TREATMENT OF INCOMPETENT PERFORATOR VEINS: WHO, WHY, WHEN AND HOW?
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DISCLOSURES

• None
PERFORATOR VEIN ANATOMY

- >60 PV
- 88% travel with perforator artery*
- Contain valves which direct flow *predominately* superficial to deep (Direct and Indirect)
- Axial deep veins
- Calf venous sinuses

- Anatomic nomenclature changes adopted in 2002#

*Haruta, et al; JCVS 2006
# Caggiati et al; JVS 2002
VEIN NOMENCLATURE

FIGURE 2.10 The small saphenous vein and lateral venous system of the calf.
NORMAL PERFORATOR VEIN FUNCTION

Fan et al, Endovascular Today, 2015
PATHOLOGIC PV

• PV dilatation, valvular incompetence and retrograde flow (deep to superficial)

• 2 primary mechanisms by which PV valves become incompetent:
  – Antegradal “Overload”
    • CEAP class 1-3
  – Retrogradal “Blow-out”
    • CEAP class 4-6

Delis KT; Radiology 2005
ANTEGRADE “OVERLOAD” MECHANISM OF PERFORATOR INCOMPETENCE
RETROGRADE “BLOW-OUT” MECHANISM OF PERFORATOR INCOMPETENCE
The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

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The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) have developed clinical practice guidelines for the care of patients with varicose veins of the lower limbs and pelvis. The document also includes recommendations on the management of superficial and perforating vein incompetence in patients with associated, more advanced chronic venous diseases (CVDs), including edema, skin changes, or venous ulcers. Recommendations of the Venous Guideline Committee are based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system as strong (GRADE 1) if the benefits clearly outweigh the risks, burden, and costs. The suggestions are weak (GRADE 2) if the benefits are closely balanced with risks and burden. The level of available evidence to support the evaluation or treatment can be of high (A), medium (B), or low or very low (C) quality. The key recommendations of these guidelines are: We recommend that in patients with varicose veins or more severe CVD, a complete history and detailed physical examination are complemented by duplex ultrasound scanning of the deep and superficial veins (GRADE 1A). We recommend that the CEAP classification is used for patients with CVD (GRADE 1A) and that the
SVS/AVF CLINICAL PRACTICE GUIDELINES

- Recommend IPV Treatment: (Grade 2b)
  Pathologic Perforator Vein (PPV)
  - IPV with reflux ≥ 500msec
  - Vein diameter ≥ 3.5 mm
  - Located near a healed or active venous ulcer

  Recommended against IPV treatment for C1/2 patients (Grade 1b)

  Value for C3/4 patients?-- Unproven

Gloviczki et al, JVS, 2011
IPV DIAMETER/REFLUX RELATIONSHIP

- As the diameter of the PV increases, the incidence of reflux increases.

  - 2mm       10%
  - 2.5mm     50%
  - 3mm       80%
  - 4mm       88%

Sandri et al, JVS, 1999;30:867-875
IPV

- IPV are present in the majority of patients with CVI
  - CEAP 3 52%
  - CEAP 4 83%
  - CEAP 5/6 90%

Stuart et al; JVS 32:138
ROLE OF PERFORATORS IN CHRONIC VENOUS INSUFFICIENCY (CVI)?

- Assn between IPV and increased severity of venous disease
- ~2/3 of pts with C4b+ will have IPV
- 28% IPV prevalence in CVI vs 0 in normal control#
- Increases perforator diameter in C4-C6 limbs#
- Increased IPV flow and velocity in pts with more severe disease*

# Labropoulos et al, Eur J Vasc Endovasc Surgery 1999
*Delis, JVS 2001
ROLE OF IPV IN CHRONIC VENOUS INSUFFICIENCY?

• No conclusive evidence IPV’s play a causal role in CVI
  – Isolated perforator insufficiency is rare in VSU patients (3.2%)
  – Most studies on vein Rx fail to isolate IPV intervention from other concomitant/prior treatments
    • saphenous vein ablation, excisions, sclerotherapy
INCOMPETENT PERFORATOR VEIN (IPV) DIAGNOSIS

Duplex US
PERFORATOR VEIN CLOSURE METHODS

• Linton—open surgical ligation (1938)
• SEPS (subfascial endoscopic perforator surgery)
• US guided sclerotherapy (1992)
  – Liquid
  – Foam
• Ablation
  – Thermal
  – Others (adhesive, etc)
LINTON PROCEDURE
SUBFASCIAL ENDOSCOPIC PERFORATOR SURGERY (SEPS)
SEPS
RFS Stylet for ablation of perforators
VNUS ClosureRFS Benefits:

- Minimally invasive
- Outpatient procedure
- Quick patient recovery
- Only device cleared by the FDA for the endovenous ablation of incompetent perforator veins
RFA PERFORATOR ABLATION

- US guided
- Intraluminal with impedance 150-350 Ohms
- Local anesthesia or tumescence
- 4 quadrants @85C, 1 min each
- Withdraw 1-2 mm and repeat
ENDOVENOUS LASER PERFORATOR

- 400 micron fiber
- Micropuncture or 21g needle
- Local or tumescent
- Ablate 6W, ~50J, pull back and repeat (spot-welding)
- 1470 nm
FOAM SCLEROTHERAPY

- (Off-label) Ultrasound guided
- Polidocanol and Sodium tetradecyl sulfate (~1%) agitated with air or CO2.
- Widely used: low cost, ease of use, low side effects, and easily repeatable.
- May derive benefit from closure of IPV and surrounding varicosities.
Cyanoacrylate adhesive perforator embolization (CAPE) of incompetent perforating veins of the leg, a feasibility study

Irwin M Toonder¹, Yee Lai Lam¹, James Lawson² and Cees HA Wittens¹,³

Abstract
Consideration of treating incompetent perforating veins remains a conundrum based on scientific evidence available till date. While subfascial endoscopic perforator surgery (SEPS) proved to be a worthy alternative for open surgery, other even less invasive techniques were being introduced by the late nineties of the last century. Percutaneous thermoablation techniques are still being used today and seem more effective than non-thermal techniques. However, thermal techniques require anaesthesia and potentially may cause inadvertent damage to surrounding tissues such as nerves. Cyanoacrylate adhesive has a proven record, but not for the treatment of chronic venous disease of the leg. Innovation has led to the development of the VenaSeal® Sapheon Closure System which has been designed to use a modified cyanoacrylate glue as a new therapy for truncal vein incompetence. This paper explores the feasibility of ultrasound guided cyanoacrylate adhesive perforator embolization (CAPE). Results show a 76% occlusion rate of incompetent
WHY TREAT IPV FOR C5/6 DISEASE?

Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial

Jamie R Barwell, Colin E Davies, Jane Deacon, Kate Harvey, Julia Minor, Antonio Sassano, Maxine Taylor, Jenny Usher, Clare Wakely, Jonathan J Earnshaw, Brian P Heather, David C Mitchell, Mark R Whyman, Keith R Poskitt

No improved ulcer healing with saphenous vein intervention, but, reduced ulcer recurrence (level 1A evidence). 3.1% had IVP treatment.

From the American Venous Forum

Treatment of superficial and perforator venous incompetence without deep venous insufficiency: Is routine perforator ligation necessary?

Robert R. Mendes, MD, William A. Marston, MD, Mark A. Farber, MD, and Blair A. Keagy, MD, Chapel Hill, NC

**Purpose:** We investigated whether routine ligation of incompetent perforator veins is necessary in treatment of symptomatic chronic venous insufficiency (CVI) due to combined superficial and perforator vein incompetence, without deep venous insufficiency.

**Methods:** This was a retrospective review of prospectively collected data. Twenty-four limbs with both superficial and perforator venous incompetence but no deep venous insufficiency were identified at venous duplex scanning. Air plethysmography (APG) was performed preoperatively, to obtain venous volume (VV), venous filling index (VFI), ejection fraction (EF), and residual volume fraction (RVF) of the affected limb. Saphenous vein stripping from the groin to knee and powered transilluminated phlebectomy for varicosity ablation were performed in all patients. Postoperatively, all patients underwent duplex scanning and APG to determine the status of the perforator veins and hemodynamic improvement from surgery.

Results: In patients with 56.8% of the patients, CVI grade 2 or higher, 61% of the limbs had venous incompetence detected.
SEPS RESULTS

• NA SEPS registry
• 146 pts, 84% CEAP 5/6
• 71% concomitant superficial procedures
• 88% ulcers healed 1 yr after surgery
• Ulcer recurrence
  • 16% 1 yr, 28% 2 yrs
  • 46% in post-thrombotic limbs

Gloviczki et al, JVS 1999; 29:489
SEPS RESULTS

- Metanalysis--1140 treated limbs (526 w/ ulcers)
- 70% CEAP 5/6

- 88% Ulcer healing at 1 yr, 13% recurrence after 1 yr (28% 2 yr)

Tenbrook et al, JVS, 2004
RCT OF PERFORATOR TREATMENT

- Compression vs GSV + perforator SEPS
  - Of 91 SEPS pts, 51 had superficial vein surgery, 29 had prior superficial vein surgery, 11 SEPS alone
- 29m f/u
- 73% control healing, 83% study (not significant)
- VSU recurrence: 53% surgical grp v 72% in compression grp.
- 2015 re-eval of data showed ‘complete” SEPS had lower VSU recurrence rate than ‘incomplete” Rx (IPV found on p-op US)
  - -? IPV’s contribute to VSU recurrence

Van Gent et al, JVS 2006; 44;563-571
Van Gent et al, Phlebology, 2015
SEPS

- 9 yr retrospective review
- 832 pts with IPV’s and SEPS
- 55% has concomitant saphenous surgery
- 92% ulcers improved
- 4% ulcer recurrence
- Reduced AVP in subset of C4 patients

- “Until level 1 evidence is available, SEPS is advocated as optimal therapy for CVI”

Tawes et al, JVS 2003; 37:545
RFA IPV

- 121 IPV’s, 67 limbs
- C1/C2 – 58% C5/C6 --- 9%
- ½ had “concomitant procedure”
- 82% closure at 1 yr (22+ new IPV’s)
- 12% neuropraxia
- Slightly improved clinical score if IPV’s closed vs. persistent

Marsh et al, Phlebology, 2010
LASER PERFORATOR ABLATION

• 58 IPV’s in 33 limbs
• All C4-C6
• 78% occlusion at 3 mos
• No clinical data presented

Hissink et al, EurJ Vasc EndovascSurgery 2010
LASER PERFORATOR ABLATION

- 67 IPV in *mainly C2 limbs*, 35 w/ GSV or SSV ablation
- 98% closed at 3 mos
- 940 and 1320 mn laser

Proebstle et al, Derm Sur, 2007
## PERFORATOR VEIN THERMAL ABLATION RESULTS

<table>
<thead>
<tr>
<th>RFA</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumsden SCVS</td>
<td>Elias et al</td>
</tr>
<tr>
<td>34 IPV’s</td>
<td>50 IPV’s w/ 120J</td>
</tr>
<tr>
<td>91% occl @3 wk f/u month</td>
<td>90% occl 1m</td>
</tr>
<tr>
<td>2 asympt tibial DVT</td>
<td>No signif DVT</td>
</tr>
</tbody>
</table>
THERMAL ABLATION OF PERFORATORS

- More technically challenging than saphenous vein ablation—deep, tortuous, short
- Lower rates of vein closure than saphenous vein (59-90% vs 96%+)
- RCT suggest +4% VSU healing and -13% VSU recurrence
- Repeat treatment may be necessary
- Predictors of failure: anticoagulation, obesity, and venous pulsatility

Bacon et al, Phlebology, 2009
ULTRASOUND GUIDED SCLEROTHERAPY (UGS)

- Masuda:
  - 80 limbs, 98% technical success (immediate vein occlusion)
  - 5% sodium morrhuate
  - 1 injection site ulcer, no DVT
  - 32/37 ulcers healed
  - 68% of limbs with ulcers healed a mean of 36d p 1 injec
  - Improved quality of life data (VSCC, VDS)
  -- 33% new or recurrent PV, and there were more recurrent ulcers in those pts with recurrent PV

Masuda et al, JVS 2006
ULTRASOUND GUIDED SCLEROTHERAPY

- 73 longstanding ulcers in 62 C6 patients
- UGS (polidocanol or STS foam)
- 59% ulcer healing (23% with single injection)
- 66% IPV closure rate with 1 injection
- IPV thrombosis was most significant predictor of ulcer healing
- Trend towards decreased ulcer recurrence in healed group with IPV thrombosis

Kiguchi, et al, JVS, 2014
Table II. Technical success of radiofrequency ablation (RFA), endovenous laser ablation (EVLA), and ultrasound-guided foam sclerotherapy (UGFS)

<table>
<thead>
<tr>
<th>Primary author (year)</th>
<th>Perforator treatment modality</th>
<th>No. of patients/procedures</th>
<th>Mean follow-up, months</th>
<th>Method and timing of evaluating procedure success</th>
<th>Overall success rate, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rueda10 (2013)</td>
<td>RFA and SEPS</td>
<td>64</td>
<td>37</td>
<td>DUS, 1 week</td>
<td>100</td>
</tr>
<tr>
<td>Kiguchi11,12 (2014)</td>
<td>UGFS</td>
<td>62</td>
<td>30</td>
<td>DUS, 2 weeks</td>
<td>54</td>
</tr>
<tr>
<td>Harlander-Locke14 (2012)</td>
<td>RFA</td>
<td>20/28</td>
<td>25</td>
<td>DUS, 48-72 hours</td>
<td>96</td>
</tr>
<tr>
<td>Harlander-Locke15 (2012)</td>
<td>RFA</td>
<td>88/140</td>
<td>12</td>
<td>DUS, 48-72 hours</td>
<td>82</td>
</tr>
<tr>
<td>Dumantepe16 (2012)</td>
<td>EVLA</td>
<td>13/23</td>
<td>14</td>
<td>DUS, 12 months</td>
<td>87</td>
</tr>
<tr>
<td>Köroglu17 (2011)</td>
<td>EVLA + UGFS</td>
<td>24</td>
<td>6</td>
<td>DUS, 24 hours</td>
<td>75</td>
</tr>
<tr>
<td>Lawrence18 (2011)</td>
<td>RFA</td>
<td>45/51</td>
<td>13</td>
<td>DUS, 48-72 hours</td>
<td>71</td>
</tr>
<tr>
<td>Corcos19 (2011)</td>
<td>EVLA</td>
<td>303/534</td>
<td>28</td>
<td>DUS; mean, 28 months</td>
<td>72</td>
</tr>
<tr>
<td>Nelzén11 (2011)</td>
<td>SEPS</td>
<td>37</td>
<td>12</td>
<td>DUS; 6-9 months</td>
<td>87</td>
</tr>
<tr>
<td>Hissink20 (2010)</td>
<td>EVLA</td>
<td>28/33</td>
<td>3</td>
<td>DUS, 3 months</td>
<td>78</td>
</tr>
<tr>
<td>Marrococ21 (2010)</td>
<td>RFA</td>
<td>241</td>
<td>5</td>
<td>DUS, 1-7 days</td>
<td>100</td>
</tr>
<tr>
<td>Marsh22 (2010)</td>
<td>RFA</td>
<td>53</td>
<td>14</td>
<td>DUS; mean, 14 months</td>
<td>82</td>
</tr>
<tr>
<td>van den Bos23 (2009)</td>
<td>RFA</td>
<td>12/14</td>
<td>3</td>
<td>DUS, 3 months</td>
<td>64</td>
</tr>
<tr>
<td>Hingorani24 (2009)</td>
<td>RFA</td>
<td>38/48</td>
<td>2</td>
<td>DUS, 3-7 days</td>
<td>88</td>
</tr>
<tr>
<td>Bacon25 (2009)</td>
<td>RFA</td>
<td>37</td>
<td>60</td>
<td>DUS, 5 years</td>
<td>81</td>
</tr>
</tbody>
</table>
Table III. Effects of perforator treatment on ulcer healing and recurrence

<table>
<thead>
<tr>
<th>Primary author (year)</th>
<th>Perforator treatment modality</th>
<th>No. of patients/procedures</th>
<th>Mean follow-up, months</th>
<th>Outcomes, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alden\textsuperscript{26} (2013)</td>
<td>UGFS</td>
<td>86</td>
<td>12</td>
<td>Ulcer healing: 78, Ulcer recurrence: 23</td>
</tr>
<tr>
<td>Rueda\textsuperscript{10} (2013)</td>
<td>RFA and SEPS</td>
<td>64</td>
<td>37</td>
<td>Ulcer healing: 92, Ulcer recurrence: 20</td>
</tr>
<tr>
<td>Abdul-Haqq\textsuperscript{27} (2013)</td>
<td>EVLA</td>
<td>17</td>
<td>2.5</td>
<td>Ulcer healing: 71, Ulcer recurrence: 0</td>
</tr>
<tr>
<td>Bush\textsuperscript{28} (2013)</td>
<td>UGFS</td>
<td>35</td>
<td>4</td>
<td>Ulcer healing: 100, Ulcer recurrence: 52</td>
</tr>
<tr>
<td>Kiguchi\textsuperscript{13} (2014)</td>
<td>UGFS</td>
<td>62</td>
<td>34</td>
<td>Ulcer healing: 76, Ulcer recurrence: 80</td>
</tr>
<tr>
<td>Harlander-Locke\textsuperscript{14} (2012)</td>
<td>RFA</td>
<td>20/28</td>
<td>25</td>
<td>Ulcer healing: 90, Ulcer recurrence: 4</td>
</tr>
<tr>
<td>Harlander-Locke\textsuperscript{15} (2012)</td>
<td>RFA</td>
<td>88/140</td>
<td>12</td>
<td>Ulcer healing: 84, Ulcer recurrence: 16</td>
</tr>
<tr>
<td>Dumantepe\textsuperscript{16} (2012)</td>
<td>EVLA</td>
<td>13/23</td>
<td>6</td>
<td>Ulcer healing: 100, Ulcer recurrence: 0</td>
</tr>
<tr>
<td>Lawrence\textsuperscript{18} (2011)</td>
<td>EVLA</td>
<td>45/51</td>
<td>13</td>
<td>Ulcer healing: 80, Ulcer recurrence: 3</td>
</tr>
<tr>
<td>Hissink\textsuperscript{20} (2010)</td>
<td>EVLA</td>
<td>28/33 limbs</td>
<td>3</td>
<td>Ulcer healing: 80, Ulcer recurrence: 0</td>
</tr>
<tr>
<td>Marrocco\textsuperscript{21} (2010)</td>
<td>RFA</td>
<td>24</td>
<td>5</td>
<td>Ulcer healing: 84, Ulcer recurrence: 16</td>
</tr>
<tr>
<td>Marsh\textsuperscript{22} (2010)</td>
<td>RFA</td>
<td>53</td>
<td>14</td>
<td>Ulcer healing: 100, Ulcer recurrence: 0</td>
</tr>
<tr>
<td>Hingorani\textsuperscript{24} (2009)</td>
<td>RFA</td>
<td>38/48</td>
<td>2</td>
<td>Ulcer healing: 63, Ulcer recurrence: 0</td>
</tr>
</tbody>
</table>

Hager et al, JVS, 2016
• NO RCT has shown clear benefit from treating IPV, so treatment recommendations for CEAP 5/6 patients is based on extrapolated data. (SEPS)
IPV MANAGEMENT SUMMARY

• Perforator veins help maintain the hemodynamic balance between the superficial and deep venous system.

• IPV are not likely a primary cause of CVI, but, may play an active role in a pathologic circuit.

• Treat perforators in the setting of advanced venous insufficiency, especially with venous ulceration
• No convincing role for Rx of IPV in C2/3 pts

• Close PPV in C5/6 pts after saphenous reflux and compression have failed

• Thermal ablation technical success 60-80%

• US guided sclero is less successful, but, easier to perform, cheaper, and easier to repeat
TREAT IPV IN ASYMPTOMATIC PATIENT?

NO!
TREAT IPV IN SYMPTOMATIC PATIENT?

< 3.5mm
< 500ms reflux
TREAT IPV IN SYMPTOMATIC PATIENT?

< 3.5mm
<500ms reflux

GSV/SSV reflux? Only if irresistible...
TREAT IPV IN SYMPTOMATIC PATIENT?

≥3.5mm
≥500ms
C5/6
? Severe C2
TREAT IPV IN SYMPTOMATIC PATIENT?

≥3.5mm
≥ 500ms
C5/6 ?
? SevereC2

Rx saphenous reflux

Close IPV
TREAT IPV IN SYMPTOMATIC PATIENT?

< 3.5mm
< 500ms reflux
GSV/SSV reflux?
Only if irresistible...

≥3.5 mm
≥ 500ms reflux
C5/6,
? Severe C2
Rx saphenous vein
Close IPV

UGS RFA EVLA