Superficial Venous Ablation: Techniques

8/28/17
David A. Rigberg, MD
Clinical Professor
UCLA/Geffen School of Medicine
• No Disclosures
Introduction

- 80 million Americans with venous insufficiency
- 25-50 million with VVE
- Over one million pts/year in U.S. seek tx
- 4-5 x more prevalent than arterial dz
Venous Insufficiency

- Visual deformity
- Swelling
- Chronic Pain
- Cellulitis
- Ulceration
- Bleeding
- Hyperpigmentation
- Stasis Dermatitis
- Lipodermatosclerosis
- Atrophe Blanche
Vein Stripping

- Invasive
- Painful
- Recovery period
- Cosmetic result varies
- Recurrence
GSV Stripping

- Stripping has recurrences
- **Expansion of pre-existing tributaries**
- **Reflux from pelvic/abdominal veins**
- **Dwerryhouse et al.**
  - 10% recurrence rate
  - 6% reoperation at 5 years
Endovenous Ablation

• Leave vein *in situ*; change hemodynamics by stopping flow
• Energy sources available for heat with shallow penetration:
  - Radiofrequency ablation (*RFA*)
  - Endovenous laser (*EVLT*)
  - Steam Vein Sclerosis (*SVS*)
• *Mechanical/Chemical Ablation* (*Clarivein*)
• Cyanoacrylate (*Venaseal*)
• Microfoam (*polidocanol*)
• V Block (nitinol frame with hooks)
Treatment (In General!)
Need the Appropriate Patients!

- Document REASON for intervention
- Document conservative trial:
  - 4 rules of compression stockings
  - NSAID’s
  - Document results of duplex scanning
- Check scan yourself to make sure patient is good candidate
  - size, depth, tortuosity, is it the right vein?
Where to do the Procedure?

• OR:
  - patient relaxed
  - allows you to focus on procedure

• Office:
  - easier for patient and eventually physician!
  - financial incentives
Pre-op Mapping & Marking

• Evaluate for and note:
  – Depth of vein from skin surface
  – Maximum vein diameter
  – Significant anatomy
    • Tortuous and aneurysmal segments
    • Duplicate saphenous system
    • Tributaries, branches and perforators
  – Potential vein access sites

• Mark vein pathway and significant anatomical findings
Vein Access

Optimal vein access site is:

- Close to skin surface
- Free from branches or tortuosity
- At least 4mm in diameter

Nitropaste
Warm prep
Reverse Trendelenberg
EMLA?
PATIENCE!!!
Longitudinal View of Percutaneous Access
Catheter Positioning

- Estimate length of catheter to insert in vein
- Obtain longitudinal or oblique view of SFJ
  - Advance catheter into sheath until tip enters image
- If treating near SFJ, position catheter tip ~2.5 cm distal to SFJ
- Insert slowly – monitor patient!
- Wire available
Sapheno-Femoral Junction - Transverse View: ("Mickey Mouse" Sign)
Perivenous Tumescent Infiltration

- Purposes of tumescent infiltration:
  - Helps uniformly *compress* vein around heating element
  - Creates fluid cushion to *exsanguinate* treatment vein
  - Create *depth* between skin surface and anterior vein wall
  - Acts as *heat sink* to protect perivenous tissue from thermal injury
Final Tip Position Check

• Confirm tip position with ultrasound:
  – In longitudinal and oblique view, gently manipulate catheter to see tip move in and out of image
  – Scan GSV in transverse view from proximal thigh towards SFJ
    • Note transition where echogenic dot of catheter and corresponding vertical shadow disappear from the image

• Catheter tip should be 2.5cm distal to SFJ

• Learn well before Clarivein!
Importance of Confirming Tip Position

- Forward propagation of heating occurs during treatment 0.5 cm on average, but can be >1.5 cm
- Positioning catheter tip 2.0 cm distal to SFJ minimizes potential for heating too close to deep system
External Compression

- Good vein wall contact is important to procedure success
- Apply external compression over entire heating element using
  - Ultrasound probe longitudinally aligned over heating element + 2 fingertips just distal to probe

Probe + finger compression
Post-Op Instructions

• Return to normal activities
• Ambulate at frequent intervals, at least 30 minutes daily
• Do not sit or stand for long periods
• Refrain from strenuous activities or heavy lifting for several days
• Compression bandage for 48h followed by compression stockings for at least 1 week
• Analgesics as needed per physician’s orders
• Follow up ultrasound within 72 hours
• Periodic follow up with duplex assessment
ClosureFAST Catheter

- 7F fixed diameter
- 7 cm length heating element on distal end of catheter
- Temperature-controlled energy delivery – old catheters BIPOLAR anode to cathode and vein restrictive element
- Now wall direct recipient
- Non-stick surface minimizes coagulum build-up on heating element
- Center lumen accommodates a .025” guide wire
- Available in 60 cm and 100 cm lengths
Closure *FAST*: Segmental Ablation

- 7cm length treated all at once
- No energy delivery during repositioning
- Energy delivery does not vary by pullback speed
- 40 Watts maximum power at 120°C
EVLT

- Multiple wavelengths
- 810 nm, 940 nm, 980 nm, 1320 nm, 1470 nm
- HSLW versus WSLW
  - Hgb affinity leads to dc and steam
  - Water works at lower energy densities
  - Decreased perfs = less pain/bruising
Results


- 499 GSV’s
- 810 nm diode laser
- 98.2 % initial closure
- 93.4 % occluded at 2 years
Results

• **Italian Endovenous-laser Working Group (iewg) - 1999-2003**
  - 1076 limbs; most GSV
  - Tx with 810-980nm diode
  - 36 month F/U
  - Early occlusion 99 %
Results

- Arizona Heart, Ravi et al.
  - Combination of EVL and RFA
  - 1149 GSV’s tx
  - 3.4% recanalization rate at 1 year
  - no differences in efficacy or comps
Results

• EVOLVeS Study (2003)
  - 44 limbs RFA vs 36 HLS
  - Early results (4 months)
  - RTW 1.2 vs 3.9 days
  - QOL global/pain scores favored RFA
  - Benefits decreased with time

• EVOLVeS Follow Up (2005)
  - Cumulative recurrence at one and two years: 14% (RFA) vs. 21% (HLS)
Results

- **CLOSURE GROUP**
  - Multicenter (31 sites)
  - 330 limbs
  - VVE “free” rates 90.1% (1 yr), 87.2% (2 yrs), and 88.2% (3 yrs)
  - Total occlusion rates 81%, 80.4% and 75% respectively
RECOVERY (2009)

- Radiofrequency endovenous ClosureFAST versus laser ablation for the treatment of great saphenous reflux: a multicenter, single-blinded, randomized study (RECOVERY study).
- 87 veins
- Prospective, randomized
- RF thermal ablation was significantly superior to EVL: postprocedural recovery and QOL parameters in a randomized prospective comparison between these two thermal ablation modalities for closure of the GSV.
Complications

• Thrombophlebitis/cellulitis
  - rare with RFA; 0-5 % with EVLT
  - related to blood with EVLT?
• Thermal Injuries - uncommon
  - skin
  - nerve injury
Complications

• DVT
  - *Hingorani et al (2004):* 16%
  - Everyone gets post procedure U/S
  - Most studies range from < 1% to 2%
  - No difference with EVLT and RFA
  - HLS not a panacea! (5.7%) *Van Rij et al*
Complications

• Thrombus Extension or EHIT
  - Need to distinguish from true DVT
  - Need to treat unclear; we do!
  - Usually resolves quickly
  - Again, every pt needs scan!

• Establishing system for scans
  - 2009 WVS
Level 3
Classification of Closure Level and Treatment Algorithm

Level 1 - no Rx
Level 2 - no Rx
Level 3 - surgeon's choice
Level 4 - LMWH
Level 5 - LMWH
Level 6 - LMWH plus warfarin
LEFT CFV
Short Saphenous Vein

Level A: No Rx
Level B: No Rx
Level C: Surgeons Choice
Level D: LMWH and Warfarin
Diffuse Phlegmonous Phlebitis
Clarivein
Technique

• Access the same
• Must be proficient with U/S!
• Pullback rate is key. Get used to using timer!
• 1 cm/6 sec
• 1.5 % STS or 2% polidocanol
• Length x Diameter table
• Volume not as critical – will follow!
<table>
<thead>
<tr>
<th>Author/Journal</th>
<th>Title/Objective</th>
<th>Result/Conclusion</th>
</tr>
</thead>
</table>
| Bishawi et al, Phlebology, 2013   | Prospective, multicenter study on MOCA in 126 Patients with lower extremity chronic venous disease | • Closure at 3 months = 98%  
• Closure at 6 months = 94%  
• No VTE  
• Significant improvement of VCSS score (p < 0.001) |
| Boersma, et al, European Journal of Vascular and Endovascular Surgery, 2012 | 1 year results of MOCA in the SSV in 50 patients                              | • Technical Success = 100%  
• Closure at 1 year = 94%  
• No major complications, no nerve injury  
• VCSS decrease from 3 to 1 |
| Van Eekeren, et al, Journal of Vascular Surgery, 2013 | Prospective Observational Study 68 patients with GSV incompetence treated with either RFA or MOCA | • MOCA achieved 74% reduction in post operative pain compared to RFA  
• Lower post operative pain scores associated with significant earlier return to normal activity and work resumption |
| Elias, S, Raines JK, Phlebology, 2011 | ClariVein system for ablation of the GSV Conducted in 30 legs                  | • Mean closure at 260 days = 97.6%  
• Primary closure rate at 6 months is comparable to the best results with other techniques |
MOCA (ClariVein™) vs. RFA (Venefit™)  
Intra Op Pain

• Randomized controlled trial

• 120 pts – 60 MOCA, 59 RFA

• Intra op procedural pain (VAS 0 – 100 mm)

• Post procedure QoL and closure rates

## PAIN SCORES

<table>
<thead>
<tr>
<th></th>
<th>Max. Intra-Op (0 -100 mm)</th>
<th>Avg. Intra-Op (0 -100 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOCA (ClariVein)</td>
<td>19.3</td>
<td>13.4</td>
</tr>
<tr>
<td>RFA (Venefit)</td>
<td>34.5</td>
<td>24.4</td>
</tr>
</tbody>
</table>
VenaSeal
4) Inject 0.10 cc adhesive into the vein
call back 1 cm

5) Inject 0.10, pull back 3 cm,
compress 3 minutes

6) Pull back 3 cm, compress for 30 secs

7) Repeat process throughout vein
Results – Cyanoacrylate

• 689 veins (Registry Data)
  -100 % initial closure
  -98.5% at 30 days
  -98.2 % at 90 days
  -97.7% at 2 years

• US FDA Approval in 2/2015

• VeClose roll in: similar to RFA

<table>
<thead>
<tr>
<th></th>
<th>Mean VCSS Score</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.1 ± 2.7</td>
<td></td>
</tr>
<tr>
<td>6 Month (n=36)</td>
<td>1.3 ± 1.1</td>
<td></td>
</tr>
<tr>
<td>12 Month (n=36)</td>
<td>1.5 ± 1.4</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>24 Month (n=24)</td>
<td>2.7 ± 2.5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=38</td>
<td></td>
</tr>
<tr>
<td>Age mean (yrs)</td>
<td>51</td>
</tr>
<tr>
<td>Gender</td>
<td>76% Female</td>
</tr>
<tr>
<td>BMI mean</td>
<td>27.6</td>
</tr>
<tr>
<td>Treated Segment Length (cm)</td>
<td>33</td>
</tr>
<tr>
<td>Treated Diameter (mm)</td>
<td>8 ± 2.2</td>
</tr>
<tr>
<td>Procedure Time (min)</td>
<td>20.3</td>
</tr>
<tr>
<td>Total Vol. of Cyanoacrylate Injected (ml)</td>
<td>1.3</td>
</tr>
</tbody>
</table>
VeClose RCT Results

Bruising at Day 3

- None: 67.6
- <25%: 48.2
- 25-50%: 26.9
- 50-75%: 3.5
- 75-100%: 0.9

Venaseal
RFA
Polidocanol Injectable Foam (Varithena™, BTG)

- FDA Approved
- Approved for GSV, AAGSV, VVE but not SSV

VANISH – 2 Trial
- Used VVSymQ® score (heaviness, aching, swelling, throbbing, itching)
- Improved Sx, Appearance (IPR-V³ and PA-V³), VCSS, VEINES-QOL Scores.

- Similar “EHIT”
- No neurological events reported
V Block
V Block

- Animal studies also utilized sclerosant
- Presented data in 2014 – promising?
- Data since 2014?
Perforator Anatomy
Perforator Catheter

- Office Procedure
- Well-tolerated
- Learning curve
- Avoids incisions


Each ulcer was electronically circumscribed and then area was calculated. A-C, The ulcer increased in size as compression therapy failed to promote ulcer healing. D-F, These ulcer decreased in size until completely healed after vein ablation of incompetent veins. G, The graph is of ulcer measurements throughout treatment before and after incompetent vein ablation for a single ulcer.
Kaplan-Meier life-table of patient freedom from ulcer recurrence. All patients with CEAP 5 ulcers remain healed at a mean of 24.8 months with a maximum follow-up of 51 months.
Five hundred consecutive patients (580 legs) with GSV reflux were randomized to endovenous laser ablation (980 and 1470 nm, bare fibre), radiofrequency ablation, ultrasound-guided foam sclerotherapy or surgical stripping using tumescent local anaesthesia with light sedation. Miniphlebectomies were also performed.

The patients were examined with duplex imaging before surgery, and after 3 days, 1 month and 1 year.
QOL

- Disease-specific quality-of-life and Short Form 36 (SF-36) scores had improved in all groups by 1-year follow-up. In the SF-36 domains bodily pain and physical functioning, the radiofrequency and foam groups performed better in the short term than the others.

- All treatments were efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping.
Conclusions

• Tremendous need for treatment
• Patients appreciative; burdensome disease process!
• Take time to do correctly and learn well
• Know the full range of options
• All technologies seem to give = QOL
• Need more QOL data!