Cyanoacrylate Adhesive: more than one product is available: Is there a difference?
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Conflict of interest: none
Disclosures: none

VenaSeal (Medtronic) and Variclose (Biolas) endovenous acrylocyanate glues
“Non-thermal-non-tumescent”

Variclose glue
• N-butyl acrylocyanate glue
• Formulated for intravascular use
• CE mark awarded

Glue differences
• Viscosity
  — VenaSeal is thick like honey, Variclose is runny

• Procedure
  — VenaSeal is segmental, Variclose is continuous though the actual dose the same

• Data
Clinical Studies with the VenaSeal System

Feasibility Study
- 36 patients treated in 2010
- Safety and efficacy
- 50% closure maintained out to 3 years
- Improved VCSS

eSCope (European multicenter study)
- 39 patients treated in 2012
- Primary endpoint: GSV closure at follow-up
- 40% occlusion at 1 year
- Improved VCSS

VeClose (prospective RCT)
- 402 patients enrolled in 2013
- Primary endpoint: GSV closure at 3 months
- Secondary endpoint: ecchymosis and patient-reported pain

VeClose Trial: prospective RCT
- 322 Subjects Randomized (1:1) and treated
  - VenaSeal
    - N=118
  - RFA
    - N=114
- 3 Month Endpoint Data
  - VenaSeal (N=108)
  - RFA (N=114)
  - P-value
    - 99%
    - 96%
    - <0.01
- 3 Month Visit (CoreLab data*)
  - Number with Non-Closure (>5cm)
    - VenaSeal 1
    - RFA 5
  - 3 Month Follow-up Compliance
    - VenaSeal 97.0%
    - RFA 91.7%
  - Time to Recanalization of the Target Vein
    - Free from Recanalization at 12-Months
      - VenaSeal 97.0%
      - RFA 91.7%
  - P<0.0001 for non-inferiority
- 3 Month Follow-up Compliance
  - VenaSeal N=108
  - RFA N=114
  - 12 Month Follow-up Compliance N=95

VeClose Results
Ecchymosis at Day 3
Ecchymosis assessed with a 5-point scale on Day 3.
1213 bruising with glue (p<0.01)

VeClose Results
Time to Recanalization of the Target Vein
Free from Recanalization at 12-Months
VenaSeal 97.0%
RFA 91.7%

VeClose Results
VCSS Mean & (SD) by Visit and Treatment
(No adjuctive procedures before 3 months)
VeClose Results

**AVVQ, Mean & (SD) by Visit and Treatment**

<table>
<thead>
<tr>
<th>Follow-Up</th>
<th>VSCS</th>
<th>RFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>22.2 (8.4)</td>
<td>20 (8.1)</td>
</tr>
<tr>
<td>1-Month</td>
<td>20 (8.4)</td>
<td>19 (8.1)</td>
</tr>
<tr>
<td>3-Month</td>
<td>18.2 (7.9)</td>
<td>16 (7.6)</td>
</tr>
<tr>
<td>6-Month</td>
<td>15 (7.9)</td>
<td>13.2 (7.6)</td>
</tr>
<tr>
<td>12-Month</td>
<td>9.1 (6.3)</td>
<td>9.2 (6.4)</td>
</tr>
</tbody>
</table>

**Adverse Events Through 6-Months**

<table>
<thead>
<tr>
<th>Reported AEs</th>
<th>Venaseal (N=108)</th>
<th>RFA (N=114)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebitis, any zone</td>
<td>22 (20.4%)</td>
<td>20 (18%)</td>
<td>0.357</td>
</tr>
<tr>
<td>Phlebitis in treatment zone</td>
<td>11 (10.2%)</td>
<td>10 (8.8%)</td>
<td>0.819</td>
</tr>
<tr>
<td>Phlebitis not in treatment zone</td>
<td>0.7 (0.7%)</td>
<td>0 (0%)</td>
<td>0.243</td>
</tr>
<tr>
<td>Phlebitis in both treatment zone</td>
<td>2.3 (2.1%)</td>
<td>2.2 (2.0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Access site infection</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Superficial thrombophlebitis</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Access site burn</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Paresthesia not a treatment zone</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Paresthesia in treatment zone</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

NO SAEs were categorized as device- and/or procedure-related.

Variclose data (unpublished)

- Yasim et al
  - 180 patients
  - 3-7 month follow up, no recanalisations
  - VCSS reduced from mean of 10.2 to 3.9

- Calik et al
  - 181 patients
  - 97% occlusion at 6 months

Unpublished RCT: Bozkurt et al

- 310 patients randomised
- Variclose glue versus 1470 radial laser
- Primary endpoint: occlusion of target GSV anything over 5cm considered failure

Unpublished RCT: Bozkurt et al

- Mean GSV diameter 7.2 mm
- Mean length treated 30 cm
- No serious adverse events
- 4% paraesthesia in EVLT group
- Closure rate: 92% EVLT and 95% glue at one year
- Similar VCSS and AVVQ improvement in both groups

VenaSeal (Medtronic) and Variclose (Biolas)

- All data for VenaSeal suggests it's as good as endothermal
- Variclose:
  - Similar product
  - No published data