Endovenous repair in ulcer patients: Why, when and how.

Johann Chris Ragg, MD

CEO SWISS VX vein research labs
CEO, Chief Physician angioclinic® Vein Centers
Berlin – Munich - Zurich
Disclosures

• Counselor Venartis Inc.
congenital lesions
• missing valve
• missing cusp
• cusp lesions

acquired vein (valve) lesions
inappropriate stress

+ activity

hypertension
physical stress - dilatation

stasis
inflammation - destruction

vicious circle

valve failure

main modifications:
genetics
pregnancies
therapy

Ragg JC, 2017
Any venous ulcer is due to neglected care.

- Congenital valve damage
- Acquired valve damage
- D = 0.8 mm
- D = 0.14 mm
- C0 - C1 correlate

Severity of disease:
- C0
- C1
- C2
- C3
- C4
- C5
- C6

- > 10
- > 20
- > 30
- > 40 y.
What is a venous leg ulcer?

SVS-AVF Definition

„We suggest use of a standard definition of venous ulcer as an open skin lesion of the leg or foot that occurs in an area affected by venous hypertension“

Implication:
No venous hypertension – no venous ulcer.
Many guidelines: Focus on compression and wound care

<table>
<thead>
<tr>
<th>No</th>
<th>Title</th>
<th>Organisation</th>
<th>Published/updated</th>
<th>Country/international collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Association for the Advancement of Wound Care (AAWC) venous ulcer guideline</td>
<td>Association for the Advancement of Wound Care</td>
<td>(2005) 2010</td>
<td>USA</td>
</tr>
<tr>
<td>2</td>
<td>Management of chronic venous leg ulcers (SIGN CPG 120) (6)</td>
<td>SIGN (GB) - Scottish Intercollegiate Guidelines Network</td>
<td>2010</td>
<td>Scotland</td>
</tr>
<tr>
<td>3</td>
<td>Varicose ulcer (M16) [Varicose ulcer (NL: Ulcus cruris venosum)]</td>
<td>NHG (NL) - Dutch College of General Practitioners</td>
<td>2010</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>4</td>
<td>Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers</td>
<td>Australian Wound Management Association and the New Zealand Wound Care Society</td>
<td>2011</td>
<td>Australia &amp; New Zealand</td>
</tr>
</tbody>
</table>

Is compression and wound care all we can do?

Presscise/Lundatex medical
What are we supposed to do?

Ulcer recurrence: 57-97%*,

- chronicity of the problem
- failure to effectively address the underlying etiology

*Paquette & Falanga, 2002
## Berlin Ulcer Study 2009 – 2017

<table>
<thead>
<tr>
<th>Patients: n = 110</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active ulcers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription: Compression therapy</td>
<td>38</td>
<td>97.4</td>
</tr>
<tr>
<td>Compression media applied/worn daily</td>
<td>16</td>
<td>41.0</td>
</tr>
<tr>
<td>Wound care</td>
<td>27</td>
<td>69.2</td>
</tr>
<tr>
<td><strong>Healed but symptomatic ulcers</strong></td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>Prescription: Compression therapy</td>
<td>69</td>
<td>95.8</td>
</tr>
<tr>
<td>Compression media applied/worn daily</td>
<td>42</td>
<td>58.3</td>
</tr>
<tr>
<td><strong>Vein treatment suggested</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Eligible for endovenous therapy</td>
<td>96</td>
<td>87.3</td>
</tr>
</tbody>
</table>

* Standard hospitals, practitioners. 34/110 cases had former vein surgery
Imaging

Standard for superficial and deep vein lesions:
**Ultrasound 3 – 16 MHz... sufficient for 88% of the cases**

Options:
Phlebography (obese patients, deep veins, complex lesions)

CT/CTA, MRI/MRA: Pelvic obstruction/congestion

185 Kg/160 cm, complex recurrent varices, pelvic congestion, May Thurner syndrome
### Berlin Ulcer Study 2009 – 2017

Relevant pathology in ulcer patients (n = 110)  

<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic obstruction*</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Femoral obstruction</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Popliteal obstruction</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Infrapopliteal obstruction</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Recanalized thrombotic obstructions (PTS)  

<table>
<thead>
<tr>
<th>Obstruction</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Femoral</td>
<td>3</td>
<td>2.7</td>
</tr>
<tr>
<td>Popliteal</td>
<td>10</td>
<td>9.0</td>
</tr>
<tr>
<td>Infrapopliteal**</td>
<td>24</td>
<td>21.8</td>
</tr>
</tbody>
</table>

*All obstructions due to thrombosis*

**lower leg deep veins: history not well documented**
Venous obstruction

Pelvic vein obstruction: Interventional recanalization meanwhile established, yet without clear guidelines

Still a problem: Determination of pressure change to be expected after recanalization.

Neglén P, Raju, S. Balloon Dilation and Stenting of Chronic Iliac Vein Obstruction: Technical Aspects and Early Clinical Outcome. Journal of Endovascular Therapy, 2000; 7(2); 79 – 91


SVS – AVF Clinical Practical Guidelines for Venous Ulcers

> 90%

Venous Ulcer

Diagnostics

+ reflux

- reflux

+ superfiical

+ perforator

Rx Endo (open)

Failed/ not option Reevaluate

+ Superficial/perforator

Deep reflux

Valvular reconstruction

+ obstruction

< 10%

+ proximal

Rx Endo

Failed/ not option Reevaluate

+ infrainguinal

Bypass unilateral

+ proximal

Bypass/ endophtlebectomy

Not option/ Reevaluate

Bypass bilateral

Highest risk

*** clarification:
+/- ulcer treat both, no ulcer treat only superficial

similar risk/benefit: Moderate risk

similar risk/benefit: Less risk

Copyright © 2014 Society for Vascular Surgery

Endovenous treatment: Usually several steps

First step

Second step
**Suspected source of ulcer (n = 110)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant reflux at time of presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Superficial only (GSV, SSV)*</td>
<td>3</td>
<td>2.7</td>
</tr>
<tr>
<td>Superficial + perforators</td>
<td>39</td>
<td>23.6</td>
</tr>
<tr>
<td>Perforators only</td>
<td>7</td>
<td>6.3</td>
</tr>
<tr>
<td>Superficial + perforators + lower leg deep veins</td>
<td>48</td>
<td>34.5</td>
</tr>
<tr>
<td>Perforators + lower leg deep veins</td>
<td>27</td>
<td>7.2</td>
</tr>
<tr>
<td>Deep veins lower leg only</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Severe PTS femoral – popliteal – lower leg veins</td>
<td>14</td>
<td>12.7</td>
</tr>
<tr>
<td>Other (e.g. additional vascular malformations)</td>
<td>2</td>
<td>1.8</td>
</tr>
</tbody>
</table>

*Tributaries involved in all cases, but not relevant for ulcer genesis*

*Green: Selected for endovenous therapy*
## Superficial reflux

<table>
<thead>
<tr>
<th>Year</th>
<th>C5 healed ulcer</th>
<th>C6 active ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 – 2017</td>
<td>39</td>
<td>25</td>
</tr>
</tbody>
</table>

### Superficial reflux

- **No. of cases:** 64
- **Criterion improvement***
- **Success***

<table>
<thead>
<tr>
<th></th>
<th>C5</th>
<th>C6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>39</td>
<td>25</td>
</tr>
<tr>
<td>Pain relief, decay of inflammation</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Laser, RF, ScleroGlue (foam + glue), biomatrix sclerofoam
Superficial reflux

GSV 16-32 mm
massive reflux
ectasias
phlebitis
chronic ulcer (>10 yrs)
Superficial reflux

Treatment:

Single catheter access

SFJ: laser 810 nm
Biomatrix sclerofoam

Compression film bandage

Tennis pain free on day 3!

4 weeks
3 months
Cochrane Review*: Endovenous thermal ablation suggested

State-of-the-art: All methods eligible!

Near to ulcera, skin damage or inflammation:
Remote catheter techniques preferred!
Non-thermal techniques preferred!

For decades, invasive therapy was strictly by surgery.

Endoscopically guided perforator dissection (HACH): Novelty 25 years ago!

## Perforator reflux: Endovenous treatment

<table>
<thead>
<tr>
<th>Year</th>
<th>C5 healed ulcer</th>
<th>C6 active ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 – 2017</td>
<td>89</td>
<td>48</td>
</tr>
</tbody>
</table>

**Perforator reflux**
- Treated: 89
- C5: 48
- C6: 41

**Criterion**
- Improvement**: 48
- Healing: 41

**Success**: 48
- 100%

---

* single or multiple, alone or with saphenous disease, first or second session
** Pain relief, decay of inflammation
*** all cases: biomatrix sclerofoam (investigational)
Study *Biomatrix sclerofoam* for perforator insufficiency, 2009 – 2017; patients: n = 1443 (ulcer cases: n = 89).
Primary closure: 93.1%. No DVT. FU 3 - 9 yr.: 86.2% occluded.

- no anesthesia
- no thermal risk
- no risk of arterial lesion
- no stump*
- no source for emboli

*Viscous microfoam containing 20% denaturized autologous blood*
**Infrapopliteal deep vein reflux – holy cow?**

<table>
<thead>
<tr>
<th>Year</th>
<th>C5 Healed Ulcer</th>
<th>C6 Active Ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 – 2017</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ulcer related to reflux of ATV, PTV, FibVv.*

| No. of cases: 34/55 | 19 | 15 |

<table>
<thead>
<tr>
<th>Criterion improvement**</th>
<th>Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success***</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td></td>
</tr>
<tr>
<td>89.5%</td>
<td>13</td>
</tr>
<tr>
<td>86.7%</td>
<td></td>
</tr>
</tbody>
</table>

*eligible if single or double vessel disease, other lower leg veins not diseased

**Pain relief, decay of inflammation

***biomatrix sclerofoam (investigational)  **FAILED CASES: TREATMENT STILL IN COURSE (2017)**
Example: Tibial posterior vein reflux

Ulcer 3 x 4 cm, healing slowly after 8 months of intensive compression therapy, stockings German class III (28-34 mmHg).

Reflux: Posterior tibial vein (2 x!) + distal GSV + medial perforators cm 18 + 12
Tibial posterior vein reflux

Popliteal vein:
Post-thrombotic, Recanalized, stagnant flow

Session 1: GSV + Perforators:
Not sufficient, still pain.
Session 2: Tib. post. veins

Details:
- ant. fib. Post. GSV
Distal GSV, perforator, TPV (2 sessions): Biomatrix Sclerofoam
Tibial posterior vein reflux

6 months post

One year FU
skin almost normalized
totally pain-free
tiny refluxive residual
Tibial posterior vein reflux

24 months FU:
One PTV occluded, the other with minor reflux. Skin: Perfect status. Patient highly satisfied.
<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2009 – 2017</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not eligible:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe PTS with femoral and popliteal reflux</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>+ all lower leg deep veins involved</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
<td>12.7</td>
</tr>
<tr>
<td>Eligible for advanced endovenous therapy</td>
<td>96</td>
<td>87.3</td>
</tr>
</tbody>
</table>
Aim: To allow wearing of compression stockings.
Biomatrix Sclerofoam (2.5 ml) for an 8 cm fibular vein segment (foam plug)
PTS - deep vein reflux

Summary of guidelines

- Analyze venous hemodynamics and vein morphology from heart to foot
- Try to understand the individual history of insufficiency
- Determine reflux which is relevant for the ulcer

- Eliminate major causes of venous hypertension
- Check changes in ulcer area (2 – 3 months)
- If not satisfactory, consider additional reflux elimination
- Try all supportive modalities (activation, compression...
Due to an oath, he would not sit or lay down for 30 years. When he reached the age of 60, a non-healing venous ulcer, maybe even with malignant degeneration, led to the suggestion of open amputation. The night before surgery he had a vision of Jesus Christ who bent down from the cross and touched his leg. In this moment, Peregrine was fully cured.
Endovenous repair in ulcer patients:

A majority of hemodynamic disorders (reflux, hypertension) is well treatable - we are able to succeed (WHY).

Exact analysis of hemodynamics is crucial for an appropriate treatment strategy. Can flow be improved? Do it! (WHEN).

The nearer a venous target is located to an ulcer or to diseased skin, the clearer is the decision for endovenous methods.

Endovenous techniques, in particular such with no heat and no need for tumescence, should be preferred (HOW).
Glimpse at the future

Within the next 25 years, the incidence of venous ulcers will decrease significantly in “developed countries”, as superficial and perforator reflux becomes easily detectable and stoppable.

If this process is not induced by the increasing awareness of patients and physicians, it will be induced due to cost pressure by the authorities.

For the majority of cases with risk for ulcers, a 50 USD diagnosis (10 min. color doppler) and a 150 USD treatment (microcatheter, improved foam), maybe combined with low-pressure compression stockings, maybe repeated after years, will be sufficient for vein restoration and status maintenance.

Artificial vein valves will become a standard for deep vein insufficiency.
Thank you very much for your attention.

Ideas for innovations?

Submit your idea* NOW and win a 1,000 USD Travel Stipend!

*abstract, poster, publication or text > 250 words.
Scan QR code to access web site!
Submission until 30th of September 2017.
Winner will be announced during the meeting.

www.venartis.org

Work Group Dr. Ragg www.venartis.org

“To improve everything in the field of phlebology”