



Physician Compounded Foam For Truncal Vein Disease: When And Where



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Disclosures :

- Servier : Consulting
- Medtronic : Consulting
- Kreussler : Consulting

Where ?

Recommendation 1: We recommend sclerotherapy for all types of veins, in particular:

- Incompetent saphenous veins (GRADE 1A)
- Tributary varicose veins (GRADE 1B)
- Incompetent perforating veins (GRADE 1B)
- Reticular varicose veins (GRADE 1A)
- Telangiectasias (spider veins) (GRADE 1A)
- Residual and recurrent varicose veins after previous interventions (GRADE 1B)
- Varicose veins of pelvic origin (GRADE 1B)
- Varicose veins (refluxing veins) in proximity of leg ulcers (GRADE 1B)
- Venous malformations (GRADE 1B)

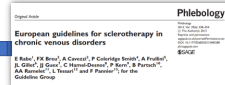


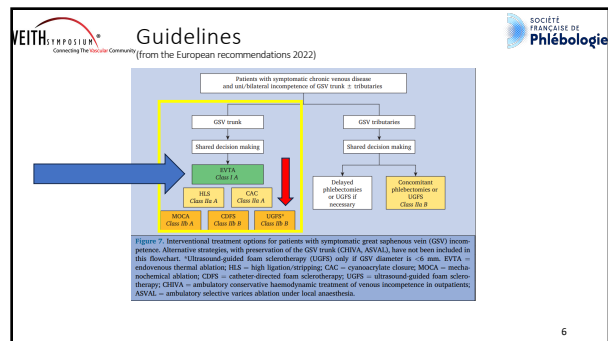
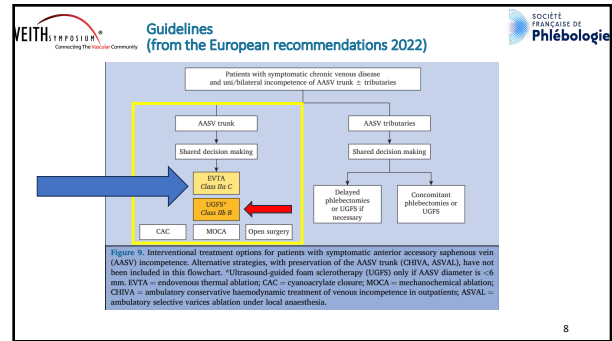
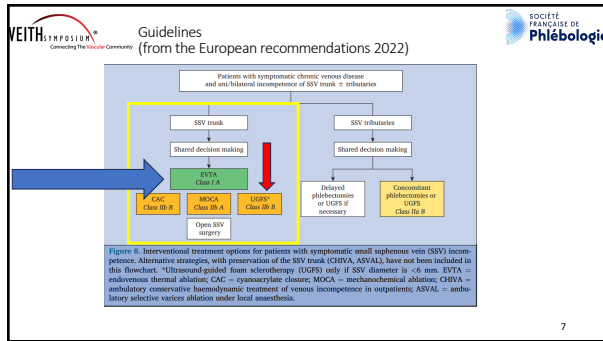




Table 4. Suggested concentrations of POL and TDSS in foam sclerotherapy

Diamètre veineux (mm)*	Polidocanol % **	Tétradécyl Sulfate de Sodium % **	% POL, tol	Concentration % of TDSS, sodium tetradecyl sulfate
≤ 2	0,12 à 0,25	0,1	Grade 1B	Up to 0.25 Grade 2C
[2-3]	0,25	0,2	Grade 2C	Up to 0.5 Grade 2C
[3-4]	0,5	0,5	Grade 1B	Up to 1 Grade 1C
[4-6]	1	1	Grade 1B	Up to 1 Grade 1C
[6-8]	2	1 à 3	Grade 1A	between 1-3 Grade 1B
8 et plus	3	3	Grade 1A	3 Grade 1B
			Grade 2B	between 1-3 Grade 2B
			Grade 2B	between 1-3 Grade 2B
Venous malformation			between 1-3	Grade 2B between 1-3 Grade 2B

Off-label





Guidelines (from the North American recommendations 2023)

A12. For patients with symptomatic varicose veins and axial reflux in the SSV who are candidates for intervention, we recommend treatment with endovenous ablation over ligation and stripping of the SSV.	2 (weak)	C (low to very low)
A13. For patients with symptomatic varicose veins and axial reflux in the AACSV or PACSV who are candidates for intervention, we suggest treatment with endovenous ablation with additional phlebectomy if needed, over ligation and stripping of the accessory vein.	2 (weak)	C (low to very low)
A14. For patients with symptomatic varicose veins and axial reflux in the CSV or SSV, we recommend treatment with HLES of the saphenous vein if technology or expertise in endovenous ablation is not available, or if the venous anatomy precludes endovenous treatment.	1 (strong)	D (procrustean)
A15. For patients with symptomatic varicose veins and axial reflux in the AACSV or PACSV, we suggest treatment with ligation and stripping of the accessory saphenous vein, with additional phlebectomy if needed, if technology or expertise in endovenous ablation is not available or if the venous anatomy precludes endovenous treatment.	2 (weak)	C (low to very low)
A16. For patients with symptomatic varicose veins and axial reflux in the CSV who place a high priority on the long-term outcomes of treatment (quality of life [QoL] and recurrence), we suggest treatment with endovenous laser ablation (EVLA), endovenous ablation (EVA), or HLES over physician-compounded ultrasound-guided foam sclerotherapy (UGFS), because of long-term improvement of QoL and reduced recurrence.	2 (weak)	D (procrustean)
A17. For patients with symptomatic varicose veins and axial reflux in the SSV, we suggest treatment with EVLA, EVA, or ligation and stripping from the knee to the ankle or distal or physician-compounded UGFS because of long-term improvement of QoL and reduced recurrence.	2 (weak)	C (low to very low)
A18. For patients with symptomatic varicose veins and axial reflux in the AACSV or PACSV who place a high priority on the long-term outcomes of treatment (QoL and recurrence), we suggest treatment of the refluxing superficial trunk with endovenous laser ablation, EVA, or HLES, with additional phlebectomies if needed, over physician-compounded UGFS, because of long-term improvement of QoL and reduced recurrence.	2 (weak)	C (low to very low)

Phlebology

A review of randomized controlled trials comparing ultrasound-guided foam sclerotherapy with endothermal ablation for the treatment of great saphenous varicose veins

Author	Year	Study	Intervention	Comparator	Outcomes
FLA	2014	Randomized controlled trial	Fluoropolymer foam sclerotherapy	Endothermal ablation	Similar outcomes
CONV	2015	Randomized controlled trial	Conventional foam sclerotherapy	Endothermal ablation	Similar outcomes
MA	2016	Randomized controlled trial	Mechanochemical ablation	Endothermal ablation	Similar outcomes
UGFS	2017	Randomized controlled trial	Ultrasound-guided foam sclerotherapy	Endothermal ablation	Similar outcomes

Cochrane Library

Cochrane Database of Systematic Reviews

Injection sclerotherapy for varicose veins (Review)

de Añla Oliveira R, Riera R, Vasconcelos V, Baptista-Silva JCC

- 28 RCT
- No significant differences in the SAFETY of the different sclerosant agents concentrations

Physicochemical properties and reproducibility of air-based sodium tetradecyl sulphate foam using the Tessari method

Mike R Watkins¹, Richard J Oliver¹

Affiliations + expand
PMID: 27329670 DOI: 10.1177/0268355516650578

Table 2. Summary results of foam density (g/ml).

STS concentration	Sclerosant ratio	Operator							Mean	SD	
		1-1	1-2	2-3	3-4	4-5	5-6	6-7			
1%	1:3	0.270	0.270	0.273	0.273	0.274	0.275	0.271	0.265	0.271	0.003
	1:4	0.219	0.215	0.218	0.219	0.222	0.217	0.221	0.218	0.219	0.002
3%	1:3	0.268	0.268	0.270	0.274	0.272	0.275	0.269	0.269	0.271	0.003
	1:4	0.218	0.217	0.223	0.213	0.218	0.221	0.220	0.217	0.218	0.003

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To produce good quality foam: 8 criteria:

- 1. Sclerosant concentration:** Foam can only be prepared with Aetoxiscérol 1%, 2% or 3% specialties.
- 2. Syringe volume:** Use plastic syringes that slide easily and are easy to handle. Aetoxiscérol 2% and 3% buffered: use a 10 mL syringe and a 5 mL low-silicone syringe to make the foam. For foam injection, it is preferable to use the 5 mL low-silicone syringe. Aetoxiscérol 1%: use the 3 mL syringe supplied in the kit and a 2.5 - 5 mL low-silicone syringe to make the foam. For injection, use the low-silicone 2.5-5 mL syringe.
- 3. The sclerosing air ratio :** The ratio is 1 volume of sclerosant + 4 volumes of air, i.e. 5 volumes of preparation.

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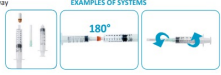
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4. Fitting safety : Connections must allow syringes to be locked and pressurized during preparation/homogenization.

1) 2-way

EXAMPLES OF SYSTEMS



2) 3-way



For this method, we recommend the use of a Luer lock tip. It should be positioned at an angle during the homogenization phase. The associated turbulence will depend on the angle at which the valve is positioned.

5. The number and nature of back-and-forth movements: A movement consists of the transition of the entire contents of syringe n°1 into syringe n°2 and then of the entire contents of syringe n°2 into syringe n°1. This movement can be performed with or without compression. Foam production may consist, for example, of 5 back-and-forth movements with no pressure, then 7 back-and-forth movements with 3/5 pressure (the 10 mL of foam are compressed in a syringe whose plunger is held at the 5 mL graduation). Scrupulously respect the number of back-and-forth movements defined according to the chosen technique.


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6. The macroscopic appearance of foam in the syringe : Always check the appearance of the foam by expelling a small amount from the syringe before injection. The foam must be compact and homogeneous, with no bubbles visible to the naked eye (diameter < 0.3 mm). In the event of visible bubbles, preparation must be repeated. The foam obtained must be of good quality:


Good foam



Bad foam



The foam must be sufficiently dense: The appearance should be close to that of "whipped cream".



7. Total preparation time : From the first to the last back and forth, it should take about ten seconds.


8. Maximum time from preparation to injection: Foam should be injected no more than 60 seconds after the start of preparation. After 60 seconds, any residual foam should be discarded. Do prepare foam 1!

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When?



- EVERYDAY
- Respect for manufacturing rules and equipment
- Compliance with concentrations and volumes
- Compliance with local rules

And ...non compounded endovenous microfoam ?

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Phlebology

European guidelines for sclerotherapy in chronic venous disorders

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