

**Patient Radiation Exposure from Embolo-sclerotherapy of Peripheral Vascular
Malformations**

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Short title: Radiation Exposure from Embolo-sclerotherapy of Vascular Malformations

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Key words

Vascular malformation, arteriovenous malformation, embolo-sclerotherapy, sclerotherapy, embolization, ionizing radiation

Table of Contents Summary

This retrospective study analyzed the radiation exposure for patients who underwent embolo-sclerotherapy (EST) for peripheral vascular malformations (VMs). The single and cumulative radiation exposure in patients with VMs who had EST were generally less than many common endovascular arterial and deep venous interventions. However, since some patients with VMs received relatively high radiation doses from EST and some require multiple interventions, the authors recommend that clinicians who perform these procedures keep the radiation exposure to a minimum.

Article highlights

Type of research

Single-center, retrospective, cohort study

Key findings

The median (range) dose-area product, DAP measured for single and cumulative embolo-sclerotherapy (EST) for peripheral vascular malformation (VM) 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. Significantly higher DAP was found in single and cumulative EST for patients with high-flow VMs than those with low-flow VMs.

Take home message

Though overall patient radiation exposure in EST for patients with VM was relatively low, in comparison with many common endovascular arterial and deep venous interventions, the

DAP and fluoroscopy time measured in some of these procedures were still high. Therefore, it is important that clinicians who perform these procedures keep the radiation exposure to a minimum.

Abstract

Objectives

Embolo-sclerotherapy (EST) is the mainstay therapy for peripheral vascular malformations (VMs) which involves the exposure of patients to ionising radiation. We aimed to analyze the radiation exposure to patients from EST of peripheral VMs over five years in a single specialist center.

Methods

All patients who had EST performed at single specialist tertiary centre for peripheral VMs between January 1st 2013 and January 8th 2018 were identified from a prospectively collected database. Data collection included basic demographics, date of the procedure, anatomical site, flow classification of VMs and procedural details. Radiation exposure, measured in dose-area product (DAP) and fluoroscopy time, of all patients identified to have EST of VM during the period were retrospectively reviewed. Statistical analysis was performed using Mann-Whitney *U* and Kruskal-Wallis tests for comparison between subgroups. $P < 0.05$ was considered significant.

Results

A total of 237 patients (median age 30 years; range 1 – 73 years) underwent 419 ESTs during the study period. Of these, 61 (25.7%) patients had high-flow VM (HFVM) and underwent 140 (33.4%) ESTs. Meanwhile, 176 (74.3%) patients had low-flow VM (LFVM) and underwent 279 ESTs (66.6%). Patients with HFVM had a median of 2 procedures (range 1 - 13), compared to a median of 1 (range 1 - 6) for LFVM within the study period. The median

DAP for single and cumulative EST for VM were 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. Whereas, the median fluoroscopy time for single and cumulative EST were 19 seconds (range 1 – 3845 seconds) and 30 seconds (range 1 – 5843 seconds), respectively. Significantly higher patient radiation exposure in DAP and fluoroscopy time was measured for single and cumulative EST for HFVM when compared with LFVM (both $P < 0.01$; Mann Whitney U). A significant difference in DAP but not fluoroscopic time were found when anatomical areas of VMs by were compared.

Conclusions

Patient radiation exposure for EST of peripheral VMs measured in DAP and FT appeared to be generally less than those reported for endovascular arterial and deep venous interventions in the literature. However, some patients with peripheral VMs received relatively high radiation doses by our measures. Therefore, further studies should investigate the long-term side-effects of radiation exposure in these patients and strategies to reduce it.

Introduction

Vascular malformations (VMs) are a common, heterogenous group of abnormally developed blood vessels that can be divided into high-flow (HFVM) arteriovenous malformations and low-flow (LFVM) venous, lymphatic and capillary malformations depending on the aetiology involved. The mainstay of treatment for peripheral VMs involves embolo-sclerotherapy (EST), for which fluoroscopy and, therefore, ionizing radiation, is required in many cases ^{1, 2}. The deleterious effects of ionizing radiation are well documented and include an increased risk of malignancy ^{3, 4}. As a result, patient and operator exposure during common endovascular procedures, such as endovascular aortic aneurysm repair (EVAR) and peripheral arterial and venous interventions, including angioplasty and stenting, have already been the subject of investigation ⁵⁻⁸. The cohort of patients who undergo endovascular treatment for VMs are, in general, more likely to be younger than those treated for arterial disease. In addition to this, multiple procedures may be required during the course of their treatment ^{1, 2}. Despite these inherent concerns, there is currently no published data with regards to the cumulative radiation exposure received by patients undergoing EST for peripheral VMs. This study aimed to determine the radiation exposure received by patients with peripheral VMs undergoing EST requiring fluoroscopy over five years at a single specialist tertiary center.

Methods:

This is a retrospective audit study of a prospectively collected departmental database, with no patient identifiable data. Hence, institutional review board approval or informed consent was not required.

Patients

All patients who had EST performed at a single specialist tertiary center for peripheral VMs between January 1st 2013 and January 8th 2018 were identified from a prospectively collected database. All patients with peripheral VMs treated in our hospital underwent 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 and/or rapidly growing peripheral VMs and/or those at risk of causing systemic complication were considered for EST. Patients were treated on joint lists, with a vascular surgeon and an interventional radiologist with a specialist interest in VMs, present. All ESTs of HFVM were performed under selective catheter angiography and direct injection. LFVM were treated with direct injection only.

Data collection

Data collection included basic demographics, date of the procedure, anatomical site, flow classification of VMs and procedural details. Radiation exposure was measured in dose-area product (DAP) and fluoroscopy time. DAP refers to the radiation absorbed by irradiated tissue multiplied by the area irradiated, which gives a rough estimation of the risk of stochastic effects^{7, 9, 10}. Procedures were cross-referenced with computer records and those who did not require endovascular treatment, with no recorded fluoroscopy data or with radiation exposure data not in DAP form, were excluded from analysis. DAP and fluoroscopy times were collected directly through the radiology software Clinical Radiology Information System Live, CRIS Live.

Operating theatres and C-arm

All ESTs were performed either in a vascular hybrid theatre with a ceiling mounted C-arm, (Siemens Artis Zeego, Siemens Healthcare, Erlangen, Germany) or in a vascular operating theatre with a mobile C-arm (Siemens Cios Alpha VA20, Siemens Healthcare, Erlangen,

Germany). Default settings of a pulse rate of 3.0 - 7.5 pulses/second for background fluoroscopy and two frames per second 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 needed.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences, version 17 (SPSS, Chicago, IL). Data was reported in medians, ranges and frequencies. DAP was rounded to the nearest second decimal point in this report including those of less than 0.05 Gy cm^2 , which were rounded to 0.00 Gy cm^2 . Comparisons between groups were performed using the Mann-Whitney *U* or Kruskal-Wallis test depending on number of comparisons. $P < 0.05$ was considered significant.

Results:

Patient demography

A total of 237 patients (91 males and 146 females; median age 30 years; range 1 – 73 years) underwent 419 ESTs during the study period. Of these, 61 (25.7%) patients had HFVMs and underwent 140 (33.4%) ESTs. Meanwhile, 176 (74.3%) patients had LFVMs and underwent 279 ESTs (66.6%). Table I summarizes the anatomical distributions of VM in the studied patients. Patients with HVFM had a higher number of interventions (median 2; range 1-13) when compared to those with LFVM (median 1; range 1-6) requiring EST during the study period .

Dose-area product

Single EST

Overall, the median DAP per EST for VM was 1.26 Gy cm^2 (range 0.00 – 698.36 Gy cm^2 ; 419 ESTs). Higher patient radiation exposure in DAP was measured per EST for HFVM (median 2.83 Gy cm^2 and range 0.00 – 698.36 Gy cm^2 ; 140 ESTs) than LFVM (median 0.92 Gy cm^2 and range 0.00 – 182.14 Gy cm^2 ; 279 ESTs) ($P < 0.01$; Mann Whitney *U*). A significant difference in DAP per EST of VMs of different anatomical sites was also found ($p < 0.01$; Kruskal-Wallis) (Table II).

Cumulative EST per patient

The median cumulative DAP from EST per patient in the study period was 1.91 Gy cm^2 (range 0.00 – 1300.24 Gy cm^2 ; 237 patients). Higher cumulative DAP was measured per patient for HFVM (median 6.95 Gy cm^2 and range 0.00 – 1300.24 Gy cm^2 ; 61 patients) when compared with LFVM (median 1.53 Gy cm^2 and range 0.00 – 182.14 Gy cm^2 ; 176 patients) ($P < 0.01$; Mann Whitney *U*). A significant difference in cumulative DAP per patient of different anatomical sites was also found in the study period ($p < 0.01$; Kruskal-Wallis) (Table III).

Fluoroscopy time

Due to incomplete records of fluoroscopy time, only 176 VM patients with 292 ESTs during the study period were analyzed.

Single EST

The median fluoroscopy time per procedure was 19 seconds (range 1 – 3845 seconds; 292 ESTs). Significantly higher fluoroscopy time per EST was measured in patients with HFVM (median 109 seconds and range 1 – 3486 seconds; 105 ESTs) when compared with those with LFVM (median 12 seconds and range 1 – 1644 seconds; 187 ESTs) ($P < 0.01$; Mann-Whitney

U). There were no significant differences in fluoroscopy times for ESTs in relation to the anatomical distribution of VMs.

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). Higher cumulative fluoroscopy times were measured per patient for HFVM (median 295 seconds and range 1 - 5843 seconds; 45 patients) when compared with LFVM (median 20 seconds and range 1 – 1739 seconds; 131 patients) ($P < 0.01$; Mann Whitney *U*). There were no significant differences in cumulative fluoroscopy times per patient in relation to the anatomical distribution of VMs ($P = 0.82$; Kruskal-Wallis).

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 malignancies¹³. Whereas some malignancies, such as leukemia show an age-related risk, depending on the age at exposure³, the likelihood is that the development of adverse effects following ionizing exposure is multifactorial, with higher 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}. A systematic review by Monastiriotis and colleagues found that for a regular, infrarenal EVAR, the mean radiation exposure to the patient in DAP was 79.48 Gy cm^2 (range 4.3 – 619 Gy cm^2)⁵. Despite a 78% reduction in the radiation dose received

by patients during coronary angiography, with or without intervention, over a ten-year period, Faroux and colleagues found the overall mean DAP per procedure in 2016 was 19.94 Gy cm^2 with standard deviation of 24.90 Gy cm^2 ¹⁶. Meanwhile, Majewska and colleagues reviewed a series of peripheral arterial angioplasty and stenting which revealed a wide range of radiation exposure according to the site and complexity of the procedure involved. The highest exposures were found for iliac artery TASC II class C and renal artery procedures (mean DAP of 199 Gy cm^2 and 148 Gy cm^2 , respectively). The lowest exposures, with a mean DAP of 6.3 Gy cm^2 , was found in femoral artery TASC II class A interventions ⁶. More recently, Lim and colleagues concluded that endovascular deep venous interventions for central venous outflow obstruction measured in DAP and fluoroscopic time seemed to be less than and, at most, comparable to anatomically similar arterial interventions ⁸.

Although there is a relatively large body of literature on arterial interventions and, more recently, venous procedures, very little is known regarding the radiation exposure of patients undergoing EST for HFVM and LFVM. This is one of the very few studies, if any, in the literature that directly estimated the radiation exposure of patients having EST for peripheral VM; a mainstay intervention for the condition. As expected, patients undergoing procedures for HFVM received a significantly higher radiation exposure in DAP and fluoroscopy times for both single and cumulative exposures compared to those with LFVM. This reflects the often more challenging treatment of the former compared to the latter. This study has also found that both single and cumulative radiation exposures measured in DAP for procedures involving the torso and head and neck were higher than those required for upper and lower limbs. Understanding the patient radiation exposure in EST of VM will help clinicians and other responsible radiation safety officers in developing strategies to minimize risk of ionizing radiation exposure to both patients and operators.

In our study, we have demonstrated that most patients with both LFVM and HFVM undergoing EST, received lower doses of radiation measured in DAP and fluoroscopy time when compared to many common endovascular interventions. These include percutaneous coronary interventions, percutaneous transluminal angioplasty, stenting of the lower limb arteries, iliofemoral vein, inferior vena cava and EVAR (Table IV)^{5, 7, 8, 16}. However, the ranges of DAP and fluoroscopy time for single and cumulative EST of both HFVM and LFVM were large, ranging from almost zero to 1300.24 Gycm² and 1 to 5843 seconds, respectively. This indicates that some patients with VMs did receive relatively high radiation exposures from their treatment and, for a few, as high as that seen in 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 VMs. Meanwhile, those with relatively superficial, small and localized VMs are exposed to negligible radiation from their straightforward EST. Moreover, just as those who require arterial and venous interventions, patients with peripheral VMs, especially those that are complex, extensive and diffuse, may also require more than one EST, as shown in this study. This need increases 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-up²⁰. It is concerning that the patients who undergo EST for peripheral VMs, as shown in this study, are likely to be within a younger age group than those who require arterial interventions. Therefore, some of these patients, particularly those with challenging and extensive peripheral VMs, potentially receive a higher cumulative radiation from multiple ESTs, at a younger age and with an expected longer life-span than their arterial counterparts.

With the potential for such exposure, not only to patients, but also to the operators, a limitation of exposure as much as possible is of importance ^{11, 12, 14}. Basic training for protective equipment and an awareness of X-Ray protocols essential for the safety of theatre 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. Further use of low dose and pulsed fluoroscopy will contribute to an overall radiation reduction ^{12, 18}. Lastly, newer digital technology, and the use of non-ionizing radiation imaging modalities including ultrasonography and fusion imaging have contributed in significant dose reductions for endovascular procedures ^{11, 21, 22}.

There are several limitations to this study. Firstly, as a single center retrospective study with a relatively small number of patients, potential biases cannot be ruled out. As with any medical procedure with exposure to radiation, the risks need to be quantified and limited as much as possible, with further research into this area required. Secondly, DAP and fluoroscopy time are exposure radiation indices that only provide theoretical radiation risk estimates, which do not factor in individual variations in susceptibility to radiation damage ⁹⁻¹¹. There are many additional factors that determine the radiation dose of a procedure, including the patient's build, operative field, the use of digital subtraction and procedural complexity. DAP and fluoroscopy times were used as they are easily obtained as they are automatically computed by modern fluoroscopy units^{7, 9-11, 23}. Furthermore, many studies on radiation exposure, including those for endovascular arterial and deep venous interventions, have reported their findings using these indices, allowing for comparison between studies ^{5, 7, 8, 16}. However, these comparisons between procedures for differing pathologies should be made cautiously, due the differences in the nature of the pathology, complexity of the interventions and in the patient cohorts studied.

Conclusion:

Patient radiation exposure for EST of peripheral VMs measured in DAP and FT appeared to be generally lower than those reported for endovascular arterial and deep venous interventions in the literature. However, some patients with peripheral VMs received relatively high radiation doses from EST. Furthermore, patients with peripheral VMs are usually much younger than those with arterial diseases and may require multiple interventions, leading to further radiation exposure during their lifetime. Further studies should investigate the long-term side-effects of radiation exposure in these patients and strategies to reduce this.

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Table I. Anatomical distribution of the peripheral vascular malformations of the patients included in this study. VM: vascular malformation

Anatomical site	Type of VM	Number of patients	
Head and Neck	High-flow	13	48
	Low-flow	35	
Upper Limb	High-flow	27	68
	Low-flow	41	
Lower Limb	High-flow	13	84
	Low-flow	71	
Torso	High-flow	8	37
	Low-flow	29	
Total			237

Table II. Patient radiation exposure in dose-area product (DAP) per embolo-sclerotherapy for peripheral vascular malformations of different anatomical sites. *Kruskal-Wallis test.

Anatomical site	Number of Embolo-sclerotherapies	Median DAP (Gycm²)	Range DAP (Gycm²)	P value*
Head and neck	94	4.05	0.00 - 246.51	<0.01
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	

Table III. Cumulative patient radiation exposure in dose-area product (DAP) per patient for peripheral vascular malformations of different anatomical sites. *Kruskal-Wallis test.

Anatomical site	Number of patients	Median DAP (Gycm²)	Range DAP (Gycm²)	P value*
Head and neck	48	5.19	0.00 – 1300.24	<0.01
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	

Table IV. Comparative radiation exposures in dose-area product and fluoroscopy time with endovascular procedures in previously published literature.

Interventions	Median / Mean (range) DAP, Gycm²	Median / Mean (range) FT, seconds
Embolo-sclerotherapy of peripheral high-flow vascular malformations (this study)	Median 2.8 (Range 0.0 – 698.4)	Median 109 (Range 1 – 3486)
Embolo-sclerotherapy of peripheral low-flow vascular malformations (this study)	Median 0.9 (Range 0.0 – 182.1)	Median 12 (Range 1 – 1644)
Percutaneous coronary interventions ¹⁶	Mean 19.9 (+/- standard deviation 24.9)	Mean 582 (+/- standard deviation 672)
Percutaneous transluminal angioplasty and stent lower leg ⁷	Mean 6.5 (Range 4.1 – 10.5)	Mean 833
Percutaneous transluminal angioplasty and stent 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)	-
Unilateral chronic iliofemoral venous stenting ⁸	Median 32.4 (0.1 – 289.6)	Median 660 (246 - 4200)
Endovascular inferior vena caval reconstruction ⁸	Median 60.8 (2.5 – 269.1)	Median 2846 (836 – 11682)