Clinical Studies

Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study

Part II: Skin Dose

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PURPOSE: To determine peak skin dose (PSD), a measure of the likelihood of radiation-induced skin effects, for a variety of common interventional radiology and interventional neuroradiology procedures, and to identify procedures associated with a PSD greater than 2 Gy.

MATERIALS AND METHODS: An observational study was conducted at seven academic medical centers in the United States. Sites prospectively contributed demographic and radiation dose data for subjects undergoing 21 specific procedures in a fluoroscopic suite equipped with built-in dosimetry capability. Comprehensive physics evaluations and periodic consistency checks were performed on each unit to verify the stability and consistency of the dosimeter. Seven of 12 fluoroscopic suites in the study were equipped with skin dose mapping software.

RESULTS: Over a 3-year period, skin dose data were recorded for 800 instances of 21 interventional radiology procedures. Wide variation in PSD was observed for different instances of the same procedure. Some instances of each procedure we studied resulted in a PSD greater than 2 Gy, except for nephrostomy, pulmonary angiography, and inferior vena cava filter placement. Some instances of transjugular intrahepatic portosystemic shunt (TIPS) creation, renal/visceral angioplasty, and angiographic diagnosis and therapy of gastrointestinal hemorrhage produced PSDs greater than 3 Gy. Some instances of hepatic chemoembolization, other tumor embolization, and neuroembolization procedures in the head and spine produced PSDs greater than 5 Gy. In a subset of 709 instances of higher-dose procedures, there was good overall correlation between PSD and cumulative dose ($r = 0.86$; $P < .000001$) and between PSD and dose–area–product ($r = 0.85$, $P < .000001$), but there was wide variation in these relationships for individual instances.

CONCLUSIONS: There are substantial variations in PSD among instances of the same procedure and among different procedure types. Most of the procedures observed may produce a PSD sufficient to cause deterministic effects in skin. It is suggested that dose data be recorded routinely for TIPS creation, angioplasty in the abdomen or pelvis, all embolization procedures, and especially for head and spine embolization procedures. Measurement or estimation of PSD is the best method for determining the likelihood of radiation-induced skin effects. Skin dose mapping is preferable to a single-point measurement of PSD.

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Abbreviations: CD = cumulative dose, DAP = dose–area–product, FDA = Food and Drug Administration, IEC = International Electrotechnical Commission, IRP = interventional reference point, IVC = inferior vena cava, PSD = peak skin dose, RAD-IR = Radiation Doses in Interventional Radiology (study), TIPS = transjugular intrahepatic portosystemic shunt, TLD = thermoluminescent dosimeter

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RADIATION-induced skin effects are deterministic in nature, with a generally accepted threshold dose of 2 Gy (1,2). The likelihood and severity of radiation injury at any point on the skin are related to the dose delivered to that portion of skin (1,3). The likelihood and severity of radiation-induced skin injury to the patient as a whole are a function of the highest radiation dose at any point on that patient's skin: the peak skin dose (PSD).

It is desirable to measure PSD during interventional radiology procedures, but this has proved difficult in practice (4). As an alternative, methods have been developed to measure other analogues of patient dose. These yield either point measurements, indicating dose to a single point on the patient's skin, or overall measurements, which reflect the entire dose delivered during the course of the procedure, regardless of where on the patient the dose was delivered. Overall measurements are far more common in clinical practice and include fluoroscopy time, dose–area–product (DAP), and cumulative dose (CD) at a reference point. These methods measure various quantities (minutes, Gy·cm^2, Gy) that are analogues of the total dose delivered to the patient during a procedure. All overall measurements are indirect measurements of skin dose. Patient dose can be estimated from these indirect measurements but cannot be determined precisely.

Fluoroscopy time is the only method of dose estimation currently required by the Food and Drug Administration (FDA) on fluoroscopic equipment sold in the United States. Many manufacturers supplement the fluoroscopic timer with an acquisition frame counter, which indicates the number of images obtained. These measurements (fluoroscopy time and number of images) provide a poor analogue of dose because they provide no information regarding x-ray field size or position and do not account for differences in dose rates resulting from differences in equipment, technique, or patient size. Monitoring fluoroscopy time alone underestimates the risk of radiation-induced skin effects (5).

The European Union requires that all new interventional and pediatric fluoroscopic equipment incorporate DAP measurement capability. This technology is often available (frequently as an added-cost option) on interventional equipment sold in the United States. DAP is measured in units of Gy·cm^2 and expresses the total x-ray flux in the beam (6). Because dose decreases proportionately to the square of the distance from the focal spot, and the area of the irradiated field increases proportionally in the same way, DAP is independent of source-to-skin distance (7). DAP is a poor analogue of skin dose because a large dose delivered to a small skin area yields the same DAP as a small dose delivered to a large skin area. DAP does not correlate well with skin dose (8–14). Estimation of absorbed skin dose from DAP data and knowledge of the clinical procedure has a potential error of at least 30%–40% (15).

The International Electrotechnical Commission (IEC) recently introduced the concept of CD (16), which is the air kerma value at a specific point, the Interventional Reference Point (IRP). The IRP is defined for fluoroscopic systems that have an isocenter as a location along the central ray 15 cm from the system isocenter in the direction of the focal spot. CD does not include tissue backscatter. Depending on the patient's size, the table height, and the angulation of the beam, the IRP may be outside the patient, may coincide with the skin surface, or may be inside the patient. CD is an approximation of the total radiation dose to the skin, summed over the entire body.

During the course of virtually all interventional radiology procedures, the x-ray beam is moved periodically with respect to the patient and is directed at different areas of the patient's skin. Typically, no point on the patient's skin is within the irradiated field for the entire procedure. For this reason, CD is usually greater than PSD. Therefore, in general, estimates of the likelihood of radiation-induced skin injury that are based on CD tend to overstate this risk.

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," but no specific method of dose measurement or unit of dose was recommended (17). In a separate publication, the FDA recommended that dose information be collected and maintained for certain specific procedures (18). This recommendation was based on anecdotal reports of injuries, because no published dose data were available for many of these procedures.

As a result, the FDA invited the Society of Interventional Radiology (SIR) to gather information on dose levels associated with common interventional radiology procedures. SIR formed a task force to develop and implement a protocol for collecting dose information prospectively and in a systematic way for each of 21 interventional radiology procedures. Over a 3-year period, seven academic medical centers in the United States participated in the SIR Radiation Doses in Interventional Radiology (RAD-IR) Study, which collected data from 2,142 cases.

Part I of the RAD-IR Study provided overall dose data for a number of interventional radiology procedures, identified procedures associated with higher radiation doses, analyzed the effect of operator training level on dose, and provided recommendations for recording overall dose (19). Part II, the present report, provides skin dose data for the subset of instances in which these data were collected, compares various measures of 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 the number of images obtained; and provide a method to permit estimation of PSD from other dose metrics.

METHODS

Details of the study design are provided in part I of this report (19). Briefly, instances were included in the study if the subject underwent one of the medically indicated interventional radiology procedures listed in **Table 1**, the procedure was performed in an interventional radiology suite that had previously been registered into the study through a radiation physics evaluation, and informed consent had

Table 1
Values for a Variety of Interventional Radiology and Neuroradiology Procedures in 800 Procedures with Skin Dose Data

Procedure Description	Total No.	Fluoroscopy Time (min)				Number of Images				Dose-Area-Product (cGy · cm^2)				Cumulative Dose (mGy)			
		Mean	95% C.I.	Min	Max	Mean	95% C.I.	Min	Max	Mean	95% C.I.	Min	Max	Mean	95% C.I.	Min	Max
TIPS	19	40.7	30.4–51.1	15.0	93.2	289	195–382	69	715	43,114	29,602–56,626	8,935	101,326	2,732	1,815–3649	487	6,917
Biliary drainage	23	19.0	12.3–25.6	1.7	64.5	18	13–24	2	52	9,160	5,104–13,215	676	38,631	1,157	668–1646	39	4,831
Nephrostomy (all)	27	9.5	7.3–11.8	2.8	30.4	12	8–17	1	44	3,328	2,142–4,514	468	13,596	400	259–540	27	1,431
Obstruction	23	8.7	6.9–10.4	2.8	18.9	14	8–19	1	44	2,901	1,985–3,817	468	9,676	323	230–415	27	884
Stone access	4	14.5		4.9	30.4	5		3	10	5,780		491	13,596	844		42	1,431
Pulmonary angiography, no IVC filter	13	11.8	4.8–18.7	3.7	43.1	169	91–247	86	579	7,347	4,812–9,882	2,511	15,870	355	228–482	109	749
Pulmonary angiography, with IVC filter	5	17.3		9.8	34.2	188		121	306	10,344		7,095	11,934	485		259	750
IVC filter placement only	73	3.0	2.6–3.4	0.8	9.9	31	25–36	3	152	5,393	4,506–6,280	609	20,327	220	182–258	23	680
Renal/visceral PTA (all)	39	20.4	16.7–24.1	5.1	47.0	139	112–166	25	344	20,811	15,039–26,582	2,619	104,075	1,729	1,341–2,117	157	5,482
No stent	18	17.1	11.5–22.7	5.1	39.3	112	81–143	25	230	16,975	5,665–28,284	2,619	104,075	1,397	753–2040	157	5,482
With stent	21	23.2	18.1–28.4	7.1	47.0	162	121–204	71	344	24,099	18,743–29,454	7,503	46,381	2,015	1,534–2,495	794	4,240
Iliac PTA (all)	31	14.9	11.9–17.9	5.5	39.8	200	158–243	55	675	22,357	17,032–27,682	4,205	65,740	1,284	995–1573	407	3,619
No stent	9	14.9	10.2–19.6	8.8	24.8	177	128–225	123	326	17,140	10,575–23,705	7,030	30,099	993	690–1297	407	1,428
With stent	22	14.9	11.0–18.8	5.5	39.8	210	152–268	55	675	24,491	17,383–31,599	4,205	65,740	1,403	1,012–1,794	455	3,619
Central venous reconstruction-SVC	2	16.3		12.9	19.6	199		87	310	5,176		1,709	8,643	595		128	1,062
Central venous reconstruction-IVC	3	20.6		8.6	31.1	361		101	831	19,549		11,243	35,375	1,247		610	2,316
Bronchial artery embolization	6	25.7		10.9	46.5	277		153	581	13,820		7,220	31,453	1,061		507	2,663
Hepatic chemoembolization	26	14.8	10.4–19.3	2.7	48.7	194	155–234	16	436	27,012	20,396–33,629	2,046	61,574	1,447	894–1999	61	6,198
Pelvic arterial embolization (all)	23	25.0	20.6–29.5	8.6	58.0	415	316–514	78	869	29,885	23,145–36,625	3,769	62,358	2,594	2,044–3,143	675	5,454
Trauma	1	26.6		26.6	26.6	580		580	580	62,358		62,358	62,358	4,797		4797	4,797
Tumor	5	15.6		8.6	19.6	309		133	516	25,446		13,282	57,049	1,340		675	2,740
Fibroids	14	27.2	21.1–33.3	13.5	58.0	447	303–590	78	869	29,327	20,779–37,876	3,769	60,611	2,752	2,096–3,407	1,218	5,454
AVM	1	41.1		41.1	41.1	223		223	223	31,970		31,970	31,970	2,117		2,117	2,117
Aneurysm	2	24.7		21.5	27.9	471		243	699	27,614		27,327	27,900	3,761		3,636	3,885
Pelvic vein embolization-ovarian vein	1	56.6		56.6	56.6	142		142	142	16,950		16,950	16,950	1,667		1,667	1,667
Pelvic vein embolization-varicocele	1	10.3		10.3	10.3	33		33	33	1,286		1,286	1,286	106		106	106
Other tumor embolization	23	25.2	15.5–34.8	5.0	89.7	226	174–278	63	488	32,269	21,734–42,804	8,696	97,212	2,198	1,364–3,032	379	7,986
Peripheral AVM embolization	3	11.6		3.4	26.7	179		18	420	530		364	814	101		16	260
GI hemorrhage-diagnosis/therapy	25	26.2	20.5–32.0	5.9	56.8	270	188–352	77	883	34,334	27,580–41,088	9,733	81,206	2,772	2,033–3,510	520	7,088
Neuroembolization-head (all)	356	87.1	81.4–92.8	2.6	313.7	1053	1,007–1,100	71	2,654	31,987	29,904–34,070	398	13,511	3,762	3,542–3,981	43	12,683
AVM	169	91.5	82.3–100.8	2.6	313.7	1034	965–1,103	71	2,654	33,919	30,295–37,542	398	135,111	3,746	3,366–4,127	43	12,683
Aneurysm	143	73.8	68.5–79.0	15.2	199.7	1070	1,004–1,135	292	2,440	28,157	26,064–30,251	6,788	82,515	3,777	3,522–4,033	1,284	9,809
Tumor	44	113.6	91.0–136.1	16.2	276.5	1074	911–1,236	364	2,612	37,012	30,545–43,479	4,587	95,590	3,768	3,140–4,397	598	10,907
Neuroembolization-spine (all)	18	71.5	52.6–90.4	31.9	170.4	978	727–1,229	215	1,995	49,761	34,805–64,716	8,079	103,399	5,511	4,223–6,798	2,080	10,526
AVM	7	78.9		34.4	170.4	1426		656	1,995	70,036		8,079	103,399	6,996		2,080	10,526
Tumor	11	66.8	49.1–84.5	31.9	119.4	692	479–906	215	1,181	36,858	27,517–46,200	17,559	62,154	4,565	3,462–5,668	2,380	7,504
Stroke therapy	5	35.9		19.1	74.9	491		344	676	17,679		7,924	24,671	2,112		992	3,040
Carotid stent	17	39.3	31.8–46.7	18.5	64.5	633	491–774	167	1,062	16,110	9,874–22,347	3,193	51,544	1,204	797–1,610	326	3,123
Vertebroplasty	61	17.4	15.1–19.7	4.2	54.0	82	62–102	0	484	7,763	6,146–9,381	663	33,533	1,279	1,042–1,516	146	3,993

Note.—95% C.I. = 95% confidence interval; shown for all procedures with 9 or more instances.

been obtained for the medically indicated interventional radiology procedure. Some procedures were divided into subgroups, as shown in **Table 1**. These subgroups were defined prospectively before data collection. Accrual of individual cases 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 their procedure was performed in one of these suites.

Relevant procedure definitions include the following: "TIPS creation" includes only procedures where a new transjugular intrahepatic portosystemic shunt (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."

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 then only for a portion of the study. Written informed consent was obtained from these subjects.

Site enrollment was limited to sites with angiographic equipment containing a built-in dosimeter. These systems are compliant with the dosimetry portion of IEC standard 60601–2–43 (16). Exposure measurements were performed automatically by the fluoroscopic unit and displayed directly on the operator's console. Dosimetry information was readily available to the operator during the performance of the procedure. All medical centers participating in the RAD-IR Study were equipped with either Multistar single-plane units or Neurostar biplane units (Siemens Medical Systems, Malvern, PA).

The requirement for "built-in" instrumentation was instituted to ensure that there would be no increase in procedure time and no increase in dose to the patient as a result of the study. The use of data from built-in dosimeters also minimized the effort required for data collection and the potential for measurement errors.

The fluoroscopic unit automatically calculated and displayed fluoroscopy time, number of images, DAP, and CD. All CD data reported in this study conform to the definition of CD in the final IEC standard (16). 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. 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 images, total DAP, and total CD. The total values were used for data analysis.

Seven of the 12 fluoroscopic units in this study incorporated skin dose calculation capability. These units were equipped with an additional dose measurement system (CareGraph; Siemens Medical Systems). This skin dose mapping software uses a mathematical model of the patient's height and weight to model surface shape. This is used, along with the patient's location on the procedure table, to calculate x-ray entrance field size, location, and air kerma incident on the skin (20). The measured DAP, collimator field size, tabletop position, and C-arm angulation are used to monitor skin irradiation in real time. The peak air kerma level (ie, PSD) and spatial distribution of the dose on the skin (skin dose map) are displayed on a graphical representation of the skin surface (**Fig 1**). The software also indicates the size of the skin area exposed to dose levels greater than the 95th percentile of dose for that patient (95% area load). Both single-plane and biplane fluoroscopic units generate a single value for PSD and a single value for 95% area load.

With use of the CD data and PSD data generated by the fluoroscopic unit and the skin dose mapping software, we calculated the dose index, defined as the ratio between the PSD and the CD (20). Dose index is a dimensionless quantity. It provides a measure of the spread of dose on the patient's skin, ie, whether the irradiated field changes in size and position over the course of the procedure. Changes in the size, shape, and position of the irradiated field result from a complex interaction of patient, procedure, and operator-specific variables that are difficult to quantify. Dose index is a convenient measure of these variables and their effect on skin dose distribution (21).

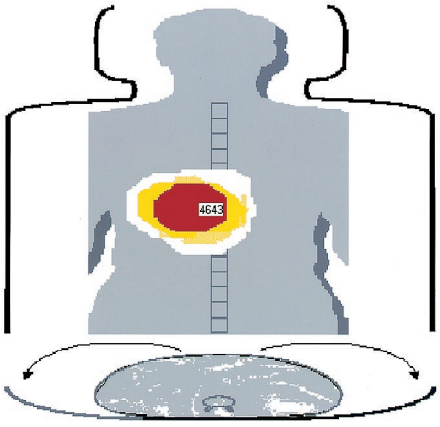

Figure 1. Skin-dose map display at the conclusion of a TIPS procedure. A map of the skin dose distribution is shown. The map is displayed as if the skin surface were cut along the midline anteriorly and reflected laterally, as shown in the diagram at the bottom of the figure. As skin dose increases, the color of the corresponding portion of the skin map changes from white through various shades of yellow and orange to red. The final value of PSD for the entire skin surface is displayed (4,643 mGy in this example). The display also includes, in tabular form, CD, DAP, fluoroscopy time, PSD, and 95% area load (not shown). On skin dose maps displayed while the procedure is in progress, the current radiation field is also indicated on the skin dose map (not shown).

To confirm that each angiographic unit's dosimeter was functioning properly, an initial comprehensive physics evaluation was conducted on each unit. This full evaluation compared the internal reference air kerma readout to an external ionization chamber measurement over a range of exposure conditions. 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 to verify the stability and consistency of the reference

Table 2
Values for 800 Instances of Interventional Radiology and Neuroradiology Procedures With Skin Dose Data

Procedure Description	Total No.	Peak Skin Dose (mGy)				Dose Index				95% Area Load (cm^2)			
		Mean	95% C.I.	Min	Max	Mean	95% C.I.	Min	Max	Mean	95% C.I.	Min	Max
TIPS	19	2,168	1,541–2,795	438	4,644	0.85	0.78–0.93	0.56	1.13	41.4	27.3–55.5	2.8	118.3
Biliary drainage	23	781	396–1,166	40	4,238	0.75	0.64–0.86	0.33	1.24	26.4	12.4–40.4	3.3	119.8
Nephrostomy (all)	27	258	156–360	27	667	0.68	0.60–0.76	0.32	1.12	18.3	10.7–25.9	1.0	8.8
Obstruction	23	204	142–266	27	667	0.69	0.60–0.78	0.32	1.12	19.0	10.4–27.6	1.0	88.8
Stone access	4	568		31	1,104	0.65		0.40	0.81	14.2		1.5	35.8
Pulmonary angiography-no IVC filter	13	221	142–300	101	476	0.68	0.54–0.82	0.39	0.98	41.8	23.6–60.1	2.5	106.8
Pulmonary angiography-with IVC filter	5	352		226	618	0.73		0.55	0.87	44.1		8.3	164.3
IVC filter placement only	73	193	158–227	19	722	0.93	0.86–1.00	0.47	2.84	134.9	113.6–156.2	2.3	366.5
Renal/visceral PTA (all)	39	1,442	1,129–1,755	152	4,427	0.87	0.80–0.94	0.44	1.35	46.9	35.0–58.8	1.8	136.5
No stent	18	1,009	522–1,497	152	4,427	0.78	0.67–0.88	0.44	1.11	47.6	29.6–65.5	1.8	117.0
With stent	21	1,812	1,447–2,177	850	3,642	0.96	0.87–1.05	0.55	1.35	46.2	28.9–63.6	2.0	136.5
Iliac PTA (all)	31	900	655–1,145	194	2,568	0.70	0.61–0.79	0.31	1.36	29.7	19.3–40.1	2.3	129.8
No stent	9	606	357–854	194	1,246	0.62	0.46–0.79	0.31	0.97	30.3	6.0–54.5	5.5	102.8
With stent	22	1,021	694–1,348	233	2,568	0.73	0.62–0.84	0.39	1.36	29.5	17.1–41.8	2.3	129.8
Central venous reconstruction-SVC	2	554		70	1,038	0.76		0.55	0.98	39.3		5.3	73.3
Central venous reconstruction-IVC	3	1,121		409	2,430	0.79		0.64	1.05	69.3		2.5	199.0
Bronchial artery embolization	6	1,008		462	2,392	0.98		0.67	1.23	72.3		2.3	360.0
Hepatic chemoembolization	26	1,380	883–1,877	72	5,471	1.00	0.94–1.06	0.59	1.22	72.7	52.8–92.5	5.3	224.3
Pelvic arterial embolization (all)	23	1,817	1,473–2,161	418	3,503	0.75	0.65–0.85	0.29	1.36	28.5	13.8–43.2	2.0	122.3
Trauma	1	2,892		2,892	2,892	0.60		0.60	0.60	14.3		14.3	14.3
Tumor	5	1,150		418	2,338	0.84		0.51	1.01	54.0		7.5	116.8
Fibroids	14	1,975	1,551–2,399	930	3,503	0.75	0.62–0.89	0.43	1.36	23.3	5.5–41.2	2.0	122.3
AVM	1	1,861		1,861	1,861	0.88		0.88	0.88	14.3		14.3	14.3
Aneurysm	2	1,820		1,143	2,496	0.49		0.29	0.69	15.4		13.3	17.5
Pelvic vein embolization-ovarian vein	1	1,199		1,199	1,199	0.72		0.72	0.72	1.5		1.5	1.5
Pelvic vein embolization-varicocele	1	73		73	73	0.69		0.69	0.69	0.3		0.3	0.3
Other tumor embolization	23	1,869	1,101–2,637	212	8,293	0.86	0.77–0.96	0.50	1.15	54.1	34.3–73.9	2.0	161.3
Peripheral AVM embolization	3	70		1	180	0.58		0.06	1.00	218.6		1.8	350.8
GI hemorrhage-diagnosis/therapy	25	1,888	1,460–2,316	257	3,896	0.74	0.64–0.83	0.33	1.18	26.7	17.6–35.9	1.5	83.5
Neuroembolization-head (all)	356	1,977	1,850–2,104	2	6,658	0.54	0.52–0.56	0.05	1.67	16.2	14.1–18.3	0.3	191.3
AVM	169	2,038	1,823–2,253	2	6,658	0.55	0.53–0.57	0.05	1.33	18.3	14.6–22.0	0.3	191.3
Aneurysm	143	1,880	1,723–2,036	329	6,414	0.51	0.48–0.54	0.08	1.67	11.8	9.7–13.9	0.5	60.0
Tumor	44	2,057	1,693–2,420	445	4,886	0.56	0.51–0.61	0.19	1.20	22.6	15.8–29.4	1.0	105.8
Neuroembolization-spine (all)	18	3,739	2,870–4,608	823	7,273	0.72	0.59–0.85	0.20	1.17	23.7	14.2–33.2	2.5	78.3
AVM	7	3,624		823	7,273	0.53		0.20	1.06	29.8		2.5	78.3
Tumor	11	3,811	2,836–4,787	2,284	5,961	0.84	0.73–0.96	0.61	1.17	19.9	10.5–29.2	2.5	41.8
Stroke therapy	5	1,209		594	1,735	0.56		0.45	0.61	16.0		2.5	42.5
Carotid stent	17	597	303–891	136	2,331	0.47	0.39–0.55	0.11	0.75	15.6	8.4–22.9	0.3	53.5
Vertebroplasty	61	684	558–809	78	2,183	0.59	0.54–0.64	0.12	1.13	23.6	18.6–28.5	0.3	80.5

Note.—95% C.I. = 95% confidence interval; shown for all procedures with 9 or more instances.

air kerma readout and the automatic brightness control. A brief summary of the physics evaluations is presented in part I of this report (19). Procedural details and a full analysis of the physics evaluations will be published elsewhere.

Descriptive and summary statistics were calculated with use of Access 2000 (Microsoft, Redmond, WA). Some data manipulation and linear regression analyses were performed with Excel 2000 (Microsoft). Confidence intervals were calculated with Excel 2000, and standard techniques were used for determining confidence intervals with the Student *t* distribution (22). Scatter-plots and trend lines were created with Excel 2000. Tests for statistical significance were performed with SAS version 8 (SAS Institute, Cary, NC). For continuous data, Student *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.

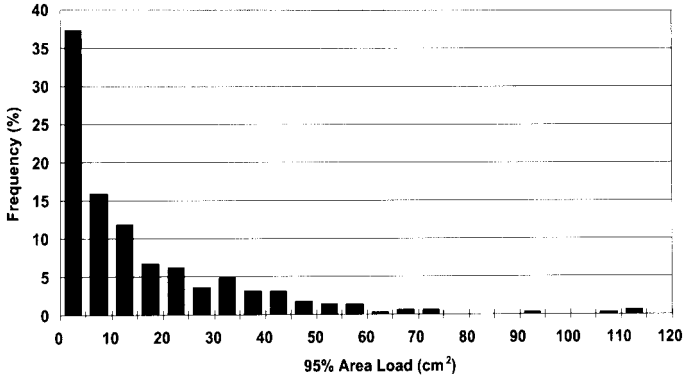

Figure 2. Histogram of 95% area load (the area of skin with an entrance dose greater than the 95th percentile of skin dose) for 356 instances of embolization of the head, neck, or brain. One instance (not shown) had a 95% area load of 191.3 cm^2.

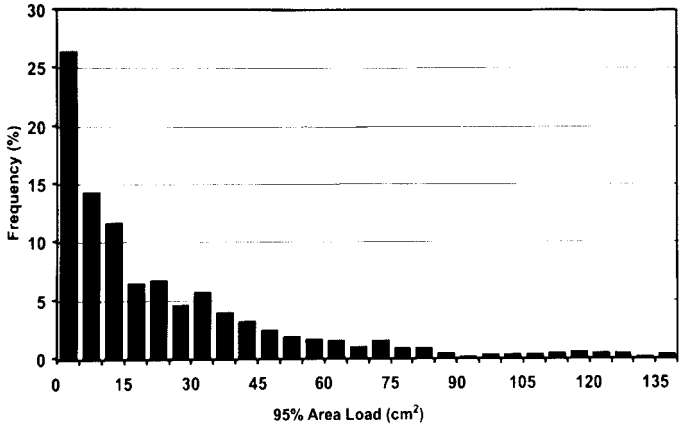

Figure 3. Histogram of 95% area load (the area of skin with an entrance dose greater than the 95th percentile of skin dose) for 709 instances of higher-dose procedures. Pulmonary angiography and IVC filter placement procedures are excluded from this analysis (see text). Eight instances (not shown) had a 95% area load > 150 cm^2.

The significance level was set at $P = .05$. For frequency data, χ^2 tests were used, with a significance level of $P = .05$.

RESULTS

Skin dose data were recorded for 800 (37%) of the 2,142 cases in the RAD-IR Study. Of these, 57% ($n = 457$) were instances of interventional neuroradiology procedures. The mean, range, and 95% confidence intervals for fluoroscopy time, number of images, DAP, and CD for these 800 instances are given in **Table 1**, tabulated by procedure type. (The same data are given for all 2,142 instances in **Table 1** of part I of this report [19]) Measurement capability for all four of the dose analogues shown in **Table 1**—fluoroscopy time, number of images, DAP, and CD—is or soon will be available on interventional fluoroscopy units.

Skin dose data (PSD, dose index, and 95% area load) for these 800 instances are given in **Table 2**. Note that there are fewer than 10 instances of many procedures and procedure subgroups. Measurement capability for the three measures of skin dose shown in **Table 2**—PSD, dose index, and 95% area load—is not generally available.

As indicated in **Table 2**, the mean PSD for many of the procedures we studied is near or above the 2-Gy threshold for radiation-induced skin effects. Most of these procedures may produce a skin dose sufficient to cause at least transient skin effects. Mean dose index ranged from 0.47 to 1.0, with the majority of procedures having a mean dose index between 0.5 and 0.8. Therefore, CD overestimates PSD in most instances of procedures. There is a wide range for 95% area load in most procedures. However, 95% area load may be quite small and is occasionally < 1 cm^2 (**Fig 2**; **Fig 3**).

We determined the frequency with which each of the procedures we studied resulted in a PSD greater than 1 Gy, 2 Gy, or 3 Gy. These data are presented in **Table 3**. For those procedures for which data were collected for more than 6 instances, only nephrostomy, inferior vena cava (IVC) filter placement, and pulmonary angiography never resulted in a PSD greater than 2 Gy. All of the other procedures we studied have the potential to cause a PSD greater than the 2-Gy threshold for radiation-induced skin effects. Infrequently, PSD may be substantially higher. Fifteen (1.9%) of the 800 instances of procedures in our study resulted in a PSD > 5 Gy (**Table 4**). All of these 15 instances were embolization procedures. Spine embolization in particular is associated with very high PSDs. The mean PSD was > 5 Gy for the 18 instances of spine embolization in this report.

There were statistically significant differences in dose index ($P < .0001$, analysis of variance) and 95% area load ($P < .0001$, analysis of variance) among the different procedures. There was also substantial within-procedure variation in PSD and 95% area load for many of these procedures, as illustrated for embolization of the head, neck, and brain in **Figures 2 and 4**. The variability of dose index was evaluated by calculating the coefficient of variation (the standard deviation divided by the mean) for procedures and subgroups of procedures in which dose index data were available for more than 10 instances (**Table 2**). In these groups and subgroups, the coefficient of variation ranged from 0.16 to 0.37.

We analyzed data on PSD, dose index, and 95% area load for procedures with subgroups to determine whether these measurements differed among the subgroups. The results are shown in **Table 5**.

Because measurement of skin dose is of interest primarily in those procedures in which there is concern over the possibility of high PSD, we excluded instances of pulmonary angiography and IVC filter placement from further analysis. None of the 91 instances of these procedures resulted in a PSD greater than 750 mGy (**Table**

Table 3
Frequency with which Interventional Radiology Procedures Resulted in a Peak Skin Dose Greater Than 1 Gy, 2 Gy, or 3 Gy

Procedure Description	Total Cases	>1 Gy		>2 Gy		>3 Gy	
		n	%	*n*	%	*n*	%
TIPS	19	14	74	9	47	6	32
Biliary drainage	23	6	26	1	4	1	4
Nephrostomy, obstruction	23	0	0				
Nephrostomy, stone access	4	1	25	0	0		
Pulmonary angiography, no IVC filter	13	0	0				
Pulmonary angiography, with IVC filter	5	0	0				
IVC filter placement only	73	0	0				
Renal/visceral angioplasty, no stent	18	7	39	1	6	1	6
Renal/visceral angioplasty, with stent	21	18	86	7	33	2	10
Iliac angioplasty, no stent	9	1	11	0	0		
Iliac angioplasty, with stent	22	8	36	3	14	0	0
Central venous reconstruction, SVC	2	1	50	0	0		
Central venous reconstruction, IVC	3	1	33	1	33	0	0
Bronchial artery embolization	6	2	33	1	17	0	0
Hepatic chemoembolization	26	12	46	5	19	2	8
Pelvic arterial embolization, trauma	1	1	100	1	100	0	0
Pelvic arterial embolization, tumor	5	3	60	1	20	0	0
Pelvic arterial embolization, fibroids	14	12	86	7	50	1	7
Pelvic arterial embolization, AVM	1	1	100	0	0		
Pelvic arterial embolization, aneurysm	2	2	100	1	50	0	0
Pelvic vein embolization, ovarian vein	1	1	100	0	0		
Pelvic vein embolization, varicocele	1	0	0				
Other tumor embolization	23	13	57	8	35	5	22
Peripheral AVM embolization	3	0	0				
GI hemorrhage, diagnosis/therapy	25	18	72	10	40	5	20
Neuroembolization, head, AVM	169	129	76	69	41	31	18
Neuroembolization, head, aneurysm	143	122	85	49	34	19	13
Neuroembolization, head, tumor	44	35	80	18	41	10	23
Neuroembolization, spine, AVM	7	6	86	5	71	4	57
Neuroembolization, spine, tumor	11	11	10	11	100	6	55
Stroke therapy	5	3	60	0	0		
Carotid stent	17	3	18	1	6	0	0
Vertebroplasty	61	15	25	1	2	0	0

Table 4
Number and Frequency with which Instances of Interventional Radiology and Interventional Neuroradiology Procedures Resulted in a Peak Skin Dose Greater than 5 Gy

Procedure	Total Instances	Number >5 Gy	%
Neuroembolization, head, aneurysm	143	2	1.4
Hepatic chemoembolization	26	1	3.8
Neuroembolization, head, AVM	169	7	4.1
Other tumor embolization	23	1	4.3
Neuroembolization, spine, AVM	7	1	14.2
Neuroembolization, spine, tumor	11	3	27.3
All other procedures	421	0	0
Total	800	15	1.9

2). These procedures also yield relatively large 95% area loads (**Table 2**).

For convenience, we refer to the remaining 709 instances as the higher-dose subset. We evaluated the relationships among PSD, dose index, and 95% area load to determine how these quantities were related. The higher-dose subset demonstrated poor correlation between PSD and dose index (Pearson $r = 0.118$; $P < .002$; **Fig 5**), between PSD and 95% area load (Pearson $r = 0.209$; $P < .00001$; **Fig 6**), and between dose index and 95% area load (Pearson $r = 0.218$; $P < .00001$; **Fig 7**).

The relationship between CD and DAP was analyzed in the larger set of 2,142 cases in part I of this report (19) and was not repeated for the higher-dose subset. Scatter-plots of PSD and CD (**Fig 8**) and PSD and DAP (**Fig 9**) were created for the higher-dose subset to evaluate the relationship between more readily available measures of dose (DAP and CD) and the more-accurate but less-available PSD. Linear regression demonstrated good correlation between PSD and CD (Pearson $r = 0.862$; $P < .000001$; PSD [mGy] = 206 + 0.513 × CD [mGy];

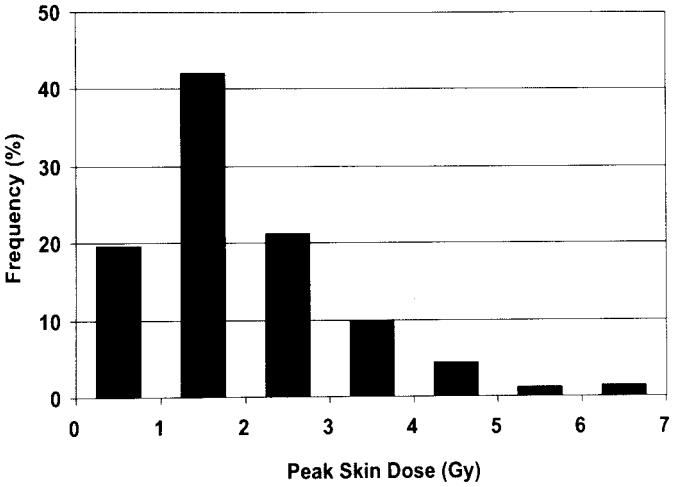

Figure 4. Histogram of PSD for 356 instances of embolization of the head, neck, or brain.

Table 5
Statistical Significance of Comparisons of Peak Skin Dose, Dose Index, and 95% Area Load between Subgroups of Certain Interventional Radiology Procedures

Procedure	Peak Skin Dose, *P*	Dose Index, *P*	95% Area Load, *P*
Nephrostomy, obstruction vs. stone access	.084 (NS)	.33 (NS)	.29 (NS)
Renal/visceral angioplasty, no stent vs. stent	.028	.029	.46 (NS)
Iliac angioplasty, no stent vs. stent	.014	.12 (NS)	.245 (NS)
Pelvic arterial embolization, trauma/tumor/fibroids/AVM/aneurysm	.21 (NS)	.44 (NS)	.46 (NS)
Neuroembolization, head, AVM/aneurysm/tumor	.47 (NS)	.080 (NS)	.0016
Neuroembolization, spine, AVM vs. tumor	.42 (NS)	.007	.15 (NS)

Note.—Comparisons for procedures with two subgroups were performed with *t*-tests; comparisons for procedures with more than two subgroups were performed with ANOVA. Statistical significance level is $P < .05$. NS = not statistically significant.

adjusted $r^2 = 0.744$) and between PSD and DAP (Pearson $r = 0.848$; $P < .000001$; PSD [mGy] = 249 + 0.052 × DAP [cGy·cm^2]; adjusted $r^2 = 0.720$). However, there was wide variation among individual instances, particularly at higher doses (**Figs 8, 9**). Predictions of PSD from regression equations for CD or DAP are therefore imprecise.

DISCUSSION

High-dose Procedures

In part I of this report, we identified certain procedures that were associated with high overall patient dose (19). These procedures included renal/visceral angioplasty with stent placement, TIPS creation, and embolization procedures of all kinds. We recommended that, at a minimum, radiation dose data should be recorded for all patients undergoing these procedures because of the risk of radiation-induced skin effects. This recommendation was based on assumptions about the relationship between PSD and overall measures of dose such as DAP and CD.

Our observations of PSD in a subset of 800 of the 2,142 instances of the procedures we described in part I confirm the validity of our earlier recommendations, which were based on CD. The same procedures that are associated with a high CD are also associated with a high PSD. As is apparent from **Tables 3 and 4**, instances of many of the procedures we evaluated resulted in a PSD > 2 Gy, the conventional threshold for radiation-induced skin effects (2). In particular, hepatic chemoembolization, tumor embolization, and neuroembolization procedures in the head, and especially in the spine, can produce a PSD greater than 5 Gy (**Table 4**). Doses this high have been observed previously for some of these procedures (**Table 6**) (5). However, in general, the risk of deterministic skin effects has not been adequately appreciated. Publication 85 of the International Commission on Radiological Protection (ICRP), for example, markedly underestimates the PSD associated with these procedures (23).

Radiation doses greater than 6 Gy may result in permanent skin injury (2). Some of the high-dose procedures we studied (particularly TIPS creation, embolization of intracranial aneurysms, and embolization of intracranial and spinal arteriovenous malformations) must often be repeated in individual patients. The cumulative effect of the skin doses associated with each instance of these procedures is of particular concern. These procedures must be performed with exceptional care to optimize radiation dose and minimize PSD. All these procedures have in common fluoroscopic visualization of a small area of the body, often in a magnified field of view, with relatively long fluoroscopy times. Large numbers of images of the same area are often also obtained.

Methods for minimizing skin dose during these procedures are available. These include optimizing technical factors, limiting fluoroscopy and image acquisition to the extent possible, tight collimation, and dose spreading (distributing the radiation dose over the skin surface by angling the gantry, moving the table, or using a second plane) (21,24,25).

Adequate operator training is essential if deterministic injuries are to be avoided (26). In our opinion, operators who perform these procedures must have formal training in radiation safety, radiation biology, and radiation dose management. These operators may require training in radiation dose management above and beyond that required for diagnostic radiologists.

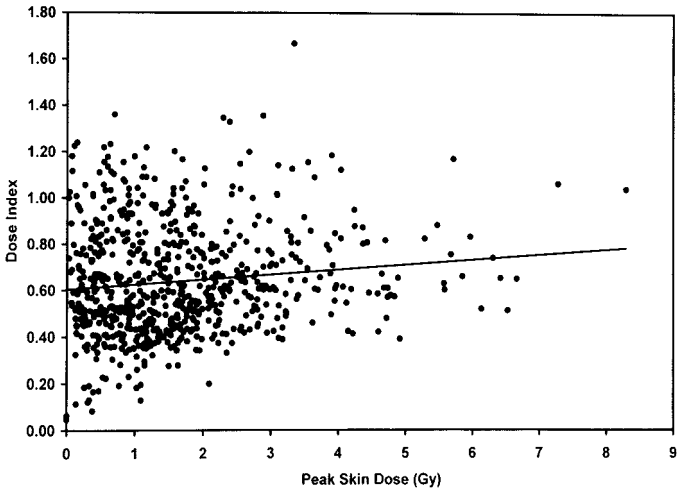

Figure 5. Scatter-plot with trend line of PSD and dose index for 800 instances of procedures with skin dose data.

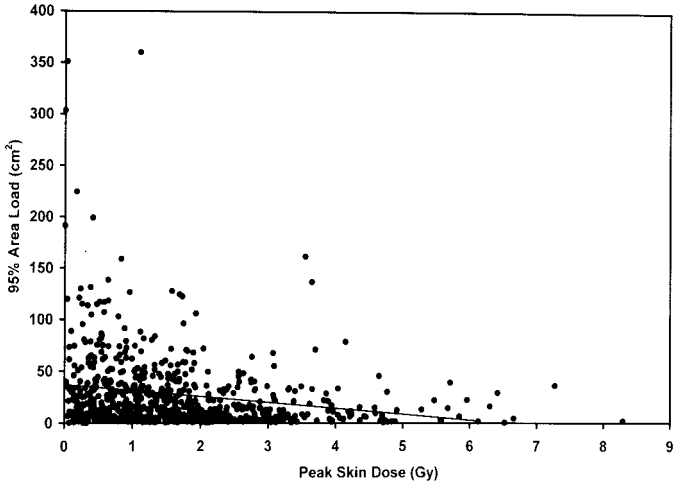

Figure 6. Scatter-plot with trend line of PSD and 95% area load for 800 instances of procedures with skin dose data.

Dose Data from Other Reported Studies

Table 6 compares skin dose and fluoroscopy time data from our study to other data in the literature (5,10, 15,24,27–30). O'Dea and colleagues studied a series of 94 patients undergoing neuroembolization procedures (5). When overlap of frontal and lateral radiation fields was considered, they observed PSDs similar to those we observed. In almost all other reported studies, investigators appear to have underestimated PSD. There are two reasons for this. First, most of these studies reported skin doses derived from DAP data or determined with thermoluminescent dosimeters (TLDs). As will be described later, these techniques are subject to substantial error. Second, we have shown statistically significant differences in PSD between subgroups of certain procedures (**Table 5**). If the procedure groups are dissimilar in composition, the dose data will not be comparable (31). The definitions of different procedures and the composition of groups of procedures vary from report to report. For example, one report describes skin dose data for 114 neuroradiology procedures, but these procedures include instances of both diagnostic and interventional procedures (32). The number of instances of interventional procedures is not stated, and no data are given for these procedures alone. The term "interventional" is sometimes used to describe both diagnostic and therapeutic procedures (30).

Skin Dose Measurement

One of the reasons for earlier underestimations of PSD for interventional radiology procedures is the difficulty in measuring PSD accurately. Skin dose is substantially more difficult to determine than overall dose. A number of methods are available. Skin dose may be measured directly with use of an area-measurement device such as radiation therapy verification film or a point measurement device such as a radiolucent probe or TLD (33).

When skin dose is measured directly with radiation therapy verification film, the film is placed against the patient's skin in the region of the entrance beam before the procedure and developed at the conclusion of the procedure. The developed film provides both a map of skin dose and a measurement of PSD (34). Radiation fields outside the film area will not be recorded. Film is cumbersome to use and requires physicist time for interpretation. Direct measurement of skin dose with film is relatively labor-intensive, expensive, and intrusive for the patient. For these reasons, it is not commonly used.

Point measurements may be obtained with a radiolucent probe. Either a metal oxide semiconducting field effect transistor or a scintillation dosimeter can be placed at the point of presumed PSD to provide a real-time measurement (35–37). Alternatively, TLDs can be placed on the skin for direct measurement of skin dose. TLDs are accurate and readily available, but they require the services of a medical physicist for calibration and interpretation.

Skin dose data derived from point measurements are likely to underestimate true PSD unless the measurement device is placed at the exact site of the PSD. This is unlikely because the PSD is usually confined to a small area of skin, and the exact location of the PSD is not known before the procedure. For example, we observed that the 95% area load (the area of skin which received doses equal to or greater than the 95th percentile of skin

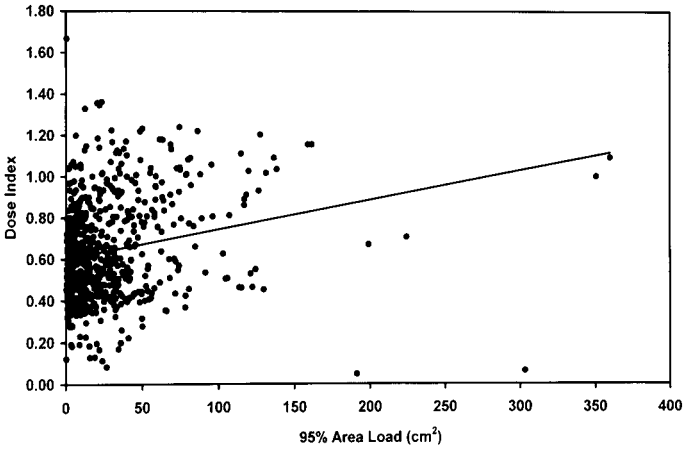

Figure 7. Scatter-plot with trend line of dose index and 95% area load for 800 instances of procedures with skin dose data.

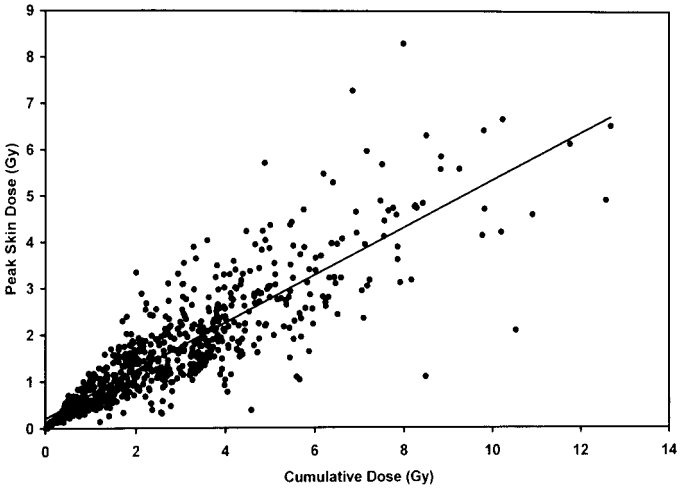

Figure 8. Scatter-plot with trend line of CD and PSD for 709 instances of procedures with skin dose data (pulmonary angiography and IVC filter placement are excluded).

dose during a case) was less than 5 cm^2 in more than a quarter of the 709 instances of procedures in the higher-dose subset and less than 10 cm^2 in more than half the instances (**Fig 8**). We also observed a mean 95% area load of 18.3 cm^2 in 169 instances of brain arteriovenous malformation embolization and a mean 95% area load of 11.8 cm^2 in 143 instances of brain aneurysm embolization (**Table 2**). Because it is not possible to predict the site of PSD a priori, a limited number of point measurement devices cannot be placed in such a way that PSD is certain to be recorded (35,38). Even small gaps between devices may cause PSD to be substantially underestimated. Also, without large numbers of devices, it is difficult to construct an accurate skin dose map.

Neither TLDs nor film provide real-time dose information. Real-time display of dose data is desirable because it provides feedback to the operator and can provide a warning at predetermined levels below the threshold for skin injury (39). With this information, it is possible to modify technique during the procedure by changing gantry angulation, table position, or collimation to minimize skin dose (21). The dose-mapping software used to estimate skin dose in this study was selected because it is simple to use, requires little operator intervention, and provides real-time displays of PSD and skin dose distribution. The PSD and skin dose map are easily incorporated into the patient record. Unfortunately, the software is manufacturer-specific and is not generally available.

DAP data have been used to provide an estimate of PSD. DAP is a measure of overall dose. It provides an accurate estimate of skin dose only when the geometry of the tube, table, and image intensifier and the size of the irradiated field are known for each episode of fluoroscopy and image acquisition. Changes in focus–to–skin and focus–to–image intensifier distances can introduce uncertainties of as much as 30%, and changes in image intensifier field of view or field collimation can introduce uncertainties of as much as 40% in the estimate of skin dose (15). Although McFadden and colleagues (40) observed good correlation between DAP and skin dose for cardiac radiofrequency ablation procedures, for most procedures, there is no general correlation between DAP and PSD, and there is poor correlation between skin doses calculated from DAP data and measured skin doses (12–14). Van de Putte and colleagues (13) found large differences between the calculated skin doses derived from DAP data and measured skin doses for individual patients. Even when DAP correlates well with CD and PSD, there is wide variability among individual instances of the same procedure (41). Our results confirm these findings.

CD demonstrates better correlation with PSD than DAP does, but like DAP, CD demonstrates variability for individual instances of the same procedure (**Table 1**; **Fig 8**). If only CD or DAP is known, published data for dose index (or the corresponding DAP index) can be used to estimate PSD, as will be presented in a subsequent part of this report.

Dose Index

Dose index is a measure of the various operator, procedure, and patient factors (eg, operator technique, procedure complexity, patient anatomy) that affect PSD. It is a convenient way to incorporate and express these factors that are otherwise difficult to quantify. Operator-dependent techniques that reduce PSD, such as dose spreading, reduce the dose index (21). Dose index is therefore operator-specific as well as procedure-specific (41). If PSD and CD have been measured,

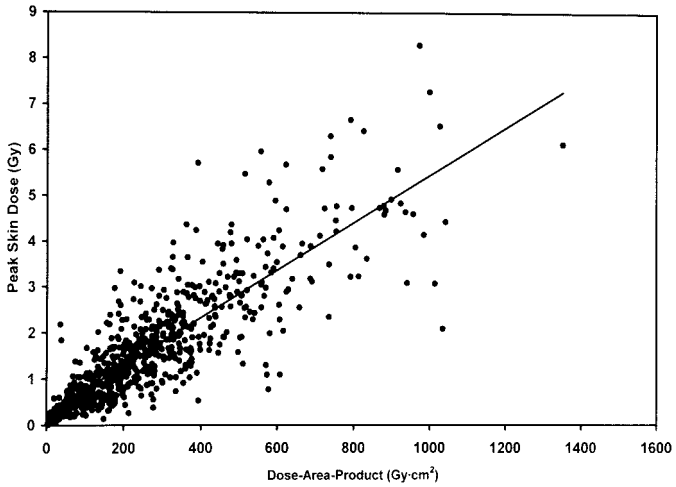

Figure 9. Scatter plot with trend line of DAP and PSD for 709 instances of procedures with skin dose data (pulmonary angiography and IVC filter placement are excluded).

dose index can be calculated and used to quantify the effectiveness of specific techniques and of individual operators with regard to minimizing PSD (21). Also, as noted before, dose index data can be used to estimate PSD when CD is known.

The dose index is usually less than 1.0, but it need not be. As noted earlier, the dose index is the ratio between the PSD and CD at the IRP. The IRP is an arbitrary point in space and may or may not coincide with the patient's skin surface. If the IRP is within the patient, CD is an underestimate of skin dose. In addition, the PSD calculated by the dose-mapping software used in this study is an overestimation of actual PSD because the dose-mapping software does not compensate for the thickness of the table and mattress (1–2 cm) on which the patient lies, nor the beam filtration caused by the table and mattress. An overestimation of PSD caused by the dose-mapping software, combined with an underestimation of skin dose based on CD, can result in a dose index greater than 1. The maximum dose index exceeded 1.0 for a number of the procedures in this study (**Table 2**).

The mean dose index for neuroembolization of the head (0.51–0.56) tended to be lower than for interventional radiology procedures (0.49–1.00; **Table 2**). This is caused by differences in the way these procedures are performed. Three hundred forty-two (99.7%) of the 343 instances of nonneuroradiologic interventional radiology procedures in this report were performed with a single-plane fluoroscopic unit. Single-plane fluoroscopic units suffice for interventional radiology procedures because most of the radiation is delivered in the frontal plane, with varying but generally small amounts of gantry angulation. Conversely, 96.9% (345 of 356) of the neuroembolization procedures in the head, neck, or brain in our series were performed with a biplane fluoroscopic unit, with radiation delivered in both planes. Biplane units are preferred for interventional neuroradiology procedures because a substantial proportion of the dose is delivered in the lateral plane.

In our series of 345 neuroembolization procedures in the head, neck, or brain, approximately 55%–60% of the total dose was delivered in the frontal plane (**Table 7**). By comparison, in Gkanatsios and colleagues' series (30) of 17 therapeutic interventional neuroradiology procedures performed with a biplane system, 68% of the dose was delivered in the frontal plane. When dose is distributed between the frontal and lateral planes, no single area of skin receives the full dose unless there is beam overlap. The dose index therefore tends to be lower for procedures performed in this fashion than for procedures performed with the radiation field distributed in only one plane. As indicated by the dose index data, spreading the radiation dose in two planes helps minimize PSD. The dose index data clearly indicate the importance of dose spreading for minimizing dose index and PSD.

The mean dose index for spine embolization procedures (0.53–0.84) is intermediate between the other two groups. Fourteen of 18 (78%) spine embolization procedures were performed with a biplane fluoroscopic unit, but the average dose for the lateral plane was approximately 10% of the total dose for embolization of spine tumors and 20% of the total dose for embolization of spine arteriovenous malformations (**Table 7**). Spine embolization procedures therefore have a skin dose distribution that more closely approximates that of a procedure performed with radiation administered in only one plane, even when performed with a biplane fluoroscopic unit.

Ninety-five Percent Area Load

Our data indicate that 95% area load is relatively independent of PSD and dose index (**Figs 6, 7**). A large 95% area load may be either good or bad. For example, there are instances in which a PSD that exceeds the 2-Gy deterministic threshold is unavoidable. Our study indicates that there are a number of procedures in which this may occur (**Table 3**). In these circumstances, the goal is to minimize the size and severity of the potential injury by collimating the x-ray beam to the smallest possible size. (While collimation of the x-ray beam is always desirable, it is essential during high-dose procedures.) Dose spreading—moving the x-ray beam during the procedure—is most effective when the beam is tightly collimated. Dose spreading will limit the magnitude of the PSD and therefore the severity of the injury, but the resultant increase in the 95% area load is an indicator that a larger area of skin may receive a radiation dose high enough to cause radiation-induced effects.

However, as long as the PSD can be kept below the deterministic threshold, the size of the 95% area load is irrelevant. A deterministic injury cannot occur if the PSD is below the threshold. A larger 95% area load may be desirable if this will result in a PSD below the threshold. Indeed, the entire strategy of dose spreading is predicated on decreasing PSD by increasing the size of the irradiated area of the skin (21,24). For example, a hypothetic neuroembolization procedure might generate a PSD of 3.8 Gy if the entire procedure was done through a right

Table 6
Comparison of Skin Dose and Fluoroscopy Time Data from Published Studies

Procedure	Number of Patients	Peak Skin Dose (Gy) Mean (range)	Fluoroscopy time (min) Mean (range)	Reference
TIPS	19	2.1 (0.4–4.6)	40.7 (15.0–93.2))	This study
	23	0.4; 1.7*†	22; 48	(27)
Biliary Drainage	23	1.157 (0.04–4.83)	19.0 (1.7–64.5)	This study
	14	0.08*		(10)
Nephrostomy	23	0.32 (0.03–0.89)	8.7 (2.8–18.9)	This study‡
	14	0.04*		(10)
	35	0.11 (0.01–0.41)*		(15)
Renal/visceral angioplasty				
No stent	18	1.40 (0.16–5.48)	17.1 (5.1–39.3)	This study
Stent	21	2.02 (0.79–4.24)	23.2 (7.1–47.0)	This study
	6	0.21 (0.02–0.61)*		(15)
Pelvic vein embolization, varicocele	1	0.01		This study
	10	0.27*		(10)
Pelvic arterial embolization, fibroids	14	1.98 (0.93–3.50)	27.2 (13.5–58.0)	This study
	20	1.62 (0.66–3.04)§	21.9 (8.9–52.5)	(29)
Neuroembolization head				
AVM	169	3.75 (0.04–12.68)	91.5 (2.6–313.7)	This study
Aneurysm	143	3.78 (1.28–9.81)	73.8 (15.2–199.7)	This study
	94	3.56 (0.01–12.34)‖		(5)
	94	2.14 (0.01–8.81)‖¶		(5)
	17	2.8 (5.0)‖¶**		(30)
	5	0.34 (0.19–0.07)*		(15)
	12	1.51 (0.31–2.70)††	39	(24)
	18	0.96 (0.25–2.4)††	36	(24)
	10	0.58 (0.13–1.23)††	31	(24)
	8	0.62 (0.13–1.34)‡‡	43 (31–74)	(28)

* Estimated from DAP data.
† Median values from two populations.
‡ Performed for obstruction.
§ Thermoluminescent dosimeters (TLDs) at 2 sites on the skin.
‖ Calculated with PEMNET automated dosimetry system (Clinical Microsystems, Arlington, VA).
¶ Frontal plane only, contribution from overlapping lateral field not included.
** Median and maximum doses.
†† TLDs at 8 sites on the head.
‡‡ TLDs at 10 sites on the head.

lateral field, with a 95% area load of 25 cm^2. If half the procedure was done through a right lateral field and the remainder through a nonoverlapping posterior field, the PSD would be halved to 1.9 Gy and the 95% area load doubled to 50 cm^2. PSD would then be below the 2-Gy threshold as a result of moving the beam. Total DAP and CD do not change, but in the second example, PSD is reduced by half as a result of increasing the 95% area load.

Dose Recording

The ICRP recommends recording dose data in a patient's record if the maximum skin dose is estimated to be 3 Gy or greater when the procedure is not likely to be repeated or 1 Gy or greater when the procedure will probably be repeated (23). The FDA has recommended that dose data be recorded in the patient's chart for procedures in which the skin dose exceeds a threshold defined by each medical facility. The FDA recommends a threshold between 1 Gy and 2 Gy, but leaves the choice to each institution (18). Other thresholds, such as a PSD of 1 Gy or 3 Gy, may also be used. Waite and Fitzgerald (14) believe that dose data should be recorded for all neuroembolization procedures.

Table 3 provides frequency data for 1-Gy, 2-Gy, and 3-Gy thresholds for each of the procedures in this study. According to FDA and ICRP guidelines, these data indicate that dose information should be recorded for TIPS creation, neuroembolization procedures, renal angioplasty, hepatic chemoembolization, and other tumor embolization (principally in the kidney or liver). In the present study, each of these procedures had at least a 5% chance of resulting in a PSD greater than 3 Gy. Dose data should probably also be recorded for iliac angioplasty and pelvic arterial embolization, each of which had at least a 10% chance of resulting in a PSD of at least 2 Gy in this study. To simplify our recommendation, we suggest that dose data be recorded for TIPS creation, angioplasty in the abdomen or pelvis, and all embolization procedures.

These recommendations are based on generally accepted estimates of the threshold dose for radiation-induced skin effects (1,2). It is possible that commonly used dose thresholds are excessively conservative. McFadden

Table 7
Mean Cumulative Dose, by Plane, for Neuroembolization Procedures Performed with Biplane Fluoroscopic Units

Location and Indication	Number of Cases	Mean Cumulative Dose (mGy)				
			Frontal Plane		Lateral Plane	
		Total	Dose	% of Total Dose	Dose	% of Total Dose
Head AVM	161	3,757	2,125	56.6	1,632	43.4
Head aneurysm	141	3,786	2,211	58.4	1,575	41.6
Head tumor	43	3,740	2,047	54.7	1,693	45.3
Spine AVM	7	6,995	5,588	79.9	1,407	20.1
Spine tumor	7	4,413	3,906	88.5	507	11.5
Total	359					

and colleagues (40) observed six patients who received skin doses > 2 Gy during cardiac radiofrequency ablation but in whom no skin injuries were reported. Park and colleagues (42) observed 28 patients who received skin doses > 2 Gy during the course of cardiac arrhythmia ablation procedures, none of whom exhibited clinical evidence of acute radiation-induced skin effects. Mettler and Voelz (43), in a 2002 review, described substantially higher threshold doses for radiation-induced skin injury than those that are commonly quoted, based primarily on studies of patients exposed to radiation as a result of the nuclear reactor disaster at Chernobyl.

It is also likely that generally accepted thresholds overstate the risk and severity of injury when the total dose is delivered in multiple fractions over a period of weeks or months. Váño and colleagues (44) reported a retrospective study of 14 patients who had undergone multiple instances of coronary angiography and coronary artery angioplasty over a period of 2–10 years. Estimated PSD ranged from 2.1 Gy to 9.5 Gy. Although four patients exhibited chronic skin changes (skin pigmentation in one, pigmentation and telangiectasias in one, pigmentation and subcutaneous fibrosis in one, and telangiectasias alone in one), none of the patients exhibited acute skin injuries, skin necrosis, or radiodermatitis.

The patient dose of greatest concern is the PSD (23). Regardless of the threshold chosen, we and others believe that this quantity should be recorded in the patient's record if it is known or can be estimated (14). DAP data alone are unsatisfactory (4,14,19). CD data are more helpful, but may still over- or underestimate skin dose (4,19). We recommend that PSD be estimated directly, if possible, with use of an automated method similar to the skin-mapping software we used. If this is not possible (and, unfortunately, this is true for the vast majority of fluoroscopic units in current use), PSD may be measured with use of radiation therapy verification film for those procedures in which PSD may exceed 5 Gy (tumor embolization, hepatic chemoembolization, neuroembolization). For other procedures, CD and DAP data must suffice until automated methods of PSD measurement are more generally available (19).

Our data provide strong support for Faulkner's recommendation (39): the FDA and the European Union should require that a real-time method for measuring or estimating PSD be incorporated into every interventional fluoroscopic unit. We would extend this recommendation to include a real-time skin dose map. The ICRP already recommends that "a suitable body map with the estimated doses" to the skin should be placed in the patient's record whenever dose data are recorded (23). The intent of this recommendation is to provide the operator with sufficient dose distribution information to plan subsequent interventions. Although the intent is laudable, this is a cumbersome requirement if dose-mapping software is not available on the fluoroscopic unit.

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