



Summer Veins: What's New in Varicose Vein Treatment

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Nothing to disclose

Chronic Venous Insufficiency

- More then 30 million Americans suffer from Varicose Veins or a more serious form of Venous Disease – Chronic Venous Insufficiency¹
- 10 times more common than PAD²
- Significant morbidity and lost productivity
- Varicose veins affect 25% of women and 10% of men in America

¹ Gloviczki P, et al. JVS; May 2011. ²Gordon P, et al. Soc for Vasc Nursing. 2012; Sept:10. Lower Extremity Venous Insufficiency vein valvular degeneration results in progressive vein dilatation causing varicose veins and ulceration



Varicose Veins 20+ million

Swollen Leg 6 million

Skin Changes 1 million

Skin Ulcer 500,000

Venous System Anatomy

The Normal Venous Anatomy



The Pathology of Varicose Veins





Muscle contraction returning blood to the heart

Valvular incompetence allowing reflux of blood while muscle relaxes



Saphenofemoral Reflux and Venous Hypertension

- Venous reflux
- Impaired return of venous blood from the legs or feet
- Dilated venous vessels in the legs or damaged/ absent vein valves



Risk Factors for Varicose Veins & Chronic Venous Insufficiency

- <u>Risk Factors</u>
- Older age
- Family history
- Deep Vein Thrombosis
- History of phlebitis
- Obesity
- Standing occupation
- Pregnancy
- Female Gender

- Other Risk Factors
- Smoking
- Hypertension
- Oral contraceptives or hormone replacement therapy
- Physical activity
- Constipation

Beebe-Dimmer JL, et al. Ann Epidemiol. 2005;15(3):175-184.

How Can We Treat This Disease?





Patient History

- Duration
- Common Complaints:
 - Leg Fatigue
 - Pain aching, heaviness, tiredness
 - Throbbing
 - Burning or tingling
 - Itching
 - Cramps
 - Pelvic pain

- Lifestyle limitations
- Prior venous surgery
- History of deep venous thrombosis
- Trial of conservative therapy and fails (documentation) – 3-6 months of support stockings/compression
- Use of medications
- Complications ulceration, thrombosis, bleeding

Physical Examination

- Visible varicosities
- Phlebitis
- Venous stasis ulceration
- Lipodermatosclerosis
- Edema



Lower Extremity Duplex Venous Evaluation





Initial Treatment Steps Required by most insurance companies

- Weight loss and exercise
- Elevation
- Anti-inflammatory medications
- Measured Compression stockings 20-30 mmHg and 30-40 mm Hg = wear while upright
- Assess pedal pulses, ? Co-existing arterial disease

Setting Realistic Expectations

- Most insurance companies require 3-6 months of conservative therapy
- Treatments are effective but recurrence or development of new varicose veins is common
- There are potential complications
- There is no cure a chronic problem

Patient Selection

- GSV reflux with symptoms

 Differentiate from cosmetic interests only
- Patent deep venous system
 May also be incompetent
- No known hypercoagulable condition
- Able and willing to be compliant with compression (i.e. stockings)

Indications for Treatment

- Asymptomatic varicose veins (cosmetic)
- Symptomatic varicose veins
 - Aching
 - Restless legs
 - Pain
 - Phlebitis
- Complicated varicose veins
 - Recurrent phlebitis
 - Edema, lipodermatosclerosis
 - Associated with venous dermatitis/ulcers



Treat Underlying Venous Valvular Abnormalities First

Great and Small Saphenous abnormalities



Guidelines for Surgery and Sclerotherapy

Concentration of Sclerosant

Vein Size	Hypertonic saline	STS (Sotradecol)	Polidocanol (Aethoxysklerol)
Telangiectasie (<1mm)	11.7-23.4% + lidocaine	0.125-0.25%	0.5%
1-3 mm	15-23.4% + lidocaine	0.5-0.75%	0.75-1%
3-6 mm		1-3%	2-3%
>6mm		Surgical treatment	
Saphenofemoral and saphenopopliteal		Surgical treatment	

Treatment of Saphenous Vein Reflux

- <u>Conservative management</u> with compression therapy
 - may improve the symptoms of chronic venous insufficiency but not a cure
- <u>High ligation and stripping</u>
 - eliminate incompetence using ligation of the saphenous vein at its deep vein junction and removal of the abnormal saphenous vein segments
- Thermal ablation
 - endovenous laser ablation (ELA) and radiofrequency ablation (RFA)
- Non-thermal, non-tumescent techniques

Established Minimally Invasive Techniques

- Axial Superficial Venous System
 - Venous Closure with Radiofrequency Ablation
 - Endovenous Laser Therapy
- Varicose Veins
 - Micro Phlebectomy
 - TRIVEX Phlebectomy
- Sclerotherapy

Open Surgical Approaches

- Ablation of superficial reflux
 - * Ablation of saphenous vein reflux
 - * Removal of varicose veins (phlebectomy)
- Elimination of perforator vein reflux
- Treatment of deep venous reflux
- Relief from deep vein obstruction

GSV High Ligation and Stripping





- Historical Gold Standard for over a century
- oblique incision 1 cm above and parallel to the groin crease

Endoluminal Ablation of the GSV Venefit Procedure (Closure)

- Radiofrequency Ablation (original procedure cleared by the US (FDA) in March 1999
- Newer methods of delivery of radiofrequency were introduced in 2007
- The ClosureFast[™] catheter heats the vein in 7 cm segments with 20-second treatment cycles, resulting in vein shrinkage and occlusion



RFA / Closure / Venifit



insertion of catheter





Catheter Closure Technique

goal for all thermal ablation procedures is to deliver thermal energy to the wall of an incompetent vein segment to produce irreversible occlusion, fibrosis, and ultimately disappearance of the vein



Disposable catheter inserted into vein

Vein warmed and collapses

Catheter slowly withdrawn, closing vein



Normal caprine vein wall



Fibrotic occlusion of vein lumen at 6 weeks

Pathophysiologic changes in the vein wall

Post Endoluminal Ablation

- Ultrasound of leg to rule out clot
- Compression stockings on continuously for 24 hours and then daily while upright for 3 weeks.
- Avoid heavy/strenuous exercise/ high impact activities for 3 weeks
- Frequent ambulation is encouraged
- Avoid prolonged sitting or standing
- Can anticipate soreness, erythema, discoloration along GSV for several weeks to months
- Follow up 2 weeks, 3 ,6,12 months

Echogenic GSV occlusion





Safety Summary

- Indication
 - The Closure System is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux
- Contraindications
 - Patients with thrombus in the vein segment to be treated
- Potential Risks & Complications
 - Potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, skin burns

Patient Symptom Relief

98% of patients with good result and long-term patient symptom relief



⁵ Weiss RA, Weiss MA. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: a 2year follow-up. Dermatol Surg 2002;28:38-42.

⁶ Merchant R. Long term outcome of endovascular radiofrequency obliteration for treatment of primary chronic venous insufficiency- five years follow-up of a multi-centre perspective study. Presented at 18th annual meeting of European Society of Vascular Surgery September 2004; Innsbruck, Austria. VN20-52-A 12/04



Endovenous Laser Therapy of GSV

- The mechanism of vein wall injury
 - mediated both by direct effect and indirectly via laser-induced steam generated by the heating of small amounts of blood within the vein.
 - adequately damaging the vein wall with thermal energy is imperative to obtain effective ablation



Endovenous Laser Therapy of the GSV

- Technique similar to EVA described above
- Diode lasers are most commonly used
- Laser generators exist with multiple different wavelengths
- No conclusive data demonstrating a superiority of a given fiber, wavelength and energy deposition combination, efficacy, significant adverse effects, or complications as metrics for comparison

Comparison of Results of Endovenous Ablation vs. Ligation & Stripping of GSV

- In general, there is an early post-operative advantage of Endovenous Ablation (EVA) on quality of life, but by one month the disease-specific scores were comparable.
- Return to normal activities and less postoperative pain favored EVA.
- Morbidity is less with EVA because vein is ablated in place (unless thrombophlebitis develops in the ablated vein – then there is pain)
- L&S involves stripping the vein with avulsion of branches and some tract bleeding.
- Use of Tumescent Anesthetic with both EVA and L & S lessens post-operative pain and bruising

Minimally Invasive Techniques

- National Institute of Clinical Excellence (NICE) guidelines recommend endovenous thermal ablation (July 2013) as first line tx
- Using thermal energy to denature vein wall
- Can cause pain, skin burns, skin pigmentation, nerve damage, AV fistula formation
- Require tumescent anesthesia

 Open Surgical Approaches to superficial and deep venous disease

Saphenous stripping

Perforator ligation

Phlebectomy

Timing of Phlebectomy relative to Endoluminal Ablation

- "Can phlebectomy be deferred in the treatment of varicose veins?"
- 54 legs in 45 patients
- complete resolution of visible varicose veins was seen in 13% of limbs after RFA alone,
- 63 (28.4%) varicose veins spontaneously resolved. A further 88.7% (141/159) of varicose veins decreased in size an average of 34.6% (4.3 ± 3.4 mm).
- Consider allowing for 6 months of vein improvement before having phlebectomy – result may depend on the distribution of the Varicosities

Monahan D, JVS 2005;42(6):1145-9

Micro Phlebectomy

Pre-operative Marking





Adjunct Therapies: Phlebectomy





Contraindications to Ambulatory Phlebectomy

- Deep Venous Thrombosis, obliteration or congenital abnormalities
- Infection
- Severe peripheral edema
- High risk
- Co-morbidity
- Elderly
- Allergy to local anesthetics

Post Operative Care

- No sutures
- Steri strips
- Gauze
- Compression
- Short period of observation in office or recovery



Minimally invasive treatment of perforator veins

 The ClosureRFS[™] stylet uses radiofrequency (RF) energy to treat incompetent perforator veins and tributary veins– a potential cause of bulging varicosities and leg ulcers.





Post-Operative Care

- Immediate and frequent ambulation
- Refrain from strenuous activity that may increase venous pressure (Valsalva) for one week
- Compression of 20-30 or 30-40 mm Hg for 2 weeks
- Non-narcotic pain reliever

Expected Results

- Results depend on complete treatment of underlying abnormalities
- Strict adherence to post operative regimen of ambulation and compression
- Complete resolution of visible varicosities
- Rapid recovery
- Resolution or improvement of symptoms

Complications

- Bleeding/ hematoma
- Scarring
- Pain

- Nerve injury or irritation
- DVT
- Infection
- Staining
 Blistering, skin
 Hyperpigmentation
 Phlebitis

Non-thermal Non-tumescent Techniques

- Advocated as an alternative solution
- Concept of foam sclerotherapy
- 1994 Orbach described combo air + sclerosing agent (air block technique)
 - not suitable for larger veins
- Sclerosing agent used as foam displace venous blood and increase endothelial contact
- When compared to surgery¹, EVLT, RFA – foam sclerotherapy has inferior occlusion rates^{2,3}

Darke SG, et al Br J Surg 2006;93¹ Rasmussen LH, et al Br J Surg 2011;98 Biemans AA, et al. J Vasc Surg 2013;58^{2,,3}



Tessari method 1 part liquid sclerosant : 4 parts air

Mechanochemical Ablation: ClariVein



- Combines an endovenous mechanical method using a rotating wire with simultaneous injection of liquid sclerosant
- 0.5 mm skin incision is made and with ultrasound guidance, a rotating catheter is inserted percutaneously into the saphenous vein

Suggested Advantages: ClariVein

- Disrupts the lining (the intima) of the vein allowing the drug to interact with epithelial receptors (superior to ultrasound guided sclerofoam)
- Compared to EVLT and RFA:
 - Safe, fast & effective procedure with minimal pain & discomfort
 - Negligible bruising
 - No risk of thermal damage
 - No risk of nerve injury
 - No multiple needle sticks injuries
 - No internal leg pressure
 - No need for tumescent anaesthetic
 - A rapid return to normal activities
 - 15 minutes to perform



ClariVein Short-term Results

- Elias and Raines¹ safety and efficacy
 - Mean vein diameter was 8.1 mm.
 - Treatment for each vein averaged 5 minutes and overall procedure time was 14 minutes
 - 30 patients at 6 mos 29 of 30 veins closed.
- Multicenter Venefit vs. ClariVein Study²
 - compare the degree of pain that patients experience
 - 119 patients
 - Maximum and average pain score was significantly lower in the mechanochemical ablation group
- 66% follow-up at one month
 - complete or proximal occlusion rates were 92% for both groups
 - clinical and quality of life scores for both groups had similar improvements.

¹Elias S, et al. Phlebology 2012;27. Booton R, et al. Phlebology; Sept 2014

Mechanochemical Ablation

Complications

- Superficial thrombophlebitis
- Induration along course of treated vein
- Localized hematoma
- Mild hyperpigmentation at puncture site
- Rotating wire getting caught
 - May give rise to ecchymosis, patient discomfort or resistance to pull back
- No reports of skin necrosis, DVT or nerve injury

VARITHENA™

- Injectable foam for the treatment of saphenous vein reflux
- A form of polidocanol
- VANISH-2: determine efficacy and safety of polidocanol endovenous micro foam in treatment of symptoms and appearance in patients with saphenofemoral junction incompetence
- 232 patients, polidocanol endovenous micro foam 0.5% and 1.0% were superior to placebo,
 - larger improvement in symptoms and greater improvements in physician and patient assessments of appearance (P < 0.0001)





VenaSeal[™] Sapheon Closure System

- Cyanoacrylate adhesive to embolize diseased vein safely and effectively
- close the saphenous vein, eliminating the need for surgery, ablation, anesthesia, or the use of harsh chemicals
- Percutaneously administered Cyanoacrylate adhesive to embolize saphenous vein safely and effectively
- FDA approval 2/20/2015



VenaSeal Closure System

- No tumescent, one needle stick, no support stockings needed, no risk of skin burn or nerve damage
- Return to normal activity right after procedure
- Multicenter cohort study¹ showed 12-mo. freedom from recanalization 92.9%
 - Complications: phlebitic reaction, one extension into CFV tx with LMWH
- Randomized trial²- CA embolization vs. RFA (VeClose) –at 3 months CA non-inferior to RFA

¹Proebstle TM, et al. JVS:Venous and Lym Dis 2014. ²Morrison N, et al. JVS Jan 2015.

VenaSeal Procedure





- Micropuncture kit, 7 Fr. Sheath, US, 0.035" guide wire
- 5-F delivery catheter, 3-mL syringe, dispenser gun
- Position tip 5 cm from SFJ, leg elevated 15°
- Initial double CA injection, 1 cm apart and 3 min localized compression over treated area
- Then 3-cm pull back and 30 sec compression

Sclerotherapy



Examples of Telangiectasia:





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Indications for Treatment of Varicies/ Telangiectasia

- Appearance
- Pain
 - aching, discomfort, itching
- Bleeding
- Skin changes with superficial ulceration

Treatment Options

- Chronic use of support hose
- Sclerotherapy
- Laser therapy



Before and after Sclerotherapy

Sclerotherapy

• GOAL:

- To scar (or sclerose) the veins shut so that they can no longer carry blood
- Scar tissue is reabsorbed by the body
- No longer visible
- No longer painful
- Blood is rerouted to other veins

- Informed consent
- Discuss:
 - Proposed procedure
 - Likely benefits
 - expectations
 - Possible complications
 - Multiple treatment sessions
 - Cost



Sclerotherapy Mechanism of Action

- Produces immediate endothelial cell damage
- Induces inflammatory response
- Thrombosis



Sclerosing Agents

<u>Detergents</u>	<u>Osmotic</u>	<u>Corrosive</u>
Sodium Tetradecyl Sulfate (Sotradecol)	Hypertonic saline	Chromated glycerin
Polidocanol (Sclerovein)	Hypertonic glucose	

Sclerosing Agents

• Vein Size < 1mm – Hypertonic Saline 15% – Sodium Tetradecyl Sulfate 0.1% – Polidocanol 0.3-0.5% Vein Size 1-2mm – Hypertonic Saline 23% – Sodium Tetradecyl Sulfate 0.25% – Polidocanol 1-2%

Aethoxysklerol® 1% Polidocanol 10 mg/ml

PHARMA

30 ml

Injectionslösung Injection solution Solución para inyecciones Injectievloeistof

Sclerotherapy Procedure

111111

Foam Sclerotherapy



Foaming Sotradecol



Flashback observed - in vein

- A sclerosing solution is mixed with air to produce foam and injected directly into the vein.
- causes irritation to the inner lining of the vein wall, leading to swelling and closure of the vein

Post-sclerotherapy Instructions

- Leg elevation
- Compression around the clock for 24-72 h
- Support hose daily for 7-21 days, then as prescribed
- No vigorous exercise for 1-2 weeks

Results of Sclerotherapy

Spider veins - very successful

- Any symptoms resolve quickly
- Can look inflamed for several weeks
- Best visual effect in 6 to 10 weeks
- Unsuccessful sites can be re-done timing
- Varicose veins success depends on size
 - Thrombosis causing lumpiness slow to resolve
 - Hyperpigmentation
 - Unsuccessful sites can be re-done

- Unsuccessful injection
- Ineffective injection
- Ecchymosis
- Matting
- Superficial thrombophlebitis
- Hyperpigmentation
- Blistering with or without scarring
- CNS symptoms
- Allergic reaction

Pigmentation

- Related to extravasation of RBC's → hemosiderin deposits
- brown streaks in 10-30% of cases of telangieactasia
- 80% resolve spontaneously between 6-24 months
- can occur with any of the agents
- microthrombectomy may diminish the incidence



- Skin Necrosis
 - Too high concentration of the sclerosant for the selected vein
 - Extravasation
 - Excessive pressure in the syringe
 - Fast injection
 - Injection into an arteriole (red spider veins)
- Skin Ulceration
 - Uncommon: 0.2 1.2% of patients
 - Caused by extravasation of agent bleb

Telangiectatic Matting

- Development of reddish area of very fine vessels in the surroundings of the injected vein
- Occurs in 15 20%
- Reactive inflammatory process with angiogenesis
- May resolve spontaneously
- Deep Venous Thrombosis
 - Rare
 - Associated with injections into large segments of varicose veins 8mm or more with high concentration agents

Laser Therapy

- Adjuvant therapy after surgical procedures
 - Residual spider veins
 - Matting
- Effective treatment for telangiectasias
- Probably not as effective as sclerotherapy



- Venous disease is a cause of major morbidity
- New highly effective modalities are available in treating this disease
- Minimally invasive techniques have equivalent early results to the classical modalities with less discomfort and earlier return to daily activities
- Need realistic goals for treatment in both therapeutic and cosmetic treatments





THANK YOU

Knowing changes everything."



