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## Assessing radiation exposure to patients during endovascular treatment of chronic venous obstruction

Mohammad Esmaeil Barbati, MD,<sup>a</sup> Alexander Gombert, MD,<sup>a</sup> Karina Schleimer, MD,<sup>a</sup> Drosos Kotelis, MD,<sup>a</sup> Cees H. A. Wittens, MD,<sup>a</sup> Philip Bruners, MD,<sup>b</sup> and Houman Jalaie, MD,<sup>a</sup> *Aachen, Germany*

### ABSTRACT

**Background:** Post-thrombotic obstruction can be adequately treated by percutaneous transluminal angioplasty and stenting. This procedure is rapidly emerging as a minimally invasive alternative to traditional open surgical operations. However, the patient will be exposed to a significant amount of radiation during preoperative planning and operation. The aim of this study was to evaluate the amount of radiation exposure to patients during venous recanalization.

**Methods:** All patients undergoing endovenous recanalization from February 2016 to February 2018 were included in this study. The operations were performed in an operating room using a mobile C-arm angiography system. Indirect parameters of cumulative air kerma, kerma-area product, and fluoroscopy time (FT) were recorded concurrently with direct measurements of dose (effective dose [ED]) in the pelvic and neck area using two electronic personal dosimetry devices. The direct measured doses were then correlated with indirect parameters provided by the imaging equipment manufacturers.

**Results:** In total, 78 cases were included in the study. During a median operation time of 154.5 minutes (90-323 minutes), the median FT was 43.7 minutes (15.9-77.7 minutes). Body mass index did not correlate with FT or ED. ED correlated with duration of the intervention ( $r = 0.59$ ) but better with FT, cumulative air kerma, and kerma-area product ( $r = 0.76, 0.94$ , and  $1.00$ , respectively). No patients had evidence of radiation-induced skin injury.

**Conclusions:** Radiation exposure to patients during endovenous recanalization does not reach the threshold to have a deterministic effect. Indirect parameters of radiation exposure correlated with direct measurements of the ED. Direct dosimetry is likely to be an unnecessary effort for these types of procedures when indirect dose metrics are available. (*J Vasc Surg: Venous and Lym Dis* 2018;■:1-7.)

**Keywords:** Radiation exposure; Post-thrombotic syndrome; May-Thurner syndrome; Venous recanalization; Venous intervention

The post-thrombotic syndrome (PTS) is a result of chronic venous changes after deep venous thrombosis. Severe PTS is refractory to conservative management and occurs in 5% to 10% of cases. PTS leads to considerable pain and impairment of daily life of patients.<sup>1-3</sup> Throughout the last two decades, percutaneous endovenous stenting has become the method of choice as a less invasive way to treat patients with PTS due to ilio caval occlusion.<sup>4-7</sup>

The most technically challenging step of the procedure and frequently the most time-consuming part is the recanalization of the occluded venous tract. It requires both interventional skills and the ability to interpret radiologic images in real time. However, such a procedure is coupled with extended exposure to radiation. Ionizing radiation like X-ray penetrates tissues and exposes all organs. It damages cells by interacting with DNA bases, proteins, and lipids of cellular membranes or by interacting with other molecules to generate free radicals that in turn damage DNA and other cellular structures.<sup>8</sup>

The three principal methods of calculating and reporting radiation exposure are fluoroscopy time (FT), cumulative air kerma (CAK), and kerma-area product (KAP).<sup>9-13</sup> However, these indirect parameters are just estimates of dose and have the potential for considerable error. Factors such as image magnification, tube angle, and patient's position challenge the accuracy of the reported amount of radiation by the fluoroscopy unit.<sup>14</sup> Studies comparing measured peak skin dose (PSD) with indirect methods suggest that PSD is correlated with KAP but that FT overestimates the PSD up to 50%.<sup>14,15</sup>

To the best of our knowledge, this study is the first prospective study measuring the amount of radiation dose applied to patients during venous recanalization. Our aim was to quantify the radiation exposure of the

From the Department of Vascular Surgery<sup>a</sup> and Department of Diagnostic and Interventional Radiology,<sup>b</sup> University Hospital Aachen.

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Correspondence: Mohammad Esmaeil Barbati, MD, Vascular Surgery, University Hospital Aachen, Pauwelsstr 30, 52072 Aachen, Germany (e-mail: [mbarbati@ukaachen.de](mailto:mbarbati@ukaachen.de)).

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patients and to find the relation between direct and indirect measurements of radiation dose during these procedures.

## METHODS

Between February 2016 and February 2018, all consecutive patients being treated for chronic nonmalignant obstructive lesions of femoroiliac veins and inferior vena cava were included in this prospective study. Informed consent was obtained from all patients, and the study was approved by the local Ethical Review Committee.

All procedures were performed under fluoroscopy guidance using a mobile C-arm (Philips BV 300 PLUS [Philips Medical Systems, Eindhoven, The Netherlands] or Siemens Cios Alpha [Siemens Healthcare Diagnostics Products GmbH, Erlangen, Germany]) with the image generator primarily positioned underneath the patient (posterior-anterior projections). For every procedure, the FT, CAK, KAP, and iodinated contrast material volume were prospectively documented. Radiation exposure was measured as the total time that radiation was used to create radiographic images, whether in pulsed fluoroscopy or angiography mode. Procedure time was defined as the total time from initial puncturing until closure of the puncture site at the end of the procedure.

The entrance skin dose (ESD) was calculated by means of two digital dosimeters (DMC 3000 Personal Electronic Radiation Dosimeter; Mirion Technologies Inc, San Ramon, Calif). One was placed between the legs and just below the pubic arch to measure the radiation exposure to gonads; the other one was placed at the left side of the neck to measure radiation exposure to the head and thyroid region. The effective dose (ED) was estimated from dose-area product using a 0.25 mSv/Cy·cm<sup>2</sup> factor for abdominal angiography on adult patients as demonstrated in previous guidelines.<sup>16</sup>

Clinical follow-up assessments were performed using duplex ultrasound before discharge and at 2 weeks, 3 months, and 6 months and yearly thereafter. Probable radiation-induced skin injury as well as changes of clinical symptoms are evaluated and documented in every follow-up.

Patients' demographic data were recorded prospectively for all participants. Clinical data, intraoperative details, and exposure parameters were prospectively recorded. Data were reported as median with 25th to 75th percentile (interquartile range) or mean with standard deviation. Scatter plots were created to evaluate the relationship between continuous variables, and the corresponding Pearson correlation coefficients (*r*) and *t*-test were calculated. *P* value <.05 was considered statistically significant. All statistical analyses were performed using SPSS version 20.0 software (IBM Corp, Armonk, NY).

## ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center prospective study
- **Take Home Message:** Radiation exposure to 78 patients during endovenous recanalization procedures did not reach a level to have deterministic effects. Indirect parameters of radiation exposure (cumulative air kerma, kerma-area product, fluoroscopy time) correlated with direct measurements of effective dose.
- **Recommendation:** Deterministic effects of radiation are unlikely during endovascular venous recanalization procedures, and dosimetry is likely to be unnecessary when indirect dose metrics are available. Radiation dose should still be minimized to obviate against longer term possible stochastic effects of radiation.

## RESULTS

The study included 78 patients who underwent endovenous recanalization and stenting. Details about the patients' characteristics and direct and indirect radiation parameters are depicted in [Tables I-III](#). The mean operation time was 212.1 minutes (median, 154 minutes) with a mean FT of 66.9 minutes (median, 43.7 minutes). The mean KAP was 116.3 Gy/cm<sup>2</sup> (median, 69.6 Gy/cm<sup>2</sup>; [Table II](#)). The overall means of ESD at pelvic and neck area were, respectively, 2.37 mSv (median, 1.25 mSv) and 0.18 mSv (median, 0.07; [Table III](#)). The mean of overall estimated ED was 25.16 mSv (median, 17.40 mSv; [Table III](#)).

Venous stenting in patients with nonthrombotic May-Thurner syndrome resulted in lower FT and less exposure to radiation in comparison to patients with unilateral or bilateral PTS (FT, *P* < .001; CAK, *P* < .001; KAP, *P* < .001, ED, *P* < .049). The total radiation dose delivered in patients with unilateral PTS compared with patients with bilateral PTS was not statistically significant ([Tables II and III](#)).

The correlation between body mass index (BMI) and other radiation parameters is shown in [Fig 1](#). Patients with higher BMI had a greater estimated dose (CAK; [Fig 1, c](#)), KAP ([Fig 1, d](#); *r* = 0.31; *P* = .006), and ED ([Fig 1, e](#); *r* = 0.31; *P* = .006) but no increase in the FT ([Fig 1, b](#); *r* = .25; *P* = .27).

All indirect parameters of radiation exposure (CAK, KAP, and FT) correlated with direct measurements of the ED (CAK, *r* = 0.94 [*P* < .001]; KAP, *r* = 1.00 [*P* < .001]; FT, *r* = 0.76 [*P* < .001]; [Fig 2](#)).

In none of patients did the KAP reach the 500 Gy/cm<sup>2</sup> threshold suggested for skin injury.<sup>17</sup> No deterministic or stochastic complications were observed in our study group during the median follow-up of 7 months (1-24 months).

**Table I.** Demographic data and indirect and direct radiation exposure parameters

Age, years	44.04 ± 14.62
Sex	
Male	32 (41)
Female	46 (59)
BMI, kg/m <sup>2</sup>	27.13 ± 5.13
Venous disease	
MTS	19 (24.4)
Unilateral PTS	36 (46.2)
Bilateral PTS	23 (29.5)
Length of stented segment, mm	215 (80-315)
MTS	80 (0-80)
Unilateral PTS	215 (60-200)
Bilateral PTS	490 (80-490)
Indirect radiation	
Volume of contrast agent, mL	77.5 (40-150)
Intervention time, minutes	154 (88-265)
FT, minutes	50.7 (15.9-77.7)
CAK, mGy	393.5 (156.7-693.7)
KAP, Gy·cm <sup>2</sup>	74.6 (28.6-135.1)
Direct radiation	
ESD at neck area, mSv	0.04 (0.02-0.26)
ESD at pelvic area, mSv	1.06 (0.35-4.39)
ED, mSv	17.40 (7.16-33.12)

BMI, Body mass index; CAK, cumulative air kerma; ED, effective dose; ESD, entrance skin dose; FT, fluoroscopy time; KAP, kerma-area product; MTS, May-Thurner syndrome; PTS, post-thrombotic syndrome. Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation or median (interquartile range).

## DISCUSSION

Endovenous recanalization and stenting of the venous tract in patients with chronic obstructive venous lesions has dominated during the last years. This method is

mostly performed by vascular surgeons, interventional cardiologists, and interventional radiologists. The minimally invasive nature of this procedure together with satisfying results compared with surgical operations made this method of therapy more feasible and compelling for physicians and patients.<sup>18,19</sup> A great deal of attention in published studies has been directed to the different technical aspects of treatment, like the indication for and outcome of stenting and its effect on quality of life. However, the adverse effects of radiation exposure during this procedure should also be taken into account. These data are particularly relevant because this treatment is being performed for a non-life-threatening disease in relatively young patients.<sup>20,21</sup>

The potential damage from an absorbed dose depends on the type of radiation and the sensitivity of different tissues and organs. Tissues like basal epidermis, bone marrow, thymus, gonads, and lens cells are at higher risk of DNA mutation than muscles, bones, and nervous system. Radiation can cause immediate effects (radiation sickness) but also long-term effects that may occur many years (cancer) or several generations later (genetic effects).<sup>22-27</sup> The two types of radiation effects are stochastic and deterministic injuries. Stochastic injury can be induced by even a low dose of radiation and is not related to severity of radiation exposure. It refers to long-term side effects of radiation and most important to the risk for cancer genesis. Deterministic injuries occur only after a high dose of radiation and are a predictable dose-related response. Therefore, below specific dose threshold values, the effect does not occur, and above it the severity increases.<sup>28-30</sup>

In this study, we were able to record and to compare the different direct and indirect parameters of radiation exposure along with patients' characteristics and type of venous diseases. As expected, venous stenting

**Table II.** Indirect dosimetric indicators

	Total procedure time, minutes					Contrast agent dose, mL					FT, minutes				
	Mean	SD	Median	IQR	P	Mean	SD	Median	IQR	P	Mean	SD	Median	IQR	P
Overall	149.3	129.3	154.5	90-323		104.9	84.5	77.5	50-150		66.9	56.8	50.7	25.3-115.2	
MTS	40.5	37.65	37.0	5-37	<.001	41.6	24.6	43	25-50	.013	17.3	8.2	15.2	11.5-24.4	<.001
Unilateral PTS	170.4	149.2	98.5	38-85	.514	87.5	57.4	65	50-112.5	<.001	72.1	48.4	57.8	34.3-115.9	.038
Bilateral PTS	206.1	87.5	183.0	130-183		196	100.6	165	130-210		116.3	60.4	103.8	67.4-131	
	CAK, mGy					KAP, Gy·cm <sup>2</sup>									
	Mean	SD	Median	IQR	P	Mean	SD	Median	IQR	P					
Overall	679.7	713.7	393.5	178-955		116.3	109.4	74.6	29.5-182.5						
MTS	132.7	79.8	126	58.3-190	.004	28.4	19.3	27.4	10.5-42.7	.003					
Unilateral PTS	775.9	726.2	435	247.5-1125	.203	138.5	118.9	83.8	44.6-236.2	.350					
Bilateral PTS	1143.8	735.2	901	646-1670		179.4	92.8	153	131-228						

CAK, Cumulative air kerma; FT, fluoroscopy time; IQR, interquartile range; KAP, kerma-area product; MTS, May-Thurner syndrome; PTS, post-thrombotic syndromes; SD, standard deviation.

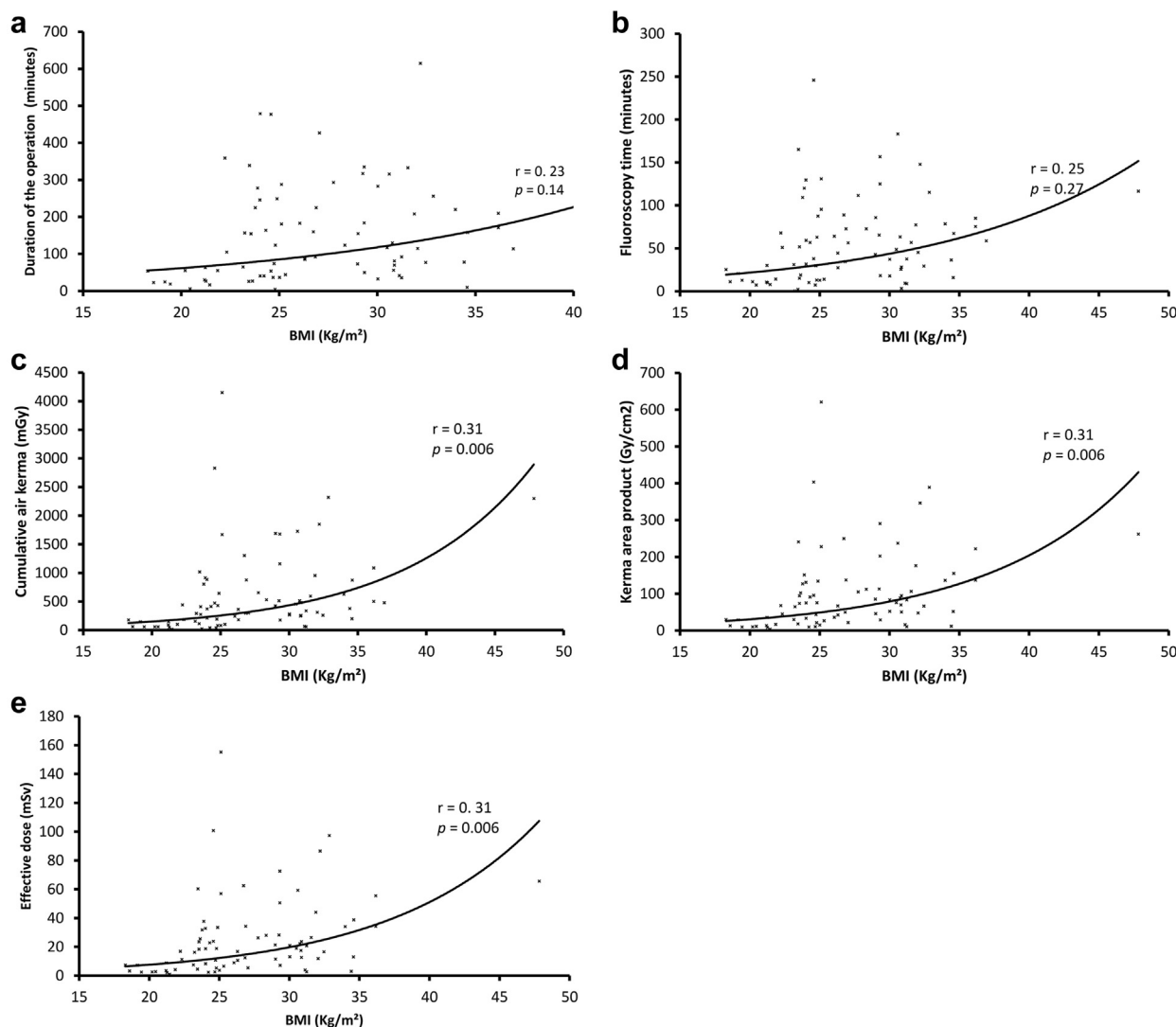
**Table III.** Direct dosimetric indicators

	ESD at pelvic area, mSV					ESD at neck area, mSV					ED, mSV				
	Mean	SD	Median	IQR	P	Mean	SD	Median	IQR	P	Mean	SD	Median	IQR	P
Overall	2.37	3.37	1.06	0.27-2.59		0.18	0.35	0.04	0.02-0.19		25.16	27.09	17.40	7.16-33.12	
MTS	0.29	0.12	0.02	0.05-0.24	<.001	0.02	0.001	0.01	0.005-0.03	.042	8.74	13.70	4.15	2.31-4.15	.049
Unilateral PTS	3.29	3.49	1.72	0.86-4.38	.879	0.18	0.26	0.04	0.02-0.24	.183	25.97	24.64	18.65	4.48-21.3	
Bilateral PTS	3.10	4.28	1.34	1.08-2.74		0.39	0.59	0.14	0.09-0.37		37.51	32.4	31.75	11.83-26.25	.211

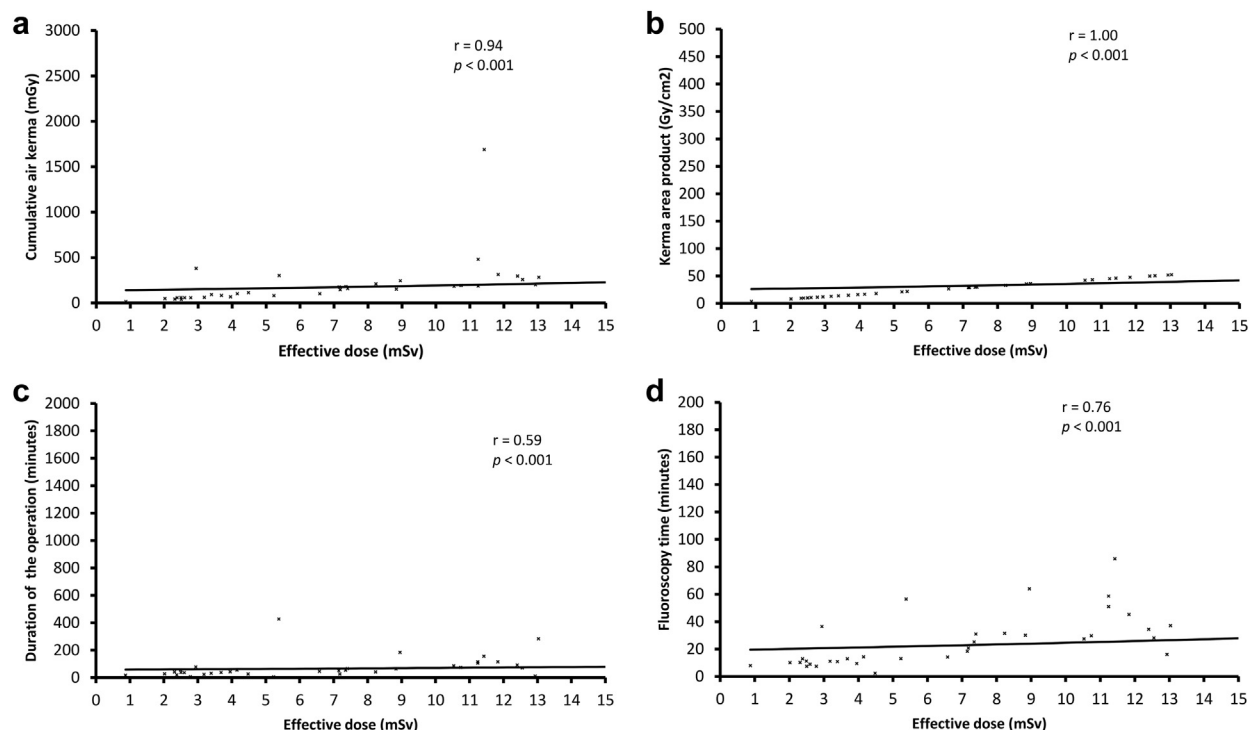
*ED*, Effective dose; *ESD*, entrance skin dose; *IQR*, interquartile range; *MTS*, May-Thurner syndrome; *PTS*, post-thrombotic syndromes; *SD*, standard deviation.

in patients with nonthrombotic May-Thurner syndrome resulted in lower FT and less amount of radiation exposure in comparison to patients with PTS who needed venous recanalization before stenting. The

endovascular intervention in all patients with bilateral PTS has been performed by two attending staff physicians at the same time from both sides to decrease the FT. As a result, the measured radiation exposure



**Fig 1.** Direct and indirect parameters of radiation dose vs body mass index (*BMI*). Scatter plot with trend line and formulas demonstrating the weak correlation of *BMI* with duration of the operation (**a**) and fluoroscopy time (FT; **b**). Scatter plot with trend line and formulas demonstrating the strong correlation between *BMI* and cumulative air kerma (CAK; **c**), kerma-area product (KAP; **d**), and effective dose (ED; **e**).



**Fig 2.** Direct measurement of effective dose (ED) vs indirect parameters. Scatter plot with trend line and formulas demonstrating the stronger correlation of the direct parameter with cumulative air kerma (CAK; **a**) and kerma-area product (KAP; **b**) than with the duration of the operation (**c**) and fluoroscopy time (FT; **d**).

in patients with unilateral and bilateral PTS did not show statistical difference. Also, as the inferior vena cava was occluded in all patients with bilateral PTS, they had a higher radiation exposure at the level of the neck (Table III).

According to this study, the reported FT, CAK, and KAP from the fluoroscopy unit correlated with ED (Fig 2). Higher BMI did not result in a longer duration of the operation and FT. However, more X-ray beams are needed to penetrate a thicker section of the body to maintain image quality (Fig 1). It is noteworthy that the

**Table IV.** Conversion factors and effective doses (EDs) at angiography and computed tomography<sup>16</sup>

Examination	Conversion factor, mSv/Cy·cm <sup>2</sup>	ED, mSv
Angiography		
Cerebrum	0.04	3.0
Coronary arteries	0.20	15.0
Abdomen	0.25	0.20
Lower limbs	0.10	5.0
Computed tomography		
Head	0.0023	2.3
Neck	0.0054	2.2
Chest	0.017	5.1
Abdomen-pelvis	0.015	8.0
Lower limbs	0.0012	0.6

KAP provides the total amount of radiation used in an examination and is not an alternative for patient doses. When the KAP is combined with information on the beam's penetrating power and the physical characteristics of the exposed patient, organ doses and patients' radiation risks can be estimated by taking into account the body region.<sup>31,32</sup>

During intervention, the geometry of the pathologic process influences the ESD measured in different body regions. Performance of venous recanalization of the lower limbs is mostly focused on the pelvic and abdomen area, so the measured amount of ESD at the neck and pelvic area showed a huge difference. The ESD at the pelvis region was almost 18 times higher than at the neck region (Table I). Under such conditions, the patient's dose in fluoroscopy should be estimated with use of another quantity that measures the radiation exposure to the whole body. The International Commission on Radiological Protection proposed a theoretical quantity, the ED.<sup>33</sup> This quantity takes the health risk of a "standard" patient who is nonuniformly exposed to ionizing radiation and translates it into a condition in which this patient would be uniformly exposed to a radiation field. It has the advantage of not being affected by the distance from the tube to the organ.

The estimated ED can be measured by means of conversion factors.<sup>34</sup> Sets of conversion factors are also available for estimating individual organ doses. To help



the reader estimate and to compare the standard examinations, sets of generic conversion factors with average dose indicators are given in Table IV.<sup>16</sup>

Our findings hold important implications for the future of venous interventions, showing that radiation exposure in these procedures does not reach the threshold for deterministic effects. However, these types of interventions are still relatively new, and no long-term studies yet exist. This study could benefit from long-term follow-up of patients to determine the long-term incidence of malignant transformation after venous intervention. Nevertheless, as a general rule, the "as low as reasonably achievable" principle should always be considered.<sup>35</sup> This purpose can be accomplished by using appropriate collimation, minimizing the object to image receptor distance, and using pulsed fluoroscopy.<sup>36</sup> Moreover, using intravascular ultrasound imaging during the procedure to mark the extension of venous disease and to ensure the entire coverage of the lesion will help reduce the amount of radiation exposure. Intravascular ultrasound also can be used as the proof of adequate stent geometry at the end of the procedure.

Future studies are needed to directly address radiation exposure parameters when head-to-head comparisons are made between high-volume and low-volume centers and between C-arm and angiography suite.

## CONCLUSIONS

Patients with higher BMI were exposed to more radiation during the same length of intervention and FT. All indirect parameters of radiation exposure (CAK, KAP, and FT) correlated with direct measurements of the ED. Considering these results, direct dosimetry is likely to be an unnecessary effort for these types of procedures when indirect dose metrics are available. Radiation exposure to patients during endovenous interventions does not reach the threshold to have a deterministic effect. Nevertheless, the stochastic effects of radiation should be taken into account on planning for venous intervention for this non-life-threatening chronic disease.

## AUTHOR CONTRIBUTIONS

Conception and design: MB, PB, HJ

Analysis and interpretation: MB, AG, DK, CW

Data collection: MB, KS

Writing the article: MB, HJ

Critical revision of the article: AG, KS, DK, CW, PB, HJ

Final approval of the article: MB, AG, KS, DK, CW, PB, HJ

Statistical analysis: MB

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