CorPath
Precision Vascular Robotics

Operator Safety in Complex PCI

The number of minimally invasive, catheter-based procedures continues to grow, usurping open surgeries in the treatment of a variety of life-threatening cardiac conditions. In order to perform these "closed chest" procedures, interventional cardiologists use X-ray-based imaging (fluoroscopy) to visualize the location, movement, and placement of catheters and devices. Fluoroscopy emits ionizing radiation, which scatters in the cath lab and has long-term health consequences for interventional teams. These radiation-related health consequences range from development of cataracts to pre-mature vascular aging to brain tumors.

To reduce radiation exposure, interventional teams wear leaded personal protective equipment (PPE). Even with PPE, interventionalists are exposed to a significant amount of scatter radiation, particularly to the head, eyes, neck, and legs. In addition, PPE may introduce another health consequence—orthopedic injury—that takes a personal toll on interventionalists and, in some cases, shortens careers.[1] Spinal injury is so pervasive among interventional cardiologists that it has been deemed "interventionalist's disc disease".[2]

Occupational Hazards for Interventionalists

ORTHOPEDIC INJURY:

Interventionalists have high rates of orthopedic injury. Long hours of standing at the patient table, combined with the weight of leaded aprons, thyroid collars, and other PPE, exert continuous pressure on the musculoskeletal system. Monitor positions, ancillary equipment, and shields used to protect interventional teams from radiation often require interventionalists to hold unnatural positions during procedures. This amplifies the taxing effect of heavy aprons and other leaded PPE.[3]

In a recent Society for Cardiovascular Angiography & Interventions (SCAI) member survey, approximately 50% of respondents reported at least one orthopedic problem. Injury was associated with the number of years in the cath lab, case load, and age. Specifically, 85% of respondents with orthopedic problems had been in practice for at least five years. However, interventionalists don't want to limit caseloads or take time off from work,[4] which gives credence to an emerging moniker for interventional cardiologists: the "working wounded".[5]

The Mayo Clinic also surveyed its interventional and non-interventional healthcare professionals about musculoskeletal problems. More than half of interventional professionals (54.7%) reported work-related pain, which was significantly higher than non-interventional workers (44.7%, $p<0.001$). Three factors were associated with musculoskeletal pain: female gender, more time per week participating in interventions, and greater use of leaded aprons.[6]

BRAIN TUMORS:

Interventionalists are typically positioned with the left side of their body close to the patient's chest and X-ray source. This means that the left side of the interventionalist's head, neck, and body are most exposed to scatter radiation. Case reports of brain tumor malignancies among interventional cardiologists were first reported in 1997.[7] As of January 2014, 34 cases have been reported. The majority of the malignances have been an aggressive tumor type (glioblastoma multiforme); 86% have been located on the left side of the brain.[8] Brain cancer was also noted in the recent SCAI survey, with 4.2% of respondents knowing a colleague with brain cancer.[9]

The recent BRAIN study quantified the differing radiation exposures to the left and right sides of the head. Dosimeters were placed on protective head gear worn during routine PCI and peripheral vascular interventions (PVIs). Dosimeters were positioned in three areas: outside the cap–left (OL), outside the cap–center (OC), and outside the cap–right (OR). The average radiation exposures to the OL (106.1 mrad) and OC (83.1 mrad) were significantly higher than that to the OR (50.2 mrad, $p<0.001$). Once accounting for the ambient radiation, the OL received 4.7 times the dose of the OR.[10]

Despite the high exposure to scatter radiation, only about 30% of respondents in the SCAI survey reported wearing a radio-protective scrub cap. In addition, nearly 30% don't wear dosimeters routinely, and almost 20% indicate that they don't use dosimeters for every procedure.[11] In other words, interventionalists' radiation exposure is likely to be much higher than reported.

BACKGROUND

Prolonged radiation exposure has stochastic effects, i.e., DNA damage and onset of cancer.

The Occupational Safety and Health Administration (OSHA) set limits on worker radiation exposure.[22] These thresholds have not been updated since 1971. Interventional cardiology became a board-certified specialty in 1999.[23]

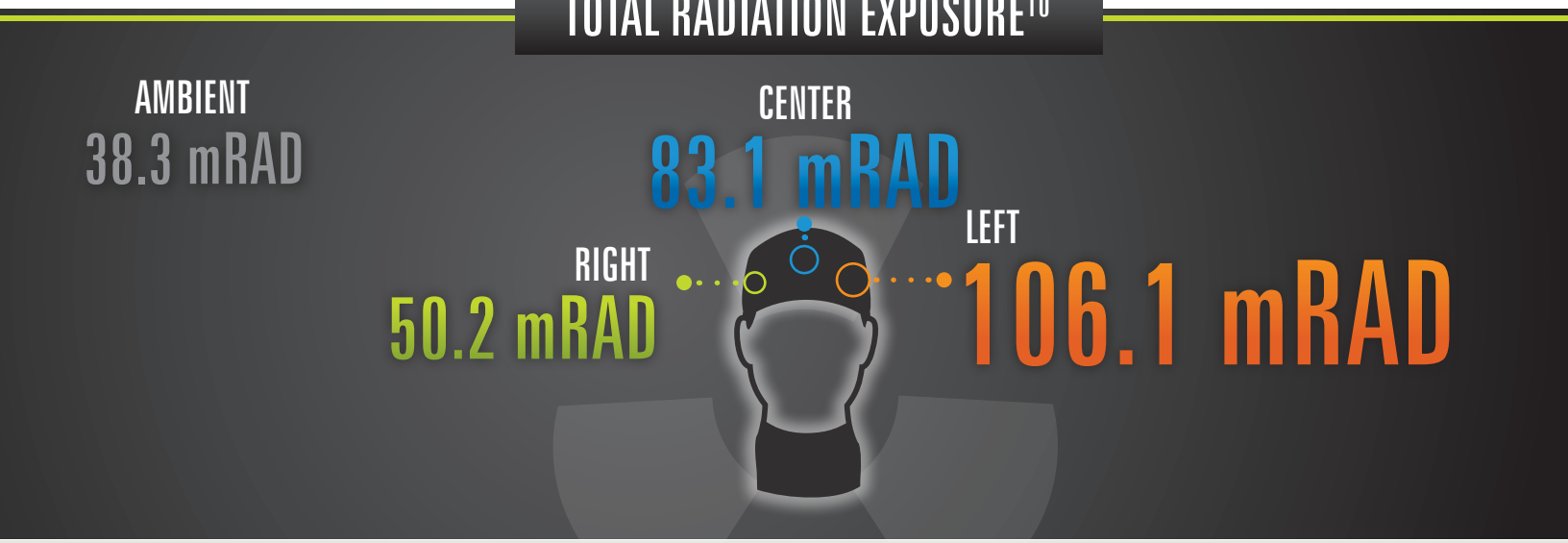
OSHA does not have a separate limit for radiation exposure to the eye,[24] which is highly radio-sensitive.

The guiding principle for radiation exposure is ALARA (as low as reasonably achievable). ALARA was first applied to dental offices and patient X-rays. Hospitals now incorporate ALARA into their procedures for cath lab personnel.[25]

Despite ALARA and protective equipment, interventional cardiologists are exposed to 50 mSv-200 mSv—the equivalent of 2,500-10,000 chest X-rays—over the course of their careers. They face up to 10 times the radiation exposure of other specialties.[26]

In order to safeguard interventionalists' health yet allow them to treat the increasing numbers of patients who seek minimally invasive treatment, cath labs need to be furnished with contemporary protective equipment that addresses all occupational hazards.[27]

TOTAL RADIATION EXPOSURE[10]



VASCULAR AGING:

New research provides evidence that continued exposure to low-dose ionizing radiation also increases cardiovascular (CV) risk. Carotid intima-media thickness (CIMT) and leukocyte telomere length (LTL) are markers for atherosclerosis and biological aging, respectively. High-volume interventionalists had significantly higher CIMT compared to low-volume medical professionals. High-volume interventionalists also had significantly higher CIMT values on the left side of the neck but not the right. In addition, high-volume practitioners had significantly shortened LTL compared to the control group. A shortened LTL has been found to be a predictor of CV disease and death.[12]

CATARACTS:

The eye is highly radio-sensitive. Cataracts are a stochastic effect of radiation exposure and a frequently reported occupational health hazard for interventionalists. In the RELID study, 50% of interventional cardiologists had posterior subcapsular lens changes (precursors to cataracts) vs. <10% in the control group. Interventionalists with lens opacities had an estimated cumulative radiation dose to the eye that was 2.8x higher than those without lens opacities.[13]

New Treatments and Techniques Increasing Occupational Risks

Advances in devices and techniques have enabled interventional cardiologists to treat more complex cases, which were previously treated through open heart surgery and are now endorsed for percutaneous treatment by medical guidelines.[14] A recent analysis of the National Cardiovascular Data Registry (NCDR) shows that over 40% of PCI cases involve complex lesions and about 15% involve bifurcated lesions.[15] The NCDR also shows that the percentage of cases performed by radial access—a new technique for introducing catheters into the body that is associated with fewer complications than the traditional access route, the femoral artery—increased 13-fold in six years.[16]

However, complex cases and those using radial access prolong the time that interventional cardiologists stand with heavy PPE and are associated with higher radiation exposure.[17,18] Radiation exposure during individual radial access procedures varies, with greater exposure experienced by interventionalists who have performed <50 radial procedures and when left (vs right) radial access is used.[19, 20]

CorPath—Effective and Critical Tool for Complex Cases

The value of the CorPath® Vascular Robotic System for protecting the primary operator is perhaps most evident in complex and radial PCI. CorPath enables the interventional cardiologist to perform the procedure while seated at the radiation-shielded interventional cockpit. This negates the need for wearing leaded PPE and can potentially reduce orthopedic stress. Monitors at the cockpit provide enhanced visualization of live and reference fluoroscopy images as well as patient clinical data, such as hemodynamic information.

During a manual PCI, interventional cardiologists often lean over the patient in order to view the fluoroscopic images. When doing this, the operator's head is exposed to significantly more scatter radiation. By positioning the

CorPath—Effective and Critical Tool for Complex Cases

fluoroscopic monitors within inches of the primary operator, CorPath provides enhanced visualization from the protection of the lead-lined cockpit.

CorPath has been used in a variety of complex cases, including those with tortuous anatomy, left main disease, total occlusion, bifurcated lesions, and multi-vessel disease. In addition, popular devices such as Guidezilla™ have been used in conjunction with the CorPath.

For these complex cases, interventional cardiologists often comment on CorPath's ease of use, radiation protection, ergonomics, enhanced visualization, and robotic precision.[21]

Recent live CorPath cases performed during the 2015 C3 (Complex Cardiovascular Catheter Therapeutics) and San Diego Cardiovascular Interventions meetings included multi-vessel disease using ABSORB stents in a 50-year-old patient, PCI of multi-vessel disease with Impella® support in an 86-year-old male, and a complex case requiring two wires in a 69-year-old patient.

Panelists viewing these procedures remarked on the operator having full control of the devices and being able to perform the procedure from a seated position without heavy PPE. It was also noted that being comfortable and unencumbered allowed the operator to be "relaxed" and focus on critical clinical decisions, rather than the procedural elements. Related to the latter, panelists commented that CorPath provides stability to guidewires, guide catheters, balloons, etc., and enables precise, controlled movement of catheters.

CorPath System in the cath lab. Physician is seated at the radiation-shielded Interventional Cockpit during PCI procedures.

Extending Clinical Practice

CorPath is a key tool for the cath lab and the protection afforded by the system will become even more crucial as complex cases become the "norm" in cath labs across the country. By providing both radiation protection and robotic precision, CorPath can potentially enhance both complex and radial procedures. Ultimately, CorPath may help extend the years in practice for interventional cardiologists, which would benefit hundreds of thousands of patients requiring life-saving treatment.

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To learn more, call **1-800-605-9635** or email: **sales@corindus.com**

CorPath 200 System is intended for use in the remote delivery and manipulation of coronary guidewires and balloon/stent catheters during PCI procedures.

Corindus Vascular Robotics

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