

The United States Food & Drug Administration has received a number of reports of serious radiation-induced skin injuries resulting from prolonged fluoroscopic imaging during interventional therapeutic procedures. Such procedures include angioplasty and radio-frequency cardiac catheter ablation, among others. In some of the reported injuries, the physicians performing the procedures appear to have been unaware that the radiation doses exceeded the expected threshold for injury, or were unaware of the intensity of the fluoroscopic beam.

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 radiation dose required to cause skin injury depends on a number of factors, including the type of injury, the area of skin exposed, the age of the patients (and other patient-specific characteristics), and the circumstances of the exposure—single exposure or fractionation. In addition to acute effects, very large doses can lead to an increased risk of delayed effects (e.g. cancer).

## RECOMMENDATIONS

Radiation Protection Services 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 be pre-planned and address all aspects of the procedure, from patient selection through termination criteria.
- ◆ Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol.
- ◆ Know the impact of the protocol for the procedure relative to the potential for radiation injury due to the cumulative radiation dose to irradiated areas skin.
- ◆ Modify the protocol, if necessary, to limit the cumulative dose to any irradiated area of the skin to avoid doses that would induce unacceptable adverse effects. Implement equipment features that aid in minimizing 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 are not immediately apparent. Other than the mildest symptoms, such as transient erythema, the effect 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 procedures and may not observe the milder symptoms when they occur. Only when symptoms of serious injury occur do the physicians become aware of the magnitude of the radiation doses associated with the procedures. For this reason, facilities should record information from the procedure in the patient's medical record; to facilitate subsequent assessment of the radiation dose should the need arise.

Physicians and medical facilities are reminded to report serious injuries associated with the use of a medical device to the manufacturer or to Radiation Protection Services.

For further information contact:

Francine Anselmo, Head, Medical X-ray Program  
Radiation Protection Services, Environmental Health Services Div  
BC Centre for Disease Control  
Main Floor, 655 12<sup>th</sup> Ave W  
Vancouver BC V5Z 4R4  
Tel: 604.707.2456 | Fax: 604.707.2441

