ANSWERING A CALL TO ACTION

Now more than ever, advances in interventional fluoroscopy provide physicians powerful tools to treat patients. From coronary artery and structural heart disease, to peripheral vascular disease, trauma, urology, and orthopedics, adding fluoroscopy to surgery leads to improved outcomes, faster recovery, and higher patient satisfaction metrics.

However, these advances come at a cost for healthcare professionals. Repeated exposure to scatter radiation during fluoroscopic surgery leads to increased risk of cancer and long-term tissue effects. Physicians also experience musculoskeletal risks caused by strained positioning while wearing personal protective equipment (PPE) with an estimated 30% to 60%[1] of interventional health care practitioners experiencing one or more musculoskeletal diseases in their lifetime.

To address these risks, in 2013 the IAEA (International Atomic Energy Agency) issued the "Bonn Call to Action" which provided a global roadmap on radiation protection in medicine.[2] While there have been meaningful steps to reduce exposure limits since the "Call to Action," significant risks still exist for the health professionals working in interventional fluoroscopy.

A false sense of security

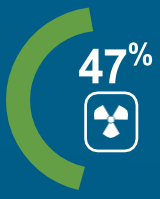
When it comes to scatter radiation, most physicians will likely remain below maximum exposure levels on a daily and annual basis. However, they are still at risk of adverse effects over the course of their careers, as the effects of scatter radiation are cumulative. In addition, the effective dose limits from the International Commission on Radiological Protection (ICRP)[3] are based on measurements obtained from protected areas, not unprotected areas. Unprotected areas such as the neck and head, or the legs, arms, and shoulders receive exponentially more exposure.[4] As a result, using data related to exposure reports as a guide may create a false sense of security and show only a portion of a bigger picture that reveals unrecognized gaps in protection, and that demonstrates how regular exposure over a number of years has serious negative effects.[5]

Scatter radiation health-related risks

The health problems caused by repeated exposure to scatter radiation take a number of forms, including increased breast cancer rates in female orthopedic surgeons,[6] increased left-sided brain tumors in interventional cardiologists,[7] and increased rates of cancers such as thyroid, breast, lymphoma, and leukemia in interventional radiation technologists.[5] There is also a known and growing list of tissue effects, including premature vascular changes and atherosclerosis from microvascular ischemia and corresponding premature cognitive decline, as well as overwhelming evidence of DNA damage from low-dose radiation.[8]

Economic impact: A price to pay

Many hospitals and practitioners overlook these risks, but the costs add up. An Organization for Occupational Radiation Safety in Interventional Fluroscopy (ORSIF)



According to a 2014 Society of Interventional Radiology survey, 47% of physicians reported not wearing radiation badges daily.[20]

From an operational standpoint, hospital compliance is even worse, with 90% of hospitals reportedly failing to enforce NRC or OSHA guidelines or take remedial actions for deficiencies in compliance.[2]

Although the majority of hospitals checked all regulatory boxes, they did not effectively monitor, educate, or enforce compliance.[20]

economics impact study demonstrated the conservative total annual cost of health effects associated with interventional fluoroscopy in the United States at $48,995,000 USD. That includes $36,000,000 related to fatal cancer ($13,500,000 for physicians and $22,500,000 for nurses and technicians), and another $12,200,000 for the effects of musculoskeletal disorders.[9]

Failure on the part of hospitals to address these risks may result in significant liability. Consider an active case in Evansville, IN where eight physicians and nurses, all diagnosed with cancer, are in litigation with Ascension St. Vincent Hospital[10] for negligence in providing adequate scatter radiation.

Offsetting factors to meaningful improvements

While improvements to imaging equipment have lowered radiation doses, multiple factors offset the gains made from hardware improvements. The obesity epidemic is one such factor. Radiation exposure risk to the patient doubles during PCI procedures when patients have a BMI of 40 versus 25, while operator exposure increases 7 times. With half of all US adults expected to be obese[11] by 2030, exposure for physicians is certain to increase in tandem.

Other factors offsetting gains include advances in medical devices and changes in how physicians approach access points. These have resulted in more complex procedures with longer exposure times. For example, treating a chronic total occlusion (CTO) of coronary arteries no longer allows for single vessel access, but requires access through two femoral and/or radial arteries. Other procedures also require multiple access points, such as limb salvage procedures and dialysis intervention. Endovascular aneurysm repair, neurovascular intervention, complex IVC filter removal, and structural heart procedures all are complex procedures creating additive exposure hazards.

Although many of these changes have revolutionized the field, leading to same-day or next-day discharge, decreased morbidity and mortality, better outcomes, and quicker recovery for patients, they have also magnified the risk for healthcare professionals by increasing cumulative scatter exposure.

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Radiation exposure takes away a physician's greatest assets

Health care professionals are no different than football players when it comes to repetitive trauma. The physical effects of the hits to a football player are palpable. And while it's rare that a single hit will lead to long-term neurologic issues, the cumulative effect of years of repetitive punishment takes an irreversible toll.

This pattern is similar with fluoroscopic physicians, though in a more subtle way. Although the trauma transmitted to healthcare workers during fluoroscopy takes place on a microscopic, subcellular and cellular level, these micro traumas occur with an exponentially higher rate and with similar end results. In effect, regular radiation exposure is taking away a physician's greatest assets — his/her mind and physical health — leading to premature retirement.

Premature decrease in IQ scores and function developing after between 5-10 years of practice.[21]

Time for a new approach

There are efforts in place to protect the health of physicians and Cath lab personnel, but it is increasingly clear they fall short of what is needed. Wearable shielding is one option, but that doesn't always provide the promised protection.[12]

In addition, sub-optimal and antiquated testing requirements and FDA recalls raise questions about the true safety of current PPE. Case in point, a leading manufacturer of lead and lead-equivalent PPE had a recall on their lead half aprons in July 2019,[13] and a German study by Eder and Schattl also demonstrated significant errors with current IEC testing, secondary to the lack of measurement of scatter radiation.[4]

Other forms of shielding can help significantly, although none is the complete solution. Ceiling-mounted shielding provides the most effective upper-body protection, but there is little room for error in positioning. Placing the shielding just 5 cm farther away from the patient's body and 20 cm closer to the x-ray tube may result in an 80% reduction in protection.[14] Fetterly et al. demonstrated that while leaded glasses reduce dose to the ocular lens by 27% to 62% on the side of the physician from which

the scatter originates, they offer no protection to the other eye. Meanwhile, radio absorbent surgical caps reduce brain dose by only 3.3%.[14]

Physicians and lab techs can supplement protection with table-mounted lower-body shields,[15] accessory shields, and horizontal table drapes, but most of those options are either cumbersome and difficult to reposition, or cover only part of the scatter cloud and, except for disposable pads, are not sterile. Disposable, radiation-absorbing pads have been reported to provide 35% to 70% upper body protection[16] for procedures during which an upper body shield cannot be used effectively. However, in a prospective, blinded and randomized Shampad study, researchers recorded only a 20% decrease in exposure and a surprising 40% increase in exposure when using the Shampad.[17] That suggests either a false sense of security with a protective pad, a relative increase in patient dose secondary to inappropriate pad positioning in the primary field, or both. Meanwhile, a radiation pad in the primary beam has been found to increase patient exposure by up to 66%.[18]

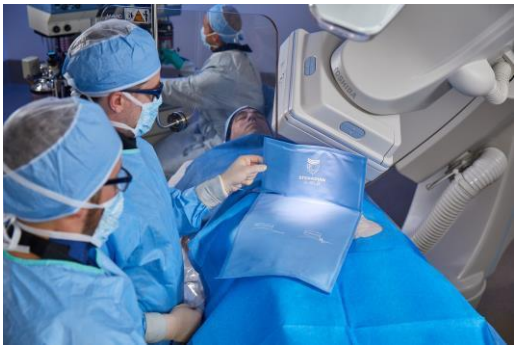
There are additional steps hospitals can take to improve scatter radiation protection for physicians and cath lab professionals. Upgrading equipment and remodeling procedure rooms can significantly reduce exposure, but these steps can come with a steep price tag. Using wearable devices with real-time feedback to track exposure — with visual feedback — is also a solid option.

Steradian Shield fills scatter cloud holes

The Steradian Shield offers a new approach, designed specifically to fill scatter cloud holes while creating a minimal footprint in the sterile field. A portable, stable, sterile device, Steradian Shield combines the benefits of a disposable attenuation pad with

added structure and side vents of a vertical shield. Addition of structure increases coverage the sterile field missed by the pad alone. This dynamic multi plane coverage provides additive and synergistic effects providing 3-8 times the protection of standard attenuation pads[19].

Proven benefits were demonstrated in a randomized prospective study comparing the effects of different shielding strategies used in the Interventional cardiac catheterization lab utilizing the 1st generation Steradian Shield. The addition of one Steradian Shield to a standard Cath lab protection protocol including a wall-mounted shield (Mavig) plus 2-3 RadPad yellow pads (90% attenuation at 90 KVp), decreased physician exposure by an additional 42%.[18]



Conclusion

Physicians, extenders, nurses, and technologists need to advocate for better protection, seek out better shielding solutions, and rethink their current protection strategies. By looking at how best to reduce exposure time, increase distance, and improve shielding on each case, physicians and Cath lab personnel can reduce their long-term risk, protect their health, and extend their careers.

Additional steps physicians can take to protect themselves, include:

Minimize, or at least increase awareness of, the increased exposure with steep left anterior oblique angles (LAO) of the detector, especially LAO caudal viewers.[18]

Lower fluoroscopy rate from 15 to 7.5 frames per second to reduce exposure by as much as 30%.[15]

Place the image detector close to patient's body to reduce the vertical gap and use the detector as a shield.[15]

Check lead aprons regularly for cracks and fit aprons properly.

Create distance when possible. Routinely stepping back when using CINE can reduce exposure by 86%[19].

Lower magnification to 10 inches from 8 inches.[18]

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