EVIDENCE BASED STATEMENT

DOMAIN 11, Statement 04

TOPIC: "**Sclerotherapy induced hyperpigmentation management**"

SEARCH TERMS & SOURCES

(sclerotherapy) AND (hyperpigmentation)

INCLUSION CRITERIA

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

SEARCH RESULT BEFORE - AFTER SELECTION

5/4

PERTINENT LITERATURE NOT IDENTIFIED BY THE LITERATURE SEARCH

1. Gonzalez Ochoa AJ, Carrillo J, Manríquez D, Manrique F, Vazquez AN. Reducing hyperpigmentation after sclerotherapy: A randomized clinical trial. J Vasc Surg Venous Lymphat Disord. 2021 Jan;9(1):154-162.
2. Bossart S, Willenberg T, Ramelet AA, et al. The skin hyperpigmentation index: An objective method of measuring the intensity of hyperpigmentation after sclerotherapy. Phlebology. 2020 Dec;35(10):833-835
3. Bogachev VY, Boldin BV, Turkin PY. Administration of Micronized Purified Flavonoid Fraction During Sclerotherapy of Reticular Veins and Telangiectasias: Results of the National, Multicenter, Observational Program VEIN ACT PROLONGED-C1. Adv Ther. 2018 Jul;35(7):1001-1008.
4. Mlosek RK, Woźniak W, Malinowska S, et al. The removal of post-sclerotherapy pigmentation following sclerotherapy alone or in combination with crossectomy. Eur J Vasc Endovasc Surg. 2012 Jan;43(1):100-5.
5. Thibault P, Wlodarczyk J. Postsclerotherapy hyperpigmentation. The role of serum ferritin levels and the effectiveness of treatment with the copper vapor laser. J Dermatol Surg Oncol. 1992 Jan;18(1):47-52
6. Myers HL. Topical chelation therapy for varicose pigmentation. Angiology. 1966 Jan;17(1):66-8.

EVIDENCE BASED STATEMENT

Domain 11; Statement 04

IDENTIFIED REFERENCES

1. Nakano LC, Cacione DG, Baptista-Silva JC, Flumignan RL. Treatment for telangiectasias and reticular veins. Cochrane Database Syst Rev. 2021 Oct 12;10(10):CD012723.
2. Bi M, Li D, Chen Z, Wang Y, et al. Foam sclerotherapy compared with liquid sclerotherapy for the treatment of lower extremity varicose veins: A protocol for systematic review and meta analysis. Medicine (Baltimore). 2020 May 29;99(22):e20332.
3. Yiannakopoulou E. Safety Concerns for Sclerotherapy of Telangiectases, Reticular and Varicose Veins. Pharmacology. 2016;98(1-2):62-9.
4. Hamdan A. Management of varicose veins and venous insufficiency. JAMA. 2012 Dec 26;308(24):2612-21.

EVIDENCE BASED STATEMENT

Domain 11; Statement 04

TEXT FOR INCLUSION IN THE DOCUMENT

DOMAIN 11, Statement 04, TOPIC: "**Sclerotherapy induced hyperpigmentation management**"

Hyperpigmentation after sclerotherapy for lower limb chronic venous disease has been reported in over 20% of cases and considered transient in the majority of cases.

[Mlosek RK, Woźniak W, Malinowska S, et al. The removal of post-sclerotherapy pigmentation following sclerotherapy alone or in combination with crossectomy. Eur J Vasc Endovasc Surg. 2012 Jan;43(1):100-5]

While an expert vein center should not experience such high incidence, the issue exists and requires proper management.

Already in the nineties Thibault et al described the patho-physiology of the phenomenon as related to the serum ferritin and the possibility of resolution by means of copper vapor laser.

[Thibault P, Wlodarczyk J. Postsclerotherapy hyperpigmentation. The role of serum ferritin levels and the effectiveness of treatment with the copper vapor laser. J Dermatol Surg Oncol. 1992 Jan;18(1):47-52]

Skin iron deposition has been known in vein pathophysiology for a long time and topical iron chelation proposed consequently.

[Myers HL. Topical chelation therapy for varicose pigmentation. Angiology. 1966 Jan;17(1):66-8].

Nevertheless, despite topical products claims, an evidence based potential benefit in their use is still missing properly collected data and scientific publications, up to the knowledge of the author.

Both MPFF

[Bogachev VY, Boldin BV, Turkin PY. Administration of Micronized Purified Flavonoid Fraction During Sclerotherapy of Reticular Veins and Telangiectasias: Results of the National, Multicenter, Observational Program VEIN ACT PROLONGED-C1. Adv Ther. 2018 Jul;35(7):1001-1008].

and Sulodexide, two venous active oral drugs, reported an associated lower incidence of post-sclerotherapy hyperpigmentation, suggesting a multi-factorial component triggering the same hyperpigmentation phenomenon.

[Gonzalez Ochoa AJ, Carrillo J, Manríquez D, et al. Reducing hyperpigmentation after sclerotherapy: A randomized clinical trial. J Vasc Surg Venous Lymphat Disord. 2021 Jan;9(1):154-162].

Future investigations on the topic are needed and, in order to move forward in a scientifically validated way, providing an objective assessment of the hyperpigmentation is mandatory. Indeed, the assessment can be currently influenced by the skin type and lack of properly validated scores. A preliminary proposal has been recently done by means of a dedicated software and related "hyperpigmentation index".

***[Bossart S, Willenberg T, Ramelet AA, et al. The skin hyperpigmentation index: An objective method of measuring the intensity of hyperpigmentation after sclerotherapy. Phlebology. 2020 Dec;35(10):833-835]**

EVIDENCE BASED STATEMENT

Domain 11; Statement 4

STATEMENT FOR PUBLIC EVIDENCE-BASED AWARENESS

DOMAIN 11, Statement 04

"Up to 20% of cases can present post-injection hyperpigmentation. The phenomenon is usually transient"

SELECTED REFEREENCES

1. **Mlosek RK, Woźniak W, Malinowska S, et al. The removal of post-sclerotherapy pigmentation following sclerotherapy alone or in combination with crossectomy. Eur J Vasc Endovasc Surg. 2012 Jan;43(1):100-5**
2. **Thibault P, Wlodarczyk J. Postsclerotherapy hyperpigmentation. The role of serum ferritin levels and the effectiveness of treatment with the copper vapor laser. J Dermatol Surg Oncol. 1992 Jan;18(1):47-52**
3. **Myers HL. Topical chelation therapy for varicose pigmentation. Angiology. 1966 Jan;17(1):66-8**
4. **Bogachev VY, Boldin BV, Turkin PY. Administration of Micronized Purified Flavonoid Fraction During Sclerotherapy of Reticular Veins and Telangiectasias: Results of the National, Multicenter, Observational Program VEIN ACT PROLONGED-C1. Adv Ther. 2018 Jul;35(7):1001-1008**
5. **Gonzalez Ochoa AJ, Carrillo J, Manríquez D, et al. Reducing hyperpigmentation after sclerotherapy: A randomized clinical trial. J Vasc Surg Venous Lymphat Disord. 2021 Jan;9(1):154-162**
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identified LITERATURE BIAS

Lack of objective hyperpigmentation assessment tools

SUGGESTED NEXT LINES OF RESEARCH

Validation of an internationally recognized hyperpigmentation score