Contraindications and Limits: Proprietary Polidocanol Microfoam

Kathleen Gibson, MD
Lake Washington Vascular Surgeons, Bellevue, WA

VEITH Symposium
New York, New York
November 15, 2018

Disclosures

Dr. Gibson is a consultant for Medtronic, Vascular Insights, Vesper, and BTG and receives current research support from Medtronic, AngioDynamics, Bayer, and Vascular Insights. She is in the speaker’s bureau for Pfizer/Bristol Myers Squibb.

Proprietary Polidocanol Microfoam-PEM (Varithena-BTG) Indications

- Treatment of incompetence of the great saphenous vein (GSV)
- Treatment of accessory saphenous veins (AASV, PASV)
- Treatment of visible varicosities that are tributaries of the GSV, AASV, or PASV
- Not indicated for treatment of the small saphenous vein (SSV) or perforator veins as these veins were not included in the pivotal trials. Considered off label use

Pros of PEM v. Physician Compounded Foam (PCF)

- Pros:
  - No reports of neurologic injury (stroke, TIA) in any patient in clinical development or since FDA approval
  - All reports of strokes in the literature have occurred with physician compounded foam
  - Demonstrated significant improvements in well validated patient reported outcome measures
  - Only foam sclerosant that is FDA approved

Cons to Varithena over Physician Compounded Foam

- Cons:
  - Expense
  - May need to “batch” patients in order to maximize use of canister (this is an issue in comparison to all of the other technologies) - now less of an issue as shelf life is one month instead of one week
  - Reimbursement challenges - non-payment “hurts more” with expensive products

Why PEM for treatment?

- Minimally invasive
- Ease of recovery
- Ability to treat branches at the same time as treating truncal incompetence
Limitations if you wish to remain on label

- Not approved for treatment of the small saphenous vein
- No specific approval for perforator vein treatment
- No on label indication for venous malformations or for pelvic-derived varicose veins

Absolute contraindication

- Polidocanol allergy
- Active acute venous thrombosis (DVT or SVT)
- Active infection/sepsis
- Pregnancy
- Breastfeeding mothers not willing or able to “pump and dump”
- Patients with known right->left cardiac shunt

Relative Contraindication

- Patients unable to tolerate post procedure compression
- Patients who cannot ambulate
- Morbid obesity limiting visualization with ultrasound
- Patients with history of neurologic event/migraine headache with PCF
- Patients with history of unacceptable (to them) hyperpigmentation with previous sclerotherapy

Considerations to think about....

- Ok to use on patients on anticoagulation, but could efficacy be decreased?
- Volume per day per label is 15cc-this can go quickly in patients with extensive varicose veins-plan for multiple sessions
- Not my procedure of choice for patients with large diameter GSVs due to volume needed to close the vein (may have none left for branches), higher recanalization rate, and possibility of phlebitis

Closure literature

<table>
<thead>
<tr>
<th>Modality</th>
<th>RFA</th>
<th>EVLT</th>
<th>PEM</th>
<th>NOCA</th>
<th>CAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short term</td>
<td>96.6% one year</td>
<td>94.2% one year</td>
<td>87.9% 8 weeks</td>
<td>96% one year</td>
<td>96.8% one year</td>
</tr>
<tr>
<td>Long term</td>
<td>91.9% at 3 years and at 5 years</td>
<td>81.2% at 5 years</td>
<td>73% at one year</td>
<td>87% at 3 years</td>
<td>94.4% at 3 years</td>
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</tbody>
</table>

Great cases for PEM-”best in class”

- Recurrent varicose veins/tortuous varicose veins
- Anterior saphenous reflux with lots of branches
- Post phlebitic veins
- Pelvic component

Remember - Closure is a surrogate outcome measure that does not always correlate with improvements in patient quality of life!
Summary
- PEM is a helpful tool for the treatment of venous insufficiency
- Has “best in class” potential for many clinical scenarios
- Contraindications typical for other vein procedures and sclerotherapy
- Like all techniques, there are limitations and recognizing clinical scenarios were other techniques may be better is important