Treatment of Superficial Venous Disease: They’re Not Just Varicose Veins

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Necessity Is The Mother Of Invention

• **Chronic Venous Disease**
  • Most Common Vascular Disease
    • >25 million people in the US are affected
    • Some estimates reach 50-60 million people
    • 20% of the adult population
    • 15% of men and 25% of women
    • Half of women over 50 years of age
    • A third of men over 50 years of age
    • As our population ages the disease will become more prevalent
  
  • Most Common Cause of Leg Edema
  • Aching Pain, Fatigue, Heaviness
  • Nocturnal Cramping + Restless Leg Symptoms = Insomnia
Necessity Is The Mother Of Invention

• Chronic Venous Disease
  • Sequelae: varicose veins, leg edema, skin discoloration, thickening, ulceration
• Almost 2 million working days are lost/year due to venous ulcers.

• Annual health care cost approx. $3 billion in the U.S.

• Associated with a reduced quality of life, particularly in relation to pain, physical function, and mobility.

• Associated with depression and social isolation.

• The impairment associated with advanced stages has been likened to the impairment associated with heart failure.

Necessity Is The Mother Of Invention

- Impacts A LOT of people
  - Medically
  - Psychologically
  - Socially
  - Financially
- Impacts our HEALTH CARE SYSTEM
- Impetus behind the development of today's treatment modalities
Necessity Is The Mother Of Invention

• How Can You Help?
  • Recognize chronic venous disease as a real medical disease
  • Understand treatment and who is suitable for treatment
  • Pass on the education to your patient

“Chronic venous disease is under appreciated, under diagnosed and under treated by the medical community.”
Who Needs Treatment?

Debridment as needed
Oral Antibiotics as needed
Good Wound Care!
Compression Therapy
Treat Underlying Superficial Venous Disease
Deep Vein and Outflow Obstruction Evaluation
Who Needs Treatment?
• 2011 SVS and AVF Practice Guidelines Published

• For patients with symptomatic varicose veins...recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation.

• The Diagnosis and Management of Varicose Veins

• Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

• Refer to a vein specialist any person with a symptomatic varicose vein, bleeding varicose vein or superficial vein thrombosis.

• It costs more health care dollars, not to treat varicose vein disease at any stage.

NICE clinical guideline 168, 2013
guidance.nice.org.uk/cg168

National Institutes for Health and Care Excellence
Stop Disease Progression

Varicose Veins ➔ ED Rule Out DVT Scan
Primary Care Visit
Blood work, CT Scan, Diuretics
New shoes!

Swollen Leg ➔ Dematologist Visit
Irreversible Skin Damage
Preulcerative changes
Pain
Jeans in the summer!

Skin Damage ➔ Wound Care
Antibiotics
Decrease Mobility
Depression
Pain

Skin Ulcers ➔
Time lost from work
Lost wages
Early retirement
Increase healthcare expenses
No vacations
No pool or beach
60% Recurrence Rate
The treatment of varicose veins, which can reduce the incidence of leg ulcers by 50% is cost-effective.
Venous Reflux → Venous Pooling → Venous Hypertension

- Disruption of the one way valve system
  - Thrombosis, dilation (multiple causes)

- Dilation to accommodate volume results in development of varicosities

- High pressure communicated to superficial compartment

- Varicosities, venectasia, telangiectasia
Identify Areas of Reflux
Venous Disease

**Manifestations of chronic venous insufficiency**
- Varicose veins
- Skin discoloration
- Venous ulcer
- Lower extremity swelling

**Mechanism of varicose vein formation**
- Incompetent venous valve: blood flows backward away from the heart and into the superficial system, causing venous congestion and high pressures within the superficial veins.
- Competent venous valve: ensures the forward flow of blood by preventing reflux of blood during the relaxation phase of the calf muscles.
Current Treatments

Surgical/Invasive

Conventional surgical ligation

Venous stripping

(1860 Trendelenberg/1905 Mayo/1950 Myers)

Minimally Invasive

EVLT ablation (2002)

Endovenous RFA (1999)

Ambulatory microstab phlebectomy (1992)

Sclerotherapy (STS 2004/POL 2010)
The Cure Is Worse Than The Disease

- **Conventional Surgical Treatment**
  - 71% successful
  - Pain
  - Scarring
  - 27% Nerve Injury
  - Lymphatic damage
  - Infection
  - 2.1% DVT
  - General anesthesia
  - 4 week recovery
  - 2-4 day bed rest
  - 30% symptomatic recurrence
  - 70% recurrent varicosities within 10 years

- **Endovenous Thermal Ablation**
  - 98% successful
  - Less pain
  - No cutting and no stitches
  - <1% DVT
  - Local anesthesia
  - Instantaneous recovery
  - 12% recurrent varicosities at 3 years
Catheter-Based Treatments

• Thermal Ablations
  • Endovenous Laser Ablation and Radio Frequency Ablation
  • Target veins include diseased saphenous truncal veins, accessory veins and large diameter tributary vessels
  • Suitable for diseased vessels > 3.5 mm in diameter, >0.4 mm below the skin and 5 cm in length
Catheter-Based Treatments

• Thermal Ablations
  • Endovenous Laser Ablation
    • Seldinger technique used to advance the laser fiber along the length of the diseased vein
    • Intravascular positioning confirmed by means of ultrasound
    • Tumescent solution with a local anesthetic is injected around the vein
    • The laser is fired producing endoluminal steam bubbles that destroys the endovascular endothelium
    • The laser is withdrawn as heat is generated leading to vein thrombosis and closure
  • Radio Frequency Ablation
    • Seldinger technique used to insert an introducer sheath into the diseased vein
    • The RF catheter is passed through the sheath and along the vein
    • Tumescent solution with a local anesthetic is injected around the vein
    • RF energy is delivered to the catheters heat coils at the tip of the catheter
    • RF thermal energy is applied directly to the vessel wall causing protein denaturation, collagenous contraction and immediate closure of the vessel
    • The RF catheter is withdrawn in short segments and the heat process is repeated until the entire vein length is treated
Catheter-Based Treatments

Outpatient procedure 30 minutes or less

Local anesthesia

No cutting and no stitches

Instantaneous recovery

Return to normal activities of daily living

Covered by most insurances
Treatment: Radiofrequency Ablation
Minimally Invasive Injection Treatments

• **Chemical Ablation**

• **Ultrasound guided foam sclerotherapy**
  • Treatment of extensive networks of varicose veins as an alternative to multiple stab phlebectomy,
  • Treatment of tortuous, superficial (less than 4mm deep) or small segments (less than 5cm in length) of saphenous truncal veins, saphenous branches and non-saphenous varicosities not amendable to laser or RF treatment,
  • Treatment of refluxing vessels in distal calf where injection with foam sclerosant is safer than thermal ablation in regards to preventing nerve injury,
  • Areas of neo-vascularization post-ablation/varicose vein surgery,
  • Venous networks surrounding venous ulcerations and
  • Where USGFS is the only approved treatment modality by the insurance carrier for treatment of symptomatic, incompetent, patent veins.
Introduction

Sclerotherapy works by injecting a chemical into the veins which causes them to collapse and fibrose.

The use of ultrasound enables the vein to be visualized so that the chemical can be injected into the vein under direct vision.

Foam preparation increases efficacy by displacing blood, preventing chemical dilution and prolonging chemical contact with vessel wall.
Ultrasound Guided Foam Sclerotherapy (USGFS)

• Procedure
  • Office based, takes 30 minutes of less.
  • Requires little or no local anesthesia.
  • More than one vein may be treated during the same session.
  • If any vein is incompletely treated, further injections may be given in the same or subsequent session.
Ultrasound Guided Foam Sclerotherapy (USGFS)

• Sclerosing Agents
  • Sotradecol - Sodium tetradecyl sulfate (STS)
    • Received FDA approval in 2004
  • Asclera - Polidocanol (POL)
    • Received FDA approval in 2010

• Different strengths of sclerosant are used for different sized veins

• Foam is made at bedside - Tessari method is most common
Ultrasound Guided Foam Sclerotherapy (USGFS)

• Post Procedure
  • Immediate return to normal activity
  • Walking encouraged
  • Limit vigorous exercise for 1-2 weeks
  • Recommend compression stockings for 3-14 days
Ultrasound Guided Foam Sclerotherapy (USGFS)

• Adverse Reactions
  • Blood Trapping- 30%
  • Staining and matting of the skin- 30%
    • due to hemosiderin in the skin as a result of extravasation of red blood cells
    • resolves spontaneously in 80 percent of patients within a year
    • occurs more commonly with Fitzpatrck skin types IV, V, and VI.
  • Headaches and transient vasospastic reactions- 2%
  • DVT- 1% to 3%
  • Allergy to compound- very rare
    • POL estimated 1 in 10,000
    • STS allergy risk 0.15%-0.30%
    • 5 deaths due to anaphylaxis published to date
  • Ulceration of the skin- very rare
    • typically does not occur with low concentrations, 0.1% to 0.5% STS
  • Stroke- 0.01%
    • 15 case reports since 1947
    • 13 case reports since 1994 (9 with foam and 4 with liquid sclerosant)
    • 3 patients with irreversible deficits
Ultrasound Guided Foam Sclerotherapy (USGFS)

• Closure Rates

• Foam Sclerotherapy 77% closure at 22 months

Ultrasound Guided Foam Sclerotherapy
Minimally Invasive Treatments

• Ambulatory Microstap Phlebectomy
  • Useful for removing any visual varicosities
  • Superficial saphenous varicosities at the time of saphenous vein closure
  • Superficial nontruncal tributaries
  • A microincision is made on top of the varicosity with a tiny blade or large needle
  • A phlebectomy hook or hemostat is introduced into the microincision and the vein is teased out through the incision
  • With light traction the diseased segment is pulled out until it breaks or is cut
Ambulatory Microstap Phlebectomy
Ambulatory Microstab Phlebectomy
Ambulatory Microstab Phlebectomy
Ambulatory Microstab Phlebectomy
Ambulatory Microstabil Phlebectomy
Clinical Outcomes

• Alleviation of symptoms
• Improved appearance
• No longer just based on vein closure rate
  • Quality of life scores (VCSS)
Ulcers Related to Vein Disease – Prevalence in the U.S.

• Difficult, if not impossible, to predict which patients with varicose veins will develop a leg ulcer.

• Venous ulcers cause the loss of approximately 2 million working days and incur treatment costs of approximately $3 billion each year in the United States.

• 40% of employed persons experience earning capacity limitations due to the ulcer.

• 5% lose their jobs due to the ulcer.

• 12% of patients with venous ulcers are forced to retire early.

• 80% of ulcers result in decreased mobility.

• Contribute to loss of quality of life, especially in the elderly.
 Venous Closure
Perforator Closure with RF and Laser

- 70 year old patient
- Ulcer for 17 years
- Performed perforator ablation with VNUS procedure
- Cleared ulcer within one month
Patient Name: TR
Date of Birth: 2/17/1936

Pre-Op Pictures Were Taken On 3/17/09

Post-Op Pictures Were Taken On 11/03/09
Patient Name: DS, M.D.,
Date of Birth: 10/13/1960

Pre-Op Pictures Were Taken On 8/19/2008
Right medial ankle ulceration

Post-Op 1 year pictures were taken on 10/13/2009
Ulcer remains healed and the patient remains symptom free and is able to run 4-5 miles a day on a daily basis again.
Patient Name: MP
Date of Birth: 10/11/22

Pre-Op Pictures Were Taken On 1/16/09

Post-Op pictures were taken on 8/03/09
Patient Name: HB
Date of Birth: 6/02/37

Pre-Op Pictures Were Taken On 1/9/09

Post-Op pictures were taken on 2/20/09
Pearls

- Common disease and not all need treatment
- Stage C2 (varicose veins) great time to intervene
  - Return the leg to normal
  - Prevent irreversible damage
  - Prevent escalating health care costs
  - Once edema develops risk to lymphatic system
- C4 disease or greater requires deep vein and outflow obstruction evaluation
Adjucts

- Use of graduated compression stocking to help prevent venous leg edema
- Implement pneumatic compression therapy to further assist in reducing venous leg edema
- Horse Chestnut Seed Extract
  - *a study published in The Lancet in 1996* — found that taking 50 milligrams of aescin (the active ingredient in horse chestnut seed) twice daily over 12 weeks worked just as well as wearing compression stockings for pain and edema due to venous insufficiency
- Vasculera diosmiplex flavonoid
New Treatments

• Mechanochemical Endovenous Ablation (MOCA) device uses a technique that combines mechanical endothelial damage using a rotating wire with the infusion of a liquid sclerosant- No need for tumescent solution. Clarivein catheter used.

• Varithena (1% POL) is the first chemical foam solution approved by the FDA to close the saphenous vein. FDA approved 2014. No anesthesia required.

• The most recent innovation in the treatment of varicose veins is the use of medical glue known as VenaSeal (cyanoacrylate) to physically shut down and seal the main defective vein.

• The ambulatory conservative hemodynamic correction of venous insufficiency (CHIVA) method is a minimally invasive surgical technique to treat varicose veins. The aim of the CHIVA treatment is to eliminate the venous-venous shunts by disconnecting the escape points, preserving the saphenous vein and normal venous drainage of the superficial tissues of the limb.
They’re Not Just Varicose Veins!

Over 30 million Americans are affected by varicose veins or C.V.I.

Only 1.9 million seek treatment annually.

The vast majority remain undiagnosed and untreated.