Physician Compounded Foam For Truncal Vein Disease: When And Where

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Thursday,November 21,

Disclosures :

Servier : Consulting
Medtronic : Consulting
Kreussler : Consulting

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Where ?

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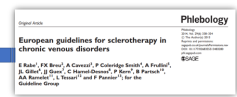
Recommendation 1: We recommend sclerotherapy for all types of veins, in particular:

- 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)*



Original Article

Phlebology

European guidelines for sclerotherapy in chronic venous disorders

E Rabe[1], FX Breu[2], A Cavezzi[3], P Coleridge Smith[4], A Frullini[5], JL Gillet[6], JJ Guex[7], C Hamel-Desnos[8], P Kern[9], B Partsch[10], AA Ramelet[11], L Tessari[12] and F Pannier[13]; for the Guideline Group

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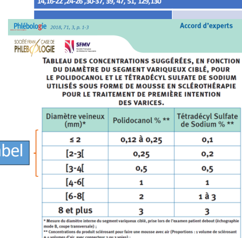
Table 4. Suggested concentrations of POL and TDSS in foam sclerotherapy [4, 7, 10, 12, 14,16-22 ,24-26 ,30-37, 39, 47, 51, 129,130]

	…% POL, …nol		Concentration % of TDSS, sodium tetradecyl sulfate	
		Grade 1B	Up to 0.25	Grade 2C
		Grade 2C	Up to 0.5	Grade 2C
		Grade 1B	Up to 1	Grade 1C
		Grade 1B	Up to 1	Grade 1C
		Grade 1A	between 1-3	Grade 1B
		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



Phlébologie 2018, 71, 3, p. 1-3 — Accord d'experts

SFMV

TABLEAU DES CONCENTRATIONS SUGGÉRÉES, EN FONCTION DU DIAMÈTRE DU SEGMENT VARIQUEUX CIBLÉ, POUR LE POLIDOCANOL ET LE TÉTRADÉCYL SULFATE DE SODIUM UTILISÉS SOUS FORME DE MOUSSE EN SCLÉROTHÉRAPIE POUR LE TRAITEMENT DE PREMIÈRE INTENTION DES VARICES.

Diamètre veineux (mm)*	Polidocanol % **	Tétradécyl Sulfate de Sodium % **
≤ 2	0,12 à 0,25	0,1
[2-3[	0,25	0,2
[3-4[	0,5	0,5
[4-6[	1	1
[6-8[	2	1 à 3
8 et plus	3	3

* Mesure du diamètre interne du segment variqueux ciblé, prise lors de l'examen patient debout (échographie mode B, coupe transversale) ;
** Concentrations du produit sclérosant pour faire une mousse avec air (Proportions : 1 volume de sclérosant + 4 volumes d'air, avec connecteur 2 ou 3 voies) ;
[n = « n » est inclus n[= « n » est exclu

Guidelines

(from the European recommendations 2022)

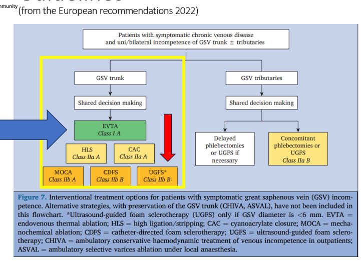


Figure 7. Interventional treatment options for patients with symptomatic great saphenous vein (GSV) incompetence. Alternative strategies, with preservation of the GSV trunk (CHIVA, ASVAL), have not been included in this flowchart. *Ultrasound-guided foam sclerotherapy (UGFS) only if GSV diameter is <6 mm. EVTA = endovenous thermal ablation; HLS = high ligation/stripping; CAC = cyanoacrylate closure; MOCA = mechanochemical ablation; CDFS = catheter-directed foam sclerotherapy; UGFS = ultrasound-guided foam sclerotherapy; CHIVA = ambulatory conservative haemodynamic treatment of venous incompetence in outpatients; ASVAL = ambulatory selective varices ablation under local anaesthesia.

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Guidelines (from the European recommendations 2022)

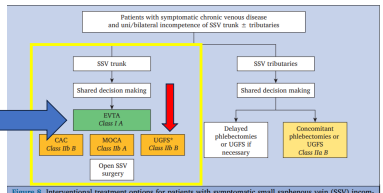

Figure 8. Interventional treatment options for patients with symptomatic small saphenous vein (SSV) incompetence. Alternative strategies, with preservation of the SSV trunk (CHIVA, ASVAL), have not been included in this flowchart. *Ultrasound-guided foam sclerotherapy (UGFS) only if SSV diameter is <6 mm. EVTA = endovenous thermal ablation; CAC = cyanoacrylate closure; MOCA = mechanochemical ablation; CHIVA = ambulatory conservative haemodynamic treatment of venous incompetence in outpatients; ASVAL = ambulatory selective varices ablation under local anaesthesia.

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Guidelines (from the European recommendations 2022)

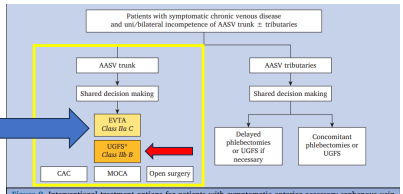

Figure 9. Interventional treatment options for patients with symptomatic anterior accessory saphenous vein (AASV) incompetence. Alternative strategies, with preservation of the AASV trunk (CHIVA, ASVAL), have not been included in this flowchart. *Ultrasound-guided foam sclerotherapy (UGFS) only if AASV diameter is <6 mm. EVTA = endovenous thermal ablation; CAC = cyanoacrylate closure; MOCA = mechanochemical ablation; CHIVA = ambulatory conservative haemodynamic treatment of venous incompetence in outpatients; ASVAL = ambulatory selective varices ablation under local anaesthesia.

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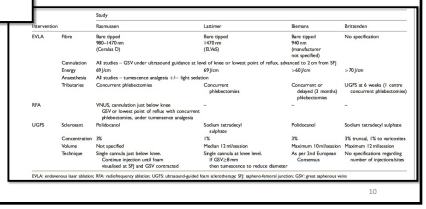
Guidelines (from the North American recommendations 2023)

4.1.2.	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.	1 (strong)	C (low to very low)
4.1.3.	For patients with symptomatic varicose veins and axial reflux in the AASV 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)
4.1.4.	For patients with symptomatic varicose veins and axial reflux in the GSV or SSV, we recommend treatment with HLAS of the saphenous vein if technology or expertise in endovenous ablation is not available or if the venous anatomy precludes endovenous treatment.	1 (strong)	B (moderate)
4.1.5.	For patients with symptomatic varicose veins and axial reflux in the AASV 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 ablations is not available or if the venous anatomy precludes endovenous treatment.	2 (weak)	C (low to very low)
4.1.6.	For patients with symptomatic varicose veins and axial reflux in the GSV 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), radiofrequency ablation (RFA), or HLAS over physician-compounded ultrasound-guided foam sclerotherapy (UGFS), because of long-term improvement of QOL and reduced recurrence	2 (weak)	B (moderate)
4.1.7.	For patients with symptomatic varicose veins and axial reflux in the SSV, we suggest treatment with EVLA, RFA, or ligation and stripping from the knee to the upper or midcalf over physician-compounded UGFS because of long-term improvement of QOL and reduced recurrence	2 (weak)	C (low to very low)
4.1.8.	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, RFA, or HLAS with additional phlebectomy, if needed, over physician-compounded UGFS because of long-term improvement of QOL and reduced recurrence	2 (weak)	C (low to very low)

HL&S ≠ NTNT

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

Phlebology



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Injection sclerotherapy for varicose veins (Review)

Cochrane Library

Cochrane Database of Systematic Reviews

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

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

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Physiochemical properties and reproducibility of air–based sodium tetradecyl sulphate foam using the Tessari method

Mike R Watkins [1], Richard J Oliver [1]

Affiliations + expand

PMID: 27329670 DOI: 10.1177/0268355516655078

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

STS concentration	Sclerosant:air ratio	Operator								Mean	SD
		I-i	I-ii	2	3	4	5	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 Aetoxisclérol 1%, 2% or 3% specialties.
2. **Syringe volume:**
   Use plastic syringes that slide easily and are easy to handle. Aetoxisclérol 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.

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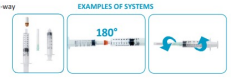
4. **Fitting safety :**
   Connections must allow syringes to be locked and pressurized during preparation/homogenization.

   1) 2-way

   EXAMPLES OF SYSTEMS

   2) 3-way

   For this method, we recommend the use of a Luer-lock tap. 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 ½ 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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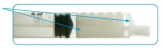
6. **The macroscopic appearance of foam in the syringe :**
   Always check the appearance of the foam by expelling a small amount from the syringe before injection.
   The foam must be compact and homogeneous, with no bubbles visible to the naked eye (diameter < 0.3 mm).
   In the event of visible bubbles, preparation must be repeated.

   The foam obtained must be of good quality:

   Good foam

   Bad moss

   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. Re-prepare foam if

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When?

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

And …non coumpounded endovenous microfoam ?

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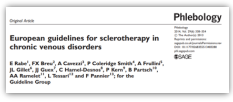

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- Recommendation 20: We recommend the use of a three-way stopcock (Tessari method) or two-way connector (Tessari-DSS method) for the generation of sclerosant foam for all indications (GRADE 1A).
- Recommendation 21: We recommend air as the gas component for generation of sclerosing foam for all indications (GRADE 1A) or a mixture of carbon dioxide and oxygen (GRADE 2B).
- Recommendation 22: We recommend a ratio of liquid sclerosant to gas for the production of a sclerosing foam of 1 / 4 (1 part liquid / 4 parts air) to 1 / 5 (GRADE 1A).

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Pauline

Thank you for your attention