

MHIF FEATURED STUDY:

Proact Xa

COMING SOON!

EPIC message: *Research MHIF Patient Referral*

CONDITION:

Anticoagulation therapy with On-X aortic valve

PI:

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RESEARCH CONTACT:

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SPONSOR:

CryoLife Inc.

DESCRIPTION:

A prospective, randomized, active (warfarin) controlled, parallel-arm clinical trial to determine if patients with an On-X aortic valve can be maintained safely and effectively on the factor Xa inhibitor apixaban.

There is an unmet need for an alternative anticoagulant drug (such as apixaban) to use instead of warfarin in participants with an aortic mechanical prosthetic valve. Patients will be randomized 1:1 apixaban versus warfarin 90 days or greater s/p surgery.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

1. 18 years or greater
2. Able to receive warfarin with a target INR of 2.0-3.0
3. Implantation of an On-X mechanical valve in the aortic position at least 90 days prior to enrollment

Exclusion:

1. Mechanical valve in any other position other than aortic
2. Any cardiac surgery 90 days prior to enrollment
3. Need to be on aspirin > 100 mg daily or a P2Y12 inhibitor
4. On dialysis or creatinine clearance of < 25 mL/min
5. Stroke within 3 months of enrollment

Providing an alternative to warfarin may lead younger patients to choose a mechanical valve with greater durability and better clinical outcomes.

Venous Insufficiency Between Diagnosis, Management and Outcome

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Disclosures



Previous consulting and speaking for Pfizer, BMS, J&J, B.I. and BSC



No financial conflict related to this talk



Received one medical fund from Medtronic for a medical mission



Peer reviewed

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Learning Objectives



Pathophysiology of different venous disorders



Medical management of venous insufficiency



Risk and benefit of different interventions



Outcome and follow up



Summary



Wide Range of Venous Disorders and Presentations



Morphologic: spider, reticular or varicose veins, skin discoloration or ulceration



Functional: venous reflux +/- loss of pumping mechanism



Anatomic: thrombosis, congenital anomalies



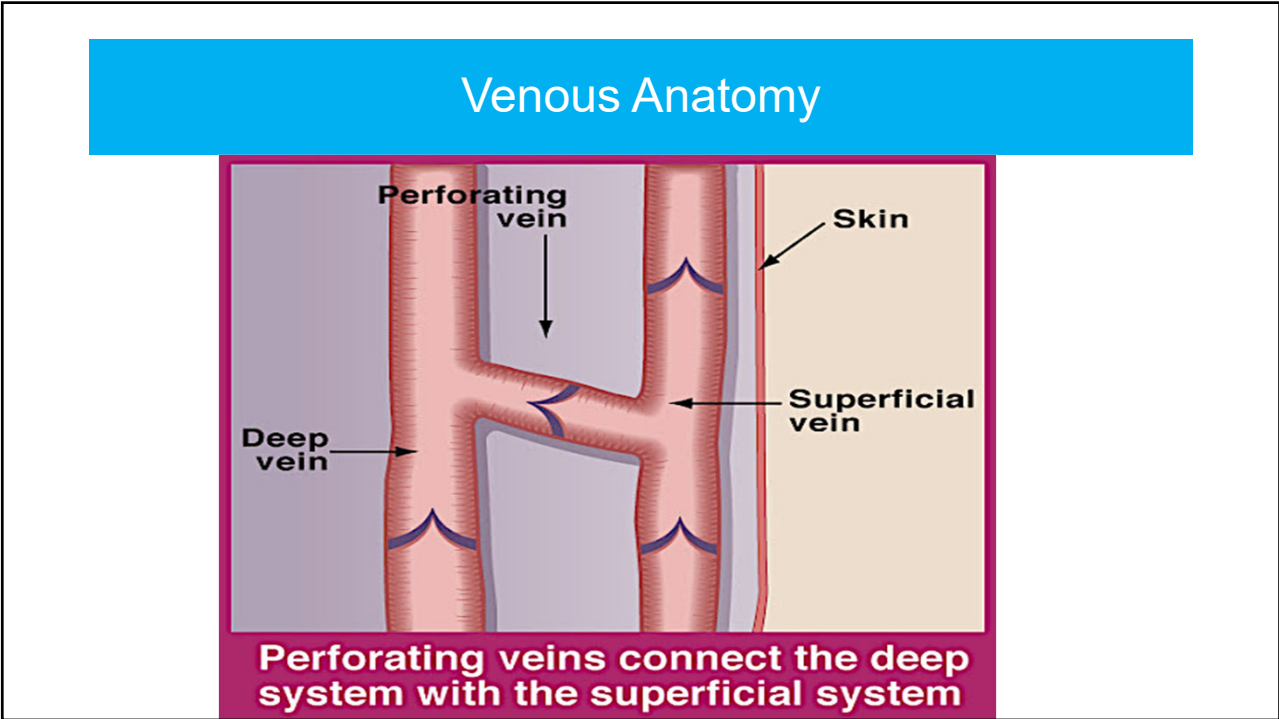
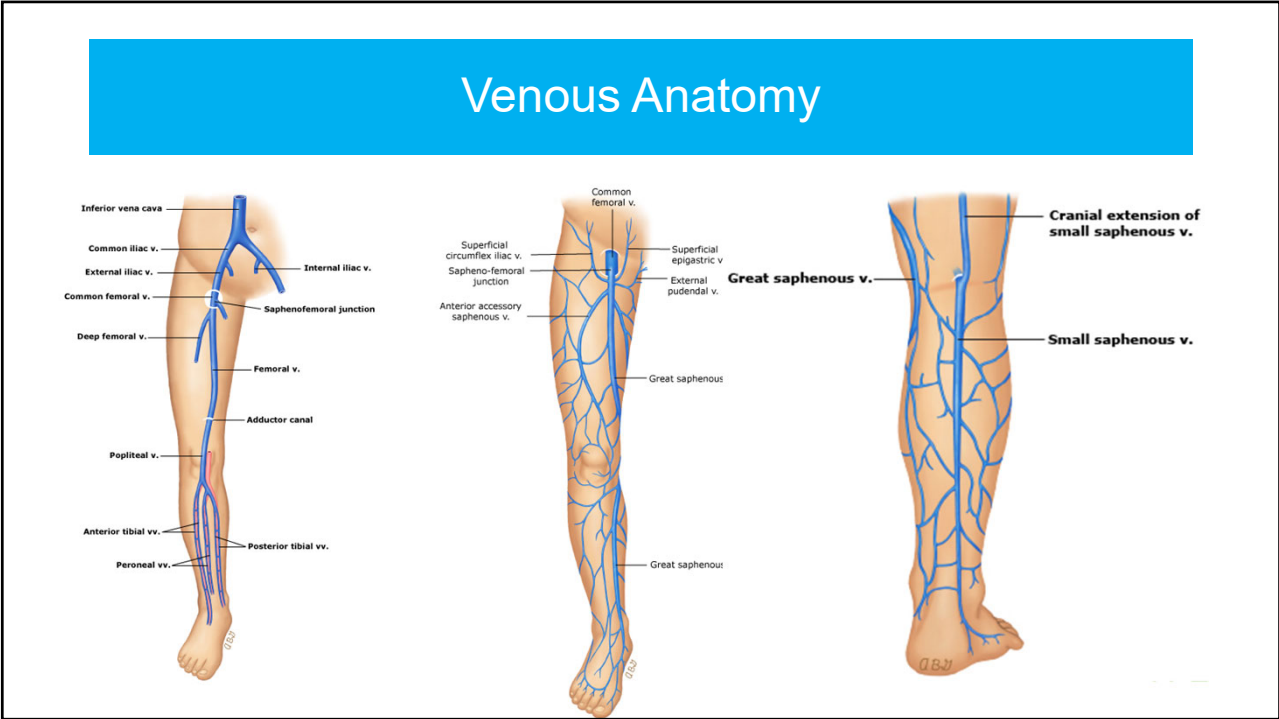
Multifactorial: More than one disorder



Presentation: symptomatic vs asymptomatic

J Vasc Surg 2011; 53:2S.





Pathophysiology

Incompetent valves (reflux)

Inadequate muscle pump function

Venous thrombosis

Venous stenosis


Venous Hypertension


Vein dilation (varicosity)

Skin changes

Skin ulceration

J Vasc Surg 2014; 60:1S.


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Epidemiology

- **Chronic vein abnormalities:** up to 50 % of individuals (varies based on the study)
- **Prevalence:** higher in Western Countries (life-style?)
- **Venous insufficiency:** affects approximately 25 million American adults annually
- **Varicose veins:** impact 25-50% of women and 7-40% of men
- **Within 5 years from a procedure:** 50% of contralateral legs will become symptomatic

Circulation. 2014; 130: 333-346
Am J Prev Med; 4 (2):96-101

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Risk Factors

- **Strong family component:**
 - Both parents: 90%
 - One parent:
 - 62% women
 - 25% men
 - Neither parent: 20%
- **Others:**
 - Venous aneurysm
 - AV shunts
 - May Thurner syndrome
 - Radiation

Circulation. 2018;138(25):2869
Circulation. 2014; 130: 333-346.

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Clinical Features

- Correlates with the severity of the venous reflux and age
- **Asymptomatic**
- **General:** heaviness, aching, swelling, dryness, tightness, itching, irritation, cramping
- **Veins:** Telangiectasias (<1 mm), reticular (1-3 mm), small (3-6 mm) and large varicose (>6 mm) veins
 - Telangiectasias and reticular veins (50-66% of individual)
 - More common in females
- **Severe:** edema, skin hyperpigmentation, lipodermatosclerosis and stasis ulcers

J Vasc Surg. 2004;40(4):650.

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Reticular and Telangiectatic Veins, Corona Phlebectasia



Varicose Veins



Edema with Stasis Dermatitis and Ulcers



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Venous Stasis Ulcers



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Disease Severity: CEAP Classification

CEAP Classification	Clinical manifestation
0	No visible or palpable signs of venous disease
1	Telangiectasias or reticular veins
2	Varicose veins
3	Edema
4	Pigmentation, eczema, lipodermatosclerosis or atrophie blanche
5	Healed venous ulcer
6	Active venous ulcer

J Vasc Surg. 2010 Apr;51(4):900-7.



Venous Clinical Severity Score (VCSS)

Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily	Daily w/ meds
Varicose Veins	None	Few	Multiple	Extensive
Venous Edema	None	Evening only	Afternoon	Morning
Skin Pigmentation	None	Limited, old	Diffuse, more recent	Wider, more recent
Inflammation	None	Mild cellulitis	Moderate cellulitis	Severe
Induration	None	<5cm focal	<1/3 gaiter	>1/3 gaiter
No. Active Ulcers	None	1	2	>2
Active Ulcer Site	None	<2cm	2-6cm	>6cm
Ulcer Duration	None	<3mo	3-12mo	>1yr
Compression	None	Intermittent	Most days	Fully comply

J Vasc Surg. 2011; 54 (19S): 2S-9S.



Disease Progression

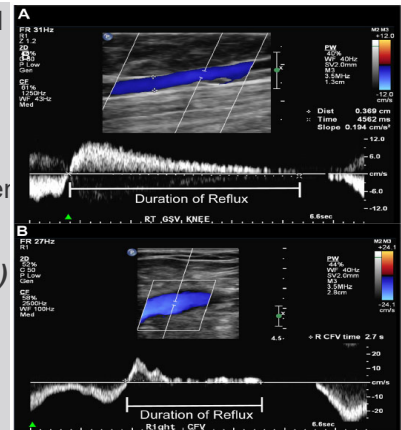
- Usually correlates with the severity of the venous reflux and age.
- Not well understood! different severity with similar venous anatomy & pathology.
- Possibly related to patient life-style, genetics, inflammation..
- Fibrinogen-to-albumin ratio was a sensitive (75%) and specific (87.5%) marker for determining severity (based on CEAP).

J Vasc Surg. 2010 Apr;51(4):900-7.



Diagnosis

- **Combination:** suggestive history, symptoms, exam findings and
- **Typical symptoms:** leg pain, heaviness, cramping..
- **Physical exam findings:** spider, reticular or varicose veins, edema
- **Venous insufficiency duplex US (standing or on tilted table!)**
 - Reflux of > 0.5 sec for superficial or perforator veins
 - Reflux of > 1.0 sec for deep veins



J Vasc Surg. 2003;38(4):793.
Eur J Vasc Endovasc Surg. 2006;31(1):83.



Differential Diagnoses

Edema

- Cardiac, renal or hepatic
- Lymphedema, lipedema
- DVT, prolonged standing, medications (CCB)
- Hypothyroidism, obesity and OSA

Skin Manifestations

- Autoimmune disease
- Hydroxyurea
- Acrocyanosis, PAD
- Liver disease, hyperthyroidism and DM)

Vein Engorgement

- Thrombosis
- Stenosis (MTS)
- Right side CHF, pulmonary HTN
- Hereditary hemorrhagic telangiectasia

J Am Acad Dermatol. 2007;57(5):814.

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Pre-Management Considerations

• Veins involved and reflux severity:

- Superficial and or deep
- Proximal or distal
- Multiple or single

• Comorbidities:

- Deep vein reflux and or thrombosis
- CHF or pulmonary HTN
- Lymphedema or lipedema
- OSA or morbid obesity

Arch Intern Med. 2005;165(12):1420.

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Asymptomatic

- Telangiectatic, reticular or small varicose veins
- CEAP 1 or 2
- Normal venous insufficiency US
- No underlying comorbidities
- Cosmetic reasons

Arch Intern Med. 2005;165(12):1420



Asymptomatic: Management

- **Visual sclerotherapy:** first option
- **Surface laser therapy:** might cause hypopigmentation
- **Complications:** skin discoloration, hyperpigmentation, ulceration, scars
- Several session
- Reimbursement issues..

Arch Intern Med. 2005;165(12):1420



Symptomatic

• Conservative therapy recommended for all symptomatic patients:

- Compression therapy
- Exercise (walking..)
- Leg elevation
- Skin care

• Vein procedures: factors to consider

- Disease severity (CEAP IV-VI, sometime III)
- Failure of conservative therapy
- Venous anatomy and function
- Patient expectations !

J Vasc Surg. 2014 Aug;60(2 Suppl):1S-2S.

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Conservative Therapy



• Leg elevation:

- Heart level for 30 mins 3-4 times/day
- Improves cutaneous microcirculation
- Reduces edema
- 41% increase in blood flow
- Promotes venous ulcer healing

• Exercise:

- Daily walking
- Ankle flexion exercises
- Safe and effective
- Adding exercise to compression improves wound healing

• Compression:

- Few high-quality data
- Symptom improvement
- Challenges:
 - ✓ Tolerability
 - ✓ Cost

J Vasc Surg. 2009;49(5):1242.
Int Angiol. 1994;13(2):119.



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Pharmacologic Therapy and Skin Care

<p>Vasoactive drugs:</p> <ul style="list-style-type: none"> • Hydroxyethylrutoside • Horse chestnut seed extract • Micronized purified flavonoid fraction (MPFF; Daflon= Detralex) 	<p>Rheologic agents:</p> <ul style="list-style-type: none"> • ASA • Stanazol • Pentoxifylline • Prostacycline analogues • Sulodexide • Defibrotide 	<p>Skin care:</p> <ul style="list-style-type: none"> • Topical steroids • Topical antibiotics • Debridement • Dressing • Hyperbaric oxygen therapy
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Cochrane Database Syst Rev. 2016;4:CD003229. Epub 2016 Apr 6.

Available Interventional Options

<p>• Sclerotherapy:</p> <ul style="list-style-type: none"> - Visual - US guided +/- 	<p>• Vein Closure Procedures:</p> <ul style="list-style-type: none"> - Thermal: Radiofrequency (RFA) or endovenous laser ablation (EVLA) - Chemical adhesive (cyanoacrylate) embolization (VenaSeal) +/- - Mechanical occlusion chemically assisted (MOCA) (ClariVein) - Polidocanol endovenous microfoam (PEM) (Varithena) 	<p>• Surgical:</p> <ul style="list-style-type: none"> - Phlebectomy - Ligation - Stripping
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J Vasc Surg. 2014 Aug;60(2 Suppl):1S-2S.
 J Vasc Surg. 2014 Aug;60(2 Suppl):1S-2S.

Pre-intervention Measures

Venous anatomy:

- Vein Mapping US: standing!
- Saphenous and Sural nerves:
 - Sensory nerves
 - Injury of either causes neuralgia

Preoperative medications:

- Aspirin and OAC:
 - Hold if bleeding > thrombosis
- Prophylactic antibiotics:
 - If skin changes and stasis ulcers
- Thromboprophylaxis:
 - In high risk (hx of VTE)

Anesthesia:

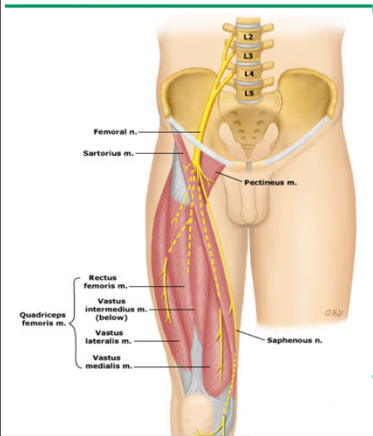
- Oral: valium
- Conscious: fentanyl + midazolam
- Light sedation: propofol
- Tumescent anesthesia:
 - Dilute mixture of epinephrine, lidocaine and bicarb

Ann Vasc Surg. 2012 Jul;26(5):612-9.
Vasc Med. 2015 Apr;20(2):117-21.

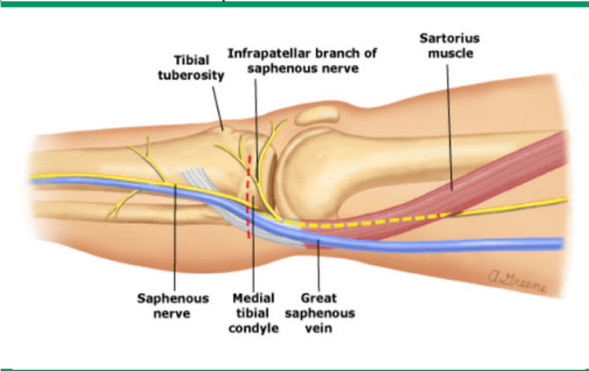


Femoral, Saphenous and Sural Nerves

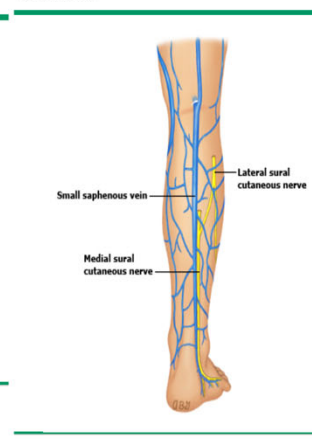
Femoral nerve anatomy



Saphenous Nerve



Sural nerve



Courtesy: UpToDate



Thermal Ablation (RFA or EVLA)

Using RF or laser energy to heat the refluxing axial or perforator veins using a catheter, fiber or stylet.

Indications:

- Persistent symptoms
- Signs of superficial venous disease despite conservative therapy
- Severe disease (CEAP 4-6)
- Documented axial venous reflux (> 0.5 sec)

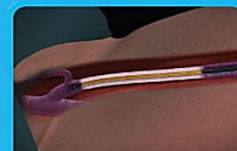
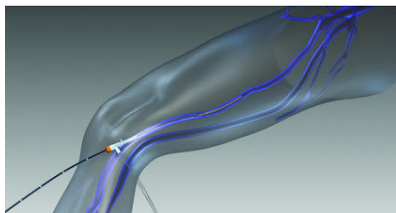
Relative Contraindications:

- Acute vein thrombosis (exception: distal GSV thrombus with patent proximal segment)
- Pregnancy
- Ulcer with concurrent severe arterial disease
- Concurrent severe deep incompetence...

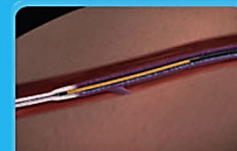
J Vasc Surg. 2011;53(5 Suppl):2S.
Eur J Vasc Endovasc Surg. 2012 Jun;43(6):726-8.



Radiofrequency Ablation (RFA)



1. Catheter tip positioned at the ostium of the superficial epigastric vein. Tumescence infiltration is administered.



2. 7 cm vein segment treated all at once during 20-second treatment cycle. Additional vein segments treated serially.



3. Catheter shaft markings allow fast and accurate catheter re-positioning between treatment cycles. No energy is delivered during re-positioning.

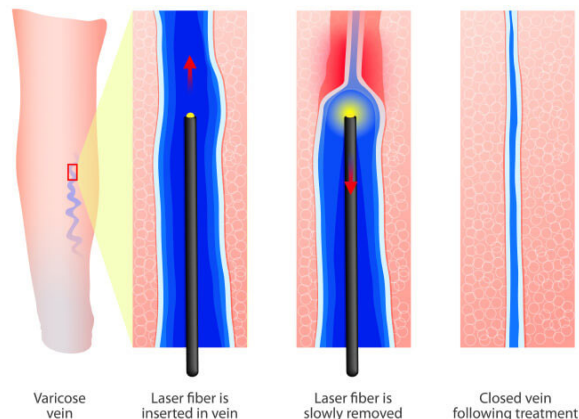


4. Treatment of 45 cm vein length takes 3 to 5 minutes (seven treatment segments).

J Vasc Surg. 2011;53(5 Suppl):2S.
Eur J Vasc Endovasc Surg. 2012 Jun;43(6):726-8.



Endovenous Laser Ablation (EVLA)



J Vasc Surg. 2011;53(5 Suppl):2S.
Eur J Vasc Endovasc Surg. 2012 Jun;43(6):726-8.



Closure Rates and Recurrence (RFA)

- **Saphenous RFA:**
 - Immediate closure rate: 89-94%. Can reach up to 99.6% based on technique!
 - VCSS: 3.9±2.1 before to 0.9±1.5 at 3 months, maintained at <1 – 2 years
 - Reopening: 15-19% at 3 years and in 26-30% at 3-5 year follow-up
- **Perforator RFA:**
 - Immediate occlusion: 78- 82%
 - Reopening: 19% at 5 years follow-up

J Vasc Surg. 2011;54(1):146.
J Vasc Surg. 2005;42(3):502.



Closure Rates and Recurrence (EVLA)

- **Saphenous EVLA:**
 - Immediate closure rate: 90-100 %.
 - Three years closure rate: 94%
 - Failure reasons: diameter >2 cm
 - Recurrent VV: up to 1/3rd
- **Perforator RFA:**
 - No enough data available, ~ 77%

J Vasc Surg. 2009;49(1):230.
Dermatol Surg. 2012 Apr;38(4):640-6.



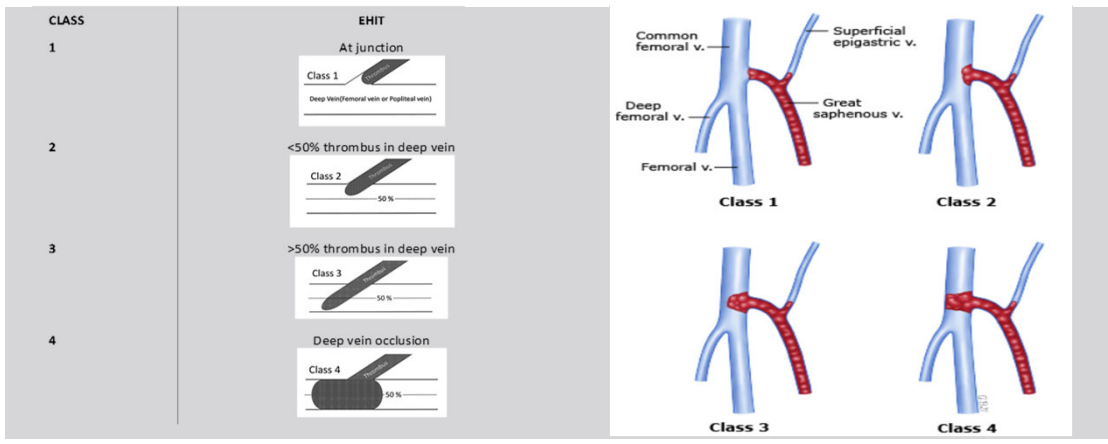
Complications (RFA and EVLA)

- **Local Events:** hematoma (1 - 5% in EVLA), bleeding, burn or skin hyperpigmentation (<1% with RFA)
- **Symptomatic phlebitic reaction:** 0 - 5.2%, higher with concurrent phlebectomy
- **Nerve injury:** sensory abnormality (0 - 22% with RFA and 1 - 7% with EVLA)
- **DVT:** < 1% at experienced centers for RFA and 0 - 2.3% for EVLA
- **Loss of guidewires, sheaths or fibers into the circulation:** very rare!
- **Endovenous heat induced thrombosis (EHIT):** ...

Ann Plast Surg. 2015 Jan;74(1):64-8.
J Vasc Surg. 2004;40(3):500.



Kabnick Classification of EHIT



Kabnick LS. Thrombus at the SFJ after endovenous ablation: What should I do now? Third International Vein Congress: In-office Techniques. Miami, FL 2005.



Endovenous Heat Induced Thrombosis (EHIT)

- **Reported Rate:** 0-11.7%
- **Our Rate (n: 642 RFA):** 6.6%: 1.2% high-grade (class: 3-4) and 5.4% low-grade (class: 1-2)
- **Risk factors:**
 - Treated vein size (>8mm)
 - Catheter distance from the femoral vein (2 vs 2.5 cm)
 - Concurrent procedures : sclerotherapy
 - History of DVT
 - Left common femoral or right femoral vein incompetence (our series)
 - DM for high grade (our series)

J Vasc Surg. 2010;52(2):388.
 J Vasc Surg Venous Lymphat Disord. 2013;1(3):257.



Management of EHIT

- Best way is prevention taking in consideration risk factors
- **EHIT 1-2:** conservative therapy (warm compresses and NSAIDs)
- **EHIT 3-4:** aspirin or a DOAC like rivaroxaban or apixaban
- **Outcome:** Most thrombi resolve in 1-2 weeks at what time antithrombotics can be discontinued

J Vasc Surg. 2010;52(2):388.



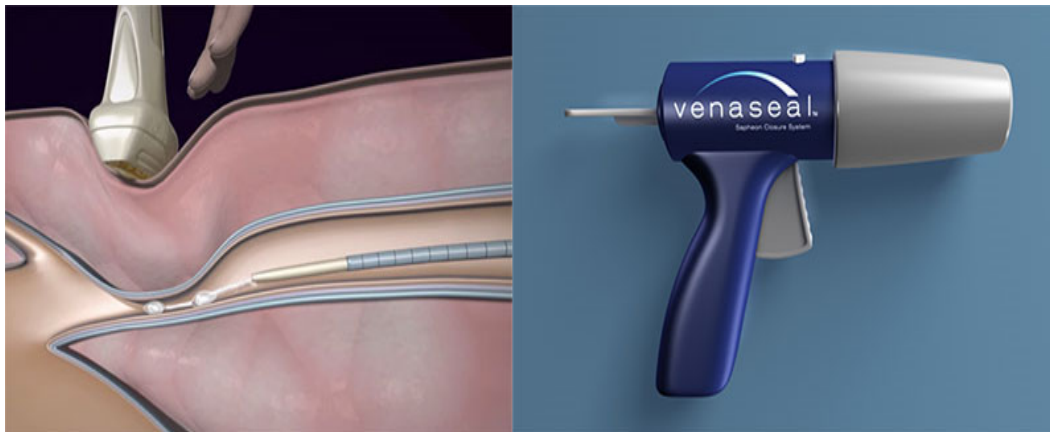
Chemical Adhesive (Cyanoacrylate) Embolization *VenaSeal*

- Injecting 0.5 mL of cyanoacrylate glue during segmental catheter pullback combined with compression.
- No need for tumescence!
- May treat distal GSV
- **Outcomes:**
 - At 3 months: Similar to RFA with no serious complication
 - At 36 months: GSV closure rates were 94.4% vs 91.9% with RFA
- **Adverse event:** *Less nerve injuries!*
 - Local reactions to the glue: cellulitis or phlebitis
 - Systemic reaction: very rare

J Vasc Surg. 2015;61(4):985.
Phlebology 2019 Jul; 34(6): 380-390.



Chemical Adhesive (Cyanoacrylate) Embolization *VenaSeal*



J Vasc Surg. 2015;61(4):985.
Phlebology 2019 Jul; 34(6): 380-390



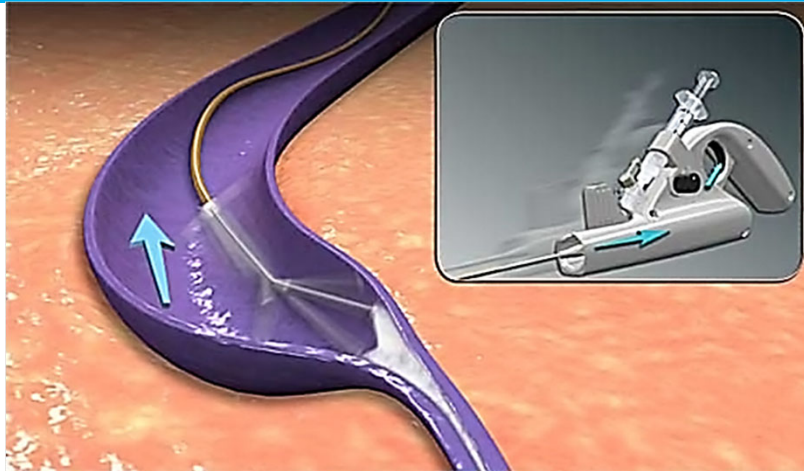
Mechanical Occlusion Chemically Assisted (MOCA) *ClariVein*

- Uses an agitating wire to injure the vein while injecting a sclerosant (polidocanol or STS)
- 1-year closure rate: 82%, lower than thermal ablation or chemical adhesive closure
- No tumescence anesthesia or foreign body
- May treat distal veins
- More thrombophlebitis

Eur J Vasc Endovasc Surg. 2013 Mar;45(3):299-303.



Mechanical Occlusion Chemically Assisted (MOCA) *ClariVein*



Eur J Vasc Endovasc Surg. 2013 Mar;45(3):299-303.



Polidocanol Endovenous Microfoam (PEM) *Varithena 1%*

- VANISH-1 and 2 confirmed efficacy and safety (based on symptom score and visible veins)
- Uniform microbubble: better wall adherence and less systemic complications (neurologic)
- *Good for tortuous veins and branches*
- *No tumescent anesthesia*
- **Closure success:**
 - Closure rate at 8 weeks: 80.4-86.2%
 - Immediate and long-term closure rates: lower than RFA, EVLA, MOCA, and chem adhesive!



J Vasc Surg Venous Lymphat Disord. 2018;6(2):256.
Eur J Vasc Endovasc Surg. 2008;36(3):366.



Sclerotherapy (*visual or US guided*)

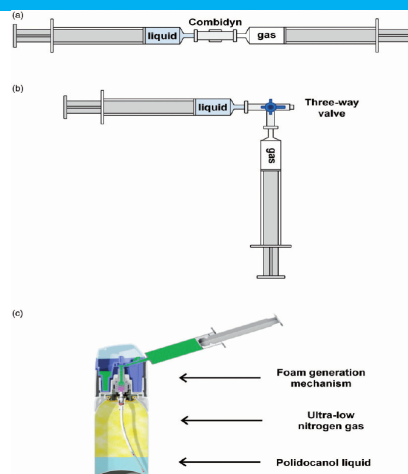
- Minimally invasive technique using chemical irritants to close unwanted veins
- Treatment of telangiectasias, reticular veins, and small varicose veins (<6 mm)
- Liquid or foam for symptomatic or asymptomatic
- Higher concentrations using foam may treat incompetent perforators or saphenous veins
- Multiple sessions, process!!
- Foam vs Liquid sclerotherapy closure at 3 weeks and 2 years: 84 vs 40 % and 53 vs 12%
- Median recurrence with foam sclerotherapy: 8.1%

Cochrane Database Syst Rev. 2011

Cochrane Database Syst Rev. 2006



Methods to Produce Foam



J Vasc Surg Venous Lymphat Disord. 2018;6(2):256.
Eur J Vasc Endovasc Surg. 2008;36(3):366.



Sclerotherapy/Laser Light

- **Sclero is favored over Laser/light treatments:** no risk for hypopigmentation
- **Laser/light:** Only for very small telangiectasias or failed sclerotherapy
- **Side effect:**
 - Minor pain (least with polidocanol)
 - Ulcers (1-5%), skin necrosis
 - Thrombosis (thrombectomy)
 - Hyperpigmentation (less with STS, avoid sun and hot weather)
 - Anaphylaxis (very rare)

Cochrane Database Syst Rev. 2011
Cochrane Database Syst Rev. 2006



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Sclerotherapy



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Agent, Class, Concentration	Advantages	Disadvantages	Vessel Size (mm)	Concentration (%)	Injection Vein (mL)	Max Dose
Polidocanol <i>Detergent</i> 1 and 3%	Less painful	Allergy	< 0.5	0.25-0.5	0.25	3% sol
	Not toxic	Telangiectatic matting	0.5-1	0.5-0.75	0.5	50 kg: 5 mL
	Rare ulceration	Hyperpigmentation	1-3	0.75-1	0.5-0.75	60 kg: 6 mL
	No skin necrosis		3-5	1-2	0.75-1	70 kg: 7 mL
			>5	3-5	To max	80 kg: 9 mL...
Sodium tetradecyl sulfate (STS) <i>Detergent</i> 1 and 3%	Less telangiectatic matting	Allergy	0.2-1	0.1-0.3	0.25	10 mL of 3% solution
		Hyperpigmentation	1-3	0.25-0.5	0.5	
		Ulceration/necrosis	3-5	0.5-1	0.5-1	
		Extravasation at higher concentrations	>5	1.5-3	To max	
Hypertonic saline <i>Osmotic</i> 14.6 and 23.4%	No allergy	Pain	< 0.5	11.7-15	0.25	None
		Muscle cramping	0.5-1	117.15	0.5	
		Ulceration/necrosis	1-3	15-23.4	0.5-1	
		Hyperpigmentation	3-5	-	-	
			>5	-	-	
Glycerin <i>Osmotic</i> 72%	No matting	Highly allergenic contact sensitivity	<1	25-72	0.25	10 mL of 72% solution
	No ulceration	Rare: Hematuria and urethral colic				
	No necrosis	Difficult to work with (extremely viscous)				



Cochrane Database Syst Rev 2006; 18: CD001732
Dermatol Surg 2002; 28:52
Eur J Vasc Endovasc Surg 2007; 34:731
J Dermatol Surg Oncol 1990; 16:800
J Vasc Surg 1989; 29:479
J Dermatol Surg Oncol 1990; 16:327
J Am Acad Dermatol 1989; 20:643



Incompetent Perforator Vein Treatment with USGS

- Success rate: 98% at time of treatment
- Ulcer healing: observed in 32/37 (86%) limbs
- >1 treatment was required in 12/37 (32%) limbs due to recurrent perforators
- Closure rate up to 5 years: Approximately 75 %
- Clinical improvement: sustained at a mean follow-up of 20.1 months

J Vasc Surg. 2006;43(3):551



Vein Closure and Wound Healing

ORIGINAL ARTICLE

A Randomized Trial of Early Endovenous Ablation in Venous Ulceration

- **Patients:** 450 patients with venous leg ulcers
- **Intervention:**
 - Early intervention: compression therapy + early endovenous ablation (thermal or non- thermal) within 2 weeks after randomization **vs**
 - Deferred intervention: compression therapy alone, with ablation deferred until after the ulcer was healed or until 6 months after randomization
- **Results:** Early ablation resulted in faster healing ($P=0.001$, median time 56 days) and more time free from ulcers than deferred ablation ($P=0.002$ during 1st year)

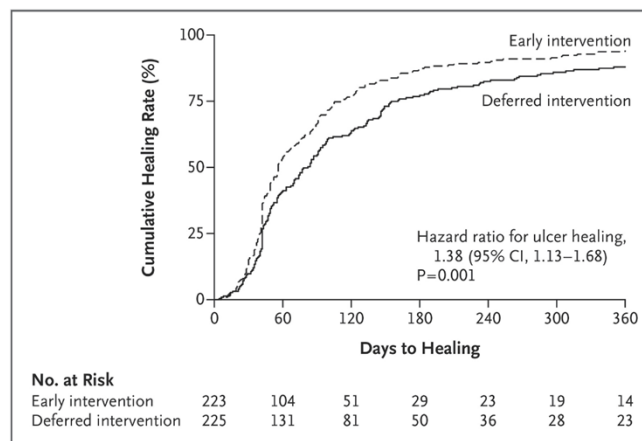
N Engl J Med 2018; 378:2105-2114



Vein Closure and Wound Healing

ORIGINAL ARTICLE

A Randomized Trial of Early Endovenous Ablation in Venous Ulceration



N Engl J Med 2018; 378:2105-2114



Direct General Comparison (CRTs)

- **RFA vs EVLA:**
 - Clinical outcomes at 6 weeks: similar
 - Postop pain: more with EVLA (mean pain score 34 versus 22)
- **Thermal (RFA or EVLA) vs chemical adhesive (cyanoacrylate) embolization:**
 - 2-yr occlusion rates and complication: similar
 - Pain, return to work and VCSS reduction: glue was superior
- **Thermal (RFA or EVLA) ablation vs mechanical occlusion chemically assisted (MOCA):**
 - 1-yr occlusion rates: higher with RFA and EVLA vs MOCA (100, 100 vs 82%)

Br J Surg. 2010;97(6):810.
Eur J Vasc Endovasc Surg. 2018;56(4):553.
Br J Surg. 2019;106(5):548.



Technique Comparison



	Treated vein	Technique	Adverse Reactions
RFA	GSV, SSV, AASV, IPV	Thermal ablation	EHIT
	Non-tortuous veins	Tumescence	Nerve injury
EVLT	GSV, SSV, AASV, IPV	Thermal ablation	EHIT
	Non-tortuous veins	Tumescence	Nerve injury and skin burns
Cyanoacrylate Glue	GSV, SSV, AASV (<10 mm)	Glue (foreign body)	Phlebitis
	Non-tortuous veins	No tumescence Compression may not be needed	Hypersensitivity to glue
MOCA	Veins <12 mm	Sclero may diffuse in branches	Sclero related
	Non-tortuous veins	No tumescence	
PEM (1% polidocanol)	Veins <10mm	Sclero may diffuse into branches	Sclero related Skin discoloration
	Tortuous and partially thrombosed veins	No tumescence	Thrombophlebitis



Current Surgical Therapy, 13th ed, Cameron JL, Cameron AM (Eds), Elsevier, 2019



Summary of Pivotal Studies

Technique	Study	Endpoint	Closure Rate	Adverse Events
RFA	Probstle et al	6 months	99.6%	DVT 0% Paresthesia 3-3.2 % Phlebitis: 0.8%-3%
	VeClose (vs glue)	3 months	96%	
EVLT	Min et al	2 years	93.4%	DVT 0% Paresthesia 1.1%
Cyanoacrylate glue	VeClose (vs RFA)	3 months	99%	DVT 0% Paresthesia 3% Phlebitis 4%
MOCA	Elias et al	6 months	96.7%	No PE or CVA
PEM (1% polidocanol)	VANISH-1 and 2	8 weeks	80.4-86.2%	DVT 1.9% Phlebitis 7.7%

J Vasc Surg 2008; 47:151.
J Vasc Surg 2015; 61:985.
J Vasc Interv Radiology 2001; 12:1167.
Eur J Vasc Endovasc Surg 2015; 50:784.
Phlebology 2012; 27:67.
Phlebology 2014; 29:508.

Outcome Comparison (CRT)

	Immediate occlusion %	Recanalization at 3 years %	New veins at 3 years %
EVLT	94	7	20
RFA	95	7	15
Foam	80	26	19
Stripping	96	7	20

Br J Surg 2011; 98:1079.

Complications Overview (Different Studies!)

	Immediate failure %	DVT/EHIT %	Thermal burns %	Infection %	Phlebitis %
RFA	<10	<5	<1	<1	<5
EVLV	<10	<5	<1	<1	<5
Cyanoacrylate	<5	<1	0	<1	<10
MOCA	<10	<5	0	<1	<5
PEM	<20	<5	0	<1	<20

J Vasc Surg Venous Lymphat Disord 2014; 2:105.
J Vasc Surg 2015; 61:985. (VeClose)
Eur J Vasc Endovasc Surg 2013; 45:299.
J Endovasc Ther 2011; 18:328.
J Vasc Surg 2013; 57:445 (RFA and MOCA obs stud)

Surgical Techniques

- Highly effective but with high complication rate!
- Minimally invasive vs ligation and removal: similar efficacy with less complications but more recurrence!
- **Saphenous vein inversion and removal (stripping)**
 - High success rate
 - Complications and inconvenience
- **High saphenous ligation (for vein size >20 mm):**
 - High recurrence
 - Thrombophlebitis

Eur J Vasc Endovasc Surg. 2017;54(6):760.

Surgical Techniques

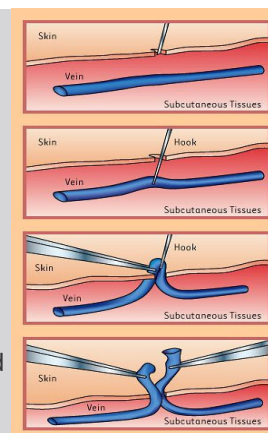


- **Ambulatory phlebectomy:**

- Used for larger varicose veins
- Requires tumescent anesthesia

- **Surgical perforator ligation:**

- *Linton procedure*: open surgical perforator ligation
- *Sub fascial endoscopic perforator surgery (SEPS)*: video scope guided
- Less invasive techniques are more used



J Vasc Interv Radiol. 2010 Jan;21(1):1-13
Srp Arh Celok Lek. 1990;118(11-12):471



Decision Making Which Procedure for What Kind of Patient?!

- **Based on multiple factors:**

- Axial vein size and tortuosity
- Presence of a branch and size of varicose veins
- Allergies
- Patient preference and expectations
- Insurance coverage!!



- Axial vein reflux with no varicose veins: RFA, EVLA, chemic-adhesive, MOCA or PEM (tortuous)
- Axial vein reflux with smaller varicose veins (<6mm): vein closure + USGS
- Axial vein reflux with larger varicose veins: vein closure + phlebectomy +/- USGS
- Very large axial veins (>20 mm): Ligation +/- other techniques



Post Intervention Care

- **Pain management:** acetaminophen or NSAIDs
- **Ambulation:** walk 15 minutes every hour/day of procedure
- **Leg elevation:** 45 minutes every hour/day of procedure
- **Compression:** continuous for 24-48 hours after procedure, then daily for 2-4 weeks. Variable!
- **If bleeding:** ice, compress, elevate
- **Return to normal activity/work:** 2 days. Heavy duty exercise after post-procedural US in 1 week
- **Post-procedural US:** within a week
- **Follow up:** 1-12 months, depends!

Ann Vasc Surg. 2017;38:72. Epub 2016 Aug 20
J Vasc Interv Radiol. 2009;20(6):752



Deep Vein Disease

- **Thrombosis:** Post-thrombotic syndrome
- **Stenosis:** May Thurner syndrome, tumors
- **Congenital:** Klippel-Trenaunay syndrome (KTS), Sturge-Weber syndrome, IVC or iliac vein aplasia
- **AV malformation**
- **Malignancy**

- **Management:**
 - Thrombolytic or thrombectomy
 - Endovascular reconstruction: angioplasty +/- stenting
 - Vein bypass, translocation or transplantation
 - Valve repair (success rates for primary and secondary incompetence are 73 and 43% respectively)


Cochrane Database Syst Rev. 2015
Vasc Med. 1998;3(2):157-64
















Summary



-  Vein disorders are very prevalent
-  Multiple medical and interventional management options
-  Procedure choice is based on anatomy in addition to risk and benefits
-  High success rate with low recurrent risk
-  Care: long term process





Sunset, Gaza City









Thank You!

Nedaa Skeik

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Questions?



HOPE
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Minneapolis Heart Institute Foundation
Creating a world without heart and vascular disease