Reference Levels for Patient Radiation Doses in Interventional Radiology: Proposed Initial Values for U.S. Practice[1]

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Purpose: To propose initial values for patient reference levels for fluoroscopically guided procedures in the United States.

Materials and Methods: This secondary analysis of data from the Radiation Doses in Interventional Radiology Procedures (RAD-IR) study was conducted under a protocol approved by the institutional review board and was HIPAA compliant. Dose distributions (percentiles) were calculated for each type of procedure in the RAD-IR study where there were data from at least 30 cases. Confidence intervals for the dose distributions were determined by using bootstrap resampling. Weight banding and size correction methods for normalizing dose to patient body habitus were tested.

Results: The different methods for normalizing patient radiation dose according to patient weight gave results that were not significantly different ($P > .05$). The 75th percentile patient radiation doses normalized with weight banding were not significantly different from those that were uncorrected for body habitus. Proposed initial reference levels for various interventional procedures are provided for reference air kerma, kerma-area product, fluoroscopy time, and number of images.

Conclusion: Sufficient data exist to permit an initial proposal of values for reference levels for interventional radiologic procedures in the United States. For ease of use, reference levels without correction for body habitus are recommended. A national registry of radiation-dose data for interventional radiologic procedures is a necessary next step to refine these reference levels.

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First introduced for diagnostic radiologic examinations in the 1990s (1–3), reference levels are a quality assurance and quality improvement tool for controlling radiation dose. They are intended to be a reasonable indication of dose for average-size patients and to provide guidance on what is achievable with current good practice rather than optimum performance (4).

The use of reference levels has been supported by national and international advisory bodies (5–7). These and other organizations have provided guidelines on measuring radiation dose and setting reference levels (1,3,4,8,9).

Reference levels for diagnostic radiologic procedures are derived from data collected for standardized examinations performed on a standard-size patient or phantom (10,11). This method is not suitable for interventional radiologic procedures, where there is no standard procedure or standard-size patient. These procedures demonstrate substantial variability in radiation dose for individual cases, owing to patient, operator, and equipment factors (2).

Advances in Knowledge

- Methods for normalizing patient body habitus yield comparable results when applied to radiation dose data for interventional radiologic procedures.
- Preliminary patient reference levels can be determined for interventional radiologic procedures performed in the United States.
- The 75th percentile kerma-area product data for interventional radiologic procedures in the United States are generally within the range of reported data from European series.
- To the extent that comparison is possible, initial reference levels proposed for the United States are comparable, in terms of fluoroscopy time, to reference levels derived from European practice, but the proposed initial U.S. reference levels allow a larger number of images and a larger radiation dose.

The International Atomic Energy Agency has explored the feasibility of establishing guidance levels for certain cardiac interventional procedures (12). Researchers in various studies have presented reference levels or radiation doses for cardiovascular procedures (12–15) and a limited number of interventional radiologic procedures (16–21).

U.S.–specific reference levels are not currently available for any interventional radiologic procedures, because of a paucity of dose data. The only large series of radiation dose data in the United States is the Radiation Doses in Interventional Radiology Procedures (RAD-IR) study, which was directed by one of the investigators (D.L.M) of this study. This series contains data from 2142 cases of a variety of interventional radiologic procedures, including many procedures that are of particular interest because they are high-dose techniques (22).

Investigators in the RAD-IR study reported mean, minimum, and maximum radiation doses; however, these data are insufficient for establishing reference levels. Constructing reference levels requires information on dose distribution and the uncertainty of the dose distribution (23). In the present publication, the RAD-IR study data are used to derive dose distributions, to evaluate methods for dose normalization, and to form the basis of the presentation of proposed reference levels.

Materials and Methods

RAD-IR Study

The RAD-IR study investigators documented radiation doses from certain interventional radiologic procedures. During 1999–2002, seven academic medical centers in the United States collected radiation dose data for each of 21 different interventional radiologic procedures, as well as for several procedure subsets defined a priori. The results were reported in three parts. Part I (24) provided overall dose data, identified procedures associated with higher radiation doses, analyzed the effect of operator training level on dose, and provided recommendations for recording overall dose. Part II (25) provided skin dose data for a subset of cases. Part III (26) presented the physics data that validated the radiation dose data.

The original RAD-IR study protocol was reviewed and approved by the institutional review board at each participating institution (24,26). The secondary analysis reported here was conducted at the National Naval Medical Center, Bethesda, Md. This analysis was reviewed and approved by the institutional review board of the National Naval Medical Center. The study was Health Insurance Portability and Accountability Act compliant.

Dose Metrics

Four radiation dose metrics, in the units provided by the equipment—reference

Implication for Patient Care

- The proposed initial reference levels will permit individuals and institutions performing interventional radiologic procedures to compare the radiation doses used in their performance of procedures with an external standard.

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Abbreviations:
AVM = arteriovenous malformation
CI = confidence interval
KAP = kerma-area product
RAD-IR = Radiation Doses in Interventional Radiology Procedures

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air kerma in milligrays, kerma-area product (KAP) in centigray–square centimeters, fluoroscopy time in decimal fractions of minutes, and number of fluorographic images—were collected for all 2142 cases.

Fluoroscopy time is easy to measure but is not strongly correlated with radiation risk because dose rates for fluoroscopy can be manually or automatically set over a wide range and because a portion of the radiation dose is owing to acquisition of digital images (27–29). Reference air kerma and KAP have been devised to better estimate the risk of radiation injury (27).

KAP, also known as dose-area product or DAP, is the integral of air kerma (the energy extracted from an x-ray beam per unit mass of air in a small irradiated air volume; for diagnostic x-rays, the dose delivered to that volume of air) across the entire x-ray beam emitted from the x-ray tube. It is a surrogate measure of the amount of energy delivered to the patient (24).

Reference air kerma (also known as reference dose, cumulative dose, or cumulative dose at a reference point) is the air kerma accumulated at a specific point in space (the patient entrance reference point) relative to the gantry of the fluoroscopy system (24). For C-arm fluoroscopy systems, the patient entrance reference point is a point along the central ray of the x-ray beam, 15 cm back from the isocenter toward the focal spot (30).

Procedures Analyzed

Age, height, and weight were recorded for each examination. To minimize the effects of large variations in subject size on the results, we excluded subjects younger than 18 years old. There were 79 such cases, 49 of which are discussed elsewhere (31,32).

Sufficient data (sample sizes ≥30) to develop reasonable 95% confidence intervals (CIs) were not available for all of the procedures in the RAD-IR study database. Some similar procedures (pelvic arterial embolization for trauma or tumor and embolization in the spine for arteriovenous malformation [AVM] or tumor) were grouped together for this analysis to achieve a sufficiently large sample size. Bronchial artery embolization and neuroembolization of spinal lesions were included in this analysis despite sample sizes smaller than 30 because they are potentially high-dose procedures and not directly comparable to other embolization procedures. All other tumor embolization cases were

Table 1

Weight Distribution for Adult Subjects

Procedure	No. of Cases of Procedures ($n = 1957$)	No. of Cases with Patients 60–80 kg ($n = 787$)	Weight of All Adult Subjects (kg)				
			Mean	SD	5th Percentile	50th Percentile	95th Percentile
Transjugular intrahepatic portosystemic shunt creation	134	53	80.2	19.7	52.8	79.4	122.2
Biliary drainage	123	64	74.1	15.6	53.2	71.7	102.1
Nephrostomy							
For obstruction	76	28	77.4	20.5	47.9	79.2	101.9
For stone access	62	21	92.5	23.9	62.3	86.2	138.4
Pulmonary angiography	104	30	89.0	28.4	54.4	81.9	136.1
Inferior vena cava filter placement	274	96	84.2	26.1	52.2	81.2	127.8
Renal or visceral angioplasty							
Without stent	53	24	76.2	17.0	54.9	72.6	106.8
With stent	103*	46	78.4	14.4	55.8	78.0	103.8
Iliac angioplasty							
Without stent	24*	9	76.2	20.4	49.1	74.4	108.2
With stent	93	35	78.2	20.8	48.6	74.8	111.7
Bronchial artery embolization	27	13	72.5	23.4	49.3	68.0	98.1
Hepatic chemoembolization	125	51	77.2	17.3	51.1	76.2	107.8
Uterine fibroid embolization	90	37	78.5	25.9	50.1	72.6	129.2
Other tumor embolization	88	42	75.8	16.4	51.0	75.5	107.4
Gastrointestinal hemorrhage localization and treatment	94	29	83.7	23.5	50.5	81.2	133.7
Embolization in the head							
For AVM	134	57	73.0	18.8	49.4	70.1	108.9
For aneurysm	148	69	72.7	16.3	47.3	72.6	99.8
For tumor	51	22	79.5	19.8	51.7	77.1	115.7
Vertebroplasty	98	41	68.3	16.1	47.6	67.6	91.1
Pelvic artery embolization for trauma or tumor	35	15	78.8	17.7	56.9	74.8	108.0
Embolization in the spine for AVM or tumor	21*	5	84.6	16.4	59.0	88.0	109.8

Note.—SD = standard deviation.

* Normally distributed.

grouped together, because 95% (86 of 91) were performed in the abdomen, 56% (51 of 91) were performed in the liver, 31% (28 of 91) were performed in the kidney, and 8% (seven of 91) were performed elsewhere in the abdomen (24). Of the 2063 cases of procedures performed in adults in the RAD-IR study database, 1957 (95%) were analyzed and were included in this report.

Statistical Analysis

Statistical analysis and graphing, as described later, were performed with R, a statistical analysis package (R Foundation, Department of Statistics and Mathematics, University of Vienna, Vienna, Austria; *http://www.r-project.org*). A difference with $P < .05$ was considered significant.

Normalization of Body Habitus

Patients vary in weight, and entrance radiation dose increases exponentially with body-part thickness. It is desirable to correct for this variation. Weight banding permits restriction of the analysis to subjects with weights between 60 and 80 kg. Size correction allows use of a mathematic transformation to normalize dose data to a standard weight of 70 kg (23,33,34). We tested both methods for normalizing reference air kerma and KAP.

Weight banding was performed by limiting the analyses to subjects with weights between 60 and 80 kg (23).

Size correction was performed as described by Chapple et al (34). A person's equivalent diameter assumes the person to be a cylinder with the density of water. The energy imparted to an individual correlates better with the individual's equivalent diameter than with the individual's weight (33). Equivalent diameter is calculated as $d_e = 2(W/\pi H)^{1/2}$, where d_e is equivalent diameter, W is weight in grams, and H is height in centimeters. Reference air kerma and KAP values can be normalized to the values expected for the reference man defined by the International Commission on Radiological Protection by using a size correction factor F, calculated as $F = \exp[k(d_{eref} - d_{emea})]$, where d_{eref} is the equivalent diameter of reference man (22.9 cm), d_{emea} is the calculated equivalent diameter of the subject, and k is a constant, determined experimentally, that reflects changes in dose for subjects of different sizes owing to changes in kilovolt, milliampere, and spectral filtration settings resulting from automatic changes in fluoroscopic and fluorographic technique for thicknesses of different parts of the body (35). The larger the value of k, the more rapidly radiation dose increases with increasing patient thickness.

The data collected with each fluoroscopy unit in the RAD-IR study were used to calculate k, as described by Chapple et al (34). Details of the data collection are provided elsewhere (26). For each imaging plane, reference air kerma was measured with 10, 20, and 30 cm of polymethylmethacrylate in the beam during fluoroscopy and during image acquisition. Sixty-four sets of measurements were available for use in the calculation of k—initial and final comprehensive dosimetry evaluations for each of the 16 imaging planes for fluoroscopy (32 sets of measurements) and 32 sets of measurements for image acquisition.

Three methods were tested for calculation of k. Each of the 12 rooms for interventional fluoroscopy was considered a separate site. For the simplest method, the uniform method, k was calculated for each of the 64 sets of measurements, and the average of the 64 values was used. For the site-specific average method, all of the k values derived from the fluoroscopic and image acquisition measurements from a site (including the lateral plane in a biplane fluoroscopy room) were averaged to determine a site-specific value of k. This k value was used to normalize the reference air kerma and KAP for subjects examined at each site. For the site-specific combined method, k values derived from the fluoroscopic and image acquisition measurements from a site (including the lateral plane in a biplane fluoroscopy room) were used to calculate separate values of k for fluoroscopy and for image acquisition. The simple average

Figure 1

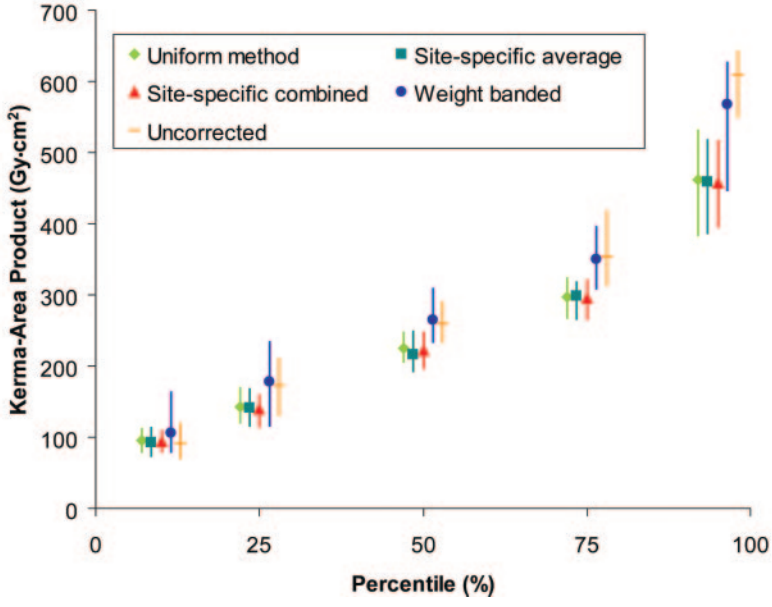

Figure 1: Values for 10th, 25th, 50th, 75th, and 95th percentiles for distribution of KAP (gray–square centimeters) for 125 hepatic chemoembolization procedures. Distributions were determined by using three methods for size correction and one method for weight banding and are compared with values not corrected for patient body habitus. Bars indicate 95% CIs for each percentile. Size-corrected values are lower than values corrected for weight banding and values not corrected for body habitus. Values corrected by using weight banding tended to be larger and had larger confidence intervals than those determined by using size correction. There is no significant difference between values obtained with weight banding and uncorrected values.

of these two values of *k* was then used to normalize the reference air kerma and KAP for subjects examined at each site. The site-specific methods might have greater accuracy if *k* varies among fluoroscopy rooms.

Dose Distributions

Radiation dose data are not normally distributed. Usual methods for determining 95% CIs are not applicable to these dose data (23). Bootstrap resampling is an effective nonparametric method for calculating 95% CIs for these data and does not require an assumption of a normal distribution (23). This method draws multiple random samples, with replacement from the parent population, and produces an estimate of the sampling distribution, the bootstrap distribution, from which better estimates of the standard errors can be obtained (36).

Bootstrap resampling was performed according to the method of Efron and Tibshirani (36). For each procedure or procedure group, we made 1000 bootstrap subsamples, with replacement from the original data, and estimated quantiles and 95% CIs from the bootstrap distribution.

Density curves describe the overall shape of the distribution of the data. A histogram is a simple estimate of density. Kernel density estimation provides a smoother density estimate. A kernel is a symmetric weighting function in which area is unity. Although a histogram is created by binning data into bins of fixed width, kernel density estimation places a kernel function at each data point and sums the result. The smoothness of the kernel density estimate depends on bandwidth, with smoother estimates resulting from larger bandwidth kernels. We used a Gaussian kernel with a bandwidth of 0.25 for reference air kerma and of 40 for KAP.

Results

Dose distributions for the 21 procedures and procedure groups, uncorrected for body habitus, are given in Table E1 (online) for reference air kerma, in Table E2 (online) for KAP, in Table E3 (online) for fluoroscopy time, and in Table E4 (online) for the number of fluorographic images.

Figure 2

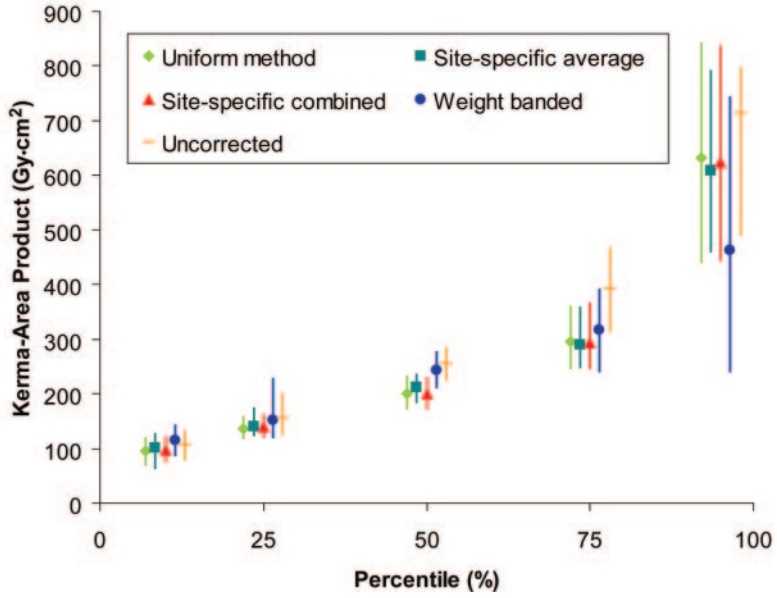

Figure 2: Values for 10th, 25th, 50th, 75th, and 95th percentiles for distribution of KAP (gray–square centimeters) for 90 uterine fibroid embolizations. Distributions were determined by using three methods for size correction and one method for weight banding and are compared with values not corrected for patient body habitus. Bars indicate 95% CIs for each percentile. Size-corrected values are lower than values not corrected for body habitus, but differences are not significant. Values corrected by using weight banding have larger confidence intervals than those determined by using size correction and can be larger, smaller, or approximately the same. Uncorrected values can be larger or approximately the same as those obtained by using size correction or weight banding. There are no significant differences among values obtained with weight banding, values obtained with size correction, and uncorrected values.

The mean weight of the 2063 adult subjects in the RAD-IR study database is 79 kg. The weight distributions for patients undergoing various procedures are shown in Table 1. Weight distribution was normal for only three of the 21 procedure groups. Median weight exceeded the standard 70 kg in all but one of the 21 procedure groups and exceeded 80 kg in six procedure groups. Weight-banding resulted in a two- to threefold decrease in sample size for each procedure group and a 60% decrease in overall sample size from 1957 to 787 subjects (Table 1).

Size correction required calculation of *k*. For 32 measurements of *k* during fluoroscopy, *k* varied from 0.0914 to 0.1709 cm^{-1}. For 32 measurements of *k* during image acquisition, *k* varied from 0.0245 to 0.2102 cm^{-1}. The mean value of *k* for fluoroscopy was 0.1574 cm^{-1}, the mean value of *k* for image acquisition was 0.1694 cm^{-1}, and the mean value of *k* for all 64 measurements (used for the uniform method) was 0.1634 cm^{-1}. The site-specific combined method yielded *k* values for individual sites from 0.1176 to 0.1803 cm^{-1} (mean, 0.1634 cm^{-1}). The site-specific average method yielded *k* values for individual sites from 0.0579 to 0.1840 cm^{-1} (mean, 0.1634 cm^{-1}).

The three methods for size correction yielded similar results, with overlapping 95% CIs. Figure 1 presents the results for a typical procedure. The weight-banding method yielded dose distributions with much wider 95% CIs, because of the smaller number of data points. Weight-banding values could be larger, smaller, or approximately the same as those obtained with size correction (Fig 2). As shown in Figures 1–3, uncorrected values were usually, but not always, greater than those obtained with size correction or weight banding. Differences were typically not significant. For body parts, such as the head, where size changes relatively little with body weight in adults, size correction and

Figure 3

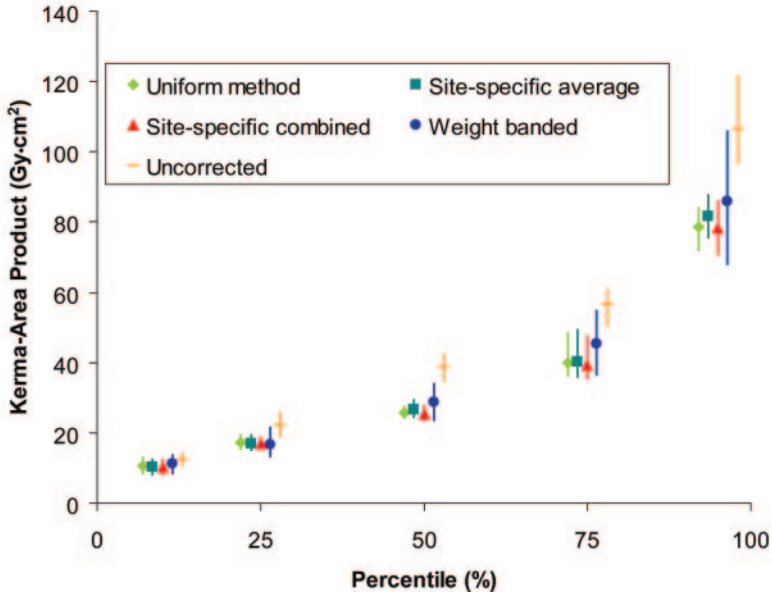

Figure 3: Values for 10th, 25th, 50th, 75th, and 95th percentiles for distribution of KAP (gray–square centimeters) for 274 inferior vena cava filter placements. Distributions were determined by using three methods for size correction and one method for weight banding and are compared with values not corrected for patient body habitus. Bars indicate 95% CIs for each percentile. In general, values corrected by using weight banding have larger 95% CIs than those determined by using size correction. Uncorrected values are larger than values obtained with size correction or weight banding. For 50th percentile values, this difference is significant.

Figure 4

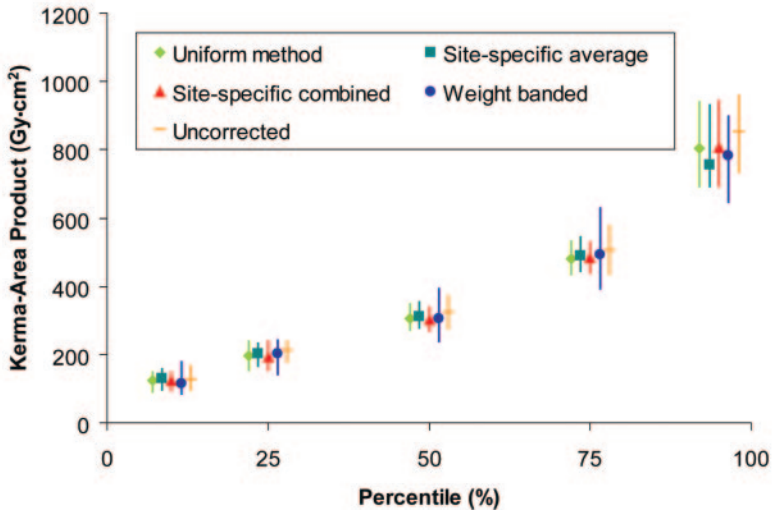

Figure 4: Values for 10th, 25th, 50th, 75th, and 95th percentiles for distribution of KAP (gray–square centimeters) for 134 cases of embolization of AVM in the brain or face. Distributions were determined by using three methods for size correction and one method for weight banding and are compared with values not corrected for patient body habitus. Bars indicate 95% CIs for each percentile. Because size of the head in adults changes relatively little with body weight, neither size correction nor weight banding values differ substantially from uncorrected values.

weight banding yielded values similar to the uncorrected values (Fig 4). Density plots for hepatic chemoembolization data (Fig 5) demonstrate the effect of size correction.

Table 2 presents 75th percentile reference air kerma and KAP for the various procedure groups in the RAD-IR study, with size corrected with the uniform method. Size correction was not necessary for fluoroscopy time or number of images.

Table 3 provides proposed reference levels, uncorrected for patient weight, for specific interventional radiologic procedures performed in adults. The proposed reference levels for each of the four dose metrics are rounded values approximately midway between the 75th percentile and the upper bound of the 75th percentile (Tables E1–E4 [online]).

Discussion

To use reference levels as a quality improvement tool, institutions or individual practitioners collect radiation dose data for cases of a procedure performed in their own practice. The recommended number of cases varies from 10 to more than 50, with the latter number suggested because of the high individual variability of cases of image-guided interventional procedures (1,19). The mean radiation dose for the procedure is then compared with the reference level. If it exceeds the reference level, the fluoroscopy equipment should be investigated. If the fluoroscopy equipment is functioning properly and within specification, procedure protocols and operator technique should be examined (37–39).

Reference levels are a guide to good practice, but they are neither dose limits nor threshold levels that define competent performance of the operator or the equipment (40). Reference levels do not apply to individual cases. If the radiation dose for a specific case or the mean dose for a number of cases of a procedure exceeds the reference level, it does not mean that the procedure or procedures have been performed improperly. Similarly, a mean dose for a procedure that is less than the reference level does not guarantee that the procedure is being performed optimally (39).

In Europe, KAP is commonly used for

Figure 5

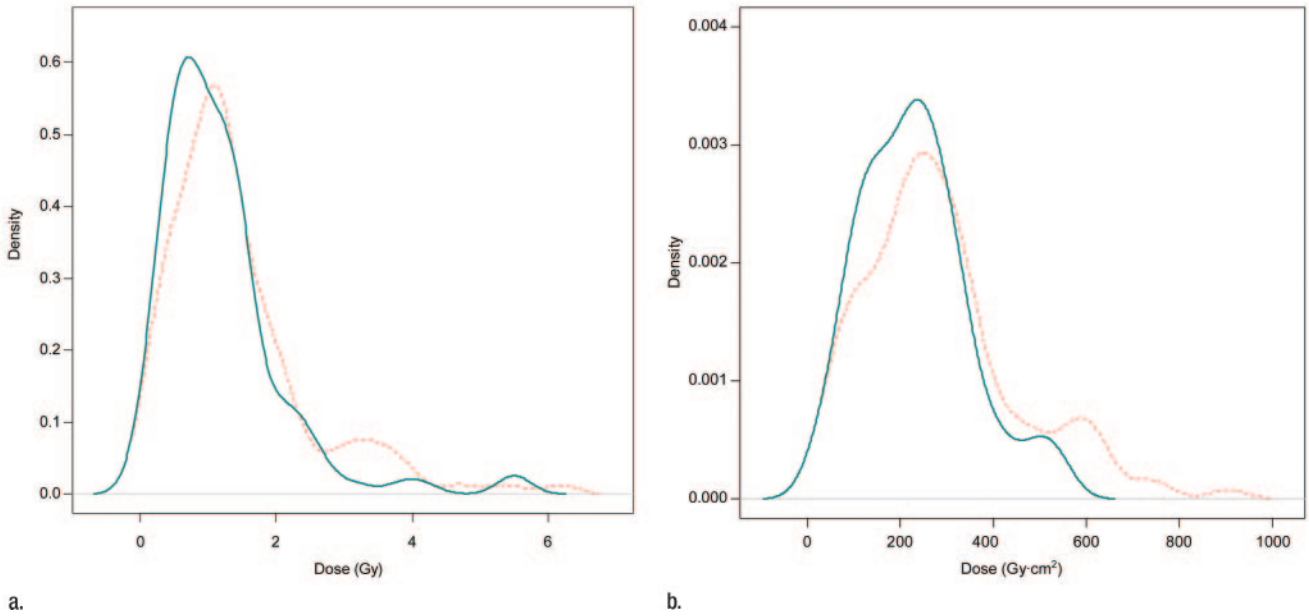

Figure 5: Density plots for **(a)** reference air kerma (grays) and **(b)** KAP (gray–square centimeters) for 125 hepatic chemoembolization procedures by using kernel density estimation, demonstrating effect of size correction. Dashed line = density for original 125 data points (uncorrected for body habitus), solid line = density for data after size correction by using uniform method.

Table 2

Size-corrected 75th Percentile Reference Air Kerma and KAP for Adult Subjects

Procedure	No. of Cases of Procedures	Reference Dose (Gy)		KAP (Gy · cm²)	
		75th Percentile Value	95% CI	75th Percentile Value	95% CI
Transjugular intrahepatic portosystemic shunt creation	134	2.162	1.689, 2.502	352.16	294.64, 428.12
Biliary drainage	123	0.965	0.767, 1.195	80.36	62.34, 97.11
Nephrostomy					
For obstruction	76	0.272	0.226, 0.342	25.15	17.67, 31.68
For stone access	62	0.406	0.283, 0.549	27.53	20.56, 38.44
Pulmonary angiography	104	0.293	0.255, 0.341	61.76	50.28, 75.90
Inferior vena cava filter placement	274	0.146	0.128, 0.169	39.83	36.42, 48.49
Renal or visceral angioplasty					
Without stent	53	1.082	0.880, 1.487	144.33	124.96, 189.92
With stent	103	1.552	1.396, 1.693	183.75	154.67, 214.67
Iliac angioplasty					
Without stent	24	1.015	0.805, 1.187	180.75	123.93, 221.06
With stent	93	1.316	1.008, 1.629	222.83	177.15, 261.98
Bronchial artery embolization	27	1.312	1.041, 1.699	159.72	123.60, 232.03
Hepatic chemoembolization	125	1.448	1.348, 1.548	296.50	267.52, 323.63
Uterine fibroid embolization	90	2.486	2.050, 3.134	295.87	247.04, 359.43
Other tumor embolization	88	1.699	1.390, 2.143	310.12	270.79, 362.83
Gastrointestinal hemorrhage localization and treatment	94	2.056	1.797, 2.599	319.15	269.16, 360.82
Embolization in the head					
For AVM	134	5.340	4.615, 5.937	479.16	435.02, 530.79
For aneurysm	148	4.441	3.960, 5.239	339.47	312.49, 387.46
For tumor	51	4.169	3.479, 5.070	403.21	319.55, 498.96
Vertebroplasty	98	1.848	1.479, 2.243	107.68	85.33, 129.72
Pelvic artery embolization for trauma or tumor	35	1.874	1.749, 2.167	353.90	257.39, 464.12
Embolization in the spine for AVM or tumor	21	5.072	3.453, 7.456	476.28	314.98, 887.63

reference levels. In the United States, reference air kerma is more available, because the U.S. Food and Drug Administration has required all new fluoroscopy units to display reference air kerma since mid-2006. Either dose metric is acceptable. It may be useful to evaluate several different dose metrics for the same procedure (39). For example, if dose levels in a particular institution exceed the reference level, evaluation of fluoroscopy time and the number of images obtained may help to determine whether fluoroscopy time is excessive, an excessive number of images were obtained, or both. If KAP is high but reference air kerma is within the acceptable range, this finding may indicate insufficient collimation.

Radiation doses that are substantially lower than expected may be associated with poor image quality or inadequate diagnostic information. Radiation doses well below the reference level may require investigation (40). An International Atomic Energy Agency study recommends the 10th percentile (termed an "action level," as opposed to a reference level) as an appropriate action level at which to initiate an evaluation of image quality (12). If the mean dose at the local institution is less than the 10th percentile for the same procedure in the population used to define reference levels, evaluation of image quality should be performed (12).

The dose rate for fluoroscopy and the dose for fluorography are both dependent, in part, on the thickness of the body part being imaged (41). U.S. and European populations differ in weight. In a United Kingdom series, the range in mean weight of the four groups of patients undergoing fluoroscopic procedures (9477 patients in total) was 66–69 kg (34). In a Belgian series, the mean weight of 7514 patients was 73 kg (42). In our series, however, the mean weight of the adult subjects was 79 kg (Table 1). For six (29%) of our 21 subgroups, the mean weight was greater than 80 kg; the mean weight was less than 70 kg for only one (5%) subgroup (Table 1).

To compare radiation dose among populations, it is necessary to normalize reference air kerma and KAP data by compensating for differences in patient size. This normalization is not necessary for fluoroscopy time or the number of images obtained, because these two dose metrics are not affected by the thickness of the body part.

We evaluated several methods for normalizing body habitus. Weight banding is the simplest method. With a large data set, weight banding appears to reduce the standard deviation of the data more successfully than does size correction by using equivalent diameters (23).

Unfortunately, weight banding requires that large amounts of data be discarded and results in wide 95% CIs. In general, there were no significant differences between the values for the distribution percentiles obtained with weight banding and the uncorrected values (ie, the 95% CIs overlapped). Weight banding is not useful for small sample sizes.

Size correction permits efficient use of dose data but is cumbersome for individual institutions to implement. A medical physicist needs to determine k, and the correction must be calculated for each patient. Individual practitioners and smaller institutions are unlikely to have resources readily available to use size correction. The method is useful, however, to compare regional or national reference levels. We observed no significant differences in the results obtained from the three methods for applying k. The simplest method—the uniform method—is adequate. Because weight banding only normalizes weight, whereas size correction also eliminates the dose increase caused by automatic adjustments in fluoroscopic and fluorographic technique, the distribution percentiles are lower for size correction than they are for weight banding.

For individual practices in the United States, it is sufficient to use reference levels that have not been corrected for patient body habitus. Recording patient weight may be useful. If the mean weight

Table 3

Proposed Patient Reference Levels, Not Corrected for Body Habitus, for Certain Interventional Radiologic Procedures

Procedure	Reference Dose (Gy)	KAP (Gy · cm^2)	Fluoroscopy Time (min)	No. of Images
Transjugular intrahepatic portosystemic shunt creation	3.00	525	60	300
Biliary drainage	1.40	100	30	20
Nephrostomy				
For obstruction	0.40	40	15	12
For stone access	0.70	60	25	14
Pulmonary angiography	0.50	110	10	215
Inferior vena cava filter placement	0.25	60	4	40
Renal or visceral angioplasty				
Without stent	2.00	200	20	210
With stent	2.30	250	30	200
Iliac angioplasty				
Without stent	1.25	250	20	300
With stent	1.90	300	25	350
Bronchial artery embolization	2.00	240	50	450
Hepatic chemoembolization	1.90	400	25	300
Uterine fibroid embolization	3.60	450	36	450
Other tumor embolization	2.60	390	35	325
Gastrointestinal hemorrhage localization and treatment	3.80	520	35	425
Embolization in the head				
For AVM	6.00	550	135	1500
For aneurysm	4.75	360	90	1350
For tumor	6.20	550	200	1700
Vertebroplasty	2.00	120	21	120
Pelvic artery embolization for trauma or tumor	2.50	550	35	550
Embolization in the spine for AVM or tumor	8.00	950	130	1500

Table 4

Comparison of 75th Percentile KAP from the RAD-IR Data with Published European Dose Data

Procedure	RAD-IR Data		Data from Switzerland*	Data from Canary Islands†	Data from Belgium‡	Data from Spain§	Data from Italy‖	Data from Europe#
	Size Corrected	Uncorrected						
Transjugular intrahepatic portosystemic shunt creation	352	437	. . .	. . .	. . .	. . .	. . .	. . .
Biliary drainage	80	94	312	184	. . .	80	. . .	. . .
Nephrostomy								
For obstruction	25	32	. . .	73	. . .	. . .	62**	18
For stone access	28	47	. . .	. . .	. . .	. . .	62**	. . .
Pulmonary angiography	62	101	. . .	. . .	. . .	. . .	. . .	. . .
Inferior vena cava filter placement	40	57	. . .	. . .	. . .	. . .	. . .	. . .
Renal or visceral angioplasty								
Without stent	144	185	. . .	. . .	. . .	. . .	. . .	. . .
With stent	184	221	. . .	. . .	. . .	. . .	. . .	. . .
Iliac angioplasty								
Without stent	181	214	. . .	. . .	80	. . .	. . .	. . .
With stent	223	277	431	. . .	. . .	94	. . .	. . .
Bronchial artery embolization	160	170	. . .	. . .	. . .	. . .	. . .	. . .
Hepatic chemoembolization	297	353	629	. . .	. . .	289	. . .	121
Uterine fibroid embolization	296	392	. . .	. . .	. . .	236	. . .	. . .
Other tumor embolization	310	357	. . .	. . .	. . .	. . .	. . .	. . .
Gastrointestinal hemorrhage localization and treatment	319	463	. . .	. . .	. . .	. . .	. . .	. . .
Embolization in the head								
For AVM	479	505	352**	. . .	. . .	. . .	338**	. . .
For aneurysm	339	341	352**	. . .	. . .	. . .	338**	. . .
For tumor	403	472	352**	. . .	. . .	. . .	338**	. . .
Vertebroplasty	108	107	. . .	. . .	. . .	. . .	. . .	. . .
Pelvic artery embolization for trauma or tumor	354	417	. . .	. . .	. . .	. . .	. . .	. . .
Embolization in the spine for AVM or tumor	476	772	. . .	. . .	. . .	. . .	. . .	. . .

Note.—KAP was measured in gray—square centimeters.

* Data are from Verdun et al (17).

† Data are from Ruiz Cruces et al (44).

‡ Data are size-corrected dose data and are from Bleeser et al (42).

§ Data are from Vano et al (15).

‖ Data are from Brambilla et al (45).

Data are from Vano et al (19).

** Data were not subdivided according to clinical indication or type of lesion.

of the patients in the individual's practice is greater or less than that observed in the RAD-IR study, reference levels may need to be adjusted toward the upper or lower bound of the 95% CI, as appropriate. This approach, while less accurate than size correction, is much simpler.

Our results can be compared with those of others. We determined a mean value of k of 0.1634 cm^{-1}. Values of 0.14, 0.158, and 0.26 cm^{-1} have been reported in the literature (34,42,43).

A limited comparison between 75th percentile dose data from the United States and data determined in other countries is possible. In European surveys, dose data are often given only for KAP. Table 4 shows the comparison of size-corrected and uncorrected 75th percentile dose data from this study with 75th percentile dose data from other countries and Europe (16,17,19,42,44,45). Substantial variability is evident. Our data are generally within the range of other reported data. Sufficient data exist to permit an initial proposal of values for reference levels for interventional radiologic procedures in the United States.

Only limited comparison is possible between the proposed U.S. reference levels and reference levels determined for practice elsewhere (19–21). Reference levels have not been published for most of the procedures in our series. Where comparative data exist, the procedures are defined somewhat differently and there are different methods for specifying reference levels. The third quartile (75th percentile) often is used to establish reference levels (21). However, Marshall and colleagues (23) recommend using the upper confidence limit of the 75th percentile of the dose distribution for procedures with wide variation in patient dose resulting from complexity. This avoids excessively stringent reference levels caused by sampling limitations in the data. We have adopted a compromise between these positions.

To the extent that comparison is possible, initial reference levels proposed for the United States are comparable to European reference levels for fluoroscopy time. Proposed initial U.S. reference levels permit a larger number of images and a greater radiation dose (Table 5). This finding is, in part, caused by both the larger body habitus of the U.S. population and the greater number of images per case in the United States. The finding might also be a result of higher dose rates for fluoroscopy in the United States. Other explanations must also be considered. Differences in procedure definitions, dose data not corrected for patient size, a heavier U.S. population, relatively small sample sizes (with resultant large 95% CIs), and reference levels constructed differently all contribute to reference levels that are relatively large compared with European values. However, reference levels are not intended to indicate an optimum level of radiation dose but are a guide to the borderline between acceptable and unacceptable radiation dose management practices (1).

Results of a comparison of U.S. and European reference levels for these procedures suggest that there is room for improvement in U.S. practice and help define where improvement efforts should be directed. These results also highlight the value of establishing reference levels for multiple dose metrics.

We expect that U.S. reference levels will decrease over time as outlier institutions improve their equipment and practices. In the United Kingdom, reference levels derived from data in the 2000 review are approximately 20% lower than those derived from data in the 1995 review and are approximately one-half of those determined in the mid-1980s (46).

The RAD-IR study data are subject to a number of limitations. First, all dose data were collected from academic medical centers in relatively large metropolitan areas. The doses might be higher than those collected from cases of procedures performed at nonacademic sites or institutions in areas of smaller population, because the cases of procedures performed at academic referral centers may be more complex and because less-experienced operators (trainees) tend to use more time and radiation to perform procedures than do experienced interventional radiologists (17,47). Doses might also be too low, because the staff interventional radiologists who performed these procedures were highly trained and experienced individuals who knew that the radiation doses for these procedures were being recorded (48).

Second, all procedures were performed with equipment from a single manufacturer (Siemens Medical Systems, Malvern Pa) equipped with dose-reduction technology. All of the fluoroscopy units used in the RAD-IR study were equipped with image intensifiers. When these data were collected, the equipment was state of the art. More modern fluoroscopy units have solid-state flat-panel detectors that may permit lower patient radiation doses (49,50).

Third, all fluoroscopy units were carefully evaluated at the beginning and end of the RAD-IR study. The accuracy of the integrated dosimeters was also checked periodically (26). Procedures performed with other equipment, performed with equipment without the same integrated dose reduction technology, or performed with equipment less carefully

Table 5

Comparison of Reference Levels Derived from the RAD-IR Data with Published European Reference Levels for Similar Procedures

Procedure	This Study			Other Surveys		
	KAP (Gy · cm^2)	Fluoroscopy Time (min)	No. of Images	KAP (Gy · cm^2)	Fluoroscopy Time (min)	No. of Images
Nephrostomy						
Indication not specified	. . .	. . .	. . .	20,* 14†	15,* 5.1†	. . .
For obstruction	40	15	12	. . .	. . .	. . .
For stone removal	60	25	14	. . .	. . .	. . .
Biliary drainage or intervention	. . .	. . .	. . .	50†	15†	. . .
Biliary drainage	100	30	20	80,‡ 240§	20,‡ 25§	27,‡ 30§
Hepatic embolization	. . .	. . .	. . .	150,* 620§	30,* 30§	100,* 160§
Hepatic chemoembolization	400	25	300	289‡	24‡	182‡
Other tumor embolization	390	35	325	. . .	. . .	. . .
Iliac angioplasty with stent	300	25	350	94,‡ 460§	11,‡ 25§	154,‡ 200§
Cerebral embolization						
Indication not specified	. . .	. . .	. . .	440§	50§	800§
For AVM	550	135	1500	. . .	. . .	. . .
For aneurysm	360	90	1350	. . .	. . .	. . .
For tumor	550	200	1700	. . .	. . .	. . .
Uterine fibroid embolization	450	36	450	236‡	30‡	192‡

* Data are from Vano et al (19).

† Data are from Hart et al (20).

‡ Data are from Vano et al (15).

§ Data are from Aroua et al (21).

and consistently maintained may result in higher patient radiation doses.

Fourth, the fluoroscopy equipment used for the procedures in the RAD-IR study is now at least 7 years old, and the procedures were performed between 7 and 10 years ago. Although similar equipment is still in common use in the United States, newer equipment, improved techniques, and greater awareness of radiation dose concerns may now allow some procedures to be performed with lower doses owing to advances in technology. There have also been advances in medical devices since the RAD-IR study was conducted, leading to changes in the way some procedures are performed.

Fifth, the sample sizes in the RAD-IR study are substantially smaller than those used for determination of national reference levels in other countries. Marshall and colleagues (23) consider that radiation dose data from at least 100 patient examinations, performed in several fluoroscopy suites, are needed for a reasonably well-defined reference level. Ideally, reference levels for a procedure should be based on data from at least 20 fluoroscopy units, with 10 cases of procedures performed by using each unit—a minimum of 200 cases (42). Series from other countries have included data on more than 7500 examinations (34,42). With fewer data points, 95% CIs become much larger.

There is a clear need for a U.S. national registry of radiation dose data for interventional procedures. This registry should also include more commonly performed, lower-dose procedures, such as central venous catheter placement (51). Continuous collection and analysis of data over time from a large number of institutions will undoubtedly permit considerable refinement in reference levels.

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