EVIDENCE BASED STATEMENT

DOMAIN 3, Statement 4

TOPIC: **Catheters injecting sclerotherapy anatomical and clinical performance**.

SEARCH TERMS & SOURCES

((mechanochemical) OR (catheter)) AND (sclerotherapy)

INCLUSION CRITERIA

- Lower limb only
- Reviews
- Publication < 10 years, only ENG

SEARCH RESULT BEFORE - AFTER SELECTION

59/22

PERTINENT LITERATURE NOT IDENTIFIED BY THE LITERATURE SEARCH

1. Alozai T, Huizing E, Schreve M, et al. A systematic review and meta-analysis of mechanochemical endovenous ablation using Flebogrif for varicose veins. J Vasc Surg Venous Lymphat Disord. 2022 Jan;10(1):248-257.e2.
2. Mohamed AH, Leung C, Wallace T, et al. A Randomized Controlled Trial of Endovenous Laser Ablation Versus Mechanochemical Ablation With ClariVein in the Management of Superficial Venous Incompetence (LAMA Trial). Ann Surg. 2021 Jun 1;273(6):e188-e195.

EVIDENCE BASED STATEMENT

Domain 3; Statement 4

IDENTIFIED REFERENCES

1. Cosín Sales O. Ultrasound-guided interventional radiology procedures on veins. Radiologia (Engl Ed). 2022 Jan-Feb;64(1):89-99.
2. Epstein D, Bootun R, Diop M, et al. Cost-effectiveness analysis of current varicose veins treatments. J Vasc Surg Venous Lymphat Disord. 2022 Mar;10(2):504-513.e7.
3. Whing J, Nandhra S, Nesbitt C, Stansby G. Interventions for great saphenous vein incompetence. Cochrane Database Syst Rev. 2021 Aug 11;8(8):CD005624.
4. Gasior SA, O'Donnell JPM, Aherne TM, et al. Outcomes of Saphenous Vein Intervention in the Management of Superficial Venous Incompetence: A Systematic Review and Network Meta-analysis. Ann Surg. 2022 Feb 1;275(2):e324-e333.
5. Siribumrungwong B, Wilasrusmee C, Orrapin S, et al. Interventions for great saphenous vein reflux: network meta-analysis of randomized clinical trials. Br J Surg. 2021 Apr 5;108(3):244-255.
6. 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.
7. Kürşat Bozkurt A, Lawaetz M, Danielsson G, et al. European College of Phlebology guideline for truncal ablation. Phlebology. 2020 Mar;35(2):73-83.
8. Epstein D, Onida S, Bootun R, et al. Cost-Effectiveness of Current and Emerging Treatments of Varicose Veins. Value Health. 2018 Aug;21(8):911-920.
9. McArdle M, Hernandez-Vila EA. Management of Chronic Venous Disease. Tex Heart Inst J. 2017 Oct 1;44(5):347-349.
10. Jones WS, Vemulapalli S, Parikh KS, et al. Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD) [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 Apr 6. PMID: 30222278.
11. Paravastu SC, Horne M, Dodd PD. Endovenous ablation therapy (laser or radiofrequency) or foam sclerotherapy versus conventional surgical repair for short saphenous varicose veins. Cochrane Database Syst Rev. 2016 Nov 29;11(11):CD010878.
12. Balint R, Farics A, Parti K, et al. Which endovenous ablation method does offer a better long-term technical success in the treatment of the incompetent great saphenous vein? Review. Vascular. 2016 Dec;24(6):649-657.
13. Boersma D, Kornmann VN, van Eekeren RR, et al. Treatment Modalities for Small Saphenous Vein Insufficiency: Systematic Review and Meta-analysis. J Endovasc Ther. 2016 Feb;23(1):199-211.
14. Whiteley MS. Glue, steam and Clarivein--Best practice techniques and evidence. Phlebology. 2015 Nov;30(2 Suppl):24-8.
15. Alder G, Lees T. Foam sclerotherapy. Phlebology. 2015 Nov;30(2 Suppl):18-23.
16. Esponda O, Sadek M, Kabnick LS. Treatment of superficial venous incompetence. Semin Vasc Surg. 2015 Mar;28(1):29-38.
17. Witte ME, Reijnen MM, de Vries JP, Zeebregts CJ. Mechanochemical Endovenous Occlusion of Varicose Veins Using the ClariVein® Device. Surg Technol Int. 2015 May;26:219-25.
18. Chwała M, Szczeklik W, Szczeklik M, et al. Varicose veins of lower extremities, hemodynamics and treatment methods. Adv Clin Exp Med. 2015 Jan-Feb;24(1):5-14.
19. van Eekeren RR, Boersma D, de Vries JP, et al. Update of endovenous treatment modalities for insufficient saphenous veins--a review of literature. Semin Vasc Surg. 2014 Jun;27(2):118-36.
20. Lin F, Zhang S, Sun Y, et al. The management of varicose veins. Int Surg. 2015 Jan;100(1):185-9.
21. Elias S, Lam YL, Wittens CH. Mechanochemical ablation: status and results. Phlebology. 2013 Mar;28 Suppl 1:10-4.
22. Mueller RL, Raines JK. ClariVein mechanochemical ablation: background and procedural details. Vasc Endovascular Surg. 2013 Apr;47(3):195-206.

EVIDENCE BASED STATEMENT

Domain 3; Statement 4

TEXT FOR INCLUSION IN THE DOCUMENT

DOMAIN 3, Statement 4,: "**Catheters injecting sclerotherapy anatomical and clinical performance**"

Latest Cochrane revision on the topic confirmed endovenous laser and radiofrequency ablation as the most performing therapeutic options for saphenous vein reflux treatment.

***[Whing J, Nandhra S, Nesbitt C, Stansby G. Interventions for great saphenous vein incompetence. Cochrane Database Syst Rev. 2021 Aug 11;8(8):CD005624].**

Mechanical Occlusion Chemically Assisted ablation (MOCA) indicates the use of a specific catheter (Clarivein®) endowed with endothelial cutting elements: the term MOCA should not be used to indicate procedures performed by other devices always aimed to cut the endothelial lining (Flebogrif®) but with different specifics and scientific literature support.

MOCA seems to be promising, but further evidence on the effectiveness, reinterventions, costs and health-related quality of life is needed.

[Epstein D, Bootun R, Diop M, et al. Cost-effectiveness analysis of current varicose veins treatments. J Vasc Surg Venous Lymphat Disord. 2022 Mar;10(2):504-513.e7].

A 2022 network meta-analysis showed the lowest risk of procedural failure at 6 weeks follow up following cyanoacrylate ablation, while in the long follow up, CHIVA saphenous sparing option and traditional surgery demonstrated the best recurrence-free performance. Mechano-chemical ablation was included in the search, but resulted to be not competitive against surgery or endovenous laser/radiofrequency.

[Gasior SA, O'Donnell JPM, Aherne TM, et al. Outcomes of Saphenous Vein Intervention in the Management of Superficial Venous Incompetence: A Systematic Review and Network Meta-analysis. Ann Surg. 2022 Feb 1;275(2):e324-e333].

A dedicated randomized comparative trial showed a significantly better reflux recurrence rate following the use of endovenous laser ablation vs MOCA, yet no significant differences in Venous Clinical Severity score and Aberdeen Varicose Veins Questionnaire.

[Mohamed AH, Leung C, Wallace T, et al. A Randomized Controlled Trial of Endovenous Laser Ablation Versus Mechanochemical Ablation With ClariVein in the Management of Superficial Venous Incompetence (LAMA Trial). Ann Surg. 2021 Jun 1;273(6):e188-e195].

A 2021 revision on Flebogrif® reported just 3 studies with a maximum of 12 months follow up and a moderate methodology quality. The same revision recommended properly conducted data collection and head to head comparison before recommending the use of the device.

[Alozai T, Huizing E, Schreve M, et al. A systematic review and meta-analysis of mechanochemical endovenous ablation using Flebogrif for varicose veins. J Vasc Surg Venous Lymphat Disord. 2022 Jan;10(1):248-257.e2].

In 2020, a meta-analysis dedicated to catheter directed sclerotherapy (without endothelial cutting elements), showed better ablation rates compared to direct injection sclerotherapy. Yet more data are needed to allow inclusion of this technical solution in the large revisions dedicated to the topic.

[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].

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STATEMENT FOR PUBLIC EVIDENCE-BASED AWARENESS

DOMAIN 3, Statement 4

Catheters injecting sclerotherapy while incising the saphenous vein demonstrated to be safe (Clarivein®, Flebogrif®)
Inferior to thermal ablation in venous reflux reappearance but not inferior in some clinical outcomes (Clarivein®).

SELECTED REFEREENCES

***1. Whing J, Nandhra S, Nesbitt C, Stansby G. Interventions for great saphenous vein incompetence. Cochrane Database Syst Rev. 2021 Aug 11;8(8):CD005624**

2. Epstein D, Bootun R, Diop M, et al. Cost-effectiveness analysis of current varicose veins treatments. J Vasc Surg Venous Lymphat Disord. 2022 Mar;10(2):504-513.e7

3. Gasior SA, O'Donnell JPM, Aherne TM, et al. Outcomes of Saphenous Vein Intervention in the Management of Superficial Venous Incompetence: A Systematic Review and Network Meta-analysis. Ann Surg. 2022 Feb 1;275(2):e324-e333

4. Mohamed AH, Leung C, Wallace T, et al. A Randomized Controlled Trial of Endovenous Laser Ablation Versus Mechanochemical Ablation With ClariVein in the Management of Superficial Venous Incompetence (LAMA Trial). Ann Surg. 2021 Jun 1;273(6):e188-e195

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IDENTIFIED LITERATURE BIAS

Lack of homogeneity in the study populations hemodynamics and short f up

SUGGESTED NEXT LINES OF RESEARCH

Flebogrif longer than 12 months head to head comparison