

Patient radiation exposure from embolo-sclerotherapy of peripheral vascular malformations

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ABSTRACT

Objective: Embolo-sclerotherapy (EST) is the mainstay therapy for peripheral vascular malformations that involves the exposure of patients to ionizing radiation. We analyzed the radiation exposure to patients from EST of peripheral vascular malformations during a 5-year period in a single specialist center.

Methods: All patients who had undergone EST at a single specialist center for peripheral vascular malformations from January 1, 2013 to January 8, 2018 were identified from a prospectively collected database. Data collection included basic demographics, procedure date, anatomic site, type of vascular malformations, and procedural details. Radiation exposure, measured as the dose–area product (DAP) and fluoroscopy time, of all patients who had undergone EST during the study period were retrospectively reviewed. Statistical analysis was performed using the Mann-Whitney *U* and Kruskal-Wallis tests for comparison between subgroups. *P* < .05 was considered statistically significant.

Results: A total of 237 patients (median age, 30 years; range, 1-73 years) had undergone 419 EST sessions during the study period. Of the 237 patients, 61 (25.7%) had had arteriovenous malformations (AVMs) and had undergone 140 EST sessions (33.4%) and 176 (74.3%) had had venous and lymphatic malformations and had undergone 279 EST sessions (66.6%). Patients with AVMs had undergone a median of 2 procedures (range, 1-13) compared with a median of 1 (range, 1-6) for venous and lymphatic malformations within the study period. The median DAP for the single and cumulative EST for peripheral vascular malformations was 1.26 Gy cm^2 (range, 0.00-698.36 Gy cm^2) and 1.91 Gy cm^2 (range, 0.00-1300.24 Gy cm^2), respectively. The median fluoroscopy time for single and cumulative EST was 19 seconds (range, 1-3846 seconds) and 30 seconds (range, 1-5843 seconds), respectively. Significantly greater patient radiation exposure, in DAP and fluoroscopy time, was measured for single and cumulative EST for AVMs compared with venous and lymphatic malformations (*P* < .01 for both; Mann-Whitney *U* test). A significant difference in DAP but not fluoroscopy time was found when the anatomic areas of vascular malformations were compared.

Conclusions: Patient radiation exposure for EST for peripheral vascular malformations, measured in DAP and fluoroscopy time, appeared to be generally less than that reported for endovascular arterial and deep venous interventions. However, some patients with peripheral vascular malformations received relatively high radiation doses. Further studies to investigate the risk factors and long-term side effects of radiation exposure in these patients and strategies to reduce these are required. (*J Vasc Surg* 2021;73:1794-9.)

Keywords: Arteriovenous malformation; Embolization; Embolo-sclerotherapy; Ionizing radiation; Sclerotherapy; Vascular malformation

Vascular malformations are a heterogeneous group of abnormally developed blood vessels that can be classified according to the vessel type. Vascular malformations include simple arteriovenous (AVM), venous, lymphatic, capillary, and/or combined malformations, which can

also be associated with other anomalies, depending on the pathology involved. The mainstay of interventional treatment of peripheral vascular malformations involves embolo-sclerotherapy (EST), for which the use of fluoroscopy and, in particular angiography, is required in many

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cases, thus exposing patients to ionizing radiation.^{1,2} The deleterious effects of ionizing radiation have been well documented and include an increased risk of malignancy.^{3,4} Thus, patient and operator exposure during common endovascular procedures, such as endovascular aortic aneurysm repair (EVAR) and peripheral arterial and venous interventions, has already been the subject of investigation.⁵⁻⁸ The cohort of patients undergoing endovascular treatment of vascular malformations is, in general, more likely to be younger than those treated for arterial disease. In addition to this, multiple procedures might be required during the course of their treatment.^{1,2} Despite these inherent concerns, at present, no data have been reported regarding the cumulative radiation exposure received by patients undergoing EST for peripheral vascular malformations. The present study aimed to determine the radiation exposure received by patients with peripheral vascular malformations undergoing EST requiring fluoroscopy during a 5-year period at a single specialist tertiary center.

METHODS

The South Central – Berkshire research ethics committee approved the present study (REC reference no. 19/SC/0090).

Patients. All patients who had had EST performed at a single specialist tertiary center for peripheral vascular malformations from January 1, 2013 and January 8, 2018 were identified from a prospectively collected database. All patients with peripheral vascular malformations treated in our hospital had undergone a multidisciplinary team review, which included vascular surgeons, interventional radiologists and a clinical nurse specialist. This directed intervention, including EST. In our practice, only patients with symptomatic vascular malformations, rapidly growing vascular malformations, and those at risk of systemic complications were considered for EST. Patients were treated on joint lists, with a vascular surgeon and an interventional radiologist with a specialist interest in vascular malformations present. All EST sessions for AVMs were performed under selective catheter angiography and direct injection. The venous and lymphatic malformations were treated with direct injection (ie, percutaneous puncture into the lesion only). Sodium tetradecyl sulfate 3% foamed with air and/or ethanol and, occasionally, coils were used as our preferred EST agents for AVMs during the present study. Sodium tetradecyl sulfate 3% foamed with air and occasionally ethanol was used for venous and lymphatic malformations. The choice of EST agent and the volume used for each procedure was at the discretion of the operator.

Data collection. Data collection included basic demographics, procedure date, anatomic site, type of vascular malformations, and procedural details. Radiation exposure was measured using the dose–area product (DAP) and fluoroscopy time. The DAP refers to the radiation

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective, cohort study
- **Key Findings:** The median dose–area product for single and cumulative embolo-sclerotherapy for 237 patients with peripheral vascular malformations was 1.26 Gy cm^2 (range, 0.00-698.36 Gy cm^2) and 1.91 Gy cm^2 (range, 0.00-1300.24 Gy cm^2), respectively. A significantly greater single and cumulative dose–area product was found in patients with arteriovenous malformations than those with venous and lymphatic malformations.
- **Take Home Message:** Although the overall patient radiation exposure from EST for patients with peripheral vascular malformations was relatively low compared with many common endovascular arterial and deep venous interventions, in some cases, the measured DAP and fluoroscopy times were still high. Therefore, it is important for clinicians performing these procedures to keep radiation exposure to a minimum.

absorbed by irradiated tissue multiplied by the area irradiated, which gives a rough estimation of the risk of stochastic effects.^{7,9,10} The procedures were cross-referenced with the computer records, and the patients who had not required endovascular treatment, those with no recorded fluoroscopy data, and those with radiation exposure data not in the DAP format were excluded from analysis. The DAP and fluoroscopy time were collected directly using the radiology software Clinical Radiology Information System Live (CRIS, Mansfield, UK).

Operating theaters and C-arm. All EST sessions were performed in either a vascular hybrid theater with a ceiling mounted C-arm (Siemens Artis Zeego; Siemens Healthcare, Erlangen, Germany) or a vascular operating theater with a mobile C-arm (Siemens Cios Alpha VA20; Siemens Healthcare). Default settings of a pulse rate of 3.0 to 7.5 pulses/s for background fluoroscopy and two frames/s for digital subtraction angiography acquisitions were used. The fluoroscopy equipment was controlled by a trained radiographer for each procedure.

Ultrasound guidance was also used if required. The Ionising Radiation Regulations 1999, revised in 2017 and the Ionising Radiation (Medical Exposure) Regulations in the United Kingdom were strictly implemented.

Statistical analysis. Statistical analysis was performed using the SPSS, version 17 (IBM Corp, Armonk, NY). Data are reported as the median, range, and frequencies. The DAP was rounded to the nearest second decimal point in the present report, including those <0.05 Gy cm^2 , which were rounded to 0.00 Gy cm^2 .

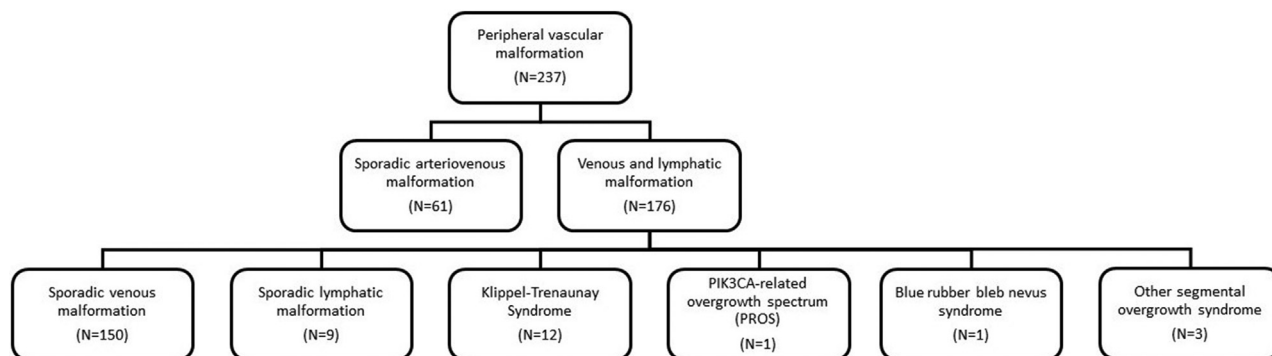


Fig. Flowchart showing distribution of the peripheral vascular malformation types included in the present study.

Because our EST technique (direct injection only) was the same for venous and lymphatic malformations, these two lesion types were classified as the same subgroup. These were compared with AVMs that had been treated with selective catheter angiography and direct injection. Vascular malformations were also categorized by the anatomic site for subgroup analysis. Comparisons between subgroups were performed using the Mann-Whitney *U* or Kruskal-Wallis test, depending on number of comparisons. $P < .05$ was considered statistically significant.

RESULTS

Patient demographics

A total of 237 patients (91 males and 146 females; median age, 30 years; range, 1-73 years) had undergone 419 EST sessions during the study period. The numbers of different types of peripheral vascular malformations included in the present study are summarized in the Fig. Of the 237 patients, 61 (25.7%) had had AVMs and had undergone 140 EST sessions (33.4%) and 176 (74.3%) had had venous and lymphatic malformations and had undergone 279 EST sessions (66.6%). The anatomic distribution of the vascular malformation is summarized in Table I. Patients with AVMs had undergone a higher number of interventions (median, 2; range, 1-13) compared with those with venous and lymphatic malformations (median, 1; range, 1-6) during the study period ($P = .03$).

Dose–area product

Single EST. Overall, the median DAP per EST session for vascular malformations was 1.26 Gy cm^2 (range, 0.00-698.36 Gy cm^2 ; 419 EST sessions). Greater patient radiation exposure using the DAP was measured for the AVM group (median, 2.83 Gy cm^2 ; range, 0.00-698.36 Gy cm^2 ; 140 EST sessions) compared with the venous and lymphatic malformation group (median, 0.92 Gy cm^2 ; range, 0.00-182.14 Gy cm^2 ; 279 EST sessions; $P < .01$; Mann-Whitney *U* test). A significant difference in the DAP for the vascular malformations at different anatomic sites was also found ($P < .01$; Kruskal-Wallis test; Table II).

Cumulative EST per patient. The median cumulative DAP from EST per patient during the study period was 1.91 Gy cm^2 (range, 0.00-1300.24 Gy cm^2 ; 237 patients). A higher cumulative DAP per patient was measured for the AVM group (median, 6.95 Gy cm^2 ; range, 0.00-1300.24 Gy cm^2 ; 61 patients) compared with the venous and lymphatic malformation group (median, 1.53 Gy cm^2 ; range, 0.00-182.14 Gy cm^2 ; 176 patients; $P < .01$; Mann-Whitney *U* test). A significant difference in the cumulative DAP per patient for the different anatomic sites was also found during the study period ($P < .01$; Kruskal-Wallis test; Table III).

Fluoroscopy time

Because of the incomplete records for the fluoroscopy time, only 176 patients with vascular malformation who had undergone 292 EST sessions during the study period were analyzed.

Single EST. The median fluoroscopy time per procedure was 19 seconds (range, 1-3846 seconds; 292 EST sessions). Significantly longer fluoroscopy times were measured for the patients in the AVM group (median, 109 seconds; range, 1-3486 seconds; 105 EST sessions) compared with those in the venous and lymphatic malformation group (median, 12 seconds; range, 1-1644 seconds; 187 EST sessions; $P < .01$; Mann-Whitney *U* test). No significant differences were found in the fluoroscopy times for EST in relation to the anatomic distribution of vascular malformations.

Cumulative EST per patient. The median cumulative fluoroscopy time from EST per patient in the study period was 30 seconds (range, 1-5843 seconds; 176 patients). Longer cumulative fluoroscopy times were measured per patient for the AVM group (median, 295 seconds; range, 1-5843 seconds; 45 patients) compared with the venous and lymphatic malformation group (median, 20 seconds; range, 1-1739 seconds; 131 patients; $P < .01$; Mann-Whitney *U* test). No significant differences were found in the cumulative fluoroscopy times per patient in relation to the anatomic distribution of vascular malformations ($P = .82$; Kruskal-Wallis test).

Table I. Anatomic distribution of peripheral vascular malformations

Anatomic site	Vascular malformation type	Patients, No.
Head and neck		48
	Arteriovenous	13
	Venous and lymphatic	35
Upper limb		68
	Arteriovenous	27
	Venous and lymphatic	41
Lower limb		84
	Arteriovenous	13
	Venous and lymphatic	71
Torso		37
	Arteriovenous	8
	Venous and lymphatic	29
Total		237

Table II. Patient radiation exposure using dose–area product^a

Anatomic site	EST sessions, No.	DAP, Gy _{cm} ²	
		Median	Range
Head and neck	94	4.05	0.00-246.51
Upper limb	138	0.48	0.00-698.36
Lower limb	128	1.38	0.00-60.23
Torso	59	7.28	0.00-405.40

DAP, Dose–area product; EST, embolo-sclerotherapy.
^aP < .01; Kruskal-Wallis test.

DISCUSSION

The use of fluoroscopic-guided interventions and, therefore, exposure to ionizing radiation, is well-documented to potentially cause harm to patients and operators.^{6,9,11,12} These effects can include, but are not limited to, skin erythema, burns, skin damage, cataracts, and malignancies.¹³ Although some malignancies, such as leukemia, have shown an age-related risk, depending on the age at exposure,³ the likelihood is that the development of adverse effects after ionizing exposure is multifactorial, with greater cumulative exposure presenting an increased risk for both patients and operators.^{6,11,14,15}

Ionizing radiation exposure has previously been the subject of investigation for endovascular procedures, including EVAR, coronary interventions, and peripheral arterial and venous angioplasty and stenting.^{5-9,15-19} Although a relatively large body of data have been reported on arterial interventions and, more recently, venous procedures, very little is known regarding the radiation exposure of patients undergoing EST for vascular malformations. As expected, patients undergoing procedures for AVMs received significantly greater radiation

Table III. Cumulative patient radiation exposure using dose–area product per patient^a

Anatomic site	Patients, No.	DAP, Gy _{cm} ²	
		Median	Range
Head and neck	48	5.19	0.00-1300.24
Upper limb	68	0.90	0.00-817.52
Lower limb	84	1.66	0.00-73.40
Torso	37	13.40	0.00-748.02

DAP, Dose–area product.
^aP < .01; Kruskal-Wallis test.

exposure in DAP and fluoroscopy times for both single and cumulative exposure compared with those with venous and lymphatic malformations. This reflects the often more challenging treatment of the former compared with the latter. The present study has also found that both single and cumulative radiation exposure measured in DAP for procedures involving the torso and head and neck was greater than the exposure required for upper and lower limbs. Understanding the patient radiation exposure in EST for vascular malformations will help clinicians and other responsible radiation safety officers in developing strategies to minimize the risk of ionizing radiation exposure to both patients and operators. This is with particular respect to patients with potentially higher risk factors, including younger patients, those requiring repeated interventions, patients with AVMs, and those with lesions located within the torso and head and neck. These patients might also require counseling and to provide consent for their potentially significant radiation exposure during discussions regarding their treatment.

In our study, we have demonstrated that most patients with vascular malformations undergoing EST received lower radiation doses, measured in the DAP and fluoroscopy time, compared with many common endovascular interventions (Table IV). However, the ranges for the DAP and fluoroscopy time for single and cumulative EST sessions of vascular malformations were large, ranging from almost 0 to 1300.24 Gy_{cm}² and 1 to 5843 seconds, respectively. Thus, some patients with vascular malformations received relatively high radiation exposure from their treatment and, for a few, the exposure was as high as that received during complex endovascular arterial and deep venous interventions, such as EVAR and vena cava stenting.^{5,8,9} These patients have relatively complex, extensive, and diffuse vascular malformations. In contrast, those with relatively superficial, small, and localized vascular malformations will be exposed to negligible radiation from their straightforward EST. Moreover, just as those who require arterial and venous interventions, patients with peripheral vascular malformations, especially those with complex malformations, might also require more than one EST session, as shown

Table IV. Previously reported comparative radiation exposure using dose–area product and fluoroscopy time in endovascular procedures

Intervention	DAP, Gy \cdot cm ²	FT, seconds
EST of peripheral AVMs (present study)	Median, 2.8 (range, 0.0-698.4)	Median, 109 (range, 1-3486)
EST of peripheral venous and lymphatic malformations (present study)	Median, 0.9 (range, 0.0-182.1)	Median, 12 (range, 1-1644)
Percutaneous coronary intervention ¹⁶	Mean \pm SD, 19.9 \pm 24.9	Mean \pm SD, 582 \pm 672
Percutaneous transluminal angioplasty and stenting of lower leg ⁷	Mean, 6.5 (range, 4.1-10.5)	Mean, 833
Percutaneous transluminal angioplasty and stenting of lower (pelvis) ⁷	Mean 66.9 (range, 50.2-89.1)	Mean, 535
Endovascular repair of infrarenal abdominal aortic aneurysm ⁵	Mean, 79.5 (range, 4.3-619.0)	NR
Unilateral chronic iliofemoral venous stenting ⁸	Median, 32.4 (range, 0.1-289.6)	Median, 660 (range, 246-4200)
Endovascular inferior vena caval reconstruction ⁸	Median, 60.8 (range, 2.5-269.1)	Median, 2846 (range, 836-11,682)

AVM, Arteriovenous malformation; DAP, dose–area product; EST, embolo-sclerotherapy; NR, not reported; SD, standard deviation.

in the present study, increasing their cumulative radiation exposure. The EVAR trial, which compared endovascular and open repair of abdominal aortic aneurysms, reported an increased incidence of malignancy in patients treated endovascularly after 15 years of follow-up.²⁰ It is concerning that the patients who undergo EST for peripheral vascular malformations are, as shown in the present study, likely to be within a younger age group than those requiring arterial interventions. Therefore, some of these patients, especially those with challenging and extensive peripheral vascular malformations, could potentially receive greater cumulative radiation exposure from multiple EST sessions at a younger age and with an expected longer lifespan than their arterial counterparts.

With the potential for such radiation exposure, not only to patients, but also to operators, limiting such exposure as much as possible is of importance.^{11,12,14} Basic training for protective equipment and an awareness of x-ray protocols is essential for the safety of the theater and radiology personnel.^{9,14,17} Operators should be aware of optimal patient and staff positioning to reduce radiation exposure and scatter.^{5,14} The judicious use of appropriate collimation and magnification should be employed, and the use of extreme angulations should also be limited.¹⁴ The use of low-dose and pulsed fluoroscopy will contribute to an overall radiation reduction.^{12,18} Finally, newer digital technology and the use of nonionizing radiation imaging modalities, including ultrasonography and fusion imaging, have contributed to significant dose reductions for endovascular procedures.^{11,21,22}

The present study had several limitations. First, as a single-center retrospective study with a relatively small number of patients, potential biases could not be ruled out. As with any medical procedure with exposure to radiation, the risks must be quantified and limited as

much as possible, with further research into this area required. Second, DAP and fluoroscopy time are exposure radiation indexes that only provide theoretical radiation risk estimates and do not factor in individual variations in susceptibility to radiation damage.⁹⁻¹¹ Many additional factors will contribute to the radiation dose of a procedure, including patient build, operative field, the use of digital subtraction angiography, and procedural complexity. The DAP and fluoroscopy times were used because they are easily obtained from modern fluoroscopy units, which compute them automatically.^{7,9-11,23} Furthermore, many studies of radiation exposure, including those for endovascular arterial and deep venous interventions, have reported their findings using these indexes, allowing for comparisons between studies.^{5,7,8,16} However, these comparisons between procedures should be performed cautiously owing to the differences in the nature of the pathology, complexity of the interventions, and patient cohorts studied.

Despite these limitations, the findings from the present study provide an important direction and baseline reference for the planning of future trials. The present study is one of the very few studies, if any, that has directly estimated the radiation exposure of patients undergoing EST for peripheral vascular malformations, a mainstay intervention for the condition. Of greater concern, we found that some patients within this population received relatively high doses of cumulative radiation. Future trials should focus on evaluating the potential adverse outcomes and risk factors for radiation damage from EST, which would help in developing strategies to reduce the radiation exposure specifically for this patient population and, especially for children. The potential risk factors identified from the present study worth evaluating include patient age, vascular malformation type, size, anatomic distribution, and EST technique. Future trials should also be prospective with large sample sizes,

sufficient follow-up, and appropriate outcome measures relevant to the patients.

CONCLUSIONS

Patient radiation exposure for EST of peripheral vascular malformations measured using the DAP and fluoroscopy time appeared to be generally lower than those reported for endovascular arterial and deep venous interventions. However, some patients with peripheral vascular malformations received relatively high radiation doses from EST. Furthermore, patients with peripheral vascular malformations will usually be much younger than those with arterial disease and might require multiple interventions, leading to further radiation exposure during their lifetime. Future studies should investigate the long-term side effects of radiation, the risk factors and strategies to reduce the exposure in these patients, and strategies to reduce the exposure.

AUTHOR CONTRIBUTIONS

Conception and design: LG, JT, GH, JB, CL

Analysis and interpretation: LG, AP, MK, JT, GH, JB, CL

Data collection: LG, NE

Writing the article: LG, GH, JB, CL

Critical revision of the article: LG, NE, AP, MK, JT, GH, JB, CL

Final approval of the article: LG, NE, AP, MK, JT, GH, JB, CL

Statistical analysis: LG, AP, MK, JT, JB, CL

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JB and CL contributed equally to this article and share co-senior authorship.

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