How to Select Patients for Treatment of Chronic Venous Insufficiency

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Chronic Venous Disease Treatment Options

- Rigid or short stretch compression (Unna's boot or Profore)
- Endovenous ablation of the saphenous vein
  - Thermal tumescent
  - Nonthermal non-tumescent
- Microphlebectomy of tributary veins
- Sclerotherapy of tributary veins
- Perforator ablation (SEPS, RFA/Laser, Sclero)
- Iliac venous stent
- Cross-femoral venous bypass
- Femoral-popliteal venous bypass

Lower Extremity Venous Anatomy

Superficial Vein System

Perforator Vein System
Pathophysiology of CVI

- Vein valves
  - Bicuspid valves
  - Blood propelled by calf muscle pump opens the valve in one direction
  - Blood moving with gravity closes the normal valve
  - Incompetence of valve at saphenofemoral junction is the source of most varicose veins

Proximal Iliac Vein Stenosis/Obstruction

Prospective study of 78 CEAP 5/6 patients to assess incidence of proximal venous disease
- Imaging modality: Duplex ultrasound plus combined with either CTV or MRV
- M:F = 50%; mean age =60
- Ulcers equally distributed between R and L
- 50% had hx of DVT
- 37% had iliofemoral stenosis of >50%; 23% had stenosis/occlusion>80%
- Independent risk factors=
  - Women
  - Hx of DVT
  - Deep venous reflux

Chronic Venous Insufficiency Classification

Revision of the CEAP classification for chronic venous disorders: Consensus statement
- Clinical
  - (1) Telangiectasias
  - (2) Varicose veins
  - (3) Edema
  - (4) Skin changes
  - (5) Ucer-healed
  - (6) Ucer-active
- Anatomic
  - Deep
  - Superficial
  - Perforator
- Pathophysiologic
  - Reflux
  - Obstruction
  - Reflux + obstruction
- Etiologic
  - Primary
  - Secondary
  - Congenital

Incidence of and risk factors for iliofemoral venous obstruction in patients with active or healed venous leg ulcers

William Marston, MD, Daniel Fisk, BS, Joshua Unger, MD, and Blair Rezai, MD, Chief HS, NC

Background: Iliofemoral venous obstruction (IFVO) can be a significant contributor to venous hypertension in patients with advanced disease. The incidence of IFVO in patients with CEAP clinical class 5 and 6 disease has not been reported. In this study, we reviewed a series of patients with healed or active venous leg ulcers to determine the incidence of IFVO and the risk factors related to this outcome.

Methods: Patients with CEAP clinical class 5 and 6 venous insufficiency underwent evaluation with duplex ultrasound scan to identify the presence of venous reflux in the deep and superficial systems and either computed tomography (CTV) or magnetic resonance Venography (MRV) to assess iliofemoral venous anatomy. A retrospective review was performed of prospectively collected data from 78 CEAP 5/6 patients. Multivariate analysis was performed to determine independent risk factors associated with IFVO.

Results: Vennography was attempted in all 78 patients, and a total of 78 CTVs and 53 MRVs were performed. The average age was 59.6 years and 58.6% were men. The skin thickness of the lower extremity was 4.5 cm on average.

Conclusions: IFVO is frequently associated with venous hypertension in patients with varicose veins and ulcers. Women and patients with a history of DVT are more likely to have proximal venous disease. Prospective studies are needed to further evaluate the incidence of IFVO and the risk factors associated with this outcome.
**Classification System**

- CEAP is the best classification system
- The most common chronic disease in the US
  - 40% of Americans have venous disease
  - 15-25% of the adult population have saphenous or branch incompetence
  - 40% of adults have telangiectasias (spider veins)
- One of the most common causes of wounds
  - 6% have a venous ulcer during their lifetime

References:
- Circulation 2005;111:2398-2409

**Assessing Venous System**

Non-invasive vascular lab

- Duplex scan in reversed Trendelenberg position to assess for:
  - Great/Small saphenous incompetence
    - Large vein > 3.5 mm
    - > 0.5 sec reflux
  - Perforator vein incompetence
    - Large vein > 3.5 mm
    - >0.5 sec reflux
    - Pulsatility
  - Tributary incompetence
  - Presence of deep vein obstruction/incompetence

References:
- JVS 2014;60:Supplement S

**Support hose, Circaid, Short Stretch Compression Bandage and Unna’s Boot**

**Heat Inducing Devices**

That Require Tumescence

- Superficial Veins
  - Laser and Radiofrequency
- Perforator Veins
  - RFA approved; Sclero and laser also used
**Radiofrequency and Laser Ablation**

**Mechanism of Action**

- RFS catheter placed at a 45 degree angle - transverse and longitudinal transducer
- Confirm stylet in vein at fascia
- Inject local anesthetic to eliminate pain
- Trendelenberg position
- Vein treated with radiofrequency energy for 1 minute in each quadrant; repeated above the fascia if possible
- Confirmation of ablation post procedure difficult due to compression from local anesthetic

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**Perforator Ablation**

(Difficult!)

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**Single Surgeon Learning Curve**

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**Stab Phlebectomy**

**Procedure**

- Incisions (Nokor Needle)
  - Adjacent to the vein to avoid cutting it
  - Length no greater than the crochet hook width (1 mm)
  - Penetrate dermis only
- Loop of vein pulled through incision
- Mosquitoes used to divide vein
- Circular motion used to remove the vein - limits the size of the incision
- More incisions better than larger incisions
- Vein path compressed with finger to reduce hematoma
- Transillumination can be used for complete vein removal
CEAP 1 Patients
Telangiectasias or reticular veins

- Elective – Cosmetic
- Treated with injection (sclerotherapy) or laser

JVS 2014;60:Supplement S

CEAP 2 Patients
Varicose veins

- Goals for Treatment
  - Elimination of reflux and any incompetence vein(s)
  - Reduce pain
  - Limited anesthesia
  - Short recovery
  - Excellent cosmetic result
  - Low complication rate
  - Low recurrence rate

SVS-AVF guidelines: compression of 20-30 mmHg recommended, knee or thigh high (Grade 1, Level B)

JVS 2014;60:Supplement S

CEAP 2 Patients
Varicose veins – Treatment Options

- Sclerotherapy
- Microphlebectomy
- Nonthermal, nontumescent
  - Mechanico-chemical
  - Rotational wire/Sclero/Glue

Endovenous laser ablation of GSV/SSV
Radiofrequency ablation of GSV/SSV


- 3-month technical success
  - 96% EVLT
  - 97% RFA
  - 95% NT NT

- Postop pain was considerably lower for RFA
- Changes in quality of life between pre and post-operative were not significantly different

**CEAP 3 Patients**

**Edema**

- Patients with edema, pain, and/or varicose veins
- Compression therapy*
  - Resolution of symptoms
  - No resolution of symptoms
  - Duplex ultrasound of superficial veins
  - Treatment of incompetent superficial veins

*For post-thrombotic patients the SVS-AVF recommends compression of 30-40, knee or thigh high (Grade 1, Level B)

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**Impact of Superficial Vein Ablation for CEAP 2-4 Patients**

<table>
<thead>
<tr>
<th>Presenting Symptoms</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle limiting pain</td>
<td>n=696 (94.8%)</td>
</tr>
<tr>
<td>Limb swelling</td>
<td>n=485 (66%)</td>
</tr>
<tr>
<td>Lipodermatosclerosis</td>
<td>n=39 (5.3%)</td>
</tr>
<tr>
<td>Bleeding varicose veins</td>
<td>n=10 (1.4%)</td>
</tr>
</tbody>
</table>

Endovenous ablation with concomitant phlebectomy is a safe and effective method of treatment for symptomatic patients with axial reflux and large incompetent tributaries.

**Impact of Superficial Vein Ablation for CEAP 2-4 Patients**

- 98.6% closure success rate at 24-72 hr
- Mean follow-up = 9 mo.
- Late GSV recanalization = 1.8%
- Late SSV recanalization = 0%

**Mid-Advanced CVI CEAP 4-6 Patients**

- **When to Intervene**
  - Patient presents with a leg that is pigmented and fibrotic in the “gaiter zone” of the ankle
  - Patient presents with non-healing ulcer that persists in spite of optimal compression
  - Patient presents with an ulcer at the location of an incompetent perforator vein
What To Do With Patients with Progressive Non Healing Venous Ulcers?

Correct the ambulatory superficial venous hypertension by:
- Great saphenous ablation - agreed
- Small saphenous ablation - agreed
- Tributary eradication - agreed
- Perforator ablation - ????
  - Linton procedure - Too many wound infections
  - SEPS - Difficult to get ankle perforators
  - Laser/RFA ablation
  - Sclerotherapy
  - Deep system valvuloplasty/bypass - not routinely used

or

Compression for life - and 25% with ulcers have weekly wound care!

Simplified Patient Algorithm

CEAP 4-6 Patients

- Did the patient have difficulty healing the ulcer with compression bandages?
- Is the patient compliant in wearing appropriate support stockings?
- Does the patient have any incompetent superficial or perforator veins?
- Does the patient's lifestyle increase their risk of recurrence?

CEAP 5 Patients

Healed venous ulcer

Guiding Information
Is Compression Enough to Prevent Ulcer Recurrence?

<table>
<thead>
<tr>
<th>STUDY</th>
<th>PATIENTS</th>
<th>THERAPY</th>
<th>1 YR RR</th>
<th>2 YR RR</th>
<th>3 YR RR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gohel et al</td>
<td>500</td>
<td>Compression</td>
<td>28%</td>
<td>N/A</td>
<td>56%</td>
</tr>
<tr>
<td>Erickson et al</td>
<td>71</td>
<td>Compression</td>
<td>35%</td>
<td>42%</td>
<td>49%</td>
</tr>
<tr>
<td>Harlander-Locke et al</td>
<td>20</td>
<td>Compression + Ablation</td>
<td>5%</td>
<td>10%</td>
<td>10%</td>
</tr>
</tbody>
</table>

- Patients with compression and ablation of incompetent superficial and perforator veins had lower ulcer recurrence rate to historic controls of compression alone.
- Patients whose ulcer recurrences often have new incompetent perforator veins in which ablation can lead to ulcer healing.

(1) JVS, 2007 (2) JVS, 1995 (3) JVS, 2012

Compression Therapy Does Not Cure All Venous Ulcers Alone

- The difference between compliant and non-compliant groups was significant, but 22% of the compliant patients had progression/recurrence.

CEAP 6 Patient
Active venous ulcer

- Compression therapy remains the mainstay treatment for a majority of patients.
  - Rigid or elastic wrap (3 months)
- Eliminate superficial reflux.
  - Saphenous, small saphenous, accessory saphenous
  - Eliminate tributary reflux.
- Eliminate perforator reflux.
  - Region of ulcer and above the ulcer.
- Compression to accelerate wound healing.
- Adjuncts.
  - Skin grafts
  - Skin substitutes
  - Growth factors/stem cells.

- Track impact of current treatment.
  - Measurement of size of ulcer- if no improvement move to next treatment.
- Radiofrequency Ablation (great and small saphenous veins).
  - Compression for 3 months.
  - Measurement of size of ulcer.
- Ablation of perforators immediately adjacent to the ulcer, if ulcer is stable or enlarging.
- Ablation of other adjacent ulcers if continued ulcer growth.
**Method of Ulcer Evaluation**

Ulcer growth = +2.66 cm²/mo

Ulcer closure = -6.08 cm²/mo

**Time (Years)**

Green: Treatment with compression therapy alone
Orange: Ongoing compression after vein ablation

**Impact of Perforator Ablation Randomized Control Trials**

- Ablation of incompetent perforator veins resulted in a mean of +4% ulcer healing
- Ablation of incompetent perforator veins resulted in a mean of -13% ulcer recurrence

**Choosing the Right Method for Perforator Ablation**

- Ultrasound guided foam sclerotherapy (UGFS) = 65%
- Radiofrequency = 83%
- Laser = 75%
- SEPS = 87% - no longer used

*Studies in last 5 years*
Single Institution Studies on Perforator Ablation for Ulcer Healing

<table>
<thead>
<tr>
<th>Primary author</th>
<th>Perforator treatment modality</th>
<th>Number of Procedures</th>
<th>Mean Follow-up</th>
<th>Mean ulcer healing</th>
<th>Mean ulcer recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rezai (2013)</td>
<td>RF and SFPE</td>
<td>64</td>
<td>37</td>
<td>92%</td>
<td>29%</td>
</tr>
<tr>
<td>Baba (2013)</td>
<td>EVLA</td>
<td>17</td>
<td>25</td>
<td>71%</td>
<td>0%</td>
</tr>
<tr>
<td>Saeedi (2013)</td>
<td>RF</td>
<td>68</td>
<td>36</td>
<td>52%</td>
<td></td>
</tr>
<tr>
<td>Harlander-Leeke (2015)</td>
<td>RF</td>
<td>29/38</td>
<td>12</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td>Huisken (2018)</td>
<td>EVLA</td>
<td>14/23</td>
<td>53</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>Marconato (2018)</td>
<td>RF</td>
<td>26</td>
<td>5</td>
<td>89%</td>
<td>15%</td>
</tr>
<tr>
<td>Herath (2018)</td>
<td>RF</td>
<td>55</td>
<td>14</td>
<td>69%</td>
<td></td>
</tr>
</tbody>
</table>

Current State of the Treatment of Perforating Veins, JVS 2015. In-Press

- Mean ulcer healing = 81%
- Mean ulcer recurrence = 10%

Diagnosis
- Inaccurate Identification of Incompetent Perforators
- Inappropriate Sequencing of Treatment of CVI

Technique
- Poor Technique in Performing Perforator Ablation
- Ablation of Wrong Perforators

Measurement of progress
- Inadequate Measurement of Ulcer Area and Volume
- Inadequate Compression and Inadequate Wound Care

Why Have Some Studies Shown No Benefit From Perforator Ablation?

- Inadequate Measurement of Ulcer Area and Volume
- Inadequate Compression and Inadequate Wound Care

Proximal Venous Outflow Obstruction

Venous outflow obstruction: An underestimated contributor to chronic venous disease

From the American Venous Forum

Comment: If saphenous reflux is present, a saphenous ablation is generally undertaken before considering venous stenting.

Raju’s Criteria for Proximal Venous Stenting

One or more of the following clinical symptoms:
- **Diffuse** venous (orthostatic) limb pain that is graded >3/10 in visual analogue scale or interfering with sleep or work or requiring regular analgesic/narcotic use.
- Venous leg swelling that is grade 3 (more than ankle edema involving the calf. Very rarely lesser degrees of swelling may be considered if it is combined with significant pain.
- Venous stasis dermatitis/hyperpigmentation/lipodermatosclerosis
- Venous stasis ulceration either active or healed if recurrent

Comment: If saphenous reflux is present, a saphenous ablation is generally undertaken before considering venous stenting.
Impact of Venous Outflow Obstruction

Table V. Comparison between limbs with obstruction grade 2-4 and limbs with no hemodynamic obstruction (grade 0-1) according to Raja test.

<table>
<thead>
<tr>
<th>Obstruction grade 2-4</th>
<th>Obstruction grade 0-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-stent</td>
<td>Post-stent</td>
</tr>
<tr>
<td>AVP (mm Hg)</td>
<td>AVP (mm Hg)</td>
</tr>
<tr>
<td>39 ± 28</td>
<td>45 ± 18.09</td>
</tr>
<tr>
<td>&lt; .0001</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Swelling grade</td>
<td>Swelling grade</td>
</tr>
<tr>
<td>1.4 ± 1.0</td>
<td>1.4 ± 1.0</td>
</tr>
<tr>
<td>&lt; .0001</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Pain scale</td>
<td>Pain scale</td>
</tr>
<tr>
<td>6.3 ± 2.6</td>
<td>4.8 ± 2.5</td>
</tr>
<tr>
<td>&lt; .0001</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Ulcer healing</td>
<td>Ulcer healing</td>
</tr>
<tr>
<td>0/15</td>
<td>15/33</td>
</tr>
<tr>
<td></td>
<td>&lt; .0001</td>
</tr>
</tbody>
</table>

Post-stenting changes
- Decrease in ambulatory venous pressure
- Reduction in swelling*
- Reduction in pain*
- Half of venous ulcers healed

*Significant (P<.0001)

JVS 2003;38:879-885

Conclusions from Literature
CEAP 5 – 6 Patients

- Venous ulcers can be healed with an aggressive approach to incompetent superficial axial veins and perforating veins
- Healed venous ulcers (CEAP 5) can be maintained with a combination of compression and ablation of incompetent axial and perforator veins
- The status of the ulcer is the key to determining if there is persistent “ambulatory venous hypertension”
- If an ulcer is not healing with optimal compression (CEAP 6) or heals and has progressive lipodermatosclerosis (CEAP 5), there is a mechanical reason: find it and treat it!