Endovascular Management of NIVL

Challenges, and the Move toward Consensus

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Disclosures

- Speaker's bureau/consulting: Cook Medical, Boston Scientific, Becton Dickinson, Medtronic, Penumbra, Tactile Medical, Philips
- Consulting: W.L. Gore, Asahi Intecc, Veryan, Cordis, Surmodics, Abbott, EnVVeno, Varian, Terumo

Challenges in the management of NIVL: Lack of Consensus

- Clinical workup and thresholds for treatment are murky at best
  - Many patients are asymptomatic
- Technical ambiguities
  - What defines a critical lesion?
  - How should we size a stent? Are longer stents necessary?
- Lack of commonality on post-procedure management and follow-up
  - Anticoagulate?
  - Surveillance?

Murky pathways for work up – maybe they don't all need treatment?

- MANY compression lesions are silent/patients are asymptomatic
  - We don't know why lesions become clinically relevant in certain patients
  - Unable to screen for patients that will develop symptoms, when they are currently asymptomatic

Iliac vein compression in an asymptomatic patient population

Melina R. Kibbe, MD, Michael Ujiki, MD, A. Lee Goodwin, RT(R)(CT), Mark Eskandari, MD, James Yao, MD, and **Jon Matsumura, MD,** *Chicago, Ill*

- CT scans on 50 consecutive patients with abdominal pain, no leg symptoms, no DVT history
- 24% of patients had greater than 50% *diameter* compression on CT
- 66% of patients had more than 25% diameter compression → correlating to 50% area stenosis
- "Stenosis" → BUT NO SYMPTOMS!

J Vasc Surg 2004

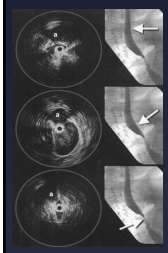
Do all treated patients show improvement?

Editor's Choice — Reconstruction of the femoro-ilio-caval outflow by percutaneous and hybrid interventions in symptomatic deep venous obstruction

- Only 63% of NIVL patients showed a clinical effect
- 24% had no response
- 14% became slightly worse
- Why is this an issue?
  - NIVL patients trend young – a stent must remain functional for several decades
  - Don't love the idea of an unnecessary implant!

EJVES 2016

Technical ambiguities



Intravascular ultrasound scan evaluation of the obstructed vein

Peter Neglén, MD, PhD, and Seshadri Raju, MD, *Jackson, Miss*

High prevalence of nonthrombotic iliac vein lesions in chronic venous disease: A permissive role in pathogenicity

Seshadri Raju, MD, and Peter Neglen, MD, PhD, *Flowood, Miss*

Neglen and Raju, JVS 2002; Raju and Neglen, JVS 2006

Analysis of threshold stenosis by multiplanar venogram and intravascular ultrasound examination for predicting clinical improvement after iliofemoral vein stenting in the VIDIO trial

- C4-C6 patients, 100 enrolled, 32 non-stented
- Subset analysis on nonthrombotic lesions demonstrated >61% diameter stenosis threshold yielded positive outcomes post-intervention
- Area stenosis not predictive of future improvement

JVS, Venous Lymphatic Dis 2018

What about the issue of migration?

- Migration/embolization of venous stents has become a major cause of clinical concern
- Seems to be almost exclusively in NIVL
- IDE trials: 1 event in 4 trials
- REAL LIFE:

42 records meeting your search criteria returned- **Product Problem:** *Migration* **Device**: *Stent, Iliac Vein* **Report Date From:** *01/01/2020* **Report Date To:** *01/31/2022*

Post-procedure management: Is there common ground?

- Should these patients be anticoagulated? With what? And how long?
  - No consensus
- How do you assess success in these patients?
  - Most stents in IDE trials placed for edema → but have we proven success?
- How and how long should you follow these patients?
  - No consensus

Non-thrombotic primary patency

- Uniformly high in IDE studies at 3 years
  - VIRTUS 96%
  - VERNACULAR 94% (3 year)
  - ABRE 97%
  - VIVO 100%

With reasonable certainty…there was variability in antithrombotic approach!

Other data

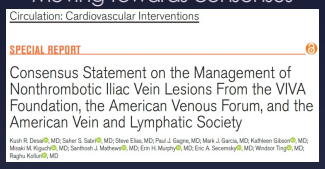
Type of anti-thrombotic therapy for venous stenting in patients with non-thrombotic iliac vein lesions does not influence the development of in-stent restenosis

Maxwell A Tran [1], Priya Lakhanpal [1], Sanjiv Lakhanpal [1, 2], Vinay K Satwah [1, 2], Gaurav Lakhanpal [1, 2], Peter J Pappas [1, 2]

- 389 patients
- Various regimens of antiplatelets or anticoagulant
- No difference between groups

Phlebology, 2020

Moving towards consensus


Circulation: Cardiovascular Interventions

SPECIAL REPORT

Consensus Statement on the Management of Nonthrombotic Iliac Vein Lesions From the VIVA Foundation, the American Venous Forum, and the American Vein and Lymphatic Society

Kush R. Desai, MD; Saher S. Sabri, MD; Steve Elias, MD; Paul J. Gagne, MD; Mark J. Garcia, MD; Kathleen Gibson, MD; Moaki M. Kiguchi, MD; Santhosh J. Mathew, MD; Erin H. Murphy, MD; Eric A. Secemsky, MD; Windsor Ting, MD; Raghu Kolluri, MD

- Multidisciplinary panel
- 80% consensus minimum
- Examined patient selection, imaging diagnosis, technical considerations, optimal medical management, future directions

Desai KR, Sabri SS, Elias S et al. *Circ Cardiovasc Interv. 2024;17:e014160.*

"Greatest Hits" from the Consensus Statement (my color commentary in red)

- Stent placement may be appropriate in asymmetric edema after excluding other causes; or in C4-C6 patients or venous claudication assuming no/treated superficial venous disease
- Edema is hard to fix!
- Stent placement is inappropriate in patients with minimal to no symptoms, or for "prophylaxis"

Desai KR, Sabri SS, Elias S et al. *Circ Cardiovasc Interv. 2024;17:e014160.*

"Greatest Hits" from the Consensus Statement (my color commentary in red)

- Using thresholds of >50% area reduction or >61% diameter stenosis on IVUS at the NIVL is correlated with symptom improvement following venous stent placement. Intervention below the stated thresholds is not recommended.
- 61% diameter stenosis WITH symptoms is my cutoff…it shouldn't be an eye test!
- Area not proven to be valid in a SMALL multicenter study
- Dynamic IVUS evaluation of NIVL is recommended; this includes breath hold and maneuvers that increase intra-abdominal pressure. Fixed lesions are more likely to be pathological, whereas dynamic compressions vary with such maneuvers and are less likely to be pathological.

Desai KR, Sabri SS, Elias S et al. *Circ Cardiovasc Interv. 2024;17:e014160.*

"Greatest Hits" from the Consensus Statement (my color commentary in red)

- Stent migration in NIVL can have devastating consequences. Measures to mitigate migration include appropriate sizing and length, with extension into the straight portion of the external iliac vein.
- CRITICAL. I personally never placed anything shorter than 120
- Size based off of the normal reference vessel. Sizing based on pre-stenotic dilation can be erroneous.
- I size off of the reference EIV

Desai KR, Sabri SS, Elias S et al. *Circ Cardiovasc Interv. 2024;17:e014160.*

"Greatest Hits" from the Consensus Statement (my color commentary in red)

- In treated patients with NIVL with no prior VTE, there is no consensus that antithrombotic therapy is necessary
- I do NOT anticoagulate patients
- Routine early and long-term clinical and imaging surveillance should be performed
- We must get a better understanding of our outcomes!

Desai KR, Sabri SS, Elias S et al. *Circ Cardiovasc Interv. 2024;17:e014160.*