EVIDENCE BASED STATEMENT

DOMAIN 11, Statement 01

TOPIC: "Sclerotherapy safety"

SEARCH TERMS & SOURCES

(sclerotherapy) AND (safety)

INCLUSION CRITERIA

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

SEARCH RESULT BEFORE - AFTER SELECTION

69/16

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. Roselli A, Khouri C, Roustit M, et al. Safety Profile of Sclerosing Agents: An Analysis From the World Health Organization Pharmacovigilance Database VigiBase. Dermatol Surg. 2019 Dec;45(12):1517-1528.
3. Gibson K, Gunderson K. Liquid and Foam Sclerotherapy for Spider and Varicose Veins. Surg Clin North Am. 2018 Apr;98(2):415-429.
4. Rathbun S, Norris A, Morrison N, et al. Performance of endovenous foam sclerotherapy in the USA for the treatment of venous disorders: ACP/SVM/AVF/SIR quality improvement guidelines. Phlebology. 2014 Mar;29(2):76-82.
5. Rathbun S, Norris A, Stoner J. Efficacy and safety of endovenous foam sclerotherapy: meta-analysis for treatment of venous disorders.

Phlebology. 2012 Apr;27(3):105-17.

EVIDENCE BASED STATEMENT

Domain 11; Statement 1

IDENTIFIED REFERENCES

1. de Ávila Oliveira R, Riera R, Vasconcelos V, et al. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev. 2021 Dec 10;12(12):CD001732. doi:10.1002/14651858.CD001732.pub3.
2. Marcoux S, Théorêt Y, Dubois J, et al. Systemic, local, and sclerotherapy drugs: What do we know about drug prescribing in vascular anomalies? Pediatr Blood Cancer. 2021 Dec;68(12):e29364. doi: 10.1002/pbc.29364
3. Li N, Li J, Huang M, Zhang X. Efficacy and safety of polidocanol in the treatment of varicose veins of lower extremities: A protocol for systematic review and meta-analysis. Medicine (Baltimore). 2021 Feb 26;100(8):e24500. doi: 10.1097/MD.0000000000024500.
4. Lim SY, Tan JX, D'Cruz RT, et al. Catheter-directed foam sclerotherapy, an alternative to ultrasound-guided foam sclerotherapy for varicose vein treatment: A systematic review and meta-analysis. Phlebology. 2020 Jul;35(6):369-383.
5. De Maria L, De Sanctis P, Balakrishnan K, et al. Sclerotherapy for Venous Malformations of Head and Neck: Systematic Review and Meta-Analysis. Neurointervention. 2020 Mar;15(1):4-17.
6. De Maria L, De Sanctis P, Balakrishnan K, et al. Sclerotherapy for lymphatic malformations of head and neck: Systematic review and meta-analysis. J Vasc Surg Venous Lymphat Disord. 2020 Jan;8(1):154-164.
7. Critello CD, Pullano SA, Matula TJ, et al. Recent developments on foaming mechanical and electronic techniques for the management of varicose veins. Expert Rev Med Devices. 2019 Nov;16(11):931-940. doi: 10.1080/17434440.2019.1682549.
8. Le Daré B, Gicquel T. Therapeutic Applications of Ethanol: A Review. J Pharm Pharm Sci. 2019;22(1):525-535.
9. Oliveira RÁ, Mazzucca ACP, Pachito DV, et al. Evidence for varicose vein treatment: an overview of systematic reviews. Sao Paulo Med J. 2018 Jul-Aug;136(4):324-332.
10. Gao Z, Zhang Y, Li W, Shi C. Effectiveness and safety of polidocanol for the treatment of hemangiomas and vascular malformations: A meta-analysis. Dermatol Ther. 2018 Jan;31(1)
11. Trivedi MK, Kroumpouzos G, Murase JE. A review of the safety of cosmetic procedures during pregnancy and lactation. Int J Womens Dermatol. 2017 Feb 27;3(1):6-10.
12. 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.
13. Yiannakopoulou E. Safety Concerns for Sclerotherapy of Telangiectases, Reticular and Varicose Veins. Pharmacology. 2016;98(1-2):62-9.
14. Horbach SE, Lokhorst MM, Saeed P, et al. Sclerotherapy for low-flow vascular malformations of the head and neck: A systematic review of sclerosing agents. J Plast Reconstr Aesthet Surg. 2016 Mar;69(3):295-304.
15. Foam Sclerotherapy for Treatment of Varicose Veins: A Review of the Clinical Effectiveness, Safety, Cost-Effectiveness, and Guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2015 Feb 12. PMID: 26985521.
16. Carroll C, Hummel S, Leaviss J, et al. Clinical effectiveness and cost-effectiveness of minimally invasive techniques to manage varicose veins: a systematic review and economic evaluation. Health Technol Assess. 2013 Oct;17(48):i-xvi, 1-141.

EVIDENCE BASED STATEMENT

Domain 11; Statement 1

TEXT FOR INCLUSION IN THE DOCUMENT

DOMAIN 11, Statement 01, TOPIC: "Sclerotherapy safety"

Following the use of properly validated drugs and injection method, sclerotherapy is safe, yet complications can arise in not expert hands. Proper training of the professionals practicing sclerotherapy is mandatory to guarantee safety and efficacy of the procedure.
[Yiannakopoulou E. Safety Concerns for Sclerotherapy of Telangiectases, Reticular and Varicose Veins. Pharmacology. 2016;98(1-2):62-9].
Polidocanol and sodium-tetradecyl-sulfate are the most investigated and used sclerotherapy agents. A systematic review reported a significantly higher complication rate following the use of absolute ethanol in sclerotherapy of vascular malformations.
[Horbach SE, Lokhorst MM, Saeed P, et al. Sclerotherapy for low-flow vascular malformations of the head and neck: A systematic review of sclerosing agents. J Plast Reconstr Aesthet Surg. 2016 Mar;69(3):295-304]. An analysis of the World Health Organization pharmacovigilance database reported different safety profiles for different sclerosing agents: polidocanol is associated with more reporting of venous embolic/thrombotic events, ethanolamine with cardiac arrhythmias and sodium tetradecyl sulfate with allergic reactions. Further properly collected clinical data are needed to confirm these findings.
[Roselli A, Khouri C, Roustit M, et al. Safety Profile of Sclerosing Agents: An Analysis From the World Health Organization Pharmacovigilance Database VigiBase. Dermatol Surg. 2019 Dec;45(12):1517-1528].
A 2021 Cochrane analysis on 28 randomised controlled trials, involving 4278 participants, pointed out the need of producing homogenous data, using standardized sclerosant doses, focusing on objective outcomes. No significant differences in the safety of the different sclerosant agents concentrations has been reported.
***[de Ávila Oliveira R, Riera R, Vasconcelos V, Baptista-Silva JC. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev. 2021 Dec 10;12(12):CD001732]**

EVIDENCE BASED STATEMENT

Domain 11; Statement 1

STATEMENT FOR PUBLIC EVIDENCE-BASED AWARENESS

DOMAIN 11, Statement 01

"Sclerotherapy is a safe effective therapy for leg veins affected by chronic venous disease, provided it is performed by experts professionals"

SELECTED REFEREENCES

1. **Yiannakopoulou E. Safety Concerns for Sclerotherapy of Telangiectases, Reticular and Varicose Veins. Pharmacology. 2016;98(1-2):62-9**
2. **Horbach SE, Lokhorst MM, Saeed P, et al. Sclerotherapy for low-flow vascular malformations of the head and neck: A systematic review of sclerosing agents. J Plast Reconstr Aesthet Surg. 2016 Mar;69(3):295-304**
3. **Roselli A, Khouri C, Roustit M, et al. Safety Profile of Sclerosing Agents: An Analysis From the World Health Organization Pharmacovigilance Database VigiBase. Dermatol Surg. 2019 Dec;45(12):1517-1528**
4. ***de Ávila Oliveira R, Riera R, Vasconcelos V, Baptista-Silva JC. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev. 2021 Dec 10;12(12):CD001732**

identified LITERATURE BIAS

Heterogenous final drug concentration in the blood stream due to not specified hemodynamics and number of injections

SUGGESTED NEXT LINES OF RESEARCH

Safety assessment in different drug concentrations, vessel calibers and related hemodynamics