

The Radiation Dose in Interventional Radiology Study: Knowledge Brings Responsibility

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Abbreviations: CD = cumulative dose, FDA = Food and Drug Administration, HOCM = high osmolar contrast material, ICRP = International Commission on Radiological Protection, IVC = inferior vena cava, LOCM = low osmolar contrast material, NCRP = National Council of Radiation Protection and Measurements, PSD = peak skin dose, RAD-IR = Radiation Dose in Interventional Radiology (study), TIPS = transjugular intrahepatic portosystemic shunt

FLUOROSCOPY is a bit like magic. During fluoroscopy, you cannot feel the radiation beam. You cannot smell it or taste it. You cannot see it or hear it. But with the touch of a button, you can use it to guide all manner of amazing medical procedures. The magic and power of fluoroscopy, along with the creativity of pioneering clinicians and inventors, have fueled an explosion of minimally invasive fluoroscopically guided interventional procedures over the last 20 years. Their proliferation over the last 10-12 years has been particularly striking as advancements in tools and techniques have made minimally invasive therapy appropriate for an increasing number of people with prevalent diseases such as atherosclerosis. Millions of people have benefited from these advances in modern medicine.

ANCIENT HISTORY

Like other types of magic, however, fluoroscopy has a bit of a dark side. This dark side was recognized soon after the discovery of x rays. More than one pioneering radiologist died

from malignant complications of radiation-induced dermatitis (1-4). The use of primitive fluoroscopes to remove facial hair in beauty parlors in the 1920s led to thousands of skin injuries (5). Use of serial x-ray examinations to monitor scoliosis from 1935 to 1965 was associated with an increased risk of breast cancer in those exposed (6). Recognition of these and other health risks associated with ionizing radiation led to guidelines and regulations designed to improve the safety of ionizing radiation, including that of medical fluoroscopy.

Several organizations contribute to this continuous process of radiation safety improvements. Among these are the International Electrotechnical Commission, an organization that sets international standards for equipment specifications, and the International Commission on Radiological Protection (ICRP). In the United States the federal government, through the Food and Drug Administration (FDA), regulates the sale of x-ray equipment. The U.S. National Council of Radiation Protection and Measurements (NCRP) was founded in 1929 as the "Advisory Committee on X-ray and Radium Protection." After the uses of ionizing radiation increased in the 1940s-1950s, this nonprofit public service scientific organization was chartered by the U.S. Congress in 1964 and charged with collecting, analyzing, developing, and disseminating information about radiation safety to the public. The reports of the NCRP have been instrumental in the development of U.S. national

standards and practices that have improved the safety of using radiation. One such report, published in 1990, articulates the ALARA principle, the concept that all radiation exposure should be kept to a level "as low as reasonably achievable" (7). Others, most recently the report published in 1993 (8), have set limits on occupational exposure to ionizing radiation.

U.S. federal rules and regulations regarding x-ray equipment have been modified repeatedly over the years to improve safety and image quality. Because of these regulations, fluoroscopy units now include such things as limits on radiation output, x-ray tube shielding, x-ray beam collimators, x-ray beam filters, and timers that buzz at 5-minute intervals during fluoroscopy to remind the operator of elapsed beam-on time. Image intensifiers were introduced in the 1950s and 1960s, contributing to lower fluoroscopy radiation doses. By the 1970s-1980s, fluoroscopy, while still acknowledged as delivering higher doses of radiation than other types of diagnostic x rays, was generally considered a standard and safe modality. The dark side of fluoroscopy was a distant memory.

Throughout the evolution of the above-mentioned radiation safety principles and equipment regulations, no patient radiation dose limits were ever established. The underlying assumption of governmental agencies, the medical community, and the general public has been that (with some exceptions, such as with fetal exposure) the immediate benefit of a med-

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ically indicated procedure involving the use of ionizing radiation outweighs the potential future risk related to that exposure. This assumption is based in no small part on 1) confidence that modern medical practices are effective in diagnosing and treating disease, 2) knowledge that the design and manufacture of medical radiation equipment is heavily regulated, and 3) trust that the users of that equipment are well trained in the safe use of ionizing radiation.

In recent history, the dominant societal and governmental concerns about medical radiation risk have been related to the possibility of cancer and genetic mutation in the exposed population. Radiation safety goals have been to minimize the exposed population and to use the least amount of radiation possible to produce images of diagnostic quality. In 1992 Edward W. Webster delivered the Lauriston S. Taylor Lecture in Radiation Protection and Measurements at NCRP's Annual Meeting. His talk was titled "Dose and Risk in Diagnostic Radiology: How Big? How Little?" (9). Although he spoke of the stochastic risks (cancer and genetic mutation) associated with fluoroscopy, not once in his keynote address did he mention the possibility of a skin burn as a consequence of a fluoroscopic examination. Why was this? I cannot be sure because I was not there, but I would guess that to the general diagnostic radiology world of 1992, the concept that medical radiation exposure might result in acute deterministic skin injury was unthinkable. Those bad old days were long gone.

Meanwhile, in the 1980s and early 1990s two important trends occurred with little fanfare. The first was the increasing use of fluoroscopy to guide complex interventional cardiac and noncardiac vascular procedures. These procedures, especially the cardiac interventions, were exciting and potentially lifesaving. The second was the increasing availability of "High Level Control" fluoroscopy. HLC fluoroscopy mode is designed to boost the radiation output of the x-ray tube to allow visualization of fine anatomic detail. Its use can aid in the diagnosis of disease and the performance of delicate technical tasks. Although U.S. regulations at the time capped standard fluoroscopy radiation output at 5

R/min, there was no regulation capping the output for HLC fluoroscopy. To some degree this was an oversight because the need for a cap was not appreciated. Before the 1980s the majority of fluoroscopy studies were GI examinations and diagnostic angiography with limited need for fluoroscopy. The result was that with increased user demand in the 1980s and early 1990s, fluoroscopy equipment that could put out greater than 50 R/min in HLC mode was built, sold, and used (10).

RECENT PAST

These trends helped to create the perfect storm that resulted in the modern iteration of fluoroscopy's dark side. *Déjà vu* all over again! In the early 1990s, the FDA began to receive reports of patients who had developed severe skin burns at beam entry sites after long fluoroscopy times. After the 14th report the FDA realized that a new public health problem was emerging. In response, they issued a warning in 1994 alerting the U.S. medical community to these incidents (11). This report was followed shortly thereafter by a Public Health Advisory (12). In addition, the FDA worked to lower the cap on HLC fluoroscopy output to 20 R/min, a regulation that has since taken effect. Note that HLC fluoroscopy was not involved in all of the initial injury cases. It is likely, however, that the very existence of increasingly powerful HLC fluoroscopy was a manifestation of a culture in which the demand for high-quality imaging was so strong that the short-term risks of high-dose fluoroscopy had simply been forgotten or ignored.

In the 1994 warning the FDA included a long list of procedures believed to be associated with prolonged fluoroscopy time and, therefore, with increased risk of skin injury. These procedures included coronary angioplasty and stent placement, cardiac radiofrequency ablation, transjugular intrahepatic portosystemic shunt (TIPS), and vessel embolization (11). The report was shocking. After all, so many safeguards were in place. Fluoroscopy had been increasingly effective and safe for years. Few had realized that pushing the envelope of clinical practice and technological possibility

could create injuries identical to those thought of as historical oddities.

Interventional radiologists accepted the reality that TIPS, cardiac radiofrequency ablation, and percutaneous coronary revascularization procedures could result in fluoroscopic exposures high enough to cause skin burns. We agreed with the need to improve patient safety. The FDA's 1994 warning, however, included inferior vena cava (IVC) filter placement, percutaneous nephrostomy, percutaneous transhepatic cholangiography, and biliary drainage among the procedures "typically involving extended fluoroscopic exposure time" (11). Most of us were skeptical that these procedures would likely cause acute skin injury. These procedures were not new and no reports of injury had occurred before 1990. IVC filter placement requires minimal fluoroscopy time; percutaneous transhepatic cholangiography and biliary drainage involve frequent changes in beam geometry, which spreads out skin dose.

Unfortunately, no data existed to support the general belief in the IR world that some procedures are at low risk for skin injury. No study had ever been done on a large population of patients undergoing fluoroscopically guided interventions to measure radiation dose. No way to stratify risk by procedure type had been established. Why? Because measuring radiation dose is quite complex and difficult, and there was no previous demand for the information. When fluoroscopy was used primarily to diagnose disease, radiation doses were low enough that injuries did not occur, and it was safe to assume that the benefits of the procedure outweighed the risks. As fluoroscopy morphed from a diagnostic modality into a guidance system for therapeutic procedures, few considered the potential for radiation-induced injury until after the first injuries occurred.

Subsequent to its 1994 warning, the FDA issued a third Public Health Advisory in 1995 clarifying which patients should have radiation dose information recorded and what information should be recorded (13). Because the accepted threshold radiation dose for temporary skin injury is 2 Gy, the FDA suggested that peak skin doses (PSDs) over 1 Gy should be recorded, although the agency left this decision

to the discretion of each facility (13). It suddenly became vital to know radiation doses for specific interventional procedures to factor this risk into medical decision-making and into protocols for record keeping. When you do not know which procedures are likely to reach the dose threshold for skin injury, you cannot possibly comply with the FDA's recommendation without recording information that allows for estimation of dose for all procedures—a daunting and time-consuming task given the dose-monitoring equipment available on most fluoroscopic equipment.

PRESENT

Recognizing the dearth of information on radiation dose for fluoroscopically guided interventions, the FDA invited professional organizations to develop practical guides for estimating the absorbed dose to the skin (13). The Radiation Dose in Interventional Radiology (RAD-IR) Project was, in part, a result of this invitation. The RAD-IR investigators have taken a snapshot of the radiation doses delivered during a wide range of interventional and neurointerventional procedures in real-life settings. They have used that information to stratify those procedures into low- and high-risk categories and have made recommendations regarding dose recording. The RAD-IR investigative group, led by Donald Miller, MD, must be respected and congratulated for accomplishing this monumental task. This project is providing the interventional radiology community with an enormous amount of dose-related information—so much information that it is hard to absorb and synthesize.

In Part I of the RAD-IR Study (14), the investigators measured overall radiation doses for 35 types of fluoroscopically guided interventions in 2142 patient encounters at seven academic centers. They looked at three dose analogs: fluoroscopy time, dose-area-product, and cumulative dose (CD). Of these, fluoroscopy time is the only dose-related measurement required in the United States, although dose-area-product meters are available on most modern interventional fluoroscopy units because they are required in Europe. Automatic CD meters are new and not yet available

to most interventionalists. Of these three ways to assess radiation dose, CD is the most accurate. The other, more available techniques correlated poorly in the RAD-IR Study with CD in individual patients.

Overall, cumulative radiation doses recorded in the RAD-IR Study were high. The CD was greater than 1 Gy for 1108/2142 (52%) of those in the study. CD was greater than 2 Gy for 30%, greater than 3 Gy for 19%, and greater than 5 Gy for 6% of the study patients (14). Although the FDA does not recommend recording CD, and CD is likely to exceed PSD, this measurement is important. Direct measurement of skin dose is unlikely to be a widely available technology in the near future. The RAD-IR investigators will include ways to calculate/estimate PSD from CD in future reports (14).

The RAD-IR findings regarding CD support the FDA's opinion about the high doses associated with TIPS, embolization, and stent procedures: 74% of TIPS, 64% of visceral/renal arterial stents, 64% of non-neuroembolizations, and 97% of neuroembolizations caused a greater than 1 Gy absorbed dose (14). Of particular concern is the finding that CD to patients undergoing uterine artery embolization for management of fibroids was quite significant: 77/90 (86%) received a CD of greater than 1 Gy, 52% received a CD of greater than 2 Gy, 30% received a CD of greater than 3 Gy, and 9% received a CD of greater than 5 Gy (14). This entire dose is essentially to the pelvis. The implications for stochastic risk (cancer, genetic mutation) were not assessed in the study and are beyond the scope of this commentary but do bear some thought.

Interestingly, the RAD-IR results do support the conventional wisdom that IVC filter procedures are associated with low radiation risk: none of 279 filter procedures exposed patients to greater than 1 Gy of absorbed dose. The study showed mixed results for biliary drainage and nephrostomies: 33% of biliary drainage procedures and 12% of nephrostomies exceeded 1 Gy (14).

Part II of the RAD-IR Study takes the next step and looks directly at skin dose in a subset of the procedures included in Part I. Eight hundred of the 2142 procedures in the study were

Procedures from the RAD-IR Study That Were Never Associated with a PSD greater than 1 Gy

Procedure type	N
Nephrostomy for obstruction	23
Pulmonary angiography (no filter)	13
Pulmonary angiography (with filter)	5
IVC filter only	73
Varicocele embolization	1
Peripheral AVM embolization	3
Total	118

Note.—Total number of procedures for which PSD was recorded was 800. AVM = arteriovenous malformation; IVC = inferior vena cava; PSD = peak skin dose.

done on interventional fluoroscopic units that were equipped with skin dose mapping computer software (15). The skin dose map allows measurement of PSD and localization of that dose to the specific area of the body receiving it (see Figure 1 on p. 980 of this journal). The authors indicate that the dose mapping software is far preferable to other means of capturing skin dose information because it does not intrude into the patient's experience, it provides real-time feedback to the operator, and it does not require the services of a medical physicist for calibration and interpretation (15).

Of the 800 procedures for which PSD was measured, 343 were non-neurointerventional procedures and 457 were neurointerventional cases. PSD among the 343 non-neurointerventional cases was greater than 1 Gy in 36%, greater than 2 Gy in 16%, greater than 3 Gy in 7%, and greater than 5 Gy in two individuals (0.5%) (15). PSD among the 457 neurointerventional procedures was greater than 1 Gy in 71%, greater than 2 Gy in 34%, greater than 3 Gy in 15%, and greater than 5 Gy in 3% (15).

Only six of the 33 types of procedures studied *never* resulted in a PSD of greater than 1 Gy (Table) (15). Of the procedure types in this lower-dose group, only IVC filter placement, pulmonary angiography, and nephrostomy for obstruction occurred with enough frequency to suggest that they might reliably be considered low-dose procedures with regard to skin injury.

The other three procedure types with total PSD less than 1 Gy occurred with extremely limited frequency (five instances or fewer). It is possible that a wider range of doses would be seen for these procedure types if data were available for more patients.

The procedure types associated with the highest CD were also associated with high PSDs indicating that they involve prolonged exposure of a single x-ray beam entry site. 74% of TIPS, 86% of visceral arterial stents, 56% of non-neuroembolizations, and 81% of neuroembolizations caused greater than 1 Gy PSD (15). In 14 patients undergoing uterine artery embolization for management of fibroids, PSD was greater than 1 Gy in 12 patients (86%), greater than 2 Gy in 7 patients (50%), and greater than 3 Gy in 1 patient (7%) (15). This correlation indicates that CD data (easier to acquire than PSD data) is predictive of PSD and could be used as a substitute metric for PSD.

As mentioned before, the accepted threshold dose for temporary skin injury is 2 Gy; the accepted threshold for permanent skin injury is 6 Gy. There is disagreement regarding the validity of these thresholds. Some investigators contend that actual thresholds for skin injury are significantly higher (16), whereas others believe that the threshold can be lower in some patients, including those with collagen vascular disease or diabetes (17). Governmental agencies provide inconsistent guidance on what threshold to use in deciding which patients need to have dose recording. The ICRP recommends recording dose data in the medical record for patients whose skin dose is greater than 1 Gy for procedures likely to be repeated or 3 Gy for procedures unlikely to be repeated (18). The FDA recommends recording dose data for procedures likely to result in a skin dose of greater than 1 Gy, but they leave the recording threshold to the discretion of the facility (13). The RAD-IR Study recommends recording dose data for TIPS, angioplasty in the abdomen or pelvis, and all embolizations (14,15). Of the 800 procedures studied, 546 of them were in these three procedure categories. Of the other 254 procedures, 19% resulted in PSD greater than 1 Gy. Because the frequency of each type of procedure in this lower dose group was lower than

the frequencies for individual procedure types in the higher dose groups, one could argue that there is insufficient data to recommend *not* recording skin dose for these procedures.

My conclusion is that the RAD-IR Study's recommendations about recording dose are logical and will capture most patients at high risk for injury. These recommendations, however, will not identify all patients at risk for radiation skin injury; after all, unexpected things happen. I suspect that the dose-recording stratification recommended by the ICRP, the FDA, and the RAD-IR investigators stems from an acknowledgment that accurate recording of dose information is currently technically impossible in the real world in the vast majority of IR suites. In the real world, compromises must be made between the ideal and the practical.

FUTURE

An alternative conclusion from the RAD-IR Study could be that valuable but complex and lengthy fluoroscopic interventions engender a high enough skin dose in a large enough proportion of patients that dose measurement should be undertaken for all interventional fluoroscopy procedures. This is the only way that the next iteration of fluoroscopy's dark side will be identified early. We will not notice the next radiation dose-related problem if we are looking backward into the past rather than forward into an uncertain future. This more conservative conclusion is the one that would undoubtedly be reached by the general public of our risk-averse society, as well as by the reporters of CBS television's *60 Minutes* news magazine show, if they absorbed the data presented in Parts I and II of the RAD-IR Study.

So a conundrum exists—a disconnect between what *should* be done to optimize patient safety and what *can* be done with existing resources. This conundrum is reminiscent of that which occurred after the introduction of low osmolar contrast material (LOCM). Many articles were written in the radiological literature about who was at high risk from standard high osmolar contrast material (HOCM) and who should receive the newer contrast agents. Stratification schemes for appropriate use of LOCM

were developed and adopted by hospital quality assurance committees. Everyone who had ever injected contrast material into a person's bloodstream knew that patients better tolerated the newer agents. The discussion existed because of the relative costs of HOCM versus LOCM. After the cost of LOCM came down, all of those papers disappeared and LOCM became the standard for intravascular injection.

When accurate recording of relevant dose measurements becomes practical, this conundrum will go away. The RAD-IR Study really provides the first important step in making dose recording a realistic goal. I look forward to the next publications from the RAD-IR Study, which promise to provide formulas to estimate overall radiation dose as well as skin dose from other (presumably more widely available) dose metrics. The ability to do such retrospective calculations will greatly improve the ability to track the outcomes of radiation management efforts.

Of course, retrospective tracking of dose measurements does not prevent high radiation doses. Asking interventionalists to record radiation dose after an interventional procedure is sort of like asking drivers to manage highway safety by calculating driving speed at the end of a car trip as a function of distance and time. The retrospective calculation could track speed but it probably would not prevent highway accidents. Cars have speedometers that track this information in real time. Interventionalists need similar real-time feedback to modify technique during procedures. Currently we are responsible for a bad outcome but have very few tools at our hands to help us manage that responsibility. Systematic modifications in work practices have been recommended (19), but their application is difficult to maintain and their benefit is hard to assess without feedback. The emergence of the RAD-IR Study's dose data increases our level of awareness and our level of responsibility but does not help much to prospectively prevent the occurrence of injury.

Fortunately there is a light at the end of this troublesome tunnel. The International Electrotechnical Commission has set standards for the next generation of interventional fluoros-

copy equipment that mandate the inclusion of real-time dose monitoring devices (20). The FDA has proposed regulations that will require all fluoroscopy equipment sold in the United States to be fitted with displays, visible to the physician in the procedure room, that monitor fluoroscopy time, CD, and active dose rate in real time (21). It is likely that these regulations will be adopted in 2004; they will go into effect one year after adoption. As the new real-time dose monitoring technology is disseminated throughout the workplace, interventionalists will have the power to factor radiation dose into clinical decision-making and not just the responsibility for the ill effects of high radiation dose after the fact. These devices will make the ideal situation—improved radiation safety for all patients undergoing interventional fluoroscopy—a practical reality.

A final thought raised by the RAD-IR Study relates to training. These data make it clear that uniform standards of training in fluoroscopic radiation management should be required for all practitioners of fluoroscopically guided interventions.

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