Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study
Part I: Overall Measures of Dose

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PURPOSE: To determine patient radiation doses for interventional radiology and neuroradiology procedures, to identify procedures associated with higher radiation doses, and to determine the effects of various parameters on patient doses.

MATERIALS AND METHODS: A prospective observational study was performed at seven academic medical centers. Each site contributed demographic and radiation dose data for subjects undergoing specific procedures in fluoroscopic suites equipped with built-in cumulative dose (CD) and dose–area–product (DAP) measurement capability compliant with International Electrotechnical Commission standard 60601–2–43. The accuracy of the dosimetry was confirmed by comprehensive measurements and by frequent consistency checks performed over the course of the study.

RESULTS: Data were collected on 2,142 instances of interventional radiology procedures, 48 comprehensive physics evaluations, and 581 periodic consistency checks from the 12 fluoroscopic units in the study. There were wide variations in dose and statistically significant differences in fluoroscopy time, number of images, DAP, and CD for different instances of the same procedure, depending on the nature of the lesion, its anatomic location, and the complexity of the procedure. For the 2,142 instances, observed CD and DAP correlate well overall ($r = 0.83$, $P < .000001$), but correlation in individual instances is poor. The same is true for the correlation between fluoroscopy time and CD ($r = 0.79$, $P < .000001$). The correlation between fluoroscopy time and DAP ($r = 0.60$, $P < .000001$) is not as good. In 6% of instances (128 of 2,142), which were principally embolization procedures, transjugular intrahepatic portosystemic shunt (TIPS) procedures, and renal/visceral artery stent placements, CD was greater than 5 Gy.

CONCLUSIONS: Most procedures studied can result in clinically significant radiation dose to the patient, even when performed by trained operators with use of dose-reducing technology and modern fluoroscopic equipment. Embolization procedures, TIPS creation, and renal/visceral artery stent placement are associated with a substantial likelihood of clinically significant patient dose. At minimum, patient dose data should be recorded in the medical record for these three types of procedures. These data should include indicators of the risk of deterministic effects as well as the risk of stochastic effects.

J Vasc Interv Radiol 2003; 14:711–727

Abbreviations: CI = confidence interval, CD = cumulative dose, DAP = dose–area–product, DPF = digital pulsed fluoroscopy, FDA = Food and Drug Administration, ICRP = International Commission on Radiological Protection, IEC = International Electrotechnical Commission, IRP = interventional reference point, IVC = inferior vena cava, PSD = peak skin dose, RAD-IR = Radiation Dose in Interventional Radiology (study), SPECF = special fluoroscopy, SPF = special pulsed fluoroscopy, TIPS = transjugular intrahepatic portosystemic shunt. Several terms have specialized meanings within the context of medical physics. These terms are defined in the Appendix and are indicated in the text with an asterisk when first used.

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None of the authors have identified a potential conflict of interest.

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DOI: 10.1097/01.RVI.0000079980.80153.4B

Table 1
Data for a Variety of Interventional Radiology and Interventional Neuroradiology Procedures

Procedure Description	Total Cases	Fluoroscopy Time (min)			Number of Images		
		Mean	Range	95% CI*	Mean	Range	95% CI*
TIPS creation	135	38.7	3.5–153.1	34.2–43.3	231	5–813	202–260
Biliary drainage	123	23.6	1.1–174.4	20.0–27.3	15	2–53	13–16
Nephrostomy							
Obstruction	79	10.5	1.3–56.9	8.7–12.2	9	1–44	7–11
Stone access	64	17.6	3.0–79.4	13.8–21.5	10	3–40	9–12
Pulmonary angiography							
No IVC filter	106	8.9	1.6–54.4	7.1–10.6	167	37–599	150–185
IVC filter	17	13.4	1.4–34.2	9.0–17.8	151	4–370	102–201
IVC filter placement only	279	2.8	0.7–11.4	2.6–3.1	33	1–183	30–36
Renal/visceral angioplasty							
No stent	53	16.5	3.1–106.6	12.1–20.9	139	25–483	115–164
Stent	103	21.6	4.1–86.9	18.5–24.6	159	11–578	138–179
Iliac angioplasty							
No stent	24	13.4	3.3–25.4	11.0–15.8	175	57–421	137–212
Stent	93	18.4	4.6–66.4	15.8–20.9	241	55–675	215–267
Central venous reconstruction							
SVC	12	13.5	6.1–20.4	10.4–16.6	131	53–310	82–179
IVC	3	20.6	8.6–31.1	–	361	101–831	–
Aortic fenestration	2	35.1	29.1–41	–	235	98–371	–
Bronchial artery embolization	27	34.7	6.7–63.1	28.7–40.8	284	119–704	227–341
Hepatic chemoembolization	126	16.8	2.1–69.5	14.8–18.9	216	16–586	197–235
Pelvic arterial embolization							
Trauma	18	20.1	5.7–61.7	13.2–27.0	321	76–580	245–396
Tumor	19	28.4	8.6–91.9	18.5–38.3	418	108–1,004	304–531
Fibroids	90	29.5	2.0–101.4	26.3–32.7	305	15–991	264–346
AVM	12	38.4	16.1–61	29.1–47.8	531	223–1,190	360–703
Aneurysm	4	24.4	11.5–36.5	–	376	113–699	–
Pelvic vein embolization							
Ovarian vein	6	44.5	23.4–64	–	139	63–187	–
Varicocele	14	17.3	6.4–40.5	12.2–22.4	31	6–127	10–51
Other tumor embolization	91	21.7	2.5–89.7	18.1–25.3	229	14–625	202–256
Peripheral AVM embolization	17	23.8	3.4–60	15.7–31.9	361	18–858	249–474
GI hemorrhage: diagnosis/therapy	94	25.8	3.5–93.7	22.2–29.5	309	8–1,300	265–354
Neuroembolization/head							
AVM	177	92.5	2.6–313.7	83.3–101.8	1,037	71–2,654	969–1,104
Aneurysm	149	75.0	15.2–401.3	68.2–81.7	1,070	292–2,440	1,005–1,134
Tumor	56	106.0	16.2–276.5	87.1–125.0	1,138	364–2,612	989–1,286
Neuroembolization/spine							
AVM	10	72.9	34.4–170.4	40.9–104.9	1,300	606–1,995	967–1,633
Aneurysm	1	34.8	–	–	229	–	
Tumor	13	73.9	31.9–136.6	55.0–92.7	699	215–1,181	523–875
Stroke therapy	9	42.9	19.1–89.5	24.2–61.7	563	290–1,092	375–751
Carotid stent placement	18	40.5	18.5–64.5	33.1–48.0	721	167–2,216	492–949
Vertebroplasty	98	16.2	3.1–54	14.4–17.9	77	0–484	63–92

* Shown for all procedures with data on more than six cases.
Note.—AVM = arteriovenous malformation; SVC = superior vena cava.

FLUOROSCOPICALLY guided medical procedures are an essential part of the contemporary practice of medicine. By and large, the risk of stochastic* or deterministic* injury as a result of radiation exposure during these procedures is low.

Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. The majority of instances reported in the literature or to the United States Food and Drug Administration (FDA) result from cardiac radiofrequency ablation or coronary angioplasty (1,2). Some reported skin injuries were associated with transjugular intrahepatic portosystemic shunt (TIPS) creation, renal angioplasty, multiple hepatic/biliary procedures, or embolization (1–6). The frequency of injury is unknown.

The highest dose is to the skin at the entrance site of the radiation beam. Typical manifestations of radiation injury to the skin range from transient erythema at low doses to dermal necrosis or chronic ulceration at very high doses (7). Radiation-induced skin effects are deterministic. The threshold absorbed dose* for transient skin erythema is typically estimated at 2 Gy (200 rad) (8). Some patients may have more severe reactions at the same or

Table 1
Continued

DAP (cGy·cm^2)			Cumulative Dose (mGy)		
Mean	Range	95% CI*	Mean	Range	95% CI*
33,535	1,427–136,443	29,071–37,999	2,039	104–7,160	1,760–2,317
7,064	302–38,631	5,848–8,281	907	21–4,831	730–1,083
2,555	41–21,225	1,805–3,305	257	3–2,169	185–328
4,514	47–41,850	2,859–6,170	611	10–6,178	364–857
7,731	957–41,416	6,520–8,942	342	34–1,479	300–384
10,826	2,596–26,514	8,072–13,580	465	76–987	356–575
4,451	170–20,327	4,079–4,822	166	9–680	152–181
15,749	2,619–104,075	11,633–19,866	1,183	157–5,482	892–1,474
19,004	983–72,420	16,654–21,355	1,605	104–7,160	1,375–1,834
16,356	2,060–30,099	13,119–19,592	885	189–1,562	729–1,041
21,282	1,148–88,650	18,215–24,350	1,335	211–4,567	1,141–1,530
10,089	585–27,695	4,880–15,298	573	34–1,209	331–815
19,549	11,243–35,375	–	1,247	610–2,316	–
23,358	21,403–25,312	–	1,178	937–1,419	–
13,943	2,821–39,289	10,119–17,767	1,123	248–2,764	840–1,406
28,232	1,712–90,415	25,241–31,224	1,406	61–6,198	1,216–1,596
31,629	9,291–62,358	23,046–40,213	1,705	455–4,797	1,237–2,173
30,284	11,002–83,811	21,128–39,441	1,846	493–4,133	1,338–2,355
29,822	416–81,575	25,830–33,815	2,460	15–6,990	2,141–2,779
48,425	21,842–98,028	34,103–62,748	2,818	1,071–6,149	1,766–3,871
22,385	16,497–27,900	–	2,599	808–3,885	–
41,355	12,217–102,605	–	2,838	1,628–5,406	–
5,082	742–19,058	1,753–8,410	344	41–1,007	168–520
27,487	1,668–152,005	23,004–31,970	1,579	24–7,986	1,298–1,860
11,911	330–54,129	2,493–21,329	990	16–4,606	245–1,735
34,757	2,713–129,465	30,599–38,915	2,367	105–7,160	2,037–2,697
33,976	398–135,111	30,313–37,640	3,791	43–13,410	3,407–4,175
28,269	6,788–82,515	26,113–30,426	3,767	1,284–9,809	3,517–4,018
35,776	4,587–95,590	30,498–41,054	3,865	598–10,907	3,317–4,414
56,039	8,079–103,399	28,089–83,989	6,288	2,080–10,526	4,219–8,356
54,014	–	–	4,214	–	–
47,062	17,559–126,411	29,222–64,902	4,935	2,380–7,504	3,877–5,993
19,824	7,924–46,171	11,333–28,315	2,369	992–4,991	1,430–3,309
16,785	3,193–51,544	10,762–22,807	1,382	326–4,405	846–1,917
7,813	642–33,533	6,578–9,048	1,253	146–3,993	1,075–1,431

lower doses because of biologic variation* (9).

For most interventional radiology procedures, there is little or no published information on skin dose for either average dose or the frequency with which skin dose exceeds a given threshold (10). Much of the published data on radiation dose provides dose–area–product* (DAP) data (10,11). This is a surrogate measure of skin dose and does not correlate well with skin dose (12–17). DAP is more reliable as an estimator of energy imparted to the patient, and therefore of stochastic risk (18).

In a Public Health Advisory of September 30, 1994, the FDA recommended that "information permitting estimation of the absorbed dose to the skin be recorded in the patient's medical record" (19). No specific method of dose measurement or unit of dose was recommended. In a separate publication (20), the FDA recommended that dose information be collected and maintained for cardiac radiofrequency ablation, vascular embolization, transjugular intrahepatic portosystemic shunt (TIPS) creation, and percutaneous endovascular reconstruction (stents and stent-grafts). This recommendation was based on anecdotal re-

ports of injuries rather than on published dose data for these procedures.

The FDA invited the Society of Interventional Radiology (SIR)—known then as the Society of Cardiovascular and Interventional Radiology—to gather information on dose levels associated with common interventional radiology procedures. In response, SIR formed a task force to develop a method for collecting dose information prospectively and in a systematic way from multiple medical centers across the United States. A multicenter protocol was developed to create a radiation dose database for each of 21 different interventional radiology procedures. Over a 3-year period, seven academic medical centers in the United States participated in the SIR Radiation Dose in Interventional Radiology Study (RAD-IR Study) and collected data from 2,142 instances of a variety of procedures. The results are reported herein.

Part I of this report provides overall dose data for a number of interventional radiology procedures, identifies procedures associated with higher radiation doses, analyzes the effect of operator training level on dose, and provides recommendations for recording overall dose. Part II of this report provides skin dose data for the subset of instances in which these data were collected, compares various measures of peak skin dose* (PSD), and provides recommendations for measuring and recording PSD. Subsequent reports will present the physics data that support the reliability of the dosimetry data in parts I and II, provide formulas for estimating overall dose based on patient demographic data, fluoroscopy time, and number of images obtained, and provide a method to permit estimation of PSD from other dose metrics.

MATERIALS AND METHODS

Case and Subject Selection

Instances of procedures were included in the study if the subject underwent one of the medically indicated interventional radiology procedures listed in the first column of **Table 1**, the procedure was performed in an interventional radiology suite that had previously been registered into the study, and informed consent had been obtained for the procedure. For subjects who underwent more than one interventional procedure on different occasions, each procedure was eligible for inclusion as a separate instance.

Instances were excluded if any of three criteria were met. First, if the subject underwent more than one of the procedures listed in the first column of **Table 1** at the same sitting, or one of the procedures in **Table 1** and any other fluoroscopically guided procedure at the same sitting, the instance was excluded. The only exception was the combination of pulmonary angiography and inferior vena cava filter placement, which could be performed at the same sitting. Second, if the procedure was performed in an interventional radiology suite not specifically registered into this study, the instance was excluded. Third, if informed consent for the interventional radiology procedure was not obtained, the instance was excluded. There were no exclusions for a subject's age, race, sex, pregnancy status, cognitive impairment, or nonvoluntary confinement or institutionalization. Accrual was not consecutive because there were interventional radiology suites at each institution that were not registered into the study and otherwise eligible subjects could not be included if the procedure was performed in one of these suites.

Procedures were defined so as to mimic real-world procedures as closely as possible. Dose data included all related imaging performed as part of the procedure. For example, if iliac angioplasty was performed as part of an instance that also included a lower-extremity runoff examination, the dose data recorded for the instance included the dose for both the runoff and the angioplasty. Dose data for renal/visceral angioplasty included doses for any aortography performed as part of the same instance. In addition, we did not modify the dose data based on the number of eligible interventions performed as part of a single instance; that is, we did not halve the dose data for instances in which two renal angioplasties or bilateral nephrostomy were performed.

Other relevant procedure definitions include the following: "TIPS" includes only procedures in which a new TIPS was created; "biliary drainage" includes stent placement if performed at the same time as the drainage procedure; "renal/visceral angioplasty" includes angioplasty of the renal artery, superior mesenteric artery, or celiac axis; "iliac angioplasty" includes angioplasty of any portion of the common iliac or external iliac arteries; "hepatic chemoembolization" does not include hepatic embolization without intraarterial administration of chemotherapy (the latter procedure was recorded as "other tumor embolization"); and all head, neck, and brain embolization procedures were recorded as "neuroembolization–head."

Sites

The following sites participated in the study and are listed in order of the number of instances contributed (the site's principal investigator[s] and number of instances contributed are shown in parentheses): Department of Radiology, Mayo Clinic (Rochester, MN), three single-plane fluoroscopic suites (B.S., $n = 715$); Department of Radiology, Cleveland Clinic Foundation (Cleveland, OH), one single-plane fluoroscopic suite (M.G., $n = 380$); The Hyman Newman Institute of Neurology and Neurosurgery, Center for Endovascular Surgery, Beth Israel Medical Center (New York, NY), two biplane fluoroscopic suites (A.B., R.A., $n = 318$); Department of Radiology, National Naval Medical Center (Bethesda, MD), one single-plane and one biplane fluoroscopic suite (J.D.G., P.T.N., $n = 233$); Department of Radiology, State University of New York, Upstate Medical University (Syracuse, NY), one single-plane fluoroscopic suite (J.S.G., J.F.C., $n = 218$); Department of Radiology, Feinberg School of Medicine, Northwestern University (Chicago, IL), one single-plane and one biplane fluoroscopic suite (E.J.R., T.W.M., R.L.V., $n = 168$); Department of Radiology, University of Texas Southwestern Medical Center (Dallas, TX), one single-plane fluoroscopic suite (G.L.M., J.A., $n = 110$).

Institutional Review Board Review and Informed Consent

The protocol was reviewed and approved by the institutional review board at each participating institution. Informed consent for participation in

the study was required at only one site, and for only a portion of the study. Written informed consent was obtained from these subjects. The institutional review boards at the other institutions determined that informed consent was not required because the protocol involved no contact with the subject, there was no risk to the subject, there was potential benefit to the subject (from monitoring of radiation dose), subjects' identities were not recorded, and the data collected at the central data repository were not sufficient to identify any individual subject.

Each subject was identified on the data form by a site code, the procedure date, and a four-digit identifier, all of which were subsequently recorded in the central database. The principal investigator at each site chose the nature of the identifier. The nature of the four-digit identifier was not disclosed to the study principal investigator and was not recorded in the central database.

There was no attempt to influence or control how any instance of any procedure was conducted with regard to fluoroscopic technique, image acquisition, criteria for success, criteria for appropriateness, choice of subject, choice of operator, choice of fluoroscopic unit, or any other factor.

Fluoroscopic Equipment

Site enrollment was limited to sites with angiographic equipment containing an integrated dosemeter. These systems are compliant with the dosimetry portion of the International Electrotechnical Commission (IEC) standard 60601–2–43 (21). The fluoroscopic unit performed exposure measurements automatically. Dosimetry information, including fluoroscopy time,* DAP, and cumulative dose* (CD) at the interventional reference point* (IRP) were displayed directly on the console in the control room. Fluoroscopic dose rate and CD were displayed in the procedure room and were readily available to the operator during the procedure. The requirement for integrated ("built-in") dosimetry instrumentation was intended to ensure that there would be no increase in procedure time and no increase in dose to the patient as a result of the research. The use of data from integrated dosemeters also minimized the effort required for data collection and the potential for measurement errors.

At the time the RAD-IR Study was designed, only Siemens Medical Systems (Malvern, PA) had delivered fluoroscopic systems with integrated dosemeters compliant with IEC standard 60601–2–43. As a result, all enrolled sites were equipped with either Multistar single-plane units or Neurostar biplane units. These units incorporate state-of-the-art dose reduction features, including modern image intensifier video systems, pulsed fluoroscopy, low-dose continuous fluoroscopy, spectral filtration, frame averaging, digital subtraction angiography without test exposures, variable-frame-rate digital subtraction angiography, visualization of collimator and filter positioning without radiation, and real-time display of CD.

Dose Measurement

Fluoroscopy time and the number of fluorographic images* recorded during a procedure give an indication of the dose delivered by fluoroscopy and fluorography. These metrics do not include effects such as imaging system configuration, patient size, beam size, or beam position. CD indicates the total air kerma* delivered to the IRP. It does not include effects such as beam size (collimator position) or beam position with respect to the patient (table position and gantry angulation). DAP indicates the total x-ray energy imparted to the patient. It does not include effects such as beam position with respect to the patient. None of these metrics directly indicate PSD (18,22).

The published version of IEC standard 60601–2–43 defines the location of the IRP as the point along the central ray 15 cm from the system isocenter toward the focal spot (21,23). Some of the data included in this study were collected with use of a provisional definition of the IRP. These data have been appropriately normalized to the final IRP. This was accomplished by recording the date at which each site's system software was updated to a version that reflected the final standard. CDs recorded before these dates were multiplied by the appropriate geometric factor (0.72 for Multistar systems and 0.84 for Neurostar systems).

Fluoroscopy time was displayed and recorded in units of 0.1 minute, DAP was displayed and recorded in $cGy \cdot cm^2$, and CD was displayed and recorded in mGy. CDs greater than 9,999 mGy for a single-plane unit and for each plane of a biplane unit are displayed as "*****" on the operator's console. For the five instances in this study in which the CD in one plane exceeded 9,999 mGy (two TIPS instances, two spine tumor embolization instances, one gastrointestinal hemorrhage diagnosis/therapy instance), the dose for that plane was recorded as 10,000 mGy. For biplane units, we recorded data for each plane separately. The data for both planes were then added to yield total fluoroscopy time, total number of fluorographic images, total DAP, and total CD. The total values were used for data analysis.

Fluoroscopic Modes

Each fluoroscopic unit in this study is capable of operation in any of eight fluoroscopic modes, all of which are operator-selectable at any time from a control panel mounted on the procedure table. The fluoroscopic mode for each instance of each procedure was chosen by the operator and reflected personal preference. No attempt was made to standardize the use of any fluoroscopic mode.

The eight available modes and their relative dose rates according to the manufacturer's standard protocols are shown in **Table 2** (24). The manufacturer's recommended fluoroscopic and fluorographic settings are the same for single-plane (Multistar) and biplane (Neurostar) systems. However, individual system settings are routinely modified to accommodate local preferences. All sites were in compliance with FDA regulations.

Continuous fluoroscopy is conventional fluoroscopy. Digital pulsed fluoroscopy (DPF) 30 is pulsed fluoroscopy without dose reduction. Special pulsed fluoroscopy (SPF) 30 and SPF 15 are pulsed fluoroscopy modes with dose increases relative to conventional fluoroscopy. Special fluoroscopy (SPECF) is continuous fluoroscopy performed with half the sampling rate and twice the dose per image. The dose rate is the same; image quality is

Table 2
Specifications of Equipment Used in the RAD-IR Study when Configured as Suggested by the Manufacturer (24)

Fluoroscopy Mode	Images per Second	Relative Dose Rate
Continuous unprocessed fluoroscopy	30	1.00
DPF, 30 pulses/sec	30	1.00
DPF, 15 pulses/sec	15	0.53
DPF, 7.5 pulses/sec	7.5	0.28
DPF, 3 pulses/sec	3	0.11
SPECF*	15	0.50
SPF, 30 pulses/sec	30	2.10
SPF, 15 pulses/sec	15	1.30

* Modified form of continuous fluoroscopy whereby x-rays are not pulsed; the camera target is read 15 times per second. 99.7% (624 of 626) of cases performed with use of this fluoroscopic mode were done at a single site. The modified configuration used at this site sets the dose rate of this mode to 50% of standard continuous fluoroscopy.
Note.—Relative dose rates are based on image receptor input exposure rate dose settings.

improved. One site had the SPECF setting modified on all systems so that it yielded half the dose rate of continuous fluoroscopy. A total of 626 procedures using SPECF were included in this study. Of these, 624 (99.7%) were performed with this lower dose rate.

Beam Filtration

A copper filter was incorporated into each fluoroscopic unit and functioned identically in each unit. The fluoroscopic beam was always filtered with 0.2 mm copper for all fluoroscopic modes and all patient thicknesses. The fluorographic (acquisition) beam was filtered with 0.2 mm copper for small beam paths. The copper fluorographic filter was automatically removed for large beam paths.

Clinical Data Collection

We prospectively collected demographic and radiation dose data for 2,142 instances of procedures during the period from April 1999 through January 2002. Data were collected at each of the participating sites. For each instance, a data form was completed which included site name, patient data (weight, height, and age), operator type (resident, fellow, staff), acquisition data (number of exposures, fluoroscopy time, DAP, and CD), fluoroscopy mode used (continuous, DPF 3, DPF 7.5, DPF 15, etc.), and procedure type. Some procedures were divided into subgroups, as shown in the first column of **Table 1**. These subgroups were defined prospectively before data collection. We hypothesized that there would be differences in dose among subgroups. Sites equipped with CareGraph skin dose mapping software (Siemens) also recorded PSD and 95% area load.

Data forms were forwarded periodically to a central site (Bethesda, MD) for tabulation. The principal investigator (D.L.M.) reviewed all data forms on receipt. Illegible, inconsistent, incomplete, or questionable data were corrected after review of the original data by the site principal investigator or his/her designee. Any procedure data forms that remained incomplete after review were discarded. All data were recorded in a computerized database (Access 2000; Microsoft, Redmond, WA).

Physics Evaluations

An initial comprehensive physics evaluation was conducted on each fluoroscopic unit to confirm that its dosemeter was functioning properly. This full evaluation compared the internal reference air kerma readout to an external ionization chamber (various models and manufacturers depending on site, but each had a calibration or compliance certificate) over a range of exposure conditions. Nine comparisons were obtained in each evaluation: two fluoroscopy modes and one acquisition mode, each with polymethylmethacrylate blocks of at least 25 cm $\times$ 25 cm (various manufacturers depending on site) and total thicknesses of 10, 20, and 30 cm. The comprehensive evaluation was repeated after any major equipment modifications and at the end of the study.

In addition, periodic consistency checks were performed on each unit every 1–2 weeks to verify the stability and consistency of the reference air kerma readout and the automatic brightness control. A standard 4.95-L water bottle (Servin' Saver model 3922; Rubbermaid, Wooster, OH) was used to simulate an average-sized patient. The C-arm and water bottle were placed in a repeatable configuration that simulated patient positioning. Generator (kV, mA, mS) and cumulative dose monitor (mGy) readings were recorded for one fluoroscopic mode and for one acquisition mode. Tolerance levels were predefined. The data from each initial physics evaluation and each periodic consistency check were forwarded to a central site for tabulation. Out-of-tolerance data were discussed with the site principal investigator. Procedural details will be published elsewhere.

For the comprehensive physics evaluations, we calculated the ratio of the cumulative dose monitor reading (from the dosemeter on the fluoroscopic unit) to the calibrated ionization chamber reading. This ratio was calculated for each measurement and then the entire data set of ratios was pooled.

For the periodic consistency checks, we first calculated a mean value for the cumulative dose monitor reading for fluoroscopy from all the consistency data obtained for each imaging plane used in the study. This mean value was then used to normalize all the fluoroscopy data. The same process was used to normalize the fluorography data. The fluoroscopy and fluorography data were pooled separately.

The root mean square error for fluoroscopy and fluorography was obtained by combining the standard deviations of the comprehensive and consistency data sets.

Table 3
Target Organ in 91 Cases of "Other Tumor Embolization"

Tumor Site	Number
Liver	51
Kidney	28
Duodenum	3
Scapula	2
Spleen	2
Femoral head	1
Humerus	1
Lung	1
Mesentery	1
Stomach	1
Total	91

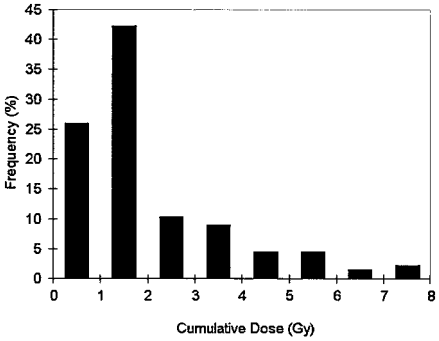

Figure 1. Histogram of cumulative dose for 135 instances of TIPS creation.

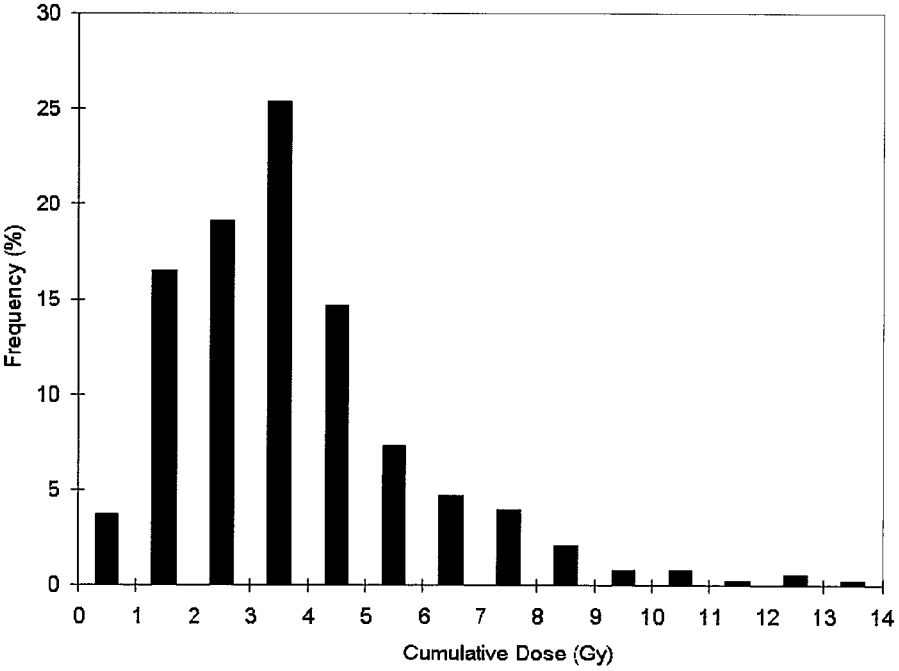

Figure 2. Histogram of cumulative dose for 382 instances of neuroembolization. Procedures include embolization of head, brain, and neck lesions.

Statistical Analysis

Descriptive and summary statistics were calculated with use of Access 2000 (Microsoft). Some data manipulation was performed with Excel 2000 (Microsoft). Confidence intervals (CIs) were calculated with use of Excel 2000 and standard techniques for determining CIs with the Student *t* distribution (25). Scatter plots, trend lines, and linear regressions were also performed with Excel 2000. Tests for statistical significance were performed with SAS version 8 (SAS Institute, Cary, NC). For continuous data, *t* tests were used to test the significance of differences between two groups and analyses of variance were used to test the significance of differences among three or more groups. The significance level was set at 0.05. For frequency data, χ^2 tests were used, with a significance level of 0.05.

RESULTS

Physics Evaluations

During the course of the project, 48 comprehensive physics evaluations and 581 periodic consistency checks were reported for the 12 fluoroscopic units included in the study. For the comprehensive physics evaluations, the normalized data sets yielded a mean of 1.03 (95% CI: 1.00–1.05) for the fluoroscopic data and a mean of 0.93 (95% CI: 0.90–0.96) for the fluorographic data. For the periodic consistency checks, the normalized data sets yielded a mean of 1.00 (95% CI: 0.98–1.02) for the fluoroscopic data and a mean of 1.00 (95% CI: 0.98–1.02) for the fluorographic data. When the data from the comprehensive physics evaluations and the periodic consistency checks were combined, the root mean square error calculations yielded standard deviations of 0.239 for fluoroscopy and 0.227 for fluorography. The root mean square error in clinical measurement of CD is estimated at ±24%. This is well within the tolerances established by the IEC and the ±25% limit recommended by others for overall uncertainty of patient dose measurements (21,26). The full results of these evaluations will be published elsewhere.

Clinical Evaluations

Subjects ranged in age from 4 days to 104 years (mean, 55.3 years). Of the 2,142 instances, 1,019 (47.6%) were performed on male patients and 1,123 (52.4%) were performed on female patients. Subjects' heights ranged from 30 cm to 208 cm (mean, 175 cm) for male patients and from 53 cm to 196 cm (mean, 162 cm) for female patients. Subjects' weights ranged from 1.8 kg to 186.0 kg (mean, 83.8 kg) for male patients and from 3.6 kg to 215.0 kg (mean, 71.6 kg) for female patients.

Certain procedures were prospectively divided into subgroups. These subgroups were defined by the indication for the procedure (nephrostomy, pelvic arterial embolization, pelvic vein embolization, embolization in the head, and embolization in the spine), whether stents were used (renal/vis-

Table 4
***P* Values of Dose Analogue Comparisons for Subgroups of Certain Interventional Radiology Procedures**

Procedure	Fluoroscopy Time	Number of Images	DAP	Cumulative Dose
Nephrostomy: for obstruction vs stone access	.0004	.221	.0158	.0029
Renal/visceral angioplasty: with no stent vs stent	.0495	.106	.085	.0116
Iliac angioplasty: no stent vs stent	.002	.0015	.0009	.0002
Central venous reconstruction: SVC vs IVC	.257	.0207	.056	.0185
Pelvic arterial embolization: trauma vs tumor vs fibroids vs AVM vs aneurysm	.0406	.0039	.0276	.0982
Pelvic vein embolization: ovarian vein vs varicocele	.00003	.000003	.0001	.0000003
Neuroembolization/head: AVM vs aneurysm vs tumor	.0008	.338	.0134	.959
Neuroembolization/spine: AVM vs aneurysm vs tumor	.609	.0015	.819	.344

Note.—Comparisons for procedures with two subgroups were performed with Student *t* tests; comparisons for procedures with more than two subgroups were performed with analysis of variance. Statistical significance level is $P < 0.05$.

ceral angioplasty, iliac angioplasty), or the anatomic site of the intervention (central venous reconstruction). Certain procedures and subgroups of procedures were represented by fewer than 10 instances each. These data may not be representative because of the small sample size.

For each procedure and subgroup studied, **Table 1** presents data on the number of instances recorded and the mean, 95% CI, and minimum and maximum values for fluoroscopy time, number of images obtained, DAP, and CD. Instances of all procedures were observed, with the exception of aortic stent-graft procedures (none of the participating institutions performed aortic stent-graft procedures in an interventional radiology suite, and therefore no instances of stent-graft procedures were eligible for inclusion in this study). The category "other tumor embolization" included 91 instances; the target organ in each is indicated in **Table 3**.

There was wide variation in the doses observed for different instances of the same procedure. **Figures 1 and 2** are histograms of the CD data for TIPS creation and head embolization procedures, respectively. For each of these procedures, CD ranged from 0.1 Gy to more than 7 Gy (more than 13 Gy for head embolization).

We analyzed data on various analogues of dose (fluoroscopy time, number of images, DAP, and CD) for procedures in which data were prospectively collected by subgroup to determine whether these analogues of dose differed among the subgroups. The results are shown in **Table 4**. Except for spine embolization, statistically significant differences in one or more of these dose analogues were present among subgroups for all these procedures. For this reason, we did not combine subgroups for further data analyses. Interestingly, there was discordance between DAP and CD with regard to statistical significance for four of the eight procedures shown in **Table 4** (ie, subgroups were significantly different with regard to DAP but not CD or vice versa).

The frequency with which each of the procedures in this study resulted in a CD greater than 1 Gy, 2 Gy, or 3 Gy is presented in **Table 5**. Infrequently, CD may be substantially greater than 3 Gy. Of the 2,142 instances in the study, there were 129 (6%) with CDs greater than 5 Gy (**Table 6**).

We analyzed the effect of operator training level on dose. The primary operator was defined as the individual performing more than half the procedure. By this definition, only one individual could be the primary operator. The staff interventional radiologist was the primary operator in more than half the instances of every procedure except for reconstruction of the IVC (there were only three instances of this procedure). Fellows functioned as the primary operator for only two (0.5%) of 406 neuroembolization procedures. There were only two procedures, pulmonary angiography and IVC filter placement, for which a resident was the primary operator at least 10% of the time. Even for these procedures, there were significant differences in the frequency with which the operator was a resident, fellow, or attending radiologist (χ^2 test, $P < .001$). For these two procedures, we evaluated fluoroscopy time, number of images, DAP, and CD to determine if these quantities varied by operator training level (**Table 7**). One-way analyses of variance demonstrated no significant differences except for fluoroscopy time ($P = .0158$) and CD ($P = .0426$) for IVC filter placement.

Table 8 displays the frequency with which each fluoroscopic mode was used for each procedure in the study. The operator chose the fluoroscopic mode for each instance. Reduced-dose fluoroscopy was employed in 86.8% of instances (1,859 of 2,142) in this study (modified SPECF is a reduced-dose fluoroscopy mode). For neurointerventional radiology procedures, the most commonly used fluoroscopy modes were continuous fluoroscopy, DPF 15, and DPF 7.5. The most commonly used modes for interventional radiology procedures were DPF 15, DPF 7.5, DPF 3, and SPECF.

Some fluoroscopy modes (SPF 15, SPF 30) increase fluoroscopy dose rates compared to those used in continuous fluoroscopy. These two fluoroscopy modes were used in 74 of 2,142 instances (3.5%; **Table 8**).

We analyzed the frequencies with

Table 5
Frequency with which Interventional Radiology Procedures Result in a Cumulative Dose Greater than 1 Gy, 2 Gy, or 3 Gy

Procedure Description	No. of Cases	Dose		
		>1 Gy	>2 Gy	>3 Gy
TIPS creation	135	100 (74)	43 (32)	29 (21)
Biliary drainage	123	41 (33)	13 (11)	7 (6)
Nephrostomy				
Obstruction	79	2 (3)	1 (1)	0 (0)
Stone access	64	9 (14)	5 (8)	2 (3)
Pulmonary angiography				
No IVC filter	106	1 (1)	–	–
IVC filter	17	0 (0)	–	–
IVC filter placement only	279	0 (0)	–	–
Renal/visceral angioplasty				
No stent	53	20 (38)	9 (17)	3 (6)
Stent	103	66 (64)	26 (25)	11 (11)
Iliac angioplasty				
No stent	24	9 (38)	0 (0)	–
Stent	93	49 (53)	15 (16)	8 (9)
Central venous reconstruction				
SVC	12	2 (17)	0 (0)	–
IVC	3	1 (33)	1 (33)	0 (0)
Aortic fenestration	2	1 (50)	0 (0)	–
Bronchial artery embolization	27	12 (44)	4 (15)	0 (0)
Hepatic chemoembolization	126	78 (62)	23 (18)	13 (10)
Pelvic arterial embolization				
Trauma	18	15 (83)	4 (22)	1 (6)
Tumor	19	14 (74)	8 (42)	2 (11)
Fibroids	90	77 (86)	47 (52)	27 (30)
AVM	12	12 (100)	7 (58)	3 (25)
Aneurysm	4	3 (75)	3 (75)	2 (50)
Pelvic vein embolization				
Ovarian vein	6	6 (100)	2 (33)	2 (33)
Varicocele	14	1 (7)	0 (0)	–
Other tumor embolization	91	49 (54)	24 (26)	13 (14)
Peripheral AVM embolization	17	5 (29)	3 (18)	2 (12)
Gastrointestinal hemorrhage: diagnosis/therapy	94	77 (82)	44 (47)	28 (30)
Neuroembolization/head				
AVM	177	165 (93)	126 (71)	98 (55)
Aneurysm	149	149 (100)	131 (88)	100 (67)
Tumor	56	54 (96)	48 (86)	34 (61)
Neuroembolization/spine				
AVM	10	10 (100)	10 (100)	9 (90)
Aneurysm	1	1 (100)	1 (100)	1 (100)
Tumor	13	13 (100)	13 (100)	12 (92)
Stroke therapy	9	8 (89)	5 (56)	2 (22)
Carotid stent placement	18	10 (56)	4 (22)	2 (11)
Vertebroplasty	98	48 (49)	18 (18)	5 (5)
Total	2,142	1,108 (52)	638 (30)	416 (19)

Note.—Values in parentheses are percentages. AVM = arteriovenous malformation.

which the three most commonly used fluoroscopy modes were selected for each of several procedures: TIPS creation, biliary drainage, pulmonary angiography, IVC filter placement, renal/visceral angioplasty, iliac angioplasty, pelvic arterial embolization, and neuroembolization procedures in the brain, head, or neck. For all these procedures except pulmonary angiography, the frequencies with which these different fluoroscopic modes were used differed significantly (χ^2 test, $P < .001$).

We evaluated the relationships between fluoroscopy time and CD and between fluoroscopy time and DAP for all 2,142 instances. Fluoroscopy time and CD showed good correlation (Pearson correlation coefficient $r = 0.79$; $P < .000001$, two-tailed t-test) (**Fig 3**). Linear regression yielded a formula for estimation of CD (mGy) from fluoroscopy time (min): CD = 531 +

Table 6
Cases of Interventional Radiology and Interventional Neuroradiology Procedures that Resulted in a Cumulative Dose >5 Gy

Procedure	Number >5 Gy, *n* (%)	Total Number
Hepatic chemoembolization	2 (1.6)	126
Nephrostomy: stone access	1 (1.6)	64
Renal/visceral angioplasty	3 (1.9)	156
Other tumor embolization	4 (4.4)	91
Gastrointestinal hemorrhage diagnosis/therapy	7 (7.4)	94
TIPS creation	11 (8.1)	135
Pelvic arterial embolization		
Fibroid	8 (8.9)	90
AVM	2 (16.7)	12
Pelvic vein embolization: ovarian vein	1 (16.7)	6
Neuroembolization/head		
Aneurysm	26 (17.4)	149
AVM	40 (22.6)	177
Tumor	13 (23.2)	56
Neuroembolization/spine		
Tumor	5 (38.5)	13
AVM	6 (60.0)	10
Total	129	1,179

Note.—AVM = arteriovenous malformation.

36.5 (fluoroscopy time); adjusted R^2 = 0.62. Fluoroscopy time and DAP showed fair correlation (Pearson correlation coefficient $r = 0.60$; $P < .000001$, two-tailed *t*-test) (**Fig 4**). Linear regression yielded a formula for estimation of DAP (cGy·cm^2) from fluoroscopy time (min): DAP = 10,430 + 304 (fluoroscopy time); adjusted R^2 = 0.36. In general, fluoroscopy time correlated better with CD than with DAP, and estimates of CD from fluoroscopy time had greater precision (greater adjusted R^2) than estimates of DAP from fluoroscopy time. However, for individual instances, fluoroscopy time is a poor predictor of dose (**Figs 3, 4**).

A comparison between CD and DAP for all 2,142 instances demonstrated good correlation between these two measures of overall dose (Pearson correlation coefficient $r = 0.83$; $P < .000001$, two-tailed *t*-test). Because both CD and DAP were measured with the same dosemeter, variations between the two are the result of the inclusion of x-ray beam area in DAP calculations but not in CD calculations. Linear regressions yielded formulas for estimating DAP (cGy·cm^2) from CD (mGy) and vice versa: CD = 162 + 0.076 (DAP); DAP = 4,755 + 9.061 (CD); adjusted R^2 = 0.70 (**Fig 5**).

DISCUSSION

The dose data in this study represent current practice among radiologists at selected academic medical centers in the United States. The RAD-IR Study was designed and is intended to provide data on "real-world" doses for a variety of interventional radiology and interventional neuroradiology procedures, with no attempt to standardize either the technical factors for each fluoroscopic unit or the way in which each procedure was performed.

The procedures included in this study were chosen for one or more of the following reasons: (1) radiation-

Table 7
Comparison of Parameters by Training Level of the Primary Operator for Pulmonary Angiography and IVC Filter Placement

Procedure and Dose Analogue	Resident (*n* = 23; *n* = 35)*			Fellow (*n* = 25; *n* = 74)*			Staff (*n* = 58; *n* = 170)*			*P* Value
	Mean	95% CI	Range	Mean	95% CI	Range	Mean	95% CI	Range	
Pulmonary angiography										
Fluoroscopy time (min)	6.5	5.4–7.6	2.7–13.7	8.3	5.9–10.7	3.1–33.5	10.1	7.1–13.1	1.6–54.4	NS
Number of images	188	161–215	97–390	175	156–194	103–291	156	127–185	37–599	NS
DAP (cGy·cm^2)	6,016	4,703–7,329	957–13,597	7,579	4,845–10,313	1,032–34,108	8,477	6,636–10,318	998–41,416	NS
Cumulative dose (mGy)	337	279–395	47–618	349	264–434	64–843	341	274–408	34–1,479	NS
IVC filter placement										
Fluoroscopy time (min)	3.6	2.8–4.4	1.4–11.3	2.8	2.5–3.1	0.9–8.7	2.7	2.4–3.0	0.7–11.4	.0158
Number of images	41	30–52	2–183	33	27–39	2–152	31	28–34	1–124	NS
DAP (cGy·cm^2)	4,516	3,352–5,680	461–14,528	3,702	3,095–4,309	448–14,985	4,764	4,268–5,260	170–20,327	NS
Cumulative dose (mGy)	177	136–218	34–523	135	112–158	19–613	178	158–198	9–680	.0426

* Numbers of pulmonary angiography procedures and IVC filter placement procedures performed, respectively.
Note.—NS = not significant ($P > .05$).

Table 8
Fluoroscopic Modes Employed for Certain Interventional Radiology Procedures

Procedure	Total No.	Continuous Fluoroscopy	DPF 30	DPF 15	DPF 7.5	DPF 3	SPECF	SPF 30	SPF 15
TIPS	135	6 (4)		66 (49)	4 (3)	16 (12)	37 (27)	3 (2)	3 (2)
Biliary drainage	123	14 (11)	2 (2)	44 (36)	3 (2)	8 (7)	49 (40)		3 (2)
Nephrostomy	143	5 (3)	2 (1)	72 (50)	7 (5)	29 (20)	24 (17)	2 (1)	2 (1)
Pulmonary angiography									
No IVC filter	106	1 (1)	2 (2)	22 (21)	37 (35)	4 (4)	38 (36)	1 (1)	1 (1)
IVC filter	17			4 (24)	2 (12)	2 (12)	9 (53)		
IVC filter placement only	279	6 (2)	4 (1)	75 (27)	25 (9)	34 (12)	127 (46)	4 (1)	4 (1)
Renal/visceral angioplasty ± stent	156	24 (15)		25 (16)	1 (1)	8 (5)	93 (60)	5 (3)	
Iliac angioplasty ± stent	117	2 (2)	2 (2)	27 (23)	4 (3)	26 (22)	53 (45)	1 (1)	2 (2)
Central venous reconstruction	15	1 (7)		5 (33)	1 (7)		5 (33)	1 (7)	2 (13)
Aortic fenestration	2			2 (100)					
Bronchial artery embolization	27			7 (26)	3 (11)	2 (7)	13 (48)		2 (7)
Hepatic chemoembolization	126	10 (8)	2 (2)	8 (6)	5 (4)	21 (17)	74 (59)	3 (2)	3 (2)
Pelvic arterial embolization	143	3 (2)	2 (1)	56 (39)	25 (17)	27 (19)	13 (9)	4 (3)	13 (9)
Pelvic vein embolization	20	1 (5)		15 (75)			3 (15)		1 (5)
Other tumor embolization	91	5 (5)		14 (15)	1 (1)	5 (5)	63 (69)	1 (1)	2 (2)
Peripheral AVM embolization	17		2 (12)	7 (41)		3 (18)	4 (24)		1 (6)
Gastrointestinal hemorrhage: diagnosis/therapy	94	10 (11)		38 (40)	8 (9)	12 (13)	18 (19)		8 (9)
Neuroembolization									
Head	382	48 (13)	2 (1)	91 (24)	233 (61)	4 (1)	2 (1)		2 (1)
Spine	24	11 (46)	1 (4)	4 (17)	7 (29)		1 (4)		
Stroke therapy	9	6 (67)		2 (22)	1 (11)				
Carotid stent	18	2 (11)		9 (50)	7 (39)				
Vertebroplasty	98	31 (32)		33 (34)	34 (35)				
Total	2,142	186 (9)	21 (1)	626 (29)	408 (19)	201 (10)	626 (29)	25 (1)	49 (2)

Note.—Percentages may total more than 100% because of rounding. See text and Table 2 for description of the different fluoroscopy modes. Values in parentheses are percentages. AVM = arteriovenous malformation.

induced skin injury has been reported as a result of the procedure; (2) the SIR Radiation Dose Task Force considered it likely that they were relatively high-dose procedures and that there might be a risk of skin injury associated with them; (3) the FDA has suggested that the procedures typically involve extended fluoroscopic exposure time; and/or (4) the Task Force believed, based on its members' clinical judgment, that they are not high-dose procedures, but objective data did not exist to support this contention.

Our data show that certain interventional radiology and interventional neuroradiology procedures have the potential to produce clinically significant radiation doses (**Table 5**). Six percent (128 of 2,142) of the instances of procedures studied resulted in a CD greater than 5 Gy (**Table 6**). There were wide variations in the doses observed for different instances of the same procedure.

Fluoroscopy time and radiation dose are known to decrease as operator experience increases (27–29). Our results suggest that the effect of operator training level on dose varies with the type of procedure performed (**Table 7**). The most likely explanation of the results of our analysis of operator training level and patient dose is that they are caused by the nonrandom assignment of the primary operator. It is probable that staff physicians performed the more technically difficult types of procedures and instances of individual procedures. For example, fellows functioned as the primary operator for only two of 406 instances of neuroembolization procedures (0.5%). It is also possible that a less-skilled operator might use greater amounts of fluoroscopy, imaging, or radiation than a fully trained operator while accomplishing less and leaving the more-skilled operator with the majority of the procedure to perform.

High-dose Procedures

Which interventional procedures are "high-dose?" "High-dose" is a relative term. In the context of our study, we considered high-dose to mean doses sufficient to cause deterministic effects (PSD > 2 Gy). Publication 85 of the International Commission on Radiological Protection (ICRP) provides a list (Annex A) and definitions of high-, medium-, and low-dose procedures (30). The ICRP report, published in 2000 after the current study was begun, defines these categories in terms of maximum cumulative absorbed dose in the patient's skin (similar but not identical to PSD, as defined in the glossary). High-dose procedures are defined as resulting in doses of hundreds of mGy, medium-dose procedures as those resulting in doses of tens of mGy, and low-dose procedures as those resulting in doses of less than tens of mGy (30).

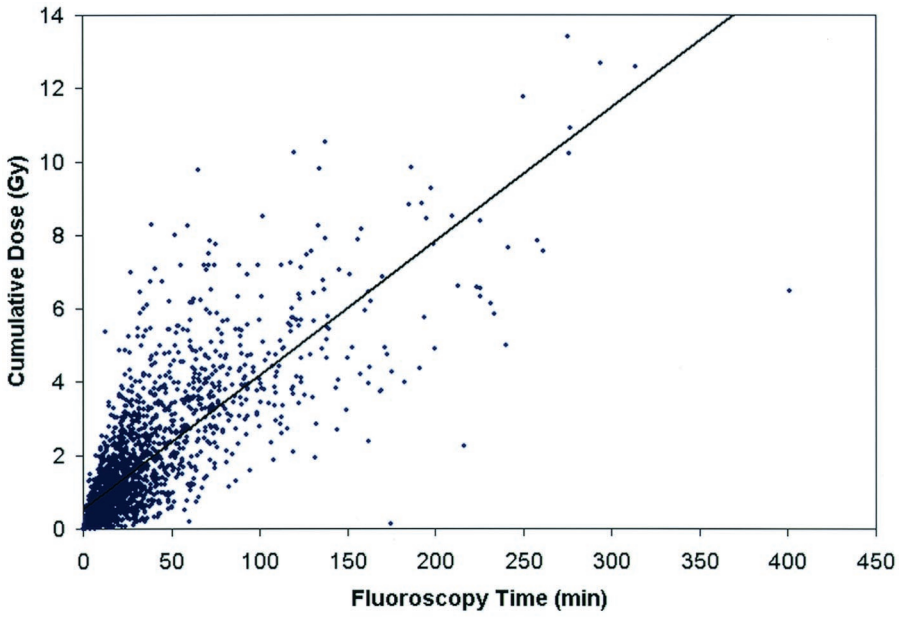

Figure 3. Scatter plot of fluoroscopy time and cumulative dose for 2,142 instances interventional radiology and interventional neuroradiology procedures. The regression line is shown.

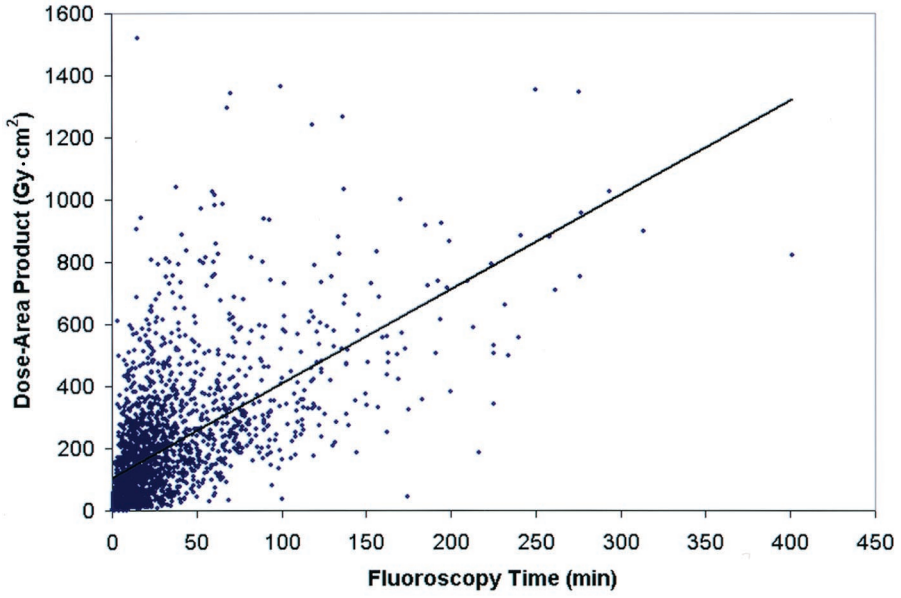

Figure 4. Scatter plot of fluoroscopy time and DAP for 2,142 instances of interventional radiology and interventional neuroradiology procedures. The regression line is shown.

Our data indicate that virtually all the procedures we studied may result in a high dose, regardless of the definition used. **Table 1** provides CD data, and PSD is typically half to four fifths of CD (31). The only exceptions are IVC filter placement, embolization of varicoceles, and nephrostomy performed for obstruction. According to our data, these three procedures should be classified as medium-dose according to the ICRP criteria (30).

The ICRP report, which was based on a review of the literature available at the time, classifies these procedures quite differently. TIPS creation and embolization of aneurysms and arteriovenous malformations are classified as high-dose procedures, embolization of tumors and varices, angioplasty, vascular stent placement, stent-graft placement, foreign body removal, percutaneous biliary drainage, and nonvascular stent placement are classified as medium-dose procedures, and embolization of bleeding, drug infusion for thrombolysis, IVC filter placement, and nephrostomy are classified by the ICRP as low-dose procedures (30).

Factors Affecting the RAD-IR Results

Because our results differ substantially from those previously reported, it is appropriate to consider factors that might be responsible for these differences. There are a number of possible explanations. In the ICRP report, skin doses were determined with a variety of different methods. We cannot compare our CD data with the ICRP report because no CD data were included in that report: the IEC definition of CD had not yet been published. The best comparison possible is between DAP data from our study (**Table 9**) and DAP data in the literature (10,14,15,28,32–38). Unfortunately, DAP is not a good indicator of PSD or CD in individual instances (12–17,23). Our own results show that, for individual instances, the relationship between DAP and CD is quite variable (**Fig 5**). CD data from the RAD-IR Study are more likely to reflect PSD than are other dose data from older studies, in which CD was not measured.

In addition, we observed statistically significant differences in various measures of overall dose among subgroups of the procedures we studied (**Table 6**). The subgroups were defined by various independent factors: the nature of the lesion being treated, the anatomic location of the lesion, and procedure complexity (whether or not angioplasty was accompanied by stent placement). It is known that different mixes of straightforward and complex instances of the same procedure will yield different dose data because complex procedures are associated with higher radiation doses (13). Comparison of radiation doses for various procedures reported in the litera-

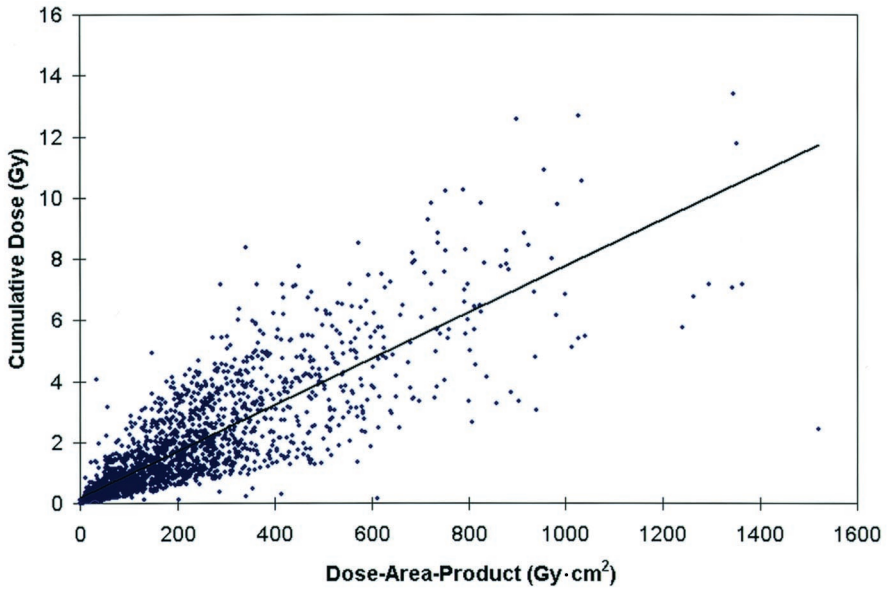

Figure 5. Scatter plot of DAP and cumulative dose for 2,142 instances of interventional radiology and interventional neuroradiology procedures. The regression line is shown.

ture may not be valid if the procedure groups are dissimilar with regard to lesion etiology or location or to complexity of the procedure.

Another possible explanation for the differences between the doses we observed and those reported in the literature is variable or inconsistent use of dose-saving techniques and technology. Consistent use of this technology reduces patient dose (10,28,34,39–45). Although we made no attempt to control how procedures were performed or to enforce the use of dose-saving techniques, all fluoroscopic units in this study were equipped with dose-saving technology. Reduced-dose fluoroscopy, for example, was used in 86.8% of instances (1,859 of 2,142; **Table 8**). Operators in the RAD-IR Study may have had additional incentive to minimize dose whenever possible because they knew that dose data were being recorded for these instances.

There are other factors as well. All the studies in our series were performed in academic medical centers. The patients seen in these centers may have more complex or difficult lesions, which require lengthier and more complex procedures. Academic medical centers are training sites that routinely involve residents and fellows in procedures. The involvement of less-experienced operators may increase procedure time and dose, even if these operators are not the primary operators for the procedure.

Optimizing Radiation Dose

The data from our study reinforce the importance of controlling and optimizing dose. Radiation dose is optimized when imaging (fluoroscopic and radiographic) is performed with the least amount of radiation required to provide adequate image quality and imaging guidance. This requires proper equipment, proper training, and constant awareness. With state-of-the-art equipment, patient dose can be optimized by careful attention to all the relevant details of operator technique and equipment factors (41,43,46). Doses are likely to be higher when these procedures are performed with equipment that lacks state-of-the-art dose-reduction features or by operators who lack adequate training in radiation protection (47).

All dose data in this study were derived from a single manufacturer's fluoroscopic units, all of which incorporate state-of-the-art imaging and dose-reduction features. It is reasonable to expect that doses would have been higher if the procedures were performed with use of equipment without these features. For example, Bakker and colleagues (48) observed that 5%–8% of total radiation exposure during interventional radiology procedures results from radiation delivered during preparation for imaging, while positioning the table and adjusting the image intensifier collimators. With state-of-the-art equipment, collimators and filters can be positioned with use of a previously stored image as a guide, without the need for additional radiation for fluoroscopic guidance.

Operator training is at least as important as equipment capability (47). Dose-saving technology is useless unless the operator knows how and when to use it and is motivated to minimize dose. All instances in this study were performed by or under the supervision of board-certified radiologists with extensive formal training in radiation safety, radiation protection, and radiation dose reduction. If untrained or poorly trained operators had performed the procedures in this study, it is likely that radiation doses would have been higher than those we observed. Untrained or poorly trained operators may benefit from the assistance of radiologic technologists who have undergone formal training in radiation safety.

Controlling radiation dose is important, but excessive dose reduction may be undesirable and counterproductive. Management of radiation dose and radiation risk must be balanced with the need to manage other risks, including the risk to the patient from suboptimal fluoroscopic guidance during the procedure and the risk of error from diagnoses made on the basis of suboptimal or insufficient number of images. The nature and magnitude of these risks may completely overshadow the risk of radiation effects or injury.

It is sometimes impossible to keep patient dose below the threshold for deterministic effects. In certain circumstances, patients may view a severe but unavoidable radiation effect as a reasonable trade-off. For example, a radiation dose sufficient to cause permanent hair loss may be acceptable if the alternative is a hemorrhagic stroke from an inoperable arteriovenous malformation of the brain. A radiation-induced skin slough that requires skin grafting may be acceptable

Table 9
Comparison of DAP and Fluoroscopy Time Data from Current Study with Previously Published Studies

Procedure	No. of Patients	Mean DAP and Range ($Gy \cdot cm^2$)	Mean Fluoroscopy Time and Range (min)*	Reference
Biliary drainage	123	70.6 (3.0–386.3)	23.6 (1.1–174.4)	This study
	9	86.7 (36.4–154.9)		14
	14	43 (11.4–90.4)	11	14
	18	150 (51–291)		32
	74	50.8 (239)†		37
Nephrostomy	143	34.3 (0.41–418.5)	13.7 (1.3–79.4)	This study
	14	22.7 (7.05–51.36)	9.9	14
	35	43 (0.6–165)	7 (1.3–20.8)	15
	21	8 (0.41–24)		33
	54	56 (1–213)		32
Pelvic vein embolization: varicocele	14	50.8 (7.4–190.6)	17.3 (6.4–40.5)	This study
	10	106.3 (43.2–108.4)	30.4	14
Pelvic arterial embolization: fibroids	90	298.2 (4.1–815.8)	29.4 (2.0–101.4)	This study
	18	30.6	14.2	28
	16	211.4	30.6	28
	20		21.9	36
TIPS creation	135	335.4 (14.3–1,364.4)	38.7 (3.5–153.1)	This study
	13	226 (111–354)		34
	10	77 (7–240)		34
	56	182 (470)†		37
Neuroembolization: head	382	320.1 (4.0–1,351.1)	87.6 (2.6–401.3)	This study
	8	116.4 (29.3–243.2)		38
	8	122.2		35
	21	129		10
	35	81		10

* Data on fluoroscopy time are not available for many of the previously published studies.
† Minimum DAP value not stated. Maximum DAP value given.

if the alternative is exsanguination from inoperable gastrointestinal hemorrhage. These are extreme examples, but they highlight the basic principle that radiation effects are only one factor to be considered in planning and conducting interventional radiology and interventional neuroradiology procedures (49). As in all of medicine, the conduct of an interventional radiology procedure must be the result of a judicious balancing of risks and benefits, of the relative strengths of indications and contraindications.

Recording Dose Data

Monitoring and recording patient dose data for all procedures can be valuable for quality-assurance purposes as well as for patient safety. Feedback to the operator may help to optimize radiation doses overall (50). Dosimetry systems like the ones used in the current study, which are integrated into the fluoroscopic unit, make this relatively simple. No additional staff time is needed for set-up, and recording radiation data typically adds less than 30 seconds per instance to the technologist's workload. If a dosimetry system of this type is available, it seems reasonable to us and others (51) to record dosimetry data for all interventional radiology procedures.

For many facilities, recording dosimetry data for all studies may be impractical. When is it essential to record these data? Documentation of patient dose in the medical record is desirable if the patient has received a clinically important radiation dose (20,30). The ICRP recommends recording dose data when the PSD is estimated to be 3 Gy or greater if the procedure is not likely to be repeated and 1 Gy or greater if the procedure probably will be repeated (30). The FDA has recommended that dose data be recorded in the patient's chart for procedures in which the PSD exceeds a threshold chosen by the institution. The FDA suggests a threshold between 1 Gy and 2 Gy (20). A CD of 2 Gy will usually indicate a skin dose of less than 2 Gy (31). **Table 5** provides frequency data for 1 Gy, 2 Gy, and 3 Gy CD thresholds for each of the procedures in this study. Whereas most procedures we studied may produce a CD greater than 2 Gy, TIPS creation, renal/visceral angioplasty, and stent placement, and virtually all types of embolization procedures, have the potential to yield CDs greater than 3 Gy. The ICRP guidelines and the FDA guidelines indicate that radiation dose should be monitored and documented for these procedures.

O'Dea and colleagues (52) argue that it is reasonable to monitor patient dose only if the results will alter the patient's care in some way. They consider two types of changes in patient

care: treatment for skin damage caused by radiation and planning for reduction of future exposure to avoid the need for treatment of radiation-induced skin damage. Because skin effects caused by radiation doses of less than 6 Gy are temporary, they argue that a procedure with a low likelihood (0.01%) of exceeding a 6-Gy skin dose might not require dose monitoring (52). However, if there is a reasonable likelihood that the same area of skin would be exposed to further radiation in the future, they argue that a lower threshold, such as 2 Gy, would be more appropriate. For those procedures in which the same area of skin is subjected to radiation on multiple occasions, they suggest a threshold of 1 Gy if the procedure results in skin doses greater than 1 Gy with a frequency of 5% or more. By these criteria, all instances of the procedures listed in **Table 6** should be monitored—nephrostomy performed for stone access, TIPS creation, renal/visceral angioplasty, and embolization procedures.

Which measures of dose should be recorded? PSD measurement is the best indicator for assessing the likelihood of deterministic effects. Unfortunately, PSD measurement is complex and this capability is not yet widely available. CD is a reasonable alternative. If CD can be measured, it should be recorded. DAP is a good measure of stochastic risk and should also be recorded if possible. We recommend against the use of DAP as the primary metric of overall dose except when the fluoroscopic unit does not have CD measurement capability. Although DAP is a useful measure for estimating the risk of stochastic effects, it is a poor indicator of skin dose and therefore a poor indicator of the risk of deterministic effects (12–17,23). In the absence of CD measurement capability, DAP may be used to estimate CD. However, it should be noted that, in individual instances, DAP does not correlate well with CD despite good overall correlation (**Fig 5**). DAP is also difficult for radiologists to use in daily practice because the unit of measurement ($Gy \cdot cm^2$) does not translate readily into standard units of dose.

The most widely available indicators of dose are fluoroscopy time and number of images obtained. These are also the least helpful because they are not measurements of dose at all. They are not acceptable substitutes for DAP or CD measurement, but if they are the only dose-related data available, they should be recorded. Even a poor estimate of dose is better than no estimate at all.

CONCLUSIONS

The dose data in the RAD-IR Study represent current practice among interventional radiologists and interventional neuroradiologists at selected academic medical centers in the United States. These data are not intended as a guide to the lowest practically achievable dose or as a guideline or indication of the highest "acceptable" dose. It is also essential to understand that radiation effects are only one factor to be considered in planning and conducting interventional radiology and interventional neuroradiology procedures. Optimizing radiation dose is not the same as minimizing radiation dose.

With state-of-the-art fluoroscopic equipment, patient doses can be managed effectively by careful attention to all the relevant details of operator technique and equipment factors (41,43,46). Doses are likely to be higher when these procedures are performed with fluoroscopic equipment that lacks state-of-the-art dose-reduction features or by operators who lack adequate training in radiation protection (47).

An integrated dosimetry system, similar to the type we used in this study, permits routine recording of patient dose. Add-on systems that may be retrofitted to existing equipment are also available. If such a system is available, radiation dosimetry data relevant to the risk of deterministic effects (PSD or CD) should be documented in the medical record for all interventional radiology procedures, along with dosimetry data relevant to the risk of stochastic effects (DAP). CD and DAP measurement capability should be specified as the minimum acceptable dose measurement capability for new interventional fluoroscopy equipment.

At facilities with existing fluoroscopic units that lack built-in dosimetry systems, it is probably not reasonable to collect radiation dose data for every procedure. However, documentation of patient dose in the medical record is strongly recommended when the patient may have received a clinically important radiation dose. Embolization, TIPS creation, and renal/visceral artery stent placement may produce doses of this magnitude.

If PSD or CD cannot be measured directly, sufficient data should be recorded in the medical record to permit estimation of CD. This can be done with DAP measurements, even though there is a substantial margin of error in individual instances. For current equipment lacking PSD, CD, or DAP measurement capability, the fluoroscopy time and number of images obtained should be documented in the medical record.

APPENDIX 1: GLOSSARY OF RADIOBIOLOGY TERMS

This glossary is provided for the convenience of the reader. It is not intended to be authoritative. These brief definitions may not match precisely the formal ICRP definitions of these terms.

Air kerma: The energy released in a small volume of air when it is irradiated by an x-ray beam. For diagnostic x-rays, air *kerma* is equivalent to the dose delivered to the volume of air in the absence of scatter. Kerma is measured in grays (Gy).

Biologic variation: With respect to radiation, the differences among individuals in the *threshold dose* required to produce a *deterministic effect*, or the differences in degree of effect produced by a given dose. Biologic variation may be idiopathic or caused by underlying disease. Different portions of the skin also differ in radiosensitivity.

Cumulative dose (CD): The *air kerma* accumulated for a procedure at a specific point in space relative to the fluoroscopic gantry (the *interventional reference point*) for a procedure. CD does not include tissue backscatter and is measured in grays (Gy).

Deterministic effect: A radiation effect characterized by a *threshold dose*. The effect is not observed unless the threshold dose is exceeded. (The threshold dose is subject to *biologic variation*.) When the threshold dose is exceeded in an individual, the severity of injury increases with increasing

dose. Examples of deterministic effects include skin burns, hair loss, and cataracts.

Dose–area–product (DAP): The integral of dose across the entire x-ray beam emitted from the x-ray tube. Dose–area–product is essentially the entire amount of energy delivered to the patient by the beam. DAP is measured in grays · square centimeters ($Gy \cdot cm^2$).

Fluorographic image: A single recorded image obtained with use of an image intensifier as the image receptor. A digital angiographic "run" consists of a series of fluorographic images.

Fluoroscopy time: The total time that fluoroscopy is used during an imaging or interventional procedure.

Interventional reference point (IRP): A point intended to be representative of the position of the patient's skin at the entrance site of the x-ray beam during an interventional procedure. For fluoroscopic systems with an *isocenter*, the IRP is located along the central ray of the x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot. IEC standard 60601–2–43 defines the IRP.

Isocenter: A point defined relative to most interventional fluoroscopic gantries. In such systems, the central ray of the x-ray beam passes through the isocenter in any beam orientation.

Kerma: Kinetic Energy Released in the Medium; the amount of energy transferred from the x-ray beam to charged particles per unit mass in the medium of interest. For diagnostic x-rays this is equivalent to dose in the specified medium (eg, air, soft tissue, bone). Kerma is measured in grays (Gy).

Peak skin dose (PSD): The highest air kerma at any portion of a patient's skin during a procedure.

Stochastic effect: A radiation effect whose probability of occurrence increases with increasing dose, but whose severity is independent of total dose. Radiation-induced cancer is an example.

Threshold dose: The minimum radiation dose at which a specified *deterministic effect* can occur. Threshold doses differ among individuals because of *biologic variation*. The threshold dose for skin injury also differs in different anatomic sites on the same individual.

Terms in italics in the definitions are defined separately in this Glossary.

Acknowledgment: The authors thank Henry Krakauer, MD, PhD, for his careful and helpful review of the manuscript.

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