Chronic Venous Insufficiency: Diagnosis and Management

Robert E. Foster MD
Chronic Venous Disease (CVD) in the U.S.

- Prevalence of varicose veins >20% affecting 11 million men and 22 million women ages 40-80
- 8% of Americans have advanced CVD with skin changes/ulceration
- 21,000 patients receive a diagnosis of venous ulcer annually

Prevalence and Etiology of Venous Insufficiency

Venous reflux disease is 2x more prevalent than coronary heart disease (CHD) and 5x more prevalent than peripheral arterial disease (PAD)\(^1\)

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Prevalence and Etiology of Venous Insufficiency

Of the estimated 25 million people with symptomatic superficial venous reflux:

- Only 1.7 million seek treatment annually
- Over 23 million go untreated

Prevalence by Age and Gender

<table>
<thead>
<tr>
<th>Age</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-29</td>
<td>8%</td>
<td>1%</td>
</tr>
<tr>
<td>40-49</td>
<td>41%</td>
<td>24%</td>
</tr>
<tr>
<td>60-69</td>
<td>72%</td>
<td>43%</td>
</tr>
</tbody>
</table>

Coon WW, Willis PW, Keller JB. Venous thromboembolism and other venous disease in the Tecumseh Community Health Study Circulation 1973; 48:839-846
## Possible Risk Factors and Symptoms of Venous Insufficiency

<table>
<thead>
<tr>
<th>Possible risk factors for venous insufficiency:</th>
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<tbody>
<tr>
<td>• Gender</td>
</tr>
<tr>
<td>• Age</td>
</tr>
<tr>
<td>• Heredity</td>
</tr>
<tr>
<td>• Pregnancy</td>
</tr>
<tr>
<td>• Standing occupation</td>
</tr>
<tr>
<td>• Obesity</td>
</tr>
<tr>
<td>• Prior injury, surgery, DVT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms of venous insufficiency:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Leg pain, aching, or cramping</td>
</tr>
<tr>
<td>• Burning or itching of the skin</td>
</tr>
<tr>
<td>• Leg or ankle swelling</td>
</tr>
<tr>
<td>• “Heavy” feeling in legs</td>
</tr>
<tr>
<td>• Skin discoloration or texture changes</td>
</tr>
<tr>
<td>• Open wounds or sores</td>
</tr>
<tr>
<td>• Restless legs</td>
</tr>
<tr>
<td>• Varicose Veins</td>
</tr>
</tbody>
</table>
- **Telangiectasias**: Dilated intradermal and subdermal veins, usually < 1mm in diameter. Also known as “spider veins.”
- **Reticular veins**: 1-3mm in diameter, intradermal, with bluish appearance
- **Varicose veins**: subcutaneous, tortuous, and >3mm in diameter
Symptoms of CVD

- Restless legs: 2102 men, 434 women
- Leg pains: 2102 men, 434 women
- Cramps: 2102 men, 434 women
- Heaviness: 2102 men, 434 women
- Swelling: 2102 men, 434 women
## Major causes of edema by primary mechanism

**Increased capillary hydraulic pressure**

A. Increased plasma volume due to renal Na+ retention
   1. Heart failure, including cor pulmonale
   2. Primary renal sodium retention
      a. Renal disease, including the nephrotic syndrome
      b. Drugs: minoxidil, diazoxide, thiazolidinediones, calcium channel blockers (particularly nifedipine), nonsteroidal antiinflammatory drugs, hydrocortisone, estrogens
   c. Refeeding edema
e. Early hepatic cirrhosis
3. Pregnancy and premenstrual edema
4. Idiopathic edema, when diuretic-induced

B. Venous obstruction
   1. Cirrhosis or hepatic venous obstruction
   2. Acute pulmonary edema
   3. Local venous obstruction

C. Decreased arteriolar resistance
   1. Calcium channel blockers (?)
   2. Idiopathic edema (?)

**Hypoalbuminemia**

A. Protein loss
   1. Nephrotic syndrome
   2. Protein-losing enteropathy

B. Reduced albumin synthesis
   1. Liver disease
   2. Malnutrition

**Increased capillary permeability**

A. Idiopathic edema (?)

B. Burns

C. Trauma

D. Inflammation or sepsis

E. Allergic reactions, including certain forms of angioedema

F. Adult respiratory distress syndrome

G. Diabetes mellitus

H. Interleukin-2 therapy
   1. Malignant ascites

**Lymphatic obstruction or increased interstitial oncotic pressure**

A. Lymph node dissection

B. Nodal enlargement due to malignancy

C. Hypothyroidism

D. Malignant ascites

**Uncertain mechanism**

A. Docetaxel

B. Pranopexole
Venous return to right side of heart accomplished thru the actions of the calf muscle pump and venous valves.
Interstitial edema

↓ Cutaneous and subcutaneous oxygenation and nutrition

Subcutaneous fat necrosis

Subcutaneous lipodermatosclerosis

Dermatitis

Pruritus

↑ Fibrinogen and/or white blood cell activation

Cutaneous ulceration
## CEAP classification for chronic venous disorders

<table>
<thead>
<tr>
<th>Clinical classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$C_0$</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>$C_1$</td>
<td>Telangiectasias, reticular veins, malleolar flares</td>
</tr>
<tr>
<td>$C_2$</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>$C_3$</td>
<td>Edema without skin changes</td>
</tr>
<tr>
<td>$C_4$</td>
<td>Skin changes ascribed to venous disease (eg, pigmentation, venous eczema, lipodermatosclerosis)</td>
</tr>
<tr>
<td>$C_{43}$</td>
<td>Pigmentation or eczema</td>
</tr>
<tr>
<td>$C_{4b}$</td>
<td>Lipodermatosclerosis or atrophie blanche</td>
</tr>
<tr>
<td>$C_5$</td>
<td>Skin changes as defined above with healed ulceration</td>
</tr>
<tr>
<td>$C_6$</td>
<td>Skin changes as defined above with active ulceration</td>
</tr>
<tr>
<td>$S$</td>
<td>Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>$A$</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Etiologic classification</th>
<th></th>
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<tbody>
<tr>
<td>$E_c$</td>
<td>Congenital</td>
</tr>
<tr>
<td>$E_p$</td>
<td>Primary</td>
</tr>
<tr>
<td>$E_s$</td>
<td>Secondary (postthrombotic)</td>
</tr>
<tr>
<td>$E_n$</td>
<td>No venous cause identified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anatomic classification</th>
<th></th>
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<tbody>
<tr>
<td>$A_s$</td>
<td>Superficial veins</td>
</tr>
<tr>
<td>$A_p$</td>
<td>Perforator veins</td>
</tr>
<tr>
<td>$A_d$</td>
<td>Deep veins</td>
</tr>
<tr>
<td>$A_n$</td>
<td>No venous location identified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pathophysiologic classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_r$</td>
<td>Reflux</td>
</tr>
<tr>
<td>$P_o$</td>
<td>Obstruction</td>
</tr>
<tr>
<td>$P_{r.o}$</td>
<td>Reflux and obstruction</td>
</tr>
<tr>
<td>$P_n$</td>
<td>No venous pathophysiology identifiable</td>
</tr>
</tbody>
</table>

Limbs in higher categories have more severe signs of chronic venous disease and may have some or all of the findings defining a less severe clinical category. Each limb is further characterized as asymptomatic ($A$), for example, $C_0-6_A$, or symptomatic ($S$), for example, $C_0-6_S$. Symptoms that may be associated with telangiectatic, reticular, or varicose veins include lower extremity aching, pain, and skin irritation. Therapy may alter the clinical category of chronic venous disease. Limbs should therefore be redclassified after any form of medical or surgical treatment.

Severity of symptoms and signs of venous disease correlate with reflux as identified by duplex ultrasound with retrograde flow.
Conservative Therapy

- Leg elevation (30 min 3-4 x daily)
- Exercise
- +/- diuretics
- Compression stockings
  - Contraindicated in setting PAD, acute cellulitis
- Skin Care
  - Daily cleansing, use of emollients, and application of barrier protection
  - In setting of itching, mid potency topical steroid
• Prescription must include size, length, and grade of compression
• Variations available: knee-high versus thigh-high, open toe, zippered or fastener-based stockings
• Should be put on in the morning after dressings for any ulcer and removed at night
• Compliance relatively low (<50%)
Ablation Therapy

• Reduces venous volume in the limb and thereby the effects of venous hypertension

• Classified according to method of vein destruction
  • Chemical – involves introduction of irritant agent
  • Thermal – involves generation of heat either through RF or laser light energy
  • Mechanical – involves physical destruction with its partial or complete removal, ie vein stripping or stab phlebectomy

• Benefits
  • Improvement in symptoms and appearance of varicose veins as reflected by venous clinical severity scales
  • Improved healing and a reduction in venous ulcer recurrence rate
Catheter-based Thermal Treatments

- Endovenous laser EVLA
- Radiofrequency ablation RFA
- Primarily to treat saphenous insufficiency (great or small), and perforators
- EVLA and RFA, are equally efficacious & have similar recanalization rates.

### Rasmussen Randomized Clinical Trial\(^1\)***

<table>
<thead>
<tr>
<th></th>
<th>RF Ablation  (n=124*)</th>
<th>Endovenous Laser Ablation  (n=124*)</th>
<th>Ultrasound-Guided Foam Sclerotherapy  (n=123*)</th>
<th>Vein Stripping  (n=123*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy at 1 year</td>
<td>95.2%</td>
<td>94.2%</td>
<td>83.7% (p&lt;0.001)</td>
<td>95.2%</td>
</tr>
<tr>
<td>(reflux-free rate)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post Intervention Pain Scores** (1 – 10)</td>
<td>1.21 (p&lt;0.001)</td>
<td>2.58</td>
<td>1.60 (p&lt;0.001)</td>
<td>2.25</td>
</tr>
<tr>
<td>Time to return to normal activities (days)</td>
<td>1 (p&lt;0.001)</td>
<td>2</td>
<td>1 (p&lt;0.001)</td>
<td>4</td>
</tr>
<tr>
<td>Time to resume work (days)</td>
<td>2.9 (p&lt;0.001)</td>
<td>3.6</td>
<td>2.9 (p&lt;0.001)</td>
<td>4.3</td>
</tr>
</tbody>
</table>

*\(\text{n}\) is the number of patients who returned for follow-up
**In the 10-day period post-procedure

\[^1\] Rasmussen Randomized Clinical Trial\(^1\) comparing endovenous laser ablation, foam sclerotherapy and surgical stripping for great Saphenous varicose veins

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**Note:** *The ClosureFast™ Catheter was used in this study***
Endovenous Laser
The Venefit™ Procedure
Using the ClosureFast™ Catheter

- Minimally invasive treatment option for patients with varicose veins and CVI
- Controlled and consistent radiofrequency (RF) energy to the ClosureFast™ catheter
- The catheter heats the vein wall and contracts the vein wall collagen, thereby occluding the vein

*Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device. CAUTION: Federal (USA) restricts this device to sale by or on order of a physician.*
Thermal Ablation: General Technique

• Prepare and position patient
• Place device sheath
• Position catheter
• Instill tumescent anesthesia
• Ablate the vein
• Perform completion ultrasound

• Ambulation encouraged
• Compression stockings and bandages worn continuously for 48h and during the day for the first 1-2 weeks
• Normal job activities resumed POD 1 generally
Complications

- Superficial thrombophlebitis
- Nerve injury
- Deep venous thrombosis

Contraindications

- Pregnancy
- Acute superficial or deep venous thrombosis
- Moderate to severe PAD
- Advanced generalized systemic disease
- Joint disease that interferes with mobility
RECOVERY Trial\textsuperscript{1}: Venous Clinical Severity Score (VCSS)

RECOVERY Trial\textsuperscript{1}: Better Quality of Life

Quality of Life Score: Global

Note: Lower score reflects a better QOL.

<table>
<thead>
<tr>
<th>Time</th>
<th>ClosureFast\textsuperscript{TM} catheter</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>2 days</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>7 days</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>14 days</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>30 days</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

Chemical Ablation: Sclerotherapy

- Most commonly used for tributaries and reticular veins.
- Sodium tetradecyl sulfate, polidocanol, and hypertonic saline most commonly used agents.
- Endothelial damage the result of either osmotic action or protein denaturation.
Foam Sclerotherapy: Complications

- Phlebitis
- Skin staining
- Failure
- Residual lumps
- Matting
- Embolus (CVA)
- DVT
- Ulceration (rare)
- Anaphylaxis (very rare)
Foam Sclerotherapy Results

- Variable depending on series
- Long-term recurrence rates are as high as 65 percent in five years, however, patients can also be retreated when veins recur
- Large veins can be a problem
- “Part of the arsenal”

Systemic Reflux in Venous Ulceration

Sources of Reflux in Venous Ulcer Patients\(^1\)

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial</td>
<td>79%</td>
</tr>
<tr>
<td>Perforating</td>
<td>63%</td>
</tr>
<tr>
<td>Deep</td>
<td>49.5%</td>
</tr>
</tbody>
</table>

Incompetent perforators found in 66.3% of venous ulcer patients\(^1\)


Photo courtesy of David MacMillian MD
Anatomy: Perforators

- Perforator valves maintain one-way flow from superficial to deep veins

- Perforator valve failure causes:
  - Higher venous pressure and GSV/branch dilation
  - Increasing pressure results in GSV valve failure
  - Additional vein branches become varicose
  - Further GSV incompetence and dilation

NOTE: The SVS/AVF Guideline Committee definition of “pathologic veins includes those with outward flow of ≥ 500 ms, with a diameter of ≥ 3.5 mm, located beneath a healed or open venous ulcer”

The Venefit™ Procedure with the ClosureRFS™ Stylet

- Single puncture percutaneous access under ultrasound guidance
- Temperature controlled 85°C heating at or below deep fascia
- Endovenous ablation specifically indicated to treat incompetent perforator veins

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Surgery

- Thermal ablation techniques are limited by an upper limit of vein diameter (>1.5 cm)
- Procedure is performed under general or spinal anesthesia
- Indications include management of superficial thrombophlebitis, and venous hemorrhage

Summary

• Symptomatic patients (aching, swelling, heaviness) with visibly dilated lower extremity veins should undergo venous duplex to identify the presence of venous insufficiency.

• Symptomatic patients with reflux should be referred to vein specialists for evaluation and management.

• Initial treatment includes leg elevation, exercise, and compression therapy.

• Patients with persistent symptoms refractory to medical therapy are candidates for invasive therapies.
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