Preservation of Saphenous Trunks: EXTERNAL VALVULOPLASTY

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I am the proposer of the Stretching Valvuloplasty technique, but ... I have no financial relationships to disclose.
What Treatment?

  Improving the management of varicose veins.
  
  "... recommends that endothermal ablation, in the form of RF or Laser treatment, should be offered as treatment"

- **Carroll C** et al. (UK). Health Technol Assess *2013;*17:1-141.
  Clinical effectiveness and cost-effectiveness of minimally invasive techniques to manage varicose veins: a systematic review and economic evaluation.
  
  "... Foam Sclerotherapy might offer the most cost-effective alternative to stripping, within certain time parameters."
Trials with 5 years f-u

(HighLigation+Sripping, EVLAser)

<table>
<thead>
<tr>
<th>RCT on 137 legs, up to 5 years</th>
<th>HL+S</th>
<th>EVLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical recurrence</td>
<td>55%</td>
<td>47%</td>
</tr>
<tr>
<td>Reoperation</td>
<td>38%</td>
<td>39%</td>
</tr>
<tr>
<td>VCSS (Venous Clinical Severity Score)</td>
<td>=</td>
<td>=</td>
</tr>
</tbody>
</table>


... did not show any significant difference between the two groups
Causes of Recurrence

- **Ostler AE et Al (UK). Phlebology 2014.** *Strip-tract revascularization as a source of recurrent venous reflux following high saphenous tie and stripping: results at 5-8 years after surgery.*

  “... 82% of legs of patients showed some strip-tract revascularization and reflux, ... 12% showed total revascularization and reflux of the stripped GSV”


  “... explains why varicose vein and reflux recurrence can occur after any mode of therapy.”
The Matter: VVs Recurrence

Diverging lines after 3 years f-u


The Matter: VVs Recurrence

Recurrence Rate of Varicose Veins at late F-U after Ablative Vs. Conservative strategy


The Recurrence % has halved after CHIVA at long-term f-u !
[1] at 5 y. f-u
Why the Gap?
- Ablation Vs CHIVA -

• Each study can be criticized for anything, but until a more reliable one proves the contrary, it remains valid

• Between the two strategies, CHIVA shows anatomic & patho-physiological peculiar difference: the VGS preservation
GSV: ablation Vs CHIVA

The Main Perforator

Weaknesses at long-term

Strengths

X: High ligation
Y: Stripping GSV (y1), Phlebectomy of tributary VV (y2)

X: High ligation
Y: Single Stripping of the incompetent segment GSV (y1), Phlebectomy of VV (y2)
Z: Subfascial closure of the Re-entry Point (PV)

1: High ligation
2: Disconnection of secondary Reflux Point
3: Preservation of the Re-entry Point (PV)
4: Phlebectomy of non-draining tributary VV
Reflux Patterns in VVs

by: Camilli S. Minerva Angiologica 1992;17:59-62
- from >1,000 descending venographies -

1\textsuperscript{st} Pattern
Typical

2\textsuperscript{nd} Pattern
Complex A
Complex B
Complex C

3\textsuperscript{rd} Pattern
Atypical

≈30%
≈30%
≈10%
≈5%
≈25%

The most of recurrencies occur in this group

Patho-Physiology process is like in PTS
In case of CVI and VVs, the best option should be:

1. **Hemodynamic approach** (like in CHIVA) by:
   - DUS + Reflux mapping

2. **Valvuloplasty** (if eligible) to:
   - Valve Repair & Reflux stopping
   - Maintain forward drainage

3. **GSV Conservative** techniques by:
   - CHIVA, Müller, ASVAL, Sclero-foam, others ...
Valvuloplasty
... on which cases?

ELIGIBILITY:
✧ VALVE CUSPS, visible, freely floating, symmetric
✧ GSV, having segmental (or subtotal) reflux
✧ PATIENT, with recent VVs (early stage) or young age

EXCLUSION:
✧ VALVE CUSPS, undetectable, frozen, asymmetric
✧ GSV, with previous phlebitis
✧ PATIENT, with severe VVs or aged (or other excluding conditions)
Valves: Some features

- duplex imaging -
Valvuloplasty
... which Technique?

The Stretching Valvuloplasty
with
OSES device implant
(Oval Shaped External Support)

Specifications:

- **material**: NiTi alloy (Nitinol)
- **A – B**: active elements
- **c/c’ – d/d’**: eyelets for fixation
- **e**: connecting element
- **f**: handling means
The OSES device:
- must be **oversized** (of about +30%) with respect to the native valve diameter
- must be **sutured** in correspondence of the intercommissural apices
- must obtain the **oval shaped valve cross section**
OSES Valvuloplasty: The procedure
# Stretching Valvuloplasty

- Personal series on 2014 -

<table>
<thead>
<tr>
<th>Patology</th>
<th>Cases N°</th>
<th>F-U at 5 aa</th>
<th>Reflux stopped</th>
<th>Reflux reduced</th>
<th>Failure</th>
<th>Post-op. procedures</th>
<th>GSV Stripping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary VVs (GSV)</td>
<td>42</td>
<td>21</td>
<td>16</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Secondary VVs in PTS (GSV)</td>
<td>3</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Recurrent VVs + PDVI (SFV)</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>*</td>
</tr>
</tbody>
</table>

* Bilateral, in a previous time

A multicentric DATA REGISTRY for STRETHCING VALVULOPLASTY is being formed
Long-term Results of V-OSES intervention in Primary VVs
No. 21/42 cases at 5 y. FU

Chart showing:
- F-U (Clinical + DUS): 21 cases
- SFJ Full competence: 16 cases
- Moderate reflux: 3 cases
- Failure: 2 cases
- Foam or Avulsion: 12 cases
- QoL: 18 cases
- GSV ablation: 0 cases
Short-term Results of V-OSES intervention in Secondary VVs in PTS
No. 3/3 cases at 20th-18th-3rd mo. FU
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Conclusions 1

- AIM: to have better long-term results in VVs -

ReVas PREVENTION:

① Hemodynamic Approach (like on CHIVA)
   – DUS (deep & superficial) + Reflux mapping

② Valvuloplasty in eligible cases
   – SFJ Valve Repair & Reflux stopping
   – Maintain forward (as well as backward) drainage

③ GSV Conservative (any technique?)
   – CHIVA, Müller, ASVAL, Sclero-foam, others...
Conclusions 2

- we need the S-Valvuloplasty procedure’s validation -

For ELIGIBILITY

• Better **knowledge** on venous valves
  – anatomy, DUS, pathology, ...

For EFFICACY

• Larger **Clinical Experience** and RCT

A **DATA REGISTRY** is being formed:
If you are **interested** in participating, you can join by e-mail
God save the vein!

God Save the Vein!

EXTERNAL VALVULOPLASTY

? 

Thanks for your Attention

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