Clinical outcome and patency rates of new generation venous stents

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Background

- Revascularization strategies have been developed aiming at restoring venous flow, thereby preventing the development of the postthrombotic syndrome (PTS).

- Catheter-directed thrombolysis followed by venous stenting has emerged as a promising revascularization strategy with venous patency rates of 70-90% and low complication rates.
The majority of iliofemoral DVTs are caused by iliac vein compression (May-Thurner Syndrome)

- Focal external compression and vicinity to the ilio-caval bifurcation hampers venous stenting using conventional stents.

**Ideal MT stent:**
- **Radial force** at the compression site and **flexibility** to accommodate the anatomy of the curved iliac vein.
Iliac vein anatomy:
Lateral view 90° hip flexion
Proximal closed cell design:
- Provides high radial force at compression site
- Oblique design (35°) prevents jailing off the contralateral iliac vein
- 4 markers for correct rotational positioning

Distal open cell design:
- Provides flexibility and less radial force for accommodating the curved anatomy of iliac veins during hip flexion
sinus-Obliquus® stent
Visualized from behind
Positioning of sinus-Obliquus® stent

Contralateral injection: Identify IVC wall and carina

AP view: two middle markers matching

Lateral view: Proximal and distal marker in line with wire
Implantation of sinus-Obliquus® stent
IVUS
pre and post sinus-Obliquus Stenting

Pre Stenting

Post Stenting

Right AIC

Left VIC compression (May Thurner)

Right AIC

sinus-Obliquus in left VIC (May Thurner)
Objective

We investigated venous patency rates and clinical outcomes of patients with iliac vein compression treated with this novel venous self-expanding oblique hybrid nitinol stent (sinus-Obliquus®, optimed, Germany)
The Bern Venous Stent Registry is a prospective registry including all patients receiving venous stents at the University Clinic of Angiology in Bern, Switzerland.

Between December 2014 and July 2015:
- 23 patients with common iliac vein compression were treated with sinus-Obliquus stent:®
- 9 patients with acute iliofemoral thrombosis after catheter-directed thrombolysis
- 10 patients with postthrombotic syndrome (PTS)
- 4 patients with non-thrombotic iliac vein compression.
Results

- Total: 23 patients; 82% women, mean age 38 ± 4 years
- 4 patients (17%) with a recurrent VTE event.
- 22 patients with stent implantation in left common iliac vein
- Mean time range between most recent DVT and intervention
  10.3 years in patients with PTS;
  7 days in patients with acute DVT
Results: Outcomes at 3 months*

- Primary patency rate: 100% (23/23)
- Clinical symptoms:
  completely resolved in 39%, improved in 52%, unchanged in 9%
- In patients with Postthrombotic Syndrome:
  Villalta score decreased by 4.7 ±3.5 points (P=0.002)
  Revised Venous Clinical Severity score (rVCSS) decreased by 2.7 ± 2.5 points (P=.007)
- No procedural complication
  2 patients minor bleeding (popliteal hematoma, and hypermenorrhea)

*Stuck AK, Kunz S, Baumgartner I, Kucher N.: Short-term Patency Rates and Clinical Outcomes of Patients with Common Iliac Vein Compression Treated with a Dedicated Venous Self-expanding Oblique Hybrid Nitinol Stent; submitted 2016.
Our findings are consistent with prior studies of other dedicated venous stents, with good patency rates, low complication rates, and no mortality.

**sinus-Venous® stent**

**Zilver Vena® stent** (Cook, Bloomington,IN, USA): O'Sullivan GJ et al., Iliofemoral venous stenting extending into the femoral region: initial clinical experience with the purpose-designed Zilver Vena stent. J Cardiovasc Surg (Torino). 2013;54(2):255-61.)
Discussion: Zilver Vena® stent*


- 20 patients (12 women; mean age 59) treated for iliofemoral vein obstruction
- Clinical patency rate: 85% (17/20 patients),
- Clinical improvement was demonstrated by decreased leg swelling in these 17 patients

* Cook, Bloomington, IN, USA

- The cumulative patency rates at 3, 6, and 12 months: 99%, 96%, and 92%, respectively.

- The cumulative assisted primary patency rates 99% at 3, 6, and 12 months. The cumulative secondary patency rate at 12 months: 100%.

- VCSS and Villalta score decreased significantly after stenting

- Morbidity was low without clinically relevant pulmonary embolism, and no mortality.

* optimed, Ettlingen, Germany
In conclusion, patency rates and clinical outcomes at 3 months in patients with common iliac vein compression treated with the sinus-Obliquus stents were excellent.

Further studies need to investigate the efficacy and safety of sinus-Obliquus stenting in a long-term perspective.

All collaborators of the Venous Stent Registry.
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