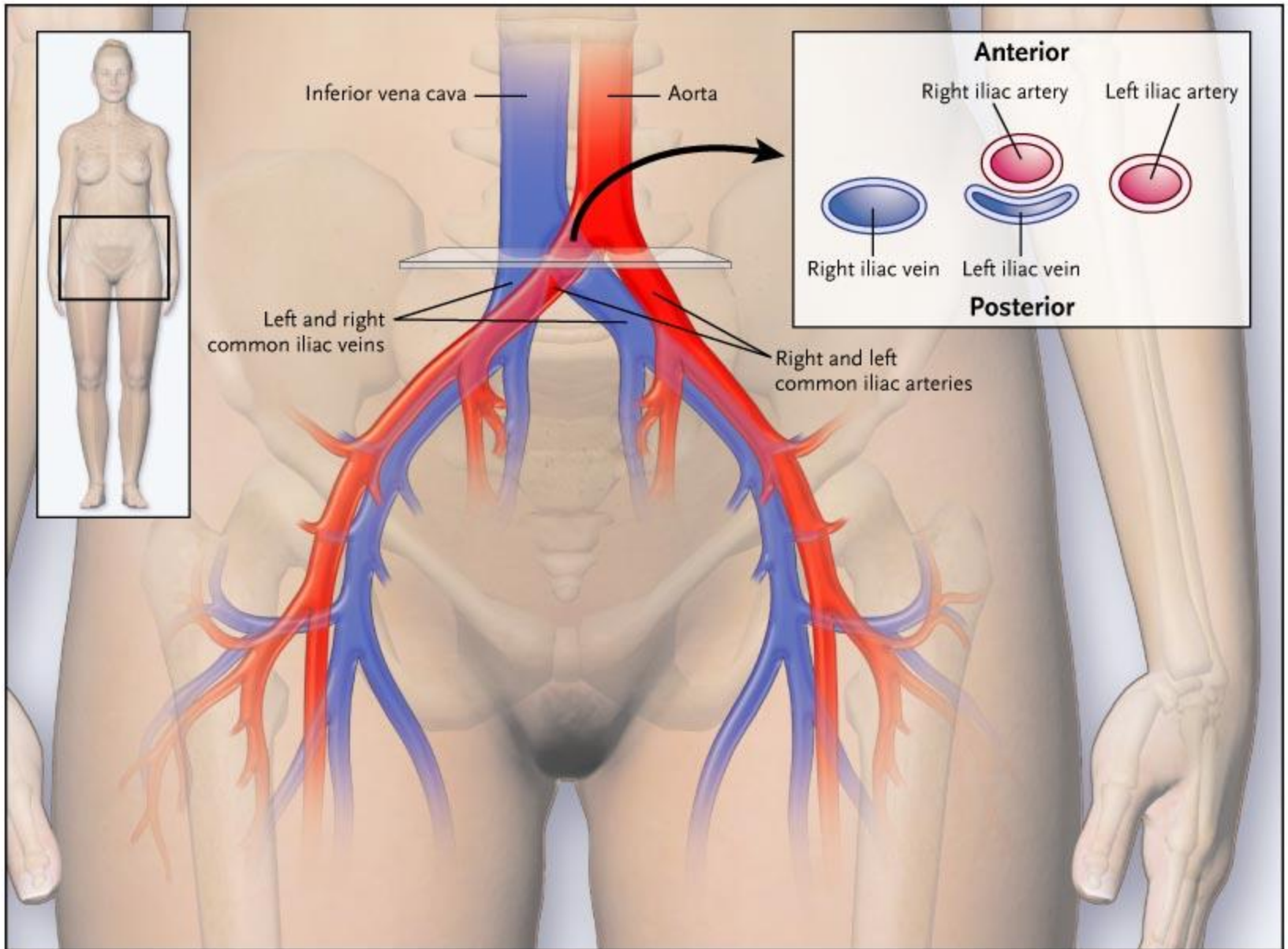


¼ of patients assessed for venous disease walk out of your door when they should have been treated.....

## **HYPOTHESIS**



Inferior vena cava — Aorta

Left and right  
common iliac veins

Right and left  
common iliac arteries

**Anterior**

Right iliac artery

Left iliac artery



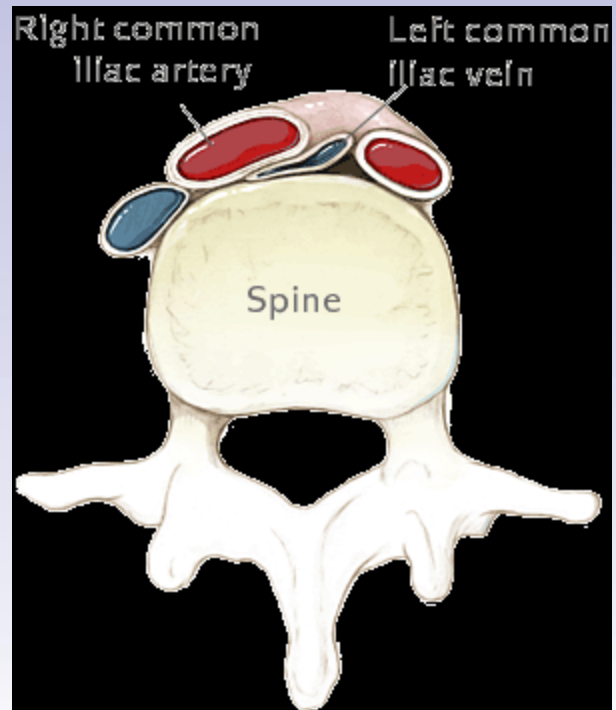
Right iliac vein



Left iliac vein



**Posterior**



**FIRST, CONSIDER THE MAGNITUDE  
OF THE PROBLEM / OPPORTUNITY**

# You probably see these patients everyday!





# Chronic Venous Disease: What is the magnitude of the problem / opportunity?

- Bonn Vein Study: 2000-2002
  - 3072 participants (from the general population in Bonn Germany)
  - Aged 18-79
  - questionnaire and duplex scanning of the limbs, and clinical exam
- Leg swelling and heaviness (venous symptoms) common
  - 57% males & 76% females
- Outcomes:
  - C0, No disease: 9.6%
  - C1, Spider Veins: 59.1%
  - C2, Varicose Veins: 14.3%
  - C3, Edema: 13.4%
  - C4, Pigmentation, eczema, atrophy blanche: 2.9%
  - C5, (healed): 0.6%
  - C6, (active) ulcers: 0.1%

# What is the frequency of iliac vein obstruction in patients with a healed(C5) or an active(C6) venous ulcer?

- Of 78 patients with C5 or C6 ulcers, reviewed with CT and MR
  - 37% had a venous stenosis >50%
  - 23% had a venous stenosis >80%
    - Associated with females, history of DVT, deep venous reflux
    - Interestingly, no limb >80% venous stenosis found to have superficial venous reflux.

Does this imply deep system obstruction?

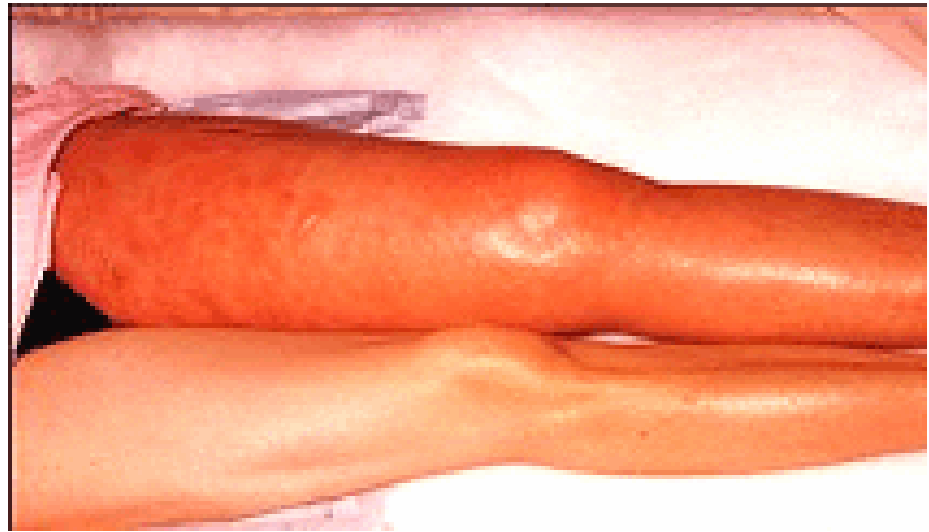
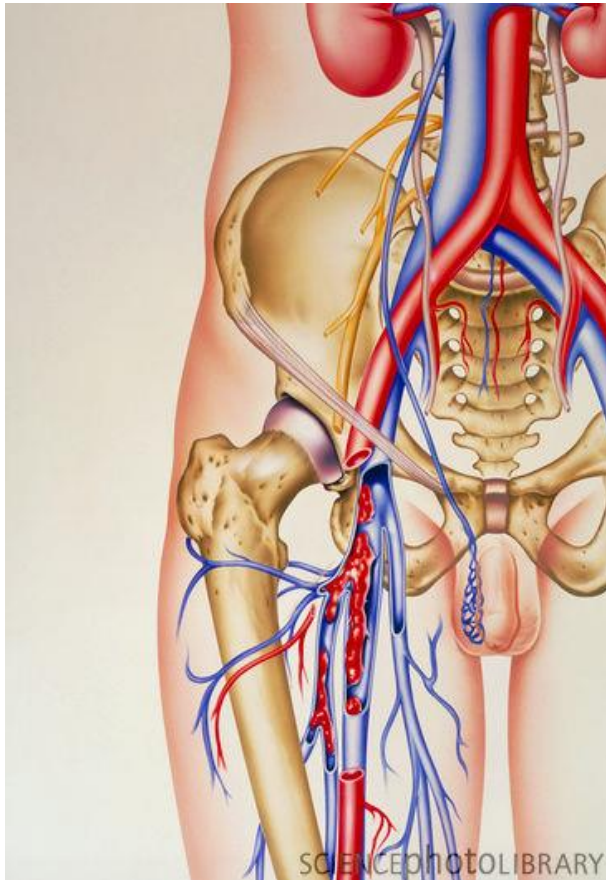
# So, how do we find this 0.7% of the population with C5 or C6 disease?



- Wound care center?
- Podiatrists?
- General Practitioner?
- You are already seeing them!



# Could the underlying cause of the DVT come from deep system obstruction? How would you determine if it is obstructed?



# DVT Patients provide further opportunity

- There are reported to be 600,000 DVT (Deep Vein Thrombosis) hospitalizations per year in the US<sup>1</sup>
- Iliac vein compression is thought to occur 18 - 49% among patients with left-sided lower extremity DVT<sup>1</sup>
- Other series report the prevalence of iliac vein compression as high as 49% - 62% in patients with DVT<sup>2</sup>

1. Al-Nouri O, Milner R. May-Thurner Syndrome. *Vas Disease Mgt.* 2011;3:53-56.
2. Rosen E, Groben L, et al. Rare Case of Bilateral Common Iliac Vein Compression by Arterial Stents and Calcification. *Vas Disease Mgt.* 2012;9(11):E172-E174.

# Importance of IVUS in Treatment of Iliofemoral disease: SVS-AVF Guidelines

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“Single-plane venography may be *relatively insensitive* in the detection of iliocaval compression *compared with IVUS*... venography has been demonstrated to have a sensitivity of only 45% for the detection of chronic iliac obstruction”

Meissner M, Gloviczki P, et al. Early thrombus removal strategies for acute deep venous thrombosis: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vas Surg. 55:5. May 2012. pp. 1449-1462.

# How does IVUS compare to single plane venography?

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- 304 consecutive limbs before and after stenting
- Used IVUS as a standard, venography single plane had a poor sensitivity 45% in detecting area stenosis >70%.
- Actual **area** demonstrated higher degrees of stenosis when measured directly with IVUS (software) as opposed to calculation of diameter (non-circular geometry of stenosis)

# Clinical need for interventional procedures

- Localized venous obstruction is a major cause of symptoms<sup>1,2</sup>
  - Greater than 90% of post-thrombotic CVI cases have obstruction<sup>3</sup>
  - Collateral flow only partially prevents symptoms associated with venous disease
- Stenting is “method of choice” for chronic venous obstruction<sup>2,4</sup>

1. Neglen P, Thrasher TL, Raju S. Venous outflow obstruction: an underestimated contributor to chronic venous disease J Vasc Surg 2003;38:879-85.
2. Neglen, P. Chronic Venous Obstruction: Diagnostic Considerations and Therapeutic Role of Percutaneous Iliac Stenting . Vascular. 2007;15(5):273-280.
3. Raju, S. Venous stenting in CVD- Tips and Tricks, VEITH 2008.
4. Gillespie. D. Stent placement after DVT thrombolysis or mechanical thrombectomy. Endovascular Today, July 2009.

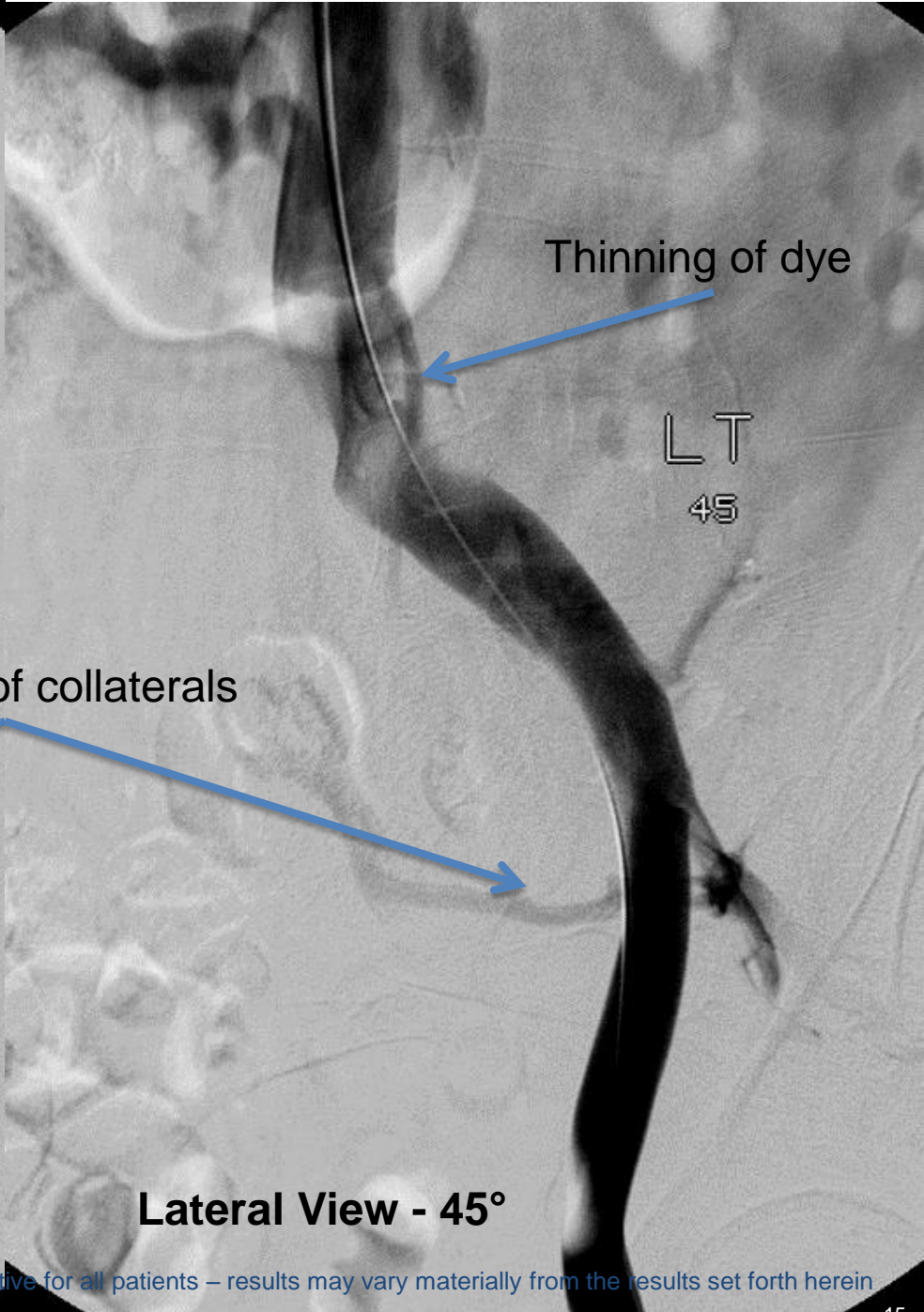
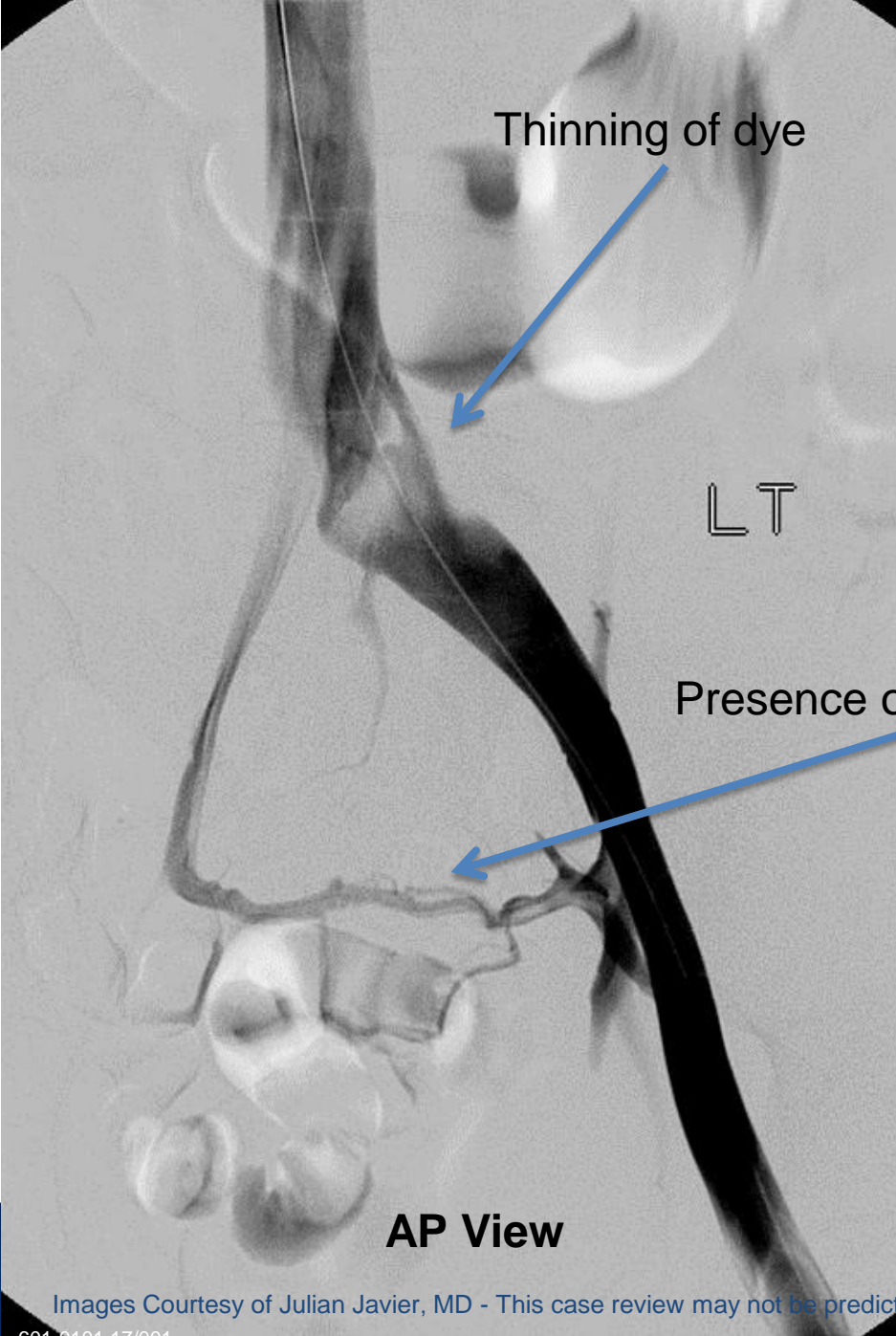


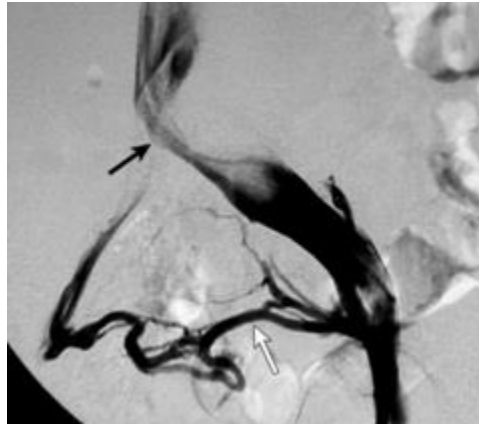
# Criteria to treat based on IVUS

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- Despite the lack of positive hemodynamic results with available methods, balloon dilation and stenting of stenotic iliac veins guided with morphologic area stenosis of more than 50% on IVUS results appear to have apparent clinical benefits for the patients.<sup>1,2,3</sup>

1. Neglén P, Raju S. Intravascular ultrasound scan evaluation of the obstructed vein. J Vasc Surg. 2002;35:694-700.
2. Neglén P, Raju S. Balloon dilatation and stenting of chronic iliac vein obstruction: technical aspects and early clinical outcome. J Endovasc Ther 2000;7:79-91.
3. Neglén P, Berry MA, Raju S. Endovascular surgery in the treatment of chronic primary and postthrombotic iliac vein obstruction. Eur J Vasc Endovasc Surg 2000;20:560-71.

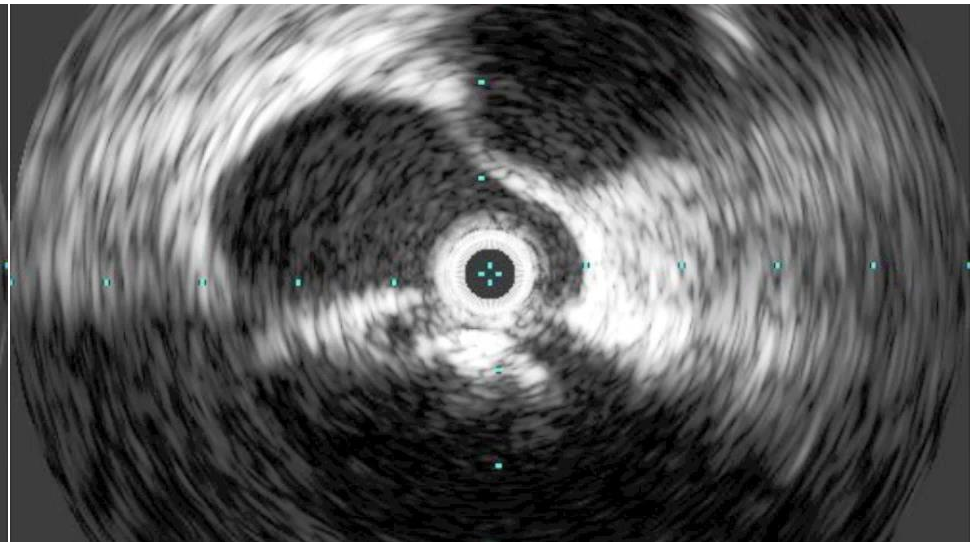
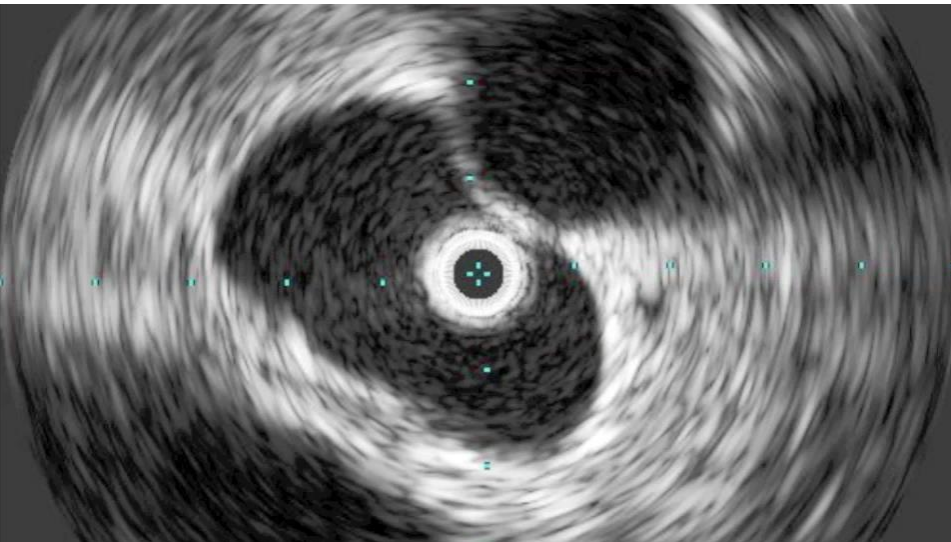




# IVUS run of iliac venous compression

Pre-Stent

Post-Stent



Images Courtesy of P. Gagne, MD

# Ah Ha!

*“Neglen et al compared the use of IVUS to venography for the evaluation of patients with venous outflow obstruction. In this study, they found that venography underestimated stenosis by 30%. In addition, they reported that venography was considered normal in one-fourth of limbs despite the fact that IVUS showed more than 50% of obstruction. IVUS shows intraluminal details, trabeculations, and webs that may be hidden by the contrast dye.”*



# Ah Ha!

*“Other advantages of IVUS are its ability to demonstrate external compression directly, wall thickness, and neointimal hyperplasia. To date, IVUS seems to be the best available method for diagnosing clinically significant chronic iliac vein obstruction.”*

# So,

- There are a large number of potential patients
  - C5 & C6 venous ulcer patients (37% >50% stenosis)<sup>1</sup>
  - DVT patients (18-49% or 49-62% have Iliac Vein Compression)<sup>2,3</sup>
- If diagnosing iliac venous compression based on venography, ¼ of limbs considered to be normal, actually may have compression >50%, so they should be considered for treatment<sup>4</sup>

1. Marston W, Fish D, et al. Incidence of and risk factors for ilio caval venous obstruction in patients with active or healed venous leg ulcers J Vasc Surg 2011; 1303-1308.
2. Al-Nouri O, Milner R. May-Thurner Syndrome. Vas Disease Mgt. 2011;3:53-56.
3. Rosen E, Groben L, et al. Rare Case of Bilateral Common Iliac Vein Compression by Arterial Stents and Calcification. Vas Disease Mgt. 2012;9(11):E172-E174.
4. Gillespie D, Johansson M, Glass C. Stent Placement After DVT Thrombolysis/Mechanical Thrombectomy - Which patients should be stented and which should not? EVToday. July 2009:55-60.