

# Patients' Radiation Exposure During Endovascular Abdominal Aortic Aneurysm Repair

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**Background:** To investigate associations between patient characteristics, intraprocedural complexity factors, and radiation exposure to patients during endovascular abdominal aortic aneurysm repair (EVAR).

**Methods:** Elective standard EVAR procedures between January 2015 and December 2020 were retrospectively analyzed. Patient characteristics and intraprocedural data (i.e., type of device, endograft configuration, additional procedures, and contralateral gate cannulation time [CGCT]) were collected. Dose area product (DAP) and fluoroscopy time were considered as measurements of radiation exposure. Furthermore, effective dose (ED) and doses to internal organs were calculated using PCXMC 2.0 software. Descriptive statistics, univariable, and multivariable linear regression were applied to investigate predictors of increased radiation exposure.

**Results:** The 99 patients were mostly male (90.9%) with a mean age of  $74 \pm 7$  years. EVAR indications were most frequently abdominal aortic aneurysm (93.9%), penetrating aortic ulceration (2.0%), focal dissection (2.0%), or subacute rupture of infrarenal abdominal aortic aneurysm (2.0%). Median fluoroscopy time was 19.6 minutes (interquartile range [IQR], 14.1–29.4) and median DAP was 86,311 mGy cm<sup>2</sup> (IQR, 60,160–130,385). Median ED was 23.2 mSv (IQR, 17.0–34.8) for 93 patients (93.9%). DAP and ED were positively correlated with body mass index (BMI) and CGCT. Kidneys, small intestine, active bone marrow, colon, and stomach were the organs that received the highest equivalent doses during EVAR. Higher DAP and ED values were observed using the Excluder endograft, other bi- and tri-modular endografts, and EVAR with  $\geq 2$  additional procedures. Multivariable linear

The first two authors contributed equally and share first authorship.

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regression analysis revealed that BMI,  $\geq 2$  additional procedures during EVAR, and CGCT were independent positive predictors of DAP and ED levels after accounting for endograft type.

**Conclusions:** Patient-related and procedure-related factors such as BMI,  $\geq 2$  additional procedures during EVAR, and CGCT resulted predictors of radiation exposure for patients undergoing EVAR, as quantified by higher DAP and ED levels. The main intraoperative factor that increased radiation exposure was CGCT. These data can be of importance for better managing radiation exposure during EVAR.

## INTRODUCTION

Over the past 2 decades, vascular surgery has witnessed an exponential growth of minimally invasive, X-ray guided procedures such as endovascular abdominal aortic aneurysm repair (EVAR).<sup>1,2</sup> As compared to open abdominal aortic aneurysm (AAA) repair, EVAR has shown favorable short-term outcomes.<sup>3,4</sup> With increasing surgeons experience and improvements in imaging modalities and endovascular devices, not only the number but also the complexity of EVAR procedures have increased significantly.<sup>5–7</sup> Factors that may complicate EVAR can be related to the patient (e.g., comorbidities and aortic anatomies) or to the procedure (e.g., endograft configuration and additional intraoperative procedures). The increasing complexity of endovascular solutions also leads to increased fluoroscopy times (FTs) and higher radiation exposure for both patients and operators.<sup>8</sup>

Radiation risks can be classified into deterministic and stochastic effects.<sup>2,7</sup> Deterministic effects, or tissue reactions, can be observed when dose thresholds are exceeded. Although deterministic effects are rare after interventional procedures, transitional erythema—a sunburn in the X-ray entry point—could occur in the first 48 hours after the procedure following exposure with a skin dose  $\geq 2$  Gray (Gy). Epilation and skin necrosis are usually observed for skin doses higher than 7 and 12 Gy, even several weeks after the procedure.<sup>8</sup> Less predictable are the stochastic effects that increase long-term risks at both low and high doses by inducing cancer.<sup>9–11</sup> According to a previous study, the second most frequent cause of mortality after EVAR are malignancies.<sup>12</sup> The 15-year follow-up study of the United Kingdom's randomized controlled EVAR trial 1 observed an increased cancer mortality in the EVAR cohort.<sup>13</sup>

Thus, limiting radiation exposure to a minimum should be a main concern for vascular surgeons, who must be aware of the importance of radiation protection during endovascular interventions and strive to reduce radiation exposure.<sup>14,15</sup> The aim of the present single-center retrospective cohort study

was to identify how radiation exposure to patients varies according to patient characteristics and procedure-related complexity factors, as quantified by the dose area product (DAP), effective dose (ED), and equivalent doses to relevant internal organs in EVAR patients.

## MATERIALS AND METHODS

### Study Design and Population

All consecutive patients that underwent elective standard EVAR between January 2015 and December 2020 at the Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico di Milano, Milan, Italy, were retrospectively analyzed. Clinical data and American Society of Anesthesiology scores were collected. Body mass index (BMI, kg/m<sup>2</sup>) was calculated and categorized as follows: normal weight (18.5–24.9), overweight (25.0–29.9), class 1 obesity (30.0–34.9), and class 2 obesity (35–39.9). Redo EVAR after previous open surgical aortic repairs were not considered. The “strengthening the reporting of observational studies in epidemiology” checklist was followed (<https://www.strobe-statement.org/checklists/>). The study was approved by the local ethical committee, and subjects provided informed consent.

### Surgical Procedure

EVAR technique follows procedural standards at our academic institution. Below, our institutional approach is briefly described. All procedures were performed by an experienced vascular surgeon, assisted by a surgeon in training. Preoperative imaging available from computed tomographic angiography postprocessing (transverse imaging, axial reconstructions, three-dimensional volume rendering, and multiplanar reconstruction) was available in the operating room on a monitor.

Fluoroscopy was under control of the vascular surgeon and was used to guide the guidewires from the femoral arteries toward the thoracic aorta. From the contralateral side, a pigtail catheter was

used for aortography of the entire abdominal aorta and iliac arteries. Less than 100 ml of contrast medium was usually administered during the entire procedure, depending on the need for supplementary intraoperative controls.

Consequently, 'gate' cannulation was performed under fluoroscopy. Usually, this maneuver is performed under  $\times 2$  or  $\times 3$  magnification. If the ipsilateral approach was not feasible, a crossover technique was performed. If this approach was impossible, the brachial cannulation technique was performed. Only in case of an intraprocedural bailout, conversion to an aorto-mono-iliac configuration was performed.

Abdominal endografts deployed in this series were Endurant (Medtronic, Minneapolis, USA), Excluder (Gore, Flagstaff, USA), AFX (Endologix, Irvine, USA), Nellix (Endologix, Irvine, USA), Zenith (Cook, Bloomington, USA), and Incraft (Cordis, Hialeah, USA), following their specific instructions for use. In case of patency of the inferior mesenteric artery or more than 2 pairs of lumbar arteries, embolization of the aneurysm sac was planned and performed with coils of different size, length, and type through a supplemental catheter inserted before the complete deployment of the endograft.

Final digital subtraction angiography confirmed the success of the procedure or showed the need for further correction (i.e., proximal cuff, distal extensions, balloon angioplasty, or stent graft deployment in the iliac axis). In these cases, further digital angiography took place.

### Fluoroscopy System

Procedures were performed in the operating room using a radiolucent table and a mobile C-arm with imaging intensifier (Vision R, Ziehm Imaging, Germany) and digital subtraction angiography software. The X-ray tube was placed in an undercouch position. The tube voltage and current were controlled through automatic exposure control, and the last image hold function was used. Fluoroscopy was used routinely with a pulsed rate of 12.5/second, X-ray field collimation was adjusted by the radiographer following as low as reasonably achievable principles. The image intensifier was as close to the patient's body as possible. Exposures were mainly in posteroanterior projection. High pulse rates per second ( $>12.5/\text{second}$ ), oblique projections, and image magnification were used at minimum.

### Data Collection

Procedural data were collected from the Picture Archiving and Communication System of the radiology department and operative reports. For every intervention, the DAP ( $\text{mGy}\cdot\text{cm}^2$ ) and FT (minutes/seconds) were collected as measurements of direct and indirect radiation exposure. Contralateral gate cannulation time (CGCT) was calculated from the Picture Archiving and Communication System images for each EVAR procedure in which this was required. The time count started at the end of the main body deployment and stopped at the first image of the guidewire inside the contralateral gate.

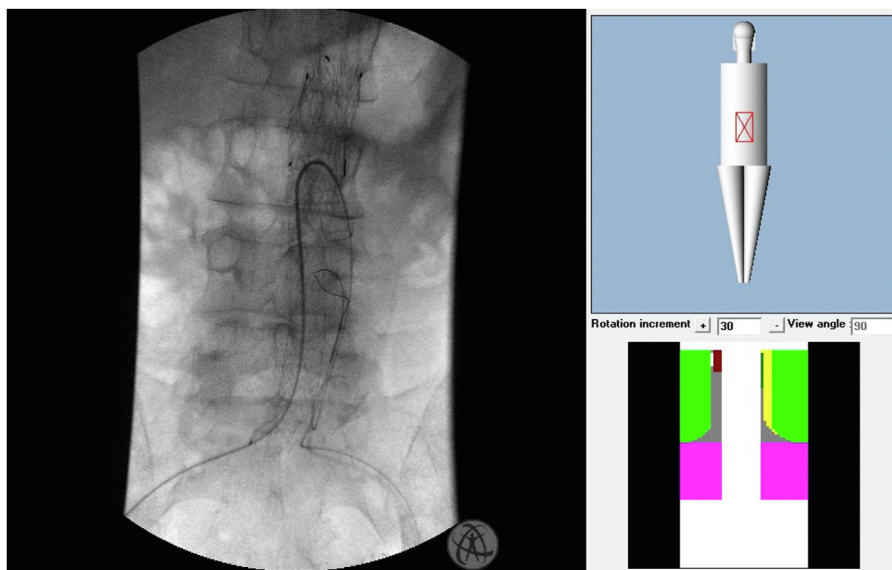
Data collected from operative reports included type of device, morphology of the endograft, and additional procedures that were considered as complexity factors. Additional procedures included aortic and iliac extensions, femoral or renal stenting, iliac branching (iliac branch endoprosthesis), embolization of the aneurysm, of the hypogastric artery, or of the iliac artery. Based on these complexity factors, EVAR patients were categorized into 3 groups: *EVAR complexity 0*, in which no additional procedure was performed other than the standard EVAR; *EVAR complexity 1*, in which one additional procedure was performed; and *EVAR complexity 2*, in which 2 or more additional procedures were performed.

### Definitions

Gy is defined as joule per kilogram. It is the unit of "absorbed dose" to evaluate the amount of energy transferred to tissue for indirect dose parameters (e.g., DAP). Sievert (Sv) is the unit used to report direct dose parameters (i.e., equivalent dose and ED). Equivalent dose is defined as the mean absorbed dose in a certain tissue or organ multiplied by the radiation weighting factor (1 for X-rays). ED is the tissue-weighted sum of the equivalent doses in the entire body. Air-kerma (AK) refers to the dose delivered by the X-ray beam to a volume of air and reflects the kinetic energy released in matter. DAP, also known as AK product, is defined as the product of the AK free in air over the area of the X-ray beam in a plane perpendicular to the beam axis (usually reported in  $\text{mGy}\cdot\text{cm}^2$ ).<sup>2</sup>

### Radiation Dose Calculation

ED and equivalent doses were calculated using the PCXMC 2.0 software (STUK [Radiation and Nuclear Safety Authority], Helsinki, Finland). The patient's mathematical phantom was designed based on every single patient's age, body height, and weight. Similarly, the radiation field was designed based on



**Fig. 1.** (A) Fluoroscopy field of view during EVAR; (B) Posteroanterior view of a phantom of a single patient created in accordance with its baseline characteristics (age, body height, and body weight). The red box indicates the matching fluoroscopy X-ray entrance area

with the same size and position as seen in part A; (C) Posteroanterior visual representation of the different human structures and organs exposed to radiation according to the irradiated area (white: vertebral column and pelvic bones; purple: small intestines; green: kidneys).

every single patient's body area exposed with their kilovolt and DAP (Fig. 1). Focus-to-skin distance was set conventionally at 80 cm, and posteroanterior projection was set. Equivalent dose rates were calculated for every organ.

### Statistical Analysis

Data are presented as median (interquartile range [IQR]), numbers (*n*), and percentages (%). Descriptive statistics and Spearman's correlation tests were used to describe the cohort. Nonparametric Mann-Whitney U and Kruskal-Wallis tests were used to investigate the association between continuous variables and radiation exposure. Univariable and multivariable linear regression models tested the association between variables and DAP and ED. Statistical analyses were performed using SPSS version 28 (IBM Corp., Armonk, NY, USA). All tests were two-sided, and statistical significance level was set at  $P < 0.05$ . Statistical analysis was performed in collaboration with the Laboratory for Modeling and Scientific Computing MOX and the Department of Mathematics at Politecnico di Milano.

### RESULTS

A total of 111 patients underwent elective EVAR during the study period. Patients with AAA and

concomitant common iliac or hypogastric aneurysm ( $n = 12$ , 10.8%) were excluded. The cohort of 99 patients was predominantly male ( $n = 90$ , 90.9%) with a mean age of  $74 \pm 7$  (standard deviation) years. Baseline cohort characteristics are summarized in Table I.

Procedural and radiation exposure details are summarized in Table II. EVAR indications were mostly AAA ( $n = 93$ , 93.9%), and Endurant was the endograft most frequently deployed ( $n = 53$ , 53.5%). The median duration of the procedure was 121 minutes (IQR, 107–151), and median FT was 19.6 minutes (IQR, 14.1–29.4). Median DAP was  $86,311 \text{ mGy cm}^2$  (IQR, 60,160–130,385) and median ED was 23.2 mSv (IQR, 17.0–34.8) for 93 patients (93.9%) due to missing height and/or weight data for 6 patients (6.1%) to calculate patients' ED.

DAP was positively correlated with patients' BMI ( $\rho [p] \text{ } 0.391, P < 0.001$ ) and CGCT ( $\rho \text{ } 0.547, P < 0.001$ ). Likewise, ED was positively correlated with patients' BMI ( $\rho \text{ } 0.268, P = 0.009$ ) and CGCT ( $\rho \text{ } 0.589, P < 0.001$ ).

Univariable linear regression showed that BMI, other than Endurant or Excluder endografts,  $\geq 2$  additional procedures, and CGCT were significant positive predictors of DAP and ED. For example, for each unit increase in BMI, DAP increased by  $7180 \text{ mGy cm}^2$ , and for each second increase in CGCT,



**Table I.** Baseline cohort characteristics

Variable	Value
Age, years	74 ± 7
Sex, male	90 (90.9)
ASA score	
2	22 (22.2)
3	56 (56.6)
4	3 (3.0)
Unknown	18 (18.2)
Height*, cm	172 (167–178)
Weight*, kg	76.8 ± 13.9
BMI*, kg/m <sup>2</sup>	
Underweight	1 (1.0)
Normal (BMI 18.5–24.9)	35 (35.4)
Overweight (BMI 25–29.9)	41 (41.4)
Class 1 obesity (BMI 30–34.9)	14 (14.2)
Class 2 obesity (BMI 35–39.9)	2 (2.0)

ASA, American Society of Anesthesiology; BMI, body mass index.

\*Height, weight, and BMI data are reported for 93 patients due to missing height and weight data for 6 patients. Data are presented as mean ± standard deviation, median (interquartile range) or number (percentage) where appropriate.

DAP increased by 34 mGy cm<sup>2</sup>. ED increased by 1.3 mSv for each unit increase in BMI, and for each second increase in CGCT, ED increased by 0.009 mSv.

The internal organs mostly exposed to radiation were the kidneys (median 211.5 mSv [IQR, 148.7–337.2]), small intestine (median 69.5 mSv [IQR, 53.0–110.7]), active bone marrow (median 54.4 mSv [IQR, 38.4–80.4]), colon (median 32.6 mSv [IQR, 24.5–51.5]), and stomach (median 30.6 mSv [IQR, 20.0–46.7]).

Higher DAP values and EDs were observed in patients treated with the Excluder endograft as compared to those treated with other devices. Monomodular systems had lower EDs compared to the bi- and tri-modular systems. Moreover, EVAR complexity group 2 had the highest EDs compared to EVAR complexity groups 1 and 2. [Table III](#) shows the DAP and ED values stratified according to procedural variables. [Figure 2](#) shows the side-to-side boxplots of the DAP and ED values stratified according to procedural variables.

Multivariable linear regression analysis revealed that higher BMI, EVAR complexity group 2, and longer CGCT were found to be positive independent predictors of higher DAP and ED values after accounting for endograft type. [Table IV](#) presents the

**Table II.** Procedural and radiation exposure details

Variable	Value
Indication for surgery	
Abdominal aortic aneurysm (AAA)	93 (93.9)
Penetrating aortic ulceration (PAU)	2 (2.0)
Focal abdominal and/or iliac dissection	2 (2.0)
Subacute rupture of infrarenal AAA	2 (2.0)
Endograft type	
Medtronic, Endurant	53 (53.5)
Gore, Excluder	33 (33.3)
Endologix, AFX or Nellix	6 (6.1)
Cook, Zenith	4 (4.0)
Cordis, Incraft	3 (3.0)
Endograft morphology	
Monomodular	14 (14.1)
Bimodular	59 (59.6)
Trimodular	26 (26.3)
Contralateral gate cannulation	
No	15 (15.2)
Yes	84 (84.8)
Contralateral gate cannulation time, sec/min	565/9.4 (199/3.3–1381/23.0)
Intraoperative embolization	
No	64 (64.6)
1–4 coils	18 (18.2)
≥5 coils	17 (17.2)
Embolization of the hypogastric or iliac artery	
No	92 (92.9)
Yes	7 (7.1)
EVAR complexity	
Group 0	45 (45.5)
Group 1	25 (25.3)
Group 2	29 (29.3)
Duration of the procedure, min	121 (107–151)
Fluoroscopy time, sec/min	1,178/19.6 (847/14.1–1 762/29.4)
Contrast usage, ml	70 (50–90)
Dose area product (DAP), mGy·cm <sup>2</sup>	86,311 (60,160–130,385)
Tube voltage, kV	90 (84–100)
Effective dose*, mSv	23.2 (17.0–34.8)

EVAR, endovascular abdominal aortic aneurysm repair.

\*Effective dose is reported for 93 patients due to missing height and weight data for 6 patients. Data are presented as number (percentage) or median (interquartile range).

β coefficients for each of these predictors with 95% confidence interval and corresponding *P* values.

**Table III.** Dose area product and effective dose stratified according to procedural variables

Variable	Dose area product, mGy·cm <sup>2</sup>	Overall <i>P</i> value	Effective dose*, mSv	Overall <i>P</i> value
Endograft type		0.002		0.006
Excluder	111,510 (82,937–158,165)		30.0 (22.2–43.6)	
Endurant	84,014 (57,122–130,732)		21.9 (14.9–35.1)	
Other	60,266 (41,791–84,734)		19.2 (13.4–22.3)	
Endograft morphology		<0.001		<0.001
Monomodular	52,045 (25,434–84,288)		16.0 (8.2–19.5)	
Bimodular	91,199 (60,212–146,570)		26.7 (17.4–42.1)	
Trimodular	103,420 (83,316–126,830)		27.5 (20.6–38.4)	
EVAR complexity		0.002		0.005
0	82,741 (52,330–121,035)		20.9 (13.4–33.0)	
1	81,223 (59,887–111,290)		20.6 (16.9–31.5)	
2	122,910 (84,988–184,765)		33.5 (22.5–48.3)	

\*Effective dose is reported for 93 patients due to missing height and weight data for 6 patients. Data presented as median (interquartile range).

Patient-related and procedure-related factors (i.e., additional procedures, CGCT, morphology of the endograft, endograft type, and BMI) were compared to find the factor that had the greatest impact on radiation exposure. This showed that CGCT was the factor that mostly affected DAP and ED levels (adjusted  $R^2 = 0.29$  and adjusted  $R^2 = 0.34$ , respectively).

## DISCUSSION

This retrospective observational cohort study of 99 patients analyzed patient-related and procedure-related factors that may influence radiation exposure to patients during standard EVAR procedures. In summary, the median FT in our cohort was 19.6 minutes, and median DAP was 86,311 mGy cm<sup>2</sup>. These FT values slightly overcome the Italian and European diagnostic reference levels that are established at 18 min and 18.1 min.<sup>16</sup> Moreover, median DAP is 46.1% less than the Italian diagnostic reference level, established at 160,000 mGy cm<sup>2</sup>. Interestingly, although the FT is higher, the median DAP is considerably lower since great efforts are made to reduce the X-ray field, the use of magnification, and the fluoroscopy frame rate by the entire operating team.

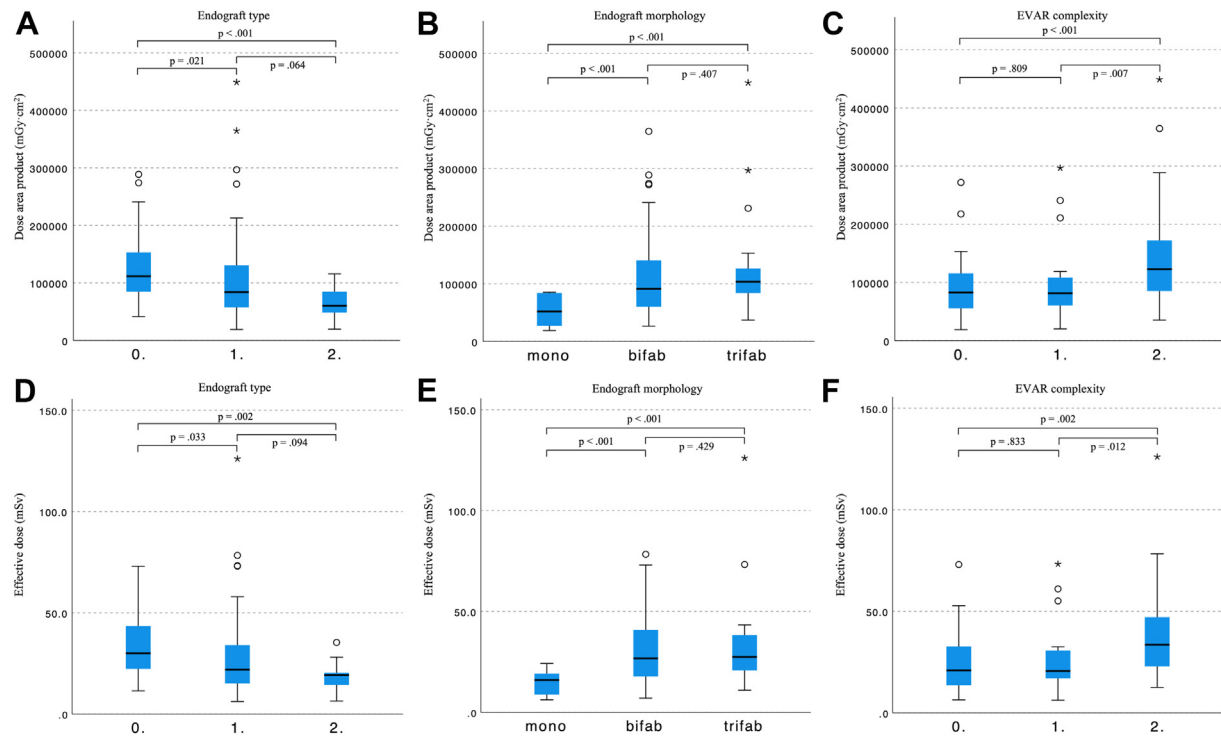
Kidneys received the highest equivalent dose rates of radiation (median 211.5 mSv [IQR, 148.7–337.2]). This could be partially explained by their higher radiation sensitivity and anatomical position since they are near the aorta and thus directly under the primary X-ray beam. In contrast, the small intestines and colon are just partially under the primary beam, reflected in their lower median radiation exposure (69.5 mSv [IQR, 53.0–

110.7] and 32.6 mSv [IQR, 24.5–51.5], respectively).

In this study, median ED was 23.2 mSv (IQR, 17.0–34.8). A proper comparison to previously reported values was not possible given the fact that there is great heterogeneity among study designs (e.g., type of procedure, direct or indirect measure of radiation exposure) and ED calculations.<sup>17–19</sup> Nevertheless, more studies have identified factors that influence radiation exposure during EVAR, such as anatomical characteristics of the aneurysm and technical difficulty of the procedure.<sup>20–22</sup>

In this cohort, BMI was the major patient-related factor influencing patients DAP and ED levels, while CGCT was the main procedure-related factor. Moreover, other procedure-related factors such as the presence of additional procedural steps and the choice of multimodular endografts have shown to increase patients DAP and ED values.

Management of AAAs has changed in the current endovascular era, with most patients opting for EVAR given its lower short-term morbidity and mortality and reduced length of hospital stay when compared with open surgical AAA repair.<sup>2,3</sup> Accordingly, advances in imaging modalities, have expanded the feasibility of EVAR procedures to the most challenging cases. Consequently, there is a growing concern regarding the rise of radiation exposure to both the patient and the endovascular operating team.<sup>7,14</sup> Operators are responsible for radiation safety; however, knowledge regarding radiation risks is not as well present among every vascular surgeon.<sup>5</sup> To highlight the importance of this issue, the European Society for Vascular Surgery recently released its first clinical practice guidelines on radiation safety to improve the overall education and guidance of the surgical community



**Fig. 2.** Side-to-side boxplots of the dose area product (DAP, [A–C]) and effective dose (ED, [D–F]) according to endograft type (A and D), endograft morphology (B and E), and endograft complexity (C and F).

in light of the increased use of radiation during endovascular procedures.<sup>2</sup>

Technological progress in endovascular devices has led to the development of third-generation endografts with smaller dimension, greater stability, major suitability for complex anatomies, and wider possibilities of treatment. However, the contralateral gate cannulation is still an issue in bi- and tri-modular endografts, which may have a significant impact on the complexity of the procedure in challenging anatomies. Few upgrades have been proposed by device manufacturers to address this undervalued issue, such as improved radiopaque markers to enhance visualization of the contralateral gate or magnetic accelerated cannulation system to facilitate and fasten this maneuver. Over time, our practice has adopted techniques to reduce the time needed to cannulate the contralateral gate. These include careful study of the iliac anatomy (i.e., angulation and tortuosity) to optimize guidewire advancement and analyzing the presence of “downward” movement of the guidewire tip by direct antegrade flow from the contralateral gate.

Patients treated with Excluder devices resulted in higher DAP and ED values as compared to other

devices. This finding appears to be in contrast with what was reported in another recent study, in which the C3 Excluder graft was associated with a lower FT given the easier deployment of the graft compared to the other devices.<sup>21</sup> A reason for this initial finding may be that the more complex cases have been treated with the Excluder device in this study. In fact, after adjusting for other covariates in multivariable linear regression, endograft type was not found to be associated with higher DAP and ED values anymore.

The calculations performed to evaluate ED and equivalent doses to the internal organs have shown that several organs are exposed to a nonnegligible dose of radiation. Radiation exposure for stochastic effects does not have a threshold, and every exposure can potentially lead to an increased risk of malignancies over time, again highlighting that every exposure should be minimized as much as possible. Furthermore, patients undergoing EVAR have multiple radiological exposure before and after the procedure itself, and existing data in the literature have shown that follow-up doses are high.<sup>22,23</sup>

Until new radiation-free methodologies like Fiber Optic RealShape technology<sup>24</sup> are widely available

**Table IV.** Multivariable linear regression analysis testing the association between predictors and dose area product or effective dose

Predictor	Dose area product, mGy·cm <sup>2</sup>			Effective dose*, mSv		
	Coefficient	P value	95% CI	Coefficient	P value	95% CI
BMI	7106	<0.001	3820–10,392	1.1	0.013	0.24–1.99
Endograft type						
Excluder	ref.			ref.		
Endurant	21,029	0.122	–5,726 to 47,784	4.7	0.192	–2.4 to 11.8
Other	22,212	0.458	–37,174 to 81,598	7.7	0.335	–8.1 to 23.4
Procedural complexity						
0	ref.			ref.		
1	–56	0.997	–32,746 to 32,633	–0.7	0.866	–9.4 to 7.9
2	49,446	0.002	19,086–79,805	13.6	0.001	5.5–21.6
CGCT	31	<0.001	20–41	0.009	<0.001	0.006–0.012

BMI, body mass index; CGCT, contralateral gate cannulation time.

\*Effective dose is reported for 93 patients due to missing height and weight data for 6 patients.

to guide endovascular procedures, it is of paramount importance to further increase awareness regarding radiation exposure among the vascular surgical community.

Limitations of the present study are inherent to its single-center and retrospective design. EVAR procedures were conducted using a mobile C-arm system, without fusion imaging, and not in a hybrid room. Anyway, it remains uncertain if hybrid operating theaters will alter radiation exposure in a positive or negative manner.<sup>19,25,26</sup>

## CONCLUSIONS

This study highlighted that patient- and procedure-related features are associated with increased radiation exposure to patients during EVAR. BMI,  $\geq 2$  additional procedures, and CGCT were found to be independent positive predictors of DAP and ED levels. The main intraprocedural factor that increased radiation exposure was CGCT. Technological advances facilitating contralateral gate cannulation and the development of radiation-free imaging techniques deserve further focus and optimization.

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