Radiation Injuries after Fluoroscopic Procedures

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Fluoroscopically guided diagnostic and interventional procedures have become much more commonplace over the last decade. Current fluoroscopes are easily capable of producing dose rates in the range of 0.2 Gy (20 rads) per minute. The dose rate often changes dramatically with patient positioning and size. Most machines currently in use have no method to display approximate patient dose other than the rough surrogate of total fluoroscopy time. This does not include patient dose incurred during fluorography (serial imaging or cine runs), which can be considerably greater than dose during fluoroscopy. There have been over 100 cases of documented radiation skin and underlying tissue injury, a large portion of which resulted in dermal necrosis. The true number of injuries is undoubtedly much higher. The highest dose procedures are complex interventions such as those involving percutaneous angioplasties, stent placements, embolizations, and TIPS. In some cases skin doses have been in excess of 60 Gy (6000 rads). In many instances the procedures have been performed by physicians with little training in radiation effects, little appreciation of the radiation injuries that are possible or the strategies that could have been used to reduce both patient and staff doses. Almost all of the severe injuries that have occurred were avoidable.

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Interventional radiology, as we know it, began in the 1960s. There was rapid growth from 1985 to 2000. In some countries the number of procedures has doubled every 2 to 4 years. As an example, in Germany the number of percutaneous transluminal coronary angioplasties (PTCA) grew from 0.1 per 1000 population annually in 1984 to 1.7 in 1998. In 1996 it was estimated that over 700,000 interventional procedures were performed in the United States. The increasing use of interventional techniques is the result of new complex procedures that either were not available earlier (eg, stent placement) or percutaneous procedures that previously required open surgical access. In addition there has been markedly expanded use of fluoroscopes by nonradiologists (cardiologists, gastroenterologists, pain-management specialists, pulmonologists, and orthopedic surgeons).

Reports of radiation skin injuries have increased dramatically since the early 1990s. The injuries have covered the full gamut from erythema to full tissue necrosis and chronic ulceration requiring grafting. These lesions often lead to severe disability and chronic intractable pain. By 1994 the U.S. Food and Drug Administration (FDA) issued alerts and other authors drew attention to the burgeoning problem. Despite these publications the number of injuries appears to still be increasing and in 2000 we reviewed 73 cases of such injuries. In almost all cases that we have reviewed, severe radiation injuries were avoidable.

One may argue that skin injuries are unavoidable in today's medical practice and some physicians have suggested that skin injuries are an expected or acceptable complication of complex procedures. Such an argument does not excuse physicians from proper training in dose abatement practices. With good dose management practices, both the severity and the frequency of effects can be reduced to improve outcomes. Wagner et al have demonstrated that many grays of excess skin dose can be delivered to a patient in a prolonged interventional procedure if careful attention is not given to operator-controlled dose-saving management of radiation. Recently, Vane et al published a paper on the incidence of injuries in patients who had repeated coronary procedures. In their retrospective review of over 7800 PTCA, 14 patients were identified who had 4 to 14 coronary angiographies and between 5 and 10 PTCA over a 2 to 10 year period. Mean values of maximum skin doses were 217 mGy (21.7 rads) for the diagnostic studies and 391 mGy (39.1 rads) for the PTCA. Within these multi-procedure cases there were three patients with slight radiation skin changes, including telangiectasia, pigmentation, and subcutaneous fibrosis. Estimated cumulative skin doses
for two of these multi-procedure patients were in the range of 7 to 10 Gy. The third patient had a cumulative dose of about 5.6 Gy and was suspected to be unusually sensitive because of lupus erythematosus. This demonstrates that attention to technique and radiation protection can prevent clinically significant injuries.

In addition to patient skin injuries, as with any radiation, there is an increased risk of neoplasms. Furthermore, the high doses incurred during some neuro-interventional procedures may cause cataracts in patients. Finally, while patient injuries are the primary focus of this article, it is clear that unnecessarily high patient doses leads to unnecessarily high doses to the medical and technical staff. In many instances if appropriate radiation protection techniques are not applied, the doses to the hands, eyes and thyroid may be sufficiently high to legally restrict the number of procedures that interventionalists can perform to adhere to mandated occupational dose limits.23,24

DIRECT RADIATION EFFECTS IN TISSUE

Following is a review of radiation effects on those tissues that have been shown to be clinically important in fluoroscopically induced injuries. Direct radiation effects are the most important in terms of the radiation injuries.25 Direct effects are those that are called nonstochastic, which in modern nomenclature are referred to as deterministic. These effects have a threshold dose below which the effect is not apparent clinically. The severity and probability of deterministic effects increase as absorbed dose increases above the threshold. An example of such a deterministic effect is radiation skin injury.

Direct effects observed in an individual depend on the dose received, volume of tissue irradiated, quality or type of radiation, and time over which the dose is delivered. Direct effects observed also depend upon the time of observation after irradiation. A given organ is composed of (1) parenchymal cells that have some specific functions for that organ, (2) structural cells that give the organ its form, and (3) vascular tissue that supplies blood to the organ. Each of these three components usually has a different sensitivity to radiation and a different time course of presentation of direct radiation effects. Initial effects that are evident clinically may result from dysfunction of the parenchymal cells; however, if the organ survives, late effects may be a result of oblitative vascular changes.

Radiation effects do not produce pathognomonic, histologic, or morphologic changes that allow a given tissue to be described as having been exposed to ionizing radiation. The tissue can be analyzed for changes that are similar to changes seen after known radiation exposure. If such changes are identified, then radiation can be included in the list of possible etiologies of these changes.

Deterministic Radiation Effects in the Skin

The skin is involved in most radiation accidents and in medical applications that cause injury. Exposure from prolonged fluoroscopy or from a localized source on the skin can result in erythema, blistering, ulceration, or necrosis. As early as 1898, Gassmann described histologic changes of chronic roentgen ulcers.26 Early radiation pioneers, including Henri Becquerel and Marie Curie, described radiation dermatitis. Comprehensive reports on radiation effects on the skin and a book chapter are recommended to the reader for further detail.27-29

Some authors have classified skin damage by clinical type.30 Type I injury has damage limited to the epidermis and dermis without much damage to the subcutaneous tissues. The progression of this type of injury is as follows: there may be an initial erythema, then a latent period of about a week, then a secondary (or main phase) erythema immediately followed by an exudative epidermitis, and recovery in 3 to 6 months. Atrophic changes may be associated with healing. Type II injury is a vascular endothelitis, and at 4 to 8 months postexposure the acute reactions are renewed with necrosis and ulceration usually requiring surgery. This is the result of damage below the basal layer of the epidermis. In type III injury there is necrosis within a few weeks of the acute exposure.

Radiation-induced skin erythema is often classified as occurring in three phases. If the radiation fields are large and there is an acute dose of X-rays in excess of 2 to 3 Gy (200-300 rad), there may be a faint early erythematous reaction within a few hours, which usually fades. This early erythema is presumably because of release of vasoactive amines and capillary dilatation. In general, no prominent erythema is expected if radiation doses are below about 6 Gy (600 rad). When doses exceed 6 Gy, the second and main erythematous
reaction can begin during the first week and usually peaks at 2 to 3 weeks after the initial insult. The higher the radiation dose, the more quickly the erythema may be identified. Depending on dose, the erythema may last for 20 to 30 days or more. When the dose is fractionated, the threshold for skin erythema rises. If there are 12 daily fractions the dose for erythema of skin rises from about 6 or 8 Gy (600 to 800 rad) to about 12 Gy (1200 rad). The third phase of erythema may occur about 2 months postirradiation at doses in excess of 15 Gy and is because of vessel damage. It is characterized by a blue or mauve discoloration of the skin.

Edema is associated with high acute exposures. It can appear in a few hours after very high doses but often does not occur until after a week or more. The higher the dose, the shorter is the period for appearance. Acute doses in excess of 8 Gy (800 rad) can produce exudative and erosive changes of the skin. If there is an exudative dermatitis in general, the margins of the lesion correspond to an acute dose to the basal layer of the epidermis of about 18 Gy (1800 rads). For quite large doses of radiation, there may be additional changes of moist desquamation, formation of bullae, or even a sloughing of the skin due to killing of cells in the basal layer. When there are penetrating acute doses in excess of 20 Gy (2000 rad), there is usually nonhealing ulceration.

Patients receiving acute doses in the range above 15 Gy (1500 rads) might report an immediate sensation of heat and those receiving acute local doses in excess of 25 Gy (2500 rads) might report immediate pain or tingling. At least in the case of two previous reports, there was a prompt sensation after the procedure of heat and pain.19

With relatively large doses of radiation such as a single dose of about 20 Gy (2000 rad) to 40 Gy (4000 rad) or more, a bullous-type, moist desquamation may occur in 4 weeks. In this situation, small blisters tend to coalesce and rupture. If the dose is high enough, blisters may be formed from beneath the basal cell layer. At this stage, the clinical lesion may appear very similar to a second- or third-degree thermal burn, but an important differential diagnostic point is that the patient will not remember having been burned by contact with a hot object or flame. The bullae may become infected, and there also may be sloughing of the epidermis. A week or 2 after sloughing of the epidermis, the affected areas may become covered with epidermis, although ulcers tend to recur with later arteriolar obliterator changes.

Skin ulceration may occur very early with high-absorbed doses (in excess of about 25 Gy). These ulcers may heal but ultimately may recur. With lower doses (in excess of 18 Gy) painful, slowly healing ulcers may occur and persist for years. The probable cause of these late ulcers is ischemia due to arteriolar and small-artery changes.

At doses in excess of about 10 Gy (1000 rads), delayed effects may be apparent at 6 months or later and may progress slowly. The sequence of pigmentation effects is variable from patient to patient. In some patients, the skin demonstrates gradual hyperpigmentation; however, in African Americans, there may be depigmentation of the skin. Depigmentation may occur if the radiation dose has been high enough to destroy the melanocytes. By 1 year, the skin usually demonstrates its final appearance. Diffuse telangiectasia; suppression of sebaceous gland activity; regrowth of hair; and thin, dry, and semi-translucent skin may result from atrophy. Skin telangiectasia may show progression up to 10 years but is individually variable.31,32 If moist desquamation occurs, there is a higher incidence of telangiectasia.33 With increasing fibrosis, there may be induration of the skin, as well as limitation of motion. The amount of severe fibrosis is greatly influenced by both dose and fractionation.

Skin reaction varies over the body and is influenced by patient factors, including age. Moist desquamation is less likely to occur in children than in adults, probably because of the epithelium’s ability to recover more rapidly. Hyperthyroidism apparently makes the erythema and skin reaction more brisk than usual. Fairer-skinned people demonstrate more skin reaction than do darker-skinned individuals. Those portions of the skin that are moist and subject to friction, such as the axilla, groin, and skin folds, are the most radiosensitive. Sensitive areas appear to be the anterior aspect of the neck and antecubital and popliteal spaces, followed in decreasing order by the flexor surface of the extremities, chest, abdomen, face, and back.34 The extensor surfaces of extremities are somewhat less sensitive. The least-sensitive areas appear to be the nape of the neck, scalp, and the palms and soles. Areas of skin grafting in which the graft is less than 3 months old generally demonstrate greater radiosensitivity than does the normal skin.
Skin tolerance to radiation depends significantly on the area of tissue irradiated. As the area of irradiated skin becomes smaller, the dose required to produce necrosis increases. For example, the skin tolerance dose (TD) for a circular field of 150 cm² is approximately 15 Gy (1500 rad) in a single dose, whereas for a circular field of 50 cm² the TD is almost 20 Gy (2000 rads). Occasionally, there are rare atypical skin reactions after radiotherapy that resemble erythema multiforme, pemphigus, and other entities. Such reactions can begin in the irradiated area but then become more generalized.

A variety of reports suggest a correlation between exaggerated reactions after radiotherapy and connective tissue diseases, especially scleroderma, systemic and discoid lupus erythematosus, and mixed connective tissue disease. Although a causative relationship for these rare observations is assumed, definite evidence is lacking. Diabetes mellitus and hyperthyroidism have also been associated with increased skin response to irradiation.

Patients carrying the homozygous form of the ataxia telangiectasia gene are also known to exhibit significant hypersensitivity to radiation. Skin sensitivity to radiation can be increased by various chemotherapeutic agents, such as actinomycin D, adriamycin, bleomycin, 5-fluorouracil, and methotrexate. An early reaction that has healed over time can even manifest itself again in the same skin area when actinomycin D is given some weeks or months after the irradiation. This effect is known as a recall reaction. A similar reaction has been described after simvastatin administration.

Temporary loss of hair (epilation) occurs in about 3 weeks with 3 to 5 Gy (300 to 500 rad); hair begins to return during the second month post exposure and continues for up to 1 year. Single doses of 7 Gy (700 rad) may cause permanent epilation, with the latent period being less than 3 weeks. Not all body areas have the same radiation epilation sensitivity. The scalp and beard are most sensitive, with chest wall, axillary, abdominal, eyebrow, eyelash, and pubic hair being less sensitive, respectively. Hair follicles of children are more sensitive than those of adults. Hair that has regrown is always finer and slower-growing than the original hair. It may also be of a different color.

**Radiation Effects on the Eye**

Because a large portion of the eye, particularly the conjunctiva, is composed of epithelial cells, it reacts as the skin does during the acute clinical period. There may be erythema and, if the dose is high enough, dry or moist desquamation. The eyebrows are quite resistant to epilation, even when it occurs at other sites.

Cataracts are the most frequent delayed reaction in the eye. Cataracts have been identified as a late effect in atomic bomb survivors and in multiple accidental exposures. The term cataract often connotes blindness or at least impaired vision; the vast majority of radiation "cataracts" identified in the atomic bomb survivors was nonprogressive and did not impair vision. There appeared to be a threshold dose below which lenticular opacities were not found. A study of the atomic bomb survivors has indicated that the lenses of children may be more sensitive to the induction of cataracts by ionizing radiation than in adults.

Radiation cataracts are among the few lesions that pathologically are quite characteristic for radiation injury. Most senile cataracts begin in the anterior pole of the lens, whereas radiation cataracts begin as a small dot in the posterior pole. Perhaps the best description of radiogenic cataracts in the literature is that of Cogan et al. As the opacity develops in the posterior pole and enlarges to 3 to 4 mm, a central clear area may be identified. Ultimately, the cataract may progress to the anterior pole of the lens, with development of a nonspecific cataract. Even though the cataract initially appears clinically in the posterior pole, the pathogenesis of the radiation cataract is usually damage to the epithelial cells of the anterior lens. With the inhibition of mitosis and actively proliferating cells, there is interference with differentiation. The damaged cells migrate toward the posterior pole, where they undergo degeneration. While posterior cataracts are characteristic of radiation exposure, they are not pathognomonic; in other words, there are other causes that can result in posterior cataracts.

Lens opacities do not always interfere with vision, and thus, a vision-impairing cataract requires higher doses. The latent period for production of cataracts from the time of exposure may range from about 6 months to 35 years, although on the average it is 2 to 3 years. The higher the absorbed
dose, the shorter is the latent period. The incidence of radiation cataracts is dose-, time-, and age-dependent. Single doses of 2 Gy (200 rad) or fractionated doses of 4 Gy (400 rad) can result in the formation of lens opacities. A single dose of 7.5 Gy (750 rad) causes cataract formation in all those exposed.

LONG TERM RISKS OF CANCER

Risks of radiation-induced cancers are a consideration both for patient and staff. Radiation carcinogenesis is a stochastic or probabilistic effect. Severity of a cancer is not considered to be related to dose. The higher the absorbed dose the higher is the potential for developing a neoplasm. There is no known threshold below which an induced neoplasm cannot occur although at doses less than 0.05 Gy (5 rads) the risk is so small that a statistically significant excess of cancer has not been detected even by very large epidemiological studies. Localized acute doses to patients from interventional procedures can be in the range of 0.1 to 30 Gy (10-3000 rads). In addition, cumulative occupational staff doses can also be in the range in which carcinogenesis has been observed.

Radiation-induced cancers and leukemias have a latent period between exposure and clinical appearance of the malignancy. Non-CLL leukemias may appear as early as 2 years postexposure although the mean latent period is usually about 7 years. Risk of leukemia then declines with time. Bone and thyroid carcinomas have a minimum latent period of about 5 years whereas other solid tumors usually do not appear before 10 years post exposure and most have a mean latent period of 20 to 25 years. This latent period is important relative to many interventional fluoroscopic procedures because many of the patients are older and critically ill. In such circumstances the risk of subsequent cancer is very small. On the other hand, children appear to be more sensitive to cancer induction than adults and they have a much longer life span during which they are at risk.

Radiation is capable of inducing many, but not all, types of malignancies. Radiation has not been shown to induce chronic lymphocytic leukemia. Prostate, cervical, uterine, and pancreatic tissue are quite resistant to cancer induction by radiation. Other tissues such as skin, lung, breast, and gastrointestinal tract are more likely to have radiation caused tumors.

The particular potential cancers of interest relative to use of fluoroscopes relates to the tissues most commonly in the primary beam and the ones with the highest absorbed tissue doses. The skin at the beam entrance site on the patient and the skin on the hands of the person performing the procedure are both obviously of concern. Radiation appears to cause squamous and basal cell cancers but not melanomas. The risk of radiation induced skin cancer is higher on those portions of the skin chronically exposed to sunlight. There have been many studies of skin cancer over the decades including patients who have had multiple fluoroscopic procedures with averages doses in the 9 to 10 Gy (900-1000 rad) range and the excess of skin cancer was small.

Thyroid cancer is an issue that appears to concern most operators of fluoroscopic equipment who routinely wear thyroid shields as well as lead aprons. Thyroid cancer is a real concern after radiation exposure of children; however, the cumulative scientific data on adults does not indicate that this is the hazard that it is perceived to be. Ron et al have conducted a pooled analysis of six studies and concluded that there is little if any, risk of thyroid cancer in persons over 20 years of age after external radiation exposure.

CHARACTERISTICS OF FLUOROSCOPIC RADIATION INJURIES

As mentioned earlier, even though alerts and notices had been promulgated by 1994, injuries continued to appear and be reported in the literature. Most of the reports concerned interventional cardiology but others involved TIPS and neuro-interventional procedures. Through study of these and other cases, a number of important aspects have emerged that are important to the causation and prevention of fluoroscopic injuries.

Location of Lesions

The location of lesions on patients who have had coronary interventions is a function of the beam orientation. The lesions are usually mid back or in the right or left scapular or subscapular area. Injuries from TIPS placement usually are in the mid back or right subscapular area. When the X-ray field remains unchanged in size and location for extended periods of time, the lesion reflects the
Exposure Time

Long exposure time to the same skin area is the most common factor in all injuries that have been reported. Fluoroscopy time should be monitored and times in excess of 30 minutes should be a cause for concern. Pulsed fluoroscopy units reduce the effective beam on time with lower pulse rates and can be very effective in reducing the skin dose. Interestingly enough, lower dose rates may not happen with all pulsed units and some actually produce higher dose rates. Therefore, operators are cautioned to understand the dose-control operations of pulsed fluoroscopy for the unit that is employed.

Prior Exposure

Prior exposure is an issue in some patient injuries. There are many patients who have multiple procedures at the same or different hospitals. The prior dose is almost never known and the fluoroscopy time may only exist in room logs and not in the procedure report. A history of prior procedures should make the physician wary about the potential for skin injury and a brief physical examination to detect any skin changes is appropriate so that the examination can be tailored to avoid further irradiation of the site if practical. In the least the patient should be advised that the previous procedure may have reduced the tolerance of the skin and risk of injury is a concern.

High Dose Rate Modes

Many fluoroscopic machines have a high dose rate specially activated mode of fluoroscopy. These modes routinely deliver more than 0.1 Gy (10 rads) per minute to the skin and dose rates in excess of 1 Gy (100 rads) per minute are achievable with some units (Table 1). With use of this mode, hair loss and cataracts can be induced within minutes of operation. Skin necrosis may be induced at less than 30 minutes of exposure. Table 2 offers some examples of how dose rate and fluoroscopy time relate to risk for direct effects. The difficulty at present is that the physician has no real time indication of the doses that are being delivered. The physician must therefore rely on good judgment knowing how to perform the procedure using low dose rate modes when they are adequate and use higher dose modes only when they are necessary.

Equipment Type

Equipment design and operation are important aspects of dose management. Radiation injuries are not just from older equipment. Even the new digital equipment is capable of generating very high dose rates. Not all modern fluoroscopes are appropriately designed for minimum dose delivery during complex interventions. Dose-saving variable pulsed fluoroscopy and variable computer-controlled beam filtration are proven techniques for dose management, but not all machines offer these features. Typical continuous fluoroscopy doses are about 50 mGy (5 rads). Use of dose-saving pulsed fluoroscopy can lower doses to about 10 mGy (1 rad)/minute if the pulse rate is slow (7.5 pulses/second). However, as the pulse rate is increased to about 30 pps the dose rate is close to that of continuous fluoroscopy. For identical procedures large differences in doses (on the order of grays) are possible among various contemporary machines. Physicians must be aware of these deficiencies and know how to best operate their equipment for effective dose management.
## Table 1. Example of Radiation Exposure from a Cardiac Catheterization Unit in an Average Adult

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<td>Ip/mm</td>
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### Fluorography

Patients are not only subjected to dose from fluoroscopy but also from multiple image acquisitions (e.g., serial fluorography or cine fluorography runs) during which over 1,000 images may be obtained. An absorbed skin dose from fluorography depends primarily upon the frame rate and mode of operation (DSA, DA, or cine). Typical doses during cine, for example, can range from about 0.4 Gy (40 rads)/minute at 15 frames/second to about 1 Gy (100 rads)/minute at 60 frames/second (see Table 1).

### Patient Size

Patient size has a major effect on skin dose. The amount of radiation that must be applied at the entrance skin surface of the patient is governed by how much of the radiation actually penetrates through the thick body part that is being examined. For thicker body masses more radiation must be applied to penetrate through the patient. The radiation dose at depth in tissue (i.e., inside the patient) is reduced by a factor of two for every 4.5 to 5.0 cm of tissue depth. This means that patients who are 10-cm thicker than thin patients will require about four times more dose to adequately penetrate their bodies. Most fluoroscopes will automatically adjust the dose rate to maintain a certain level of brightness on the image intensifier. Dose rates to large patients are often 4 to 10 times higher than for thin patients. Changes in dose rate as a result of patient size or change in beam angulation are usually not obvious to the operator but can be very considerable. Either performing examinations on obese patients or using steeply angled projections (that require the beam to traverse more tissue) will
**Table 2. Potential Effects of Fluoroscopic Exposures on the Reaction of Skin and Lens of the Eye**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Approximate threshold dose (Gy)</th>
<th>Time of onset</th>
<th>Minutes of fluoroscopy at typical normal dose rate of 0.02 Gy/min (20 mGy/min = 2 rad/min)</th>
<th>Minutes of fluoroscopy at typical high dose rate of 0.2 Gy/min (200 mGy/min = 20 rad/min)</th>
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<td>2-24 hours</td>
<td>100</td>
<td>10</td>
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<td>Main erythema reaction</td>
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<td>1.5 weeks</td>
<td>300</td>
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<td>Moist desquamation</td>
<td>18</td>
<td>4 weeks</td>
<td>900</td>
<td>90</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>24</td>
<td>&gt;6 weeks</td>
<td>1200</td>
<td>120</td>
</tr>
<tr>
<td>Late erythema</td>
<td>15</td>
<td>8-10 weeks</td>
<td>750</td>
<td>75</td>
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<tr>
<td>Ischaemic dermal necrosis</td>
<td>18</td>
<td>&gt;10 weeks</td>
<td>900</td>
<td>90</td>
</tr>
<tr>
<td>Dermal atrophy (1st phase)</td>
<td>10</td>
<td>&gt;52 weeks</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>10</td>
<td>&gt;52 weeks</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>Dermal necrosis (delayed)</td>
<td>&gt;12</td>
<td>&gt;52 weeks</td>
<td>750</td>
<td>75</td>
</tr>
<tr>
<td>Skin cancer</td>
<td>none known</td>
<td>&gt;15 years</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Eye</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lens opacity (detectable)</td>
<td>&gt;1.2</td>
<td>&gt;5 years</td>
<td>&gt;50 to eye</td>
<td>&gt;5 to eye</td>
</tr>
<tr>
<td>Lens/cataract (debritilating)</td>
<td>&gt;6</td>
<td>&gt;5 years</td>
<td>&gt;250 to eye</td>
<td>&gt;26 to eye</td>
</tr>
</tbody>
</table>

*Potential effects of fluoroscopic exposures on the reaction of the skin. Adapted from Wagner and Archer (1998) with reference to Hopewell as a personal communication (1996).*

*Potential effects of fluoroscopic exposures on the lens. Indicates the doses capable of causing significant visual impairment or debilitation.*

*Without knowing the actual dose rate(s) of various modes of operation, an interventionist can inadvertently reach the thresholds. Columns 4 and 5 show the impact of realistic dose rates in terms of minutes required to reach the thresholds. This emphasizes the importance of knowing the dose rates being delivered by specific equipment. Any "rule of thumb," eg, 100 minutes, should not be used, unless it represents the impact of actual dose rates.*

*With permission of International Commission on Radiological Protection.*

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**Fig 2.** Skin injury in a 350-pound diabetic patient 7 months after coronary artery angioplasty and stent placement. Total fluoroscopy time 70 minutes. The large size of the patient predisposes that the entrance dose rates will be high. The diabetes may be a factor that also increases radiation sensitivity. (Reprinted with permission from reference.)

**Fig 3.** Skin injury 1 year after the second of two procedures in a man with coronary artery disease. The first procedure involved 173 minutes of fluoroscopy and the second 73 minutes. Both involved steeply angled beam projections that increase the tissue that must be penetrated, thus elevating dose rates. (Reprinted with permission from reference.)
increase the dose intensity at the skin by a factor of 10 over that of good practice. This will result in injury in a very short period of time. The arm injury in Fig 4 occurred in just this way.

Field of View

Although it is not intuitively obvious, the field of view (also known as the magnification mode) has a significant impact on dose rate and the clinical development of skin injuries. Relative to injury there is often a trade off with magnification. The extent of the tradeoff depends on how the machine works. As the operator electronically magnifies the image, there is a loss in image brightness that occurs inside the system. To compensate for this loss so that it is not apparent to the operator, the machine will make some other modification. Often this modification will be to increase radiation output, although some manufacturers choose a different modification that doesn’t affect dose rate. How any individual system operates is unknown unless physical investigation by a physicist is performed.

As mentioned earlier the larger the irradiated area, the more poorly the radiation damage is tolerated...
and the more difficult healing becomes. Thus, one might be tempted to always use the smallest possible field of view. This is not appropriate logic because as magnification is increased, the machine will likely increase X-ray output and whatever tissue remains in the smaller field will actually receive a higher dose, much higher (~2 to 4 times higher) in some cases. Figure 5 is an example of an injury subsequent to prolonged use of a high magnification (small field of view) mode.

**Collimation**

The use of collimation to "reduce exposure" is often misunderstood. Collimating the radiation field to the area of interest has the following advantages:
- It reduces radiation burden to the patient by reducing the volume of directly exposed tissue;
- It reduces scatter radiation exposure to personnel in the room;
- It improves image quality by reducing scatter in the image;
- By reducing the area exposed, it is easier to move the beam to a different skin site without overlapping radiation fields.

Collimation does not reduce radiation dose rate to the directly exposed skin. In fact, dose rate to this skin is likely to be greater than to that of a larger field. This is because the machine output must compensate for radiation imaging changes that occur when collimation is employed. Attention to other standard methods of dose control must be employed to ensure that dose rate to the exposed skin is managed well. Because of the other benefits, collimating to the area of interest is strongly encouraged.

**Grids**

Grids are designed to improve image quality by removing scatter. The grid attenuates the beam and decreases the image brightness. The machine usually will compensate by increasing the output or dose rate. If there is a large air gap between the patient and the image intensifier a grid is often not needed and this can reduce dose by up to one-third. This is particularly useful in pediatric imaging and has been reported to be useful in neuroradiological work.  

**Difficult Procedures**

Essentially all radiation injuries that we have seen followed long and complex interventional procedures. Injuries are extremely rare after diagnostic angiography and most have involved some sort of therapeutic interventions (such as stent placement, embolization of aneurysms, or multiple balloon angioplasties). As the procedure becomes more complex, the physician often inappropriately concentrates less on the total radiation dose. In addition, there is a tendency to want to have more magnification, which only increases radiation dose. There also is a tendency to want to have the optimal projection and to keep the machine locked in that projection thereby exposing a certain area of skin to a very high dose. Using methods to reduce the likelihood of injury becomes most important in these circumstances.

**MANAGING THE POTENTIAL FOR INJURIES**

**Before the Procedure**

Before performing a fluoroscopically guided interventional procedure, there exist certain actions that the interventionalist can take to reduce the risk to a patient for radiation-induced skin injury and to advise the patient about the potential for injury. For instance, many patients return for interventional work due to recurrent disease. Several injuries reported by Koenig et al, Vano, and others are associated with multiple procedures performed at intervals of days, weeks, months, and even years. This type of information can be useful in patient management. Possible actions before a procedure include:
- Drain ascites before a TIPS procedure to reduce patient size;
- Obtain a thorough medical history to determine if the patient has had any previous radiation related procedures, such as radiation therapy or a previous fluoroscopically guided interventional procedure;
- If a previous radiation history exists, examine the patient for signs of skin changes related to radiation exposure and plan to avoid further irradiation of any such area, if possible;
- Review the patient's medical history for con-
ditions that might increase radiation sensitivity, such as collagen vascular disease (particularly scleroderma, lupus erythematosus, and mixed connective tissue disease), diabetes mellitus, hyperthyroidism, and homozygosity for ataxia telangiectasia, as well as certain chemical and pharmaceutical agents;

- Written informed consent is obtained before most interventional procedures. The International Commission on Radiological Protection (ICRP) has recommended that patients should be counseled on radiation risks if the procedure carries a significant risk of injury. In our experience, patients who have suffered fluoroscopically induced radiation injuries have almost never had radiation risks mentioned in the consent forms. For many interventional procedures the radiation risks are small, however, if the patient has had multiple prior procedures, is diabetic, has collagen vascular disease or other sensitizing health condition, or is overweight or is likely to have a complex procedure it would certainly be prudent to not only counsel the patient but to specifically include the potential of radiation injury in the informed consent.

During the Procedure

A feature common to all reported injuries is the lack of any dose monitoring system. Most new units now have dose-area product meters. But these types of meters, although better than no meter at all, do not provide information on skin dose at entrance beam site. The effects of X-ray tube position and beam collimation make the utility of these devices for skin dose monitoring problematic at best. For X-ray systems indicated by the manufacturer to be for “interventional use,” the recently completed 2000 standard of the International Electrotechnical Commission require that manufacturers report in real time the free-in-air air kerma produced at a point along the central axis. For C-arm systems, this “interventional reference point” is 150 mm toward the X-ray tube from isocenter. This is very helpful in that it provides a reasonable estimate of the cumulative entrance air kerma (CEAK) that can be converted into an estimate of the cumulative entrance skin dose (CESD):

$$\text{CESD}(\text{mGy}) = 1.4 \times \text{CEAK}(\text{mGy})$$

Where the f-factor is 1.4 is an approximation that depends on the field of view.

This cumulative skin dose is an approximation of the total dose delivered to skin, but it may overestimate the skin dose because there is no accounting for movement of the beam to different entrance skin areas during the procedure. On the other hand, it can underestimate or overestimate the dose because the skin might not be located 150-mm tube-side of isocenter. Regardless of these and other slight deficiencies in this type of monitor, this data will prove to be valuable information to physicians because they will have reasonable data on just how much radiation they are actually delivering to their patients. Some manufacturers have developed even more sophisticated computer based dosimetry programs that more accurately track skin dose and provide a real-time graphical display of skin dose.

To monitor dose from fluoroscopic equipment that has no dose monitoring capability, some have used other available technologies for real time monitoring, including, computerized monitoring of technique factors with assessment of cumulative dose, direct skin dose monitoring with tiny light-emitting sensors, and portal dose monitoring. Each of these methods provide useful information in the management of dose to patients. The pros and cons of these techniques are well discussed in the referenced material. In lieu of real-time monitoring methods, other methods of postprocedure dose evaluation are available and are useful as a quality assurance tool. These include luminescent dosimeters and film-based technologies. While these have been reviewed in the literature, recent advances make these devices more appealing in their practical application and the reader is encouraged to investigate the commercial availability of these technologies.

During the procedure some common rules for minimizing skin dose to a patient include:

1. Keep the air gap between the patient and the image intensifier at a minimum unless geometric magnification is essential to the procedure.
2. Use a practical maximum distance between the X-ray source and the patient (if the distance between the source and the image intensifier is too great, this might adversely affect image quality by increasing the kVp or fluorographic exposure time).
3. Use the largest field-of-view (least magnification mode) practicable.
4. Collimate to the area of interest.
5. Use the lowest dose and dose rate modes practicable.
6. Be sure physicians are properly trained in the technical skills of the procedure to assure efficient, effective and sparing use of radiation, keeping the beam-on time to a minimum.
7. Remember that dose rates are much higher and dose accumulates much more quickly in large patients.
8. Remove the grid during procedures on small patients or when the image intensifier cannot be placed close to the patient.
9. If a physician performs fluoroscopy and resets the 5-minute timer many times (eg, six), consider a procedural consult with another staff member to review the progress and assist in the expeditious completion of the procedure.
10. Consider changing the beam angle to another skin site to avoid over-irradiation of a single site.
11. Use special dose limiting features, such as dose-saving variable pulsed fluoroscopy and heavy copper filtration that is software driven for appropriate application.
12. Avoid direct entry-site irradiation of the female breast in order to reduce the known risk of radiation-induced cancer in this radiosensitive organ.
13. Ensure that arms are not present in the beam path. Arms in the beam only force the machine to drive up the radiation output and degrade image quality.

After the Procedure

Koenig et al. also noted that physicians often misdiagnose radiation-induced injuries. Many interventionalists express disbelief that their procedures could cause such injuries. This inability to recognize the effects of radiation in the skin has delayed the medical community’s ability to respond with assertive action to help manage radiation injury. Knowledge that certain procedures are causing reactions is an important quality control feedback to alert physicians that radiation skin dose is approaching serious risk levels. For this reason, patients who undergo complex procedures that deliver high doses to the skin should be advised to examine themselves 2 to 3 weeks later for any skin changes, such as reddening, and report the event back to the interventionalist. The interventionalist will not only be able to refer the patient to an appropriate dermatologist, but will also have feedback that might assist in better management of future procedures. The erythema and papules of Fig 6 were reported back to the physician after one failed and one successful TIPS procedure [total of procedure times was about 6-7 hours]. Fortunately, this erythema healed with only conservative treatment. It is possible that the skin will be at reduced threshold for future radiation effects. At this facility, the response to this information was to reduce the pulse rate for their TIPS procedures and to vary the obliquity of the beam if the procedure time is lengthy.

It has been recommended by the International Commission on Radiological Protection (1) that if an estimated skin dose of 3 Gy (300 rads) or more is likely records of exposure should be kept. This is also true for estimated doses of 1 Gy (100 rads) for procedures that are likely to be repeated. If the dose during the procedure or the cumulative dose of the current and prior procedures is sufficient to
cause observable effects the patient should be counseled after the procedure.

Training

Interventional procedures are often very complex and the physician has many items to consider other than radiation exposure. The procedures also tend to be very individualized so that use of rigid protocols becomes impractical. Regardless, physicians performing these procedures should be specifically trained in the potential hazards and effects of the radiation. They should not only be aware of the factors that influence patient dose but also the strategies to minimize dose while still being able to achieve the necessary medical ends. Physicians also need to be trained in recognition of radiation injuries and the time course of the clinical appearance. Practical actions that should be included in training include the items of this section and the following items for personnel safety:

- Personnel must learn to wear protective aprons, use shielding, monitor their doses, and know how to position themselves and the machines for minimum dose.
- If the beam is horizontal, or near horizontal, the operator should learn to stand on the image intensifier side (to reduce dose) when possible.
- If the beam is vertical, or near vertical, it is best for personnel safety to keep the tube under the patient and to use leg shields.

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