Varithena®
(polidocanol injectable foam) 1%

Comparative Treatment of Superficial Venous Insufficiency Patients with Varithena™ vs Endovenous Laser Ablation

Objective

To evaluate outcomes among symptomatic patients with superficial venous insufficiency treated with Varithena or endovenous laser ablation (EVLA).

Patients

(n = 1070; single center)

- Symptomatic patients with C2–C6 superficial venous reflux
- Superficial axial reflux of the great saphenous vein or anterior accessory saphenous vein classified as retrograde flow in the saphenous vein > 0.5 seconds when standing and a vein diameter > 2 mm
- Failure to have improvement in symptoms after three months of compression therapy (20 – 30 mmHg stockings)

Methods

- Retrospective chart review between October 2013 and June 2019
- 550 patients were treated with Varithena and 520 were treated with EVLA
- Patients were followed up post operatively to collect data on the following:
  - Presence or absence of symptoms
  - Duplex ultrasound assessment
  - Observation of spontaneous bleeding and wound healing in C4 and C6 patients, respectively
- Treated veins were also evaluated along entire length to document occlusion and/or reflux
- Veins were determined closed if there is occlusion along entire length of treated segment with no distinct segment of patency that were greater than 5 cm.
- Due to the extensive nature of chronic venous disease in many patients, and limitation that no more than 15 ml of Varithena be administered in one treatment, some patients required a second treatment (at follow-up) to close areas of patent veins.

1. Deak ST. Treatment of superficial venous insufficiency in a large patient cohort with retrograde administration of ultrasound-guided polidocanol endovenous microfoam versus endovenous laser ablation. J Vasc Surg Venous Lymphat Disord. 2021 Dec 24:S2213-333X(21)00609-0. doi: 10.1016/j.jvsv.2021.11.007. Epub ahead of print. PMID: 34958977.

Key Results

- The Varithena patients were observed for 43 ± 13 months and the EVLA for 57 ± 18 months
- Elimination of reflux was 93.5% (514/550) and 92.8% (482/520) of the Varithena- and EVLA-treated patients
- Closure rates were maintained through three-year follow-up.
- 18% of EVLA-treated patients returned for additional treatment to address residual symptoms in the affected leg
- In C6 patients treated with Varithena, 69% of ulcers were healed in less than one-month compared to 5% of patients treated with EVLA
- No neurological or cardiac adverse events in the Varithena patients
- Minor complications included asymptomatic DVT (0.5%), 1 CFVTE, and superficial venous thrombosis (4%) in Varithena-treated patients and asymptomatic DVT (0.8%) and 2 EHITs in EVLA-treated patients
- This study concluded that Varithena is comparable in safety and efficacy to EVLA for treatment of saphenous reflux

Study Limitations

- Retrospective chart review limits outcomes measured to those collected at various time points post treatment
- Subjective measure of patient symptoms which were self-reported and binary (present, not present)

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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