CASE STUDY

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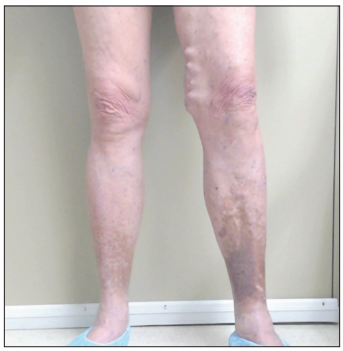
Varithena®
(polidocanol injectable foam) 1%

Varithena® as an optimal treatment choice for a patient with tortuosity and skin changes

Patient

- An 86-year old male sought treatment for bilateral pain, skin changes, and bleeding in his legs.
- He had previously undergone bilateral superficial vein ablations, and a phlebectomy on the veins in his left leg.
- As a result of his venous insufficiency, the patient complained that he had trouble walking down stairs and kneeling, and the pain that he felt on a daily basis interfered with his mood as he felt tired quickly.



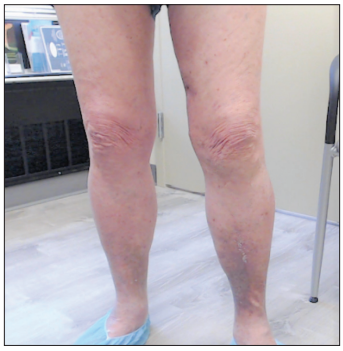
Pre-treatment, the patient had significant tortuosity as well as skin changes in the lower leg.

Patient Work-up: CEAP Class 4a

- The patient was evaluated while seated upright in a reverse Trendelenburg position. Reflux was documented in the Right and Left legs, predominantly in the proximal and mid-calf Great Saphenous Vein (GSV), and the tortuous tributaries of the calf.
- Reflux times ranged from 1.2 – 3.4 seconds. Vein diameters ranged from 3.3 – 5.3 mm in the proximal and mid-calf GSV, and 4.4 – 5.9 mm in the tributaries.

Treatment

- A 27g butterfly needle was used to access the vein using the anterior wall technique. The patient's leg was elevated 45 degrees for several minutes before treatment in order to drain the veins to be treated. After injection of the Varithena® into the veins, visualization under ultrasound guidance confirmed spasm of the vein within 3-5 minutes of injection.
- Total treatment volume of Varithena® was 5 cc per leg.



One month post-treatment with Varithena®, skin changes in the lower leg had improved, bleeding had stopped, and the patient reported less pain.

Results

- One month post-treatment, the patient returned for a follow up visit. He reported that he had significant improvement in the pain in his legs and they did not feel as tired. Visually, the bleeding was minimized since the initial visit.
- Prior to treatment, the patient reported a VCSS score of 16 and 19 in his right and left legs, respectively. VCSS scores decreased to 11 in both legs one month post-treatment.
- Ultrasound assessment confirmed that pathological reflux was absent in the newly treated areas.

Outcome

- One week Post-Treatment: Venous Duplex ultrasound of the lower extremity revealed a patent deep vein system and occluded GSV throughout the leg. The perforator vein in the calf was patent and compressible. The proximal extent of the thrombus in the GSV was approximately 2.5 cm from the SFJ.
- The patient is doing well as a result of Varithena® ablation of the incompetent veins in his left leg.
- The patient is pleased with his results and has scheduled Varithena® treatment for the veins in his right leg.

"Varithena® is an easy procedure, both on the patient and the provider, with great outcomes"

Priya Thirumlai, MD, FACS

Conclusion

- Skin changes and bleeding can easily progress to venous ulcerations that severely impact patient Quality of Life and may take years to heal. This patient sought treatment to correct venous insufficiency that may have worsened, leading to an ulceration. Elimination of reflux and cessation of bleeding in these tortuous tributaries will have significant impact on this patient's well-being.

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.

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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®.

See Full Prescribing Information for Varithena®.

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