


## Approaching the NIVL Patients: How to Ensure Success

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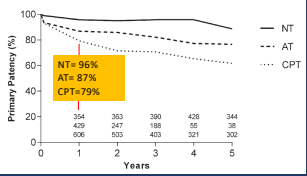


## Disclosures

- For the 12 months preceding this CME activity, I disclose the following types of financial relationships:
  - Abbott Vascular, Akura, Asahi/Invatec, Avanteq, Boston Scientific, Edwards Life Sciences, Heraeus, Medtronic, Merit Medical, Mercator Medsystems, Microvention/Terumo, Phillips, R3, Reflow Medical, Sirtex

## Disease State

- NIVL > acute thrombotic > chronic post thrombotic



1. Razavi M et al. Circ CVI 2015.

## Dedicated Venous Stents IDE Trial Overview

Venous Stent	FDA Status	Stent Design	Disease States	PP Imaging	Stent Sizing Imaging	Study Outcomes
Bard Venovo	Approved 2019	Open Cell, Homogenous	NIVL PTS aDVT	Venogram	Venogram	Venovo <sup>1</sup> , N = 170 30d Safety: 93.5% 12mo Patency: 88.3% 24mo Patency: 84.4%
Boston Scientific VICI	Approved 2019	Closed Cell, Homogenous	NIVL PTS Excluded aDVT	Venogram	Venogram & IUS	Vivo <sup>2</sup> , N = 243 30d Safety: 96.7% 12mo Patency: 89.5% 24mo Patency: 79.1%
Cook Medical Zilver Vena	Approved 2020	Open Cell, Homogenous	NIVL PTS Included aDVT no PTS	Venogram	Venogram	Vivo <sup>2</sup> , N = 243 30d Safety: 96.7% 12mo Patency: 89.5% 24mo Patency: 80.2%
Medtronic Abire	Approved 2020	Open Cell, Homogenous	NIVL PTS aDVT	DUS & Venogram	Venogram, IUS Cephalad	Phosol IDE <sup>3</sup> , N = 200 30d Safety: 98% 12mo Patency: 85% 24mo Patency: 86.2%
Philips (Disape) Duo Venous Stent System	Approved 2023	Open Cell, Hybrid, two stents	NIVL PTS aDVT	DUS & Venogram	IUS Mandator	Vivo <sup>2</sup> IDE <sup>4</sup> , N = 162 30d Safety: 98.7% 12mo Patency: 90.2%

1. Saha, et al. Catheterized 2019  
2. Saha, et al. Catheterized 2019  
3. Hoffmann, et al. JVS 2023  
4. Razavi, et al. JVS 2023

## Summary of U.S. Pivotal Trials

	1-yr PP (NT)	1-yr PP (AT)	1-yr PP (CPT)	3-yr PP (NT)	3-yr PP (CPT)	Freedom from CD-TLR 1-yr (all)	Freedom from CD-TLR 3-yr (all)
Meta analysis	96%	87%	79%	>95%	~70%	n/a	n/a
VIRTUS	97.8%	excluded	80.1%	96.4%	64.1%	92%	88.6%
VIVO	100%	86.3%	85.3-91.3%			94%	90.2%
VERNACULAR	97.1%	NR	81.7%	93.6%	70%	92.6%	88.4%
ABRE	98.6%	87.1%	79.8%	97.1%	70.4%	92.4%	83.7%
VIVID	95.2%	86.7%	79.4%			96.2%	

pp= primary patency; NT= non-thrombotic; AT= acute thrombotic; CPT= chronic post thrombotic

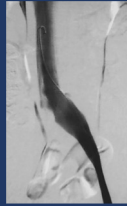
1. Razavi, et al. Circ CVI 2015  
2. Razavi, et al. Circ CVI 2019  
3. Hoffmann, et al. JVS, 2023  
4. Dake et al. JVR 2019 & CVR 2021  
5. Murphy et al. Circ CVI 2022  
6. Black S et al. JVR 2024  
7. Razavi et al. JVS-VLD in press

## Data is already excellent, why worry about "success"?

- Majority of reported stent migrations have been in NIVL pts
- There is 4-5% risk of stent obstruction at 1-year, increasing by about 1-2%/yr
- In this patient population, alteration of the natural hx of the veins involved has to be weighed against the benefit
- LCIV compression is present in >25% of population !!
- Therefore potential for harm is real

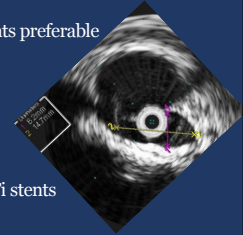
**Indications for stent placement in patients with NIVL**

- Symptomatic obstruction
  - Asymmetrical edema impacting QoL in absence of other etiologies
  - >C4 w/o superficial venous dz
  - In presence of refractory chronic pelvic pain & venous reflux (possibly)
- Lower extremity venous stasis sx are common and so is iliac vein compression
- 50% stenosis is unlikely to be validated in rigorous studies
- Exercise caution!



**Technical considerations: Stent diameter**

- Confirm presence of lesion on IVUS
- Stent type: Dedicated NiTi venous stents preferable
- Stent diameter:
  - Various methods use
    - EIV as ref vessel
    - Mean of LD+SD/2 + 2mm
  - Rule of thumb for stent diameters
    - CIV:  $\approx 1.4$  mm (most common location)
    - EIV:  $\approx 12$  mm (less common location)
- Wallstent behaves differently than NiTi stents

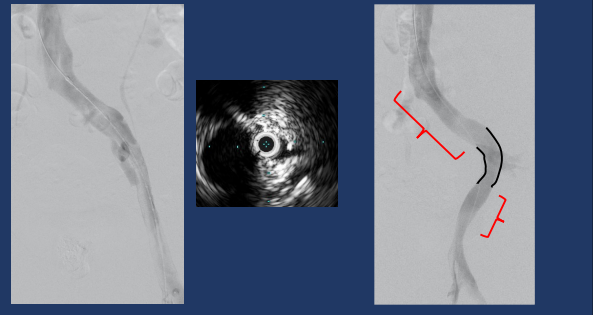


**Technical considerations: Stent length**

- NIVLs by definition are short lesions
- The length of the CIV should be covered
- Should the stent be extended into the EIV?

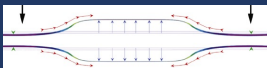
Circulation: Cardiovascular Interventions  
**SPECIAL REPORT**  
 Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the IVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society

4. Stents for NIVL should be extended into the straight portion of the external iliac vein to limit stent migration and other complications.

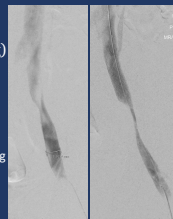


**Technical considerations: Stent length**

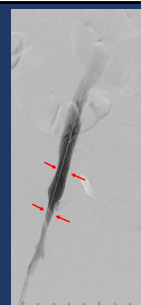
- Extension into the EIV:
  - More secure (in cases where there is no real lesion!)
  - Creates a diameter mismatch between stent & the vein
  - Predisposes to Poisson effect (edge crush pancaking)



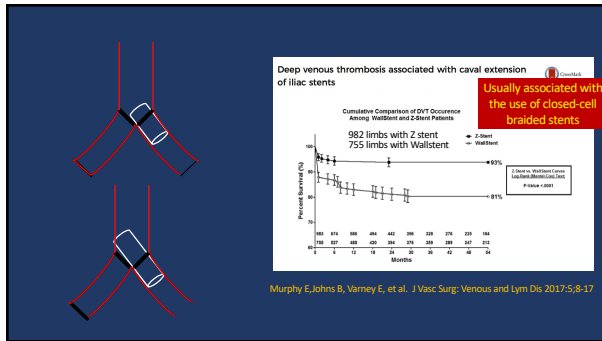
As the vein expands in one segment, the adjacent segments stretch leading to a decrease in diameter. Li N et al JVIR 2020



- Iliofemoral stents in 77 limbs with acute or chronic DVT
- Assessed the mismatch between post-stent inflow vein diameter to stent diameter
- Post-stent placement diameter mismatch highly correlated to stent patency



Farsad K et al JVIR, submitted for publication



**Post stent medical therapy**

1. The routine use of anticoagulation or antiplatelet therapy for untreated NIVL is not supported.
2. In treated patients with NIVL with no evidence of previous venous thromboembolism (either by imaging or history), there is no consensus that anticoagulation or antiplatelet therapy is necessary.
3. An assessment of thrombotic risk in patients with NIVL should be made. If anticoagulation or antiplatelet therapy is indicated, the agent, dose, and duration should be tailored accordingly.

Desai K et al. Circ Cardiovasc Interv. 2024;17:e014160

**Conclusion**

- Iliac vein compression is a common finding in general population
- There is potential for harm if stent placement is inappropriate
- Exercise caution
- There is no substitute for good judgement and technique