Quality of Life Assessment After Iliac Vein Stenting for DVT from May-Thurner Syndrome

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Endovascular Iliac Vein Interventions

- Becoming increasingly prevalent
- Lack of QOL and patient-reported outcomes data
- Existing forms are cumbersome and not specifically designed for iliac vein interventions
- Discuss relevant literature
- Conclude with our own experience

Quality of Life Scores – Which One?

Many Scores are available

VCSS CIVIQ-20 CEAP VEINES-QOL VEINES-Sym VVsymQ Vascu-QOL AVVS SCOR-V SF-36 WIQ Villalta NHP CVXUQ

Clinical Assessment of Endovascular Stenting Compared with Compression Therapy Alone in Post-thrombotic Patients with Iliofemoral Obstruction

Table 1. Villalta’s PTS score

<table>
<thead>
<tr>
<th>Symptom/clinical sign</th>
<th>New</th>
<th>Mild</th>
<th>Moderate 10-14</th>
<th>Severe 215</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Claudication</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Hiccup</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Venous ulceration</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Venous bleeding</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Venous ulcers</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Venous pain from calf compression</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Venous edema</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
| PTS score change before and after treatment: | Moderate PTS | 13 (10-14) | 51 (18-36) | 0.001
| Compression therapy    | Moderate + severe PTS | 22 (18-36) | 80 (18-90) | 0.001

Table 4. Villalta score before and after treatment.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Compression Therapy</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
</table>
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| Villalta score after treatment | Moderate + severe PTS | 22 (18-36) | 80 (18-90) | 0.001

* Concluded that only post-thrombotic patients with severe PTS (as assessed by Villalta) benefit from endovascular treatment.
A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction

M.I. Aprag, A. Bouzid, S. Sharman, A. Piotrowski
Department of Vascular and Endovascular Surgery, Chelsea and Westminster Hospital, London, UK

- Total of 16 studies
- 2373 PTS and 2586 NIVL
- Too heterogeneous to perform meta-analysis
- 56%-100% Ulcer healing rate in limbs that had often already failed conservative therapy
- Major complication rate < 2%

Quality-of-life in interventional treated patients with post-thrombotic syndrome

Quality of Life (QOL) was evaluated by
- VEINES-QOL/Sym and the generic Short-Form (SF)-36 questionnaires
- At baseline and at 3, 12, and 24 months post procedure

Primary, assisted primary, and secondary patency was 65%, 78%, 89% at 24 months

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Overall VEINES-QOL and Sym scores (disease specific) at baseline (T0), at 3 months (T1), at 12 months (T2) and at 24 months (T3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VEINES-QOL</td>
<td>Phases</td>
</tr>
<tr>
<td>Phase 1</td>
<td>44.9 (10.6)</td>
</tr>
<tr>
<td>Phase 2</td>
<td>45.3 (12.0)</td>
</tr>
<tr>
<td>VEINES-QOL</td>
<td>p value</td>
</tr>
<tr>
<td>Symptom</td>
<td>p value</td>
</tr>
</tbody>
</table>

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- At baseline and at 3, 12, and 24 months post procedure

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Any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.

- National Quality Forum

Patient-reported outcomes will ultimately be linked to reimbursement by CMS and private carriers.

NYU Experience - Methods
• Single Center Retrospective study
• 116 limbs in 100 patients included
• All patients underwent intraoperative IVUS to determine lesion location and % stenosis
• > 50% reduction in cross-sectional area was considered significant
• Standard endovascular techniques - 16-18mm wallstents

Follow-up
• Follow-up patency determined by duplex ultrasound
• Questionnaire filled out at 8-12 weeks postop on telephone (74/116 questionnaires filled 68%)
• All patients with stents were placed on Plavix for 3 months postop and left on ASA for 1 year thereafter
• Median follow up time 18 months
Patient Characteristics

- Age (yrs): 52.1 ± 14.3
- Sex (%): M 37.7, F 62.2
- BMI (kg/m²): 29.4 ± 7.1

Clinical Characteristics (%)

<table>
<thead>
<tr>
<th>CEAP</th>
<th></th>
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<tbody>
<tr>
<td>C3</td>
<td>55.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C4a</td>
<td>10.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C4b</td>
<td>4.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C5</td>
<td>5.4</td>
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<td></td>
</tr>
<tr>
<td>C6</td>
<td>23.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Laterality

- L: 63.2%
- R: 29.3%
- B/L: 7.5%

Superficial incompetence: 37%

h/o Superficial ablation: 29%

h/o DVT: 27%

Simple Questionnaire

- Pain
- Swelling
- Other Symptoms
- Time to symptom improvement
- Pain during procedure
- Pain during recovery
- Recommend procedure to others

Patient Reported Symptoms

Baseline

Percentage of patients (N=79)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>83%</td>
</tr>
<tr>
<td>Swelling</td>
<td>84%</td>
</tr>
<tr>
<td>Pain + Swelling</td>
<td>79%</td>
</tr>
<tr>
<td>Other Sx</td>
<td>21%</td>
</tr>
</tbody>
</table>

Patient Reported Outcomes - Pain

83% (N=49)

Patient Reported Outcomes - Swelling

84% (N=70)
Patient Reported Outcomes – Other Sx

89% (N=53)

Percentage of patients

Greatly Improved 40%
Somewhat Improved 30%
Unchanged 10%
Worsened 20%

Time to symptom improvement

Percentage of patients

Almost Immediate 30%
Within 2 weeks 20%
Within 6 weeks 10%
Greater than 6 weeks 40%

Pain during procedure

Not Painful 83%
Somewhat Painful 15%
Painful 2%

Pain during recovery

Not Painful 50%
Somewhat Painful 40%
Painful 10%

Recommend procedure to others

YES - 89%
NO 11%

Stent Patency

94% primary patency
Are patient reported outcomes different between Post-thrombotic syndrome (PTS) and May-Thurner syndrome (MTS)?

Reported improvement in pain

<table>
<thead>
<tr>
<th>Percentage of Patients</th>
<th>Improvement</th>
<th>No Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTS</td>
<td>90%</td>
<td>10%</td>
</tr>
<tr>
<td>MTS</td>
<td>80%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Reported improvement in swelling

<table>
<thead>
<tr>
<th>Percentage of Patients</th>
<th>Improvement</th>
<th>No improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTS</td>
<td>95%</td>
<td>5%</td>
</tr>
<tr>
<td>MTS</td>
<td>85%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Reported pain during recovery

<table>
<thead>
<tr>
<th>Percentage of Patients</th>
<th>Very Painful</th>
<th>Somewhat Painful</th>
<th>No Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTS</td>
<td>50%</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>MTS</td>
<td>45%</td>
<td>35%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Conclusions

- Marked improvement in pain and swelling as REPORTED DIRECTLY by patients in NYU study
- Data in literature is varied but favors increased QOL
- Low risk of major complications
- Infrequent that patients are worse after intervention
- Require long term follow-up data