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Update on FOVELASS - French Society of Phlebology Study: RCT comparing Foam and EVLA in SSV incompetence

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Randomised clinical trial

FOVELASS: A Randomised Trial of Endovenous Laser Ablation *Versus* Polidocanol Foam for Small Saphenous Vein Incompetence

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State of the art

Contemporary management of incompetence of the small saphenous vein in the light of the recent results of the FOVELASS study

Claudine Hamel-Desnos

Supplementary data and additional discussion were published in December 2023

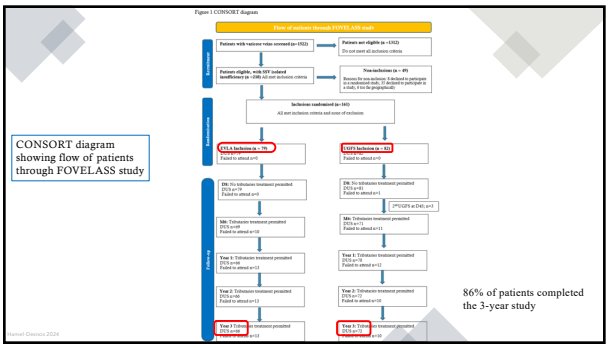
Hamel-Desnos C, Nyamekye I, Chauzat B, Gracia S, Jeanin M, Abbadie F. FOVELASS: A Randomised Trial of Endovenous Laser Ablation Versus Polidocanol Foam for Small Saphenous Vein Incompetence. European Journal of Vascular and Endovascular Surgery. 2023;65:415-423. MARCH 2023;

Hamel-Desnos C. Contemporary management of the small saphenous vein in the light of the recent results of the FOVELASS study. J Mal Vasc 2023

design

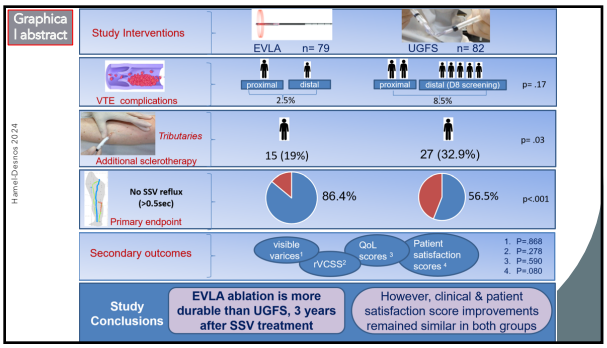
- Multicentre (11 centres) RCT on SSV incompetence treatment
- 2 parallel arms FOAM versus LASER (1470 nm)
- FIRST OBJECTIVE : technical success (reflux) at 3-y
- Second objectives: clinical results at 3-y

In both groups, **treatment of the tributaries** was only permitted after 6 months (at the discretion of the investigators: either phlebectomies or sclerotherapy)



CONSORT diagram showing flow of patients through FOVELASS study

86% of patients completed the 3-year study



Discussion/comments

Treatment of tributaries

Treatments of TRIBUTARIES during the 3 y-FU only allowed from M6

SCLEROTHERAPY only (no phlebectomies performed)

- EVLA group : 19% (1.2 session per patient on average)
- UGFS group : 33% (1.5 session per patient on average)

Approximately 70% of UGFS patients and 80% of EVLA patients did not require treatment for tributaries

Systematic concomitant treatment of tributaries is questionable at least for the SSV

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Reflux outcomes in percentage

43%

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Diameter reduction in case of **recanalisation**

FOVELASS study (**SSV**) (1, 2)

In case of recanalisation in UGFS group, SSV mean diameter was **2 mm at 3 years** (mean diameter before treatment= 5.7 mm)

'3/1 study' (**GSV**) (3)

In case of recanalisation, GSV mean diameter was **2.8 mm at 2 years** (mean diameter before treatment = 6 mm)

The reduction in the diameter of the saphenous veins could explain good clinical results of the foam despite a "technical failure"

1) Hamel-Desnos C et al. Eur J Vasc Endovasc Surg. 2023
2) Hamel-Desnos C. J Mal Vasc 2023
3) Hamel-Desnos C. et al Eur J Vasc Endovasc Surg. 2007

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DVTs

- EVLA : 1 EHIT 2, not classified as DVT
- UGFS: 2 partial popliteal DVTs (but were EFIT 2)

Need for EFIT* classification
Or use "ARTE**" [1]?

In Foam group, 5 gastrocnemius vein thromboses
(4 asymptomatic)
on Day 8 screening, no treatment

* EFIT : Endovenous Foam Induced Thrombosis
**ARTE: Ablation Related Thrombus Extension
1- 2023 American Guidelines – Part II (SVS, AVF, AVLS). Gloviczki et al. JVS VLD 2023

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Treatment parameters used for UGFS and EVLA endovenous treatment

	UGFS (n =82)	EVLA (n =79)
Treatment room setting	100%	66% (34% in operating theatre)
TLA supplementary anaesthesia given (protocol violation)	Not applicable	7 patients (8.8%)
Mean (SD) length treated	Not applicable	20.7cm (5.6cm)
Mean (SD) treatment parameter	POL: 1.5% (0.7%) Foam: 3mls (1.5 mls)	LEED 75.5 j/cm (13.5 j/cm)
Mean (SD) procedure time (minutes)	17 (8-35)	36 (15-60)
'D0' tributary treatment (protocol violation)	10 (12.1%): 3 phlebectomy, 7 UGFS	8 (10.1%): 4 phlebectomy, 4 UGFS
Post procedure compression prescribed	45.7%	92%
Patients prescribed LMWH prophylaxis;	2 (2.4%)	59 (75%)
duration in days [min-max]	5.5 [1.0-10.0]	2.5 [1.0-10.0]
Number needing time off work	0 (0%)	3 (3.8%)
Patient given additional tributary treatment (M6-M36)	27 (32.9%)	15 (19%)

several questions arise

- Why do practitioners still use systematic thromboprophylaxis for EVLA even in the absence of risk factors?
- Could this explain the difference between the 2 groups in terms of gastrocnemius vein thromboses?
  - ➢Should we be searching for them systematically ?
  - ➢Should this type of vein thrombosis be treated?
  - ➢Should they be classified as DVTs?

- Danneil O et al. Factors influencing superficial and Deep vein thrombosis after foam sclerotherapy in varicose veins. JDDG 2022
- 2023 American Guidelines – Part II (SVS, AVF, AVLS). Glovicki et al. JVS VLD 2023

Treatment COSTS (do not include DUS scan costs)

	EVLA (N=79)	UGFS (N= 82)
Private Hospital expenses for SSV treatment	1108.76€ (including equipment and fibre costs) per treatment x 79 patients = 87592€	NA
Doctor's fees for SSV treatment	EVLA of the SSV=157.02€ x 79 patients = 12405€	UGFS of the SSV=94,64€ for first session x 82 patients = 7760€
Doctor's fees for additionnal SSV treatments	NA	37.46€ for second session (at 6 weeks) x 3 patients = 112 €
Doctor's fees for visual sclerotherapy of SSV tributaries	18.93€ per session x 19 sessions = 360€	18.93€ per session x 41 sessions = 776€
Total costs	Total costs for 79 patients = 100357€	Total costs for 82 patients = 8648€
Total mean cost per patient	100357€/ 79 =1270.34 €	8648.99 €/ 82 =105.46€

IN CONCLUSION: Many issues arise

- There is no doubt about the technical superiority of laser over foam in the treatment of incompetent saphenous veins, but
  - ➢Failure should be better defined
  - ➢What role do clinical results play in daily practice?
  - ➢Foam is cost-effective (can be the first choice even for saphenous veins in some countries)
- Why is venous thromboprophylaxis after the treatment of varicose veins so poorly standardised in everyday practice?
- The debate about 'concomitant or staged treatment of tributaries' remains open

Thanks to our patients

Thank you for listening

Thanks to the investigators : F. Abbadie, B. Chauzat, P. Desnos, A. Diard, J.L. Gérard, S. Gracia, C. Hamel-Desnos, M. Josnin, L. Moraglia, P. Ouvry, O. Pichot, S. Skopinski, C. Stirneman

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