OVERVIEW OF CONTEMPORARY INTERVENTIONAL FLUOROSCOPY PROCEDURES

Donald L. Miller*

Abstract—Interventional fluoroscopy procedures are increasingly important in medical practice. As new procedures are introduced and validated, they tend to replace the equivalent surgical procedure. There is wide variation in patient dose, both among procedures and for a specific procedure. Stochastic risk is present, but interventional fluoroscopy procedures may also present deterministic risk. Radiation risk/benefit analyses are different for interventional fluoroscopy procedures than they are for diagnostic imaging procedures. The radiation risk component of an interventional fluoroscopy procedure is substantially less than the other procedural risks, and there is always clear and measurable benefit to the patient from a successful procedure. Optimizing patient dose will require both improvements in equipment technology and greater attention from regulators, accrediting bodies and medical organizations. Ensuring adequate operator training is essential.

Health Phys. 95(5):638-644; 2008

Key words: National Council on Radiation Protection; medical imaging; fluoroscopy; radiation risk

INTRODUCTION

Interventional fluoroscopy procedures use ionizing radiation for guidance as small instruments such as catheters, guidewires, balloons, and stents are manipulated through blood vessels or other pathways in the body. These procedures are used to treat a wide variety of diseases and disorders in virtually every organ system in the body.

As compared to open surgical procedures, interventional fluoroscopy procedures require a very small incision and permit shorter recovery times. They often have lower complication rates as well. As a result, these less invasive procedures have become very common, and are replacing open surgical procedures.

(Manuscript accepted 1 July 2008)

0017-9078/08/0

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Compare, for example, open surgical coronary artery bypass grafting (CABG) and interventional fluoroscopic percutaneous transluminal coronary angioplasty with stent placement (PCI), procedures used to treat coronary artery narrowing and occlusion. When multivessel PCI is compared to multi-vessel CABG, PCI demonstrates shorter hospital length of stay (2.9 d vs. 8.5 d) and no difference in the rates of stroke, death, or myocardial infarction at 1 y (Serruys et al. 2001). In patients with disease in the left main coronary artery, the 30 d major adverse cardiac and cerebrovascular event rate for PCI is 2%, vs. 17% for CABG (Lee et al. 2006). In comparison, the probability of radiation-related skin injury from a PCI is estimated at <0.03\%, or 1/67 the risk of a major adverse cardiac or cerebrovascular event (Padovani et al. 2005).

The number of CABG procedures performed annually in the United States increased between 1990 and 1997, but stabilized after 1998 (CDC/NCHS 2004). From 1996 to 2000 the rate of PCI procedures for the entire U.S. population more than doubled, from 66 to 163 per 100,000 persons. In 2002, approximately 450,000 hospital stays in the United States included a PCI procedure (CDC/NCHS 2004). The less invasive interventional fluoroscopy procedure is rapidly replacing the more invasive open surgical procedure in patients for whom it is an option.

More complex interventional fluoroscopy procedures are continually being introduced. This is due to the development of new devices and procedures, such as endografts for the treatment of abdominal aortic aneurysms, distal protection devices for carotid artery stent placement, the development of vertebroplasty, kyphoplasty, and uterine fibroid embolization, and increasing use of fluoroscopic guidance during complex endoscopic biliary and upper urinary tract procedures.

These procedures also present clear advantages over the corresponding open surgical procedures, even when they are less likely to be successful. For example, uterine fibroid embolization has a lower clinical success rate for symptom relief (80-95%) than the surgical equivalent,

^{*} Department of Radiology and Radiological Sciences, Uniformed Services University, 4301 Jones Bridge Road, Bethesda, MD 20814.

For correspondence contact: D. L. Miller, Department of Radiology, National Naval Medical Center, 8901 Wisconsin Avenue, Bethesda, MD 20889-5600, or email at donald.miller@med.navy.mil.

hysterectomy (100%), but it also demonstrates a lower incidence of major complications (3.9% vs. 12.0%) (Spies et al. 2004). The length of hospital stay (mean 0.83 d vs. 2.3 d) and the length of time lost from work (mean 10.7 d vs. 32.5 d) are both significantly shorter for uterine fibroid embolization than for hysterectomy (Spies et al. 2004; Pron et al. 2003). These advantages compensate for the lower clinical success rate. They also far outweigh any radiation-related risk of the interventional fluoroscopy procedure.

PATIENT DOSE

There is now a substantial amount of information available on radiation doses to patients from interventional fluoroscopy procedures. Data on radiation doses for interventional cardiac procedures have been gathered from procedures performed by cardiologists (Stisova 2004; Leung and Martin 1996; den Boer et al. 2001; McFadden et al. 2002; Park et al. 1996; Rosenthal et al. 1998). The majority of the published data on patient radiation doses for other interventional fluoroscopy procedures have been gathered from procedures performed by radiologists (Miller et al. 2003a and b; Tsalafoutas et al. 2006). This literature is characterized by a fairly large number of studies comprising relatively small series of patients, because many of these procedures are performed relatively infrequently, even at major medical centers (Ruiz-Cruces et al. 1997; McParland 1998; Andrews and Brown 2000; Ruiz Cruces et al. 1998; Zweers et al. 1998; Marshall et al. 1995; Nikolic et al. 2000; Williams 1997; Bergeron et al. 1994; Gkanatsios et al. 2002; Theodorakou and Horrocks 2003; Livingstone and Mammen 2005). Relatively little data exist for the same kinds of procedures performed by surgeons, gastroenterologists, urologists, etc. (Lipsitz et al. 2000; Perisinakis et al. 2004; Buls et al. 2002).

Patient dose depends on numerous factors, including operator experience, patient body habitus, the availability of dose-reducing technology in the fluoroscopic equipment, the maintenance of the fluoroscopic equipment, the type of procedure, the location of the lesion, the complexity of the procedure and the indication for the procedure (Miller et al. 2003b). The effect of procedure complexity on dose is well established (Vehmas 1997; Peterzol et al. 2005). Increased complexity results in increased patient dose in a predictable and quantifiable way. As the complexity of these procedures has increased, radiation doses to patients and health care personnel have also increased.

Determination of procedure dose from the published literature is difficult for several reasons. First, dose distribution among cases of a single type of procedure is

not Gaussian—the distribution curve is skewed toward lower doses and approximates a lognormal curve. This is evident for virtually all studied procedures, and the shape of the curve seems remarkably constant, regardless of the type of procedure or the dose metric used (Miller et al. 2003a and b; Storm et al. 2006). Neither the mean nor the median is an ideal descriptor. All of these dose metrics vary widely across procedure types as well as for a specific type of procedure (Tsalafoutas et al. 2006). Second, many reports lump together related diagnostic and interventional procedures with very different patient doses. Third, patient dose depends on numerous factors, as noted above. A consequence of the wide variability in dose among patients undergoing the same interventional fluoroscopic procedure is that doses to populations can be estimated, but reasonable determinations of effective dose and skin dose for an individual patient undergoing a specific procedure require some dose metric indicating the patient's actual dose.

Patient dose from interventional fluoroscopy procedures is typically reported as either kerma area product (P_{KA}) or effective dose or, more recently, as cumulative dose as defined in International Electrotechnical Commission Standard 60601-2-43 (IEC 2000). Effective dose is typically estimated from P_{KA} measurements (Ruiz Cruces et al. 1998). This calculation requires estimates of field size. For cardiac interventions, where collimation is less commonly used and field size approximates the size of the image receptor, estimates of field size may be appropriate. In this setting, PKA measurements can yield reasonable estimates of effective dose and may provide a reasonable estimate of peak skin dose (Theocharopoulos et al. 2002; Chida et al. 2006). However, the relationship between P_{KA} and peak skin dose is dependent on procedure type, technical protocols (imaging sequences), equipment set-up, and operator technique, and cannot be easily translated from one medical center to another (Padovani et al. 2005; Trianni et al. 2005). For other interventional fluoroscopy procedures, where collimation is more commonly used (particularly when performed by radiologists), assumptions about field size are less reliable, and the other caveats mentioned above still apply. Absorbed skin dose is calculated or, less frequently, measured directly.

CARDIAC PROCEDURES

There are wide variations in dose for cardiac interventions. The highest dose procedures are PCI and radiofrequency (RF) cardiac ablation (an electrophysiology procedure performed for treatment of cardiac dysrhythmias). In a recent review of the literature, Padovani and Quai found that $P_{\rm KA}$ values ranged from 14–116

Gy cm $^{-2}$ for PCI in several series comprising 1,208 patients and from 95–257 Gy cm $^{-2}$ for RF ablation procedures in several series comprising more than 960 patients (Padovani and Quai 2005). Chida and colleagues demonstrated a mean P_{KA} of 149 Gy cm $^{-2}$ for PCI (172 patients) and 110 Gy cm $^{-2}$ for RF ablation (28 patients) (Chida et al. 2006). Note that the mean P_{KA} in Chida and colleagues' series is outside the range in Padovani and Quai's series.

In the review by Padovani and Quai cited above, a peak skin dose of 1.8 Gy was reported for PCI and mean skin dose values of 1.5–1.8 Gy were reported for RF ablation (Padovani and Quai 2005). Trianni and colleagues demonstrated a peak skin dose of 3.4 Gy for PCI and lower peak skin doses for RF ablation (Trianni et al. 2005). For extremely complex PCI procedures in patients with chronic occlusions of the coronary arteries, Suzuki and colleagues observed a median peak skin dose of 4.6 Gy; one patient received a peak skin dose of 9.7 Gy (Suzuki et al. 2006).

In a study of 322 patients undergoing either diagnostic coronary arteriography (134 patients) or PCI (188 patients), den Boer and colleagues observed that 13% (42/322) received a peak skin dose >2 Gy, and 1% (4/322) received a dose >4 Gy (den Boer et al. 2001). Rosenthal and colleagues observed a peak skin dose >2Gy in 22% of 859 RF cardiac ablation procedures; the mean estimated entrance skin dose was 1.3 Gy (Rosenthal et al. 1998). Six of the 624 adult patients (1%) in this series received a peak skin dose >7 Gy. In a series of 500 patients undergoing RF cardiac ablation, Park and colleagues found that 28 patients (5.6%) received a peak skin dose >2 Gy (Park et al. 1996). In McFadden and colleagues' series of 50 patients undergoing RF cardiac ablation, 6 (12%) received a peak skin dose >2 Gy (McFadden et al. 2002). It is apparent that cardiac procedures often result in peak skin doses >2 Gy and have the potential to yield skin doses high enough to cause deterministic effects.

OTHER INTERVENTIONAL FLUOROSCOPY PROCEDURES

Published data have been extensively tabulated and summarized in recent publications (Miller et al. 2003a and b; Tsalafoutas et al. 2006). The wide variety of interventional fluoroscopy procedures makes it difficult to provide generalized dose data. In one publication, 21 separate procedures were studied, as well as subtypes of these procedures, categorized by lesion etiology and location, for a total of 35 procedure categories; this was not considered a comprehensive list (Miller et al. 2003a).

These subtypes sometimes demonstrated substantial differences in dose. For example, mean P_{KA} for nephrostomy was 26 Gy cm⁻² when performed for relief of urinary obstruction, but 45 Gy cm⁻² when performed for treatment of stone disease (Miller et al. 2003a). Even for a single type of procedure at a single medical center there can be an extraordinarily large dose range—the ratio of maximum to minimum dose (P_{KA} or cumulative dose) often exceeds 100, and may exceed 1,000 (Tsalafoutas et al. 2006). This variability is due primarily to patient body habitus and lesion characteristics (procedure complexity).

Some interventional fluoroscopy procedures, such as venous access procedures, are essentially always "low dose" (Storm et al. 2006). Others, particularly neuroembolization procedures, are generally "high dose," as defined in ICRP Publication 85 (ICRP 2000). Some procedures yield patient doses high enough to be of concern only in rare outlier cases, and some procedures usually result in patient doses high enough to be of concern. Transjugular intrahepatic portosystemic shunt (TIPS) creation, all embolization procedures, and angioplasty of arteries in the abdomen and pelvis fit within the latter group (Miller et al. 2003a).

Two specific examples illustrate the opposite ends of the dose spectrum. Cerebral embolization, an interventional fluoroscopy procedure, is typically performed for the treatment of life-threatening diseases—intracranial aneurysms, arteriovenous malformations, or tumors. Without question, this is a high dose procedure. In a series of 356 patients, the mean P_{KA} was 320 Gy cm⁻² and the mean cumulative dose was 3.8 Gy (Miller et al. 2003b). The stochastic risk from this procedure has been estimated, and in pediatric patients it is not negligible (Thierry-Chef et al. 2006). The lifetime relative risk of developing brain cancer was estimated at 1.02–1.10 for a pediatric patient who received a relatively low dose and 1.10-1.80 for a pediatric patient who received a relatively high dose from the procedure. In terms of stochastic risk, this is a high dose procedure.

Cerebral embolization may also produce high skin doses; in a series of 356 patients undergoing this procedure, the mean peak skin dose was 2 Gy, 17% of patients had a peak skin dose over 3 Gy, and 4% of patients had a peak skin dose over 5 Gy. The highest peak skin dose observed was 6.7 Gy (Miller et al. 2003b). In terms of deterministic risk, this is a high dose procedure.

On the other hand, a different interventional fluoroscopy procedure, placement of a chest port for venous access, does not present an important radiation risk; in Storm and colleagues' series of 303 chest port placements, median P_{KA} was 3.7 Gy cm⁻² (Storm et al. 2006). In the same series, median peak skin dose was 0.02 Gy,

and the highest peak skin dose observed was 0.76 Gy. Further, most patients who undergo this procedure have a limited life expectancy because they are being treated for cancer. In terms of both stochastic risk and deterministic risk, this is a low dose procedure.

RADIATION INJURIES

It is evident that many interventional fluoroscopy procedures have the potential to produce high patient radiation doses, and that some are typically high dose procedures. Skin doses >5 Gy may occur.

However, most patients who undergo interventional fluoroscopy procedures are either elderly, or have some underlying medical problem which can be expected to sharply reduce their life expectancy without treatment (atherosclerosis, diabetes, cancer, liver or kidney failure, etc.) or both. Even with treatment, these patients may have a limited life expectancy. While stochastic effects *may* occur at some time in the distant future, for an individual patient who has received a sufficiently high absorbed skin dose, deterministic effects are *certain* to occur in the near future. As a result, deterministic effects, principally skin injury, are usually of greater concern than stochastic effects.

Fortunately, serious injuries are uncommon. The majority of reported radiation-induced skin injuries have been associated with coronary artery angioplasty and stent placement, cardiac radiofrequency ablation procedures, embolization procedures or transjugular intrahepatic portosystemic shunt (TIPS) creation (Shope 1996; Koenig et al. 2001).

Most of the published data on patient radiation dose, particularly for non-cardiac procedures, are for individual procedures. In clinical practice, patients may undergo multiple procedures in a relatively short period of time. The dose from these procedures is cumulative to some degree, depending on the time interval between them. Dose from diagnostic procedures must also be included, particularly from computed tomography (CT). Radiation-induced temporary hair loss has been reported in patients undergoing diagnostic angiography of the brain and CT cerebral perfusion studies with multi-detector row CT scanners (Imanishi et al. 2005). No interventional fluoroscopy procedure had been performed on any of these patients. The deterministic effect, hair loss, was due to radiation from diagnostic procedures alone.

RISK/BENEFIT ANALYSIS

The risk/benefit analysis for interventional fluoroscopy procedures differs from the analysis for diagnostic radiology procedures, and both differ from the risk/benefit analysis for occupational exposure. There is economic benefit to the recipient of occupational exposure, but no medical benefit. There is medical benefit to patients undergoing diagnostic radiology or interventional fluoroscopy procedures. There is minimal procedure-related risk for patients undergoing diagnostic radiology procedures. There may be significant procedure-related risk for patients undergoing interventional fluoroscopy procedures.

Attempts have been made to use risk bands to categorize the radiation risk of diagnostic medical procedures because "it is very difficult to quantify the benefits of diagnostic x-ray examinations in any way that is comparable with the radiation risks, so an accurate quantitative weighing of benefits against risks is usually impossible" (Wall et al. 2006). In general, this is not true for interventional fluoroscopy procedures, since they are performed for treatment of a disease state, rather than for diagnosis.

Unlike diagnostic radiology procedures, all successful interventional fluoroscopy procedures provide a clear and obvious benefit for the patient. They would not be performed otherwise since (also unlike diagnostic radiology procedures) they subject the patient to numerous additional and often substantial procedure-related risks. The risk of radiation-related injury is typically far less than that of other procedure-related complications, so the risk/benefit analysis for radiation-related risks is relatively straightforward. The patient is far more likely to be injured by catheter manipulation than by the radiation beam.

Because of the inherent procedural risk of interventional fluoroscopy procedures, formal risk/benefit analyses have been performed for many of them, and an informal risk/benefit analysis is performed for each patient as part of the decision to perform the procedure. In addition, an ongoing risk/benefit analysis is part of the procedure. These assessments include consideration of a wide variety of risks: the medical risks of the proposed procedure, the medical risks inherent in not performing the procedure and the medical risks of substituting a different procedure that does not employ ionizing radiation. Indications and contraindications for the procedure are developed through literature review and consensus (Hovsepian et al. 2004). The current controversy over the appropriateness and indications for carotid artery stent placement is a good example of the kind of risk assessment that these procedures receive (Goodney et al. 2006). Uterine artery embolization is another good example (Spies et al. 2002, 2004; Pron et al. 2003).

RADIATION SAFETY

An important goal of all interventional fluoroscopy is to achieve technical and clinical success while optimizing radiation dose to the patient. "Optimizing" means using the least amount of radiation consistent with providing adequate imaging guidance. Optimizing patient dose is not the same as minimizing patient dose. Most interventional fluoroscopy procedures require high quality images, long fluoroscopy time, or both. It is critically important to train operators how to achieve the maximum possible dose reduction consistent with acceptable image quality. Simple techniques exist which can accomplish this. These include the use of reduced-dose pulsed fluoroscopy, collimation, and attention to the numerous technical factors which affect dose (Wagner et al. 2000; Miller et al. 2002). These techniques require modern fluoroscopy equipment with dose reduction technology and a trained, motivated operator.

It is desirable to reduce patient skin dose, when possible, in order to limit or avoid deterministic effects. Technology plays a critical role here. For maximum effectiveness, the operator requires a real-time map of patient skin dose (Miller et al. 2002). As of 2008, this technology is not commercially available. When it does become widely available, it will permit a well-trained operator to manage skin dose far more effectively than is currently possible.

Many laymen assume that these procedures are performed exclusively by radiologists, since fluoroscopy involves ionizing radiation. This is not correct. Many interventional fluoroscopy procedures were developed by radiologists, but these procedures are now performed by a rapidly expanding number of health care providers in a wide range of medical specialties. Since modern medicine is organized along specialty lines, with medical specialties defined in large measure by organ system, these procedures are performed by physicians in a very wide range of specialties. These operators include cardiologists, nephrologists, anesthesiologists, gastroenterologists, and surgeons of almost every kind, including neurosurgeons, vascular surgeons, urologists, and orthopedic surgeons. For some organ systems, there is considerable specialty overlap. For example, in the United States renal artery angioplasty is performed by interventional radiologists, interventional cardiologists and vascular surgeons.

Training in radiation physics, biology, and safety has long been incorporated into radiology residency programs. The cardiology and pain management communities have recently recognized the need for training in radiation physics and radiation safety. Unfortunately, most other operators have little formal training in radiation science or protection measures. These physicians often rely on medical physicists and radiologic technologists for radiation safety expertise, to the extent that they are concerned about it at all.

At present there are few external forces that might motivate or compel operators to become trained. Training requirements may be mandated by professional societies, certification bodies ("board certification"), accreditation organizations (e.g., the Joint Commission) or governmental regulation. In some other countries, training requirements are mandated by law on a national basis (Vano et al. 2003). In the United States, only the individual States have the authority to require an operator to have specific training or a defined knowledge base prior to operation of fluoroscopy equipment. To date, only a handful of States have mandated specific training or licensing for physicians who wish to perform fluoroscopy.

Physicians, technologists, medical physicists, fluoroscopy equipment manufacturers and medical and governmental organizations share the responsibility to optimize radiation doses to patients undergoing interventional fluoroscopy.

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