

# EVIDENCE BASED STATEMENT

DOMAIN **11**, Statement **02**

TOPIC: “Foam sclerotherapy production validated methods”

## SEARCH TERMS & SOURCES

((foam) AND (sclerotherapy)) AND (production)

### INCLUSION CRITERIA

- Lower limb only
- Systematic Reviews, Meta-Analysis, Reviews
- Publication < 10 years, only ENG

## SEARCH RESULT BEFORE - AFTER SELECTION

14/5

### PERTINENT LITERATURE NOT IDENTIFIED BY THE LITERATURE SEARCH

1. Davies HO, Watkins M, Oliver R, et al. Adverse neurological events after sodium tetradecyl sulfate foam sclerotherapy - A prospective, observational study of 8056 treatments. *Phlebology*. 2022 Mar;37(2):97-104.
2. Roche E, Pons R, Roche O, Puig A. A new automated system for the preparation of sclerosant foam: A study of the physical characteristics produced and the device settings required. *Phlebology*. 2020 Oct;35(9):724-733.
3. Bottaro E, Paterson J, Zhang X, Hill M, Patel VA, Jones SA, Lewis AL, Millar TM, Carugo D. Physical Vein Models to Quantify the Flow Performance of Sclerosing Foams. *Front Bioeng Biotechnol*. 2019 May 21;7:109.
4. Watkins MR, Oliver RJ. Physiochemical properties and reproducibility of air-based sodium tetradecyl sulphate foam using the Tessari method. *Phlebology*. 2017 Jul;32(6):390-396
5. Tan L, Wong K, Connor D, et al. Generation of sclerosant foams by mechanical methods increases the foam temperature. *Phlebology*. 2017 Aug;32(7):501-505.
6. Cameron E, Chen T, Connor DE, et al. Sclerosant foam structure and stability is strongly influenced by liquid air fraction. *Eur J Vasc Endovasc Surg*. 2013 Oct;46(4):488-94

# EVIDENCE BASED STATEMENT

## Domain 11; Statement 2

### IDENTIFIED REFERENCES

1. Meghdadi A, Jones SA, Patel VA, et al. Foam-in-vein: A review of rheological properties and characterization methods for optimization of sclerosing foams. *J Biomed Mater Res B Appl Biomater*. 2021 Jan;109(1):69-91.
2. Star P, Connor DE, Parsi K. Novel developments in foam sclerotherapy: Focus on Varithena® (polidocanol endovenous microfoam) in the management of varicose veins. *Phlebology*. 2018 Apr;33(3):150-162.
3. Alder G, Lees T. Foam sclerotherapy. *Phlebology*. 2015 Nov;30(2 Suppl):18-23.
4. Carroll C, Hummel S, Leaviss J, et al. Systematic review, network meta-analysis and exploratory cost-effectiveness model of randomized trials of minimally invasive techniques versus surgery for varicose veins. *Br J Surg*. 2014 Aug;101(9):1040-52.
5. Willenberg T, Smith PC, Shepherd A, Davies AH. Visual disturbance following sclerotherapy for varicose veins, reticular veins and telangiectasias: a systematic literature review. *Phlebology*. 2013 Apr;28(3):123-31.

# EVIDENCE BASED STATEMENT

## Domain 11; Statement 2

### TEXT FOR INCLUSION IN THE DOCUMENT

DOMAIN 11, Statement 02, TOPIC: “Foam sclerotherapy production validated methods”

Foam sclerotherapy represents a pillar in chronic venous disease treatment. Its production method is of paramount importance to guarantee safety, efficacy, standardization and reproducibility of the result.

The two main sclerosing agents for foam production are polidocanol and sodium tetradecyl sulfate.

Foam can be produced by physician compounded or by automatic methods.

Foam physical properties can vary based on the syringe and needle features, as well as liquid/air ratio and production method.

The currently most commonly used method is the Tessari one, whose standardization and reproducibility has been demonstrated by Watkins et al.

**[Watkins MR, Oliver RJ. Physiochemical properties and reproducibility of air-based sodium tetradecyl sulphate foam using the Tessari method. Phlebology. 2017 Jul;32(6):390-396]**

Automated foam production methods have been reported in the literature but, up to our knowledge, not in a head to head comparison with physician compounded production, therefore the clinical benefit can not be determined.

**[Star P, Connor DE, Parsi K. Novel developments in foam sclerotherapy: Focus on Varithena® (polidocanol endovenous microfoam) in the management of varicose veins. Phlebology. 2018 Apr;33(3):150-162].**

**[Roche E, Pons R, Roche O, Puig A. A new automated system for the preparation of sclerosant foam: A study of the physical characteristics produced and the device settings required. Phlebology. 2020 Oct;35(9):724-733].**

A recent large study on 8056 patients treated by foam sclerotherapy confirmed the procedure safety with a very low incidence of neurological adverse events. Migraine history, physiological gas use and foam volume increased the risk of these complications.

**\*[Davies HO, Watkins M, Oliver R, et al. Adverse neurological events after sodium tetradecyl sulfate foam sclerotherapy - A prospective, observational study of 8056 treatments. Phlebology. 2022 Mar;37(2):97-104].**

# EVIDENCE BASED STATEMENT

## Domain 11; Statement 2

### STATEMENT FOR PUBLIC EVIDENCE-BASED AWARENESS

DOMAIN 11, Statement 02

“Foam produced by expert hands, using proper syringes and method is standardized, reproducible, safe and effective”.

### SELECTED REFERENCES

1. **Watkins MR, Oliver RJ. Physiochemical properties and reproducibility of air-based sodium tetradecyl sulphate foam using the Tessari method. Phlebology. 2017 Jul;32(6):390-396**
2. **Star P, Connor DE, Parsi K. Novel developments in foam sclerotherapy: Focus on Varithena® (polidocanol endovenous microfoam) in the management of varicose veins. Phlebology. 2018 Apr;33(3):150-162**
3. **Roche E, Pons R, Roche O, Puig A. A new automated system for the preparation of sclerosant foam: A study of the physical characteristics produced and the device settings required. Phlebology. 2020 Oct;35(9):724-733**
4. **\*Davies HO, Watkins M, Oliver R, et al. Adverse neurological events after sodium tetradecyl sulfate foam sclerotherapy - A prospective, observational study of 8056 treatments. Phlebology. 2022 Mar;37(2):97-104**

### identified LITERATURE BIAS

Materials (syringes, needles, etc) not always specified in the related papers

### SUGGESTED NEXT LINES OF RESEARCH

1. Head to head comparison between compounded and not compounded foam