

Measuring and Monitoring Radiation Dose During Fluoroscopically Guided Procedures

John W. Jaco, MD, CPT, MC, USAR,* and Donald L. Miller, MD^{†,‡}

The principal problem in measuring patient radiation dose during fluoroscopically guided procedures is that dose is not administered uniformly throughout the patient's body. Four dose metrics have been developed to quantify patient radiation dose for fluoroscopically guided procedures: fluoroscopy time, peak skin dose, reference dose, and kerma-area-product. Each metric must be understood to be used appropriately. Fluoroscopy time correlates poorly with other dose metrics. It should not be used as the sole method to estimate, monitor, or record patient radiation dose unless no alternative is available. Kerma-area-product is a good metric for estimating stochastic risk. Reference dose is a conservative method to estimate peak skin dose and deterministic risk and is recommended for this purpose. Every fluoroscope sold in the USA since mid 2006 is able to measure, display, and record reference dose. Radiation dose should be monitored during fluoroscopically guided procedures, either by the operator or by a designated individual in the procedure room, such as a technologist or nurse. Patient radiation dose should be recorded appropriately in the medical record. Patients who have received a sufficiently large radiation dose should have follow-up at 10-14 days and at 1 month after the procedure for possible deterministic effects.

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"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meager and unsatisfactory kind."

—Lord Kelvin

Measuring patient radiation dose and using this information appropriately are an important part of the practice of every interventional radiologist. Because patients are irradiated in a non-homogeneous way during interventional procedures, their radiation dose is not uniform throughout the body. Measuring patient radiation dose is therefore not straightforward. Four dose metrics have been developed to quantify patient radiation dose for fluoroscopically guided procedures. These are fluoroscopy time, peak skin dose, reference dose, and kerma-area-product (KAP) (also called dose-area-product). These metrics measure different aspects

of dose in different ways. These differences must be understood if the metrics are to be exploited to their fullest.

What Is Dose?

Radiation dose is the amount of energy absorbed by matter. It is measured in grays (J/kg). This is different from exposure, which is the amount of radiation produced by a radiation source. Dose can be further characterized as absorbed dose, equivalent dose, and effective dose.

Absorbed dose is the most fundamental measure of dose. It is the amount of energy absorbed by a particular organ or tissue. It does not take into account the radiosensitivity of that tissue or the type of ionizing radiation delivering the energy. These factors are included in effective dose and equivalent dose. These quantities are measurements developed and used for some regulatory and radiation protection purposes. These quantities must be calculated; they cannot be measured directly. They are not discussed further here.

Biological Effects of Ionizing Radiation

There are 2 types of detrimental effects of ionizing radiation: stochastic and deterministic. The probability of a stochastic effect increases with total dose, but the severity of a stochastic effect is con-

*Department of Radiology, National Capital Consortium, Washington, DC/Bethesda, MD.

†Department of Radiology, National Naval Medical Center, Bethesda, MD.

‡Department of Radiology and Radiological Sciences, Uniformed Services University, Bethesda, MD.

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Address reprint requests to Donald L. Miller, MD, Department of Radiology, National Naval Medical Center, 8901 Wisconsin Avenue, Bethesda, MD 20889-5600. E-mail: Donald.Miller@med.navy.mil

stant. Deterministic effects do not occur until a dose threshold is reached. Their severity increases from that point on. A good analogy is sunburn.

Clinically, the most important stochastic effect is cancer induction. The mechanism is damage to DNA (strand breaks) with mis-repair. The cell is still able to divide, but the progeny are abnormal. The risk depends not only on the dose a patient receives but also on the patient's age and sex, the type of cells irradiated, and other factors.^{1,2} It has been established that the risk of developing cancer increases with increasing radiation dose, but the relationship between radiation dose and risk is not clear. For radiation protection purposes, the relationship is assumed to be linear, with no "safe" radiation dose. This is called the linear no threshold hypothesis.

Children are much more susceptible to the stochastic effects of radiation dose than adults, both because of more rapid cellular turnover and because their risk extends over a longer period of years. Stochastic risk is approximately 15 times higher for a newborn than for a 60-year-old adult.¹ Additionally, due to their smaller body size, it is possible to irradiate larger portions of children's bodies if careful attention is not paid to X-ray beam collimation. Adolescents are a special case: they combine the increased sensitivity of children with the greater dose requirements of an adult body habitus.

Despite the potential for radiation-induced carcinogenesis, the lifetime risk of developing a malignancy is typically not substantially increased by interventional or other radiologic procedures.³ Another stochastic effect of radiation exposure is genetic mutation, but this risk is substantially smaller than that of carcinogenesis.²

While the potential for stochastic effects in patients should always be considered, especially when dealing with children, in the day-to-day practice of most interventional radiologists, the more immediate concern is deterministic effects.³ Deterministic effects exhibit a threshold, a dose below which they are not observed. The severity of the effect increases as dose increases above the threshold level.

Deterministic effects are caused by radiation damage to cellular DNA so severe that it cannot be repaired. This results in either immediate cell death or, more commonly, disruption of the ability of cells to reproduce. Deterministic effects include skin injuries, hair loss, cataract formation, and sterility.^{4,5} Skin injuries are the most commonly encountered clinical effects from fluoroscopically guided procedures. They can be so severe that they extend into the deeper subcutaneous tissues and muscle.⁶ Radiation-induced skin injuries can cause years of misery, with prolonged pain, disfigurement, and the need for surgical intervention.⁷

The frequency of these effects because of fluoroscopically guided procedures has been estimated at between 1:10,000 and 1:1 million.^{3,8} This is clearly a large range and probably an underestimate, as many such injuries likely go unreported.

Estimating Radiation Dose in Fluoroscopically Guided Procedures

The principal problem in measuring patient dose during fluoroscopically guided procedures is that dose is not ad-

ministered uniformly throughout the patient's body. Typically, the radiation field is moved over the patient's body during a procedure and changes in size and shape as the beam is collimated or the C-arm are angled. As a result, the distribution of radiation throughout the patient's body is heterogeneous. Also, patient dose is due to a combination of fluoroscopy and radiography (eg, digital subtraction angiography).

Four different metrics have been developed for estimating patient radiation dose from fluoroscopically guided procedures. These are fluoroscopy time, peak skin dose, reference dose, and KAP. Kerma is an acronym for kinetic energy released in matter. Each of these methods measures a different aspect of patient radiation dose. It is essential to understand what is being measured with each method, and the advantages and disadvantages of each method, and to apply these metrics appropriately in clinical practice.

Fluoroscopy time is the length of time that fluoroscopy is in use during a fluoroscopically guided intervention. Measuring and recording this value is simple. The United States Food and Drug Administration (FDA) has required fluoroscopy timers on all fluoroscopic equipment sold in the USA for many years, so this dose metric is universally available. Unfortunately, fluoroscopy time is a poor measurement of dose. It does not take into account either fluoroscopy dose rate or the dose due to radiography (Fig. 1). Fluoroscopy time correlates poorly with other dose metrics.⁹ It should not be used as the sole method to estimate, monitor, or record patient radiation dose unless no alternative is available. Rooms that are equipped only with fluoroscopy time monitoring should be avoided for procedures that may result in a clinically significant radiation dose.³

Skin dose varies considerably from point to point on the patient's body. Peak skin dose is the maximum radiation dose at any point on the patient's skin surface. It includes radiation from the primary X-ray beam and from backscatter from the patient. Because the likelihood and severity of deterministic

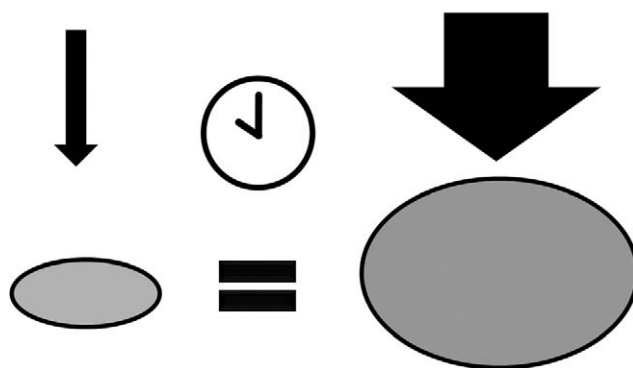


Figure 1 Fluoroscopy time is a poor metric for estimating dose. It is a measure of time, not dose. It does not account for fluoroscopy dose rate or any of the radiation dose from radiography, such as digital subtraction angiography. This figure demonstrates that 2 different patients with different body part thicknesses will experience different fluoroscopy dose rates. If both undergo fluoroscopy for the same length of time, their fluoroscopy time will be the same, but their radiation dose will be different.

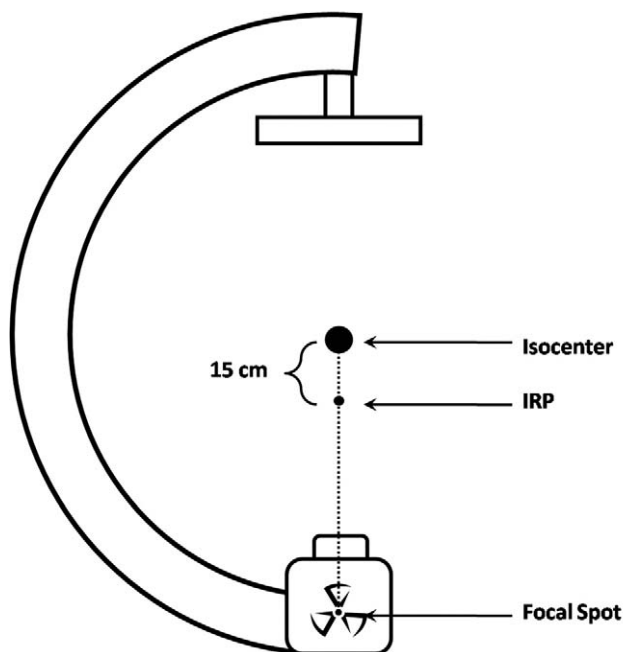


Figure 2 Representation of a C-arm, demonstrating the location of the interventional reference point (IRP). It is located along the central ray of the X-ray beam, 15 cm back from the isocenter of the C-arm toward the focal spot. The isocenter is the point in space about which the C-arm rotates.

effects in a tissue are determined by the dose to that tissue, peak skin dose can be used to predict the occurrence and severity of skin injuries.

Unfortunately, at present peak skin dose is difficult to measure. As of 2009, no commercially available fluoroscopic equipment is able to estimate or record peak skin dose. Measurements can be made using devices, such as thermoluminescent detectors or special film (Gafchromic; International Specialty Products, Wayne, NJ) placed on the skin surface. These devices do not indicate dose directly; they must be analyzed after the procedure. They do not provide real-time feedback, are expensive, often require the services of a medical physicist, and can be cumbersome to use.¹⁰ At present, they are used primarily for research.

Some earlier interventional fluoroscopes had available a software/hardware option that displayed, in real-time, an estimate of skin dose in the form of a skin map.^{11,12} This option is no longer available, but several manufacturers have a similar product in development as of 2009.

Reference dose was first introduced in 2000 by the International Electrotechnical Commission, an international standards organization.¹³ It was originally called cumulative dose. Reference dose is the air kerma for the entire procedure, measured (in Gy) at a fixed point in space called the interventional reference point (or, more recently, the patient entrance reference point). Scatter radiation is not included in the measurement of reference dose. The interventional reference point is a defined point in space, fixed relative to the X-ray equipment, not the patient. For C-arm fluoroscopes, this point is fixed relative to the X-ray tube and is located along the central ray of the X-ray beam, 15 cm back from the

isocenter of the C-arm toward the X-ray tube (Fig. 2).¹³ Modern fluoroscopes measure or calculate reference dose and display the information in real-time at the operator's working position. Since mid 2006, the FDA has required that every fluoroscope sold in the USA be able to measure, display, and record reference dose.¹⁴ This capability has also been available as an option on some interventional fluoroscopes since the mid-1990s.

Reference dose can be thought of as an approximation of the patient's total skin dose for the procedure, but it is not the same as skin dose. It is a substitute for measuring skin dose at multiple points on a patient's body.¹⁵ The radiation field typically moves over a patient's skin during a procedure, and the radiation dose at all these points is included in the reference dose (Fig. 3). Since the reference point is fixed in relation to the X-ray tube and not the patient, it is not always at a constant distance from the patient's skin surface, and in fact, is rarely directly on the skin surface.^{12,15} The reference dose tends to be higher than the peak skin dose.¹⁰ Using reference dose to estimate peak skin dose during a procedure is a conservative method that generally overstates the risk to the patient.¹⁰

KAP is a measure of the total X-ray energy absorbed by the patient. It is the radiation dose (air kerma) at a point in space along the central ray of the X-ray beam, multiplied by the area of the X-ray beam at that point. It is measured in Gy cm^2 . KAP is independent of the source-to-skin distance, since radiation dose decreases as the inverse square of the distance from the focal spot of the X-ray tube (inverse square law), but the area

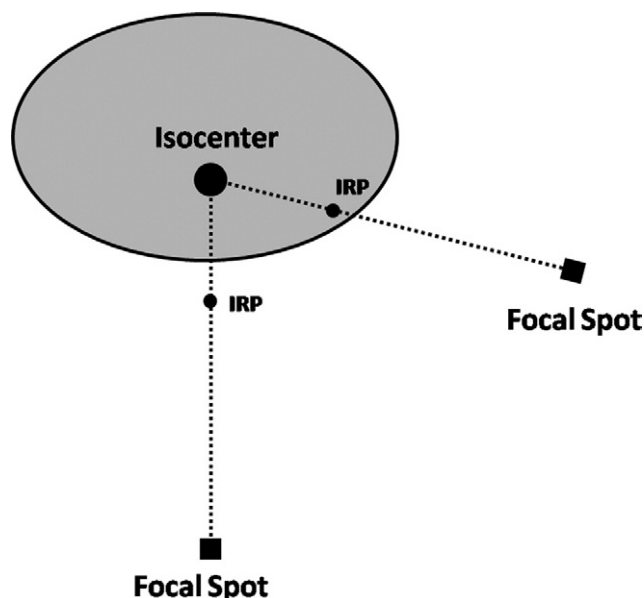


Figure 3 Reference dose measures the air kerma at the interventional reference point (IRP), which is fixed in relation to the X-ray tube but not in relation to the patient. Changes in C-arm angulation or table height have no effect on the reference dose, but do affect peak skin dose. Here, angulation of the C-arm is seen to move the IRP from a point overlying the skin surface to a point inside of the patient. Changes in table height also affect the relationship between the IRP and the skin surface.

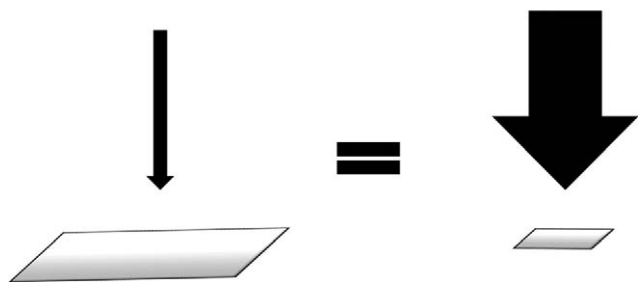


Figure 4 Kerma-area product (KAP) is the product of radiation dose and the area of the irradiated field. This figure demonstrates that a small dose irradiating a large field may yield a KAP similar or identical to that of a large dose irradiating a small field.

of the X-ray beam increases as the square of the distance. The 2 effects cancel each other out.

KAP is a poor estimator of deterministic effects. The KAP when a small area receives a large radiation dose may be the same as the KAP when a large area receives a small radiation dose (Fig. 4). In general, KAP correlates reasonably well with peak skin dose for large groups of patients, but correlates poorly for individual patient procedures.^{9,10}

However, KAP is a useful method for approximating the total X-ray energy absorbed by a patient, as long as the radiation field is confined to the patient through appropriate collimation techniques. KAP is therefore a good metric for estimating stochastic risk from interventional procedures. KAP is widely used in Europe as the standard for comparing doses among procedures and institutions.¹⁶

KAP may be determined using an ionization chamber placed near the collimator or calculated internally in the fluoroscope. Since it is very commonly used in Europe, KAP measurement capability is widely available on interventional fluoroscopes in the USA, as either a standard feature or an option.

Each of the 4 dose metrics has value, but all are different and each estimates a different quantity or aspect of radiation dose. Each must be understood to be used appropriately. Ideally, peak skin dose would be used to estimate patient dose, as it is the most accurate estimate of deterministic risk to a patient.^{3,9} However, since it is difficult to measure, the alternatives from most to least reliable are reference dose, KAP, and fluoroscopy time combined with a count of the number of radiographic images obtained. Reference dose is a reasonable substitute for peak skin dose, but tends to overestimate true risk. KAP is not as reliable a tool for estimating skin dose, but it is particularly useful for measuring the total X-ray energy imparted to a patient and can thus be used to estimate stochastic risk.³ Fluoroscopy time is easily measured, but is a poor estimate of dose and should not be used for this purpose if other metrics are available.³

Limitations of Dose Estimates

Regardless of the metric used to measure patient dose, there is an inherent degree of uncertainty in the measurement. Even the most sophisticated measurement equipment has unavoidable variations in response due to different beam

energies, dose rates, and collimation. Measurement of peak (air) dose at the patient's skin is probably accurate to within $\pm 50\%$ of the actual peak air dose.¹⁵ This means that a reported value of 2 Gy more precisely represents a skin dose value between 1.3 and 3.9 Gy (including the effect of backscatter). Dose data reconstructed from fluoroscopy time and number of radiographic frames are much more uncertain and, after all corrections are factored in, are probably not more accurate than a factor of approximately $+130\%$ and -70% of the best estimated value.¹⁵ For example, a 2 Gy calculated peak air dose at the patient's skin, reconstructed from fluoroscopy time and the number of radiographic frames, is probably more precisely stated as between 0.6 and 4.6 Gy. The uncertainties of estimates of peak skin dose derived from reference dose and KAP are between these 2 extremes.

Using Dose Estimates

It is essential to understand that patient radiation dose alone should never be the reason to halt or not undertake an interventional procedure. High radiation doses and the risks they entail are only 1 piece of the clinical benefit:risk equation that is evaluated when managing complex patients who may have previous high-dose exposures, confounding comorbidities, or require emergency care in an acute setting. The International Commission on Radiological Protection has clearly stated that patient radiation dose must be justified (provide more good than harm) and optimized (no more radiation should be administered than is necessary), but radiation dose limits are inappropriate for patients, as they may do more harm than good.^{17,18}

Although the federal government does not regulate radiation dose during interventional procedures, the FDA has provided guidelines and some state governments have passed laws to enforce certain requirements. The Society of Interventional Radiology and the American College of Radiology have provided guidelines as well.^{3,15,19-21}

Radiation dose should be monitored during procedures either by the operator or by a designated individual in the procedure room, such as a technologist or nurse. Once a certain dose threshold is met, the operator should be notified, and if the procedure continues, notification should be repeated at increments of increasing dose (Table 1).³ This assures operator awareness of patient radiation dose and allows the operator to modify the procedure and make decisions

Table 1 Notification Thresholds for Monitoring Radiation Dose During Fluoroscopic Procedures

Dose Metric	First Notification	Subsequent Notifications
Fluoroscopy time	30 min	15 min
Peak skin dose	2000 mGy	500 mGy
Reference dose	3000 mGy	1000 mGy
Kerma-area product*	300 Gy cm ²	100 Gy cm ²

Adapted from Stecker et al³

*Assumes a 100-cm² irradiated field at the patient's skin surface.

Table 2 Radiation Doses That Should Prompt Patient Follow-up

Dose Metric	Threshold
Fluoroscopy time	40-60 min
Peak skin dose	3000 mGy
Reference dose	5000 mGy
Kerma-area product	500 Gy cm ²

Adapted from Stecker et al³

about the risk versus benefit of continuing a procedure in real time.

Recording radiation dose after all fluoroscopic procedures is important for quality assurance and quality improvement purposes. It is also essential to permit tracking radiation dose in patients who may receive multiple interventions and to ensure that high-dose procedures do not go unrecorded.³ In patients who undergo multiple fluoroscopically guided interventional procedures, using this dose information can help reduce excessive radiation exposure at any single skin site and is an effective way to reduce possible long-term deterministic effects.

When a sufficiently large radiation dose is imparted to the patient during a procedure, certain actions should be taken to ensure that proper follow-up is arranged.³ Radiation dose thresholds that should trigger automatic patient follow-up can be seen in Table 2. When these values are exceeded, the operator should write an appropriate note in the patient's medical record, stating that a significant radiation dose has been administered and indicating the reason.^{3,22} This information may be included in the postprocedure note. The patient should be made aware that a substantial amount of radiation was administered and educated regarding signs of radiation-induced injury.

Patients who have received a sufficiently large radiation dose should have follow-up at 10-14 days and at 1 month after the procedure for possible deterministic effects.^{3,22-24} This can usually be done by telephone. The patient should be instructed to notify the operator and/or medical physicist of the results of self-examination of the irradiated area (either positive or negative). Clinical follow-up should be arranged if the examination is positive. The patient's caregivers or responsible health-care professionals should contact the operator (or designee) if any signs or symptoms of a possible radiogenic deterministic effect are observed. All relevant signs and symptoms should be regarded as radiogenic unless an alternative diagnosis is unambiguously established.⁵

Conclusions

There is no question as to the value of interventional radiology procedure in modern medical care. However, the increasing number and complexity of these procedures have led to more patients receiving higher radiation doses.²⁵ It is therefore more important than ever before to estimate accurately and record appropriately the radiation doses our patients receive, and to follow those patients who have received substantial doses of radiation. Understanding the dose met-

rics used for fluoroscopically guided procedures and using them appropriately are essential for good patient care and the optimal practice of interventional radiology.

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