ORSIF
Organization for Occupational Radiation Safety in Interventional Fluoroscopy

Occupational Exposure to Ionizing Radiation in Interventional Fluoroscopy: **Severity of Adverse Effects of a Growing Health Problem**

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Organization for Occupational Radiation Safety in Interventional Fluoroscopy
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In February 2015, the Organization for Occupational Radiation Safety in Interventional Fluoroscopy (ORSIF) released a white paper detailing the scientific data on the health consequences for medical professionals faced with chronic exposure to low-dose ionizing radiation. The adverse health effects include brain tumors, premature development of cataracts, and thyroid disease, among others. In addition, because of the need to wear personal protective equipment (PPE) to reduce exposure to scatter radiation, many exposed workers (physicians, nurses, and technicians) sustain orthopedic injuries.

Since the issuance of ORSIF's report, there has been growing awareness of occupational hazards—and interest in reducing the risks that interventionalists face—as evidenced by the increase in the number of scientific publications on these topics. In 2015, there were approximately 45 scientific manuscripts (studies, surveys, and editorials) on occupational hazards or methods to reduce operator exposure to scatter radiation, more than double the number published in 2014.

This supplement summarizes new clinical data on the health consequences of chronic radiation exposure, presents findings from new physician surveys on the musculoskeletal impact of PPE, and provides an overview of various methods being investigated to enhance radiation protection for interventionalists.

NEW CLINICAL DATA ON HEALTH HAZARDS

Three notable studies evaluating the effects of chronic exposure to ionizing radiation in the cath lab were published in 2015. These studies—one comparing radiation doses to operators' left and right sides, another assessing occupational radiation's effect on brain function, and the last investigating the relationship between radiation exposure and vascular aging—add to the body of scientific evidence on the health hazards associated with fluoroscopic guidance.

BRAIN TUMORS AND CANCER

The first malignant brain tumors among interventionalists were diagnosed in 1997.[1] Most of the reported tumors have been located in the left hemisphere. It's been hypothesized that the cause of the brain tumors was interventionalists' greater exposure to ionizing radiation on the left side of the body and head, in keeping with the operator's positioning during percutaneous procedures. These malignant brain tumors were the first—and most alarming signs—that interventionalists are subject to ionizing radiation's stochastic effects, i.e., damage to DNA that can lead to cancer. As of December 2015, 43 malignant brain tumors, of which 85% of those with known location were in the left hemisphere, have been reported among interventionalists, including two nurses who assist in fluoroscopy-guided procedures.[2]

The BRAIN study, published in 2015, demonstrated that the left side of an interventionalist's head receives significantly more exposure to scatter radiation than the right side. Dosimeters were positioned on the outside left, center, and right of protective head gear. Readings from these dosimeters showed that the left side of the head receives more than double the amount of scatter radiation than the right side at 106.1 mrad and 50.2 mrad, respectively ($p<0.001$). The BRAIN study also showed that the left side of an interventionalist's head receives 4.7x times the amount of radiation, after subtracting ambient radiation, than the right side ($p<0.001$). The authors of the publication indicated that "a direct causal link between operator exposure and the risk of brain cancer may be impossible to establish", given the duration needed for such a study and the number of interventionalists who would need to be enrolled.[3] However, the BRAIN study was the first to quantify the significantly higher left-sided radiation doses, which adds credence to the supposition that reported brain malignancies are related to operators' consistent proximity to fluoroscopy when taken in the context of the known stochastic effects of ionizing radiation.

There is also new evidence suggesting that prolonged exposure to ionizing radiation could put interventional medical staff at increased risk for breast cancer. In a Mayo Clinic survey published in 2015, there was a higher incidence of breast cancer among interventional workers compared to a control group of non-interventional healthcare personnel at at 19% and 9%, respectively.[4] While the difference wasn't significant, these results may represent a "disquieting signal" that chronic exposure to ionizing radiation could be associated with breast cancer.[5]

IMPACT ON COGNITIVE FUNCTIONING

A recent study evaluated the consequences of chronic exposure to ionizing radiation on cognitive function for interventional physicians/personnel (n=83) compared to a control group of non-interventional medical personnel (n=83). The mean ages for men and women in the interventional arm were 46 and 43, respectively, similar to those in the control group. Study participants were given 12 neuropsychological tests that examined short- and long-term memory (verbal and spatial), logic, and strategic planning, among others. There were no differences between the groups on tests assessing right hemisphere function. The interventional group showed lower scores on verbal long-term memory and fluency—left hemisphere activities—as well as short-term visual memory, which involves input from the posterior hippocampus. These deficits matched areas of the brain most exposed to ionizing radiation, suggesting that, although the data set is too small to conclusively prove causation, premature brain aging is another occupational hazard in the cath lab.[6]

PREMATURE VASCULAR AGING

Another study assessed the effect of repeated exposure to fluoroscopy's scatter radiation on cardiovascular (CV) risk.

Researchers compared carotid intima-media thickness (CIMT) and leukocyte telomere length (LTL) between interventional personnel participating in the Healthy Cath Lab study (n=223) and a control group (n=222). CIMT is an indicator of subclinical atherosclerosis, and reduced LTL is associated with biological aging and a predictor of CV disease and mortality. The average age in the interventional and control groups were similar at 45 and 44, respectively. In the interventional group, the mean number of years of working in the cath lab was 12.2 years.[7]

An occupational radiation risk score (ORRS) was calculated based on workers' years in the cath lab and the number of annual procedures. The resulting number was halved for nurses and technical staff to account for their relative distance from the X-ray source. The mean ORRS for interventional staff was 18.5; the median was 11.[7]

High-volume interventional staff (n=91) had significantly higher overall CIMT compared to low-volume interventional personnel (n=80) and the control group. There was a significant association between ORRS and left-sided, but not right-sided, CIMT for high-volume interventional workers. Regarding LTL, interventional personnel had a significantly shorter LTL compared to the control group. In addition, higher ORRS correlated with a reduced LTL.[7]

The higher left-sided CIMT for high-volume interventional staff and ORRS was a notable finding, which the investigators concluded provides "further support for a causal connection between occupational radiation exposure and early signs of subclinical atherosclerosis."[5] In addition, given the young age of cohort (mean age: 45), it's alarming that the interventional staff already had significantly reduced LTL versus control.[7]

CATARACTS

Cataract development is a recognized adverse effect of prolonged exposure to ionizing radiation.[8] While there was no new clinical data on the prevalence of posterior subcapsular lens changes (i.e., precursors to the development of cataracts) among interventionalists published in 2015, several articles strived to evaluate operator exposure or assess the practice impact of lower dose thresholds mandated in Europe.[9, 10, 11] Related to the latter, an analysis of endovascular procedures performed at two centers estimated that just 1,404 minutes of fluoroscopy would put interventionalists at the International Commission on Radiation Protection's recommended annual eye-dose threshold of 20 mSv.[12]

ORTHOPEDIC HAZARDS: SURVEYS AND STUDIES

As early as 1997, spinal injury was seen as an occupational hazard for interventionalists.[13] The weight of PPE, notably leaded aprons, places constant pressure on the musculoskeletal system. To view monitors and use other protective equipment (e.g., shields), interventionalists often have to hold awkward positions during percutaneous procedures, which intensifies the strain caused by heavy PPE.[14]

In 2015, the Society for Cardiovascular Angiography & Interventions (SCAI) published its updated membership survey on occupational hazards, including the incidence of musculoskeletal problems. Roughly half of respondents (n=314) reported having at least one orthopedic injury.[15] The mean age of respondents was 49, with an average of 16 years in practice. Approximately one quarter of respondents had cervical spine disease, 34% reported lumbar spine pain, and nearly 20% had problems with hips, knees, or ankles. Age, years in the cath, and case load were associated with orthopedic injury. Of respondents who had been in practice for at least five years, 85% had a musculoskeletal problem.[15]

Comparatively, in the SCAI survey (n=434) performed 10 years earlier, 60% of respondents working 21 years or more in the cath lab had spinal injury.[16] Thus, a higher percentage of interventionalists are experiencing musculoskeletal problems after fewer years of work in the cath lab. This likely reflects changes in interventional cardiology practices over the past decade: higher case volumes, more complex cases, and an increase in the number of PCIs performed by radial access.[15]

In the previously mentioned Mayo Clinic survey of interventional (n=1042) and non-interventional (n=499) medical staff, more than half of the interventional group (54.7%) had work-related pain, which was significantly higher than the control group (p<0.001). Analysis found three variables to be associated with work-related pain: female gender, more hours spent in the interventional lab, and greater use of leaded aprons. Interestingly, analysis did not find less work-related pain for interventional workers who used two-piece leaded aprons,[4] which some consider to be one way to reduce back pain.[17] Interventional workers were also more likely to seek treatment for pain (p=0.02) than the control group.

Given the increasing prevalence of orthopedic injury over the past 10 years, greater attention needs to be paid to reducing musculoskeletal pain among interventionalists.[12] These work-related injuries result in absences, may necessitate spinal surgery, and can shorten careers.[17] Related to the latter, the SCAI and Mayo Clinic surveys only included active interventional medical workers. Thus, the prevalence of orthopedic injury and other occupational hazards (e.g., brain tumors) could be higher than that discussed above. Without adequate solutions to the orthopedic hazards in the interventional lab, “depletion of the ranks [of interventionalists]…seems inevitable.”[17]

ASSESSING OPERATOR EXPOSURE TO RADIATION

There were several publications assessing radiation dose or exposure to the operator, specifically, published in 2015. One study showed significant differences between patient radiation doses emitted by four standard fluoroscopy machines.[18] Although the study was focused on the impact to patients, the corollary is that operators are exposed to varying amounts of scatter radiation depending on which fluoroscopy system is used.

Two studies evaluated the differences in operator exposure based on access route. The REVERE trial randomized patients (n=1,493) undergoing PCI to either femoral, left radial (LR), or right radial (RR) access groups. REVERE’s primary endpoint was air kerma but operator exposure to scatter radiation, measured by personal dosimeters, was a secondary endpoint. LR access was associated with significantly higher median operator exposure than both RR (p=0.0001) and femoral (p=0.001) access even though air kerma did not differ significantly by access route.[19] However, another study comparing operator exposure during LR and RR showed different results. Dosimeters recorded significantly lower radiation doses at the operator’s thorax (p<0.001) and wrist (p=0.01) during LR procedures but higher exposure at the hip level (p=0.02) compared to RR.[20] According to authors of the papers, factors that likely contributed to the differing results include: learning curve with radial procedures, actual clinical cases performed in REVERE vs. a phantom diagnostic “case” in the second study, and beam orientation.

In addition, an international survey of interventional cardiologists (n=1084) assessed physician attitudes to radiation and access route. Radial access was performed by the majority (54%) of respondents, with right radial access being used in 80% of cases. Respondents indicated that radial access was associated with higher radiation exposure than femoral access. On average, respondents estimated that radial access increased radiation exposure by more than 30% and procedure times by 23%. Clinicians who performed a higher percentage of radial access PCI also had greater concern about their own radiation exposure. Nearly half of respondents indicated they would perform radial procedures more frequently if operator radiation exposure could be reduced.[21] As clinical data demonstrate patient benefits for radial (versus femoral) access, one can argue that improved safety for interventionalists could result in improved patient outcomes.

Interestingly, the survey showed geographic differences in attitudes about, and use of, radiation protection. Approximately 44% of respondents were from the United States (US). US respondents were less likely than interventionalists in the rest of the world to use radiation protection drapes and armbands and placed a lower priority on the radiation reduction principle “as low as reasonably achievable” (ALARA).[21]

This under-adoption of ALARA in the US is evident in the updated SCAI membership survey discussed earlier. The SCAI survey revealed that interventionalists do not routinely wear personal radiation badges or certain protective gear. Nearly 30% of respondents never wear dosimeters, and 18.5% reported “occasional failure” to wear radiation badges. In addition, the majority of participants do not wear cranial protection.[15]

LOOKING FOR SOLUTIONS

Industry stakeholders are seeking solutions to minimize interventionalists' exposure to ionizing radiation. The BRAIN study, discussed earlier, evaluated radiation protection afforded by a non-lead-lined cranial cap.[3] Other studies assessed a radio-protective drape attached to a shield and a leaded pelvic shield for use during radial procedures.[22, 23] The drape significantly reduced operator exposure during right radial procedures but increased exposure during femoral access procedures.[22] While the pelvic shield significantly reduced the clinician's exposure to scatter radiation, the radiation dose to the patient increased. The authors of the study concluded that given clinicians' cumulative exposure to ionizing radiation, the benefit to the physician should outweigh the increased risk for the patient.[23] While some physicians support this view[24], others have ethical concerns about accepting the premise, which is contrary to the principle of "first do no harm".[25]

However, these "solutions" do not offer a remedy for work-related musculoskeletal problems, which many clinicians see as a clear occupational hazard that is not being adequately addressed.[11-17, 26 -27] Some clinicians believe that "it is time to consider a fundamental change to the way these [interventional] procedures are performed."[27] There are a number of emerging technologies, including robotics and ceiling-mounted protective systems, which can play a role in this change.

CONCLUSION

Since the publication of the ORSIF white paper on occupational hazards in February 2015, there has been a substantial increase in scientific manuscripts on the health hazards of ionizing radiation as well as PPE for medical professionals. With complex and radial PCI being increasingly performed, interventionalists are faced with longer procedure and fluoroscopy times. Based on the research and surveys discussed in this brief, performing longer procedures with increased fluoroscopy times implies that clinicians are increasing their own risk of premature brain and vascular aging as well as CV disease. The international survey of cardiologists also suggests that greater appreciation of ALARA is needed in the US. Moreover, none of the studies evaluating radiation reduction methods that were published in 2015 address the orthopedic injury experienced by approximately half of interventionalists. As these clinicians are expected to manage an increasing percentage of complex cases, ORSIF believes that interventional labs must use contemporary radiation protection controls, with the operator properly distanced and shielded from the source of radiation and protected from orthopedic injury. Immediate attention from all stakeholders is needed to implement interventional lab tools, technologies, and protocols to safeguard these health care providers from the stochastic effects of radiation and enable the continued minimally invasive treatment of patients.

ABOUT 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.

Learn more at www.orsif.org.

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2015 Peer-Reviewed Publications on Fluoroscopy-Related Occupational Hazards

AUTHORS	TITLE	PUBLICATION
Adverse Health Effects of Ionizing Radiation		
Reeves RR, Ang L, Bahadorani J, Naghi J, et al.	Invasive cardiologists are exposed to greater left side cranial radiation: The BRAIN study (Brain radiation exposure and attenuation during invasive cardiology procedures)	JACC Cardiovasc Interv. 2015;8:1197-206.
Andreassi MG, Piccaluga E, Gargani L, Sabatino L, et al.	Subclinical carotid atherosclerosis and early vascular aging from long-term low-dose ionizing radiation exposure: a genetic, telomere, and vascular ultrasound study in cardiac catheterization laboratory staff.	JACC Cardiovasc Interv. 2015;8:616-27
Marazziti D, Tomaiuolo F, Dell'Osso L, Demi V, et al.	Neuropsychological testing in interventional cardiology staff after long-term exposure to ionizing radiation.	J Int Neuropsychol Soc. 2015;21:670-676.
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Principi S, Delgado SC, Ginjaume M, Beltran MV, et al.	Eye lens dose in interventional cardiology.	Radiat Prot Dosimetry. 2015;165:289-93.
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Vano E, Miller DL, Dauer L.	Implications in medical imaging of the new ICRP thresholds for tissue reactions.	Ann ICRP. 2015;44 (1 Suppl):118-28.
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Prevalence of Orthopedic Injury		
Klein LW, Tra Y, Garratt KN, Powell W, et al.	Occupational health hazards of interventional cardiologists in the current decade: Results of the 2014 SCAI membership survey.	Catheter Cardiovasc Interv. 2015;86:913-24.
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Gray B, Klimis H, Inam S, Ariyathna N, et al.	Radiation exposure during cardiac catheterisation is similar for both femoral and radial approaches.	Heart Lung Circ. 2015;24:265-9.
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Miller DL, Vano E, Rehani MM.	Reducing radiation, revising reference levels.	J Am Coll Radiol. 2015;12:214-6.
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