Health Impacts of Radiation Exposure During PCI

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Concern regarding the health hazards associated with interventional fluoroscopy is growing, as evidence of the damaging effects of chronic exposure to ionizing radiation builds. More than 17 million fluoroscopy-guided interventional procedures take place each year.[1] This article discusses the increase in interventional cardiology procedures that rely on fluoroscopy and describes the research on the health effects, including cancer, cataracts, cognitive function, and reproductive effects. Musculoskeletal injuries associated with the use of heavy personal protective equipment (PPE), as well as other radiation-protection methods and their limitations, are also discussed.

Radiation Exposure During Image-Guided Minimally Invasive Procedures

Although the number of percutaneous coronary interventions (PCIs) has stabilized over the past several years, interventional cardiology teams face increasing amounts of scatter radiation exposure because of an increase in the number of complex and radial PCIs performed in the cath lab. The number of peripheral vascular interventions (PVIs) for lower limb ischemia is increasing, driven by demographics and the prevalence of diabetes, as well as advancements in endovascular tools and techniques.[2] Other fluoroscopy-guided procedures, such as the rapidly growing field of transcatheter valve replacements, are creating demand for cath lab time and skills. The ability to treat cardiovascular, peripheral, and valve disease in a minimally invasive manner is expanding the addressable patient population (i.e., providing treatment to patients deemed inoperable or at high risk for surgery) and offers patients the benefits of shorter recovery times and fewer complications. However, these advancements are also putting interventional teams' long-term health at risk.

Over the course of his or her career, an interventional cardiologist is exposed to an estimated 50 mSv-200 mSv of ionizing radiation, which equates to 2,500-10,000 chest X-rays. The brain is subject to higher-intensity exposure, given the proximity of the head to the radiation source. The career exposure to the head is estimated to be 1,000 mSv, which is equivalent to 50,000 chest x-rays.[3] However, it is unclear whether these estimates fully account for the shift in the complexity of PCI cases, as well as the preferred access route. Specifically, complex lesions now account for more than 40% of total PCIs[4], and the use of radial access grew 13-fold in 2007-2012.[5] Both complex cases and radial PCI have longer procedure times than simple single-vessel and femoral PCI, respectively, and have been associated with higher exposure to scatter radiation.[4] However, as shown by a recent meta-analysis, once centers become more experienced with the radial approach, radiation exposure becomes equivalent to that of transfemoral procedures.[6] Given the benefits to patients, it is unlikely that complex PCI and the use of transradial access will diminish in the coming years. In fact, their use is likely to increase to accommodate the aging population in an era of cost containment.

Health Effects of Chronic Exposure to Fluoroscopy

Over the past several years, a spate of scientific evidence has demonstrated the health risks that interventional teams incur while performing life-saving minimally invasive procedures. The health effects range from skin erythema to premature aging (cataracts, reduced cognitive function, etc.), to cancer.[7]

The first isolated cases of malignant brain tumors for interventional healthcare professionals (HCPs) were reported in 1997.[8] Because there is no formal reporting mechanism and epidemiological studies of brain tumors in the interventional HCP population have not yet been conducted, the true incidence of brain tumors is unknown. However, in the 43[8] known cases, the majority of these tumors are located in the left hemisphere, which coincides with the orientation of an interventionalist's head during PCI. Data reported by Roguin (2013) showed that 85% of interventional HCP's brain malignancies occurred on the left side of the brain.[9] It has long been assumed that the left hemisphere is subject to greater radiation exposure than the right, but recent research has quantified the degree. The BRAIN study documented that the left side of an interventionalist's head is exposed to more than double the amount of scatter radiation as the right side (106.1 mrad vs 50.2 mrad, $P<0.001$). Subtracting ambient radiation, the left hemisphere receives 4.7x more radiation than the right hemisphere ($P<0.001$).[10] Although the BRAIN study was not designed to prove a causal relationship, its data support the hypothesis that occupational fluoroscopy heightens the risk of brain tumors.

The Healthy Cath Lab project recently showed that occupational exposure to ionizing radiation also affects cognitive function. Interventional and non-interventional HCPs were given neuropsychological tests that assessed functions associated with left and right hemisphere activity. While no between-group differences were found on right hemisphere activities, interventionalists posted lower scores on tests involving long-term verbal memory and fluency, and short-term visual memory. These tasks are governed by areas of the brain which have greater radiation exposure during image-guided interventions. Of note, participants in the interventional arm were young, with average ages of 46 for men and 43 for women. Thus, the data suggest a premature aging of the brain, which the investigators of this study believe is a "neglected and underestimated" repercussion of chronic exposure to ionizing radiation.[11]

There is evidence that premature vascular disease is also a consequence of working in the cath lab. Another study within the Healthy Cath Lab project compared carotid intima-media thickness (CIMT) — higher CIMT values indicate subclinical atherosclerosis — and leukocyte telomere length (LTL) — shorter lengths are predictors of cardiovascular disease (CVD) and mortality — for interventional and non-interventional HCPs. There were approximately 220 individuals in each group, with mean ages of 45 for the interventional arm and 44 for the control group. High-volume interventionalists had a higher overall CIMT as well as a higher left-side CIMT than low-volume interventionalists and control. The overall interventional cohort had significantly shorter LTL versus control.[12]

Occupational exposure to low dose ionizing radiation may also put HCPs' reproductive capability at risk. If cumulative exposure "below the apron" reaches 0.5-1.0 Sv, sperm count can be reduced. Pregnant women can spontaneously miscarry, particularly during the first trimester.[13] With exposure of 1-2 Sv, fetal abnormalities can occur.[14]

The development of premature cataracts is a recognized stochastic effect of radiation exposure and an occupational health hazard of the cath lab.[15] The RELID study revealed that half of interventional cardiologists had evidence of cataract precursors (i.e., posterior subcapsular lens changes) compared to less than 10% of the control group. Within the interventional group, HCPs with documented lens opacities had 2.8x higher cumulative radiation dose to the eye than those who did not have lens opacities.[16] Of note, the U.S. permits a higher annual eye dose threshold than Europe at 150 mSv and 20 mSv, respectively, but is investigating lowering the U.S. threshold for occupational exposure to 50 mSv.[17] A recent analysis of endovascular procedures estimated that the European threshold of 20 mSv could be reached with <23 hours (1,404 minutes) of fluoroscopy.[18] However, it should be noted that endovascular procedures of the lower limbs (i.e., peripheral vascular interventions [PVIs]) are associated with higher operator exposure to scatter radiation than PCI.[19]

As discussed in more detail below, there are several methods to reduce interventionalists' exposure to ionizing radiation. One way is through the use of personal protective equipment (PPE). However, leaded aprons and other PPE exert continuous pressure on the spine, hips, knees, etc. In addition, interventionalists often have to place their bodies in awkward positions to view monitors or maintain positioning behind radio-protective shields, which intensifies the strain that PPE places on the musculoskeletal system. Orthopedic pain has been associated with work absences[20] and some interventionalists have needed spinal surgery.[21]

The prevalence of spinal problems among interventionalists was first published in 1997.[22] Since then, the Society for Cardiovascular Angiography & Interventions (SCAI) has surveyed its members twice regarding orthopedic injury. In the most recent survey, approximately half of the respondents had at least one musculoskeletal problem. Unsurprisingly, the percentage increased dramatically based on length of time in the cath lab. What's surprising is that just five years of practice was associated with development of orthopedic pain or injury for 85% of respondents.[20] In the previous survey, 60% of interventionalists with ≥21 years of experience reported musculoskeletal problems.[23] In other words, more interventionalists are facing orthopedic injury earlier in their careers. This likely reflects the increase in annual caseloads, as well as the greater complexity of PCI and use of radial access.[20]

A survey performed at the Mayo Clinic (n=1,543) demonstrated a significantly ($P<0.001$) higher incidence of work-related orthopedic pain among interventional HCPs compared to non-interventional HCPs. Three variables were associated with experiencing work-related pain: more time

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spent in the cath lab, use of leaded aprons, and female sex. Interventional workers were also more likely to seek treatment for pain (P=0.02) than the control group.[24]

The possibility of shortened careers because of orthopedic injury is a concern.[25] The SCAI and the Mayo Clinic surveys only included active interventionalists. Thus, there isn't a clear picture of whether musculoskeletal problems forced an early retirement for some physicians. However, it is clear that practical, safe solutions are needed to protect interventionalists from ionizing radiation as well as orthopedic injury. If physicians are not given the appropriate tools and safeguards to perform procedures without jeopardizing their own health, some see a "depletion of the ranks" (i.e., trained interventionalists) as "inevitable".[25]

Protective Measures

"As low as reasonably achievable" (ALARA) is the guiding principle of diagnostic and interventional procedures using radiation, including fluoroscopy. ALARA is not restricted to minimizing fluoroscopy time or dose. It also embodies protective equipment (e.g., leaded aprons) and other control measures, such as distance from the radiation source.[26] Although ALARA is the cornerstone of hospital radiation safety programs, U.S. interventional cardiologists have ranked ALARA as less important for radiation protection than interventionalists in other parts of the world (P=0.0001).[27] This attitudinal difference suggests a lack of clarity regarding the implementation of ALARA in the U.S. and signifies a need for raising awareness.

Use of PPE and Dosimetry

PPE encompasses leaded garments (aprons/vests/skirts), thyroid collars, gloves, eyewear, face masks, and scrub caps. PPE should be fitted to the individual and frequently inspected for cracks and defects.[28] The effectiveness of PPE relies on the willingness of HCPs to wear all the equipment for the duration of the procedure. In general, clinicians acknowledge that PPE is not worn consistently. While the recent SCAI survey did not ask participants to enumerate the PPE used in clinical practice, more than 30% of respondents use "some sort of cranial protection" and 72% wear lightweight leaded garments.[20] Regarding the latter, the National Council on Radiation Protection (NCRP) notes that there is a wide variation in attenuation values of lighter-weight compositions and recommends that dosimeters be worn under the apron as an additional safeguard if lead <0.5mm is used.[28] The rationale for wearing personal radiation dosimeters is that interventional HCPs will be restricted from procedures if monthly dosage limits are met or exceeded. Perhaps because of this, some interventionalists may choose not to wear dosimeters.[15] Nearly half (47.1%) of respondents in the SCAI survey reported no or variable use of dosimeters: 28.6% indicated they never wear dosimeters and 18.5% reported occasionally failing to use dosimeters.[20] Thus, monitoring radiation exposure through dosimeters cannot be viewed as a reliable protective measure.

Control Measures

Other protection methods include shielding and distance from the radiation source. There is an array of shields (equipment-mounted, ceiling- or floor-mounted, etc.) available. These shields and drapes may offer better protection for nurses and technical staff than for operating physicians, although ceiling-mounted shields may lower the exposure to the eyes and head for interventionalists.[15] However, research has shown that proper positioning of this equipment is essential to reduce radiation exposure, and that "gaps" between various ceiling- and table-mounted shields can occur.[29] This, combined with the time needed to coordinate placement of multiple shields, may be a factor in relative underuse of radio-protective drapes by U.S. interventionalists compared to their peers in other countries.[27]

Distance from the radiation source is a core element of radiation exposure reduction.[26] Recent advancements in robotic technology have enabled PCI to be performed behind lead-shielded equipment that is not at the bedside, i.e., at a distance from the beam, and the use of robotic systems has been shown to significantly reduce the amount of scatter radiation to which an operating physician is exposed.[30]

Summary

With the growing evidence regarding the occupational hazards of fluoroscopy, steps need to be taken to safeguard the health of interventional teams who perform life-saving procedures, particularly as demand for complex, minimally invasive treatments is expected to increase. Because of lengthening procedure times, clinicians are assuming greater risk for a host of conditions — brain tumors, premature brain and vascular aging, early development of cataracts, and heightened CV and mortality risk — in their pursuit of improving the health of others. As is well known, there are deficits to current PPE and radio-protective drapes, most notably orthopedic injury. Immediate attention from all stakeholders is needed to implement interventional lab tools, technologies, and protocols to safeguard these HCPs from the stochastic effects of radiation and enable the continued minimally invasive treatment of patients.

ORSIF

The Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF) raises awareness of the health risks of occupational ionizing radiation exposure and associated musculoskeletal risks occurring in interventional fluoroscopy laboratories. ORSIF develops support for medical professionals and hospitals for new and better ways to create the safest possible work environment for those dedicated to the wellness of others. ORSIF is composed of members from industry, as well as physicians and staff from interventional fluoroscopy labs, and will partner with other physician associations, academic institutions, labor groups, and government bodies. ■

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