CASE STUDY

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Varithena®
(polidocanol injectable foam) 1%

Marked Changes in symptoms and appearance post-Varithena® Treatment

Patients

- Three patients (N = 3) with chronic venous insufficiency (CVI) who were not ideal candidates for catheter-based or surgical interventions were treated.
- Reasons for selecting Varithena® treatment in these patients included:
  - Discontinuous GSV; distal thigh to proximal calf GSV segment found to be absent in otherwise refluxing GSV.
  - Need to complete double stick for thermal ablation or combination of thermal and chemical closure.
  - Large varicosities originating from shorter segments (SFJ-MT) of the GSV.
  - Patient preference to avoid incisions for microphlebectomy.

Patient Work-up

- Patients were assessed for symptoms using the validated Venous Clinical Severity Score (VCSS) and the Global Index Score (GIS) calculated from the CIVIQ20. The CIVIQ20 is a 21-item questionnaire that captures the impact of patient pain, psychological well-being, and physical ability on overall Quality of Life (QoL). It is scored from 0 (worst QoL) to 100 (best QoL).
- All patients were women. Pre-treatment characteristics were as follows:
  - Patient 1: Age- 78 yrs; VCSS- 6 RL, 9 LL; GIS: 75
  - Patient 2: Age- 72 yrs; VCSS- 8 RL, 9 LL; GIS: 79
  - Patient 3: Age- 63 yrs; VCSS- 9 RL, 5 LL; GIS: 55
- Figure 1 and 2 are Patients 1 and 3 before treatment. The AAGSV and GSV were prominent in Patient 1 and 3, respectively. Both patients complained of symptoms including heaviness, aching, and swelling. Pathological reflux was present in all three patients.

Treatment

- Varithena® instructions for use were followed for all patients. Patients were placed in Trendelenburg position with the leg elevated 45 degrees for approximately ten minutes pre-treatment. Varithena® was administered in 5cc doses through three access sites. Mean volume of Varithena® used was 6 cc's per session, average 2 sessions for 12cc's of Varithena total.
- All patients wore compression stockings for at least one week post-treatment; 2 of the 3 patients complied with two week stocking use post procedure.
- Follow-up visits were performed at 4 weeks post-treatment.

Results

- Figures 3 and 4 are Patients 1 (36 days) and 3 (32 days) post-treatment.
- Reflux and symptoms improved in all patients:
  - Patient 1: VCSS- 4 RL, 4 LL; GIS: 95
  - Patient 2: VCSS- 5 RL, 5 LL; GIS: 94
  - Patient 3: VCSS- 3 RL, 3 LL; GIS: 71

Conclusion

- On average, patients experienced a 46% reduction in VCSS score (range 33-67%), and a 25% improvement in GIS score (range 19-29).
- Duplex assessment on all patients revealed sizeable reductions, including resolution of varicosities, elimination/reduction of pathological reflux, and GSV vein closure.
- This case series highlights the significant improvements in patient symptoms, appearance, and pathological reflux post-Varithena® treatment.

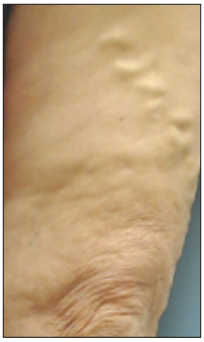

Figure 1. Patient 1
Pre-treatment

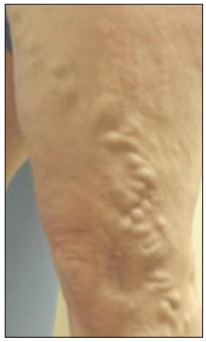

Figure 2. Patient 3
Pre-treatment

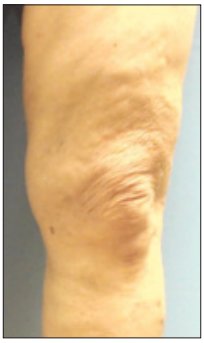

Figure 3. Patient 1
36 days post- Varithena®
treatment

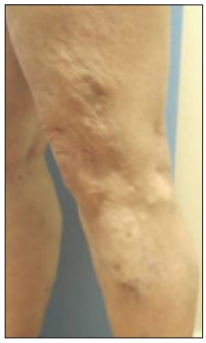

Figure 4. Patient 3
32 days post- Varithena®
treatment

"Varithena's efficacy and minimal discomfort fulfills my commitment to a quality patient experience promised from procedure through results."

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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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