Interventional Fluoroscopy

Reducing Radiation Risks for Patients and Staff

CONTENTS

NIH Publication No. 05-####
March 2005

Introduction

Interventional fluoroscopy uses ionizing radiation to guide small instruments such as catheters through blood vessels or other pathways in the body. Interventional fluoroscopy represents a tremendous advantage over invasive surgical procedures, because it requires only a very small incision, substantially reduces the risk of infection and allows for shorter recovery time compared to surgical procedures. These interventions are used by a rapidly expanding number of health care providers in a wide range of medical specialties. However, many of these specialists have little training in radiation science or protection measures.

The growing use and increasing complexity of these procedures have been accompanied by public health concerns resulting from the increasing radiation exposure to both patients and health care personnel. The rise in reported serious skin injuries and the expected increase in late effects such as lens injuries and cataracts, and possibly cancer, make clear the need for information on radiation risks and on strategies to control radiation exposures to patients and health care providers. This guide discusses the value of these interventions, the associated radiation risk and the importance of optimizing radiation dose.

Increasing use and complexity of interventional fluoroscopy

In 2002, an estimated 657,000 percutaneous transluminal coronary angioplasty (PTCA) procedures were performed in adults in the United States. In addition, the rate of coronary artery stent insertion doubled from 157 to 318 per 100,000 adults, aged 45-64, from 1996 to 2000 (CDC 2004). At the same time, the complexity of interventional fluoroscopy has been increasing rapidly. This is due to the development of new devices and procedures, such as endografts for the treatment of abdominal aortic aneurysms, the development of vertebroplasty, kyphoplasty and uterine artery embolization, and increasing use of fluoroscopic guidance during complex endoscopic biliary and upper urinary tract procedures. As the complexity of these procedures has increased, the dose to patients and health care personnel has increased as well.

Determinants of radiation dose from interventional fluoroscopy

The radiation beam in interventional fluoroscopy procedures is typically directed at a relatively small patch of skin for a substantial length of time. This area of skin receives the highest radiation dose of any portion of the patient's body. The dose to this skin area may be high enough to cause a sunburn-like injury, hair loss, or in rare cases, skin necrosis (Mettler 2002). Threshold doses for potential radiation effects with related time of onset are presented below (ICRP 2000). The highest doses have been reported most frequently as a result of PTCA, radiofrequency cardiac ablation procedures, transjugular intrahepatic portosystemic shunts (TIPS) procedures and embolization procedures in the brain (Koenig 2001).

Appearance of radiation-induced skin injury approximately 18 to 21 months following multiple coronary angiography and angioplasty procedures – evidence of progressive tissue necrosis (Source: www.fda.gov/cdrh/rsnaii)

Potential clinical effects of radiation exposures to the skin and eye lens

Effects	Threshold dose (Gy)	Time of onset
SKIN		
Early transient erythema	2	2-24 hours
Main erythema reaction	6	~1.5 weeks
Temporary epilation	3	~3 weeks
Permanent epilation	7	~3 weeks
Dermal necrosis	>12	>52 weeks
EYE		
Lens opacity (detectable)	>1-2	>5 years
Lens/cataract (debilitating)	>5	>5 years

Source: ICRP, 2000

During a procedure, several major parameters influence dose:

- Number of images taken
- Fluoroscopy time, field size and overlap of fields (Miller 2002)
- Tube filtration, generator voltage and current
- Reduced-dose pulsed fluoroscopy versus continuous fluoroscopy (Wagner 2000)
- Distance between the X-ray tube and the patient and between the patient and the image receptor
- Patient body habitus

Radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality and imaging guidance. Optimizing patient radiation dose also provides a direct benefit to the operator and assistants: scattered radiation in the room is directly proportional to the patient dose. If patient dose is reduced, so is the dose to the operator.

Radiation risks from interventional fluoroscopy

The benefits of properly performed interventional fluoroscopy almost always outweigh the radiation risk experienced by an individual. However, unnecessary exposure to radiation can produce avoidable risk to both the patient and operator.

Risk to patients

The short-term risk to patients is radiation-induced skin damage, which can result from acute radiation doses of ≥ 2 Gy. The extent of the skin injury may not be known for weeks after the procedure. Repeated procedures increase the risk of skin injury, because previous radiation exposure sensitizes the skin. Long term effects include the potential risk of cancer. It is generally accepted that there is probably no low dose "threshold" for inducing cancers, i.e. no amount of radiation should be considered absolutely safe. Recent data from the atomic bomb survivors (Pierce 2000) and medically irradiated populations (UNSCEAR 2000) demonstrate small, but significant increases in cancer risk even at the level of doses that are relevant to interventional fluoroscopy procedures. The increased risk of cancer depends upon the age and sex of the patient at exposure. Children are considerably more sensitive to radiation than adults, as consistently shown in epidemiologic studies of irradiated populations.

Risk to health care providers

Health care providers are also at risk of radiation damage from chronic exposure to radiation from these

Strategies to Manage Radiation Dose to Patients and Operators

IMMEDIATE	LONG-TERM
OPTIMIZE DOSE TO PATIENT	
Use proper radiologic technique: • Maximize distance between x-ray tube and patient • Minimize distance between patient and image receptor • Limit use of electronic magnification **Control fluoroscopy time:** • Limit use to necessary evaluation of moving structures • Employ last-image-hold to review findings **Control images:** • Limit acquisition to essential diagnostic and documentation purposes **Reduce dose:** • Reduce field size (collimate) and minimize field overlap • Use pulsed fluoroscopy and low frame rate	**Include medical physicist in decisions** • Machine selection and maintenance **Incorporate dose-reduction technologies and dose-measurement devices in equipment** **Establish a facility quality improvement program that includes an appropriate x-ray equipment quality assurance program, overseen by a medical physicist, which includes equipment evaluation/inspection at appropriate intervals.**
MINIMIZE DOSE TO OPERATORS AND STAFF	
Keep hands out of the beam **Use movable shields** **Maintain awareness of body position relative to the x-ray beam:** • Horizontal x-ray beam – operator and staff should stand on the side of the image receptor. • Vertical x-ray beam – the image receptor should be above the table **Wear adequate protection** • Protective well-fitted lead apron • Leaded glasses	**Improve ergonomics of operators and staff:** • Train operators and staff in ergonomically good positioning when using fluoroscopy equipment; periodically assess their practice • Identify and provide the ergonomically best personal protective gear for operators and staff • Urge manufacturers to develop ergonomically improved personal protective gear • Recommend research to improve ergonomics for personal protective gear

procedures. There are an increasing number of case reports of skin changes on the hands and injuries to the lens of the eye in operators and assistants (Faulkner 2001). Although cancer is uncommon, cancers associated with radiation exposure in adults may include leukemia and breast cancer (Yoshinaga 2004).

Strategies to optimize radiation exposure from interventional fluoroscopy

An important goal of all interventional fluoroscopy is to achieve clinical success using the least amount of radiation consistent with adequate imaging guidance. However, most interventional procedures require high quality images, long fluoroscopy time or both. Using appropriate operating parameters for x-ray machines will lower radiation doses to patients, and therefore to operators and assistants as well. It is critically important to adequately train operators and their assistants to use equipment that provides acceptable image quality along with the maximum possible dose-reduction, and to have equipment regularly inspected and maintained. Physicians, technologists, medical physicists, fluoroscopy equipment manufacturers and medical and governmental organizations share the responsibility to optimize radiation doses to patients undergoing interventional fluoroscopy.

Physician-patient communication before and after interventional fluoroscopy

Operators should always ask the patient about any previous history of interventional fluoroscopy before undertaking another procedure. It is important to communicate the details of the procedure, patient dose, and immediate and potential long-term health effects to patients and their primary care providers.

Before Procedure - Patients should be counseled on radiation-related risks, as appropriate, along with the other risks and benefits associated with the procedure. If patients are likely to have multiple interventional fluoroscopy procedures in a short period of time, they should be informed if there is a possibility that significant radiation exposures may accompany these procedures and may cause potential short-term and long-term radiation-related health effects.

After Procedure - After a procedure, the measured or estimated radiation dose should be reviewed (Miller 2004), and appropriate steps should be taken to insure adequate patient follow-up:

- Schedule a follow-up visit 30 days after the procedure for all patients who received a radiation skin dose of 2 Gy or more or a cumulative dose of 3 Gy or more.
- Send the interventional fluoroscopy procedure description, operative notes, doses and information about possible short-term and long-term effects to the patient's primary care provider.
- The patient and primary care physician should be specifically requested to notify the operator if observable skin effects occur.

DOSIMETRY RECORDS AND FOLLOW UP	
Measure & record patient radiation dose: • Record fluoroscopy time • Record available measures – DAP (dose area product), cumulative dose, skin dose **Inform patients who have received high doses to examine the x-ray beam entrance site for skin erythema**	**Develop methods to quantify late effects:** • Design medical records to clearly document the number and types of interventional procedures received by the patient • Maintain a database of all patients with procedure and dose information • Review dose information to identify patients with high doses (>2Gy) for follow up • Establish procedures for follow-up, including skin examination at 30 days

EDUCATION AND TRAINING

Comprehensive training of operators in radiation biology, physics and safety:

- Attend high-quality courses or complete a self-training course given by appropriate professional societies; comply with applicable state requirements

Monitor and improve performance of operator:

- Audit outcomes of procedures (including patient radiation dose) for each operator
- Share information learned in audits with operators and provide additional training as needed
- Provide annual radiation safety education for all operators
- Collaborate in clinical trials to identify best practices for optimizing doses to patients and minimizing doses to health care providers

Conclusion

Interventional fluoroscopy is an increasingly important and valuable tool for treating disease, but it is not without risk. It is important for the health care community, manufacturers and regulators to work together to optimize patient radiation dose. Physicians must continuously think about optimizing radiation dose to the patient. Used prudently and optimally, interventional fluoroscopy is one of the valuable treatment modalities for a wide variety of diseases and disorders.

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