Clinical outcomes of the Zilver Vena Stent™ in a private practice setting

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Disclosure

Speaker name:
Marta Ramirez Ortega.

I have the following potential conflicts of interest to report:

☑ Consulting for Cook
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Vein ≠ Artery

✓ LARGER
✓ ↓ PRESSURE & SLOW BLOOD FLOW
✓ THINNER WALL
  ✓ Thinner tunica media
  ✓ Thicker tunica externa
  ✓ ↑ collagen ↓ elastine ↓ SMC

More compliant + less elastic
PT disease ≠ Arteroesclerotic disease
✓ Fibrosis venous wall & valves → ↓ compliance
✓ Thrombus fibrotic transformation → intraluminal channels
Background

✓ Since 2011 I’ve been involved in venous pathology management with >270 procedures.

✓ By now we perform 4-6 endovascular procedures for venous outflow obstruction p/month.
Diagnostic algorithm

- Chronic DVT
- Thrombophilia (+)
- Edema
- PCS
- Atypical VV

Abdominal US

MRV/CTV

Venography+/-IVUS+/-STENT
Diagnostic algorithm

- Chronic DVT
- Thrombophilia (+)
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Abdominal US

MRV/CTV

Venography+/IVUS+/-STENT
Diagnostic algorithm

- ✓ Chronic DVT
- ✓ Thrombophilia (+)
- ✓ Edema
- ✓ PCS
- ✓ Atypical VV

Abdominal US

MRV/CTV

Venography +/- IVUS +/- STENT
IVUS-PTS
IVUS-MTS
WHAT TO DO IF YOU DON´T HAVE AN IVUS???

DON´T PANIC!!!!!!!
WHAT TO DO IF YOU DON´T HAVE AN IVUS???

✓ In Spain every Vascular Surgeon is able to perform US.
✓ Transabdominal US is a convenient tool for the whole process
  ✓ Diagnostic
  ✓ Intraoperative
  ✓ Follow up
✓ Learning Curve
Stent deployment-MTS
Checking-MTS

1,12 mm

1,69 mm

1,12 mm
What we need to be success?????

- Good planning
- Good outflow
- Good inflow
What we need to be successful:

- Enough femoro-popliteal flow
- Cover the entire lesion
- Appropriate stent
Enough femoro-popliteal flow
Cover the entire lesion
• Cover the entire lesion: protect inflow:
  • Profunda
  • Femoral
  • cirmunflex
• Stent: **VENOUS DEDICATED STENT**
  • Self-expandable
  • **Crush resistant**
  • Radial force
  • Vein wall apposition
  • **Flexibility**
  • Durability
  • **Accuracy**
FLEXIBILITY

VS.

RADIAL FORCE
Crush resistant
Technique of endovascular recanalization

- General anaesthesia.
- Femoral/popliteal US-guided approach (RJV?)
- Systemic anticoagulation NFH (ACT 250-300”)
- Short 9/10F sheath → Venography
- Stiff guidewire + angiographic catheter (5F: MP or Bern or Dav)
  - 6-7F 55cm sheath + CTO catheter

- PTS: Progressive predilatation: 4, 6 & 10 mm PTA standard balloon.
- PTS&MTS: Aggressive predilatation with high pressure balloon.
Stenting

✓ Proximal landing: VCI: healthy wall
✓ >1 stent: overlap 1.5-2 cm
✓ Oversize 1 mm
✓ Distal landing under crural ligament, healthy wall
✓ Good inflow
✓ Avoid overlap in ligament
✓ Postdilatation with high pressure balloon
✓ Final run
✓ IVUS and/or transabdominal US
Our results

✓ Follow-up
✓ My personal experience (since 2011): >400 MTS and >120 PTS

✓ January 2014-December 2019 224 patients (ZV)
✓ Hospital La Luz + Hospital Universitario Quiron Madrid
Our results

✓ Follow-up

✓ January 2014-December 2019 224 patients (ZV)

✓ 146 MTS: 144 ♂️, 2 ♂️: mean age 42y.o. (28-67)
✓ 54 PTS: 40 ♂️, 14 ♂️: mean age 51 y.o. (21-85)
✓ 8 ACUTE I-Fem DVT: 3 ♂️, 5 ♂️: mean age 45 y.o. (16-71)
✓ 1 Neoplastic iliac compresión
✓ 4 NCS (Out of IFU): 4 ♂️: mean age 33 y.o. (23-46)
✓ 11 SCS (Out of IFU): 6 ♂️, 5 ♂️: mean age 52 y.o. (20-85)
Our results-PTS

✓ 20.37% PE, 37.03% trombophilia (+)
✓ 75.92% under inguinal ligament
✓ 1.75 stents pp (1-3)
✓ Mean preprocedure VCSS was 11 (5-26)
✓ Mean preprocedure Villalta Score was 12.8 (5-28)
Our results-PTS

✓ Mean length of stay 24 hrs
✓ Anticoagulation was given in all cases except 3 (AAS) at least 6 months

<table>
<thead>
<tr>
<th>Results:</th>
<th>Complications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Clinical improvement 98%</td>
<td>- Mortality/PE events 0%</td>
</tr>
<tr>
<td>- Mean postintervention VCSS 3.2 (0-15)</td>
<td>- Contralateral limb thrombosis 1.8% (1)</td>
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<tr>
<td>- Mean postintervention Villalta Score 3.3 (0-20)</td>
<td>- Stent fracture 5.5% (3)</td>
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<tr>
<td>- 75.6% of C3 improvement to C2, C1.</td>
<td>- Restenosis 3.7% (2)</td>
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<td>- 75% of ulcer healing</td>
<td>- No Bleeding</td>
</tr>
<tr>
<td>- Primary stent patency 88.8%, 96.2% Assisted primary patency and 98.14% secondary patency</td>
<td>- No Stent migration</td>
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<td>- Mean follow up 29 months (1-72)</td>
<td>- No stent disconnection.</td>
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Our results - MTS

- 3.4% trombophilia (+)
- 1 stents pp
- Mean preprocedure VCSS was 7(1-12)
- C1-C2: PCS and Atypical VV
Our results-MTS

✓ Mean length of stay 24 hrs
✓ Antiplatelet therapy (AAS or Clopidogrel) was given in all cases except 2 (HBPM)

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<td>Clinical improvement 93.8%</td>
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<tr>
<td>Mean postintervention VCSS 1,7(0-9)</td>
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<td>93 % of C3 improvement to C2, C1.</td>
<td>- No Stent fracture</td>
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<td>Primary stent patency 97.95%, assisted primary patency 100%.</td>
<td>- 1.36% Reestenosis (2)</td>
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<tr>
<td>Mean follow up 17 months (1-65)</td>
<td>- No Bleeding</td>
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Our results

✓ FU at 1 week, 1, 3, 6 and 12 months: DUS and then yearly: DUS + RX
Our results

✓ FU at 1 week, 1,3,6 and 12 months: DUS and then yearly: DUS + RX
Take Home Messages

✓ Veins and arteries are different so we need Dedicated Venous Stents.
✓ To be success we need good planning, good inflow and good outflow.
✓ Young and active patients: stents should last many years.
✓ Balance between flexibility, radial force and crush resistance
✓ In MTS and PTS Endovascular treatment with Zilver Vena™ is an effective and safety option with excellents results, long-term high rate patency, low morbi/mortality and low rate of reestenosis.
Thanks!!!!

#dollypartonchallenge
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