Proprietary Polidocanol Microfoam (Varithena®): What We Should Know

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Disclosures
- None

What is Polidocanol Endovenous Microfoam
- FDA approved 2015 for the treatment of the Great Saphenous Veins, accessory saphenous veins and their tributaries above and below the knee. (not the small saphenous vein)
- Device that generates Polidocanol foam
- Consistent bubble size and density
- Longer lasting foam compared to Tessari method
- Small bubbles <100 µm average
- No bubbles >500 µm
- Low nitrogen gas 65:35 O2:CO2 Ratio

- Twice the dwell time as PCF with air
- 8X the dwell time as PCF with CO2 O2
- Smaller more uniform bubbles
- Slower degradation

Procedure
- Vein mapping
- Gaining access
- Elevating the leg
- Generating the foam
- Injecting the foam
- Following the foam compressing and releasing
- Compression wrap

Vein mapping
- Mark all veins to be treated
- Mark all junctions and perforators in the treatment zone
Gain access
- Micropuncture
- Angiocath
- Butterfly

Elevate leg 45 degrees
- Hold leg up
- Or tilt table
- Empties veins
- Keeps foam in the treatment area longer

Generating foam
- Connect the syringe
- Prime the syringe by generating and purging 3-5 mL of foam

Tip:
- An activated canister generates 90 mL of foam, which is sufficient to yield 45 mL of usable injectable foam.

Prime the syringe by generating and purging 3-5 mL of foam

Note:
- Do not proceed to generate foam unless all patient preparation has been completed.
- Foam must be used within 75 seconds of generation.
- Do not exceed 15 mL of foam per treatment session; each injection should consist of no more than 5 mL.

Generating foam (cont’d)
- Generate up to 5 mL of foam
- Inspect syringe for bubbles
- Remove, inspect again

Injection technique
- With finger pressure, occlude GSV distal to venous access site
- Inject PEM slowly
- Approximately 1 mL/second in GSV
- Approximately 0.5 mL/second in accessory veins and varicosities
- Inspect foam as it’s injected

Follow the foam
- Monitor SFJ in longitudinal view
- Stop injection when foam is 3 cm to 5 cm from SFJ.
- Gently compress terminal GSV to stop foam from advancing
- Remove compression distal to venous access site to allow retrograde filling
Injection technique (cont)
- Keep SFJ compressed until venospasm is fully established
- Confirm by ultrasound in transverse and longitudinal views
- Spasm onset is usually rapid, but might take up to 5 minutes

Compression wrap
- Keep leg elevated for 10 minutes while bandages and compression stockings are applied
- Place compression pads over path of treated vein
- Apply undiastocking and compression stocking

How I use PEM
- Easy answer is when and where I would use Foam Sclerotherapy and I can get the insurance to pay for it.
- Early stage varicose veins
- Recurrent varicose veins
- Neovascularization
- Below knee saphenous
- Ulcer bed
- Vulvar varicosities
- Instead of phlebectomy

Recanalization or neovascularization

Venous Ulcers below knee GSV and ulcer bed

Early stage C2
Very tortuous GSV

What is the evidence supporting Varithena’s® efficacy?

Summary of Peer-reviewed publications

<table>
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<th>Publication</th>
<th>Study Details</th>
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<td>King et al.</td>
<td>VANISH-1 Study: 8-week outcome data improvement in PROs/VVSymQ</td>
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<td>Carugo et al.</td>
<td>Review of ideal foam properties to optimize ablation</td>
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<tr>
<td>Carugo et al.</td>
<td>Varithena® properties (cohesiveness, vein wall contact, dwell time) are superior to compounded foam</td>
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<td>Vasquez et al.</td>
<td>Improved outcomes when Varithena® is combined with thermal ablation</td>
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<tr>
<td>Gibson et al.</td>
<td>Improved symptoms and appearance</td>
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<td>Regan et al.</td>
<td>Use of low nitrogen micromicrofoam in patients with known PFO is safe</td>
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New Data: In Press

- Kolluri et al. Annals of Vascular Surgery, 2018
  - Case Series: 10 patients treated with Varithena® due to inability to treat with other modality. Successful outcomes

  - Use of low nitrogen micromicrofoam in patients with known PFO is safe

- Deak. Journal of Vascular Surgery: Venous and Lymphatic Disorders, 2018
  - 250 Patients treated with Varithena®: Single center, 94.5% closure rate, <1% DVT
IMPORTANT DRUG WARNING

Subject: Warnings and Precautions associated with Use of Asclera (polidocanol) Injection

Venous Thrombosis and Pulmonary Embolism
Arterial Embolism
Tissue ischemia and necrosis

Dear Health Care Provider:

The purpose of this letter is to inform you of important modifications in the safety information for Asclera, a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. This revision has been performed following a review of the worldwide experience of sclerotherapy with polidocanol, including its use in higher concentrations and for other types of veins, as approved in other countries.

We need a FDA approved foam
- And we have one
- It is very expensive
- Therefore we need insurance coverage

CPT codes

36465
- Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein)

36466
- Multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg

Insurance coverage

- Most major insurances have positive policy coverage (30 of 34)
- Almost all MACS…….. All but Floriduh

Devils in the details

Truncal
- Example of criteria (not all inclusive)
  1) Ulceration secondary to venous stasis; OR
  2) Recurrent superficial thrombophlebitis; OR
  3) Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; OR
  4) Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, AND the symptoms significantly interfere with activities of daily living, AND conservative management including compression therapy for at least 3 months has not improved the symptoms.

Adjunctive
- Aetna considers liquid or foam sclerotherapy (endovenous chemical ablation) (e.g., Varithena) medically necessary adjunctive treatment of symptomatic saphenous veins, varicose tributaries, accessory, and perforator veins.

Example of criteria (not all inclusive)
- 2.5 mm or greater in diameter
- Intractable ulceration secondary to venous stasis; or
- More than 1 episode of minor hemorrhage from a ruptured superficial varicosity; or a single significant hemorrhage from a ruptured superficial varicosity, especially if transfusion of blood is required; or
- Saphenous varicosities result in either of the following, and symptoms persist despite a 3-month trial of conservative management (including analgesics and prescription gradient support compression stockings):
  1) Recurrent superficial thrombophlebitis; or
  2) Severe and persistent pain and swelling interfering with activities of daily living and requiring chronic analgesic medication

Conclusions

- It's hard comprehensively treat superficial venous disease without using foam
- The use of room air foam is highly not recommended by the sclerosant manufacturers
- There is only one FDA approved foam sclerosant
- It happens to be very expensive
- The only way our patients are going to be able to afford it is if their insurance covers it