doses (in mSv) of the breast can be substantially higher than the corresponding value for E (also in mSv).

Radionuclide Studies

Given its definition, radiation exposure is not a preferred parameter for radionuclide studies, which use internally administered radioisotopes capable of producing both photon and particulate radiation. Instead, the number of nuclear disintegrations per second, expressed in megabecquerels (MBq), is used to quantify the activity of radionuclides. Organ dose estimates are based on mathematical models of male and female torsos with standardized organ size, mass, and geometry. These geometric parameters are combined with the activity, half-life, distribution, and elimination kinetics of the radionuclide to calculate dose estimates.

The difficulties related to the changing definitions and methodologies of the estimation of E also apply in nuclear medicine. Consistent dose information is not always available. For cardiac radionuclide studies, the radiation-dose estimates listed in the package inserts of radiopharmaceuticals may reflect outdated information. For organ doses, there may be variation between the values listed in package inserts and the values in current publications, because the package inserts may not reflect the newest kinetic data. Package inserts that have not been updated may report an older dosimetry concept called whole-body dose, expressed in units of mGy, because the concept of E was not widely used when many of the current radiopharmaceuticals were introduced and studied. The whole-body dose represents the total energy absorbed by the body divided by the mass of the standard reference human body. The numerical values for whole-body dose are typically ≤50% of the value for E. In addition, the changes in tissue-specific weighting factors discussed above may not be reflected in package inserts. Current updated estimates of organ doses and E for different radiopharmaceuticals are available from sources other than package inserts.

Appropriate Use and Reporting of E

Because the generic modeling of the human body in Monte Carlo simulations does not take into account the many variations of human anatomy, and because considerable uncertainties exist regarding the radiation sensitivity of organs and tissues, it follows that E cannot be an exact indicator of the absolute risk of the biological effect on an individual.
patient. Instead, E is a calculated indicator that provides a rough estimate of relative risk based on evolving knowledge of radiation biology and radiation epidemiology. The E applies generically to types of imaging studies but not to individual patients. For risk estimates relevant to individual patients, actual organ doses and organ-specific absolute risk data based on age and gender must be used, as opposed to the generic risk-estimate E.11

The ICRP emphasizes that E is intended for use as a parameter in radiation protection and should not be used for epidemiological evaluation or for estimations of specific human exposures; however, E is useful in comparisons of the biological risk of different medical procedures against each other or against background radiation, as well as to optimize radiological procedures that involve multiple organs. The absolute accuracy of E cannot be determined, because there is no measurable physical gold standard. Given the uncertainties regarding organ risk and the inability of E to reflect individual patient risk, differences between estimates of the E by a factor of less than 2 cannot be considered significant. Therefore, the reporting of ranges for E (Table 1), rather than single values with decimal precision, most accurately reflects the reality that quantitative certainty does not exist.23,24

**Risks Related to Exposure to Ionizing Radiation**

The consequences of exposure to ionizing radiation can be discussed from various perspectives. The risk for radiation workers related to occupational exposure and the cost to society (eg, related to the disposal of radioactive waste) are beyond the scope of this document, which focuses on the risks to patients posed by exposure to medical radiation.

The biological consequences of ionizing radiation fall into 2 categories. Deterministic effects such as skin erythema, epilation, or cataract formation predictably occur at certain thresholds of absorbed dose to a specific tissue. The hypothetical complication of diagnostic medical radiation exposure that is of greatest concern, the risk of inducing malignancies, is a stochastic, or random, effect in which the interaction of radiation with cellular molecules may cause damage sufficient that a malignancy may result later.

**Radiation Dose and Risk of Carcinogenesis**

The recent Biological Effects of Carcinogenesis VII report from the National Research Council of the
National Academies is a scientific summary of the current knowledge of the relationship between exposure to ionizing radiation and human health. The Life Span Study of malignancies associated with radiation exposure in survivors of the atomic bomb explosions in Japan in 1945 was the principal source for the development of these risk estimates. However, there is no consensus as to whether the effects observed in Japanese individuals who experienced whole-body acute exposures to primarily high levels of radiation can be extrapolated to the partial-body exposures at much lower levels of radiation that are delivered to patients of different ethnic origins who are undergoing medical imaging procedures.

Two different, important hypotheses apply to the discussion of carcinogenesis at low radiation doses. The linear no-threshold hypothesis states that there is no threshold below which radiation cannot cause malignancies and that the risk of malignancies increases linearly with radiation dose. This hypothesis implies that it is appropriate to extrapolate linearly from the risk of malignancies at high radiation doses to the risk of malignancies at low radiation doses. The linear-quadratic hypothesis states that the risk of malignancy at low radiation doses is so low that it is nearly impossible to quantify in humans but that it increases quadratically with dose at high levels.

The consensus opinion in the BEIR VII report advocates the conservative approach of the linear no-threshold hypothesis. In that report and a prior report by the National Commission for Radiation Protection, the age- and gender-averaged lifetime risk of dying of a malignancy attributable to radiation exposure was estimated to be 5 to 7.9 in 100 individuals of the general population per 1 Sv of E; however, the public summary of the BEIR VII report also states on page 7 that “at doses less than 40 times the average yearly background exposure (100 mSv), statistical limitations make it difficult to evaluate cancer risk in humans.” In individuals receiving an estimated E <100 mSv, the relative risk of developing solid tumors was not statistically significantly different from no increased risk, despite the large sample size and long follow-up period (1950 to 2000). Similarly, a study of 407 391 radiation workers with 5.2 million person-years of observation did not demonstrate a statistically significant increased risk of cancer among those workers with an estimated cumulative E of <100 mSv.

Carcinogenesis at Low Radiation Dose

There are several reasons why it is very difficult to estimate the risk of malignancies associated with low values of E (<100 mSv). Malignancies generated by ionizing radiation are indistinguishable from malignancies generated by other carcinogenic agents or random biological processes. All people are exposed to background radiation due to cosmic rays, radon, and other low-level radiation sources that on average amount to ~3 mSv per year (range, 1 to 10 mSv). Because of the random nature of the interaction between photons and cellular molecules, there is a small statistical chance that even the low levels of background radiation may result in carcinogenic damage. This makes it difficult to discern between the risk attributable to a single exposure to medical radiation and the risk of the exposure to natural background radiation.

It is useful to consider not only the absolute but also the relative risk of radiation exposure. The low potential risk of developing a malignancy as a result of exposure to low levels of medical radiation is incrementally superimposed on the substantial intrinsic risk that an individual will develop a malignancy in his or her lifetime. The population-averaged lifetime risk of developing a malignancy in the United States is 41%, and the risk of dying of a malignancy is 21%. Compared with these risks, the relative risk of carcinogenesis resulting from radiation exposure due to a cardiac imaging study is small. Using the example of a typical coronary CT angiogram, the estimated increase in the lifetime risk of dying of a malignancy associated with 10 mSv of ionizing radiation is ~0.05%. This 0.05% increase in risk is added to the 21% background risk for the US population. More specific estimates for relative risk require the use of estimated organ doses, age- and gender-specific organ radiation risk data, and the intrinsic risk data from the National Cancer Institute, which are stratified for age, race, gender, and type of malignancy.

As an example, estimates of the absolute risk for women of developing breast cancer due to a coronary CT angiogram, which were based on the BEIR VII linear no-threshold model, have been published recently. The relative risk of developing breast cancer due to a coronary CT angiogram, calculated for women at various ages from those data and the National Cancer Institute cancer statistics, is presented in Table 2. The relative risk of coronary CT angiography is small (1.02 to 1.06) compared with other well-documented risk factors for breast cancer, such as a family history of breast cancer (2.1 to 3.6). A direct comparison in Japanese atomic bomb survivors provides another example of the magnitudes of risk imparted by radiation exposure and by other known risk factors. The relative risk of lung cancer ranged from 4.9 in individuals who smoked 1 to 15 cigarettes per day to 13.3 in individuals who smoked >25 cigarettes per day. By comparison, the relative risk of lung cancer associated with an E of 1000 mSv (approximately 50 to 100 coronary CT angiograms) was 2.2.

Risk Associated With Activities in Daily Life

When speaking to patients about the risk of developing malignancies as a result of exposure to ionizing radiation in medical imaging, it may be instructive to compare this risk to the risks of developing a malignancy or dying as a result of conditions or activities of everyday life. Examples compiled from various sources are listed in Table 3.

Risks Resulting From Not Performing Imaging Studies

It is also important to weigh the small hypothetical risk of inducing malignancies against the risks of not performing an imaging study, which may include misdiagnoses and failure to administer treatments that could improve medical outcomes. However, the latter argument is currently difficult to support.
Effective radiation dose

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Estimated Risk of Fatal Malignancy or Lifetime Odds of Dying (per 1000 Individuals)</th>
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<tbody>
<tr>
<td>Effective radiation dose</td>
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<tr>
<td>1 mSv (calcium score/lung screen)</td>
<td>0.05</td>
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<tr>
<td>10 mSv (coronary CTA/abdomen CT,</td>
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<tr>
<td>invasive coronary angiography,</td>
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<td>radionuclide myocardial perfusion</td>
<td>0.5</td>
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<td>study)</td>
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<tr>
<td>50 mSv (yearly radiation worker</td>
<td>2.5</td>
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<tr>
<td>allowance)</td>
<td></td>
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<tr>
<td>100 mSv (definition of low exposure)</td>
<td>5</td>
</tr>
<tr>
<td>Natural fatal cancer</td>
<td>212</td>
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<tr>
<td>Passive smoking</td>
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<tr>
<td>Low exposure</td>
<td>4</td>
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<td>High exposure, married to a smoker</td>
<td>10</td>
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<td>Radon in home</td>
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<tr>
<td>US average</td>
<td>212</td>
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<tr>
<td>High exposure (1% to 3%)</td>
<td>212</td>
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<tr>
<td>Arsenic in drinking water</td>
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<tr>
<td>2.5 µg/L (US estimated average)</td>
<td>1</td>
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<tr>
<td>50 µg/L (acceptable limit before</td>
<td>13</td>
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<tr>
<td>2006)</td>
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<tr>
<td>Motor vehicle accident</td>
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<tr>
<td>Pedestrian accident</td>
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</tr>
<tr>
<td>Drowning</td>
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</tr>
<tr>
<td>Bicycling</td>
<td>0.2</td>
</tr>
<tr>
<td>Lightning strike</td>
<td>0.013</td>
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</table>

CTA indicates CT angiogram.

National Safety Council estimates are based on data from National Center for Health Statistics and US Census Bureau. Deaths are classified on the basis of the Tenth Revision of the World Health Organization’s International Classification of Diseases. Lifetime odds are approximated by dividing the 1-year odds by the life expectancy of a person born in 2005 (77.8 years).

with appropriate statistics, because there are no prospective, randomized trials that demonstrate that cardiac imaging with ionizing radiation can convey survival benefit.

Because radiation-induced malignancies have a biological latency of approximately 10 to 40 years, they are less likely to manifest in older individuals. Recent publications endorsed by the American Heart Association\(^{38,39}\) have emphasized that cardiac CT and radionuclide studies are most appropriate in symptomatic patients with an intermediate likelihood of having coronary artery disease.\(^{40}\) This patient cohort is predominantly older than 50 years of age.\(^{41}\) Many of these patients may not live long enough for a radiation-induced malignant to become clinically apparent. Conversely, if an imaging study uncovers a condition for which tailored management can improve patient outcomes,\(^{42,43}\) the imaging study may result in survival benefit without which the patient might not have lived long enough for a potential malignancy to develop.

For example, for 50-year-old asymptomatic individuals, the lifetime risk of developing coronary artery disease is 52% for men and 39% for women.\(^{44}\) An argument has been made that if the entire US population of 50- to 55-year-old individuals (18.8 million people) were screened for coronary artery disease with coronary CT angiography every 5 years until the age of 70, the estimated total increase in the number of fatal malignancies over the period of screening would be \(\approx 42,900.\)\(^{45}\) If such screening could be translated into management strategies that prevented only 10% of sudden cardiac deaths, \(\approx 35,500\) fewer cardiac deaths might occur per year.\(^{45}\) However, such potential benefits remain unproven. Rigorous studies are needed to establish that, for example, the rapidly expanding use of cardiac CT\(^{46}\) conveys individual and societal benefits. The present Writing Group does not endorse screening for heart disease in asymptomatic low-risk patients with imaging modalities that expose asymptomatic individuals to ionizing radiation.

### Summary

The key messages of this Science Advisory are as follows:

- Unlike radiation exposure, which can be measured, the radiation dose to internal organs cannot be measured directly. Instead, human organ doses are estimated with...
generic modeling techniques and used to calculate a broad indicator of risk that is not patient-specific. E may be useful, however, to compare estimated risk between different medical radiation procedures.

- As a result of recent changes in the calculations used to estimate E, the numerical values of E will differ by 50% to 100% and will be difficult to compare with those reported in the previous literature, even though the name of the metric and its units (mSv) remain the same. During the transition from the tissue-specific weighting factors listed in ICRP publication 60 to those listed in ICRP publication 103, confusion and disparity in reported values of E can be expected.

- There is conflicting evidence regarding the potential presence and degree of carcinogenesis at the levels and types of radiation associated with medical imaging. In the absence of definitive data, it is prudent to assume a conservative linear no-threshold relationship between radiation dose and risk of malignancies for the purpose of making recommendations relating to radiation protection of workers and the general public. However, the present Writing Group notes the following:

  - The use of the linear no-threshold model is not scientifically supported.
  - Because of the many confounding issues related to the determination of actual patient dose and intrinsic risk of cancer, the small increase in risk of malignancies hypothesized by the linear no-threshold model cannot be confirmed observationally.

- Even though the accuracy of radiation-dose estimates and the relationship between the radiation dose received from cardiac imaging and the risk of malignancies may be uncertain, this Writing Group supports the concept of keeping patient doses as low as reasonably achievable but consistent with obtaining the desired medical information. Thus, we give the recommendations listed below.

Please note that these recommendations use the American College of Cardiology Foundation/American Heart Association grading schema. The recommendations in this American Heart Association Science Advisory may be incorporated into future practice guidelines as deemed appropriate by the relevant writing committees.

**Classification of Recommendations**

**Class I**: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

**Class II**: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

  - **Class IIa**: Weight of evidence/opinion is in favor of usefulness/efficacy.
  - **Class IIb**: Usefulness/efficacy is less well established by evidence/opinion.

**Class III**: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

**Levels of Evidence**

**Level of Evidence A**: Data derived from multiple randomized clinical trials or meta-analyses.

**Level of Evidence B**: Data derived from a single randomized trial or nonrandomized studies.

**Level of Evidence C**: Only consensus opinion of experts, case studies, or standard of care.

**Recommendations**

- Medical imaging is the largest controllable source of radiation exposure to the US population, and its most important determinant is the ordering healthcare provider. Therefore:

  - Physician education should emphasize that cardiac imaging studies that expose patients to ionizing radiation should be ordered only after thoughtful consideration of the potential benefit to the patient and in keeping with established appropriateness criteria (Class I, Level of Evidence C).38,39 Considerations should include options for answering the clinical question at hand by means that do not use ionizing radiation or choosing the type of study that exposes the patient to the lowest amount of radiation.

  - The risks of missing important diagnoses imparted by not performing appropriate diagnostic imaging studies because of radiation dose concerns should be considered (Class IIa, Level of Evidence C).

  - Healthcare providers should diligently review patient records, including those from other medical institutions, to ensure that imaging studies that use ionizing radiation are not repeated needlessly (Class I, Level of Evidence C).

  - Healthcare providers should discuss the risks and benefits of planned imaging procedures with patients whenever practical and appropriate (Class I, Level of Evidence C).

- Routine surveillance radionuclide stress tests or cardiac CTs in asymptomatic patients at low risk for ischemic heart disease are not recommended (Class III, Level of Evidence B).38,39

- Once it has been established that a cardiac imaging study that uses ionizing radiation is needed, every effort should be made to reduce patient dose while balancing image noise and quality sufficient for confident interpretation (Class I, Level of Evidence C). The procedural details for minimizing radiation dose in various imaging modalities are beyond the scope of this advisory but have been detailed elsewhere.4,46–51

- Longitudinal tracking of individual cumulative lifetime dose for patients is currently not practical. The modeling required to individualize dose is very complex and difficult to achieve, and the necessary tools and information systems to accomplish this for different imaging modalities are currently not available. The usefulness and societal value of such an undertaking are uncertain (Class III, Level of Evidence B).

- Imaging experts and manufacturers should continue working on developing consistent radiation output metrics for
each diagnostic modality and on making such information automatically part of the imaging record (Class I, Level of Evidence C). This will facilitate efficient and reliable analysis of dose reference levels and trends.

- The imaging community should actively participate in the voluntary determination of diagnostic reference levels for radiation doses from cardiac radiographic imaging procedures to establish radiation doses as benchmarks for comparisons between practices on a national level (Class I, Level of Evidence B).

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## Disclosures

### Writing Group Disclosures

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*Modest.
†Significant.

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### Reviewer Disclosures

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<thead>
<tr>
<th>Reviewer</th>
<th>Employment</th>
<th>Research Grant</th>
<th>Other Research Support</th>
<th>Speakers' Bureau/Honoraria</th>
<th>Expert Witness</th>
<th>Ownership Interest</th>
<th>Consultant/Advisory Board</th>
<th>Other</th>
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</thead>
<tbody>
<tr>
<td>John M. Boone</td>
<td>UC Davis</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>None</td>
<td>None</td>
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</tr>
<tr>
<td>Claire Cousins</td>
<td>Addenbrookes Hospital, United Kingdom</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Patrick O’Gara</td>
<td>Brigham &amp; Women’s Hospital</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>BMS Imaging</td>
<td>None</td>
</tr>
</tbody>
</table>

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*Modest.
References


Gerber et al  Ionizing Radiation in Cardiac Imaging  1065


Ionizing Radiation in Cardiac Imaging: A Science Advisory From the American Heart Association Committee on Cardiac Imaging of the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention


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