Outcome assessment

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

• help determine the progress of a patient.

• Specific questionnaires relevant to the patient’s chief complaint.

• Given to the patient before treatment and again at various re-examination intervals.

• Considered to be indicators as to whether a patient is improving, staying the same, or getting worse.
Generic QOL Instruments

• This 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.

They are the most frequently used and validated for venous disease.

Specific instruments include:

- VEINES-QOL
- VEINES-Sym
- CIVIQ
- AVVQ
- CXVUQ
- VVSymQ

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

Validated

VVSymQ

• Proprietary

• Patient reported
  • Physical symptoms and Duration
  • HASTI Score 0-5

• Validated
Physician generated measurement tools include:

- CEAP
- VCSS

Outcome assessment

<table>
<thead>
<tr>
<th>Clinical Severity of Superficial Venous Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAP Clinical signs of venous disease (C), Etiology (E), Anatomy (A), Pathophysiology (P)</td>
</tr>
<tr>
<td>Description of signs and symptoms (MD generated)</td>
</tr>
<tr>
<td>VCSS Venous Clinical Severity Score Grades the severity of Chronic Venous Disease (MD generated)</td>
</tr>
</tbody>
</table>

Physician-generated measurement tools

- PRO
  - Perception of Quality of Life Assessment
  - (Patient generated)

CEAP

**C Class: Clinical Manifestation**

- C0: No visible or palpable signs of venous disease
- C1: Telangiectasia or reticular veins
- C2: Varicose veins, distinguished from reticular veins by a diameter ≥ 3 mm
- C3: Edema
- C4: Changes in the skin or subcutaneous tissue
  - C4a: Pigmentation or eczema
  - C4b: Lipodermatosclerosis or atrophic blanche
- C5: Healed venous ulcer
- C6: Active venous ulcer

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

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* 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.

* At the 6th annual AVF meeting, February 1994, Maui, Hawaii, an international ad hoc committee chaired by Andrew Nicolaides developed the first CEAP consensus document.
Physician-generated measurement tools

**CEAP Classification**

- Relatively static system.
- Represents a spectrum of disease severity.
- Does not allow assessment of change in response to treatment or adverse events.

**Venous Clinical Severity Score (VCSS)**

- In response to the need for a disease severity measurement, the AVF committee on outcomes assessment developed the Venous Severity Scoring System in 2000.
- Generates a dynamic score and can be used prior to treatment and post-intervention.


**VCSS Descriptor Absent (0) Mild (1) Moderate (2) Severe (3)**

- Pain: None, Occasional, Daily, Daily limiting
- Varicose veins: None, Few, Calf or thigh, Calf and thigh
- Venous edema: None, Foot and ankle, Above ankle, below knee, To knee or above
- Skin Pigmentation: None, Perimalleolar, Diffuse, lower 1/3 calf, Wider, above lower 1/3 calf
- Inflammation: None, Perimalleolar, Diffuse, lower 1/3 calf, Wider, above lower 1/3 calf
- Induration: None, Perimalleolar, Diffuse, lower 1/3 calf, Wider, above lower 1/3 calf
- No. active ulcers: None, 1, 2, > 3
- Active ulcer size: None, < 2 cm, 2 – 6 cm, > 6 cm
- Ulcer duration: None, < 3 mo, 3 – 12 mo, > 1 yr
- Compression Therapy: None, Intermittent, Most days, Fully comply

Physician-generated measurement tools

**VVSymQ**

Patient-generated measurement tools
The VQI Varicose Vein Registry  
First ten months results  
Andrea Obi, Jose Almeida, Lowell Kabnick, Jack Cronenwett,  
Dan Neal, Nick D’Alonzo, Danielle Horne, Catherine Raftery,  
Carrie Bosela, Thomas Wakefield  

Disclosures:   JC - Medical director of SVS/PSO, funded by SVS and NGS

Number treated
- 2661 veins were treated on 1803 limbs with 1751 procedures (either in office or operating room).
- Laterality:
  - 48% right
  - 49% left
  - 3% bilateral

C score change
- N=739; Mean change of -0.71 ± 1.18 p<0.001

VCSS
- N=714
- Change: -4.68 ± 3.35
- P<0.001

Patient reported outcomes
- Pre and post procedure data available for 607 patients
- Mean total change: -10.74±6.94, p<0.001

48 y/o F c/o R Leg VV with sx and GSV reflux
<table>
<thead>
<tr>
<th>Pre op</th>
<th>Post op</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAP C3</td>
<td>CEAP C3</td>
</tr>
<tr>
<td>VCSS 6</td>
<td>VCSS 3</td>
</tr>
<tr>
<td>Pain interfering daily activities</td>
<td>Pain interfering daily activities</td>
</tr>
<tr>
<td>– Varicosities at calf</td>
<td>2</td>
</tr>
<tr>
<td>– Edema above ankle</td>
<td>2</td>
</tr>
<tr>
<td>– Intermittent use of stockings</td>
<td>1</td>
</tr>
<tr>
<td>VV SymQ 11</td>
<td>VV SymQ 4</td>
</tr>
<tr>
<td>Heaviness</td>
<td>Heaviness</td>
</tr>
<tr>
<td>– Some of the time</td>
<td>None of the time</td>
</tr>
<tr>
<td>– Good bit of the time</td>
<td>Little of the time</td>
</tr>
<tr>
<td>– Swelling</td>
<td>Some of the time</td>
</tr>
<tr>
<td>– Throbbing</td>
<td>Some of the time</td>
</tr>
<tr>
<td>– Itching</td>
<td>None of the time</td>
</tr>
</tbody>
</table>

48 y/o F c/o R Leg VV with sx and GSV reflux

**CEAP C2**

<table>
<thead>
<tr>
<th>Pre op</th>
<th>Post op</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCSS 5</td>
<td>VCSS 5</td>
</tr>
<tr>
<td>Pain interfering daily activities</td>
<td>Pain interfering daily activities</td>
</tr>
<tr>
<td>– Varicosities at calf</td>
<td>2</td>
</tr>
<tr>
<td>– Edema</td>
<td>3</td>
</tr>
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<td>– Intermittent use of stockings</td>
<td>1</td>
</tr>
<tr>
<td>VV SymQ 6</td>
<td>VV SymQ 6</td>
</tr>
<tr>
<td>Heaviness</td>
<td>Heaviness</td>
</tr>
<tr>
<td>– Some of the time</td>
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<tr>
<td>– Itching</td>
<td>None of the time</td>
</tr>
</tbody>
</table>

**Clinical Severity of Superficial Venous Disease**

**PROs**

**I'M Star d'Argent**

Thank you
lsk@lowellkabnick.com