



FDA Public Health Advisory: Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically- Guided Procedures



(We encourage you to copy and distribute this Advisory)

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To: Healthcare Administrators
Risk Managers
Radiology Department Directors
Cardiology Department Directors

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has received reports of occasional, but at times severe, radiation-induced skin injuries to patients resulting from prolonged, fluoroscopically-guided, invasive procedures. Procedures typically involving extended fluoroscopic time are:

- percutaneous transluminal angioplasty (coronary and other vessels),
- radiofrequency cardiac catheter ablation,
- vascular embolization,
- stent and filter placement,
- thrombolytic and fibrinolytic procedures,
- percutaneous transhepatic cholangiography,
- endoscopic retrograde cholangiopancreatography,
- transjugular intrahepatic portosystemic shunt,
- percutaneous nephrostomy,
- biliary drainage and
- urinary/biliary stone removal.

Physicians performing these procedures should be aware of the potential for serious, radiation-induced skin injury caused by long periods of fluoroscopy during these procedures. It is important to note that the onset of these injuries is usually delayed, so that the physician cannot discern the damage by observing the patient immediately after the treatment.

The absorbed dose in the skin required to cause skin injury depends on a number of factors, but typical threshold doses for various effects are about 3 Gy (300 rad) for temporary epilation, about 6 Gy (600 rad) for main erythema, and 15 to 20 Gy (1,500 to 2,000 rad) for moist desquamation, dermal necrosis and secondary ulceration (see Reference).

The absorbed dose rate in the skin from the direct beam of a fluoroscopic x-ray system is typically between 0.02 Gy/min and 0.05 Gy/min (2 to 5 rad/min), but may be higher, depending on the mode in which the equipment is operated and the size of the patient. Even typical dose rates can result in skin injury after less than one hour of fluoroscopy.

FDA suggests that facilities performing fluoroscopically-guided procedures observe the following principles:

Establish standard operating procedures and clinical protocols for each specific type of procedure performed. The protocols should address all aspects of the procedure, such as patient selection, normal conduct of the procedure, actions in response to complications and consideration of limits on fluoroscopy exposure time

Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol. These dose rates should be derived from measurements performed at the facility.

Assess the impact of each procedure's protocol on the potential for radiation injury to the patient.

Modify the protocol, as appropriate, to limit the cumulative absorbed dose to any irradiated area of the skin to the minimum necessary for the clinical tasks, and particularly to avoid approaching cumulative doses that would induce unacceptable adverse effects. Use equipment which aids in minimizing absorbed dose.

Enlist a qualified medical physicist to assist in implementing these principles in such a manner so as not to adversely affect the clinical objectives of the procedure.

Physicians should know that radiation-induced injuries from fluoroscopy are not immediately apparent. Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physicians performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. For this reason, we recommend that information be recorded in the patient's record which permits estimation of the absorbed dose to the skin.

Patients should also be advised to report signs and/or symptoms of radiation induced injury to their attending physician.

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices. Follow the procedures established by your facility for such mandatory reporting. Practitioners who become aware of any medical device related adverse event or product problem/malfunction should report to their Medical Device User Facility Reporting person. If it is not reportable under the SMDA, it may be reported directly to MedWatch, the FDA's voluntary reporting program. Submit these reports to MedWatch, Medical Product Reporting Program, by phone at 1-800-FDA-1088 (also call for MedWatch information); by FAX at 1-800-FDA-0178; by modem at 1-800-FDA-7737; or by mail to MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Getting more information

If you have questions regarding this letter, please contact the Issues Management Staff, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

Sincerely yours,

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Health

REFERENCE

1. Wagner LK, Eifel PJ, and Geise RA. Potential Biological Effects Following High X-ray Dose Interventional Procedures, *Journal of Vascular and Interventional Radiology* 1994; 5:71-84.

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