

Comparison of Four Techniques to Estimate Radiation Dose to Skin During Angiographic and Interventional Radiology Procedures

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PURPOSE: Four techniques used to estimate radiation risk were compared to determine whether commonly used dosimetry measurements permit reliable estimates of skin dose. Peak skin dose (PSD) is known to be the most reliable estimate of risk to skin. The purpose of this study is to determine peak skin dose with use of real-time software measurements and to correlate other measures of dose with PSD.

MATERIALS AND METHODS: Two hundred twelve patients undergoing arch aortography and bilateral carotid arteriography (referred to as "carotid"), abdominal aortography and bilateral lower extremity runoff ("runoff"), or tunneled chest wall port placement ("port") were studied. Fluoroscopy time, dose-area product (DAP), and cumulative dose at the interventional reference point were recorded for all procedures; PSD was recorded for a subset of 105 procedures. The dose index, defined as the ratio between PSD and cumulative dose, was also determined.

RESULTS: In general, correlation values for comparisons between fluoroscopy time and the other measures of dose ($r = .29$ to $.78$) were lower than values for comparisons among DAP, cumulative dose, and PSD ($r = .52$ to $.94$). For all procedures, pair-wise correlations between DAP, cumulative skin dose, and PSD were statistically significant ($P < .01$). The ratio between PSD and cumulative skin dose (dose index) was significantly different for ports versus other procedures (carotid, $Z = 4.62$, $P < .001$; runoff, $Z = 4.52$, $P < .001$), but carotid and runoff procedures did not differ significantly in this regard ($Z = 0.746$, $P = .22$). Within each individual procedure type, the range of values for the dose index varied 156.7-fold for carotid arteriography, 3.2-fold for chest ports, and 175-fold for aortography and runoff.

CONCLUSION: Fluoroscopy time is a poor predictor of risk because it does not correlate well with PSD. Cumulative dose and DAP are not good analogues of PSD because of weak correlations for some procedures and because of wide variations in the dose index for all procedures.

Index terms: Radiation dose • Skin, effects of irradiation on

J Vasc Interv Radiol 2002; 13:391–397

Abbreviations: DAP = dose-area-product, IRP = interventional reference point, PSD = peak skin dose

FLUOROSCOPICALLY guided medical procedures are an essential part of the practice of angiographic radiology.

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Until the early 1990s, these were considered relatively low-dose procedures. Patient safety concerns focused on the relatively low risk of stochastic injury (effects in which the severity of injury does not necessarily vary with dose and no threshold is assumed to exist, such as cancer). Possible deterministic effects (in which the severity of injury varies with dose and a threshold exists, such as hair loss or skin injuries) were not considered a significant risk.

Radiation-induced skin injury has now become an important concern. It has been reported in association with interventional cardiology, interventional neuroradiology, and interventional radiology procedures, including cardiac electrophysiology studies, transjugular intrahepatic portosys-

temic shunt creation, uterine artery embolization, and neuroembolization procedures (1–5). The higher doses being delivered to the patient during these procedures cause these injuries (6,7).

The dose delivered during a fluoroscopically guided procedure differs at different points on the patient's skin for many reasons (patient pathology, radiation field size and location, specifics of the procedure, etc). Because the risk of skin injury at a specific location is related to the radiation dose to that portion of the skin (3,8), the peak skin dose (PSD; the highest dose delivered to any individual portion of the skin during a procedure) determines the risk of injury. Accurate measurement or estimation of PSD and skin dose distribution is desirable but

technically difficult. Real-time dose monitoring procedures have been developed which are capable of continually calculating the delivered patient skin dose (9,10). This real-time quantification allows the operator to evaluate the PSD delivered to the skin and more effectively monitor the risk of skin injury.

Monitoring of cumulative fluoroscopy time has long served as a convenient technique to estimate the amount of exposure to a patient. However, fluoroscopy time is not likely to correlate well with PSD because dose rates can be manually or automatically set over a wide range. In addition, fluoroscopy time is a misleading measure if a large percentage of the delivered radiation dose is from the acquisition of digital images (11). In addition, technical parameters such as beam intensity, beam energy, beam orientation, field size, and distance from the skin all affect the fluoroscopic dose delivered.

Other metrics, such as dose-area product (DAP), cumulative dose, and PSD have been devised to better estimate the risk of radiation injury. Cumulative dose is defined as the total dose delivered during the entire study and includes fluoroscopic and angiographic exposure. It is calculated as if it were delivered to a point at a defined, fixed distance from the gantry isocenter along the central ray of the x-ray beam, termed the interventional reference point (IRP; see Fig 1) (12). PSD also includes fluoroscopic and angiographic exposure.

We determined these four dose metrics (fluoroscopy time, DAP, cumulative dose, PSD) in two angiographic procedures and one interventional radiology procedure. These procedures were chosen because they are usually performed in a relatively standardized way. Our purpose was to determine PSD with use of a real-time computer monitoring system and to evaluate whether commonly used measures of radiation delivery correlate with PSD. We also examined the ratio of PSD to cumulative skin dose (the dose index) for the same procedures.

MATERIALS AND METHODS

Study Design

As part of a quality assurance dosimetry study, we evaluated three

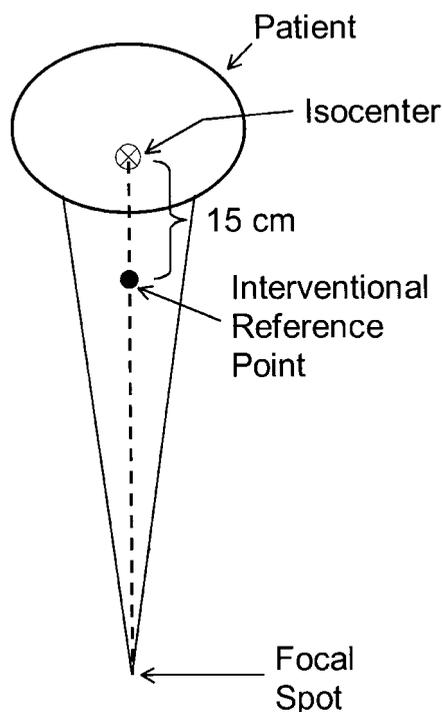


Figure 1. Diagram demonstrating the geometry of the IRP in reference to the focal spot and entrance skin distance. The IRP is located 15 cm from the isocenter, along a line between the isocenter and the focal spot. Depending on the table height and gantry angulation, the IRP may be outside the patient (as depicted here) or inside the patient.

types of fluoroscopically guided interventional or angiographic procedures: arch aortography and bilateral carotid arteriography, abdominal aortography and bilateral lower extremity runoff, and placement of tunneled chest wall venous access ports. These procedures were chosen because they are typically performed in a relatively standardized fashion. We believed that this would simplify comparisons between dose metrics. The three procedures also differ in how radiation is used: carotid arteriography requires acquisition of multiple images of the same region (the neck) with different gantry angulations, lower extremity runoff studies require acquisition of multiple images in a single plane over a relatively large area (abdomen, pelvis, and lower extremities) with relatively little image overlap, and chest port placement requires fluoroscopy over a relatively small area in a single plane with minimal image acquisition.

None of these procedures typically require large radiation doses.

The quality assurance study comprised data recorded from all patients undergoing procedures in the interventional radiology section of our institution. The only data recorded were procedure type, fluoroscopy time, DAP, cumulative dose, and PSD. The study reported here was based on a retrospective review of the quality assurance data for these three procedures. Because the data included in this report were a subset of data acquired for quality assurance purposes, the report was based on a retrospective study, data gathering involved no interaction with patients, the recorded and analyzed data included no patient identifiers, and the study involved no risk or additional radiation exposure to the patient, approval by an institutional review board was not required and informed consent was neither needed nor obtained.

All procedures were performed by one of two attending radiologists, who were assisted by second-year radiology residents in their first or second month of interventional radiology training. Both attending radiologists were fellowship-trained in interventional radiology and held a current Certificate of Added Qualifications in vascular and interventional radiology.

Data

All fluoroscopy and imaging were performed with a single system, a single-plane Multistar T.O.P. angiographic unit (Siemens Medical Systems, Iselin, NJ). As part of a separate concurrent study, an initial physics evaluation was performed on the angiographic unit. The initial evaluation independently verified the unit's entrance skin exposure calibration. We measured the beam output with use of an independent dosimeter (model 35050; Keithley Instruments, Cleveland, OH) at the prescribed focus-to-detector distance and compared the measured output with the unit's internal dosimeter calculation. This comparison was made using polymethyl methacrylate phantoms with different thicknesses in fluoroscopy and digital image acquisition modes. The unit performed within the manufacturer's specifications.

Weekly quality control evaluations

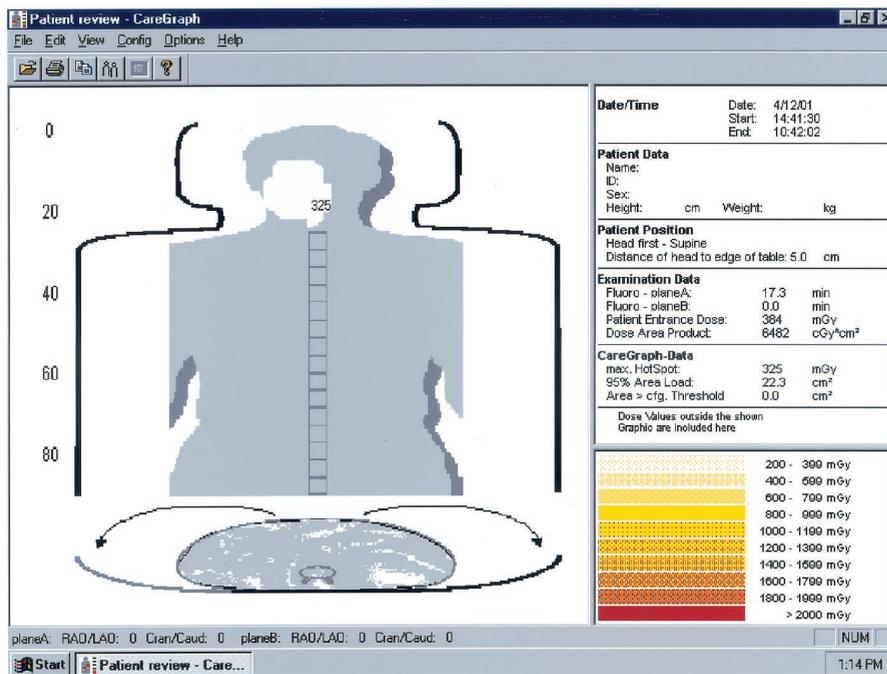


Figure 2. Screen capture image of the dose-mapping software display after carotid arteriography. The patient's name and demographic data have been intentionally obscured. The skin dose map is on the left side of the image. The patient's skin is displayed as if it were unfolded from the midline anteriorly and reflected laterally. This is indicated schematically in the diagram at the left bottom. The peak skin dose for the entire skin surface is indicated in black (325 mGy). The approximate doses to the skin are depicted by various shades of white, yellow, orange and red, with corresponding dose ranges shown in the legend at bottom right. Current values for fluoroscopy time, cumulative dose ("Patient Entrance Dose"), DAP, PSD ("max. Hot Spot"), and the skin area receiving a dose greater than the 95th percentile of skin dose ("95% area load") are shown at the right of the display.

were also performed. For these evaluations, a water phantom was used to verify the consistency of the internal dosimeter for fluoroscopy and digital image acquisition modes. During the study period, variation of fluoroscopy and digital image acquisition dose readings was within $\pm 10\%$ of the baseline established at the initial evaluation.

The angiographic unit incorporates a fluoroscopy timer and automatically measures DAP and calculates cumulative dose. This system fulfills the requirements of the newly released International Electrotechnical Commission standard on safety for interventional fluoroscopy equipment by displaying cumulative dose (12). The cumulative dose is calculated based on the definition of the IRP as described in the International Electrotechnical Commission standard. The IRP is located along the central ray, between

the focus and the gantry isocenter, 15 cm from the isocenter.

"Dose" is a commonly misunderstood word. The formal radiologic definition is the energy absorbed per unit mass of matter. Dose can be considered either in air or in tissue and may or may not incorporate backscatter. For this study, the term "dose" is used to describe absorbed dose per unit mass in matter. The dose measurements provided by the built-in equipment in the angiographic unit are calculated from the output of an ionization chamber adjacent to the collimator leaves and do not include backscatter from the patient or other material that the photons may encounter.

After the study began, the unit was equipped with a skin dose mapping software program (CareGraph; Siemens) that estimates PSD in real time (10). Neither patient preparation nor

modification of the operator's technique is required. PSD and the spatial distribution of skin dose are displayed on a computer monitor (Fig 2).

The dose mapping software uses the patient's height, weight, and position on the angiographic table to model the shape and location of the patient's skin surfaces as an array of 0.5-cm² patches. Table height is used to determine the distance between the focal spot and the skin surface. Because the angiographic system retains information about table position, table height, gantry angle, x-ray output, and beam size and shape, the software can calculate which portions of the skin model are exposed to radiation at any given time.

During the procedure, the operator may move the gantry and table and adjust the collimator. The software calculates which of the skin patches are irradiated, and the corresponding dose rate at each patch, every 500 milliseconds. The dose received by each skin patch is obtained by integrating the dose rate over time. The results are graphically displayed to the operator in real time.

Data were obtained from 212 patients: 93 undergoing carotid arteriograms (35 with data on PSD, 58 without), 57 undergoing chest port placement (34 with, 23 without), and 62 undergoing runoff procedures (36 with, 26 without). Patients in the initial portion of the study did not have data for PSD.

Statistical Analysis

Statistical analysis was performed with scatter plots of fluoroscopy time and/or dose (DAP, cumulative skin dose, and PSD) versus one another. The corresponding Pearson correlation coefficient (*r* value) was determined with use of Excel (Microsoft, Redmond, WA) to describe the linear least squares fit relationship between each pair of data sets. Pair-wise correlations are used to measure whether two ranges of data move together. A positive correlation occurs if large values of one set are associated with large values of the other; a negative correlation occurs if small values of one set are associated with large values of the other and a correlation near zero occurs when values in both sets are unrelated. For each population, we calcu-

Table 1
Dose Data for Each of Three Angiographic or Interventional Radiology Procedure Types

Comparison	Carotid Arteriography	Chest Port Replacement	Aortogram and Runoff
Fluoroscopy time (min)	11.3 ± 5.1 (2.9–28.5)	3.7 ± 1.6 (0.7–7.0)	8.3 ± 6.4 (1.6–28.7)
Dose area product (cGycm ²)	6,406 ± 3,208 (1,363–22,964)	604 ± 587 (66–3,147)	10,391 ± 6,449 (478–34,565)
Cumulative dose (mGy)	862 ± 411 (170–2,510)	89 ± 78 (12–347)	748 ± 585 (10–2,609)
Peak skin dose (mGy)	190 ± 78 (2–337)	30 ± 29 (3–149)	204 ± 189 (2–1,015)

Note.—Data are presented in the form of mean ± SD (range). Doses from fluoroscopy and digital film acquisition were not separated.

lated the two-tailed significance (P value) of the correlation values (r values) to determine whether two samples are likely to have come from the same two unrelated populations. A high correlation value (close to 1) equates to a low P value (close to 0). This low P value shows that there is a very low probability that the samples came from populations that are not correlated. For calculation of the correlation coefficients of DAP and cumulative skin dose versus time, as well as DAP versus cumulative skin dose, data from all 212 patients were used. For calculations involving comparisons with PSD, only the population with PSD data ($n = 105$) was analyzed. Bonferroni corrections (corrections applied to measures of statistical significance when multiple comparisons are performed) were applied when appropriate.

We define dose index as the ratio between PSD and cumulative dose. The dose index may differ for each type of procedure because of the details of the procedure (time spent in a certain area of the body, etc.). It might also differ for each case as a result of patient variation. Therefore, this study investigated the possibility that each procedure may have a unique dose index and that this parameter might provide insight into the correlation of specific procedure types and corresponding patterns of skin dose. For each population, we calculated the dose index for each case and the median value of the dose index. Additionally, 95% confidence intervals (CIs) for the difference between the medians of the two groups were calculated and the Mann-Whitney statistics (rank sum, Z -test) for two independent groups were determined. The Z -test generates a standard correlative

score (Z value) for the medians of rank-sum values to be within a known normal distribution, which in turn can be used to calculate the two-tailed probability (P value) for differences between two populations. In a manner analogous to the Student t test, one can use the Z -test to assess the likelihood that a particular observation is drawn from a particular population. Similarly to the t values, Z values range approximately from -5 to 5 . A high Z value indicates a large difference between the samples and equates to a low P value. It indicates that the two samples have a low probability of being from the same population. The Mann-Whitney calculation was performed with use of Interactive Data Language (Research Systems, Boulder, CO).

RESULTS

The mean, SD, and range for fluoroscopy time, DAP, cumulative skin dose, and PSD are shown for each of the three procedures in **Table 1**. The fluoroscopy times for these procedures seem longer than expected for purely diagnostic procedures and have a wide range. All of the procedures were performed in a teaching hospital in conjunction with junior residents. Because of the extra time required by residents, the DAP and cumulative dose values are higher than would be expected for these procedures when performed by staff interventional radiologists. The outlying data are probably results of patients with difficult anatomy.

Table 2 shows the linear correlation coefficients and statistical significance (P values with Bonferroni correction) for the pair-wise comparisons of the

four methods used to estimate dose for each procedure.

For all three procedures, the correlation coefficient was significant ($P < .05$) for each pair-wise comparison of the four measures of risk, except for the relationship between fluoroscopy time and PSD for runoff procedures. In general, r values for comparisons between fluoroscopy time and the other measures of dose ($r = .29$ to $.78$) were lower than for comparisons among DAP, cumulative dose, and PSD ($r = .52$ to $.94$).

Dose index was calculated separately for each case of all three procedures. The mean, median, SD, range, and 95% CIs for the dose index are shown for each of the three procedures in **Table 3**. The value of this parameter is procedure-specific and was significantly different when comparing chest ports with the other two procedures (ports/carotid arteriography, $Z = 4.62$, $P < .001$; ports/aortography and runoff, $Z = 4.52$, $P < .001$; Mann-Whitney rank-sum test). The dose index did not differ to a significant degree between carotid arteriography and lower extremity runoff procedures ($Z = 0.746$, $P = .22$). More importantly, dose index was very variable within each procedure type. The ratio between the highest and the lowest dose index for each type of procedure was 156.7 for carotid arteriography, 3.2 for chest ports, and 175 for runoff procedures. This ratio is therefore highly variable among procedure types and within individual procedure types.

DISCUSSION

The relationship among fluoroscopy time, DAP, cumulative dose, and PSD is a function of the type of proce-

Table 2
Linear Correlation Coefficients and Statistical Significance for Pair-wise Comparisons of Four Dose Estimation Methods

Comparison	Procedure		
	Carotid Arteriography	Chest Port Placement	Aortogram and Runoff
Fluoroscopy time vs DAP	0.4015; <i>P</i> < .001	0.4837; <i>P</i> < .001	0.3404; <i>P</i> < .05
Fluoroscopy time vs cumulative dose	0.2867; <i>P</i> < .05	0.6531; <i>P</i> < .0001	0.5122; <i>P</i> < .001
Fluoroscopy time vs peak skin dose	0.4491; <i>P</i> < .05	0.7771; <i>P</i> < .0001	0.2929; NS
DAP vs cumulative dose	0.8753; <i>P</i> < .0001	0.8760; <i>P</i> < .0001	0.8110; <i>P</i> < .0001
DAP vs peak skin dose	0.7140; <i>P</i> < .0001	0.9444; <i>P</i> < .0001	0.6030; <i>P</i> < .001
Cumulative dose vs peak skin dose	0.5231; <i>P</i> < .01	0.8912; <i>P</i> < .0001	0.7743; <i>P</i> < .0001

Note.—All *P* values incorporate Bonferroni corrections. Pearson correlation values (*r* values) and two-tailed significance values (*P* values) to determine whether two samples are likely to have come from the same two underlying populations that have the same mean. A high correlation value (close to 1) equates to a low *P* value (close to zero). This was performed for pair-wise comparisons of fluoroscopy time, dose-area-product (DAP), cumulative dose and peak skin dose for each of the three procedures studied.

Table 3
Dose Index Data for Each of Three Angiographic or Interventional Radiology Procedure Types

Procedure	Sample Number (<i>n</i>)	Median	Mean	SD	Range	95% CI
Carotid arteriography	35	0.22	0.25	0.11	0.003–0.47	0.21–0.29
Chest port placement	34	0.38	0.41	0.13	0.25–0.80	0.37–0.45
Aortogram and runoff	35	0.28	0.27	0.14	0.004–0.70	0.22–0.32

CI = mean \pm 1.96 (SD/ \sqrt{n}). Dose index data for each procedure, including mean, median, SD, range, and 95% CI of the mean. Dose index is the ratio between peak skin dose and cumulative dose at the interventional reference point.

procedure. The nature of the procedure determines the proportion of dose from fluoroscopy versus digital imaging, the spatial distribution of dose, and the amount of time the x-ray beam is directed at any particular tissue.

The three procedures we examined differ substantially in how radiation is used, in terms of spatial distribution of the radiation field and in the ratio between fluoroscopy and digital imaging. Carotid arteriography requires moderate amounts of fluoroscopy and substantial numbers of digital images, all directed at a relatively small area of the neck and superior chest and acquired with differing gantry angulation. Runoff studies require relatively little fluoroscopy but large numbers of

digital images of the entire inferior half of the body, acquired primarily in the frontal plane. Placement of chest wall ports requires relatively little fluoroscopy and only one or two digital images, all directed at a small area of the chest. Therefore, it is not surprising that dose index varies depending on the nature of the procedure (Table 3). Equally importantly, dose index varies widely within each procedure type. The cause of this wide variation could arise from differences between operators caused by variations in individual technique. As discussed previously, this study was performed at a teaching hospital and residents were involved in all cases. Much of this variation is also undoubtedly caused

by differences from patient to patient, probably in the form of anatomic variation.

At present, fluoroscopy time is the only dose measurement analogue required by the Food and Drug Administration (13), which regulates radiation-producing medical devices in the United States. Unfortunately, as demonstrated in this study, fluoroscopy time does not correlate well with measurements of absorbed dose for procedures that involve substantial numbers of digital images. This is understandable because the absorbed dose from digital imaging is not reflected in measurements of fluoroscopy time.

Some fluoroscopic equipment is capable of automatically measuring and displaying DAP (measured in units of Gy \cdot cm²) (14–17). DAP meters are typically required by many European regulatory agencies. As a result, they are available as standard or optional equipment in many interventional systems used around the world. DAP is not a useful metric for tracking the potential for skin injury. The same DAP can be delivered to the patient with a large beam size and a low skin dose or with a small beam size and a high skin dose. For this reason, the International Electrotechnical Commission has recently required that tools to determine dose accumulation at a standardized IRP be included in all new interventional systems (Fig 1). Use of a standardized IRP allows the determination of cumulative dose.

Cumulative dose (measured in Gy) is an estimate of the total absorbed radiation dose at the IRP during the procedure. Because it is possible to derive cumulative dose estimates from DAP data if the x-ray field size at the patient's skin is known (18), it is not surprising that DAP and cumulative dose correlated well for all three procedures we studied. However, this is of little practical value for an individual patient undergoing a procedure because x-ray field size and location usually change during the procedure. These changes have an important effect on skin dose and PSD, but they are not incorporated into cumulative dose measurements and are incompletely reflected by DAP measurements. Estimates of skin dose based on DAP measurements have an error of 30%–40% under the best conditions (18).

If some degree of biologic variability is neglected (5), when the skin dose exceeds a 2-Gy threshold, a detectable skin response becomes probable. Cumulative dose provides a rough estimate of the likelihood of skin injury. Various factors affect the accuracy of this estimate. Skin dose will be overestimated if the IRP is outside the patient (ie, when the IRP is closer to the x-ray source than the entrance of the skin surface). This is most likely to occur in axial views of smaller patients or with a high table height. Cumulative dose is also an overestimation of PSD when there is considerable beam or patient movement. Different areas of skin are exposed when different beam orientations are used or the table is moved in the horizontal plane. Skin dose will be underestimated when the IRP is inside the patient (ie, when the IRP is farther from the x-ray source than the entrance of the skin surface). This may occur with highly angulated views or low table heights.

Cumulative dose also does not include any of the effects of x-ray beam size on skin dose. Beam size is a factor if there is an overlap zone between beam ports. Assume, for example, that the dose delivered to the irradiated skin of each port is below the deterministic injury threshold. However, if the skin in the overlap zone is irradiated from more than one beam position, the total dose in the overlap zone may exceed the deterministic threshold.

The likelihood of radiation injury to the most highly irradiated area of skin (and the type of radiation injury) is a function of the dose to that area—the PSD. Fluoroscopy time does not correlate with PSD. One cannot assume that patient injury will be prevented, or the degree of risk accurately assessed, if fluoroscopy time alone is used as a guide.

Because DAP and cumulative skin dose correlate well with PSD for all three procedures we studied, it seems reasonable that either of these dose analogues could be used as a basis for a qualitative estimate of patient risk. However, correlations apply only to large groups of patients. Other studies have shown that calculations of skin dose based on DAP data are not reliable in individual patients (19,20). Analysis of our dose index data shows that there is also marked variability in

the relationship between PSD and cumulative dose. For any individual case, PSD cannot be predicted or determined from cumulative dose data. Because cumulative skin dose is often more than twice the PSD (Table 1), determinations of risk based on cumulative dose may markedly overestimate the risk of radiation injury. Therefore, PSD appears to be the only dose analogue that provides a reliable quantitative estimate of patient risk for skin injury (19,20).

Alternative methods exist to measure the distribution of skin entrance dose (21–24), but all have drawbacks. Thermoluminescent dosimeters require physicist time for calibration and interpretation. They provide an estimate of PSD, but only if they are placed at the site of maximal skin exposure, which is rarely known in advance (25). Radiation therapy verification film can be cumbersome to use and also requires physicist time for interpretation. Both methods are labor-intensive, expensive, and intrusive. None of these techniques provides real-time display of dose data. Studies have been conducted with real-time measurements with use of metaloxide silicon field effect transistors or other devices (9,26). These procedures measure the skin dose at a single point on the surface of the skin and are unable to track dose to other portions of the skin. It has been shown that it is essentially impossible to predict the site of PSD before the procedure (25) and, therefore, single-point measurements are unlikely to capture PSD.

Unlike other techniques, the use of dose-mapping software produces consistent results and does not require any special equipment. Its disadvantage is that the patient's skin is mathematically modeled to a standard body phantom of the same height and weight. This model may not represent the patient's anatomic contours exactly. However, dose-mapping software does allow the entire skin to be monitored simultaneously, whereas other systems do not. Although the data provided by software calculation are based on a model of the patient, they provide a good metric that can be used to monitor real-time doses to any patient. In daily clinical practice, we have found that attention to PSD data during the procedure can improve pa-

tient care in interventional radiology (27). With real-time display of a skin dose map and display of PSD, the interventionalist can monitor the distribution of skin dose during the procedure. In many cases, a slight modification of the position of the x-ray beam on the patient's skin, whether by angulation of the gantry, table movement, or collimation can dramatically reduce PSD. Measurement and mapping of PSD may help decrease the frequency and severity of skin injuries by increasing the operator's awareness of the risk of injury and by demonstrating ways in which PSD can be reduced.

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