Non-thermal / non-tumescent ablation of the truncal veins – indications and limitations

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I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Sigvaris, L&R, Juzo, Medi, Bauerfeind
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Thermal ablation is standard

USA: American Venous Forum 2011
UK: NICE Guidelines 2013
Big Data!

2000-2014

Laser: 85 studies, 15,055 limbs

RFA: 47 studies, 8,372 limbs

van Eekeren et al. Sem Vasc Surg 2014

USA: American Venous Forum 2011
UK: NICE Guidelines 2013
High occlusion rate!

Laser: 93.0% (3yr)
RFA: 93.2%
Stripping: 93.5%

Rasmussen et al. JVascSurg 2013

USA: American Venous Forum 2011
UK: NICE Guidelines 2013
High occlusion rate!

Laser: 84.8% (5yr)
RFA: 88.7%

Balint et al. Vascular 2016: 862 articles -17 RCT

USA: American Venous Forum 2011
UK: NICE Guidelines 2013
Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices (Review)

Nesbitt C, Bedenis R, Bhattacharya V, Stansby G

2014
Thermal ablation has side-effects

- Heat
- Tumescent anesthesia
- Needle
Thermal ablation has side-effects

- Heat
- Tumescent anesthesia
- Needle
- Pain
- Hyperpigmentation
- Risk of nerve damage
Risk of nerve damage: Small saphenous vein
Risk of nerve damage: Small saphenous vein

Damage to

**SURAL NERVE**
- sensory
- lateral heel

**TIBIAL NERVE**
- sensory
- paraesthesia
- motor
- talipes calcaneus

©Sobotta, Urban & Schwarzenberg 1988
Risk of nerve damage: Small saphenous vein

**Damage to sural and tibial nerve**

**Paraesthesia**

Boersma et al J Endovasc Ther 2016 (28 studies, 2,950 SSV)

- **RFA** 9.7%
- **EVLA** 4.8%

Van Groenendael Phlebology 2010

- **EVLA** 9%


- **RFA** 26%

©Sobotta, Urban & Schwarzenberg 1988
Non-thermal ablation of saphenous veins

- Mechano-chemical ablation (Clarivein™)
- Adhesive closure (Venaseal™)
- Duplex-guided foam sclerotherapy
Non-thermal ablation of saphenous veins

Mechano-chemical ablation (Clarivein™)

Adhesive closure (Venaseal™)

Duplex-guided foam sclerotherapy
Mechano-chemical ablation

ClariVein™ (2010)
Principle: liquid POL/STS + rotating wire (3,500 rpm)
Mechano-chemical ablation

**ClariVein™**

CT, 32y,m
SSV reflux °2
C4 $E_pA_{S4}P_R$
VCSS 6
Mechano-chemical ablation

ClariVein™

tributaries

ACCESS

SPJ

t refluxive SSV
# Mechano-chemical ablation

## Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Occlusion rate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elias, Raines, Phlebology 2012</td>
<td>97%</td>
<td>N=30, 6 months</td>
</tr>
<tr>
<td>Van Eekeren, J Endovasc Ther 2014</td>
<td>88%</td>
<td>N=106, 12 months</td>
</tr>
<tr>
<td>Lane, Bootun et al. (RCT), Phlebology 2017</td>
<td>87% vs. 93% RFA</td>
<td>N=121, 6 months</td>
</tr>
<tr>
<td>Kim et al., Phlebology 2017</td>
<td>92%</td>
<td>N=65, 24 month</td>
</tr>
</tbody>
</table>
Mechano-chemical ablation

Advantages

Low pain
Low hyperpigmentation
No nerve damage
Quickly done
No generator required
## Mechano-chemical ablation

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pain</td>
<td>Dosage limitation</td>
</tr>
<tr>
<td>Low hyperpigmentation</td>
<td>Anatomical limitations</td>
</tr>
<tr>
<td>No nerve damage</td>
<td>Stuck tip</td>
</tr>
<tr>
<td>Quickly done</td>
<td>Poor data</td>
</tr>
<tr>
<td>No generator required</td>
<td>Reimbursement (D)</td>
</tr>
</tbody>
</table>
Non-thermal ablation of saphenous veins

- Mechano-chemical ablation (Clarivein™)
- Adhesive closure (Venaseal™)
- Duplex-guided foam sclerotherapy
Adhesive closure

**Venaseal™ (2011)**

**Principle:** application of cyanoacrylate adhesive by catheter
Adhesive closure

Venaseal™

PB, 48y,m
SSV reflux °2
C3 $E_p A_{S4} P_R$
VCSS 4
Adhesive closure

**Results**

**Feasibility Study**  
Almeida et al. Phlebology 2014

**eSCOPE**  
Proebstle et al. JVS 2014

**VeClose (RCT)**  
Morrison et al. JVS (at CX 2017)

**Occlusion rate**

92%  
n=38, 24 months

93%  
n=70, 24 months

94.4% vs. 91.9% RFA  
n=146, 36 months

FDA approval 2015
<table>
<thead>
<tr>
<th>Study type</th>
<th>N</th>
<th>Follow-up Month</th>
<th>Occlusion rate (%)</th>
<th>Phlebitis (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility</td>
<td>38</td>
<td>12</td>
<td>92.0</td>
<td>16</td>
</tr>
<tr>
<td>Feasibility</td>
<td>38</td>
<td>36</td>
<td>94.7</td>
<td>-</td>
</tr>
<tr>
<td>RCT (vs. RFA)</td>
<td>108/114</td>
<td>3/24</td>
<td>99.0/96.0</td>
<td>94.3/94.0</td>
</tr>
<tr>
<td>Retrospective</td>
<td>130</td>
<td>1</td>
<td>96.5</td>
<td>3</td>
</tr>
<tr>
<td>Retrospective</td>
<td>86</td>
<td>3</td>
<td>95.4</td>
<td>-</td>
</tr>
<tr>
<td>Single centre</td>
<td>62</td>
<td>6</td>
<td>90.3</td>
<td>4.8</td>
</tr>
<tr>
<td>Prospective</td>
<td>70</td>
<td>12</td>
<td>92.9</td>
<td>11.4</td>
</tr>
<tr>
<td>Multicentre</td>
<td>795</td>
<td>6</td>
<td>97.8</td>
<td>11.7</td>
</tr>
<tr>
<td>Prospective</td>
<td>215</td>
<td>6</td>
<td>97.2</td>
<td>0.5</td>
</tr>
<tr>
<td>WAVES</td>
<td>70</td>
<td>1</td>
<td>100</td>
<td>12.0/8.5</td>
</tr>
<tr>
<td>Retrospective (vs. RFITT)</td>
<td>1139/256</td>
<td>46</td>
<td>97.5/95.3</td>
<td>12.0/8.5</td>
</tr>
<tr>
<td>Retrospective (vs. EVLA)</td>
<td>141/142</td>
<td>6/12</td>
<td>96.6/91.7</td>
<td>15.5/7.7</td>
</tr>
<tr>
<td>(vs. EVLA)</td>
<td>180</td>
<td>5.5</td>
<td>100</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

*: Venaseal™, Medtronic, USA; **: Biolas VariClose® FG Group, Turkey

occlusion rate: 92-100%

“phlebitis” 8-20%

Hirsch T, Phlebologie 2017
Adhesive closure

Advantages

Low pain procedure
Low hyperpigmentation
No nerve damage
No stockings
No generator required
## Adhesive closure

### Advantages
- Low pain procedure
- Low hyperpigmentation
- No nerve damage
- No stockings
- No generator required

### Disadvantages
- Junctions tricky
- “Phlebitis” post op
- Implant
- Costs


Non-thermal ablation of saphenous veins

Mechano-chemical ablation (Clarivein™)

Adhesive closure (Venaseal™)

Duplex-guided foam sclerotherapy
Duplex-guided foam sclerotherapy

Polidocanol/STS + air 1:4 2003

Principle: sclerotherapy of saphenous veins using micro-foam under ultrasound guidance
Duplex-guided foam sclerotherapy

Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Occlusion rate</th>
<th>n</th>
<th>Time (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gillet et al.</td>
<td>90%</td>
<td>1025</td>
<td>1</td>
</tr>
<tr>
<td>Rasmussen et al.</td>
<td>84%</td>
<td>144</td>
<td>12</td>
</tr>
<tr>
<td>Shadid et al.</td>
<td>65%</td>
<td>230</td>
<td>24</td>
</tr>
<tr>
<td>Chapman-Smith</td>
<td>35%</td>
<td>203</td>
<td>60</td>
</tr>
</tbody>
</table>
Duplex-guided foam sclerotherapy

Advantages

Low pain
Quickly done
No generator required
Low costs
Repeatable
### Duplex-guided foam sclerotherapy

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pain</td>
<td>Lower occlusion rates</td>
</tr>
<tr>
<td>Quickly done</td>
<td>Selection required</td>
</tr>
<tr>
<td>No generator required</td>
<td>Hyperpigmentation</td>
</tr>
<tr>
<td>Low costs</td>
<td>(Paradoxic embolism)</td>
</tr>
<tr>
<td>Repeatable</td>
<td></td>
</tr>
</tbody>
</table>
Conclusion

Non-thermal / non-tumescent ablation of the truncal veins

**Indications**

- Allergy to local anaesthetics
- Use of antiarrhythmic drugs
- **Add-on**
  - to protect nerves
  - for higher comfort

**Limitations**

- Data
- Reimbursement
- Allergic diasthesis
Thank you for your attention!