Step by Step: Proprietary Foam

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

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Varithena Overview

- 14 years of systematic pharmaceutical development
- Multiple clinical trials leading up to the FDA approval of Varithena rigorously proved its safety in treating patients with varicose veins
- No other clinical trial of foam sclerosants has included before and after MRIs to prove neurologic safety
- Two large Phase III trials showed that Varithena treatment provided significant improvement in both patient symptoms from varicose veins and in appearance of the leg

Step One: Choose your Patient(s)

- 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

Preauthorization/Predetermination

- Standard conservative management period
- Well crafted letter of medical necessity
- Utilize the Varithena Solutions center
- Give the process extra time

Step Three: Batch your cases

- Each can of Varithena has enough foam to treat 3 patients (minimum), or more precisely 3 sessions of 15 cc injections
- Shelf life of can is one week
- Weekends and holiday count in shelf life
- Group “can buddies”

Disclosures

Dr. Gibson is a consultant for BTG International and Medtronic and receives current research support from BTG, Medtronic, Angiodynamics, Bayer, and Takeda. She is in the Speaker’s Bureau for Bristol Myers Squibb.
Step 4: Imaging/marking
- Prescan - mark the GSV on the leg
- Mark thigh perforator into GSV
- Mark calf perforators
- Mark side branches you may want to treat

Step 5: Prep the Can
- CO2/Polidocanol on bottom, O2 on tap
- Twist cans together to activate
- “Hissing” noise during activation
- Separate components and snap microtransfer unit (MTU) on to top of bottom can

Step 6: Access with micropuncture or angiocath
- Standard access technique
- Place tip of access in mid-thigh location
- Tip of access above any large mid thigh perforators
- Attach tubing and secure

Step 7: Elevate leg

Step 8: Generate Microfoam

Step 9: Inject proximally
- Image SFJ in long view
- Compress GSV distal to access site and inject drug at a rate of about 1 cc/sec (volume of 5-10 cc typical)
- When drug reaches 3-5 cm from SFJ, stop injecting and apply pressure over site with gauze. If foam is not static, confirm with ultrasound that foam column is stable.
- Release compression distal to access site, compress proximal GSV until vasospasm occurs (1-5 minutes)
Step 10: Inject distal GSV
- May need to pull catheter back to treat distal GSV
- If vein in vasospasm, second access site may be considered
- Second access could be with angiocatheter, micropuncture kit, or direct needle stick (I use a butterfly-21G)

Step 11: Treat side branches
- Access with butterfly
- Have patient dorsiflex foot
- Compress any large perforators
- Small volumes - a little goes a long way

Step 12: Pads and compression stocking
- Under layer: Short stretch bandage
- Compression pads
- Compression stockings (30-40 mm Hg in clinical trials but I use a 20-30 mm Hg stocking)

Step 13: Patient Ambulation, discharge
- Stockings/pads for 48 hours
- Stockings daytime for two weeks
- Frequent ambulation
- Follow-up visit in 5-10 days and 3 months

Step 14: Bill/reimbursement
- Technique does not have its own CPT code at this point
- For billing, current recommendation is to use an unlisted procedure code 37799 “cross-walk” endovenous RF or laser plus phlebectomy CPT codes (36478 or 36475 plus 37785 or 37765)
- Product can either be purchased by practice and an unlisted J-code billed or drug can be prescribed to an approved specialty pharmacy
- Varithena has a “Solutions Center” on its website to assist with pre-authorization and reimbursement issues