3-year clinical outcomes of dedicated nitinol stents for acute deep vein thrombosis, post-thrombotic syndrome and non-thrombotic iliac vein lesions

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Disclosure

Speaker name:

Tim Sebastian

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ■ I do not have any potential conflict of interest

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Stent options seem limitless

- Typical characteristics of dedicated venous stents
  - Nitinol-based (superelastic, shape memory)
  - Laser-cut, mainly open-cell design matrix

- Available dedicated venous stents (in Europe)
  - **Optimed**: sinus Obliquus, sinus Venous
  - **Bard**: Venovo Venous Stent System
  - **Cook**: Zilver Vena Venous Self-Expanding Stent
  - **Boston scientific**: Vici Venous Stent System
  - **Medtronic**: Abre Venous Self-expanding Stent System
  - **Plusmedica**: Blueflow Venous Stent (woven)

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Swiss Venous Stent Registry Overview

- **Design:**
  - Observational study (with prospectively collected data)
- **Main inclusion criteria:**
  - Treatment of iliofemoral or caval venous outflow obstruction (acute thrombotic, post-thrombotic, non-thrombotic, tumor-related) with dedicated venous nitinol stents
- **Follow-Up**:
  - Up to 5 years (during routine outpatient visits)
  - Stent patency assessment with duplex ultrasound
  - Clinical outcomes including Villalta score

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Circulation: Cardiovascular Interventions
Volume 13, Issue 12, December 2020
https://doi.org/10.1161/CIRCINTERVENTIONS.120.009673

NEW TECHNIQUES

Self-Expandable Nitinol Stents for the Treatment of Nonmalignant Deep Venous Obstruction

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Inclusion criteria:

Patients ≥90 days follow-up or early stent occlusion or reintervention (<90 days)

Exclusion criteria:

Endovascular therapy to treat local tumor compression or infiltration

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Baseline and procedural details (n=379)

	DVT (n=160)	PTS (n=193)	NIVL (n=26)
Demographics			
- Age, years	48±20	44±16	39±15
- Women	62%	48%	62%
Procedural data			
- Bilateral	7%	28%	8%
- Mean number of stents	1.7±1.1	2.7±1.7	1.1±0.3
- Stent in IVC	8%	28%	-
- Stent landing above inguinal ligament	71%	32%	96%
- Stent landing below inguinal ligament	29%	67%	4%

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Stent patency after 3 years

	DVT (n=160)	PTS (n=193)	NIVL (n=26)
Primary patency, % (95% CI)	81% (73%; 88%)	59% (50%; 68%)	100%
Assisted primary patency, % (95% CI)	85% (78%; 92%)	78% (71%; 85%)	100%
Secondary patency, % (95% CI)	96% (92%; 100%)	92% (87%; 97%)	100%

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Stent patency after 1 year (dedicated/ non-dedicated)

	DVT	PTS	NIVL
Primary patency, % (95% CI)			
Dedicated stents (this study), % (95% CI)	88% (82-93%)	74% (67-80%)	100%
Non-dedicated stents* (historic data)	87% (80-92%)	79% (76-83%)	96% (93-98%)
Secondary patency, % (95% CI)			
Dedicated stents (this study), % (95% CI)	98% (95-100%)	95% (92-98%)	100%
Non-dedicated stents* (historic data)	89% (76-95%)	94% (90-96%)	99% (88-100)

- Based on meta-analysis of historic data of non-dedicated venous stents (n=2869, 37 mainly retrospective studies). Razavi et al. Circulation cardiovascular interventions, Oct 2015, Vol 8, Issue 10

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Clinical outcomes following endovascular therapy

Index diagnosis	<5 points (no PTS)		5–9 points (mild PTS)		10–14 points (moderate PTS)		>14 points (severe PTS)	
Acute DVT (follow-up)	143/160	89%	15/160	9%	1/160	1%	1/160	1%
PTS (baseline)	13/178	7%	98/178	55%	38/178	21%	29/178	16%
PTS (follow-up)	113/180	63%	48/180	27%	11/180	6%	8/180	4%

Among the 17 patients with DVT who developed PTS:

- 30% had recurrent VTE at baseline
- 40% had varicose veins at baseline
- 25% had permanent stent occlusion at last follow-up

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Adverse Events

	DVT (n=160)	PTS (n=193)	NIVL (n=26)
Patients with (recurrent) VTE	15.6%	22.3%	0%
Stent occlusion	12.5%	21.2%	…
DVT outside stented segment	3.1%	2.1%	…
Pulmonary embolism	1.2%	1.0%	…
Annualized rate of stent occlusion or recurrent VTE	7.8 events per 100 patient years	15.0 events per 100 patient years	0 events per 100 patient years
Proc. related major bleeding	3.1%	1.0%	0%

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Conclusion

- Data on outcomes of dedicated venous stents show a similar pattern of stent patency loss distribution across groups as compared to historic data on steel-alloy stents.
- VTE complications after stenting did not occur in NIVL patients, and their rate was higher in PTS versus DVT patients.
- Stent occlusion was the most frequent type of VTE accounting for 75% of events in DVT and 90% of events in PTS.
- Strategies to reduce occurrence of stent occlusion should be investigated next (antithrombotic therapy).

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