3RF Trial
Randomised Controlled Trial of 3 Radiofrequency Thermal Ablation Treatments of the Great Saphenous Vein: Comparison of Venefit, RFITT and EVRF devices
ClinicalTrials.gov Identifier: NCT02441881

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Disclosures
Past and present financial relationships:
- Consultant for Olympus OSTE
- Received travel support from Bard-Impra Medical
- Received educational support from Medtronic
- Received research support from AstraZeneca
- Received research support from Bayer Plc
- Educational grant from B Braun Medical

3RF powered Endovenous Thermal Therapies

<table>
<thead>
<tr>
<th>Applicator tip (length)</th>
<th>Venefit</th>
<th>RFITT</th>
<th>EVRF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat coil (10mm)</td>
<td>Resiste</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bipolar (15mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monopolar (5mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method of ablation</th>
<th>Conductive</th>
<th>Conductive</th>
<th>Resistive</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Applicator withdrawal</th>
<th>Segmented</th>
<th>Continuous</th>
<th>Stepped</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device activation</td>
<td>Hard</td>
<td>Fast</td>
<td>Not stated</td>
</tr>
<tr>
<td>Ablation temperature</td>
<td>120°</td>
<td>80-100°</td>
<td>No</td>
</tr>
<tr>
<td>Device feedback / autostop</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Evidence for RF Ablation: 1 year ablation rates

<table>
<thead>
<tr>
<th>Venefit</th>
<th>RFITT</th>
<th>EVRF</th>
</tr>
</thead>
<tbody>
<tr>
<td>94-98%</td>
<td>89–98%</td>
<td>89%</td>
</tr>
</tbody>
</table>

3RF study
Aim - to compare clinical effectiveness of Venefit, RFITT and EVRF in a randomised clinical trial

- GSV ablation (No phlebectomy or Foam)
- Randomised Controlled Trial (RCT)
- Single UK NHS Hospital Vascular Unit
- Single surgeon
- Blinded patients
- Blinded assessors (clinical, duplex)

3RF Funding: This research was performed without industry support. We received no grants from any funding agency in the public, commercial, or not-for-profit sectors.
Outcomes

Primary: GSV Ablation 6/12

Secondary: Treatment time
- Complications
- Pain scores & tablet counts in week 1
- HR-Quality of Life (QoL): EQ-5D & AVVQ

Results: Outcomes:

NS: age, sex, vein length, vein diameter

No DVT events
No Thermal injury events

GSV Ablation time

7-day Pain scores & tablet counts

<table>
<thead>
<tr>
<th>Method</th>
<th>Score</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit</td>
<td>53</td>
<td>3</td>
<td>0-27</td>
</tr>
<tr>
<td>RFITT</td>
<td>50</td>
<td>2.5</td>
<td>0-43</td>
</tr>
<tr>
<td>EVRF</td>
<td>55</td>
<td>5</td>
<td>0-44</td>
</tr>
</tbody>
</table>

P > 0.05

Results: 1\textsuperscript{st} outcome:

Truncal Ablation at 6 months

Results: 2\textsuperscript{nd} outcome: HR-Quality of Life Scores

EQ5D: Pain/discomfort domain score

Aberdeen Varicose Vein Questionnaire score

Conclusions of the 3RF Trial

- Benefit and RFITT had 100% and 98% ablation at 6 months
- EVRF had inferior ablation rates (21% failure at 6 months)
- EQ5D and AVVQ - HR QoL scores did not differ at 12 months

Existing EVRF users should take special measures for consent and must study and audit their outcomes.