Varithena®
(polidocanol injectable foam) 1%

Multi-center, randomized evaluation of thermal ablation with and without Varithena®

Objective

To determine the efficacy and safety of Varithena (PEM) when administered in combination with ETA

- Co-primary endpoints were change in appearance assessed by both physicians and patients from Baseline to Week 8.
- Secondary endpoint of symptom improvement using VEINES-QOL/Sym and VCSS.

Patients

(n= 117; multicenter, randomized, placebo-controlled, blinded)

- Symptomatic patients with C2–C5 chronic venous insufficiency
- Patients had to be candidates for ETA (endovenous thermal ablation) of the proximal incompetent GSV (great saphenous vein) who also required treatment for visible varicosities
- PA-V3 of moderately noticeable or worse and IPR-V3 of moderate or worse

Methods

- Study drug could be used above andbelow the knee for visible varicosities and incompetent areas of the GSV system or tortuous areas of the saphenous trunk not treated with ETA.
- Patients were randomized prior to ETA on a 1:1:1 basis receive ETA and either PEM 0.5% or 1.0% or placebo.
- Unblinded ETA was immediately followed by treatment with either double-blind PEM (patients and care providers) or single-blind placebo (patients) up to 15 mL.

Assessment

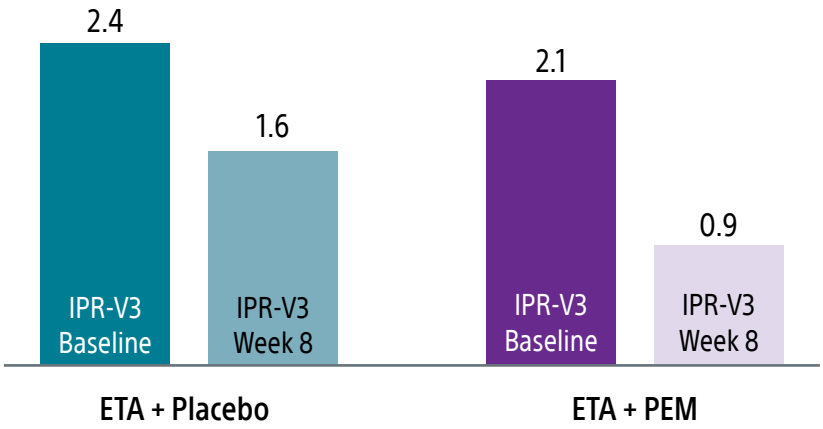
- An IPR Panel independently scored standardized photographs (Baseline, Week 8, Month 6) for varicose veins appearance using the IPR-V3 instrument.
- Patients assessed the live appearance of their veins, without comparison to baseline using the PA-V3 instrument.
- Patient Global Impression of Change in Appearance (PGIC-Appearance) and Clinician Global Impression of Change in Appearance (CGIC-Appearance) rated the change as Much worse (-3 points) to Much better/Much Improved (+3 points).

Vasquez, Michael. "A multicenter, randomized, placebo-controlled trial of endovenous thermal ablation with or without polidocanol endovenous microfoamtreatment in patients with great saphenous vein incompetence and visible varicosities." Phlebology.2017 May;32(4):272-281. doi: 10.1177/0268355516637300. The author is a consultant for Boston Scientific.

Key Results

- A significantly higher percentage of patients achieved clinically meaningful change with (pooled) PEM than with placebo for both IPR-V3 (Week 8: 84% vs. 58%, p=0.004) and PA-V3 (Week 8: 72% vs. 55%, p=0.06).
- Change scores for VCSS and m-VEINES-QOL at Week 8 were slightly better for PEM recipients than for placebo recipients, though not statistically significant.
- Mean PEM volume administered during the initial procedure was 11.5 mL for PEM 0.5% and 12.3 mL for PEM 1.0%.
- Fewer patients required retreatment if they were treated with ETA + PEM.
- ETA alone eliminated reflux through the SFJ in 78.9% of patients vs 87.3% with ETA + PEM patients.
- Minor adverse events included asymptomatic DVT in two PEM patients — both in the 0.5%, three occurrences of isolated gastrocnemius vein thrombosis and superficial thrombophlebitis in 28 patients — 13 with 0.5% PEM and 15 with 1.0% PEM.

Change in IPR-V^3 Score



Varithena (polidocanol injectable foam)
INDICATIONS Varithena (polidocanol injectable foam) 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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