Veith 2018

Venous outcomes in Medicare beneficiaries: A multi-center study

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Introduction

In July of 2016 MEDCAC met to review the quality of evidence for the treatment of CVI.

MedCAC July 2016

MEDCAC Issues

- Lack of data on Medicare Beneficiaries.
  - Presenting signs and symptoms
  - Quantitative assessment of disease severity
  - Effectiveness of currently available interventions and outcomes data

- Concern regarding the sensitivity and specificity of patient reported symptoms to predict the presence of CVI.

- Lack of data on disease progression
**Center for Vein Restoration Study**

- Retrospective review of prospectively collected data on 38,750 CVI patients seen in 2015 and 2016.
- Patients divided into two groups:
  - Group A: Patients less than 65 years of age \( (n=27,536) \)
  - Group B: Patients 65 or older \( (n=11,214) \)
- Data collected from 69 centers from 10 states in the United States.

**Primary Presenting Symptoms**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage of all patients</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Ulcer</td>
<td>10%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>17%</td>
<td>17%</td>
<td>17%</td>
</tr>
<tr>
<td>Skin change</td>
<td>25%</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>Varicosities</td>
<td>55%</td>
<td>24%</td>
<td>24%</td>
</tr>
<tr>
<td>Restless Legs</td>
<td>17%</td>
<td>27%</td>
<td>24%</td>
</tr>
<tr>
<td>Spider Veins</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Aching</td>
<td>23%</td>
<td>29%</td>
<td>25%</td>
</tr>
<tr>
<td>Swelling</td>
<td>25%</td>
<td>24%</td>
<td>24%</td>
</tr>
<tr>
<td>Cramping</td>
<td>30%</td>
<td>27%</td>
<td>24%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>61%</td>
<td>61%</td>
<td>61%</td>
</tr>
<tr>
<td>Pain</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Heaviness</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

**Predictive Value of Signs and Symptoms for the Presence of CVI**

<table>
<thead>
<tr>
<th>Variable</th>
<th>ProbChiSq</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicosities</td>
<td>&lt;.0001</td>
<td>22.548</td>
</tr>
<tr>
<td>Ulcer</td>
<td>&lt;.0001</td>
<td>8.061</td>
</tr>
<tr>
<td>Bleeding</td>
<td>&lt;.0001</td>
<td>5.613</td>
</tr>
<tr>
<td>Skin change</td>
<td>&lt;.0001</td>
<td>5.015</td>
</tr>
<tr>
<td>Swelling</td>
<td>&lt;.0001</td>
<td>4.238</td>
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<tr>
<td>Pain</td>
<td>&lt;.0001</td>
<td>1.739</td>
</tr>
<tr>
<td>Heaviness</td>
<td>&lt;.0001</td>
<td>1.663</td>
</tr>
<tr>
<td>Fatigue</td>
<td>&lt;.0001</td>
<td>1.658</td>
</tr>
<tr>
<td>Aching</td>
<td>&lt;.0001</td>
<td>1.608</td>
</tr>
<tr>
<td>Superficial Thrombosis</td>
<td>&lt;.0001</td>
<td>1.521</td>
</tr>
<tr>
<td>Restless Legs</td>
<td>0.0002</td>
<td>1.233</td>
</tr>
<tr>
<td>Spider Veins</td>
<td>&gt;0.05</td>
<td>0.476</td>
</tr>
</tbody>
</table>

**Intervention Rates**

- Intervention Rate by CEAP and Age
- Treatment Outcomes
**Treatment Principles**

- All definitive therapies for CVI must address the underlying cause of disease which is venous hypertension.
- The history, physical exam and venous duplex scan must all correlate to establish a diagnosis of symptomatic CVI.
- Physician and patient reported outcomes measurements must be utilized to assess the degree of impairment and post-intervention improvement (i.e. rVCSS and a Qol survey).
- Arbitrary vein diameter measurements as a pre-requisite for intervention should be eliminated.

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**Treatment Principles**

- Compression therapy is not definitive therapy.
  - Compression only manages symptoms and does not prevent disease progression.
- CVI disease progression increases with Age. Early intervention decreases the development of severe disease.
- CVI is currently not curable. The goal of therapy is to improve the patient’s quality of life and enable patients to return to daily activities:
  - Work
  - Childcare
  - Exercise

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**Compression modalities**

- Unna Boot
- Multi layer Bandage

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**Edema reduction demonstrated by Duplex**

- Subcutaneous edema
- After 5 days of compression
**Compression Therapy**

- **Sox Trial:**
  - A multi-centre randomised placebo-controlled trial of active versus placebo ECS used for 2 years to prevent PTS after a first proximal DVT in centres in Canada and the USA.
  - The primary outcome was PTS diagnosed at 6 months or later using Ginsberg's criteria (leg pain and swelling of ≥1 month duration).

- From 2004 to 2010, 410 patients were randomly assigned to receive active ECS and 396 placebo ECS.
  - The cumulative incidence of PTS was **14.2% in active ECS** versus **12.7% in placebo ECS** (hazard ratio adjusted for centre 1.13, 95% CI 0.73-1.76; p=0.58).

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**Location of Reflux**

  - BK GSV - 85%
  - AK GSV - 55%
  - SFJ - 32%

- Strongly suggests genetic and or environmental cause for varicose vein development.

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**Pathophysiology**

- **Primary Etiologic Factor**
  - Chronic Venous Insufficiency is a primary degenerative disorder of the venous architecture that causes excessive venous hypertension.
    - Macrovascular level
      - Varicose Vein Formation
    - Microvascular level
      - Pain, limb edema, skin damage and venous ulcer formation

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**Macrovascular Dysfunction**

**Anatomy of Vessel Wall**

Structure of Blood Vessels - 3 Layers “Tunics”
Relative Venous Hydrostatic and Dynamic Pressures at Various Heights

\[ P = \rho g H + P_{atm} \]

- \( \rho \) is density
- \( g \) is gravity
- \( H \) is height

Normal Venous Return: Superficial and Deep Vein Systems

Venous Hypertension: Microvascular Disease

Valvular Reflux

Outflow Obstruction

Chronic Venous Obstruction Evaluation

- Think obstruction (Good History)

- Clinical signs and symptoms
  - postthrombotic disease
    - Severe C3, C4
    - pain out of proportion to lesion
    - Symptoms out of proportion to lower extremity venous reflux
  - scan

- Positive indicators of obstruction
  - stenosis/occlusion on duplex, venogram, MR-V, CT-V
  - presence of collaterals
Microvascular Dysfunction

CVI Dermal Microcirculation

- RBCs
- PMN
- Capillary Endothelium
- Pericapillary Cuff
- Migrating Macrophages
- Fibroblast
- Postcapillary Venule
- Lymphatic