Managing High-Dose Fluoroscopically Guided Interventional Procedures

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SUMMARY

Fluoroscopically guided interventional (FGI) procedures provide both clinical and economic benefits to patients. Radiation-induced tissue reactions are an uncommon side effect of FGI. They are usually self-limiting but can be catastrophic. FGI injuries should never be a surprise to either the operator or the patient. Injury cannot always be avoided, but its magnitude can usually be minimized. This requires appropriate action before, during and after each procedure. Normal clinical quality processes support appropriate radiation use over time.

INTRODUCTION

Radiation-induced tissue reactions (e.g., hair loss and skin burns) are rare side effects of FGI procedures [1,2,3]. Based on court records, it is estimated that several catastrophic injuries occur in the United States each year. A tissue reaction cannot always be avoided, but its magnitude can usually be minimized. Radiogenic tissue reactions should never come as a surprise to either the operator or the patient. Physicians and staff must take appropriate action before, during and after each procedure to minimize the likelihood and severity of tissue reactions [4,5,6].

Properly functioning fluoroscopes can deliver more radiation to a patient's skin during a complex interventional procedure than most radiation therapy systems deliver in a single treatment. Monitoring and controlling radiation dose during the procedure and using dose information for continuous benefit-risk analysis is essential.

The majority of fluoroscopic radiogenic injuries are self-limited and can be managed conservatively [3]. Major injuries rarely occur, but may require extensive surgical repair when they do. Most of these occur because the operator does not take appropriate measures to manage radiation, often because they are

unaware of the patient's radiation dose. Not surprisingly, patients are often not appropriately followed after their procedures. Subsequent major and minor radiogenic injuries are often misdiagnosed and can be inappropriately treated for months to years [1].

Tissue reactions occur when the local radiation dose overwhelms repair and repopulation processes for a critical number of cells. The effects on hair and skin injury are dependent on both dose and time, and vary from patient to patient. The severity of the injury increases as the local dose increases and the number of cells damaged increases. Some transient skin effects are seen as early as hours to days after a procedure. Most signs of a major injury do not appear until weeks after irradiation, and may not be fully expressed for a year or more [3].

Although the literature usually reports "skin injuries," major fluoroscopic injuries actually extend to a depth of several centimeters below the surface. Typically, the radiation intensity is 50 percent of the surface level at a depth of 3–5 cm. In addition, the presence of calcium will increase the bone dose by a factor of 2–4 above that of adjacent soft tissue [1]. Injuries from these effects include deep fat necrosis and osteoradionecrosis of ribs, vertebral bodies and the skull. Deep surgical debridement is required in such cases.

Dermatologists evaluating a skin injury without an accompanying history of irradiation frequently perform a punch biopsy to establish a diagnosis. This biopsy site may not heal if visible or latent major tissue reactions are present. Protecting radiation damaged skin helps minimize the possibility of secondary infection of the skin and subcutaneous tissues.

RADIATION MANAGEMENT

Skin injury is almost always avoidable. Minimizing the likelihood and severity of skin injuries requires attention before, during and after the procedure is performed [5,6].

Before the procedure

Previous irradiation of an area of skin can increase the risk and/or severity of an injury performed through the same area of skin. If a potentially high-dose procedure is planned, a history of previous radiation to the area (including radiation therapy) and the time course of previous irradiation should be sought. The patient should be examined for any form of skin injury (e.g., radiation, surgical, infection)

prior to starting the procedure. These results should be considered in planning the proposed procedure and may suggest procedural modifications to avoid inadvertently irradiating damaged skin.

The informed consent process should always include appropriate discussions of radiation risk. Discussions should be extended if there is an increased likelihood of injury due to previous irradiation, obesity or other factors [7].

Potentially high-dose procedures should only be performed using fluoroscopes labeled as "interventional systems" in compliance IEC standard 60601-2-43 [2]. Such equipment incorporates dose monitoring and management tools as well as additional technologies that enhance the safety of both patients and staff.

During the procedure

The basic principles of radiation dose management during fluoroscopy are summarized in Table 1. These principles should be followed to the extent practicable.

Dose metrics should be monitored during the procedure. As these dose metrics increase, consideration should be given to conserving radiation delivery. If the substantial radiation dose level (SRDL), a value that indicates that there is a risk of a clinically important skin effect, is exceeded, the primary operator should consider reducing the radiation delivery rate or postponing completion of the procedure if either of these is clinically appropriate. However, a procedure should never be stopped just because a particular radiation dose has been exceeded.

After the procedure

All available radiation dose metrics should be recorded in the patient's medical record. If any dose metric exceeds the SRDL, the operator should document the reasons in the medical record as well.

Following a SRDL procedure, the patient should be advised of the radiation dose and possible effects, instructed to perform self-examination four weeks after the procedure, and given instructions on what to look for, where to look, and who to call at the facility that performed the procedure. All possibly relevant signs and symptoms should be considered due to radiation unless and until an alternative diagnosis has been established. A minor skin reaction will have disappeared by four weeks after the procedure, but is of no clinical consequence and does not require further follow-up. Telephone follow-

up is sufficient if the patient reports no evidence of a tissue reaction. Follow-up in the interventionalist's office or clinic is necessary if the patient has observed any abnormality.

Information that radiation was used and all available skin dose information should be provided to all other caregivers as part of the patient's medical history. The interventionalist is responsible for patient follow-up until the likelihood of a tissue effect has passed. If a tissue effect is observed, the patient should be referred to a physician experienced in managing radiation injuries.

QA/QI AND PEER REVIEW

Though rare, severe tissue reactions resulting from FGI procedures can be catastrophic. All interventional services should implement policies and processes designed to minimize the number and severity of radiation-induced injuries. Appropriate consideration of radiation use and radiation injuries should be included in periodic departmental peer review. The evaluation should include a careful assessment of procedure justification, radiation dose optimization, the time course over which radiation doses were administered and patient outcome.

SUMMARY

Minimizing the likelihood and severity of skin injuries requires attention before, during and after a procedure is performed. Tissue reactions will occur if the peak skin radiation dose is high enough. The injury threshold, the nature and severity of the injury, and its time course vary from patient to patient. The severity of the reaction increases as the local dose increases. Most radiation-induced skin injuries are self-limiting and can be managed with conservative medical care, but some are major, require extensive surgical repair, and cause pain and disfigurement. Skin injury cannot always be avoided, but its magnitude can usually be minimized and it should never come as a surprise to either the operator or the patient.

Table 1. Measures to Manage Patient Dose[a]

Measures
• Radiation dose to the patient should be limited to that required for the procedure being performed • Appropriate collimation should be used for the imaging task to reduce the size of the irradiated area when possible • Patient should be positioned as close as reasonably possible to the image receptor • Distance between the patient and the X-ray tube should be maximized to the extent practicable • Each arm of the patient should be kept outside the radiation field unless an arm is intentionally imaged as part of the procedure • Lowest dose rate that is clinically acceptable should be used at all times • When electronic magnification is necessary, the lowest acceptable magnification factor should be used • Fluoroscopy should be used sparingly and only when real-time imaging guidance is needed • Last-image-hold feature or loop replay should be used whenever possible • Image acquisition should be activated only when higher quality image review is essential, and it should be limited to the frame rate and run duration necessary to accomplish the immediate task • In some cases, retrospectively-stored fluoroscopy may reduce the need for image acquisition

[a]*adapted from NCRP 168*[5]

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