A prospective multicentre randomized clinical trial comparing endovenous laser ablation, using a 1470 nm diode laser in combination with a Tulip-Tip™ fiber versus radiofrequency (Closure FAST™ VNUS®), in the treatment of primary varicose veins

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Affiliations  + expand

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Background

Chronic venous disease
Chronic venous disease

Belgium and Luxembourg prevalence

Great Saphenous Vein Incompetence

C1 to C6 61.3%
C3 to C6 25%

1. Vuylsteke ME, Eur J Vasc Endovasc Surg 2015
Objective

Comparing Endothermal ablation techniques
Endovascular thermal ablation techniques

1470-nm laser with a Tulip-Tip™ fiber Tobrix®

Radiofrequency Closure FAST™ VNUS®
Methods

Randomised Clinical Trial

Non-inferiority design
# Methods

<table>
<thead>
<tr>
<th>Sample</th>
<th>Follow-up</th>
</tr>
</thead>
</table>
| ● 18-75 years  
● GSV incompetence, unilateral  
● CEAP 2-6 and duplex  
● GSV diameter < 20 mm | 12 months |

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Secondary outcomes</th>
</tr>
</thead>
</table>
| GSV occlusion   | ● Pain  
● Ecchymosis  
● Quality of life CIVIQ-20  
● r-VCSS |
Flow chart

2336 patients visited the outpatient vascular clinic

280 fulfilled inclusion & exclusion criteria

142 EVLA

138 RFA

Exclusion criteria

- proven peripheral arterial disease (ankle: brachial pressure index below 0.8 or known PAD)
- deep vein insufficiency or thrombosis (ultrasound proven)
- cross dilation with two or more insufficient side branches
- cross insufficiency of AASV
- history of surgical or endovenous treatment of the GSV or SSV
- BMI 35 kg/m²
- Oncological disease less than one year ago
- Bilateral treatments
- Concomitant incompetence of the AASV and/or SSV
- pregnancy, lactation and women less than three months after childbirth
Intervention

Endovenous laser ablation (EVLA)
142 patients
Sint-Andries ziekenhuis, Tielt

Radiofrequency ablation (RFA)
138 patients
University Hospitals, Leuven

Marc VUYLSTEKE
Daphne VAN DEN BUSSCHE
Beate BECHTER-HUGL
Sarah THOMIS
04 Results

Primary and Secondary outcomes
Primary Outcome

Occlusion rate of the great saphenous vein on duplex ultrasound imaging

<table>
<thead>
<tr>
<th></th>
<th>EVLA</th>
<th>RFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete occlusion</td>
<td>108</td>
<td>102</td>
</tr>
<tr>
<td>Partial occlusion</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>No occlusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>112</td>
<td>108</td>
</tr>
</tbody>
</table>

Loss to follow-up 27%
Success rate at 1 year

96.4% Endovenous laser ablation
108/142 patients

94.5% Radiofrequency ablation
102/138 patients

P = 0.15
Shrinkage rate

Evolution of Occlusion

<table>
<thead>
<tr>
<th>mGELEV</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>no occlusion, refluxing vein, unchanged vein</td>
</tr>
<tr>
<td>1</td>
<td>partial occlusion with proximal reflux</td>
</tr>
<tr>
<td>2</td>
<td>partial occlusion without reflux</td>
</tr>
<tr>
<td>3</td>
<td>complete occlusion with unchanged diameter</td>
</tr>
<tr>
<td>4</td>
<td>complete occlusion with diameter reduction &gt;30%</td>
</tr>
<tr>
<td>5</td>
<td>complete occlusion with diameter reduction &gt;50%</td>
</tr>
<tr>
<td>6</td>
<td>fibrotic cord, vein not visible</td>
</tr>
</tbody>
</table>

Postoperative months

mean mGELEV

Graph showing the evolution of occlusion with different stages and corresponding mean mGELEV values at 1, 6, and 12 months postoperatively.
## Secondary outcomes

### Median from 4 to 1
- Statistically significant for both intervention groups

### 0%
- At 1 year

### r-VCSS

### 9/10
- Mean value

### Patient satisfaction
- others: postoperative pain, use of analgesics, absenteeism

### Major adverse events
- DVT, pulmonary embolism, ...

### AASV incompetence
- with fully obliterated GSV

### 8/220
<table>
<thead>
<tr>
<th></th>
<th>EVLA (n=142)</th>
<th>RFA (n=138)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS (first 5 days)*</td>
<td>1.8 (1.33)</td>
<td>1.46 (1.42)</td>
<td>.04</td>
</tr>
<tr>
<td>VAS (first 14 days)*</td>
<td>2.24 (1.68)</td>
<td>1.88 (1.49)</td>
<td>.061</td>
</tr>
<tr>
<td>Use of analgesics* (days)</td>
<td>1.65 (8.59)</td>
<td>2.12 (11.86)</td>
<td>.535</td>
</tr>
<tr>
<td><strong>Absenteeism</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Return to work† (days)</td>
<td>4 (1-7.5)</td>
<td>3 (0-7)</td>
<td>.787</td>
</tr>
<tr>
<td>Return to daily activities†  (days)</td>
<td>2 (1-5)</td>
<td>2 (1-5)</td>
<td>.997</td>
</tr>
<tr>
<td>Patient satisfaction*</td>
<td>8,89 (1,43)</td>
<td>9,00 (1,37)</td>
<td>.588</td>
</tr>
</tbody>
</table>

*Table note:*
Values are *mean(s.d.) and †median (i.q.r).*
VAS Visual Analogue Scale
Conclusions

Treatment of the great saphenous vein resulted in equal occlusion rates at one year follow-up, with comparable side-effect profiles.

No between-group differences in quality of life were shown.