Outcome assessment

"Outcome assessment of therapy of varicose veins and more advanced CVD includes standardized objective criteria that reflect patient symptoms, characteristic signs, and objective measures of functional and disease-specific QOL."

Disclosures

• No Conflicts
Generic QOL Instruments

- Allows comparison with population norms and other disease states and provide a measure of any ill effects of treatment.

Short Form 36-Item Health Survey (SF-36)

Venous disease-specific QOL Instruments

- Disease-specific QOL measurements are sensitive to the beneficial effects of treatment.
- Most frequently used validated venous disease – Specific instruments include
  - VEINES-QOL/Sym
    - Venous insufficiency Epidemiologic and Economic Study of Quality of Life
  - CIVIQ
    - Chronic Venous Insufficiency Questionnaire
  - AVVQ
    - Aberdeen Varicose Vein Questionnaire
  - CXVUQ
    - Charing Cross Venous Ulceration Questionaire

VEINES INSTRUMENT*

- Consists of 35 items in 2 categories
- VEINES-QOL questionnaire 25 items
- Study the effect of disease on QOL
- VEINES-Sym questionnaire 10 items
  - That measure symptoms
- *Focus on physical symptoms rather than psychological and social aspects

Validated

CIVIQ 2

- Measures physical, psychological, social and pain factors
- Equal weight to each category – 20 questions that provide a global score

Validated

AVVQ

- 13 question survey addressing all elements of VV disease. Scored 0-100 (most severe)
- Physical symptoms and social issues
  - Pain, edema, ulcers, compression therapy use effect on daily activities

Physician generated measurement tools

- CEAP
  - Accurate description of signs and symptoms
  - Issues with the static elements C4-C6
- VCSS
  - Based on 9 clinical signs or symptoms of CVD
    - As well as compliance with compression
  - Correlates well with the CEAP
Outcome assessment

**Clinical Severity of Superficial Venous Disease**

<table>
<thead>
<tr>
<th>CEAP</th>
<th>Clinical signs of venous disease (C), Etiology (E), Anatomy (A), Pathophysiology (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCSS</td>
<td>Venous Clinical Severity Score</td>
</tr>
<tr>
<td>PROs</td>
<td>Patient-Reported Outcomes</td>
</tr>
</tbody>
</table>

**Physician-generated measurement tools**

- At the 5th annual meeting of the American Venous Forum (AVF) in 1993, John Porter suggested using the same approach as TNM (Tumor/Node/Metastasis) for cancer to develop a classification system for venous diseases.

- The AVF in the 6th annual meeting in February 1994 on the island of Maui, Hawaii, an international ad hoc committee, chaired by Andrew Nicolaides, developed the first CEAP consensus document.

**CEAP**

- C Class: Clinical Manifestation
  - C0: No visible or palpable signs of venous disease
  - C1: Telangiectasias or reticular veins
  - C2: Varicose veins, distinguished from reticular veins by a diameter 3 mm
  - C3: Edema
  - C4: Changes in skin and subcutaneous tissue
    - C4a: Pigmentation or eczema
    - C4b: Lipodermatosclerosis or atrophie blanche
  - C5: Healed venous ulcer
  - C6: Active venous ulcer

  - Further subdivided with subscript S (symptomatic) or A (asymptomatic)

- Relatively static system.

- The CEAP clinical class of disease represents a spectrum of disease severity.

- Does not allow assessment of change in response to treatment or adverse events.
• In response to the need for a disease severity measurement, the AVF committee on outcomes assessment developed the Venous Severity Scoring system in 2000.

### Revised VCSS

<table>
<thead>
<tr>
<th>Description</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 limiting</td>
</tr>
<tr>
<td>Venous ulcers</td>
<td>None</td>
<td>Painless</td>
<td>Calf or thigh</td>
<td>Calf and thigh</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>None</td>
<td>Few</td>
<td>Calf or thigh</td>
<td>Calf and thigh</td>
</tr>
<tr>
<td>Skin pigmentation</td>
<td>None</td>
<td>Perimalleolar</td>
<td>Lower 1/3 calf</td>
<td>Wider, above lower 1/3 calf</td>
</tr>
<tr>
<td>Ulceration</td>
<td>None</td>
<td>Perimalleolar</td>
<td>Lower 1/3 calf</td>
<td>Wider, above lower 1/3 calf</td>
</tr>
<tr>
<td>No. active ulcers</td>
<td>None</td>
<td>1</td>
<td>2</td>
<td>2 or more</td>
</tr>
<tr>
<td>Ulcer size</td>
<td>None</td>
<td>&lt; 2 cm</td>
<td>2 – 6 cm</td>
<td>&gt; 6 cm</td>
</tr>
<tr>
<td>Ulcer duration</td>
<td>None</td>
<td>&lt; 3 mo</td>
<td>3 – 12 mo</td>
<td>&gt; 1 yr</td>
</tr>
<tr>
<td>Compression Therapy</td>
<td>None</td>
<td>Untreated</td>
<td>Most days</td>
<td>Fully compliant</td>
</tr>
</tbody>
</table>

### PROs

AVVQ, VEINES-QoL, CIVIQ, SQOR-V, VVSymQ
Case Study 1

48 Y/O F C/O R LEG VV WITH SX AND GSV REFLUX

Case Study 2

48 Y/O F C/O R LEG VV WITH SX AND GSV REFLUX

Pre op | Post op
---|---
CEAP | C3 | CEAP | C3
VCSS | 7 | VCSS | 2
Pain interfering daily activities | 2 | Pain interfering daily activities | 1
- Varicosities at calf | 2 | - Varicosities | 0
- Edema above ankle | 2 | - Edema above ankle | 1
- Intermittent use of stockings | 1 | - Intermittent use of stockings | 0
VV SymQ | 11 | VV SymQ | 4
- Heaviness | 2 | - Heaviness | 0
- Achiness | Some of the time | - Achiness | None of the time
- Swelling | Most of the time | - Swelling | Little of the time
- Throbbing | Some of the time | - Throbbing | Some of the time
- Itching | None of the time | - Itching | None of the time

Clinical Severity of Superficial Venous Disease

PROs

NEED TO ESTABLISH SEVERITY BEFORE YOU CAN MEASURE OUTCOMES