MHIF FEATURED STUDY: Proact Xa

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.

CONDITION: Anticoagulation therapy with On-X aortic valve
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RESEARCH CONTACT: Alyssa Taffe, RN Alyssa.Taffe@allina.com | 612-863-7821
SPONSOR: CryoLife Inc.
Venous Insufficiency Between Diagnosis, Management and Outcome

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Section Head, Vascular Medicine
Medical Director, IAC Accredited Vein Center
Medical Director, Thrombophilia/Anticoagulation Clinic
Medical Director, Vascular Laboratory
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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
**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

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*J Vasc Surg* 2011; 53:2S.
Venous Anatomy

- Superior vena cava
- Common iliac v.
- External iliac v.
- Common femoral v.
- Femoral v.
- Popliteal v.
- Anterior tibial v.
- Posterior tibial v.

Venous Anatomy

- Perforating vein
- Deep vein
- Superficial vein
- Skin

Perforating veins connect the deep system with the superficial system
Pathophysiology

- Incompetent valves (reflux)
- Inadequate muscle pump function
- Venous thrombosis
- Venous stenosis
- Venous Hypertension
  - Skin changes
  - Skin ulceration
- Vein dilation (varicosity)

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
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

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
Reticular and Telangiectatic Veins, Corona Phlebectasia

Varicose Veins
Edema with Stasis Dermatitis and Ulcers

Venous Stasis Ulcers
## Disease Severity: CEAP Classification

<table>
<thead>
<tr>
<th>CEAP Classification</th>
<th>Clinical manifestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No visible or palpable signs of venous disease</td>
</tr>
<tr>
<td>1</td>
<td>Telangiectasias or reticular veins</td>
</tr>
<tr>
<td>2</td>
<td>Varicose veins</td>
</tr>
<tr>
<td>3</td>
<td>Edema</td>
</tr>
<tr>
<td>4</td>
<td>Pigmentation, eczema, lipodermatosclerosis or atrophie blanche</td>
</tr>
<tr>
<td>5</td>
<td>Healed venous ulcer</td>
</tr>
<tr>
<td>6</td>
<td>Active venous ulcer</td>
</tr>
</tbody>
</table>

[Refer to: J Vasc Surg. 2010 Apr;51(4):900-7.]

## Venous Clinical Severity Score (VCSS)

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

[Refer to: 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).

Diagnosis

• **Combination**: suggestive history, symptoms, exam findings and imaging.

• **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
### 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

### 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.
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!

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
### Pharmacologic Therapy and Skin Care

**Vasoactive drugs:**
- Hydroxyethylrutoside
- Horse chestnut seed extract
- Micronized purified flavonoid fraction (MPFF; Daflon=Detralex)

**Rheologic agents:**
- ASA
- Stanazol
- Pentoxifylline
- Prostacycline analogues
- Sulodexide
- Defibrotide

**Skin care:**
- Topical steroids
- Topical antibiotics
- Debridement
- Dressing
- Hyperbaric oxygen therapy


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### Available Interventional Options

**Sclerotherapy:**
- Visual
- US guided +/-

**Vein Closure Procedures:**
- Thermal: Radiofrequency (RFA) or endovenous laser ablation (EVLA)
- Chemical adhesive (cyanoacrylate) embolization (VenaSeal)
- Mechanical occlusion chemically assisted (MOCA) (ClariVein)
- Polidocanol endovenous microfoam (PEM) (Varithena)

**Surgical:**
- Phlebectomy
- Ligation
- Stripping

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

Femoral, Saphenous and Sural Nerves

Femoral nerve anatomy

Saphenous Nerve

Sural nerve
### Thermal Ablation (RFA or EVLA)

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

<table>
<thead>
<tr>
<th>Indications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Persistent symptoms</td>
<td>• Acute vein thrombosis (exception: distal GSV thrombus with patent proximal segment)</td>
</tr>
<tr>
<td>• Signs of superficial venous disease despite conservative therapy</td>
<td>• Pregnancy</td>
</tr>
<tr>
<td>• Severe disease (CEAP 4-6)</td>
<td>• Ulcer with concurrent severe arterial disease</td>
</tr>
<tr>
<td>• Documented axial venous reflux (&gt; 0.5 sec)</td>
<td>• Concurrent severe deep incompetence…</td>
</tr>
</tbody>
</table>

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### Radiofrequency Ablation (RFA)

1. Catheter tip positioned at the ostium of the superficial epigastric vein.Thoracic inflation is administered.
2. 7 cm vein segment treated all at once during 20 second treatment cycle. All treated vein segments treated serially.
3. Catheter shaft markings allow fast and accurate catheter repositioning between treated locations. No energy is delivered during repositioning.
4. Treatment of 45 cm vein length takes 3 to 5 minutes (seven treatment segments).
Endovenous Laser Ablation (EVLA)

**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
Closure Rates and Recurrence (EVLA)

- **Saphenous EVLA:**
  - Immediate closure rate: 90-100%.
  - Three years closure rate: 94%
  - Failure reasons: diameter >2 cm
  - Recurrent SV: up to 1/3rd

- **Perforator RFA:**
  - No enough data available, ~ 77%

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):** …
Kabnick Classification of EHIT

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>At junction</td>
</tr>
<tr>
<td>2</td>
<td>&lt;50% thrombus in deep vein</td>
</tr>
<tr>
<td>3</td>
<td>&gt;50% thrombus in deep vein</td>
</tr>
<tr>
<td>4</td>
<td>Deep vein occlusion</td>
</tr>
</tbody>
</table>

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)
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

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
**Chemical Adhesive (Cyanoacrylate) Embolization**

*VenaSeal*

1. Uses an agitating wire to injure the vein while injecting a sclerosant (polidocanol or STS)

2. 1-year closure rate: 82%, lower than thermal ablation or chemical adhesive closure

3. No tumescence anesthesia or foreign body

4. May treat distal veins

5. More thrombophlebitis

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**Mechanical Occlusion Chemically Assisted (MOCA)**

*ClariVein*


Mechanical Occlusion Chemically Assisted (MOCA) 
ClariVein

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!
**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%

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**Methods to Produce Foam**

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23 of 35
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)
### 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
Vein Closure and Wound Healing

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)

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%)

Technique Comparison

<table>
<thead>
<tr>
<th>Treated vein</th>
<th>Technique</th>
<th>Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFA</td>
<td>Thermal ablation</td>
<td>EHIT</td>
</tr>
<tr>
<td>Non-tortuous veins</td>
<td>Tumescence</td>
<td>Nerve injury</td>
</tr>
<tr>
<td>EVLT</td>
<td>Thermal ablation</td>
<td>EHIT</td>
</tr>
<tr>
<td>Non-tortuous veins</td>
<td>Tumescence</td>
<td>Nerve injury and skin burns</td>
</tr>
<tr>
<td>Cyanoacrylate Glue</td>
<td>Glue (foreign body)</td>
<td>Phlebitis</td>
</tr>
<tr>
<td>Non-tortuous veins (&lt;10 mm)</td>
<td>No tumescence</td>
<td>Hypersensitivity to glue</td>
</tr>
<tr>
<td>MOCA</td>
<td>Sclero may diffuse in branches</td>
<td>Sclero related</td>
</tr>
<tr>
<td>Non-tortuous veins</td>
<td>No tumescence</td>
<td></td>
</tr>
<tr>
<td>PEM (1% polidocanol)</td>
<td>Sclero may diffuse into branches</td>
<td>Sclero related</td>
</tr>
<tr>
<td>Veins &lt;10 mm</td>
<td>No tumescence</td>
<td>Skin discoloration</td>
</tr>
<tr>
<td>Tortuous and partially thrombosed veins</td>
<td></td>
<td>Thrombophlebitis</td>
</tr>
</tbody>
</table>
### Summary of Pivotal Studies

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

References:
- Eur J Vasc Endovasc Surg 2015; 50:784.
- Phlebology 2014; 29:608.

### Outcome Comparison (CRT)

<table>
<thead>
<tr>
<th></th>
<th>Immediate occlusion %</th>
<th>Recanalization at 3 years %</th>
<th>New veins at 3 years %</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVLT</td>
<td>94</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>RFA</td>
<td>95</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>Foam</td>
<td>80</td>
<td>26</td>
<td>19</td>
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<tr>
<td>Stripping</td>
<td>96</td>
<td>7</td>
<td>20</td>
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</tbody>
</table>

References:
Complications Overview *(Different Studies!)*

<table>
<thead>
<tr>
<th></th>
<th>Immediate failure %</th>
<th>DVT/EHIT %</th>
<th>Thermal burns %</th>
<th>Infection %</th>
<th>Phlebitis %</th>
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<tbody>
<tr>
<td><strong>RFA</strong></td>
<td>&lt;10</td>
<td>&lt;5</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;5</td>
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<td>&lt;10</td>
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<tr>
<td><strong>MOCA</strong></td>
<td>&lt;10</td>
<td>&lt;5</td>
<td>0</td>
<td>&lt;1</td>
<td>&lt;5</td>
</tr>
<tr>
<td><strong>PEM</strong></td>
<td>&lt;20</td>
<td>&lt;5</td>
<td>0</td>
<td>&lt;1</td>
<td>&lt;20</td>
</tr>
</tbody>
</table>

*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

References:
- Eur J Vasc Endovasc Surg 2013; 45:299.
- J Endovasc Ther 2011; 18:328.
Surgical Techniques

- **Ambulatory phlebectomy:**
  - Used for larger varicose veins
  - Requires tumescent anesthesia

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

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!

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)
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
Thank You!

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612-863-6800

Questions?