CASE STUDY

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Varithena®
(polidocanol injectable foam) 1%

Symptom resolution and wound healing following Varithena® treatment

Patients

- A 71 year old male sought treatment for a 2cm x 2cm wound on his right ankle that was not healing. The wound was accompanied by pain, swelling, and inflammation in the affected leg.
- The patient did not smoke and had no history of chronic venous insufficiency (CVI) requiring treatment.

Patient Work-up: CEAP Class 6

- The Venous Clinical Severity Score (VCSS) in the affected leg pre-treatment was 9, CIVIQ 20 was 25, and the Global Index Score (GIS) was 94.
- Ultrasound work-up revealed a cluster of refluxing veins in the patient's lower right leg. The right GSV diameter measured 5.2 and 3.7mm at the junction and proximal calf, respectively. Reflux time was 1.39 seconds.

Treatment

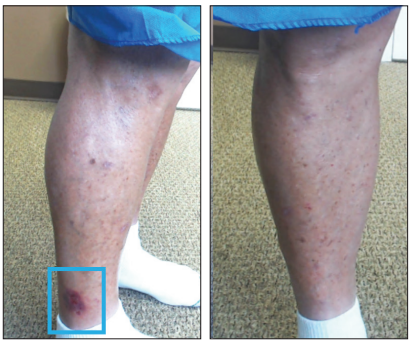
- Vein mapping was performed to identify associated tributaries, varicosities, and incompetent perforating veins.
- Varithena® instructions for use were followed. The patient was placed in Trendelenburg position with the leg elevated 45 degrees pre-treatment.
- A 5cc dose of Varithena® was administered to a 10 cm length of vein using a 25G needle through a single access site in the proximal calf.

Results

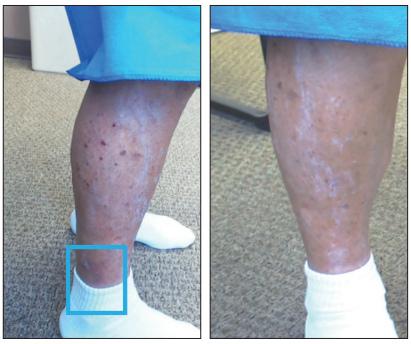
- Six weeks post-Varithena® treatment, the patient's wound was completely healed and superficial bleeding varicosities were no longer visible or problematic for the patient.
- Clinical measures indicated that the VCSS score had dropped from 9 to 1, CIVIQ 20 was reduced from 25 to 20, and the GIS increased from 94 to 100.
- Ultrasound examination revealed that the GSV had complete occlusion in area of treatment from the proximal calf to the distal calf. No evidence of reflux from proximal thigh to distal thigh was reported.
- The patient had no reported side effects related to treatment.

Conclusion

- On his final visit six weeks post Varithena® treatment, the patient indicated that he was pleased with his outcome, his overall experience was positive, and he was motivated to recommend this practice and treatment to friends and family who suffered from similar symptoms in their legs.



Pre-treatment: Edema and ulceration on patients lower right leg



Post-treatment: Six weeks following treatment with Varithena®. Ulcer is healed.

"This patient was an ideal candidate for Varithena®. In one treatment session we were able to address his pathology with 5cc of Varithena®. The rapid healing of his wound improved his symptoms and quality of life"

Khanh Q. Nguyen, DO, RPVI
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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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