Consequences of DVT/PE

- 60,000-100,000 in U.S. die each year
  - 10-30% die within 1 month of diagnosis
- 33% recurrence over 10 years
- 50% develop PTS syndrome
  - Swelling, pain, skin discoloration, varicose veins, chronic ulcers
- Avg. 548,000 hospitalizations each year due to VTE

Costs of VTE

- Hospital claims from 30 hospitals over 7 years
- 8.96% patients had readmission within 1 year
  - Costs 21% higher for readmission
  - Stays longer
- Annual cost for DVT - $9,321
  - Avg. stay 5.6 days
- Annual cost for PE - $15,655
  - Avg. stay 7.0 days
- Avg. cost for DVT + PE - $27,909

Annual US healthcare cost of $2-$10 Billion

VTE Risk Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td>Surgery</td>
</tr>
<tr>
<td>Obesity</td>
<td>Cancer</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Oral Contraceptives</td>
</tr>
<tr>
<td>Hormone Therapy</td>
<td>Smoking</td>
</tr>
<tr>
<td>Age</td>
<td>Genetic Clotting Disorders</td>
</tr>
<tr>
<td>Prolonged Immobility</td>
<td>Hospitalization</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>Prolonged Travel</td>
</tr>
</tbody>
</table>

DVT Location

- 40% occurs in common femoral or iliac veins
- Iliofemoral DVT associated with more severe symptoms

Vernacular (Venovo) Stent Trial and Methodology

VEITHsymposium 2016
Session 94
Friday, November 15, 2016
Michael D. Dake, M.D.
Theelma and Henry Doelger Professor
Department of Cardiothoracic Surgery
Stanford University School of Medicine
Falk Cardiovascular Research Center


May-Thurner Syndrome

- Compression of left iliac vein by right iliac artery
- 22-24% of lower extremity DVT cases
- Prevalence may be underestimated


Increased Awareness

- CDC Thrombophilia pilot sites
- AHRQ: VTE #1 prevention opportunity
- APHA-CDC leadership conference
- US Senate declares March DVT awareness month
- NQF/Joint Commissions, and CMS policies
- NIH funding DVT and venous disease
- CDC Thrombosis and Hemostasis Centers Research and Prevention Network established; CDC & NATT promote awareness
- ASH Surveillance Workshop
- Surgeon General Call to Action
- SVS/AVF DVT Guidelines
- CIRSE Stent Guidelines
- AHA PTS Guidelines
- AHA DVT Guidelines
- ATTRACT Trial

Venous Disease Treatment Options

**DVT & PE Prevention**
- Anticoagulation
- Mechanical Prophylaxis
- IVC Filter

**Interventional Treatment**
- Thrombolysis (systemic, CDT, PMT)
- Thrombectomy
- PTA + Stent

What We Know

- VTE has significant recurrence rate
- Conventional treatment for iliofemoral DVT is unsuccessful most of the time
- Morbidity of VTE is significant and costly

Goals of Interventional Treatment

- Rapid delivery of thrombolytic therapy
- Relieve acute pain and edema
- Prevent PE
- Prevent PTS
- Restore vessel patency
- Preserve valve function
- Correct underlying anatomic lesions

The Ideal Venous Stent

- Dedicated venous stent design
- Easy and accurate deployment
  - Easy to deploy
  - Radiopaque
  - Limited foreshortening
- Large diameters
- Long lengths
- Balance between radial force and flexibility
  - High radial force
  - High compression resistance
  - High flexibility
VENOVO® Venous Stent Design

- 3 radiopaque tantalum markers
- 6 nitinol connectors
- 3 nitinol connectors
- 3 non-radiopaque nitinol markers

VENOVO® Venous Stent Delivery System

- Tri-axial system
- 0.035”, over-the-wire
- Safety lock slider
- Dual speed thumbwheel
  - Large thumbwheel for slow deployment
  - Small thumbwheel for fast deployment

VENOVO® Venous Stent System

- Stent Diameters:
  - 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm
- Stent Lengths:
  - 40 mm, 60 mm, 80 mm, 100 mm, 120 mm, 140 mm, 160 mm

VERNACULAR Trial

- The巴尔® VENOVO® Venous Stent Study - A Prospective, Non-Randomized, Multi-Center, Single-Arm Study of the Treatment of Iliofemoral Occlusive Disease – an Assessment for Effectiveness and Safety
- Design: Prospective, multi-center, non-randomized, single-arm
  - Core lab & DSMB
- Purpose: to assess the safety and effectiveness of the VENOVO® Venous Stent for the treatment of iliofemoral occlusive disease including Acute or Chronic Deep Vein Thrombosis (DVT), May-Thurner Syndrome, or any combination of the above.
- Investigative Sites: 35 sites in the US, Europe, and Australia/NZ
- Subjects: 170 subjects

Inclusion/Exclusion

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Unilateral DVT</td>
<td>• Contralateral DVT</td>
</tr>
<tr>
<td>• Common femoral, common/external iliac</td>
<td>• Extends in IVC or below lesser trochanter</td>
</tr>
<tr>
<td>• Symptomatic venous outflow obstruction ≥ 50% by venography</td>
<td>• Uncorrectable bleeding diathesis or active coagulopathy</td>
</tr>
<tr>
<td>• CEAP ≥3 or VCSS ≥2</td>
<td>• Previous venous stents</td>
</tr>
<tr>
<td>• RVD 7 mm - 19 mm</td>
<td>• Can’t cross occlusion</td>
</tr>
</tbody>
</table>

VERNACULAR Trial

- Primary endpoints:
  - Primary patency (12 months)
  - Freedom from MAE (30 days)
  - Evaluated against literature derived performance goals
- Secondary endpoints:
  - VCSS/CEAP QoL assessment
  - Procedure/technical success
  - Freedom from TVR/TLR
  - Primary patency at 24 and 36 mo.
  - Stent fracture
Summary Slide

- VTE is a major health and economic concern
- Current clinical guidelines vary on appropriate treatment algorithms
- Multiple endovascular treatment options needed
- VENOVO® Venous Stent may provide innovative treatment option for iliofemoral DVT