CLINICAL RESEARCH STUDIES

From the Society for Vascular Surgery

Comparison of indirect radiation dose estimates with directly measured radiation dose for patients and operators during complex endovascular procedures

Giuseppe Panuccio, MD,[a] Roy K. Greenberg, MD,[a] Kevin Wunderle, MSc,[b] Tara M. Mastracci, MD,[a] Matthew G. Eagleton, MD,[a] and William Davros, PhD,[b] *Cleveland, Ohio*

Background: **A great deal of attention has been directed at the necessity and potential for deleterious outcomes as a result of radiation exposure during diagnostic evaluations and interventional procedures. We embarked on this study in an attempt to accurately determine the amount of radiation exposure given to patients undergoing complex endovascular aortic repair. These measured doses were then correlated with radiation dose estimates provided by the imaging equipment manufacturers that are typically used for documentation and analysis of radiation-induced risk.**

Methods: **Consecutive patients undergoing endovascular thoracoabdominal aneurysm (eTAAA) repair were prospectively studied with respect to radiation dose. Indirect parameters as cumulative air kerma (CAK), kerma area product (KAP), and fluoroscopy time (FT) were recorded concurrently with direct measurements of dose (peak skin dose [PSD]) and radiation exposure patterns using radiochromatic film placed in the back of the patient during the procedure. Simultaneously, operator exposure was determined using high-sensitivity electronic dosimeters. Correlation between the indirect and direct parameters was calculated. The observed radiation exposure pattern was reproduced in phantoms with over 200 dosimeters located in mock organs, and effective dose has been calculated in an in vitro study. Scatter plots were used to evaluate the relationship between continuous variables and Pearson coefficients.**

Results: **eTAAA repair was performed in 54 patients over 5 months, of which 47 had the repair limited to the thoracoabdominal segment. Clinical follow-up was complete in 98% of the patients. No patients had evidence of radiation-induced skin injury. CAK exceeded 15 Gy in 3 patients (the Joint Commission on Accreditation of Healthcare Organizations [JCAHO] threshold for sentinel events); however, the direct measurements were well below 15 Gy in all patients. PSD was measured by quantifying the exposure of the radiochromatic film. PSD correlated weakly with FT but better with CAK and KAP ($r = 0.55$, 0.80, and 0.76, respectively). The following formula provides the best estimate of actual PSD = 0.677 + 0.257 CAK. The average effective dose was 119.68 mSv (for type II or III eTAAA) and 76.46 mSv (type IV eTAAA). The operator effective dose averaged 0.17 mSv/case and correlated best with the KAP ($r = 0.82$, $P < .0001$).**

Conclusion: **FT cannot be used to estimate PSD, and CAK and KAP represent poor surrogate markers for JCAHO-defined sentinel events. Even when directly measured PSDs were used, there was a poor correlation with clinical event (no skin injuries with an average PSD >2 Gy). The effective radiation dose of an eTAAA is equivalent to two preoperative computed tomography scans. The maximal operator exposure is 50 mSv/year, thus, a single operator could perform up to 294 eTAAA procedures annually before reaching the recommended maximum operator dose. (J Vasc Surg 2011;53:885-94.)**

Over the last 40 years, there has been a proliferation of fluoroscopically-guided minimally invasive procedures. Technological advances relating to imaging equipment coupled with greater procedural complexity has resulted in the potential for substantial radiation exposure risks for both patients and operators.[1] Consequently, the quantification of radiation exposure and assessment of any radiation effects are now heavily scrutinized by the medical community, general public, and regulatory agencies.[2] Detrimental effects from exposure to radiation can be classified as either deterministic or stochastic. Deterministic effects are predictable dose-related responses and, therefore, have a specific dose threshold below which the effect does not occur, and above which the severity increases, usually in proportion to the dose. Stochastic effects,

From the Department of Vascular Surgery[a] and the Imaging Institute,[b] Cleveland Clinic Foundation.

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Reprint requests: Roy K. Greenberg, MD, Cleveland Clinic Foundation, Department of Vascular Surgery, Desk H-32, 9500 Euclid Avenue, Cleveland, OH 44195 (e-mail: greenbr@ccf.org).

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Table I. Summary of the radiation quantity with comparison between the indirect parameter normally available and the ideal parameter

	Indirect[a]			*Direct*[a]		
	FT	*CAK*	*KAP*	*PSD*	*Isodose*	*ED*
Description	Amount of time the X-ray beam is activated.	The sum of initial kinetic energies of all charged particles liberated by X-rays per unit mass of air.[b]	Total X-ray flux in the beam, product of kerma and beam area.	Highest amount of energy locally deposited per unit mass in a defined skin area.	Amount of area or volume that reach a defined threshold.	An attributed whole-body dose that produces the same stochastic risk as an absorbed dose to a limited portion of the body.
Units of measurement	Minutes	Gy	Gy × cm^2	Gy	Area, often cm^2	Sv
Limits	Does not take beam quality or output rate into account.	Does not account for different beam projections. Also does not inform how much area was exposed.	Does not account for different projections. Beam size and cumulative dose unknown.	No real time assessment.	No real time assessment.	Impossible in vivo and no real-time assessment.
Availability	Provided by all fluoroscopy units.	Provided by most fluoroscopy units.	Provided by most fluoroscopy units.	Labor intensive – must use Gafchromic film and either a film densitometer or analysis software.	Labor intensive – must use Gafchromic film and analysis software.	Not available, must be estimated.
Accounts for acquisitions	No	Yes	Yes	Yes	Yes	Yes

CAK, Cumulative air kerma; *ED,* effective dose; *FT,* fluoroscopy time; *Gy,* Gray; *KAP,* kerma area product; *PSD,* peak skin dose; *Sv,* Sievert.
[a]Direct parameters provide data that directly relate to deterministic or stochastic effects. Indirect parameters do not.
[b]Generally measured at 15 cm toward a focal spot from the isocenter of a C-arm type fluoroscope (interventional reference point). This is used to monitor the skin dose and eventual sentinel with a threshold of 15 Gy.

in contrast, are probabilistic in nature, the primary effect being carcinogenesis. Severity has no relationship to dose and no absolute threshold can be defined; however, the incidence increases with the dose.

The potential for unintended injury or illness underscores the importance of attempting to quantify the risk to operators and patients; the techniques used to quantify exposure dose remain imprecise. The two principal methods used to report approximate radiation dose are fluoroscopy time (FT; in minutes) and cumulative air kerma (CAK; in Gy), yet such indirect parameters are global estimates of dose and have the potential for considerable error (Table I). Factors such as image magnification, tube angle, patient position, body habitus, and other variables challenge the accuracy of the automated exposure methods and reports. Studies correlating direct measurements of exposure using the commonly supplied automated estimates of exposure for vascular procedures are lacking. In an attempt to further define radiation risk to patients and operators during endovascular procedures, we chose to evaluate one of the most complex endovascular procedures, endovascular thoracoabdominal aneurysm repair (eTAAA) using branched endografts, by directly measuring radiation exposure. Accurate quantification of radiation dose allows correlation to the automated dose reporting systems with the measured dose to better predict the deterministic effects while also providing information on exposure patterns to allow for the stochastic risk estimate to be calculated.

METHODS

Between May and December 2009, consecutive TAAA patients treated with custom-designed endovascular devices were prospectively enrolled in this study. All procedures were intended to be single-stage, complete TAAA repair. Informed consent was obtained from all patients and the study was approved by the Institutional Review Board of the Cleveland Clinic Foundation. The procedures were performed by experienced operators in conjunction with an assistant clinical fellow and a scrub nurse. Three interventional surgeons (authors RKG, ME, and TM) were involved, and the specifics relating to the procedure and technical details have been previously described.[3-5] Skin changes were assessed daily postoperatively until discharge and then during a clinical follow-up, which occurred between 20 and 45 days.

Indirect estimates of dose. All procedures were performed under fluoroscopic guidance using a fixed imaging system (Artis Zeego or Artis TA, Siemens, Erlangen, Ger-

Table II. Parameters available and automatically collected from the radiographic system

Acquisitions
Cranio-caudal and lateral angulations
Field of view
X-ray tube current (mA)
X-ray tube potential (kVp)
Additional filtration
Total number of frames
Frame rate
Kerma area product
Cumulative air kerma
Combined fluoroscopy and acquisition summary
Fluoroscopy time
Kerma area product
Cumulative air kerma

many) with the image generator primarily situated underneath the patient (posterior-anterior projections). Indirect estimates of exposure included the FT and the kerma area product (KAP), sometimes referred to as the dose area product (DAP), and CAK. Additional information was available for digital subtraction acquisition runs (Table II). Although the default settings could be changed at any time by the operator, the fluoroscopy pulse rate was set at 7.5 pulses per second and the acquisition frame rate was set at three frames per second.

Direct measurement of skin dose. Multiple pieces of Gafchromic film (International Specialty Products, Wayne, NJ) were placed beneath the patient facing the X-ray tube to record the total radiation dose distribution. Given the large film size and wide energy response, this method is considered to be the most reliable way to record the entrance radiation dose distribution during interventional procedures.[6,7] This resulted in total coverage of the thoracoabdominal region and ability to detect any exposure with the exception of a perfectly lateral (90°) C-arm angle. The X-ray film was removed postprocedure and allowed to stabilize for at least 48 hours before analysis.[6] A calibration strip of Gafchromic film was created for each lot of film used in a range of absorbed doses between 0.5 Gray (Gy) and 12.5 Gy using methods recommended by the manufacturer. Each patient's X-ray film along with the associated calibration strip was scanned using an Epson Expression 10000 XL (Epson, San Jose, Calif) at 48-bit depth and 50-dpi resolution. The Radiological Imaging Technology software package (Radiological Imagining Technology, Denver, Colo) was used to perform radiation dose mapping. For each set of patient films, a peak skin dose (PSD), three-dimensional (3D) dose profile, and isodose curves (for the 95% PSD) were computed, while the 2 Gy and 0.05 Gy isodose areas were calculated (Fig 1). In an effort to account for the effect of patient size and radiation field on skin dose distribution, the ratio between PSD and the CAK was computed and defined as the dose index.[8] A ratio close to one is indicative of a focused region of exposure with a potentially high dose, whereas when the ratio approaches zero, the implication is that the exposure is diffuse or distributed over a considerable body surface area.

Direct measurements of specific organ dose and estimate of effective dose. To calculate effective doses, specific organ dose information is necessary. Once known, the organ doses are multiplied by a tissue-weighting factor and summed to establish the effective dose. Estimates of the organ doses were obtained using a Rando-Alderson anthropomorphic tissue equivalent phantom (Rando-Alderson Laboratory, Salem, NY). The phantom (without extremities) consisted of 34 individual sections ranging from the head through the pelvis (overall height of 163 cm, weight of 53 kg, density of 0.985 g/cm, and effective atomic number of 7.3). Lithium fluoride thermoluminescence dosimeters (TLD) were inserted into the phantom material at specific locations to measure relative organ dose in a manner consistent with the literature standards.[9-11] The mean patterns of exposure to the patients were determined from the recorded projections data (Table II) by the imaging system along with the average KAP delivered in each projection. These projections and KAP measurements were then reproduced on the phantom models loaded with organ-specific TLDs (separate phantoms were used for the two patterns of exposure—type II and III eTAAA repair vs type IV eTAAA repair). The TLDs were supplied and evaluated by a third party, NAVLAP, which is an accredited dosimetry vendor (Mirion Technologies, San Ramon, Calif). Organ doses were determined from the TLDs based on methodology established by Huda and Sandison.[9] The organ doses were then used to compute an effective dose for each pattern of exposure using tissue weighting factors (w_T) established by the International Commission on Radiological Protection (ICRP) in Publication 103.[12] To provide an effective dose reference value, we evaluated each patient's exposure during a preoperative chest, abdomen, and pelvis computed tomography (CT) scan. To calculate the effective dose (ED; measured in mSv), the dose length product (measured in mGy•cm and provided by the imaging system in a patient study-specific manner) was multiplied by the specific conversion factors (coefficient κ = 0.017 mSv mGy^{1} cm^{1} for CT scans).[13]

Operator exposure. All the operators wore radiation protective glasses and personal custom-made aprons with a thickness of 0.5-mm lead equivalent. However, supplemental shielding methods differed slightly between the two types of imaging system rooms (Fig 2). Measurements of operator dose were carried out using electronic personal dosimeters (Unfors EDD-30; Unfors Instruments AB, Gothenburg, Sweden). The dosimeters were positioned external to the clinician's lead apron at the level of the neck. The sensor has a spherical response that is capable of measuring the dose independent to the incident angle of radiation. The range of detectable accumulated dose is 10 nSv to 9999 Sv, and a trigger level dose was not set. Compared with the standard badges for the monthly operator surveillance, this system is intended to be reliable for the assessment of exposure during a single procedure (deep dose equivalent [DDE]). The operator ED was calculated according to the Webster methodology multiplying the DDE times 0.3.[14]

Data collection and statistical analysis. Clinical data, intraoperative details, and exposure parameters from the preoperative CT scan were prospectively recorded in a computerized database (ORACLE; Oracle Corporation,

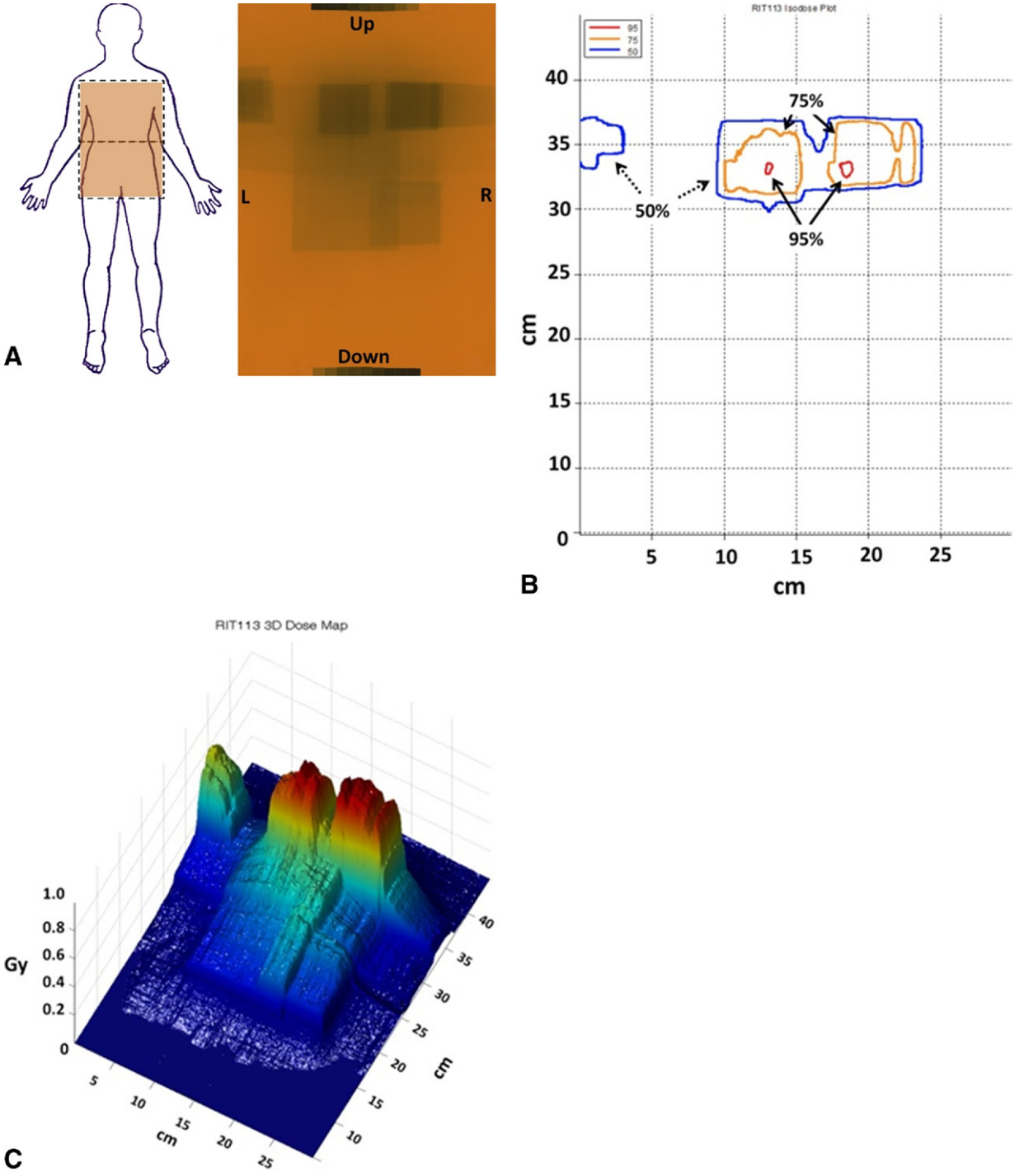

Fig 1. Skin dose distribution in patients treated with an endovascular branched graft for a type IV thoracoabdominal aortic aneurysm (TAAA) is depicted here. The body habitus in relation to the Gafchromic film is displayed in **(A)**. The film is then automatically analyzed to construct a plot of the peak skin dose (PSD) and the isodose areas **(B)** where it can be displayed as a 3-dimensional (3D) histogram **(C)**. The *blue*, *orange*, and *red* regions on **(B)** correspond to 50%, 75%, and 95% isodose areas, respectively.

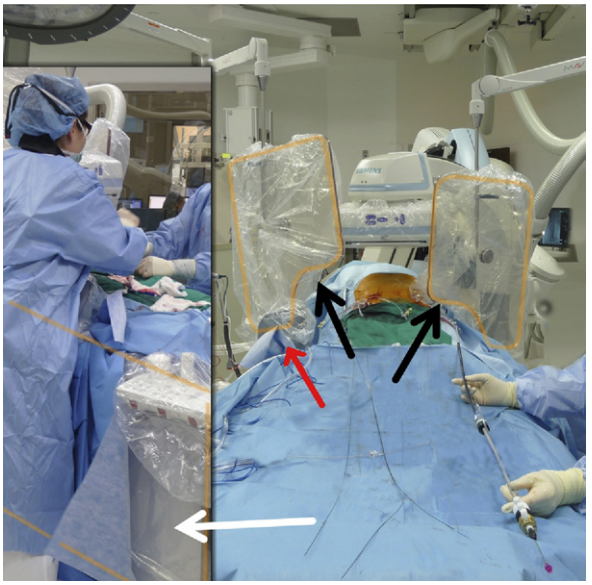

Fig 2. Maximal protection for the operators is emphasized in the operating room environment. These images depict the two mobile transparent lead shields (Mavig Inc, Munich, Germany) that are placed between the operator and flat panel detector (*black arrows*). Additionally, a lead skirt is mounted on either side of the table (BT Medical Company, Inc, Bridgeport, Pa) that is intended to reside between the image generator and operators (*white arrow*). A shoulder attached to the under table skirt further helps to prevent scatter (*red arrow*).

Redwood Shores, Calif). Mean values and SDs as ranges were calculated for all the variables. Scatter plots were created to evaluate the relationship shape between continuous variables and the corresponding Pearson correlation coefficients (r) and t test were calculated. P value $< .05$ was considered statistically significant.

RESULTS

The study included 47 patients who all underwent eTAAA repair. There were seven additional patients treated for TAAAs during the time period, all of which included at least one hypogastric branch in addition to the eTAAA repair and were thus excluded from analysis. Details about the patient population and procedures are depicted in Table III. Clinical and imaging follow-up compliance through the study period was 98%. The indirect radiation parameters provided by the imaging system software are depicted in Table III. As expected, type II and III eTAAA repair resulted in greater amounts of fluoroscopy time and higher estimates of exposure in comparison to type IV TAAA (FT $P = .001$; CAK $P = .009$; KAP $P = .032$,). Similarly larger patients (major body mass index) had a higher estimated dose (CAK and KAP, $r = 0.3$, $P = .038$ and $r = 0.3$, $P = .031$, respectively) but no increase in the FT ($r = 0.1$, $P = .489$).

Direct measurement of the skin dose. PSD was determined by analyzing the Gafchromic film. Each field (including 95% of the exposure in continuity with the region of PSD) of exposure was assessed separately using the digitized scanned image. The mean PSD was 2.5 Gy and the average size of the area surrounding 95% of the PSD area was 4 cm^2. The PSD center varied from patient to patient and general patterns are depicted in Fig 3. A 2-Gy threshold is commonly used to estimate a "high risk of skin damage," and 51% of our patients exceeded the "high risk" 2-Gy threshold. Higher PSDs were correlated with the extent of the aneurysm (type II and III vs type IV; $P = .035$) and larger body mass index ($r = 0.49$, $P = .001$). The dose index was 0.37, perhaps explaining the absence of any clinical evidence of radiation-induced skin damage in any of our patients.

Table III. Demographic data, indirect and direct radiation exposure parameter related with the procedures

Age	74.7 (±7.6)	
Male	83%	
ASA 3	68%	
ASA 4	32%	
	n	*%*
TAAA		
Type II	6	12.8
Type III	12	25.5
Type IV	29	61.7
Branch vessels per procedure		
2	8	17
3	17	36
4	22	47
	Median	*IQR*
INDIRECT		
Contrast dose (mL)	137	94.2
Operation time (min)	312	177.25
FT (min)	82.7	80.5
CAK (Gy)	6.3	5.0
KAP (Gy cm^2)	696.6	520
DIRECT		
PSD (Gy)	2.0	2.3
Dose index	0.38	0.18
Isodose area (cm^2)		
95%	3.1	4.2
2 Gy	95.0	118.0
0.05 Gy	1262.5	721.5

Comparison based on the aneurysm type

TAAA type	*II & III (n = 18) Mean (SD)*	*IV (n = 29) Mean (SD)*	P *value*
CAK (Gy)	9.6 (±5.7)	6.1 (±3.1)	.009
KAP (Gy cm^2)	1005.7 (±627.8)	642.5 (±311.6)	.032
FT (min)	140.7 (±64.4)	81.9 (±45.8)	.001
PSD (Gy)	3.2 (±1.6)	2.2 (±1.3)	.035

ASA, American Surgical Association; *CAK,* cumulative air kerma; *FT,* fluoroscopy time; *Gy,* Gray; *IQR,* interquartile range; *KAP,* kerma area product; *PSD,* peak skin dose; *TAAA,* thoracoabdominal aortic aneurysm. The area interested by highest radiation (isodose area at 95% of the PSD) is usually very small, results of the small overlapping of different beam projection, in the same time, total area exposed is wide as shown by the isodose area at 0.05 Gy and by the dose index. The radiation exposure comparison was based on the aneurysm type, it shows that the extension of the treatment is associated with an increase of radiation exposure for the patient.

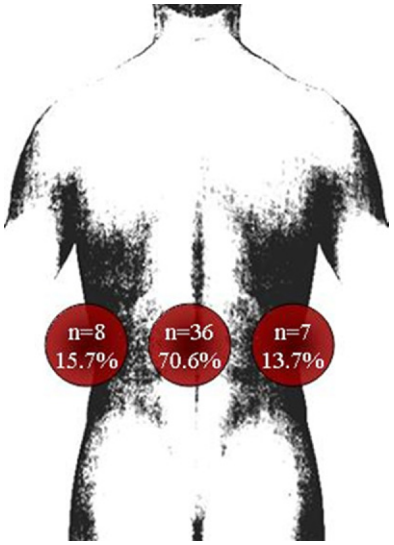

Fig 3. Localization of the peak skin dose (PSD). In most of the cases, the PSD was focused on the central part of the back and attributed to work related to the renal branches. High PSD in the lateral regions occurred when challenges with the celiac or superior mesenteric artery (SMA) were encountered

Correlation between direct and indirect measurements. All indirect parameters of radiation exposure (FT, CAK, and KAP) correlated with direct measurements of the PSD (FT: $r = 0.55$, $P < .001$; CAK: $r = 0.80$, $P < .0001$; and KAP: $r = 0.76$; $P < .0001$; Fig 4). Based on the correlation analysis, it was possible to provide a better estimation of the measured PSD using the indirect dose estimates (except for FT) provided by the imaging system by applying the formulas depicted in Fig 4.

Stochastic effects. Organ and tissue doses measured in the anthropomorphic phantom using the average exposure conditions for the patients in this study are shown in Table IV (online only) and Fig 5. Doses were then calculated for each patient based on their specific exposures and patterns of exposure using the ratio of the DAP and ED in the phantom; the results are depicted in Table IV (online only). The average effective doses were estimated to be 103.1 mSv (range, 24.5-218.1 mSv) and 127.6 mSv (range, 33.2-373.8), respectively, for TAAA type 4 and types 2 and 3. The associated conversion factors were 0.160 $mSv \cdot mGy^{-1} \cdot cm^{-2}$ (TAAA type 4) and 0.127 $mSv \cdot mGy^{-1} \cdot cm^{-2}$ (TAAA types 2 and 3). As a point of reference, the average effective dose for a two- or three-phase CT scan in this patient population was 34 mSv and 60 mSv, respectively.

Operator exposure. The DDE was 0.56 mSv (range, 0.22-2.70 mSv), and all indirect parameters correlated with measured operator dose (KAP: $r = 0.82$, $P < .0001$; Fig 6; CAK: $r = 0.75$, $P < .001$; FT: $r = 0.69$, $P < .001$). Using the Webster's method, the average operator effective dose was estimated to be 0.17 mSv/procedure. Comparing this value to the limit for occupational exposure suggested by the ICRP

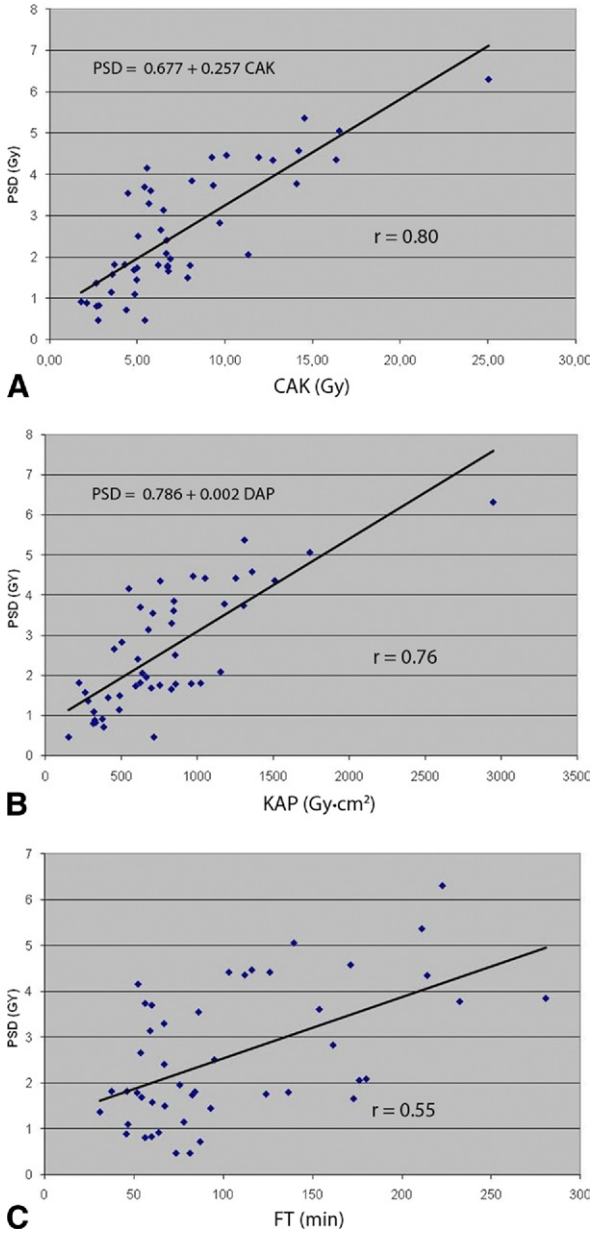

Fig 4. Scatter plot with trend line and formulas demonstrating the strong correlation between the direct parameter versus cumulative air kerma (*CAK*) and dose area product (DAP; respectively, **A** and **B**). **C,** Scatter plot showing the weak correlation between the direct parameter and the fluoroscopy time (*FT*). *Gy,* Gray; *PSD,* peak skin dose; *KAP,* kerma area product.

(100 mSv in 5 years and maximal 50 mSv/year), using our calculated operator dose estimates, the maximum number of procedures each operator can perform annually is 294.[15]

DISCUSSION

The Euratom 97/43 directive introduced the obligation to carry out a dosimetric evaluation of radiation exposure for "high-dose practices," including interventional

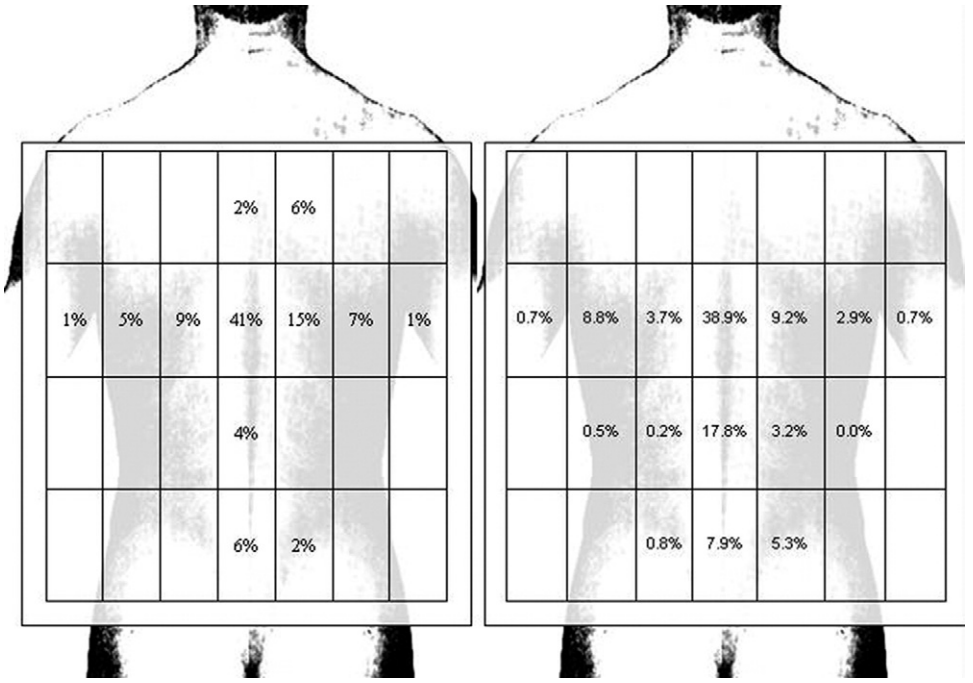

Fig 5. To establish a pattern in an effort to simulate the procedure, projection patterns were determined using the kerma area product (KAP) and the magnification data from each acquisition. These data were replicated for phantom exposure intended to assess effective dose during the endovascular thoracoabdominal aneurysm repair (eTAAA) repair. The average KAP used in each sector is reported as a percentage of the average KAP per procedure. (On the left side is depicted the pattern for types 2 and 3 TAAAs and on the right for type 4.)

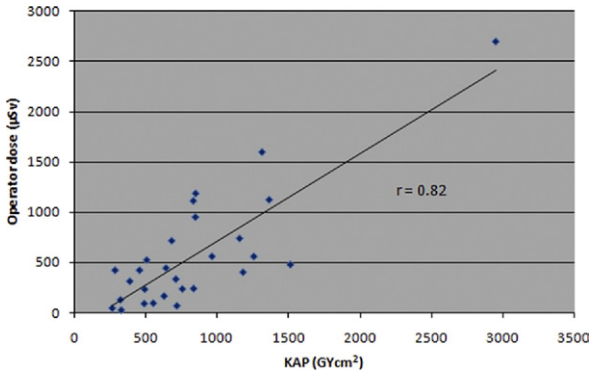

Fig 6. Scatter plot with trend line demonstrating the correlation between the operator exposure detected with a dosimeter worn externally to the apron and the kerma area product (*KAP*). *Gy,* Gray.

radiology procedures.[16] The US Food and Drug Administration requires the identification and registration of all procedures exposing patients to a maximum skin dose of more than 1 Gy over a period of 6 months (thus, procedure plus perioperative scans for eTAAA and reintervention or staged procedures).[17]

In addition, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes radiation events that are reviewable under the "Sentinel Event Policy" such as high-dose fluoroscopy with cumulative dose >15 Gy to a single field.[18] However, the method by which dose is established is not defined in the JCAHO or Food and Drug Administration requirements. Furthermore, there exists no single indirect dosimetry quantification method that is capable of accurately providing unequivocal information regarding the induction of deterministic radiation. FT, although the simplest parameter measure, is the least accurate assessment of dose. In our analyses, all three indirect parameters overestimated the directly measured PSD. Furthermore, given that there were no clinical effects of relatively high PSDs in any patient, these "high-risk skin injury" guidelines did not accurately apply to this patient population. These observations cause one to question the applicability of such guidelines for peripheral vascular (aortic) interventions where the exposure is distributed over a relatively greater area than coronary or neurointerventional procedures, perhaps best exemplified by the low dose index in comparison to other procedures.[19]

Film-based methods for determination of PSD have long been considered the most reliable method for measuring skin dose. However, such methods are labor intensive and the results are not available in real time, thus are usually delegated to investigative reports such as this. We found a relatively strong relationship between PSD and both CAK and KAP making it possible to use these indirect parameters as real time indicators, which increase in accuracy using the

formulas provided in Fig 4. A value of 5.14 Gy for the CAK and of 607 Gy-cm^2 for KAP, corresponds to 2 Gy of directly measured PSD. FT, on the other hand, does not seem to be a reasonable assessment of the dose assessment. In our study, over half of the patients (51%) had a measured PSD in excess of 2 Gy, yet skin changes were not observed in any of our patients. However, it is obviously prudent to minimize the PSD in any one region. This can be accomplished by optimization of the beam collimation, reduction of the milliampere (mA), fewer fluoroscopy pulses, and acquisition images coupled with frequent changes in the pattern of the radiation field by altering the tube angle. New methods of estimating patient dose that incorporate maps of the patient body surface, allowing the operator to redirect the beam to "cold" areas of exposure during prolonged procedures are under investigation.

The KAP (Gy-cm^2) is a quantity, which historically has been used to correlate with stochastic effects of radiation exposure. Fundamentally, the KAP is a good marker for the number of X-ray interactions with the patient. The effects of doubling either the dose or irradiated area will double the number of interactions, and thus will theoretically double the risk of a stochastic effect. However, the KAP value alone does not take into account which portion of the body is exposed, and given that some organs have a greater risk of carcinogenesis (such as the breast, thyroid, and liver), the stochastic risk must be calculated using organ-specific information. To quantify organ-specific risk simulations, use of phantom models is required. However, the application of phantom model data requires fundamental assumptions in addition to a reproducible pattern of radiation exposure. Our data depicted two different patterns of exposure that were most closely related to the proximal extent of the aortic disease. Therefore, two separate phantom models were used to assess the organ-specific dose for each type of repair group. Factors that cannot be accounted for include any tissue healing that may occur, and the time interval between radiation exposures. The calculated effective dose must then be compared to that of other procedures, and viewed in the context of the clinical necessity of the procedure or imaging study. It is hypothesized that 1 Sv of exposure will result in a 4% increased risk of a fatal cancer. If a patient were to undergo a single preoperative (two-phase) CT scan, followed by an eTAAA repair for a type IV TAAA, and two (three-phase) follow-up CT scans over a 1-year period, he or she would receive an average effective dose of 200 mSv. Again, this assessment does not account for any tissue healing that occurs between exposures which is not well understood.[20] Therefore, the 1 Sv exposure estimate is cumulative to a certain extent but less likely simply additive as the gap between exposure incidents increases. The estimate that the effective dose of eTAAA repair is equivalent to two three-phase CT scans allows for the risk to be viewed in the context of everyday procedures. Ironically, it seems relatively simple to require a patient to undergo a endograft follow-up study, but it is much more complicated to expose him or her to the radiation associated with an eTAAA repair. Clearly, efforts must be made to decrease procedural doses, yet the bulk of exposure (over time) for patients undergoing endovascular aneurysm repair resides within the multiple CT scans used to assess aneurysms either preoperatively or postoperatively. Attention must be directed at the true need for such follow-up studies, and the minimization of the radiation dose during each follow-up examination. We have devoted efforts into means of decreasing the radiation exposure for each follow-up CT scan using specific CT imaging equipment (dual energy source data)[21] and newer technologies are now available that further decrease the dose by a factor of up to 10 with respect to conventional CT scanners. However, no clinical data have been generated documenting dose reduction in the setting of preserved image quality. Thus, there exists a balance between the desire for dose reduction, the preservation of image quality, and the perception and interpretation that the physician has with regard to the imaging.

Operator dose is also a critical factor that requires analysis. Interventionalists are required to wear film badges, which undergo monthly analysis at our institution. Should an operator exceed 30% of the recommended ICRP limit annually, he or she is required to take a "refresher" examination relating to the use of radiation equipment. Operator exposure is partially related to the complexity of the procedure, but it is tempered by the appropriate use of specific shielding. All operators are required to wear the standard lead aprons (typically two-piece systems inclusive of a vest and skirt) in addition to thyroid collars. Additional protection measures at our institution include lead skirts attached to the tables in all of our endovascular suites, and two types of mobile shielding (ceiling mounted and above the lead skirts). We would strongly discourage performing overly complex procedures using portable C-arm imaging systems, where a potential lower-image quality might be coupled with fewer shielding options, thus there may be unnecessary radiation exposure. However, the proper positioning of all of the shielding are operator dependent, thus designs (even with non-fixed imaging systems) could be implemented to accommodate such systems. The distance of the operator from the radiation source also plays a critical role in the reduction of exposure, and attention to such details during acquisitions is critical. The average operator exposure was 0.17 mSv/procedure, resulting in a maximum average of 294 eTAAA repairs annually.[22] This would be a very large number of such procedures, yet we must remain cognizant of the cumulative effect of such procedures over several years.

The application of these data to other complex endovascular procedures may not be reliably performed. For example, lower extremity procedures may involve some of the same limitations for PSD. However, the intensity of the beam (mA) is markedly reduced given the lesser amount of tissue penetration required for image clarity, and the absence of organs at high risk for carcinogenesis may lessen the significance of a calculated effective dose. In contrast, cardiac-based procedures may result in a higher risk of carcinogenesis given the proximity of the breasts and thyroid to the beam focus. Thus, as patterns of exposure are

developed for specific procedures, similar studies should be carried out.

Several weaknesses exist within this analysis. A continuous learning curve existed for individuals performing eTAAA. Greater levels of experience resulted in less radiation exposure ranging with a mean exposure dose of 5.4 Gy for the most experienced operator to 7.7 Gy for others. Furthermore, the mere effect of running a study to assess radiation dose triggers awareness in the operators that may affect their patterns of imaging applications. Finally, the number of patients and phantoms used in this study were limited, thus, the statistically derived calculations were not necessarily powered to supply the required information.

These data provide useful information regarding the measured radiation for eTAAA repair. There was a lack of correlation between the industry-supplied means of dose estimate with the directly measured dosing regimens used in this study. These differences had implications with regard to the required reporting of "high-dose" events to regulatory agencies. Although conversion factors or formulas allow estimates to move close to the actual measured dose, they are procedure (pattern)-specific. The dose for these complex procedures is significant, but seems to pale in comparison to the potential for several remote CT scans that are routinely obtained during the follow-up of unoperated-on aneurysms of patients and the follow-up after open or endovascular repair. Despite the fact that the measured PSD remained substantial for this procedure, no skin changes were observed. Formulas capable of estimating the PSD using the indirect parameters available real time from the imaging equipment were developed and correlate well with the direct measurements of PSD, but again, given the absence of clinical evidence of radiation damage, may have limited applicability. The effective dose of eTAAA repair is roughly equivalent to two standard chest, abdomen, and pelvis CT scans. The operator dose is somewhat variable, but roughly 300 of these procedures can be performed annually before reaching the recommended exposure limits for interventionalists. New methods of reporting PSDs and effective doses are under development and will allow operators to better visualize the areas of exposure and thus mitigate risks.

AUTHOR CONTRIBUTIONS

Conception and design: GP, RG, KW
Analysis and interpretation: GP, KW
Data collection: GP
Writing the article: GP, RG, KW, TM, ME
Critical revision of the article: GP, RG, KW, TM, ME
Final approval of the article: RG, KW, TM, ME, WD
Statistical analysis: GP
Obtained funding: RG
Overall responsibility: GP, RG

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DISCUSSION

Dr Stephan Haulon, MD (*Lillie Cedex, France*). I noticed that you used the fusion-imaging technique during the procedures performed at the Cleveland Clinic, and you mentioned that maybe it lowered the fluoroscopy time. I wonder if your conclusions are applicable to other centers.

Dr Panuccio. Although we used fusion-imaging techniques on most of the procedures (in which the preoperative CT scan is registered with the fluoroscopic image to provide road marks of branching aortic vessels), the pattern of exposure did not differ significantly from cases in which fusion imaging was not available. There is a benefit to fusion imaging in that the procedure may be faster given that the general location of all the vessels is known, but a cost in terms of radiation exposure because an intraoperative Dyna CT scan must be performed. We think that these issues balance out and there is not likely a significant difference in exposure with or without fusion. Given the relatively linear relationship between the estimated and calculated exposure over small changes in dose, the formulas provided should be accurate in either situation.

Linda Harris, MD (*Buffalo, NY*). Did you measure the radiation under the lead as is done for women who are pregnant?

Dr Panuccio. We measured the exposure external to the lead worn by clinicians to provide a more accurate dose estimate. The most accurate sensor available was chosen, and this seemed to be sensitive enough to detect small changes in operator exposure based on individual procedures, whereas such a practice would not be possible inside the lead protection.

Dr Marc Mitchell (*Jackson, Miss*). I think this is a big issue for vascular surgeons. When vascular surgeons started doing endovascular procedures, we sort of jumped into it and really did not think about the radiation. Our interventional radiology colleagues spend a great deal of time and effort training in how to reduce the radiation dose. Do the faculty and staff at the Cleveland Clinic receive any training regarding how to limit the radiation dose during these procedures?

Dr Greenberg. We have a set policy that requires anyone intending to use a fluoroscope to complete a fluoroscopic training module. It involves a PowerPoint presentation, and at the end of it, they have to take a test and pass the test. Furthermore, anyone whose occupational exposure exceeds the 30% ALARA limit on a given year has to retake the test. Now, whether or not that works, with respect to properly instructing individuals and decreasing radiation dose, is the subject of some concern. We have never had an operator who actually has been prohibited from operating because they have exceeded their radiation dose. However, I do think that vascular surgeons as a whole are not well educated on the risks and how we calculate the potential differences between deterministic and stochastic effects of radiation, and it is something that we as a group should probably focus on more.

Dr Benjamin Starnes (*Seattle, Wash*). Radiation safety is clearly a hot topic today. My question mainly has to do with the exposure of the operating room staff and/or the operating personnel. Hybrid operating rooms have become increasingly popular these days and some have advocated that these hybrid operating rooms do not need control rooms or radiation safety zones for the operative staff. Are you are suggesting, based on your data that control rooms are not needed or, stated another way, a radiation-safe zone is not needed in a hybrid operating room? Thank you for your clarification.

Dr Panuccio. No. The hybrid room can help us to reduce the amount of personnel that we need during the procedure. One operator can control the entire machine and that is better. The goal is to always be more than 6 feet away from the imaging system, and at that point, the amount of exposure is minimal. However, the protection adjuncts, such as lead shielding, skirting for the tables, thyroid collars, and whatnot are obviously critical to reduce scatter and personnel dose. These are all portable methods of reducing dose and can be used in any kind of room with imaging equipment.

Table IV, online only. Effective dose estimation based on organ and tissue exposure directly measured in the phantom model for two different radiation patterns (TAAA type 2 and 3 and for TAAA type 4)

	Type 2 & 3 TAAA				*Type 4 TAAA*		
Organ	*Weighting tissue factor*[a]	*Phantom dose (mGy)*	*Phantom organ ED (mSv)*	*Patient organ ED (mSv) (mean)*	*Phantom dose (mGy)*	*Phantom organ ED (mSv)*	*Patient organ ED (mSv) (mean)*
Breast	0.12	24.6	3.0	2.97	9.2	1.10	0.71
Colon	0.12	164.0	19.7	19.79	360.8	43.30	27.79
Lung	0.12	85.4	10.2	10.31	32.8	3.94	2.53
RBM	0.12	88.9	10.7	10.73	104.4	12.53	8.04
Stomach	0.12	237.1	28.5	28.61	297.1	35.65	22.88
Gonads	0.08	14.1	1.1	1.13	33.6	2.69	1.73
Bladder	0.04	15.4	0.6	0.62	26.3	1.05	0.67
Esophagus	0.04	44.8	1.8	1.80	15.2	0.61	0.39
Liver	0.04	324.9	13.0	13.07	291.3	11.65	7.48
Thyroid	0.04	3.9	0.2	0.16	1.6	0.06	0.04
Bone	0.01	69.2	0.7	0.70	66.4	0.66	0.42
Brain	0.01	1.0	0.0	0.01	0.07	0.00	0.00
Salivary glands	0.01	1.7	0.0	0.02	0.9	0.01	0.01
Skin	0.01	141.1	1.4	1.42	74.9	0.75	0.48
Remainder	0.12	300.8	36.1	36.29	387.7	46.53	29.86
Mean total effective dose			126.90	127.61		160.52	103.01
Mean KAP Gy cm^2			1000.27	1005.73		1001.22	642.51
Remainder							
Adrenals		801.3			937.4		
Gall bladder		175.7			236.4		
Heart		53.8			28.1		
Kidney		695.0			969.4		
Oral mucosa		1.7			0.7		
Pancreas		565.9			809.4		
Prostate		9.6			9.8		
Small intestine		236.4			394.9		
Spleen		640.9			806.4		
Thymus		27.8			3.7		
Uterus		55.3			82.6		
ET tissue		77.3			32.3		

ED, Effective dose; *ET,* extra thoracic tissue; *Gy,* Gray; *KAP,* kerma area product; *RBM,* red bone marrow; *Sv,* Sievert; *TAAA,* thoracoabdominal aortic aneurysm.
[a]In the last column, the estimated mean value for a patient.