My Patient has Varicose Veins or Ulcers: What Can Be Done in 2017?

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Disclosures

None
Chronic Venous Disease
Spectrum of Disorders

- Venous Thrombo-Embolic Disease: (VTE) DVT, PE
- Venous Obstruction: May-Thurner, Iliac Vein Compression
- Chronic Venous Insufficiency: Varicose Veins, Ulcers
More than 30 million Americans suffer from varicose veins and Chronic Venous Insufficiency (CVI).\(^1\)

Of the over 30 million Americans affected:

- Only 1.9 million seek treatment annually.\(^1,2\)
- The vast majority remain undiagnosed and untreated.

Chronic Venous Insufficiency is primarily a disease of the superficial veins

- Great saphenous vein (GSV)
- Small Saphenous vein (SSV)
- Perforator veins
Underlying Cause of Chronic Venous Insufficiency
Vein valve damage causing Venous Reflux

Calf muscle contracts forcing venous blood toward heart

Tiny valves help the leg veins work against gravity to push blood back to the heart.

But if valves weaken, blood can leak backwards and pool, resulting in varicose veins.
Venous Reflux and Varicose Veins

Primary venous reflux can occur in any superficial or deep vein of the lower limbs but is more frequent in the former.
Effects of Venous Hypertension

- Varicose veins
- Increased tissue capillary permeability
- Leaking of proteolytic enzymes, fluid and blood cells into the tissue
- Inflammatory response
- Changes in microvascular circulation with reduced skin and tissue oxygenation
- Edema, Skin changes / fragility
- Increased risk of ulcers with poor healing
Chronic Venous Insufficiency: Symptoms

- Varicose Veins
- Leg Pain, aching and cramping
- Leg heaviness and fatigue
- Restless leg syndrome
- Burning or itching of the skin
- Leg or ankle swelling
- Hyperpigmentation
- Skin Changes
- Lower extremity ulcers
Venous Duplex Ultrasound

- Specify a “Reflux Study”
- Standing position
- Provocative maneuver: Augmentation of normal venous flow, calf squeeze or cuff inflation/deflation, valsalva
- Visualize / measure reflux duration
Treatment Options: Conservative Therapies

First line therapy for symptomatic patients

- Exercise
- Weight loss
- Leg elevation
- Compression stockings: 20–30 mmHg
- Trial required before Endovenous therapies are reimbursed by Medicare and many insurance carries (except C6 disease)
- Treats symptoms only, not the underlying disease
Surgical Vein Ligation and Stripping

- Ligation of the GSV at the confluence with the CFV
- Stripping of the GSV
- Performed for > 100 years
- Effective
- O.R., General anesthesia
- Excessive pain and bruising
- Prolonged recovery time
- Now rarely performed
Endovenous Ablation

Minimally Invasive closure of the vein

Thermal Tumescent Ablation
- Endovenous Laser Ablation
- Endovenous Radiofrequency Ablation

Non Thermal Non Tumescent Ablation
- Mechanochemical Ablation
  - ClariVein System
- Chemical Ablation
  - Varathena
  - Venaseal
Minimally Invasive Procedures
Endovenous Ablation

- Tip laserfiber
- SFJ

- Disposable catheter inserted into vein
- Vein heats and collapses
- Catheter withdrawn, closing vein
Thermal Ablation: Tumescent Anesthesia

- Saline, Lidocaine, bicarb solution
- Injected along entire course of treated vein in the perivenous space
- Anesthetic effect
- Fluid insulates surrounding tissues from thermal injury
- Prevents nerve injury and skin injury
Endovenous Laser Ablation

Variable Inputs

**Wavelengths**
- Hemoglobin-targeted
- Water-targeted

**Fiber Tip**
- Bare / Radial / Covered

**Power Settings**
- 15W/30W/Joules/sec

**Speed**
- Pullback Speed
- Manual/Automated

Mechanism of Action

Temperature at the laser tip hot 200 – 400 °C

Damage to the vessel wall is from the generation of a steam bubble (boiling)

Steam transmits heat to the vein wall causing endothelial injury, vessel contraction, occlusion
**Endovenous Radiofrequency Ablation**

**Mechanism of Action**

- Temperature controlled heating of the vein wall – 120°C
- Vein segment treated at one time
- No energy delivered during catheter pullback
- Energy delivery does not vary by pullback speed

- Controlled and consistent radiofrequency (RF) energy delivery
- The catheter heats the vein wall causing endothelial injury, contracts the vein wall collagen, fibrotic scarring thereby occluding the vein.
Vein Occlusion Rates thru 5 Years

<table>
<thead>
<tr>
<th></th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein Occlusion</td>
<td>96.6%</td>
<td>94.3%</td>
<td>92.8%</td>
<td>91.1%</td>
<td>90.0%</td>
</tr>
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Trial Comparing RFA, EVLA and Surgical Stripping

<table>
<thead>
<tr>
<th></th>
<th>RF Ablation (n=124*)</th>
<th>Endovenous Laser Ablation (n=124*)</th>
<th>Vein Stripping (n=123*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy at 1 year (reflux-free rate)</td>
<td>95.2%</td>
<td>94.2%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Post Intervention Pain Scores* (1 – 10)</td>
<td>1.21 (p&lt;0.001)</td>
<td>2.58</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>4</td>
</tr>
<tr>
<td>Time to resume work (days)</td>
<td>2.9 (p&lt;0.001)</td>
<td>3.6</td>
<td>4.3</td>
</tr>
<tr>
<td>Indirect cost (€) Lost work</td>
<td>560</td>
<td>840</td>
<td>1120</td>
</tr>
<tr>
<td>Total costs (€)</td>
<td>1996</td>
<td>2200</td>
<td>2199</td>
</tr>
</tbody>
</table>
# Thermal Ablation: RFA or Laser

## Procedure Advantages
- Proven results and positive patient outcomes
- Outpatient / office based procedure
- Performed under local/tumescent anesthesia
- Resume normal activities within a few days
- Covered by most insurance providers

## Potential Complications
- Pain and bruising
- Potential skin injury
- Potential nerve injury
- Potential of DVT
- Need to wear compression stockings
Non Thermal Non Tumescent Ablation

**Mechanochemical Ablation**
- ClariVein

**Chemical Ablation**
- Varithena
- Venaseal
Mechanochemical Ablation: ClariVein System
Mechanochemical Ablation: ClariVein

Procedure Highlights

▪ Minimally invasive procedure
▪ Comparable vein occlusion rates acutely, need longer term data
▪ No requirement for tumescent anesthesia
▪ Minimal down time
▪ No requirement for compression post procedure
▪ Reimbursement issues
Chemical Ablation

- **Varithena - Polidocanol Endovenous Microfoam**
  - Ultrasound guided injected foam sclerosant – causes chemical injury and vein closure
  - Status of the trials – Safe
  - FDA approved 12/13
  - Reimbursement issues
  - Expensive
Varithena – Microfoam chemical ablation

• Local anesthesia only – no tumescent: only one or two small micro-catheter / needle entry sites

• No thermal injury risk

• Treat GSV, AASV, large varicose veins both above and below the knee

• Treat tortuous vessels

• Requires compression post procedure

• Early return to normal activities
Chemical Ablation
Venaseal™ Procedure:

Non-tumescent
Non-thermal
Non-sclerosant
Chemical Ablation: VenaSeal

- Cyanoacrylate glue
- Polymerizes when in contact with blood or plasma
- Inflammatory reaction results in vein occlusion
- No need for tumescence
- No need for post procedure compression stockings
- Rapid return to normal activities
- Reimbursement issues
Advantages of MOCA / Chemical Ablation

No tumescent anesthesia

- More comfortable for the patient
- Fewer needle sticks

No thermal injury risk

- Minimal risk for nerve, skin injury, DVT
- Treat lower ( calf, ankle, SSV ), treat tortuous veins

Reduced start up cost – no generator
Results from Endovenous Ablation

Before treatment

After treatment
Conclusions:

• Chronic Venous Insufficiency is a VERY common and significant disease – under diagnosed and under treated

• More than a cosmetic problem

• Superficial vein reflux is the predominate pathology

• Endovenous ablation therapies are effective and safe and have replaced surgical ligation and stripping

• Non–thermal endovenous techniques can potential replace thermal ablation. Awaiting long term results and reimbursement issues
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