Varithena®
(polidocanol injectable foam) 1%

Varithena retrospective 250 patient chart review

Objective

Retrospective chart review to evaluate treatment outcomes among symptomatic patients with superficial chronic venous insufficiency using Varithena™:

- **Efficacy** – Elimination of symptoms/pathological reflux; vein closure; venous leg ulcer status[2] (e.g. open/closed)
- **Safety** – Incidence of adverse events (e.g. DVT, SVT)

Patients

(n= 250; single center, community practice)

- Symptomatic patients with C2–C6 chronic venous insufficiency
- Minimum 3 months of prior compression therapy
- Ideal patients for Varithena were those with tortuous veins, incompetent veins below the knee or a history of a previous vein ablation procedure
- Sixteen of the 250 patients (6.4%) had venous leg ulcers, and 56 (22.4%) were treated previously with thermal ablation or surgery
- Mean vein diameter of 8.0 ± 2.5 mm

Methods

- Patients underwent a duplex ultrasound (DUS) to map perforators/veins to be treated
- The Great Saphenous Vein (GSV) was accessed with a micropuncture needle distal to the mid-thigh perforator followed by a 0.018 guidewire — the guidewire was replaced by a 5F catheter
- The leg was placed on a foam wedge at an angle of 45° to empty the varicose veins of blood
- 5 mL of Varithena (Polidocanol 1%) was injected into the catheter at 0.5 to 1.0 mL/second under ultrasound observation
- Once the microfoam arrived within 3 to 5 cm of the saphenofemoral junction, the GSV was compressed for 2 to 3 minutes to limit the flow of microfoam into the common femoral vein
- A second injection of 4–5 mL of Varithena was administered through the same catheter directing the microfoam to flow in a retrograde fashion through the incompetent venous valves to the ankle
- Following confirmed venospasm, the patient was instructed to dorsiflex the foot for approximately 30 seconds to activate the calf pump and close patent perforators after each injection
- The lower extremity was kept elevated on the foam wedge at 45° as dressings were applied to prevent blood from entering the treated vein

Key Results

- All patients were treated with Varithena, then followed for 16 ± 7 months
- Complete elimination of venous valvular reflux and vein closure was documented in 94.4% of patients (vein diameters in this study ranged from 4.1 to 18.7 mm)
- 94.4% of patients reported symptom relief
- Minor adverse events included asymptomatic DVT in two patients (<1%) and superficial venous thrombi in four patients (2%)
- Of the 16 patients with venous leg ulcers, 80% of the wounds closed within 4 weeks of treatment[2]
- Mean Varithena volume administered during the initial procedure was 9.5 ± 2.5 mL
- 55 patients had an additional follow-up treatment with Varithena between 5 days and ~2 years after initial treatment

Study Limitations

- Retrospective chart review eliminates methodologic rigor leading to lack of control of intervention timing, data collection, and patient behaviors after the procedure
- No comparator dataset
- No disease-specific quality of life data
- Variable time points for patient follow-up

1. Deak, Steven T. "Retrograde Administration of Ultrasound-Guided Endovenous Microfoam Chemical Ablation for the Treatment of Superficial Venous Insufficiency." Journal of Vascular Surgery: Venous and Lymphatic Disorders, vol. 6, no. 4, July 2018, pp. 477–484., doi:https://doi.org/10.1016/j.jvsv.2018.03.015. The author is a consultant for Boston Scientific.
2. Healing of venous leg ulcers was not an endpoint in Varithena pivotal trials.

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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