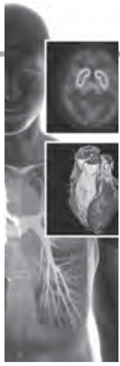

The evidence supporting radiation safety methods- working towards zero operator exposure

The potential dangers of exposure to X-rays were apparent early after the first clinical applications, prompting the eventual development of standards regarding exposure. Physicians performing interventional procedures that are guided by X-rays are not immune to these potential dangers despite remaining outside of the primary beam. Contemporary studies regarding deleterious subclinical and clinical effects associated with chronic exposure to medical radiation have raised awareness in the interventional community. In recent years, investigations regarding feasible processes to reduce operator exposure have been published and are summarized in this review. Immediate universal implementation of many of these methods may result in significant decreases in operator and patient exposure. Future research in this field will help further define the risk posed by X-ray guided procedures and lead to a safer interventional environment for patients, operators, and staff.

KEYWORDS: radiation safety; interventional; fluoroscopy

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Introduction

The potential dangers of fluoroscopy became evident with its initial use in research endeavors. Clarence Dally was a research assistant of Thomas Edison and focused his efforts on fluoroscopy. Years of exposure led to a myriad of medical problems that prompted his physician, Dr. Graves to comment, "Dally's case has told science that the continuous exposure of any part of the human anatomy to the influence of the X rays is deadly to the part so exposed. Of course, it does not interfere with the use of the light for medical purposes when it is handled by experienced persons, but it is not a thing to be trifled with. Under proper care it is of great use" [1]. This continues to hold true today and the effects of chronic exposure to low dose radiation continue to unfold. The use of radiation guidance by interventional physicians results in relatively high levels of occupational exposure, the complete effects of which remain unknown. Occupational exposure limits have been set by the International Commission on Radiological Protection and are summarized in Table 1 [2,3]. Levels of exposure are affected by multiple factors beyond operator control and vary widely across different procedure types. With technological advancements, procedural complexity has increased across all interventional fields and is uniformly associated with increased radiation exposure [4-8]. Increased patient habitus is also a nonmodifiable factor resulting in higher radiation doses during procedures as varied as endovascular repair, joint injections, ureteroscopy and cardiac interventions [9-13]. The radial access site is gaining in popularity during coronary procedures due to lower access site bleeding compared to femoral access, but results in a measurable increased risk of radiation exposure [14]. Shorter operator height may also be a predictor of increased operator exposure [15]. A recent evaluation of the National Cardiovascular Data Registry identified operator and hospital factors as having a moderate impact on fluoroscopy time variation after controlling for patient and procedural characteristics [7].

Table 1. A Summary of the occupational exposure limits from the 2007 and 2011 Recommendations from the International Commission on Radiological Protection [2,3].

Tissue Exposure Site	Maximum Exposure Level
Effective doseα	100 mSv over 5 years, with no yearly dose > 50 mSv
Equivalent doseβ to the lens of the eyeγ	100 mSv over 5 years, with no yearly dose > 50 mSv
Equivalent doseβ to the skin, hands and feet	500 mSv

α Effective dose: total body biological effectiveness from the tissue-weighted sum of equivalent doses
β Equivalent dose: biological effectiveness of the absorbed dose to denote the stochastic health effects
γ updated in 2011

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Population aging is likely to continue as will the demand for interventional procedures. Therefore, determining the risks of performing x-ray guided procedures and optimizing the interventional suite for the personnel providing patient care should continue to accompany advances in imaging systems and interventional techniques.

Deleterious effects of operator radiation exposure

The effects of radiation exposure at the molecular level include DNA double-strand breaks and increased micronuclei [16,17]. A comparison of peripheral lymphocytes between clinical cardiologists and high-volume interventional cardiologists revealed significantly higher micronuclei values in the interventionalists [18]. By testing for high-risk alleles in DNA repair genes, an interactive effect was seen between chronic exposure, smoking, and the high-risk alleles in DNA damage [17]. In another recent study, subclinical effects were observed in high-exposure cath lab staff who had increased carotid intima-media thickness compared to low-exposure and unexposed contemporaries (Figure 1) [19]. Left-sided carotid intima-media thickness correlated with lifetime exposure, as did a biological marker of aging, leukocyte telomere length. In addition, morphologic abnormalities on nail bed capillaroscopy are associated with duration of exposure in interventional operators [20]. The risks of cataracts are another well-established complication of radiation exposure in multiple interventional disciplines [21-23]. Reports of predominantly left-sided brain cancer in high-volume interventional physicians question a causal relationship given standard operator positioning [24,25]. It would be nearly impossible to prove that the incidence of malignancy from chronic exposure to low dose radiation is higher than that of the general population, but statistical data suggest the risk is not negligible [26]. Further studies are required to completely determine causality and to strengthen the current body of evidence regarding the risk of biological effects in the interventional suite.

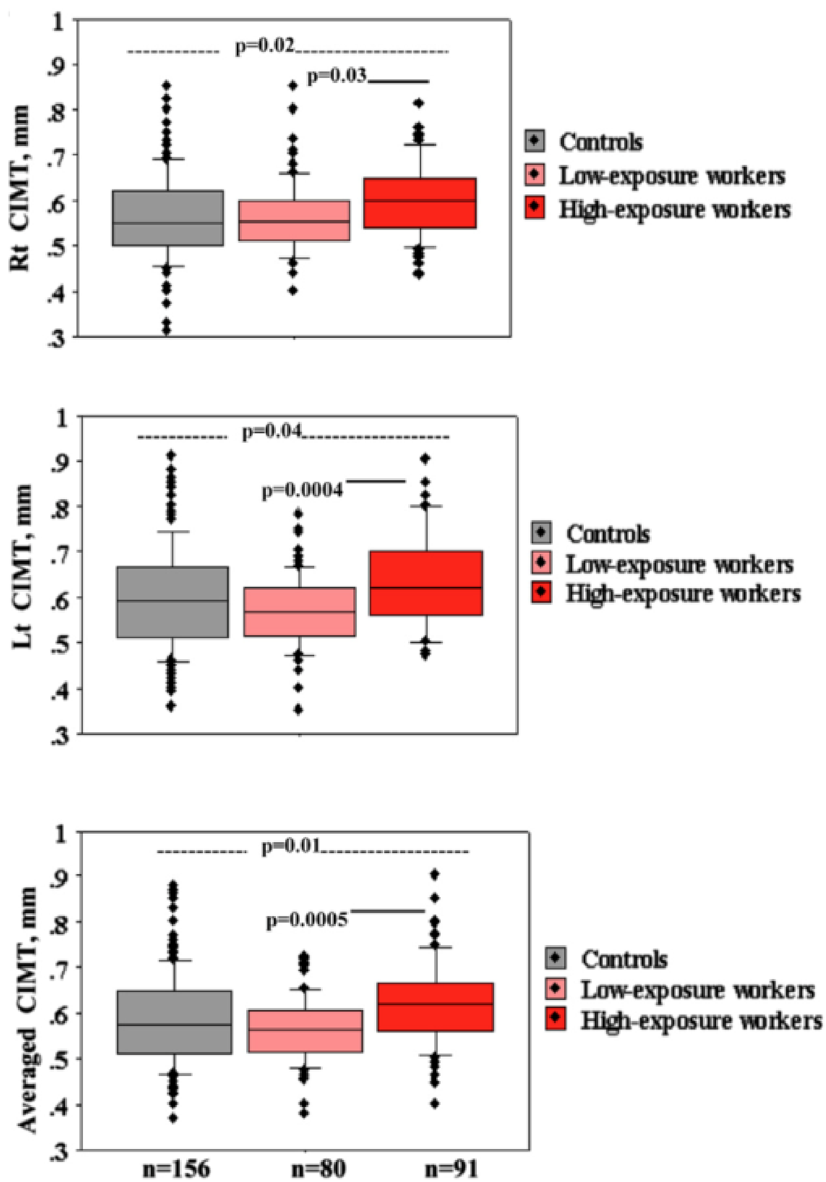

Figure 1. Carotid Intima-Media Thickness (CIMT) and Cath Lab Exposure. Exposure was determined by an occupational risk score based on individual case load, years of employment, and proximity to the source of radiation [19].

Methods to reduce operator radiation exposure

■ Radiation safety training

Operator awareness and training, barrier protection, imaging equipment, technique, and robotic assisted procedures have all been identified as targets to reduce radiation exposure. The fundamental principle of "as low as reasonably achievable" [ALARA] remains the cornerstone for limiting patient and staff exposure to ionizing radiation [27-32]. Focused training sessions for interventional staff and trainees are centered on the principle of ALARA and increase efficient use of imaging modalities and decrease markers of exposure without compromising patient care [33-37] (Table 2). The effects of training programs, including simulation center training, are enhanced over time and periodic review courses are of value in maintaining optimal operator awareness [38]. Despite the universally recognized importance

Table 2. Operator dependent dose reduction principles highlighted in multiple radiation safety programs.

Review previous fluoroscopy times
Use of effective collimation
Minimizing source-detector distance
Use of lead shielding
Less irradiating angulations
Less irradiating Magnification
Inspiration during cineangiography
Adequate pulse rates
Copper filtering
Well-rested operators

of the ALARA principle and the strong evidence behind radiation safety training, a recent survey of cardiology fellows in training revealed that though 82% had undergone formal radiation safety training, only 52% regularly wore a dosimeter and 74% were unaware of the safe levels of radiation exposure [39]. A similar survey of vascular surgery residents also revealed that the ALARA principle is underutilized but is more prevalent in training programs that provided formal radiation safety training [40]. Standardized radiation safety training programs that highlight the ALARA principle and reinforce dose reduction methods are a foundation for operator safety.

■ Radiation monitoring

Operator awareness is the foundation of radiation safety training and the ALARA principle. Periodic and real-time exposure monitoring enhance operator awareness and allow for operator adjustments to reduce radiation dose. Real-time monitoring devices that produce visual or auditory information regarding the level of operator exposure are available and have been shown to reduce patient and operator exposure [41,42]. Christopoulos et al. showed that a real-time monitoring device that provides auditory feedback has a major effect on operator behavior, reducing operator exposure without an effect on fluoroscopy time or patient exposure [42]. Therefore, by enhancing awareness with real-time feedback, behavior associated with shielding and distance may significantly reduce operator exposure. Monthly monitoring may also alert individual operators or an entire interventional team to issues associated with radiation safety and the need for an investigation into the reasons for increased measurements. Practice modifications or systems maintenance may then be implemented to optimize operator protection.

■ Barrier protection

Barrier protection with lead aprons is nearly universal in interventional suites. The clinical effectiveness of lead aprons in attenuating operator exposure is well documented [43,44]. However, the prolonged use of relatively heavy aprons results in physical strain and potential cervical and lumbosacral spine issues. While difficult to demonstrate causality, self-reported orthopedic problems of leadwearing, invasive operators is high [45,46]. In a 2014 survey of members of the Society for Cardiovascular Angiography and Interventions, 49% reported at least one orthopedic injury, while 9.3% required a health-related period of absence [45]. Caseload and age were associated with orthopedic illnesses, which included cervical spine, lumbar spine, hip, knee, and ankle injuries. In a survey comparing multiple sub-specialties, lead apron use was associated with axial skeletal complaints [47]. Relatively light weight barriers that provide a level of protection similar to standard lead barriers have been produced by stacking two different attenuating materials to cover a broad energy range [48,49]. These materials have been fashioned into a myriad of protective barriers and further studies are needed to determine whether the incidence of orthopedic issues may be reduced with their routine use. Standard lead aprons do not provide protection to uncovered areas, namely the head and the extremities. Radiation exposure to the head is well documented and is affected by procedural complexity [8,50-52]. The concern for cranial exposure has led to an interest in developing a tolerable cap with attenuation capabilities. Leadbased protective caps provide cranial protection [53], however routine use has likely been limited due to poor tolerability. The Brain Radiation Exposure and Attenuation During Invasive Cardiac Procedures (BRAIN) study revealed that a light-weight, non-lead cap can reduce exposure across the cranium to near ambient levels [Figure 2] [54]. Other studies confirm the protective ability and tolerability of lightweight, non-lead caps [55-57] and consideration should be given to routine cranial protection during radiation-guided procedures. Strong evidence exists for the protective ability of leaded-goggles, which should also be considered standard radiation safety equipment [23,58]. Given that the major source of radiation relevant to operator exposure is scatter from the patient, placing protective barriers on the patient has been investigated as a target for exposure

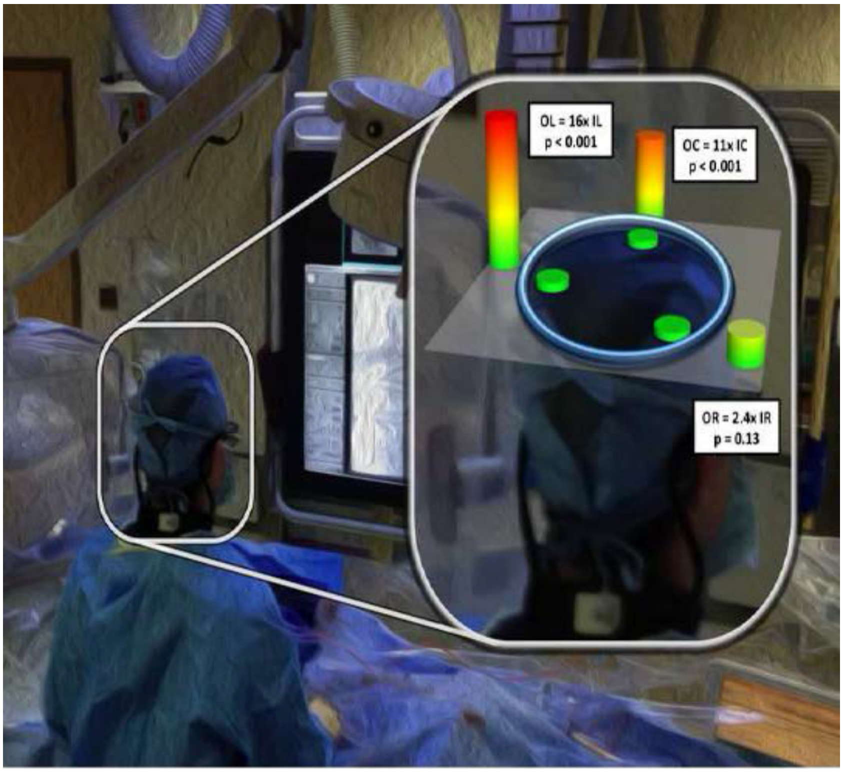

Figure 2. Comparison of the radiation exposure between inside and outside dosimeters after controlling for ambient exposure. Exposure outside the cap was 16 times and 11 times higher at the left and center locations, respectively relative to the corresponding inside location. There was no difference on the right side of the head [54].
OL = Outside Left; IL = Inside Left; OC = Outside Center; IC = Inside Center; OR = Outside Right; IR = Inside Right.

reduction. The randomized use of a non-lead drape placed over the patient during 36 EVAR procedures resulted in a greater than 50% reduction in operator exposure [59]. Transcatheter aortic valve replacement is a novel procedure that is dependent on fluoroscopic guidance for optimal results. The placement of a non-lead drape over the patient resulted in a nearly 40% reduction in operator exposure [60]. Similarly, large relative and absolute reductions in operator exposure have been shown during vascular procedures with both femoral and radial access sites [56,61-63]. Sensible use of room shielding can also have a significant effect on operator exposure. Ceiling suspended, transparent lead glass screens reduce normalized eye dose by a factor of 19 during cardiovascular procedures [64]. The most effective placement of room shielding is in between the source and the operator, with the operator as close as possible to the shield. This requires the operators to frequently adjust mobile shields to maintain and maximize protection. Proper positioning of the ceiling suspended shield results in significantly higher levels of protection. For example, if the shield is 20 cm cephalad from the femoral access point, the operator is exposed to twice the amount of scatter radiation relative to more optimal placement [65]. Moving the shield 5 cm from the patient's body in addition to 20 cm cephalad from the access site, increases operator exposure by four-fold (Figure 3) [65]. Therefore, one major focus of the aforementioned training courses is reinforcement of the operator's role in shield management [35,37]. Expanded shielding systems offer high levels of protection that decrease the interventional physician's role in shield management (Figure 4). The use of a larger shield with flexible, protective lamellae attached to the base, in combination with a protective drape, resulted in a nearly 50% reduction in radiation exposure to staff and physicians [66]. Nearly complete operator isolation from radiation scatter has been demonstrated in a series of nonrandomized cases. Multiple shielding components with translucent sections create a complete attenuation barrier between the operator and the patient while access to catheterization equipment is permitted through flexible drapes. In the case series, operator exposure normalized to fluoroscopy time at various sites was barely detectable, and approached background levels [67]. Modifications of room shielding for non-vascular, fluoroscopic guided procedures have also been shown to reduce operator exposure. Non-lead attenuation drapes (n=50) and sham drapes (n=50) were secured to the image intensifier in a randomized fashion during endoscopic retrograde cholangiopancreatography demonstrating relative risk reduction of 90% for the physician and assisting nurse [68]. While standard-shielding systems may not provide equal or optimal protection for all access sites or complex procedures, these contemporary studies suggest that alternative barrier interventions may effectively be applied to provide increased levels of protection without negatively affecting the interventional procedures.

■ Imaging systems

Focus has also been placed on imaging systems and software to reduce the exposure of interventional operators and staff. The availability and use of collimation allows for control of the size of the primary beam and therefore, the amount of scatter radiation. Like shielding, collimation requires operator awareness, has been a focus of radiation safety training courses, and results in exposure reduction within

multiple interventional disciplines [33-

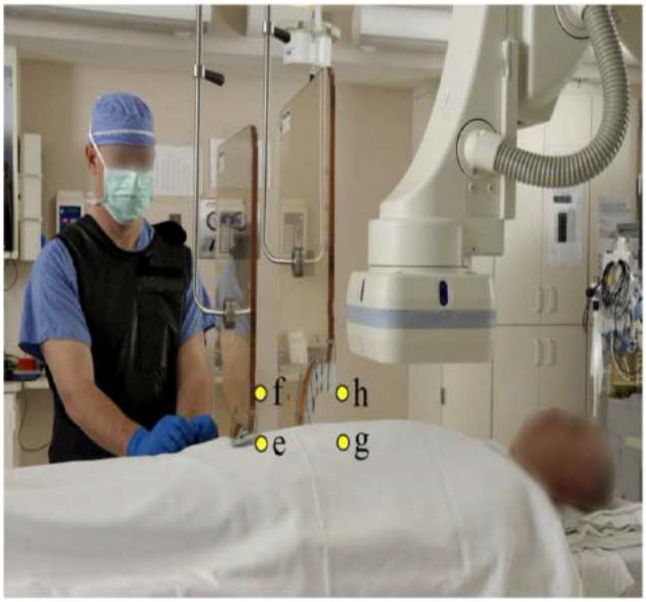

Figure 3. Shield Positioning and Operator Exposure. Point e: the corner of the shield is just cephalad to the access point and flush to the patient. Point f: 5cm anterolaterally from the patient results in three to four times the amount of upper body exposure. Point g: 20cm cephalad from the access point and flush to the patient results in twice the amount of exposure. Point h: both 20cm cephalad from the access point and 5cm anterolaterally from the patient results in four times the amount of exposure [65].

Figure 4. Expanded Shielding System. (a) Large upper body shield with flexible attenuating lamellae, (b) movable lower body shield, (c) vertical extension, (d) disposable radiation absorbing pad to be placed on the patient [65].

35,69,70]. Alternative imaging modalities, such as ultrasound may be used to guide access and other components of interventional procedures. For example, the intermittent use of ultrasound reduces radiation dose during the creation of transjugular intrahepatic portosystemic shunts (TIPS) [71]. The combination of large detector systems and larger display monitors allows for adjusting magnification without a perceived degradation in image quality. With a large detector, the zoom setting may be reduced using less radiation dose to create a larger picture, but the region of interest will appear smaller. Larger, customizable monitors allow for a significant increase in image size, producing an image similar to a higher zoom setting on a standard monitor. Comparable quality on larger display monitors with reduced magnification and radiation dose has been demonstrated across a range of zoom setting and display sizes [72]. Simple technical upgrades on many different modern fluoroscopy machines may be performed that contribute to dose reduction. Many of these changes, such as alteration of the pulsed frame rate, may be activated and deactivated as needed at any point during interventional cases. This has been proven in TAVR and coronary procedures, where controlled comparisons of different frame rates resulted in reductions in radiation dose or operator exposure [73,74]. Current fluoroscopic systems can offer advanced imaging processing algorithms that allow for production of high quality final images from lower quality raw images. Enhanced processing allows for technical changes, including increased thickness of spectral filters, lower detector dose rate, and routine use of a lower fluoroscopic dose rate to be instituted without compromising final image quality or affecting the course of the interventional procedure. During diagnostic and therapeutic coronary procedures, radiation dose was decreased by 68% at 7.5 fps and 44% at 15 fps (Figure 5) [75]. Similar image quality with comparable fluoroscopic time, cine imaging, and contrast use with dose reduction protocol compared to standard protocols has been demonstrated [76]. Comparable improvements in dose reduction have also been demonstrated with dose reduction protocols during transarterial chemoembolization for hepatocellular carcinoma procedures [77], TIPS creation [78], and advanced aortic repair and revascularization interventions [10,79]. There is also potential for meaningful dose reduction after the implantation of iterative reconstruction techniques for CT guided procedures [80]. The development of feasible rotational angiography is another technical upgrade that may result in a decreased radiation dose. Rotation through various left-right and cranial-caudal angles during contrast injection produces a cineangiogram with different planar images for each frame of the imaging run. During coronary angiography, an entire coronary system may be imaged with one injection and cineangiogram. The evaluation of standard and rotational anonymized angiograms by three independent cardiologists resulted in high concordance of observer agreement across multiple levels of diagnostic interpretation [81]. Contrast use and patient radiation dose were nearly 40% and 60% lower, respectively.

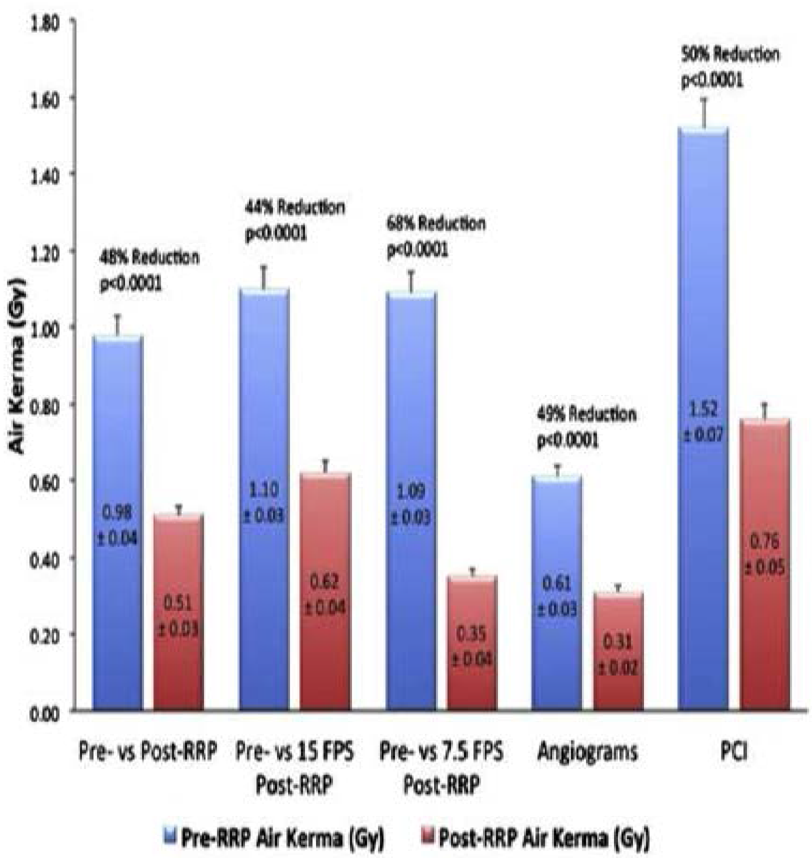

Figure 5. Effect of a Radiation Reduction Protocol on Radiation Dose Before and After Implementation [75]. FPS = frames per second; PCI = Percutaneous Coronary Intervention; RRP = Radiation Reduction Protocol.

■ Robotically assisted interventions

The safety and feasibility of robotically assisted PCI with the CorPath System (Corindus Vascular Robotics, Natick, MA) is described [83]. The bedside unit consists of a disposable cassette placed on a permanent robotic drive that is prepped into the field with a sterile plastic cover. The interventionalist commands the robotic drive by manipulating joysticks and a touch-screen console while sitting in a remote, shielded cockpit (Figure 6). Interventional guidewires may be rotated and advanced with qualitative joystick rotation and toggling or by selecting discrete distances and degrees of torque on the touch-screen. The balloon and stent catheters are manipulated in a similar fashion. In the PRECISE registry technical success without manual conversion was achieved in 162 of the 164 cases, with median operator radiation exposure reduction of 95.2% at the console compared to the traditional table-side operator position. This has been followed by successful reports of complex coronary and percutaneous peripheral arterial interventions given the potential for relatively high operator exposure levels [8,82-85]. Hypothetically, if the bedside operator is 1 meter from the scatter source and exposed to 'X' level of radiation, assuming a standard kVP and 0.5 mm lead apron, exposure to the thorax may be estimated at 0.013'X'. If the robotic operator is 3 meters from the source, the cockpit is exposed to 1/9'X' level of radiation. The transmission through a 2 mm lead shield around an interventional cockpit is estimated at 0.0007 of the afferent radiation level. Therefore exposure is a mere 0.00008'X' to the robotic operator, or 163 fold lower than at the bedside position. By combining shielding and distance, the potential for operator exposure likely approaches ambient levels.

Figure 6: Standard Room Design for Robotically Assisted Cardiovascular Interventions. The two main components of the CorPath System (Corindus Vascular Robotics, Natick, MA) include the bedside disposable cassette and a shielded operator console, consisting of joysticks, a touchscreen, and monitors. The operator console is mobile and may be positioned anywhere in the catheterization laboratory.

Conclusions

Radiation safety and meaningful reduction of operator and patient exposure begins at operator awareness. Knowledge of the fundamentals of radiation allow for application of the ALARA principle. Radiation safety training and periodic updates provide reinforcement of these principles and preservation of meaningful gains. Ensuring optimal operation of imaging machines, including patient and table positioning, collimation, last-image hold, use of technical settings, and keen control of gantry angulation are integral methods in augmenting exposure reduction. Many modern imaging systems are equipped with technical upgrades and software algorithms that produce comparable images with less radiation output. Advances in shielding aprons and caps have resulted in lightweight protection that may provide tolerable cranial protection and have less of a long-term musculoskeletal impact on interventional operators. Exposure monitoring is also vital in adjusting individual practice and determining modifiable individual and system factors. Optimal room shielding and robotic assistance have the potential to allow operator exposure to be nearly negligible for certain procedures. Indeed, meaningful reduction in operator exposure may be accomplished without affecting patient care and may be of benefit by reducing patient exposure. We should continue to move forward in optimizing the interventional environment with a goal of operator exposure at near ambient levels without compromising procedural outcomes.

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