Endovenous Thermal Ablation: Consensus and Polemics

Lowell S. Kabnick, MD, FACS, FACPh
New York University Langone Medical Center
Division, Vascular Surgery
Director, NYU Vein Center

President, American Venous Forum
Disclosure

• Intellectual Property: AngioDynamics, Veniti
Consensus Definition

• a general agreement about something : an idea or opinion
  • Wide agreement

• [link]merriam-webster.com/dictionary/consensus
• dictionary.cambridge.org/us/
Consensus
**Polemique (Polemic) Definition**

- an often noisy or angry expression of differing opinions.
- a strong verbal or written attack on someone or something.
AFFORDABLE CARE ACT 2010
CONSENSUS?
In the USA

- No worries, the government will pay for any vein care you want

- Clinton: You are out of your mind! You will bankrupt the government.
ALTHOUGH THERE ARE ROAD BLOCKS FOR AGREEMENT
Medically Significant Venous Incompetence

Most patients seek treatment to relieve symptoms rather than cosmetic concerns.¹

Venous incompetence
Definition

Deep veins
• CFV, FV & PopV > 1 sec
• Tibial veins > 0.5 sec
• Perforators > 0.5 sec

Superficial System
• GSV & SSV > 0.5 sec
Persistent incompetent truncal veins should not be treated immediately

P Pittaluga and S Chastanet

Abstract

Background: The traditional attitude for the treatment of chronic venous disorder is to systematically treat incompetent truncal veins. We wanted to evaluate the outcomes of not treating all incompetent truncal veins with regard to our experience of focusing the treatment to the varicose tributaries.

Methods: Retrospective study on all procedures of surgical treatment consecutively performed for varicose veins by single phlebectomy with preservation of a refluxing great saphenous vein (GSV), according to the principles of the ambulatory selective varices ablation under local anesthesia (ASVAL) during four years of practice. The clinical and hemodynamic outcomes have been evaluated at eight days, one year, and once a year.
Classification of Venous Disease:

CEAP Classification¹

- Chronic venous disease is progressive and even modest disease may translate into functional limitations and limitations in daily activities²,³
- Approximately one-third of patients will experience clinical worsening within 6 months.²
- 66% of patients have episodes of ulceration lasting more than five years⁴

CEAP = clinical, etiologic, anatomy, pathophysiologic classification of venous disorders

VCSS

- In response to the need for a disease severity measurement, the AVF committee on outcomes assessment developed the **Venous Severity Scoring System** in 2000.

- Generates a **dynamic score** and can be used previous to treatment and post-intervention.

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Absent (0)</th>
<th>Mild (1)</th>
<th>Moderate (2)</th>
<th>Severe (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>None</td>
<td>Occasional</td>
<td>Daily</td>
<td>Daily limiting</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>None</td>
<td>Few</td>
<td>Calf or thigh</td>
<td>Calf and thigh</td>
</tr>
<tr>
<td>Venous edema</td>
<td>None</td>
<td>Foot and ankle</td>
<td>Above ankle, below knee</td>
<td>To knee or above</td>
</tr>
<tr>
<td>Skin Pigmentation</td>
<td>None</td>
<td>Perimalleolar</td>
<td>Diffuse, lower 1/3 calf</td>
<td>Wider, above lower 1/3 calf</td>
</tr>
<tr>
<td>Inflammation</td>
<td>None</td>
<td>Perimalleolar</td>
<td>Diffuse, lower 1/3 calf</td>
<td>Wider, above lower 1/3 calf</td>
</tr>
<tr>
<td>Induration</td>
<td>None</td>
<td>Perimalleolar</td>
<td>Diffuse, lower 1/3 calf</td>
<td>Wider, above lower 1/3 calf</td>
</tr>
<tr>
<td>No. active ulcers</td>
<td>None</td>
<td>1</td>
<td>2</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>Active ulcer size</td>
<td>None</td>
<td>&lt; 2 cm</td>
<td>2 – 6 cm</td>
<td>&gt; 6 cm</td>
</tr>
<tr>
<td>Ulcer duration</td>
<td>None</td>
<td>&lt; 3 mo</td>
<td>3 – 12 mo</td>
<td>&gt; 1 yr</td>
</tr>
<tr>
<td>Compression Therapy</td>
<td>None</td>
<td>Intermittent</td>
<td>Most days</td>
<td>Fully comply</td>
</tr>
</tbody>
</table>
Venous Procedures

- RADIOFREQUENCY
- LASER
- FOAM
- MOCA
- ADHESIVE
- PHLEBECTOMY

Vessel Occluder

Stripper
LASER AND RFA
Consensus? Where to Perform Thermal Ablation?
Office
But Wait... Why is the OR Better

Where is the Comparative Data
Conclusions: This large retrospective study of laser procedures performed outside the operating theatre did not reveal any significant specific complications as regards the environment required. The efficacy results were equivalent to those found in the literature. Regarding cost and constraints induced by operating theatre environment, the clinic room SHOULD BE ABLE to offer an easier and economic alternative option for venous treatment.
<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Charge</td>
<td>$$$$</td>
<td>$</td>
</tr>
<tr>
<td>Staff Charge</td>
<td>$$$$</td>
<td>$</td>
</tr>
<tr>
<td>Materials Charge</td>
<td>$$$$</td>
<td>$</td>
</tr>
<tr>
<td>Extra Staff Cost</td>
<td>$$$$</td>
<td>0</td>
</tr>
<tr>
<td>??????</td>
<td>$$$$</td>
<td>0</td>
</tr>
</tbody>
</table>
Consensus

• NO Level 1 Evidence that Hospital Surgery is safer

• There is evidence that outpatient surgery is less costly

• There is evidence that patients are happier in an office setting.
Procedure
Preparation of the Patient
ACCESS
Direct/Radial

- SMA connector
- Fiber management system
- Fiber tip
- 21 G super-sharp echogenic access needle with clear hub
- 45 cm .018" nitinol/stainless steel wire
- 4F 10 cm introducer/dilator with sidearm and hemostasis valve
Fiber or Catheter Positioning

>2.5 cm
Increasing ablation distance peripheral to the saphenofemoral junction may result in a diminished rate of endothermal heat-induced thrombosis.

Sadek M¹, Kabnick LS², Rockman CB¹, Berland TL¹, Zhou D¹, Chasin C¹, Jacobowitz GR¹, Adelman MA¹.

This study suggests that by changing the distance from the deep venous junction from 2.0 to 2.5 cms may diminish the rate of EHIT 2
Placement of Sheath and Fiber

Fiber or catheter placement:

just before the SSV “dives” to the popliteal vein
2-3cms from the Junction
Tumescent Anesthesia
## Ednothermal Ablation Anesthesia

### Preparation of Tumescent Anesthetic Solution: 0.1% Lidocaine

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9% Normal saline</td>
<td>950 mL</td>
</tr>
<tr>
<td>2% Lidocaine</td>
<td>50 mL</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>1 mL (1 mg, 1:1,000,000 final concentration)</td>
</tr>
<tr>
<td>Sodium bicarbonate 8.45%</td>
<td>12.5 mL (final solution pH 7.4)</td>
</tr>
</tbody>
</table>

### Tumescent Halo

- 10 mm diameter around vein
- 10 mm between target vein & skin
Tumescent Anesthesia
Pull Back
Endovenous Laser Ablation Procedure – Pull Back  Continuous

• 1470nm in USA  5-7W  30-50J/cm

• 1470nm OUS  higher power and † J/cm

• Different powers for different wavelengths as well

• Fibers ie bare, covered - NeverTouch or Radial
Radiofrequency Ablation
Ablation Procedure

• Compression

• Each 7-cm segment is treated = 20-second treatment interval
• Except for initial

• Controversy 1-2-3 cycle Rx the entire length
Compression Hose? What Pressure?
Postoperative Complication

• 68 year old female with symptomatic VV of the left thigh.
• GSV reflux within the facial compartment to mid-thigh and then epifascial to below the knee

• RF performed, entry site below the knee
  • Extra tumescent anesthesia placed around the vein in the epifascial area (originally under the skin and post T 1cm below the skin)
Complications: skin
• 75 yo F 1 wk postop LASER

• Closed GSV
• NO EHIT 2
• Complaining of pain in around the epifascial GSV (superficial accessory saphenous vein)
• Palpable cord
• No erythema

• 3 months postoperative U/S closed GSV
35 year old female attorney

ablation, 3 months ago, proximal thigh GSV, thigh and calf SAGSV. NOW complaining of brownish discoloration.

PMH: none
PSH: none
Allergies: none
Hyperpigmentation
This is Why
Which Endovenous Procedure is Better?

- RADIOFREQUENCY
- LASER
- FOAM
- MOCA
- ADHESIVE
- PHLEBECTOMY
- VESSEL OCCLUDER
- STRIPPER

Division of Vascular and Endovascular Surgery
Both endovenous laser ablation and RFA are efficient in GSV occlusion-long term.
Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins

L. H. Rasmussen, M. Lawetz, L. Bjoern, B. Vennits, A. Blemings and B. Eklof

Danish Vein Centres, Naestved, and Surgical Centre Roskilde, Roskilde, Denmark

Correspondence to: Dr L. H. Rasmussen, Danish Vein Centres, Eskadronsvej 4A, 4700 Naestved, Denmark (e-mail: lhr@varix.dk)

Background: This randomized trial compared four treatments for varicose great saphenous veins (GSVs).

Methods: Five hundred and eighty limbs from 500 patients were randomized to one of four treated groups to endovenous laser ablation, radiofrequency ablation, foam sclerotherapy or surgical stripping.

Results: A total of 580 limbs were included in the three treatment groups respectively and one a deep venous thrombosis was excluded. The mean(s.d.) number of treated GSVs were 1 (0–25), 2 (0–25), 2 (0–25) and 2 (0–25) in the endovenous laser, radiofrequency, foam and surgical groups respectively. The mean(s.d.) age was 3.6 (0–30) and 1.9 (0–18) years in the patients and nurses respectively. The mean(s.d.) SF-36® domain scores were 44.3 (15.6–66.2) and 55.2 (20.9–85.7) for the patients and nurses respectively. The mean(s.d.) SF-36® domain scores were 44.3 (15.6–66.2) and 55.2 (20.9–85.7) for the patients and nurses respectively.

Conclusion: All treatments were efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping.
### Primary Endpoint
**GSV Closure**

### Patent GSV with Reflux

<table>
<thead>
<tr>
<th></th>
<th>EVLA N=144 n(%)</th>
<th>RFA N=148 n(%)</th>
<th><em>P</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 days</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>.053</td>
</tr>
<tr>
<td>1 month</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td>.20</td>
</tr>
<tr>
<td>1 year</td>
<td>7 (5.8)</td>
<td>6 (4.8)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Disease Specific Quality of Life (AVVSSS)

P=NS

Graph showing the Aberdeen score over time for different treatments:
- EVLA
- UGFS
- RFA
- Stripping

Time after treatment:
- Baseline
- 3 days
- 1 month
- 1 year
Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, ..... veins with 3-year follow-up.

All RFA and LASER were efficacious and resulted in similar improvement.
Concluding Remarks

• There is no significant difference between laser and RF in terms of
  • Efficacy
  • QOL
  • Safety profile

• Clinical Equipoise