Standardized microfoam for saphenous vein ablation

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Faculty disclosure

I, David Wright, disclose the following financial relationships:
Employee of BTG International Ltd
BTG is the developer of polidocanol endovenous microfoam, recently approved in the US by the FDA as Varithena™
Principles of PEM treatment of the GSV
Diagnosis, consent and marking

- Duplex ultrasound assessment
  - Deep and all superficial veins
- Plan
  - Agree the plan with the patient
- Pre-procedure
  - Marking to include all veins to be treated
Obtain Venous Access

Choose your spot

Accurate vein targeting

Prove venous access
Injection of Foam to Fill the Trunk Vein

- Fill the GSV or accessory vein towards the SFJ junction
- Stop 3-5 cm before the deep to superficial vein junction
- Compress the junction to stop flow of foam into the deep veins
Treatment of Superficial Varicosities

- From the trunk vein access
- Direct needle stick
- Butterfly needle
Post-Procedure Care

- Regular walking, 10 mins daily for 1 month
- Avoid inactivity, long car or plane journeys for one month
- Ultrasound check at 7 days
- Look for vein closure and thrombus
- Evacuate retained thrombus

- First 48 hours, eccentric compression over treated superficial varices and trunk vein
- Limited stretch bandage
- Compression stockings
- Continue stockings - 2 weeks
- Avoid strenuous for first week
Foams Are Not the Same
Polidocanol Endovenous Microfoam

- Engineered microfoam with consistent physical characteristics and performance
  - Homogeneous
  - Stable
  - Coherent
  - Echogenic
- Safety
  - Median size < 100 µm
  - No bubbles > 500 µm
- Gas mixture
  - 65% oxygen/35% carbon dioxide
  - Low nitrogen content less than 0.8%
- Liquid: gas ratio
  - Defined microfoam density 0.13g/mL
PEM vs. Physician-compounded Foam

All images compare foams within approximately 10 seconds of creation. Photos of physician-compounded foam feature examples of manually created foam made 1:4 with 1% polidocanol solution and room air, Tessari technique. Because of conditions and techniques, properties of physician-compounded foams may vary. RSSL 2014
Foam Bubble Size and Distribution at 40 seconds

- PEM possesses a narrow bubble size distribution with no large bubbles
- PCFs made by Tessari have broader bubble size distributions and large bubbles, which has an impact on stability and safety

BTG data on file
- Establish a foam plug
- Observe the decay
- Linear with time
- Represents stability
- Speed of degradation inversely proportional to the contact time
- Slower degradation rate (DR) equals better foam
Biomimetic Model

100% CO$_2$

Room Air

PEM
(a) PEM has the lowest DR compared to any PCFs, including foams made using room air (RA) \( (p<0.035) \)

(b) The same result was obtained at different liquid to gas ratios (1:4 and 1:7 liquid:gas)

100% \( \text{CO}_2 \) foams were least stable in all tests performed and different \( \text{CO}_2:\text{O}_2 \) mixtures had intermediate performance

DSS = Double syringe system
Impact of Nitrogen on Gas Absorption Rates

Foam Gas Absorption Curves

- Nitrogen
- 50:50 N₂:O₂
- 25:75 N₂:O₂
- O₂
- 65%O₂:35%CO₂
- PEM
Air = More Stable Foam  
Persistence of Bubbles = Reduced Safety

- Air foam or PEM, 2 injections into the saphenous vein of dog 5 mins apart
- 50% increase in pulmonary artery pressure with air foam
- Persistent bubbles in the pulmonary artery with air foam

Test agents infused at 0 start and 6 minutes (arrows). Values given as mean±SD. For clarity, SD not shown for air-based PD foam (2 x 5 ml) and Varithena™ (2 x 10 ml). PD signifies 1% polidocanol solution.

Butler dog studies. BTG, data on file
Conclusions

- Foams are not the same, impossible to compare clinical results unless characteristics are known and reproducible
- Air foams have good performance but have associated risks, with persistent bubbles in the circulation
- Small bubbles and narrow bubble distribution, with slow drainage and separation times, improves foam performance by enhancing stability
- PEM O$_2$:CO$_2$ low nitrogen gas composition and consistent foam generation is designed to optimize physical characteristics