Three-Year, Real-World Outcomes of Venous Stent Placement for Thrombotic and Non-thrombotic Indications in Spain

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Disclosures

Speaker Name: Marta Ramirez Ortega, M.D.

I have the following potential conflicts to report:

- [x] Consulting: Cook Medical, Medtronic, BD, Balt.
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Zilver Vena Venous Self-Expanding Stent

• Designed for the iliofemoral vein segment
• Available in > 40 countries, including the US, EU, and China
• Japanese regulatory approval received in December 2022

<table>
<thead>
<tr>
<th>Indication for Use</th>
<th>Improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent Diameters*</td>
<td>10, 12, 14, and 16 mm</td>
</tr>
<tr>
<td>Stent Lengths*</td>
<td>40, 60, 100, and 140 mm</td>
</tr>
</tbody>
</table>

* The 40 mm length is available only with 10 mm and 12 mm diameter devices; these sizes are not available outside of the U.S.
Data Analysis Information

Study Objective
- To collect data on patients treated with Zilver Vena Venous Self-Expanding Stent for iliofemoral obstructive venous disease

Data Analysis Objective
- To evaluate performance and safety outcomes in a subset of study patients treated for acute DVT (aDVT), Post-thrombotic syndrome (PTS), and Non Thrombotic Iliac Vein Lesion (NIVL)

Design of Analysis
- Ambispective, Single center (2 hospitals: same department), single-arm
- 219 patients in Spain
- Follow-up is ongoing

Endpoints of Analysis
- Primary: 1 and 3 year freedom from loss of primary, primary-assisted, and secondary patency
- Secondary:
  - VCSS, CEAP “C”, and Villalta changes from baseline at 6 and last follow-up
  - Early and late adverse event rates
  - Freedom from reintervention
  - Device measures including stent fracture and stent migration
Patient Groups Analyzed by Etiology

Patients were divided into three groups based on etiology:

- **NIVL**: 70%
- **PTS**: 26%
- **a-DVT**: 4%

Etiology
## Baseline Patient Demographics and Comorbid Conditions

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Overall N=219</th>
<th>PTS N=56</th>
<th>May-Thurner (NIVL) N=153</th>
<th>Ilio-caval Acute DVT N=10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>45.3 ± 11.9 (16 – 85)</td>
<td>51.7 ± 16.7 (21 – 85)</td>
<td>42.9 ± 7.8 (28 – 67)</td>
<td>45.7 ± 18.4 (16 – 71)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>89.5% (196)</td>
<td>73.2% (41)</td>
<td>98.7% (151)</td>
<td>40.0% (4)</td>
</tr>
<tr>
<td>Male</td>
<td>10.5% (23)</td>
<td>26.8% (15)</td>
<td>1.3% (2)</td>
<td>60.0% (6)</td>
</tr>
<tr>
<td><strong>Comorbid conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep Vein Thrombosis (DVT)</td>
<td>30.1% (66)</td>
<td>98.2% (55)</td>
<td>0.7% (1)</td>
<td>100% (10)</td>
</tr>
<tr>
<td>Pulmonary Embolism (PE)</td>
<td>5.0% (11)</td>
<td>16.1% (9)</td>
<td>0.7% (1)</td>
<td>10.0% (1)</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>13.7% (30)</td>
<td>33.9% (19)</td>
<td>4.6% (7)</td>
<td>40% (4)</td>
</tr>
</tbody>
</table>
## Procedural Information

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall N=219</th>
<th>PTS N=56</th>
<th>May-Thurner (NIVL) N=153</th>
<th>Ilio-caval Acute DVT N=10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoral vein</td>
<td>19.2% (42)</td>
<td>35.7% (20)</td>
<td>12.4% (19)</td>
<td>30.0% (3)</td>
</tr>
<tr>
<td>Common femoral vein</td>
<td>64.8% (142)</td>
<td>14.3% (8)</td>
<td>87.6% (134)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Popliteal vein</td>
<td>11.4% (25)</td>
<td>37.5% (21)</td>
<td>0% (0)</td>
<td>40% (4)</td>
</tr>
<tr>
<td>Othera</td>
<td>4.6% (10)</td>
<td>12.5% (7)</td>
<td>0% (0)</td>
<td>30% (3)</td>
</tr>
<tr>
<td>Side of stent placement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left lower limb</td>
<td>92.2% (202)</td>
<td>73.2% (41)</td>
<td>100% (153)</td>
<td>80.0% (8)</td>
</tr>
<tr>
<td>Right lower limb</td>
<td>5.9% (13)</td>
<td>23.2% (13)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>1.8% (4)</td>
<td>3.6% (2)</td>
<td>0% (0)</td>
<td>20.0% (2)</td>
</tr>
<tr>
<td>Location of stent placement (Territory)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIV/EIV/CFV</td>
<td>1.8% (4)</td>
<td>7.1% (4)</td>
<td>0% (0)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>CIV/EIV/CFV/FV</td>
<td>1.8% (4)</td>
<td>5.4% (3)</td>
<td>0% (0)</td>
<td>10.0% (1)</td>
</tr>
<tr>
<td>IVC/CIV/EIV</td>
<td>74.9% (164)</td>
<td>19.6% (11)</td>
<td>98.0% (150)</td>
<td>30.0% (3)</td>
</tr>
<tr>
<td>IVC/CIV/EIV/CFV</td>
<td>17.4% (38)</td>
<td>58.9% (33)</td>
<td>0% (0)</td>
<td>50.0% (5)</td>
</tr>
<tr>
<td>Otherb</td>
<td>4.1% (9)</td>
<td>8.9% (5)</td>
<td>2.0% (3)</td>
<td>10.0% (1)</td>
</tr>
<tr>
<td>Stent placed under the inguinal ligament</td>
<td>23.7% (52)</td>
<td>80.4% (45)</td>
<td>0% (0)</td>
<td>70.0% (7)</td>
</tr>
</tbody>
</table>

a. Other access locations include the Great Saphenous vein, Humeral/Basilic/Cephalic, double access (bilateral puncture site), Jugular vein, Profunda-femoral vein, Distal vein, and triple access.

b. Other locations of stent placement include CIV/EIV, CIV/EIV/CFV, PFV, EIV/CFV, IVC/CIV/EIV/CFV/FV, IVC/CIV/EIV/CFV/PFV, IVC/EIV/CIV, IVC/EIV/CFV.
Few procedural complications occurred

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>Percent Patients (%, n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall N=219</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Intraoperative partial thrombosis</td>
<td>0.9% (2)</td>
</tr>
<tr>
<td>Vein rupture</td>
<td>0.5% (1)</td>
</tr>
</tbody>
</table>
Clinical Assessments

- Venous Clinical Severity Score (VCSS)
- Clinical Class “C” CEAP classification
- Villalta Score for Post-Thrombotic Syndrome

Based on how data collection was designed after each follow-up clinical measures were overwritten (e.g., a patient with follow-up through 3 years would only have clinical outcome measure data at baseline and 3 years)
Venous Clinical Severity Scores (VCSS) improved in all groups following stent placement

- Overall Cohort: ↓VCSS score 6.2 points from pre-procedure.
  - aDVT: 10.3 points
  - PTS: 7.8 points
  - NIVL: 5.4 points
CEAP “C” Classification improved in all groups following stent placement

- At pre-procedure most patients had a CEAP “C” classification of C3
  - Overall: 73.1%
  - NIVL: 72.5%
  - PTS: 69.6%
  - aDVT: 100%

- At last follow-up most patients CEAP “C” classification improved to C1
  - Overall: 70.3%
  - NIVL: 77.8%
  - PTS: 48.2%
  - aDVT: 80%
Improvement in Villalta Scores were reported in patients with PTS following stent placement.

- Mean Villalta Scores improved in PTS patients from 12.9±4.3 at preprocedure to 3.1±3.9 following stent placement.
Freedom from loss of patency

- Primary patency
  - uninterrupted venous patency following initial stent deployment with no partial thrombosis, total occlusion, or restenosis present
- Primary-assisted patency
  - venous patency with partial thrombosis but without total occlusion or restenosis that required additional procedures to establish patency
- Secondary Patency
  - venous patency following initial stent deployment but with total occlusion or restenosis that required an intervention to establish patency
Primary Patency for aDVT was 100% ± 0%
Primary-Assisted and Secondary Patency

Primary-Assisted Patency for aDVT was 100% ± 0%

- Freedom from loss of secondary patency was 100% in all groups
Freedom from All Reinterventions

Freedom from all reinterventions for aDVT was 100% ± 0%
Mortality

- Two patient deaths (0.9%, 2/219) at 3 years
  - Patient 1: PTS group, death due to rectal adenocarcinoma on postprocedure day 32
  - Patient 2: aDVT group, death due to urothelial carcinoma on postprocedure day 93

- No patient deaths were due to the Zilver Vena Stent
The adverse event rate was low during the follow-up period

<table>
<thead>
<tr>
<th>Event</th>
<th>Percent Patients (%, n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall N=219</td>
</tr>
<tr>
<td>Restenosis</td>
<td>3.2% (7)</td>
</tr>
<tr>
<td>Contralateral thrombosis</td>
<td>1.8% (4)</td>
</tr>
</tbody>
</table>

a. 5 events in 4 patients
b. Contralateral thrombosis was thought to be due to contralateral jailing
   • Two patients had occlusions
• Stent Fracture at 3 years
  • 2 stent fracture in 2 patients (0.9%, 2/219) at days 617 and 825
  • Under the inguinal ligament
  • All in the PTS group (3.6%, 2/56)
  • No symptoms associated with fractures, no interventions were required

• Stent Migration
  • No stent migration (0%, 0/219).
Limitations

- Single arm, single center, ambispective, nonrandomized design
- Patient follow-up is ongoing so data is not available for all patients through 3 years
- Data set contained a large pool of patients that had a Zilver Vena Venous Stent placed during real world use - there were no restrictions on reinterventions and no exclusions were applied to this data collection
- Primary patency rates observed in this data collection reflect the high percentage of non-thrombotic, May-Thurner patients treated
- Based on how data collection was designed after each follow-up clinical measures were overwritten
- Data may not be representative of standard of care global and may be biased toward physician users in Spain
Key Findings - Conclusion

- Primary patency maintained in 98.2% of NIVL patients, 90.1% of PTS patients, and 100% of aDVT patients through 3-years.
- Primary-assisted patency maintained in 100% of NIVL patients, 94.3% of PTS patients, and 100% of aDVT patients through 3-years.
- Secondary patency maintained in 100% of NIVL, PTS, and aDVT patients through 3-year follow-up.
- Improvement in clinical assessments (CEAP “C”, VCSS, Villalta) in all groups following stent placement.
- Low adverse event rates in all groups through follow-up.
- Low all-cause and in-stent reintervention rates in all groups through follow-up.
- No stent migration and low stent fracture rate (0.9%).
Thanks!