

DISCLOSURES

Speaker name: Lowell S. Kabnick, MD, FACS

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I have the following potential conflicts of interest:

Consultant and shareholder, VENITI, Inc.
Consultant to BARD



What Really Matters to Patient is QOL: Veniti Virtus Venous Feasibility Trial



- Department of Vascular & Endovascular Surgery
- Director, NYU Vein Center





New York City- NYU Langone





New York University Medical Center





New York University Health



How Do We Avoid Over-Utilization of Stenting in Patients with Non-Thrombotic Iliac Vein Lesions (NIVLs) and Chronic Swelling?

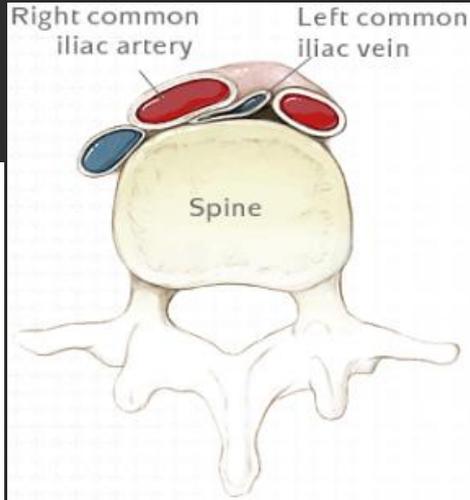
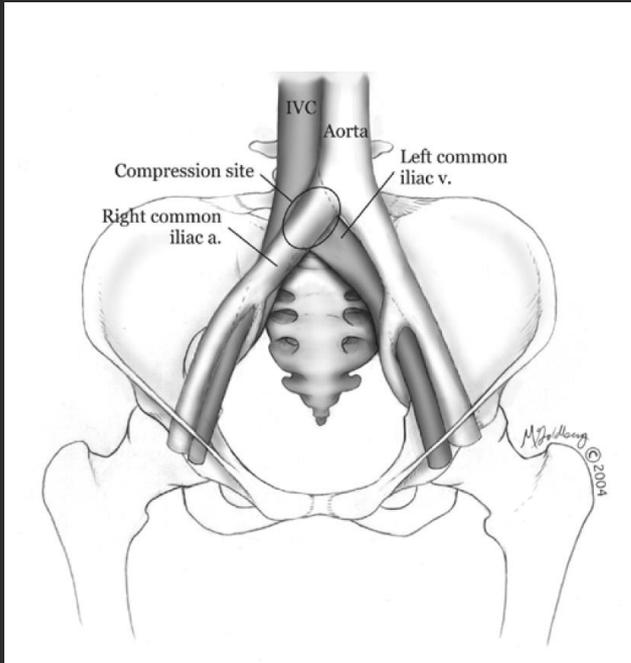


Key Points:

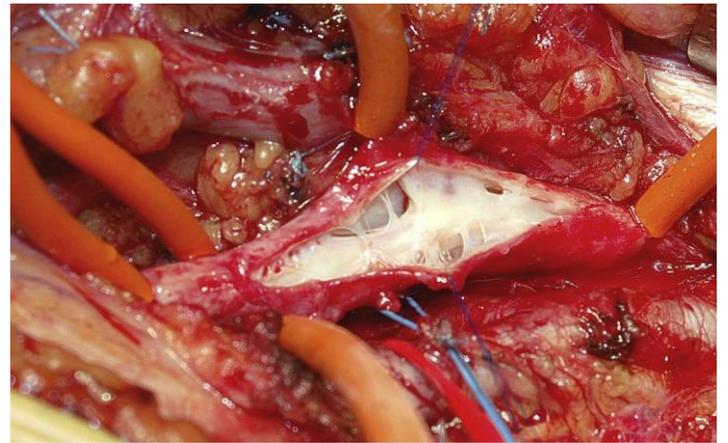
- Not known at what degree stenosis is hemodynamically critical
- > 50% morphological stenosis considered significant
- There is value of stenting recognized in treatment algorithms, especially thrombotic lesions
- Patients with swelling, but no associated signs or symptoms – Proceed with caution
- Not every patient stented will see improvement

Etiology of Chronic Venous Obstruction

Non-thrombotic lesion =
external compression



Post-thrombotic lesion =
remodeling of thrombus and
vein wall



Obstruction – Different in the Venous and Arterial Systems

	Diameter	Area
	(d)	(d^2)
		100

Most important:

an objective measure of symptom response

- Possible to measure he
- No accurate tests to me
- Unknown at what degre
- Consequently, > 50% m
- Recent research (VIDIO

70% diameter stenosis may better predict clinical improvement.

Strandness DE, Jr, Sumner DS: Hemodynamics for Surgeons, New York, 1975, Grune & Stratton.
 Neglén P, Hollis KC, Olivier J, and Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. *J Vasc Surg.* 2007;46:979-90.
 Hartung, Otero A, Boufi M et al. Mid-term result of endovascular treatment for symptomatic chronic nonmalignant ilioacaval venous occlusive disease. *J Vasc Surg* 2005;42:1138-44.
 Neglén P, Raju S. Proximal lower extremity chronic venous outflow obstruction: Recognition and treatment. *Seminars in Vascular Surgery* 2002; 15:57-64.

Strong Support for Intervention and Stenting of Thrombotic Disorders

- Society-based clinical practice guidelines for acute and postthrombotic disorders
- Significant benefits of stenting, e.g. reduction of pain and swelling

Stenting of the venous outflow in chronic venous disease: Long-term stent-related outcome, clinical, and hemodynamic result

Eur J Vasc Endovasc Surg (2015) ■, 1–60

Management of Chronic Venous Disease Clinical Practice Guidelines of the

Writing Committee ^a C. Wittens, A. C. Eggen, A. Giannoukas, M. Goheer, I. Toonder, M. Vuylsteke, ESVS Guidelines Committee ^b P. Koopman, M.V. de Ceuje, F. Vermassen, F. Verhaegh, Document Reviewers ^c M. De Maesseneer, R. Naylor, P. Nicolini, A. Rosales

Peter Neglén, MD, PhD,^a Kathryn C. Hollis, BA,^a Jake Olivier, PhD,^b and Seshadri Raju, MD,^b Jackson, Miss

thrombotic disease; thrombophilia by itself was not a risk factor. The median pain score and degree of swelling decreased significantly poststent. Severe leg pain (visual analogue scale >5) and leg swelling (grade 3) decreased from 54% and 44% pre- to 11% and 18% poststent, respectively. At 3 years, cumulative rates of complete relief of pain and swelling were 62% and 32%, respectively, and ulcer healing was 58%. The mean CIVIQ scores of QOL improved significantly in all categories. Mean hand-foot pressure differential decreased and mean ambulatory venous pressure improved in stented limbs with no concomitant reflux. The hemodynamic response was modified, depending on the presence of deep and superficial reflux in subsets of patients with adjunct saphenous procedures. No increase in venous reflux was observed.

al strategies for acute deep venous thrombosis. Clinical Practice Guidelines of the American Society of Vascular Surgery and the American

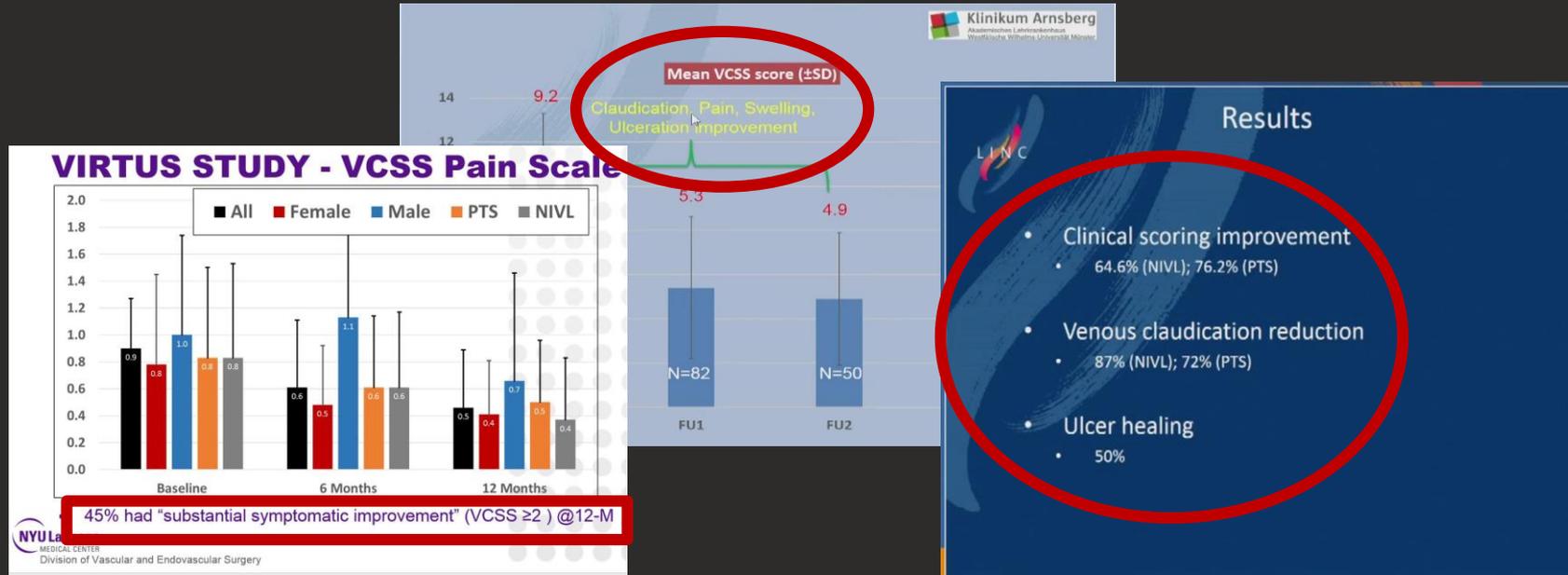
^a Anthony J. Comerota, MD,^c Michael C. Dalsing, MD,^d Johann M. Lohr, MD,^e Robert B. McLafferty, MD,^h Peter Pappas, MD,^k Joseph D. Raffetto, MD,^l and ^b Rochester, Minn; Toledo, Ohio; Indianapolis, Ind; Helsingborg, Sweden; Springfield, Ill; Newark, NJ; West Roxbury, Mass; Ann Arbor, Mich

Recommendation 56			
In patients with clinically relevant chronic iliofemoral vein obstruction, percutaneous transluminal angioplasty and stent placement should be considered.			
Recommendation 57			
Percutaneous transluminal angioplasty is not recommended as a single treatment for patients with chronic deep venous obstruction.	III	C	26, 479, 480
Recommendation 58			
After percutaneous transluminal angioplasty stent placement should be considered for patients with chronic deep venous obstruction.	Ila	C	479-483, 485-494

“We recommend the use of self-expanding metallic stents for treatment of chronic ilio caval compressive or obstructive lesions that are uncovered by any of the thrombus removal strategies (Grade 1C).” 

NIVLs – Do patient-reported outcomes justify treatment?

- Current research must validate patient outcomes/QOL, not just patency



Lichtenberg M. Patency rates and clinical results of a dedicated closed-cell design stent for the treatment of iliac vein lesions. Presented at: Leipzig Interventional Course; January 2017; Leipzig, Germany.
de Graaf R. Dedicated ring design Stent Patency rates and clinical results. Presented at: Leipzig Interventional Course; January 2017; Leipzig, Germany.

What Supports Using >50% Morphological Stenosis As A Rationale to Treat

Safety and effectiveness of stent placement for IVOO (systematic review and meta-analysis) Razavi M, Jaff M, Miller L. . *Circ Cardiovasc Interv* 2015;8

	NIVL (n = 1122)	Acute DVT (n = 629)	PTS (n = 1118)
Technical success	96.4	94.2	94.1
Major bleeding	0.3	1.1	0.9
Pulmonary embolism	0.2	0.9	0.6
Peri-procedural mortality	0.1	0.7	0.3
Early thrombosis	1.0	6.5	6.8
Complete pain relief†	81.5	100*	69.3
Complete edema relief†	68.0	100*	63.6
Complete ulcer healing†	81.1	n/a	70.8

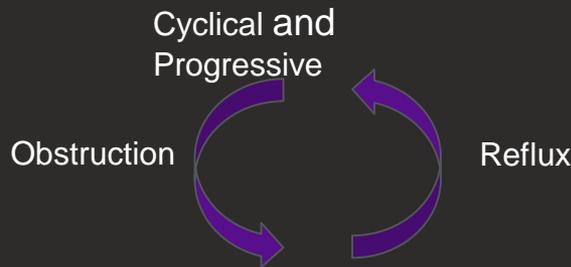
* Meta-analysis not conducted because of single study contributing data

† At the final follow-up visit

Stenting is Not a Panacea – Will Not Help Every Patient

- ❑ In the postthrombotic disease: Reflux **AND** Obstruction

Must test for both, and treat obstruction first



- ❑ In non-thrombotic disease:

- ❑ Asymptomatic population – 25-30% rate of significant NIVL stenosis
- ❑ Multi-factorial etiology of swelling
- ❑ Improvement of concomitant pain may result in subjective, but not objective, relief of swelling

Kibbe MR et al. Iliac vein compression in an asymptomatic patient population. *J Vasc Surg* 2004 May;39(5):937-43.

Raju S, Neglen P. High prevalence of nonthrombotic iliac vein lesions in chronic venous disease: a permissive role in pathogenicity. *J Vasc Surg*. 2006 Jul;44(1):136-43.

Liu Z et al. Endovascular treatment for symptomatic iliac vein compression syndrome: a prospective consecutive series of 48 patients. *Ann Vasc Surg*. 2014 Apr;28(3):695-704.

Ye K et al. Long-term outcomes of stent placement for symptomatic nonthrombotic iliac vein compression lesions in chronic venous disease. *J Vasc Interv Radiol*. 2012 Apr;23(4):497-502.

Wen-da W et al. Stenting for chronic obstructive venous disease: A current comprehensive meta-analysis and systematic review. *Phlebology* 2016 Jul;31(6):376-89

Multi-Factorial Etiology of Swelling Alone

	Abnormal lymphangiography (n=72)	Normal lymphangiography (n 205)
NIVL/PT lesion	4:3	1:1
Swelling relief		
Complete	16%	44%
Improved ($\geq 1/3$)	45%	66%
Pain Relief		
Complete	65%	71%
Improved ($\geq 3/10$ VAS)	87%	83%

All patients had swelling as the main complaint, C of CEAP 3)

Relationship of Concomitant Pain with Swelling

Iliac stenting in postmenopausal leg swelling
Raju S. et al.

- ❑ 150 menopausal women
- ❑ Median age 68 years (range:55-92)
- ❑ C of CEAP class 3
- ❑ Concomitant pain in 70%
- ❑ H/O DVT > 5 years ago

Improvement of concomitant pain may result in subjective, but not objective, relief of swelling

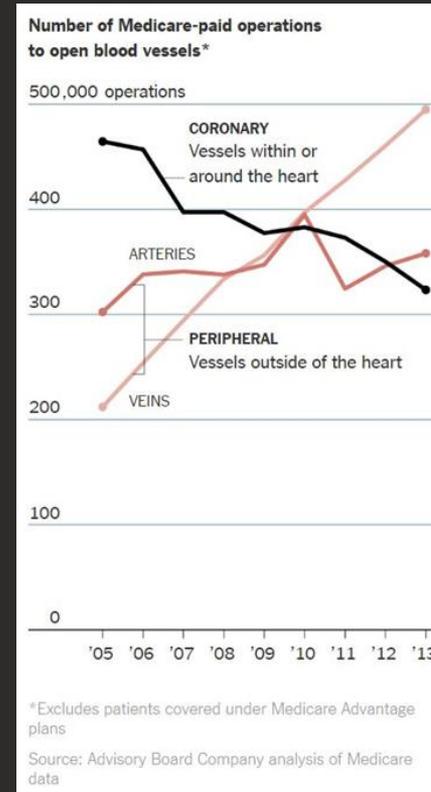
	(n=163 limbs)
NIVL/PT lesion	65%/35%
Swelling relief	
Complete	33%
Improved ($\geq 1/3$)	50%
Subjective improvement	67%
Pain Relief	
Complete	65%
Improved ($\geq 3/10$ VAS)	76%

(Cumulative result at 5 years)

Raju S. et al. Iliac stenting in postmenopausal leg swelling. *J Vasc Surg.* 2011;53:123-30.
Raju S. et al. Diagnosis and treatment of venolymphedema. *J Vasc Surg.* 2012;55:141-9.

What is/will Drive Over-Utilization of Venous Stenting?

- ❑ Stenting of NIVLs is relatively easy procedure
- ❑ Minimal clinical risk to patients
- ❑ Generally good results in patients with non-thrombotic lesions
- ❑ Imaging modalities (IVUS) supports morphological finding of stenosis
- ❑ Reimbursement drives utilization, e.g. United States



How do we Ensure Right Patients are Treated?

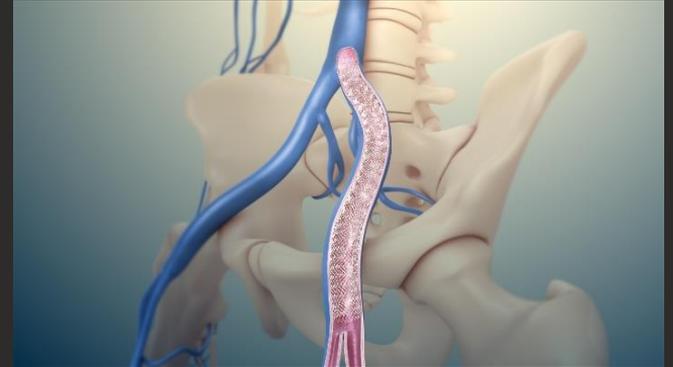
THAT IS THE OVERARCHING QUESTION??

- ❑ Practice techniques for correct stent (venous dedicated) placement
- ❑ Appropriate follow-up, e.g. anticoagulation regimen, to support outcomes



Take Home Message

- ❑ Stenting *may be* be beneficial in majority of patients with symptomatic chronic leg swelling and venous obstruction
- ❑ Without a test for hemodynamic significance of obstruction, risk of over-treating patients with chronic swelling exists
- ❑ Need better correlation between degree of morphological stenosis (NIVLs) and clinical outcome
- ❑ Since at least one-third of patients have no swelling relief, in the absence of other signs or symptoms – ***Proceed with caution***





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