Varithena™
(polidocanol injectable foam) 1%

Varithena Network Meta-analysis

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Comparative Effectiveness of Non-compounded Polidocanol 1% Endovenous Microfoam (Varithena) Ablation versus Endovenous Thermal Ablation: A Systematic Review and Network Meta-analysis[1]

Objective

To compare the effectiveness and safety of Varithena (PEM) versus endovenous thermal ablation (ETA) for treatment of venous insufficiency caused by lower extremity truncal vein incompetence, via network meta-analysis of published comparative evidence..

Study design

- Network meta-analysis consisting of 233,801 patients from 13 studies
- Systematic review, conducted under a prospective protocol
- Included CVI treatment studies with a randomized or non-randomized comparison to at least one of the two treatments of interest — PEM (Varithena) or ETA (including radiofrequency and laser treatment)

Primary Endpoints

- Closure rate (occlusion) at time points of at least 3 months post-procedure
- Mean change in Venous Clinical Severity Score (VCSS)

Secondary Endpoints

- Safety including total procedural complications, deep vein thrombosis (DVT), and any related sequalae of thrombotic events
- Patient reported outcomes

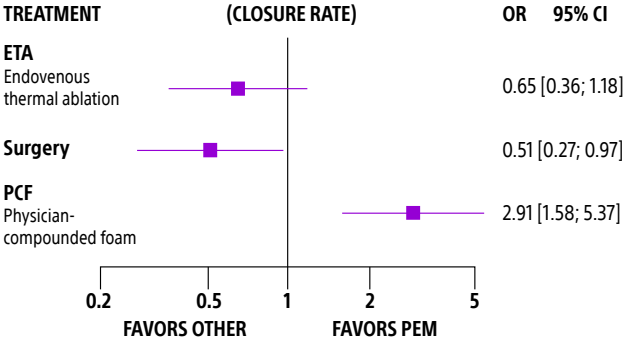
Patients	Publications Included	Characteristics
• 233,801 patients included	13 studies included published in English between January 2000 and January 2023 • 6 RCTs • 7 comparative non-randomized studies	Range of CEAP classification reported was most often C2 – C6 • 2 RCTs enrolled patients between C2 – C4 Truncal veins treated were primarily the great saphenous vein (GSV) • 2 studies limited treatment to patients with small saphenous vein incompetence

KEY RESULTS

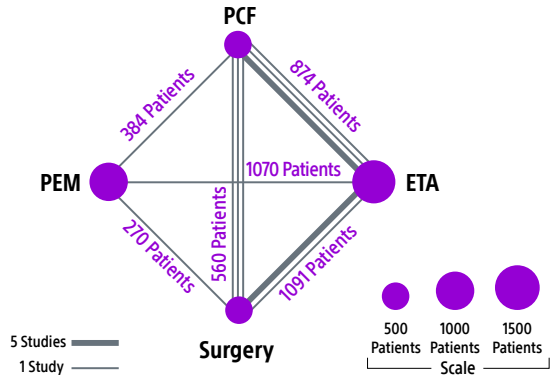
Closure Rate

- Varithena (PEM) was **not statistically significantly different** from ETA for vein closure from 3 months up to 6 years (P = 0.16)
- Varithena had higher odds for vein closure and was **statistically significantly differentiated** from physician-compounded foam (PCF) from 3 months up to 6 years (P<0.01)
  - Varithena had a 2.91-fold increase in odds of vein closure as compared to PCF
- A sensitivity analysis confirmed these results were maintained during a minimum 12-month follow-up with long-term follow-up up to 6 years

Polidocanol 1% Endovenous Microfoam (PEM) Compared to Other Treatments



Pairwise odds ratio (OR) and 95% confidence interval (CI) estimates from random-effects model comparing PEM to ETA.

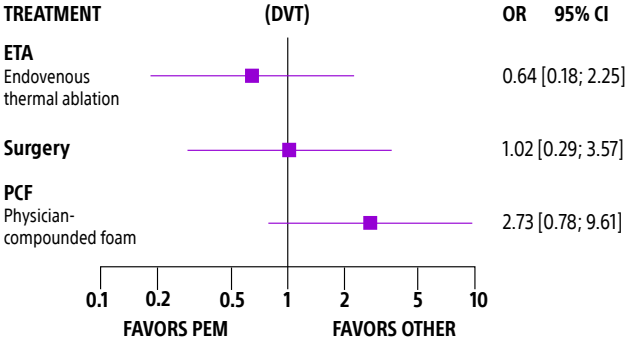


PEM and ETA connected directly (through 1 study with 1,070 patients) and indirectly (through PCF and Surgery). Diagram shows studies and patients for each treatment pair.

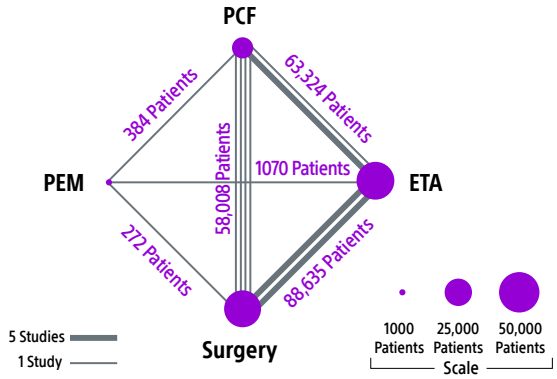
DVT Rate

There was **no evidence** that Varithena (PEM) is associated with an increased risk of DVT compared to ETA or PCF treatment

Polidocanol 1% Endovenous Microfoam (PEM) Compared to Other Treatments



Pairwise odds ratio (OR) and 95% confidence interval (CI) estimates from Mantel-Haenszel model comparing PEM to ETA.



PEM and ETA connected directly (through 1 study with 1,070 patients) and indirectly (through PCF and Surgery). Diagram shows studies and patients for each treatment pair.

OTHER OUTCOMES

There was insufficient evidence to reliably include data for change in Venous Clinical Severity Score (VCSS) or patient reported outcomes

CONCLUSIONS

This rigorous systematic review and network meta-analysis further solidfy Varithena as a safe and effective treatment when compared to ETA and PCF in truncal veins.

- Varithena was **not statistically different** from ETA for vein closure from 3 months up to 6 years
- There was **no evidence** that Varithena is associated with an increased risk of DVT compared to ETA or PCF
- Varithena had higher odds for vein closure and was **statistically significantly differentiated** from PCF from 3 months up to 6 years

New evidence will be incorporated into the living network meta-analysis periodically.

Did you know that more commercial patients now have coverage for Varithena?

Scan QR code for Varithena coding and coverage policy information.

1. Kabnick LS, Jimenez JC, Coogan SM, Gache L, Frame D, Gunnarsson C, Ozsvath K. Comparative Effectiveness of Non-compounded Polidocanol 1% Endovenous Microfoam (Varithena) Ablation versus Endovenous Thermal Ablation: A Systematic Review and Network Meta-analysis. J Vasc Surg Venous Lymphat Disord. 2024 Apr 26:101896. doi: 10.1016/j.jvsv.2024.101896. Epub ahead of print. PMID: 38679141.

Varithena™ (polidocanol injectable foam) 1%

INDICATIONS Varithena™ (polidocanol injectable foam) 1% is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

IMPORTANT SAFETY INFORMATION The use of Varithena is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease. Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately. Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra- arterial injection of polidocanol occurs, consult a vascular surgeon immediately. Varithena can cause venous thrombosis. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis. The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis. Physicians administering Varithena must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena.

For Full Prescribing Information visit Varithena.com

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