

Radiation Dose Reduction in the Invasive Cardiovascular Laboratory

Implementing a Culture and Philosophy of Radiation Safety

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CME Objective for This Article:

1. Describe the range of cumulative radiation skin dose for the various types of procedures performed in a cardiac catheterization lab.
2. Present several technical and clinical strategies to reduce patient radiation dose.
3. Describe how radiation safety principles, implemented as part of a comprehensive radiation safety program, can result in substantially reduced radiation dose.

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Objectives This paper investigates the effects of sustained practice and x-ray system technical changes on the radiation dose administered to adult patients during invasive cardiovascular procedures.

Background It is desirable to reduce radiation dose associated with medical imaging to minimize the risk of adverse radiation effects to both patients and staff. Several clinical practice and technical changes to elevate radiation awareness and reduce patient radiation dose were implemented under the guidance of a cardiovascular invasive labs radiation safety committee. Practice changes included: intraprocedure radiation dose announcements; reporting of procedures for which the air-kerma exceeded 6,000 mGy, including procedure air-kerma in the clinical report; and establishing compulsory radiation safety training for fellows. Technical changes included establishing standard x-ray imaging protocols, increased use of x-ray beam spectral filters, reducing the detector target dose for fluoroscopy and acquisition imaging, and reducing the fluoroscopy frame rate to 7.5 s^{-1} .

Methods Patient- and procedure-specific cumulative skin dose was calculated from air-kerma values and evaluated retrospectively over a period of 3 years. Data were categorized to include all procedures, percutaneous coronary interventions, coronary angiography, noncardiac vascular angiography and interventions, and interventions to treat structural heart disease. Statistical analysis was based on a comparison of the cumulative skin dose for procedures performed during the first and last quarters of the 3-year study period.

Results A total of 18,115 procedures were performed by 27 staff cardiologists and 65 fellows-in-training. Considering all procedures, the mean cumulative skin dose decreased from 969 to 568 mGy (40% reduction) over 3 years.

Conclusions This work demonstrates that a philosophy of radiation safety, implemented through a collection of sustained practice and x-ray system changes, can result in a significant decrease in the radiation dose administered to patients during invasive cardiovascular procedures. (J Am Coll Cardiol Intv 2012;5:866-73) © 2012 by the American College of Cardiology Foundation

Although the patient dose associated with invasive cardiovascular procedures is below the level that is known to be associated with elevated cancer risk, it is assumed that even low levels of radiation have a proportionate risk and that dose should be minimized as much as possible (1,2). This risk applies to patients as well as laboratory personnel who are exposed to scatter radiation. High radiation skin dose can lead to skin injury. Risks of both deterministic skin effects and stochastic cancer risk associated with cardiac catheterization procedures should be reduced by minimizing radiation dose (3,4). Patient radiation dose-reduction initiatives have been reported for radiofrequency ablation procedures (5,6) and invasive coronary artery procedures (7,8). The purpose of this work is to examine the effects of a sustained patient radiation dose-reduction initiative implemented in a large and diverse invasive cardiovascular practice.

Methods

Radiation safety. An important component of modern cardiovascular imaging is education about and implementation of processes and techniques to reduce radiation dose. This includes properly adjusting the x-ray system during the procedure and minimizing the duration of x-ray beam activation. Technical aspects of the x-ray system can be changed to reduce dose, specifically radiation dose rate. Almost without exception, and assuming that x-ray geometry is properly set, reduced dose rate is associated with decreased image quality due to the reduced frame rate and/or per-frame x-ray quantum fluence. To reduce patient radiation dose requires that the physician's expectations change from a desire for excellent image quality to a desire for low radiation dose and acceptance of clinically adequate image quality (9). To implement change also requires a good under-

standing of the technical capabilities of modern digital x-ray imaging systems, particularly the flexibility in pulse rate, dose per pulse, and x-ray spectral filtration that they provide.

In 2008, our practice established a Cardiovascular Interventional Labs Radiation Safety Committee to oversee all aspects of patient and staff radiation safety. The committee is composed of a medical physicist, a health physicist from the institutional radiation safety committee, cardiovascular laboratory nurses, x-ray technologists, cardiovascular invasive specialists, anesthesiologists, and physicians specifically interested in radiation safety.

Radiation awareness and education. Staff members were instructed to consider strategies for radiation management before each case (Table 1). Air-kerma at the reference point ($K_{a,r}$) (mGy) is a patient radiation burden metric that is reported by modern interventional x-ray systems (10). $K_{a,r}$ is specified at a fixed point in space relative to the x-ray source (to approximate patient skin location) and is cumulative for an entire procedure. Early in 2008, we began to announce intraprocedure air-kerma values in increments of 3,000 mGy,

Abbreviations and Acronyms

BMI = body mass index

CA = coronary angiography

CSD = cumulative skin dose

$K_{a,r}$ = air-kerma at the reference point

PCI = percutaneous coronary intervention

SH = structural heart

Vas = vascular

with the expectation that further strategies for radiation dose management be implemented at each announcement. Consistent with Minnesota state regulation, procedures with $K_{a,r}$ of 6,000 mGy or greater are reported to our institutional radiation safety committee. To ensure quick and appropriate communication of such procedures, the x-ray technologist, supervisor, and performing physician initiate a hard copy form containing summary information

about the procedure and radiation exposure. This form also contains instructions for immediate and 30-day follow-up communication with the patient by the physician. To further elevate radiation awareness by catheterization laboratory staff and referring clinicians, $K_{a,r}$ was included in the final report for each procedure as of December 2009. X-ray imaging and radiation safety laboratory sessions (3 h), including a practical examination, were added to compulsory fellows training in July 2010. Many radiation safety practices were routinely followed

before and during the study period. These practices include: activating x-ray imaging only when clinically indicated; ensuring maximum practical distance between the x-ray source and patient; minimizing the air gap between the patient and x-ray detector; use of fluoroscopy image store; and use of a clinically appropriate x-ray field of view. Secondary collimation to reduce the x-ray field of view was used occasionally.

X-ray system technical changes. Procedures were performed using 4 Philips Integris (Philips Medical Systems, Best, the Netherlands) and 4 Axiom Artis (Siemens Medical, Erlangen, Germany) interventional x-ray systems. Before the June 2008 start date of this retrospective study, the x-ray systems used in our laboratory were actively managed to ensure clinically sufficient image quality and acceptably low radiation dose rates. Specifically, vendor-provided default dose rates were lowered for both fluoroscopy and acquisition imaging. Throughout the period from June 2008 through May 2011, several additional x-ray system technical changes were implemented to further reduce radiation dose to patients (Table 1). When appropriate, proposed changes were first investigated with phantoms to evaluate their effect on radiation dose rate and image quality. Next, for evaluation, the changes were implemented either in a single x-ray system or within a small group of physicians. If deemed satisfactory after the evaluation period, the changes were implemented for all systems and physicians. X-ray system technical changes included: standardization of the x-ray imaging protocols among similar systems; default fluoroscopy dose rate mode changed from normal to low; reduced dose rate (detector target dose) for fluoroscopy; reduced detector target dose for acquisition imaging; increased use of Cu x-ray beam spectral filters for acquisition imaging (11); and reduced fluoroscopy frame rate from 15 frames/s to 7.5 frames/s. If required for specific clinical tasks, the fluoroscopy image quality and patient skin dose rate may be increased tableside by increasing the frame rate and/or changing from low to normal or high fluoroscopy mode. Also, a higher dose rate, improved image quality acquisition x-ray program is maintained and can be selected anytime during a procedure.

Data analysis. All invasive studies performed on adult patients over a 36-month period starting June 2008 were considered. Studies performed on patients who had not provided medical record research consent were excluded. The procedure air-kerma as reported by the x-ray system was recorded to the

Table 1. Practice and Technical Changes to Elevate Patient Radiation Dose Awareness and Reduce Radiation Dose Rate

Practice Changes	Date Initiated	Technical Changes	Date Initiated
(A) CV Invasive Labs Radiation Safety Committee	June 2008	(F) Standardized x-ray protocols	April 2009
(B) 6,000 mGy internal reporting	June 2008	(G) Increased spectral filtration for acquisition imaging	June 2009
(C) 3,000 mGy announcement	June 2008	(H) Default fluoroscopy program set to low	November 2009
(D) Include air-kerma (mGy) in final report	December 2009	(I) Fluoroscopy frame rate reduced to 7.5 frames/s	December 2009
(E) Compulsory fellows training	July 2010	(J) Reduced acquisition detector target dose	June 2010

CV = cardiovascular.

	Mean	Median	25th Percentile	75th Percentile
Age, men, yrs	64.2	65	56	74
Age, women, yrs	64.2	66	54	75
Weight, men, kg	93.1	90.7	80	103
Weight, women, kg	77.1	74.0	63	88
BMI, men, kg/m ²	30.0	29.1	26.1	32.9
BMI, women, kg/m ²	29.5	28.3	24.3	33.7

BMI = body mass index.

patient record. Whereas $K_{a,r}$ refers to the primary x-ray beam energy at a point in space, radiation dose also accounts for the dose contribution of x-ray photons scattered from within the patient and incident on a specific point within the patient tissue. As previously described, air-kerma values were multiplied by a measured air-kerma to skin dose conversion factor, resulting in the cumulative skin dose (CSD) (mGy) (12). This conversion from air-kerma to cumulative skin dose served to correct discrepancies between the system reported and actual air-kerma and normalize system-dependent differences in the units used to report air-kerma.

Preliminary investigation demonstrated that the radiation dose change could be characterized using a linear fit to the CSD data as a function of time or by direct comparison of the data from the first and last quarters. The latter method was chosen to simplify the presentation. Binary variable comparisons were tested using Pearson chi-square test. Continuous variables were tested with the rank sum test. The Armitage trend test was used to test for a trend in the proportion of procedures with radiation exposure over 6 Gy in years 1, 2, and 3. Additionally, t tests of the log of cumulative radiation dose were conducted and mean differences and 95% confidence intervals for the difference were back-transformed to estimate the percentage of CSD reduction for the last compared to the first 3 months. Data analysis was performed to include all patient procedures, as well as 4 specific procedural subsets, including percutaneous coronary intervention (PCI), coronary angiography (CA), noncardiac vascular (Vas) angiography and intervention, and interventions to treat structural heart (SH) disease. The PCI subset excluded Vas and SH; CA excluded PCI, Vas, and SH; Vas excluded PCI and SH; and SH excluded PCI and Vas. As patient size descriptors, body mass index (BMI), and sex are known to influence radiation dose (12,13), these parameters were examined to ensure lack of patient selection bias.

Results

Patient population summary. Over the 3-year study period, 18,675 patient studies were performed and 18,115 (97%) were included in the summary statistics. There were 536 (2.9%) studies excluded due to lack of research consent and 24 (0.1%) excluded due to incomplete data. The patient population included 11,583 (63.9%) male patients and 6,532 (36.1%) female patients. The

median age was 66 years, BMI 29.0 kg/m², and weight 85 kg (Table 2). Compared with male patients, female patients had a similar age distribution; on average, they weighed 16 kg less, and they had a BMI that was 0.5 kg/m² lower.

Vascular procedures (n = 459) included angiography and intervention for the following arteries: renal (394); carotid (84); and lower extremities (516). Structural heart procedures (1,070) included valvuloplasty (222); atrial/ventricular septal defect closure device implant (78); patent foramen ovale closure device implant (224); transcatheter valve implantation (42); left ventricular assist device implant (53); device implant to treat paravalvular prosthetic regurgitation (105); intra-aortic balloon pump insertion (330); shunt embolization (31); and septal alcohol ablation (43).

CSD data summary. During the 3-year study period, 27 staff cardiologists and 65 fellows-in-training performed or assisted with procedures. Individual staff physicians each performed between 100 (0.6%) to 1,515 (8.4%) procedures. Fellows participated in 86% of all procedures, although the specific level of fellow involvement in a procedure was not measured. Phillips Integris x-ray systems were used for 7,176 (40%) procedures and Siemens Axiom Artis systems were used for 10,939 (60%) procedures. The monthly calculated median and interquartile range of CSD is provided in Figures 1 to 5 for all (n = 18,115), PCI (4,062), CA (9,877), SH (1,070), and Vas (459) procedures, respectively. Also indicated on these longitudinal charts are the dates of implementation of the radiation dose-reduction initiatives. In Figures 1 to 5, the relatively large interquartile range reflects the variability in the patient- and procedure-specific CSD values.

Table 3 provides a comparison of patient variables (sex, BMI) and procedural parameters (contrast volume, fluoroscopy time, percentage of radial access) for all procedures and the 4 procedural subgroups during the first and last quarter of the

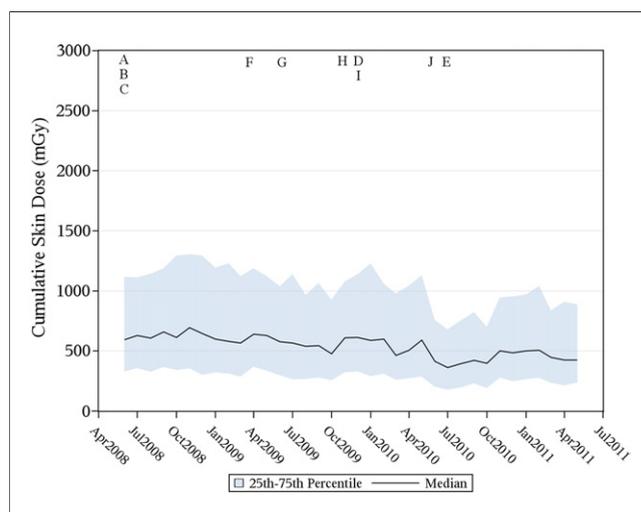


Figure 1. CSD—All Procedures

Monthly median cumulative skin dose (CSD) for all procedures. **A to J** indicate initiation date for radiation safety changes described in Table 1.

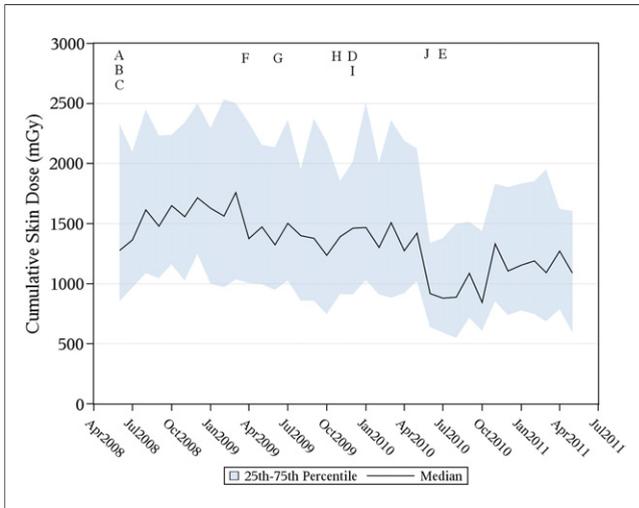


Figure 2. CSD—PCI Procedures

Monthly median cumulative skin dose (CSD) for percutaneous interventional procedures. **A to J** indicate initiation date for radiation safety changes described in Table 1. PCI = percutaneous coronary intervention.

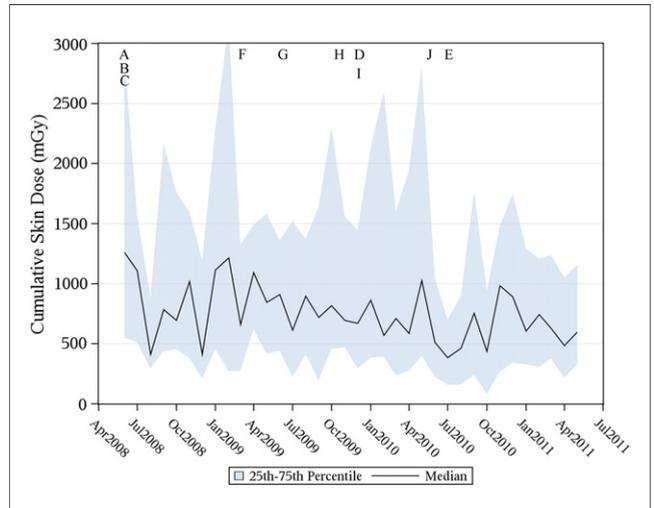


Figure 4. CSD—SH Procedures

Monthly median cumulative skin dose (CSD) for structural heart (SH) procedures. **A to J** indicate initiation date for radiation safety changes described in Table 1.

study period. Among all 5 procedural groups, the percentage of male patients and patient BMI were unchanged between the first and last quarters. The percentage of cases in which a trainee fellow participated increased from 73.0% to 83.5%. Fluoroscopy time increased significantly for all (median increase: +0.8 min; 11.4%) and CA (+1.1 min; 9.6%) procedures. The fraction of procedures performed using radial access increased for all (absolute increase: +22.2%; relative increase: 331%), PCI (+25.6%; 323%), and CA (24.4%; 348%) procedures.

CSD values for the first and last quarters are shown in Table 4 and Figure 6. Considering all procedures, the mean

CSD decreased by 40%. The CSD decrease for PCI was 41%, for CA 37%, for SH 34%, and for Vas 53%. Table 4 also provides the contribution to CSD from acquisition and fluoroscopy imaging. Considering all procedures, mean acquisition skin dose decreased by 46% and fluoroscopy skin dose decreased by 33%. Considering physicians who performed at least 10 cases in each of the first and last quarters, 19 of 21 were associated with patient radiation dose reduction in the range -22% to -69%. The remaining 2 operators were associated with patient radiation dose increases of 6% and 33%.

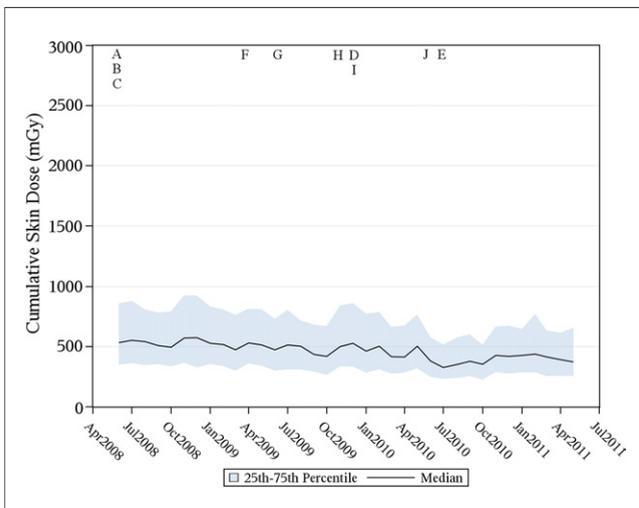


Figure 3. CSD—CA Procedures

Monthly median cumulative skin dose (CSD) for coronary angiography (CA) procedures. **A to J** indicate initiation date for radiation safety changes described in Table 1.

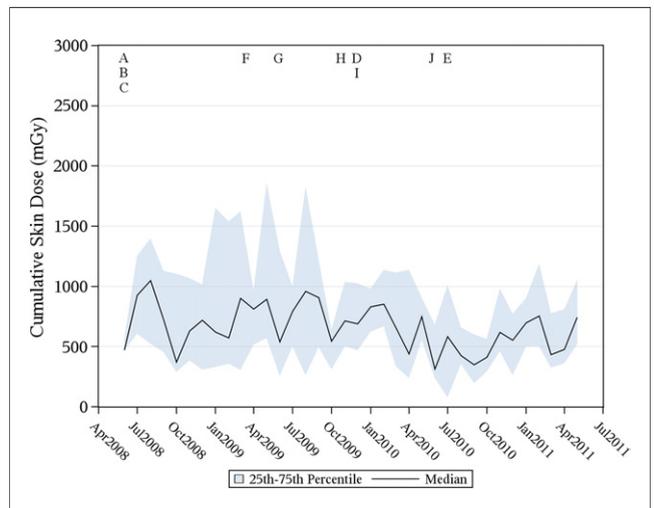


Figure 5. CSD—Vas Procedures

Monthly median cumulative skin dose (CSD) for vascular (Vas) angiographic and interventional procedures. **A to J** indicate initiation date for radiation safety changes described in Table 1.

Table 3. Statistical Summary of Patient Variables, Procedural Parameters, and CSD for the First and Last Quarters of the 3-Year Study Period

Quarter	All			PCI			CA			SH			Vas		
	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value
Patient variables															
n	1,580	1,475		364	332		897	775		77	97		34	28	
Male, %	62.5	63.0	0.77	69.0	69.6	0.86	62.8	63.1	0.89	49.4	55.7	0.41	52.9	64.3	0.37
BMI, kg/m ² , mean	29.7	29.9	0.53	30.9	30.1	0.077	29.9	30.4	0.12	28.1	28.0	0.98	28.1	29.0	0.52
Procedural parameters															
Fellow participation, %	73.0	83.5	<10 ⁻³	91.5	99.7	<10 ⁻³	65.1	76.9	<10 ⁻³	82.4	96.4	<10 ⁻³	96.1	100.0	<10 ⁻³
Contrast volume, cc, median	80	75	0.16	170	160	0.027	57.5	55.0	0.035	30.0	90.0	0.18	87.5	100.0	1.00
Fluoroscopy time, min, median	7.2	8.0	0.04	16.6	15.7	0.48	4.7	5.8	<10 ⁻³	17.1	14.7	0.44	14.6	14.9	0.94
Radial access, %	6.7	28.9	<10 ⁻³	7.9	33.4	<10 ⁻³	7.2	31.5	<10 ⁻³	1.9	1.4	0.84	0	7.7	0.10

BMI = body mass index; CA = coronary angiography; CSD = cumulative skin dose; PCI = percutaneous coronary intervention; SH = structural heart; Vas = vascular.

Table 5 provides a summary of the number of procedures for which CSD exceeded 6,000 mGy during the first and last years of the study period. Considering all procedures, there was a significant reduction from 0.33% to 0.13% of procedures for which CSD exceeded 6,000 mGy.

Discussion

This study demonstrates a 40% decrease in the radiation dose administered to patients over a 3-year period and attributes this decrease to a culture and philosophy of radiation safety implemented through a number of practice and technical changes. This overall dose reduction resulted from a combination of reduced acquisition skin dose (46%) and fluoroscopy skin dose (33%). This reduction was accomplished in a clinical environment with several x-ray systems, 27 physician operators, and 65 fellows-in-training while performing a wide variety of cardio-

vascular procedures. Because radiation scatter that results in occupational dose is directly proportional to patient dose, reductions in patient dose can be expected to have a complementary effect on radiation dose to staff.

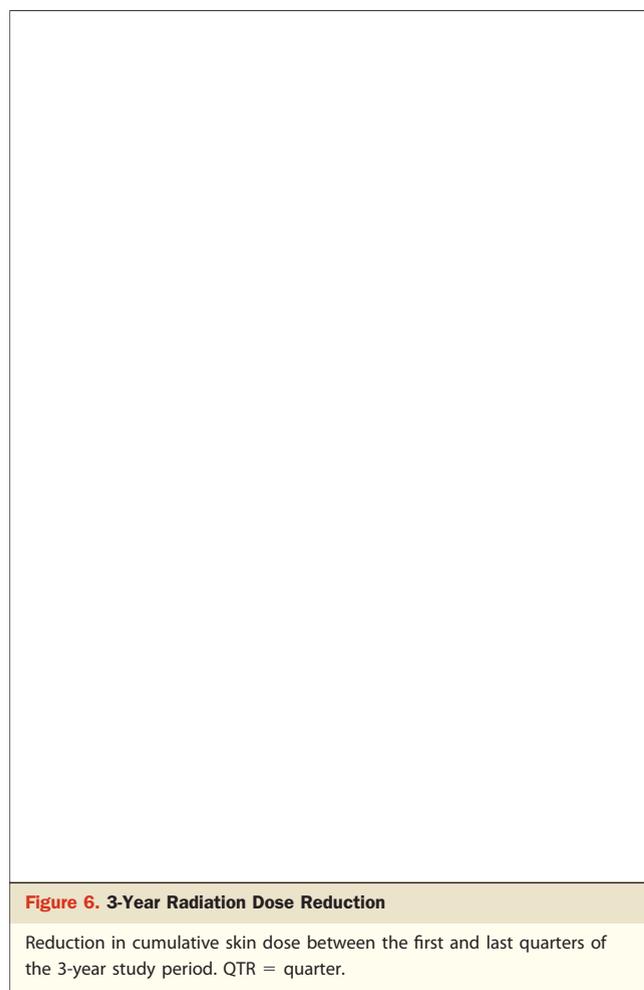
The effect of individual practice and technical changes on patient dose can be expected to vary. Examination of the CSD reported in Table 4 and Figures 1 to 5 demonstrates that there is a great deal of interpatient and interprocedure variability in CSD. Considering all procedures, the 25th and 75th percentile CSD are approximately one-half to twice the median value, respectively. This variability tends to mask CSD changes and requires long-term perspective of patient dose to assess trends. That the absolute effect of individual changes could not be determined is a limitation of this work.

CSD values were reported for procedures performed in our laboratory in 1997 (14). From 1997 to 2010, the median CSD

Table 4. Statistical Summary of CSD, Acquisition Skin Dose, and Fluoroscopy Skin Dose for the First and Last Quarters of the 3-Year Study Period

Quarter	All			PCI			CA			SH			Vas		
	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value	1st	Last	p Value
CSD, mGy															
Mean	969	586	<10 ⁻³	1,900	1,123	<10 ⁻³	712	451	<10 ⁻³	1,208	800	0.002	983	459	0.014
Median	642	401		1,609	952		557	361		831	467		652	415	
25th percentile	325	202		1,074	604		355	238		308	157		359	260	
75th percentile	1,280	759		2,328	1,491		886	559		1,353	976		1,060	610	
Acquisition skin dose, mGy															
Mean	502	271	<10 ⁻³	903	452	<10 ⁻³	440	257	<10 ⁻³	365	246	0.17	434	315	0.34
Median	383	203		752	394		371	213		164	135		293	260	
25th percentile	182	57		478	202		236	121		16	3.2		139	93	
75th percentile	684	383		1,202	606		561	337		711	376		646	477	
Fluoroscopy skin dose, mGy															
Mean	467	315	<10 ⁻³	997	682	<10 ⁻³	271	195	<10 ⁻³	844	559	<10 ⁻³	549	144	<10 ⁻³
Median	217	159		788	512		166	131		494	239		305	111	
25th percentile	84	60		395	274		76	61		210	83		156	52	
75th percentile	545	363		1,332	946		342	246		978	529		688	221	

Abbreviations as in Table 3.



in our lab has decreased by 70% for both PCI and CA procedures. Similar to the current 3-year study period, this reduction can be attributed to a combination of practice and technical changes. Since 1997, major technical changes in interventional angiography equipment that affect radiation dose include: a change from continuous to pulsed fluoroscopy; reduction in fluoroscopy frame rate from 30 frames/s to 7.5 frames/s; reduction in acquisition frame rate from 30 frames/s to 15 frames/s; improved x-ray image detection and display systems; and increased use of metallic x-ray beam spectral filters for both fluoroscopy and acquisition imaging. Further, our x-ray systems allow for service level customization of image

receptor target dose, thus providing the potential for systematic dose reduction.

The specific radiation dose-reduction methods presented in this work represent only a subset of the radiation safety practices that must be implemented routinely. The principles that contribute to good radiation safety practices are well known, and the reader is encouraged to review some of the excellent literature pertaining to this topic (3,10,15). Relatively new to the practice of radiation safety is intraprocedure announcement of radiation dose metrics and post-procedure reporting of high-dose procedures. The National Council on Radiation Protection and Measurements recommends intraprocedure announcements of air-kerma to occur at 1,000 mGy increments starting at 3,000 mGy and recommends that specific post-procedure management practices be implemented following procedures with substantial radiation dose level values >5,000 mGy. The National Council on Radiation Protection and Measurements has similar recommendations based on skin dose and air-kerma area product values. Similar to those described here, intraprocedure dose announcements and post-procedure management are expected to elevate radiation awareness and reduce the frequency of high-dose procedures.

The literature contains examples of both relatively reduced (16) and increased patient radiation dose associated with radial versus femoral artery access procedures (13,17-19). The current study demonstrated that patient dose was reduced concurrently with increased utilization of radial access. This study was not designed to analyze the effect of radial versus femoral access, and no causal association can be made regarding this issue. This is an important topic that deserves specific investigation.

The CSD, used as a measurement of radiation dose burden to the patient, was calculated directly from the air-kerma reported by the x-ray system. Strictly, air-kerma specifies the x-ray energy at a discrete point within the x-ray field but does not account for the influence of x-ray beam field size (area) on the total irradiation incident on the patient. Another metric of radiation burden reported by modern x-ray systems is the product of the air-kerma (Gy) and x-ray field area (cm²). The air-kerma area product (Gycm²) and related dose area product (Gycm²) have been used by several investigators to describe radiation burden for adult cardiovascular procedures (7,9,20-26). For the data presented here, it is straightforward to estimate dose area product as the product of CSD and x-ray field area at the interventional reference point. Given a typical x-ray field

Table 5. Summary of Procedures for Which the CSD Exceeded 6,000 mGy During the First and Last Years of the 3-Year Study Period

Year	All			PCI			CA			SH			Vas		
	1	3	p Value												
n	20	8	0.04	10	4	0.19	1	0	0.23	3	3	0.71	1	0	0.23
%	0.33	0.13		0.72	0.31		0.03	0.00		0.97	0.76		0.64	0.00	

Abbreviations as in Table 3.

area of 70 cm², the estimated mean dose area product for PCI and CA procedures performed during the last quarter was 79 Gycm² and 32 Gycm², respectively.

Conclusions

Large reductions in radiation dose can be achieved and should be implemented in the cardiac catheterization lab to minimize the risk of adverse radiation effects for patients and staff. Considering all invasive procedures performed on adult patients in our lab, CSD was decreased by 40% over a period of 3 years. Building on a philosophy of radiation safety, substantial patient radiation-dose reduction can be achieved through organized and sustained practice and x-ray system technical changes.

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Key Words: dose reduction ■ radiation dose ■ radiation safety.

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