Do Venous Procedures Have an Impact on Quality of Life?

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Disclosure

Mark Meissner, M.D.

I have no financial relationship(s) to disclose.
# Venous Outcome Measures

<table>
<thead>
<tr>
<th>Acute DVT</th>
<th>Technical</th>
<th>Clinical</th>
<th>Functional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Lysis</td>
<td>Death</td>
<td>Generic QoL †</td>
</tr>
<tr>
<td></td>
<td>Venographic Scores</td>
<td>Recurrent DVT</td>
<td>Disease Specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Villalta Score</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>VCSS</td>
<td></td>
</tr>
<tr>
<td>Chronic Venous Disease</td>
<td>Closure rates</td>
<td>Recurrent VV*</td>
<td>Generic QoL †</td>
</tr>
<tr>
<td></td>
<td>Hemodynamics</td>
<td>VCSS**</td>
<td>Disease Specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ulcer Healing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ulcer Recurrence</td>
<td></td>
</tr>
</tbody>
</table>

*VV - Varicose Veins

**VCSS - Venous Clinical Severity Score

†QoL - Quality of Life
Limitations of Outcome Measures

- **Technical outcomes**
  - Useful in evaluating potential of new technology
  - Unimportant to patient / health care system
  - Should not alter standard of care

- **Clinical outcomes**
  - Differences in physician/patient perceptions
  - Signs /symptoms differ among patients
  - Failure to capture entire burden of disease

- **Quality of life**
  - Physical
  - Psychological
  - Social
  - Patient reported
  - Capture full effect of disease
QoL: Physician vs Patient Perceptions
Chassany et al; Value Health 2006

- Patient vs physician reported QoL
  - Disease impact underestimated in CVD
  - Disease impact overestimated in claudication

Chronic Venous Disease (CIVIQ)
Claudication (CLAU-S)
Quality of Life Instruments

- **Generic (SF-36, EuroQol, Nottingham Health Profile)**
  - Provide perspective to population norms
  - Account for comorbidities
  - Responsive to ill treatment effects
  - Insensitive to positive treatment effects

- **Disease-specific**
  - Include key dimensions of specific disease
  - Responsive to positive treatment effect
  - May be insensitive to ill treatment effects

- Best used in combination
## Venous Disease-Specific Instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Items</th>
<th>Spectrum</th>
<th>Transform</th>
<th>Validated</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRQOL (Comerota)</td>
<td>80</td>
<td>Acute DVT</td>
<td>Yes</td>
<td>English</td>
</tr>
<tr>
<td>SCOR-V</td>
<td>46</td>
<td>C0-C3</td>
<td>No</td>
<td>Responsiveness not validated</td>
</tr>
<tr>
<td>Veines-QoL</td>
<td>26</td>
<td>C1-C6</td>
<td>Yes</td>
<td>English, French, Italian</td>
</tr>
<tr>
<td>AVVQ</td>
<td>13</td>
<td>C1-C6</td>
<td>No</td>
<td>English</td>
</tr>
<tr>
<td>CIVIQ</td>
<td>20</td>
<td>“Venous Insufficiency”</td>
<td>Yes</td>
<td>English, French</td>
</tr>
<tr>
<td>Charing Cross</td>
<td>20</td>
<td>C6</td>
<td>Yes</td>
<td>English</td>
</tr>
</tbody>
</table>
Thrombolytic Therapy for DVT

- Technical results predominate
- Thrombolytic agents lyse thrombus
- More bleeding complications than anticoagulation
- No evidence suggesting clinical benefit

<table>
<thead>
<tr>
<th>Drug</th>
<th>Author</th>
<th>N</th>
<th>Technical Success</th>
<th>Major Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urokinase</td>
<td>Semba</td>
<td>21</td>
<td>85%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Bjarnason</td>
<td>77</td>
<td>79%</td>
<td>6.6%</td>
</tr>
<tr>
<td></td>
<td>Mewissen</td>
<td>287</td>
<td>83%</td>
<td>11%</td>
</tr>
<tr>
<td>r-tPA</td>
<td>Verhaege</td>
<td>24</td>
<td>79%</td>
<td>25%</td>
</tr>
<tr>
<td>Retaplase</td>
<td>Ouriel</td>
<td>11</td>
<td>73%</td>
<td>9.1%</td>
</tr>
<tr>
<td></td>
<td>Castenada</td>
<td>25</td>
<td>92%</td>
<td>4%</td>
</tr>
</tbody>
</table>
Quality of Life after Iliofemoral DVT
Comerota et al, J Vasc Surg 2000

- Retrospective, non-randomized study
  - 68 patients - Catheter directed thrombolysis
  - 30 patients - Standard anticoagulation
- Validated 80 item HRQOL questionnaire

*p < 0.05
Varicose Veins and Quality of Life
Smith et al; J Vasc Surg 1999

- 137 patients undergoing GSV and / or SSV surgery
- Improvements in both generic & specific instruments

SF-36

\[ p < 0.05 \] for mental health

AVVQ

\[ p < 0.0001 \]
Generic QoL and Venous Ulceration

Iglesias et al, Qual Life Res 2005

- 12 month responsiveness of SF-12 in 387 patients

<table>
<thead>
<tr>
<th></th>
<th>Physical Component (mean)</th>
<th>Mental Component (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healed</td>
<td>Unhealed</td>
</tr>
<tr>
<td>Baseline</td>
<td>35.71</td>
<td>34.39</td>
</tr>
<tr>
<td>12 mo</td>
<td>35.46</td>
<td>32.84</td>
</tr>
<tr>
<td>Change</td>
<td>-0.42</td>
<td>-3.04</td>
</tr>
</tbody>
</table>

- Mental component improved with ulcer healing
- Physical component worsened with ulcer healing
  - Related to bodily pain
  - Bodily pain poorly related to ulcer healing
Disease-Specific QoL and Ulceration

Smith et al, J Vasc Surg 2000

- Responsiveness of Charing Cross Ulcer Score
- Validated against SF-36 in 98 patients
- Responsiveness in 10 patients with healed ulcers

* Improved QoL with lower score (*p* =0.005)
Comparative Effectiveness Research
The “New” Holy Grail of Evidence-Based Medicine

- $1.1 billion allocated under ARRA 2009
- “A rigorous evaluation of treatment options” (Congressional Budget Office 2007)
- May focus on
  - Patient important benefits/risks (clinical effectiveness)
  - Patient important cost/benefit (cost effectiveness)
- The right treatment for the right patient (… ± at the right price)
Quality Adjusted Life Years
The Universal Currency

- Allows comparison of interventions across disease states
- HRQoL based on health state valuations (EQ-5D, SF-6D, HUI)
- QALY = Life expectancy X Quality of remaining years (0 – 1)
- 1 QALY – 1 year of perfect health
- Cost-utility ratios – Cost to generate 1 yr of perfect health
CER Research – Randomized Trials
The REACTIV Trial (Ratcliffe, Br J Surg 2006)

<table>
<thead>
<tr>
<th></th>
<th>Conservative</th>
<th>Surgery</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean NHS Cost</td>
<td>£344.53</td>
<td>£733.10</td>
<td>£388.57</td>
</tr>
<tr>
<td>AUC SF-6D</td>
<td>1.42</td>
<td>1.50</td>
<td>0.083</td>
</tr>
<tr>
<td>ICER *</td>
<td></td>
<td></td>
<td>£4682</td>
</tr>
</tbody>
</table>

*Incremental cost effectiveness ratio

- 246 patients extensive vv and saphenous reflux randomized to
  - Conservative measures (n = 122)
  - Saphenous stripping / phlebectomy (n = 124)
- 24 mo cost effectiveness of £4682 per QALY gained
- Below NHS threshold of £20,000 per QALY
Conclusions

- Treatment should be driven by outcomes of importance to:
  - Patient
  - Health care system
- Limitations of clinical outcome measures:
  - Clinically important outcomes differ between patients
  - Patient and physician perceptions differ
- QoL most relevant outcome measure
- Generic / specific instruments complimentary:
  - Generic - Account for negative treatment effects
  - Disease-specific - Responsive to positive treatment effects
- Treatment of venous disease *does* improve QoL
  - Acute DVT
  - Varicose veins
  - Venous ulcers