Ultrasound Guided Foam Sclerotherapy: What We Should Know

Jean Luc GERARD (vascular physician)
Paris

Thursday, November 15, 2018
10:29 AM - 10:34 AM

SCLEROTHERAPY

- **LIQUID SCLEROTHERAPY**: Sclerotherapy without Ultrasound guidance (USG) Varicose vein injection / look and touch (1911 Linser, Sicard)

- **SCLEROTHERAPY WITH DUPLEX**: injection of the sclerosing agent under ultrasound guidance (1986 et 1989 de Simone, M.Schadeck, F.Vin, B.Knight)

- **FOAM SCLEROTHERAPY**: (1939 Mac Ausland et 1944 Orbach - air block) (1995 Cabrera et 1997 Monfreux)

« Varicose veins of the lower limbs : 20 to 35% of the French population and involve the great or small saphenous vein in 30 to 50% of cases »

67 M French ➔ 20 M suffers from varicose veins (30% of 67M)

Saphenous or non-saphenous varicose veins?

- Saphenous veins (30% of which 30% to 50% SAPHENOUS VEINS)
- Non saphenous vein (12 M)

ADVANTAGES OF FOAM

- Does not mix with blood (air push the blood)
- Sclerosing agent more in contact with the vein wall
- Induces a venous spasm
- Better efficacy++ (fewer injections, fewer sessions are done)
- less dangerous than liquid in case of extra vascular injection (less concentration)
- clearly visible in the vein on Duplex imaging
Saphenous veins: 6 trials (4 RCTs) were considered:

- F markedly more effective compared to L: difference between 20 and 50%.
- 4 studies included in a meta-analysis:
  - F 70.8% (95%CI 71-82) versus L 39.5% (95%CI 33-46) Chi ² = 60.9740; P < 0.0001

- Side effects do not differ statistically between F and L, even if Visual Disturbance seem to be more common with F.

Hamel-Desnos C., Allaert F-A. Phlebology 2009

---

**SCLEROTHERAPY**

**PRODUCTS**

The two surfactant sclerosants most widely used:
- Sodium Tetradecyl Sulphate (STS, STD®, Sotradecol, Trombovar or Fibro-vein)
- Polidocanol (Aethoxyscleron®, Macrogol 400 Ph Eur)

- Iodoclate de Sodium
- Dextrose solution (G 30%)
- Glycerin chromium (Scléremo)

---

**GAS**

- Air (room) GRADE 1B
- O₂
- CO₂
- N₂
- He

- Other gases: 
  - Ven Project 2009 = usually air
  - NICE 2009: air or other gas. There is insufficient evidence to draw conclusions on the relative safety of different types of foam-producing techniques.
  - European guidelines (Phlebology April 2013): Air as the component for generation of sclerosing foam.

---

**Sterile air is not mandatory**

- Foam sclerotherapy: Investigating the need for sterile air
  - Kees-Peter De Roos, Leon Groen, Alexander Leenders, Dermatol Surg 2011
  - Foam sclerotherapy with POL prepared in a standard room is a safe procedure without the risk of introducing a severe bacterial complication.

- Air contamination in the sclerosing foam for the treatment of varicose veins (S de Franciscis, CGA Nobile, E Larosa, R Montemurro, R Serra, Phlebology 2016): Sclerosing foam prepared with room air seems to be safe from a microbiological point of view.

---

**Ratio of liquid sclerosant to gas for production sclerosing foam**

- 1+3 (1 part liquid + 4 parts air GRADE 1A)
- 1+4
- 1+5

- European Guidelines for sclerotherapy in chronic venous disorders E Rabe et al Phlebology April 2013
FOAM PRODUCTION

The 3 ways, Tessari's method is use most frequently

Syringes (with or without silicone)

3-way stopcock

Standardizing the production of the foam should not depend on the angle of rotation of the hub

double syringe female-female

Foam volume

- Maximum 10 ml of foam per session in routine cases (GRADE 2B)
- Higher foam volumes are applicable according to the individual risk-benefit assessment (GRADE 2C)

Varisolve®

5 phials of 2CC = less than 20 euros
1 phial of 2cc liquid can produce 10cc foam
1 filter + connector = less than 2 euros
1 phial + 1 filter + 1 connector ≈ 7 euros

Homemade foam

1 filter + connector = less than 2 euros
1 phial + 1 phial + 1 connector ≈ 7 euros

Injection devices

- Needle mounted on a syringe (direct puncture)
- Butterfly needles
- Short catheter
- Long catheter

Injection devices

Direct puncture and injection with needle
- The most used technique in France and in Europe
- Reference technique in France
- Easier access into the veins (whatever the size and the depth)
- Allows various doses and overdoses limitation
Standardized procedure
UGFS

4 stages all done under Duplex imaging control:

1. The vein to be treated is identified (detection of possible nearby arteries)
2. Vein puncture + check needle position
3. Injection
4. Post-injection assessment (control of filling of the vein by the foam)

Procedure must be entirely done under Duplex control

Doses
Concentrations
Algorithm for treating saphenous vein with sclerotherapy

<table>
<thead>
<tr>
<th>Vein size</th>
<th>Polidocanol foam</th>
<th>STS foam (Sodium tetradecyl sulfate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø &lt; 4 mm</td>
<td>0.5%</td>
<td>0.2 to 0.5%</td>
</tr>
<tr>
<td>Ø 2.4 and &lt; 6 mm</td>
<td>1%</td>
<td>0.5 to 1%</td>
</tr>
<tr>
<td>Ø 6 and &lt; 8 mm</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Ø ≥ 8 mm</td>
<td>3%</td>
<td>2%</td>
</tr>
</tbody>
</table>

The maximum volume of foam per session is 10 mL.

LIMITS OF SCLEROTHERAPY

Randomized clinical trial comparing surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy for the treatment of great saphenous veins.
M. Venermo. BJS August 2016

Patency of GSV at 1 year
214 patients were included (65 conventional surgery, 73 EVLA, 76 UGFS)

<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>Occluded %</th>
<th>Partially open %</th>
<th>Open %</th>
</tr>
</thead>
<tbody>
<tr>
<td>SURG</td>
<td>97</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>EVLA</td>
<td>97</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>UGFS</td>
<td>51</td>
<td>29</td>
<td>19</td>
</tr>
</tbody>
</table>

Randomized clinical trial comparing surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy for the treatment of great saphenous veins.
M. Venermo. BJS August 2016

Patency of GSV at 1 year

<table>
<thead>
<tr>
<th>UGFS</th>
<th>Occluded %</th>
<th>Partially open %</th>
<th>Open %</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6mm</td>
<td>&gt;75</td>
<td>&gt;8</td>
<td>&gt;17</td>
</tr>
<tr>
<td>6-8mm</td>
<td>&gt;50</td>
<td>&gt;35</td>
<td>&gt;15</td>
</tr>
<tr>
<td>&gt;9mm</td>
<td>&gt;37</td>
<td>&gt;30</td>
<td>&gt;33</td>
</tr>
</tbody>
</table>

Microembolism during Foam Sclerotherapy of Varicose Veins
Roeland Coenen

Bubbles may pass from the right heart to the left through a patent foramen ovale (PFO). Some bubbles inevitably pass into the cerebral circulation.
ABSOLUTE AND RELATIVE CONTRAINDICATIONS

ABSOLUTE CONTRAINDICATIONS:
- Known allergy to the sclerosant
- Acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE)
- Local infection in the area of sclerotherapy or severe generalized infection
- Long-lasting immobility and confinement to bed
- For foam sclerotherapy in addition:
  - Known symptomatic patent foramen ovale (prevalence of PFO in general population around 25%)

RELATIVE CONTRAINDICATIONS (individual benefit–risk assessment mandatory):
- Pregnancy
- Breast feeding (interrupt breast feeding for 2–3 days)
- Severe peripheral arterial occlusive disease
- Poor general health
- Strong predisposition to allergies
- High thromboembolic risk (e.g., history of thromboembolic events, known severe thrombophilia, hypercoagulable state and active cancer)
- Acute superficial venous thrombosis
- For foam sclerotherapy in addition:
  - Neurological disturbances, including migraine, following previous foam sclerotherapy
  - Anticoagulation treatment is not a contraindication to sclerotherapy

CONCLUSION
- Efficient and safe
- Few contraindications
- Respect doses and volumes
- 6mm could be the threshold for efficiency