Discover More About **Deep Venous Disease & Optimize Your Treatment Options**

Outline

- Chapter 1: Disease Prevalence and Economics
- Chapter 2: Classification/Diagnostic Tools and Treatment Options
- Chapter 3: Patient Case Reviews

Chapter 1:
Disease Prevalence and Economics

Venous Thromboembolism (VTE) Prevalence

- True incidence of VTE unknown[1]
- As many as 900,000 people are affected by VTE in the U.S. each year[1]
- Many cases go undiagnosed[2]

1. Venous Thromboembolism: Data & Statistics. Centers for Disease Control and Prevention. (February 5, 2018). Retrieved October 11, 2018, from http://www.cdc.gov/ncbddd/dvt/data.html
2. The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. Office of the Surgeon General (US); National Heart, Lung, and Blood Institute (US). 2008

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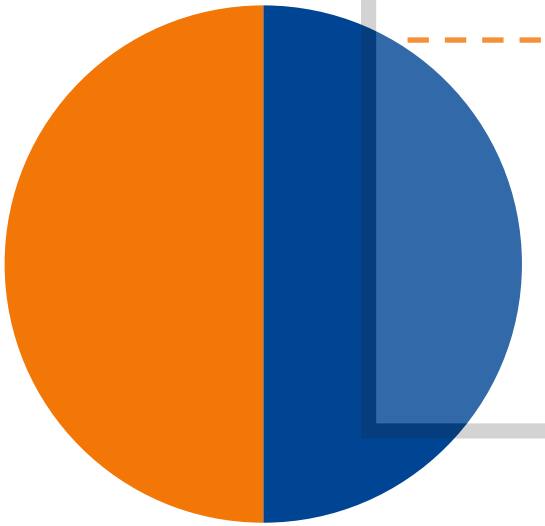
VTE Statistics

- One-half of VTEs are healthcare-associated[2]
- Incidence of VTE will continue to increase with growing aging population[3]



50%

2. The Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism. Office of the Surgeon General (US); National Heart, Lung, and Blood Institute (US). 2008
3. Venous Thromboembolism (VTE). National Center on Birth Defects and Developmental Disabilities 2012 Annual Fiscal Report. Retrieved August 24, 2016 from http://www.cdc.gov/ncbddd/aboutus/annualreport2012/documents/ar2012-vte-printversion.pdf

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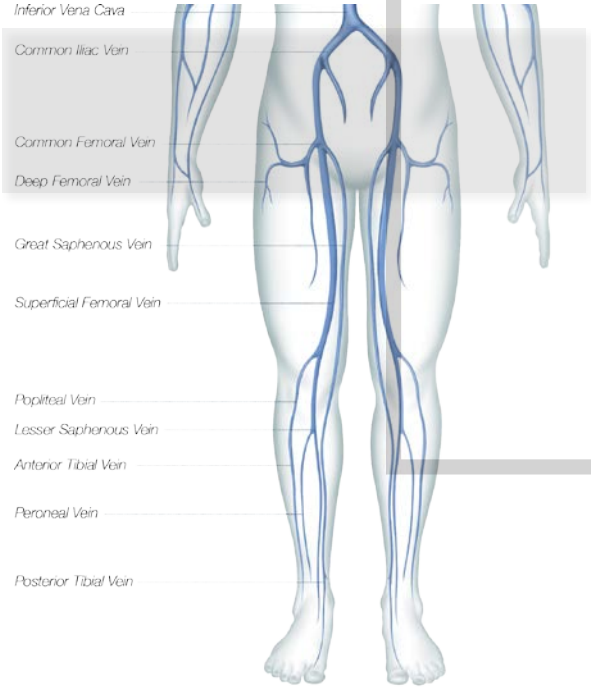
Deep Vein Thrombosis (DVT) Location

Thrombosis in the iliac and femoral veins increases the risk of:

- Recurrent deep vein thrombosis (DVT)
- Pulmonary embolism (PE)
- Post-thrombotic syndrome (PTS)

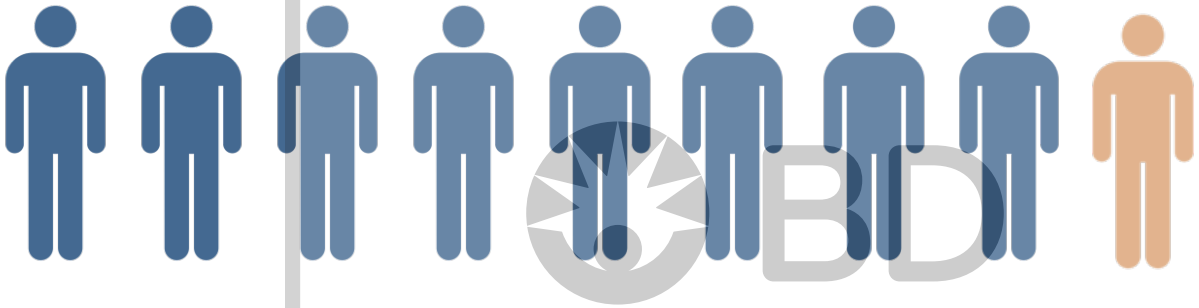


40% of acute DVTs occur in the common femoral and iliac veins[4]

Iliofemoral DVT associated with more **severe** symptoms[4]

4. Gloviczki P, et al. The Layman's Handbook of Venous Disorders. Adapted from the Handbook of Venous Disorders; Guidelines of the American Venous Forum, Third Edition (Hodder Arnold, London 2009)

Consequences of VTE



Affected by VTE

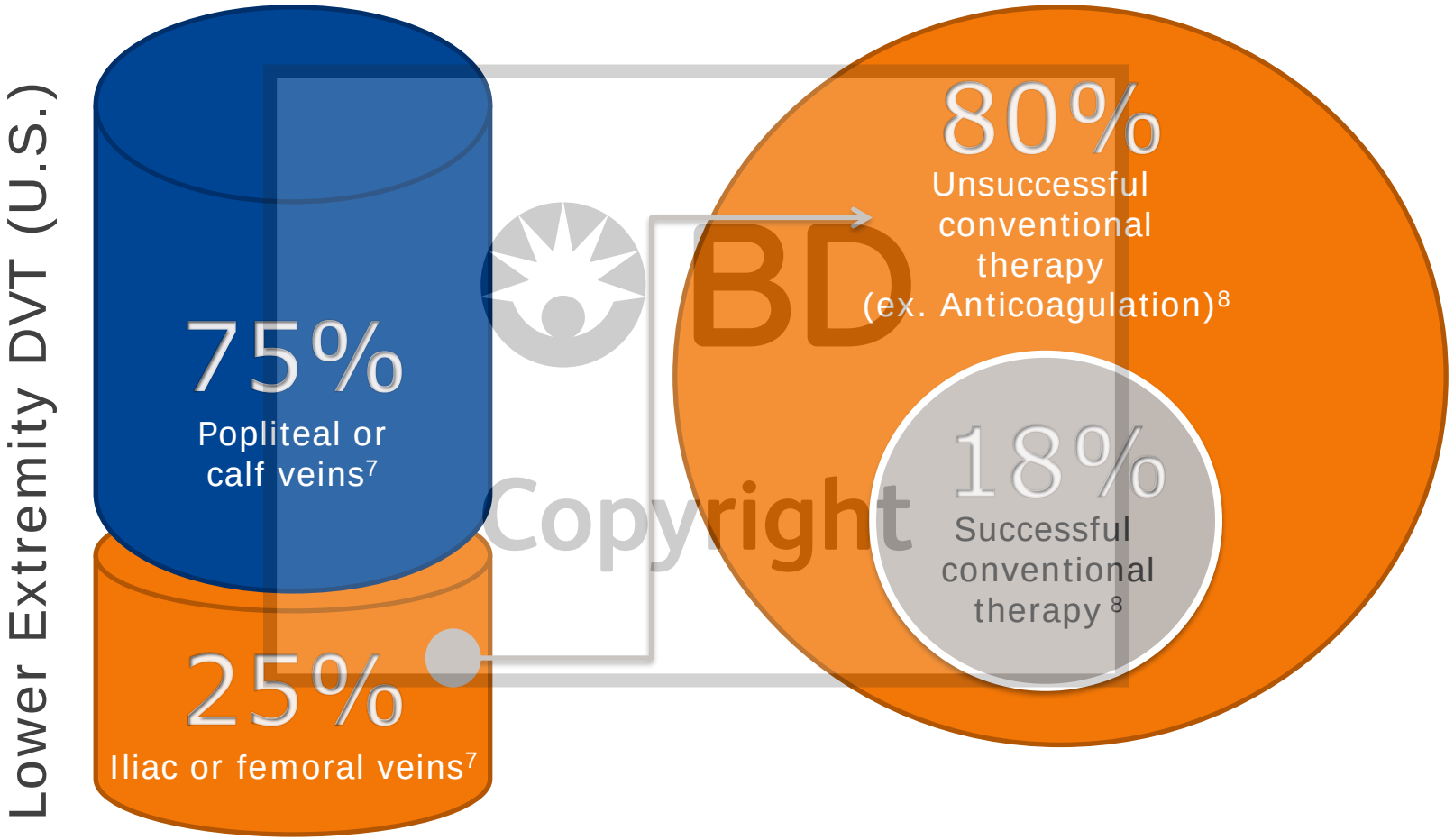
VTE-related deaths

= 100,000 people

- It is estimated that up to **100,000** of Americans die each year from VTE[1]
  - 10% - 30% die within a month of diagnosis[5]
- 33% recurrence over 10 years[5]
- **50% will have Post-Thrombotic Syndrome** (PTS)[5]
- Avg. 548,000 hospitalizations each year due to VTE[6]

5. Venous Thromboembolism: Data & Statistics. Centers for Disease Control and Prevention. (February 5, 2018). Retrieved October 11, 2018, from http://www.cdc.gov/ncbddd/dvt/data.html
6. Venous Thromboembolism in Adult Hospitalizations — United States, 2007–2009. CDC Morbidity and Mortality Weekly Report . June 8, 2012. Retrieved October 11, 2018 from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6122a1.htm

VTE Population



7. Raymond Foley, et Al. (2015). Iliofemoral Deep Vein Thrombosis. American College of Cardiology.
8. Hodder Arnold. (2009). The Layman's Handbook of Venous Disorders. Guidelines of the American Venous Forum, Third Edition.

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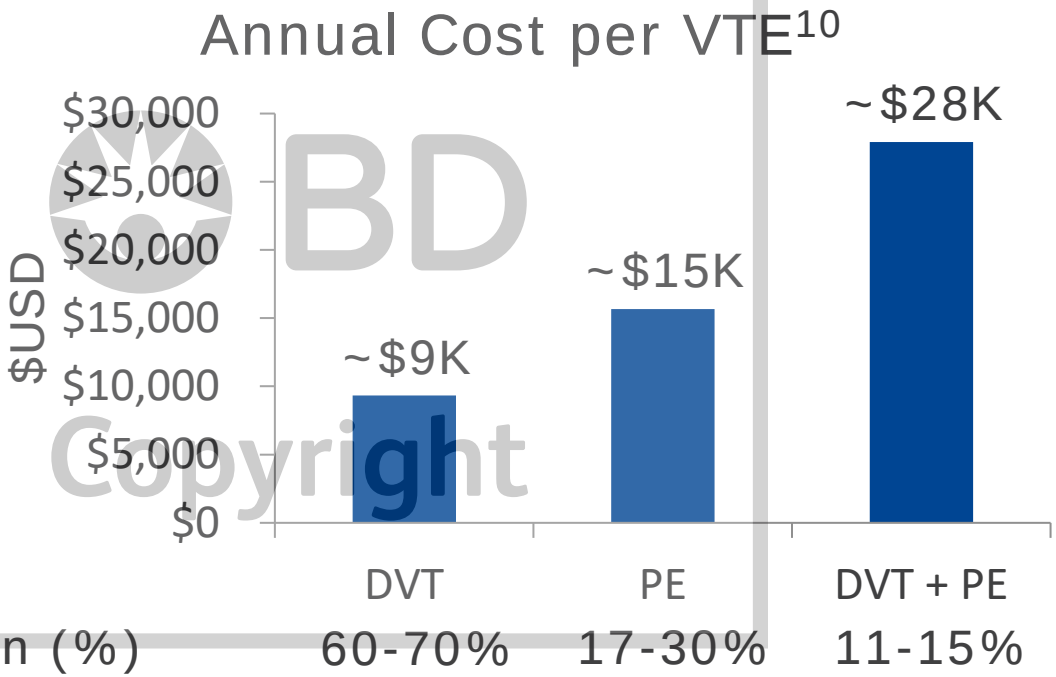
Cost of VTE

Annual U.S. healthcare cost $2 - $10 Billion[9]



Clinical Presentation (%)	DVT	PE	DVT + PE
	60-70%	17-30%	11-15%

9. Beckman M, et al. Venous Thromboembolism A Public Health Concern. Am J Prev Med. 2010 Apr;38(4 Suppl):S495-501.
10. Spyropoulos AC, Lin J. Direct Medical Costs of Venous Thromboembolism and Subsequent Hospital Readmission Rates: An Administrative Claims Analysis From 30 Managed Care Organizations. J Manag Care Pharm. 2007 Jul-Aug;13(6):475-86. Annual costs include both primary and secondary diagnosis.

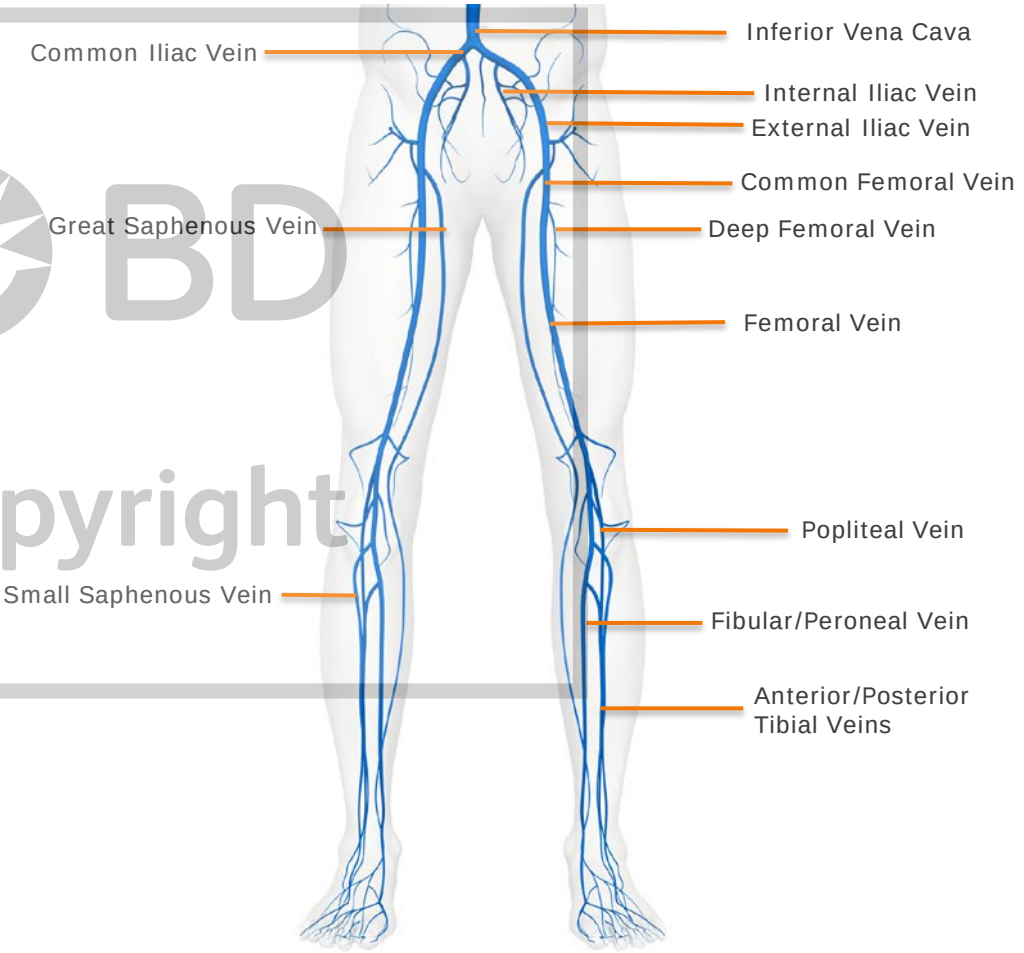
Understanding Venous Anatomy

Venous Anatomy

Superficial Veins
- Closer to skin's surface
- Drain the cutaneous microcirculation

Deep Veins
- Drain blood from lower extremities
- Located within muscle fascia
- 90-95% of venous blood returns to the heart

Perforator Veins
- Join superficial and deep venous systems



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Deep Vein Sizes

Vessel	Average Diameter (mm)	Average Area (mm^2)
Common femoral vein (CFV)	12	125
External iliac vein (EIV)	14	150
Common iliac vein (CIV)	16	200
Inferior vena cava (IVC)	18-24	300-400

Note: Area vs. Diameter
Despite being constructed of similar tissue types, the overall structure of arteries and veins is different. For this reason, often times, the area is frequently used as reference for vessel sizing.

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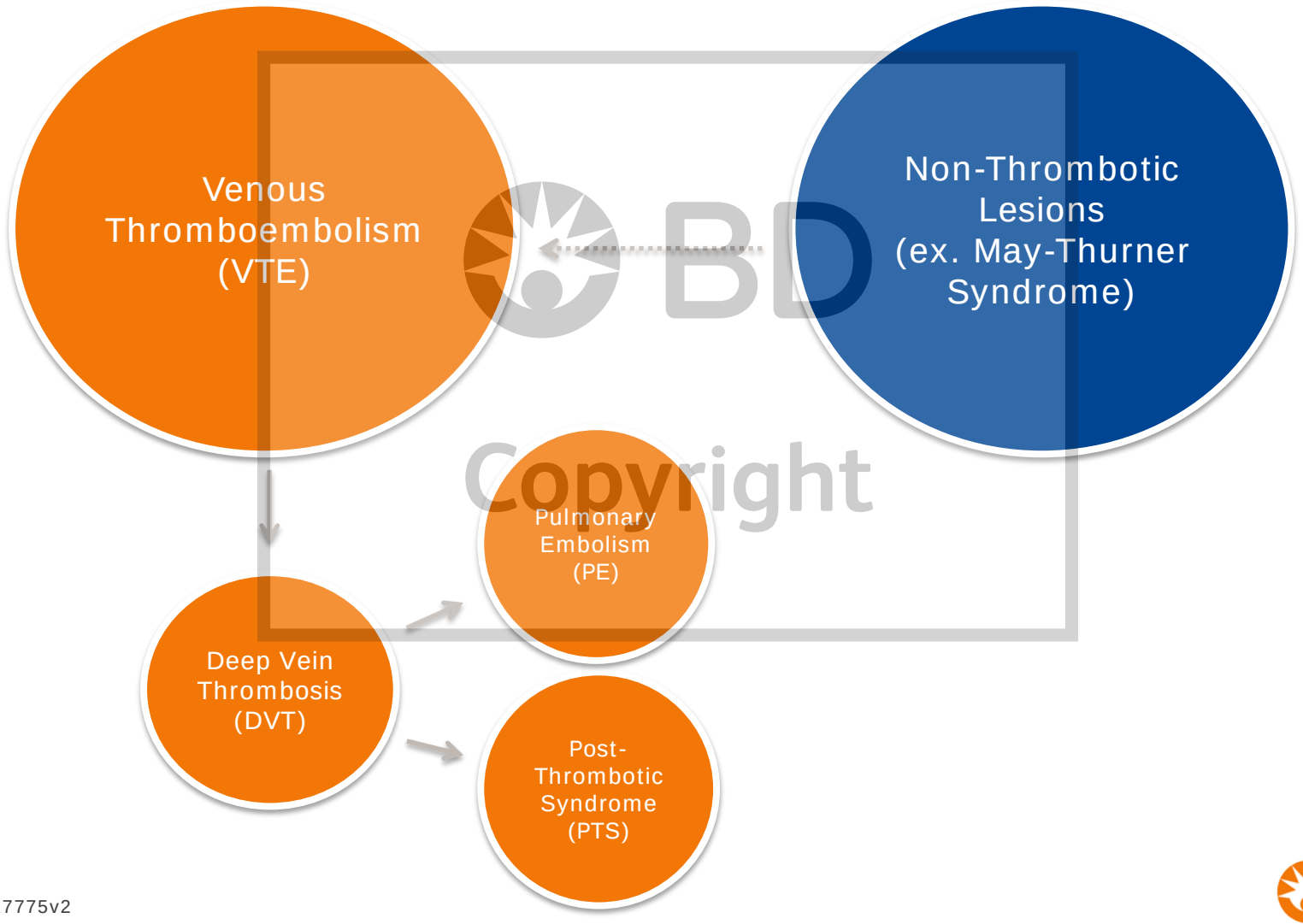
Chronic Venous Disease



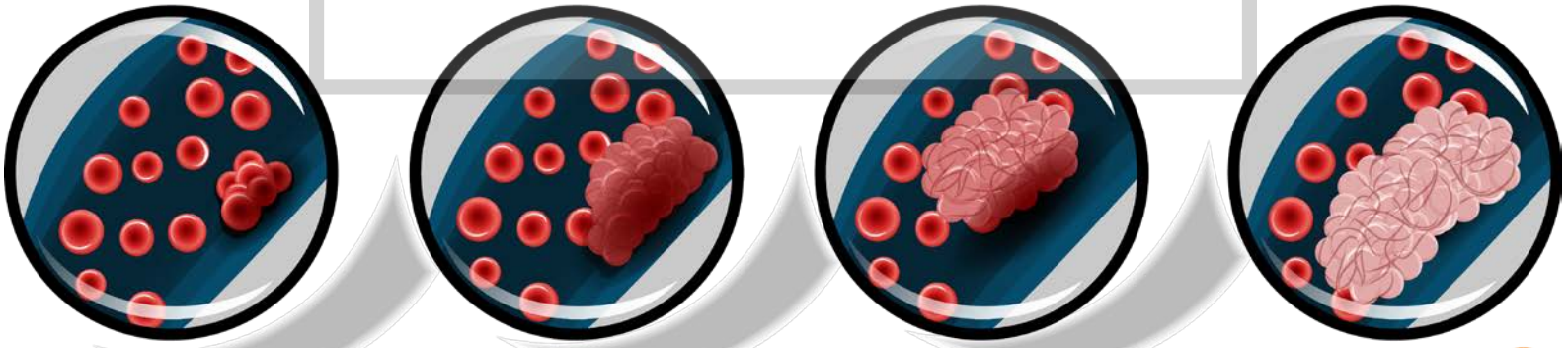
DVT Classification

Acute:
< 14 days old

Subacute:
14-28 days old

Chronic:
> 28 days old

Soft fibrotic thrombus → Dense / collagenous tissue



Post-Thrombotic Syndrome

Overview: Results from the damage of accumulated chronic DVT. It is more persistent and difficult to treat. Up to half of DVT patients will suffer from PTS.

Symptoms: Ulcers, chronic pain, swelling, discoloration, heaviness, cramping, eczema, hardening of skin, varicose veins

Risk Factors:

- Chronic DVT
- Blood clot above the knee
- Multiple blood clots in same leg more than once
- Extreme obesity
- Anticoagulation therapy complications

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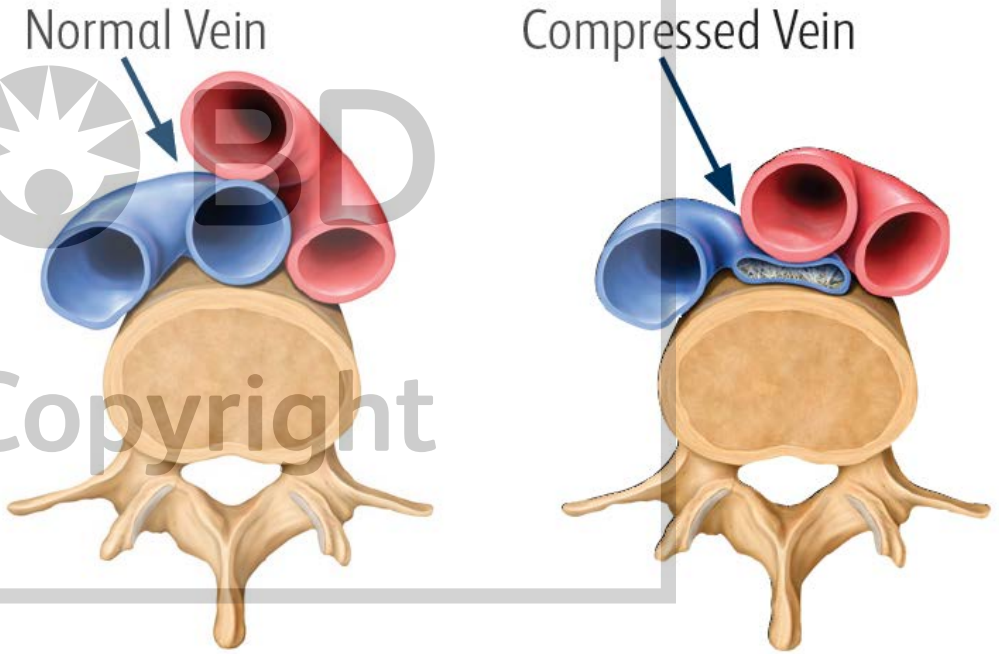
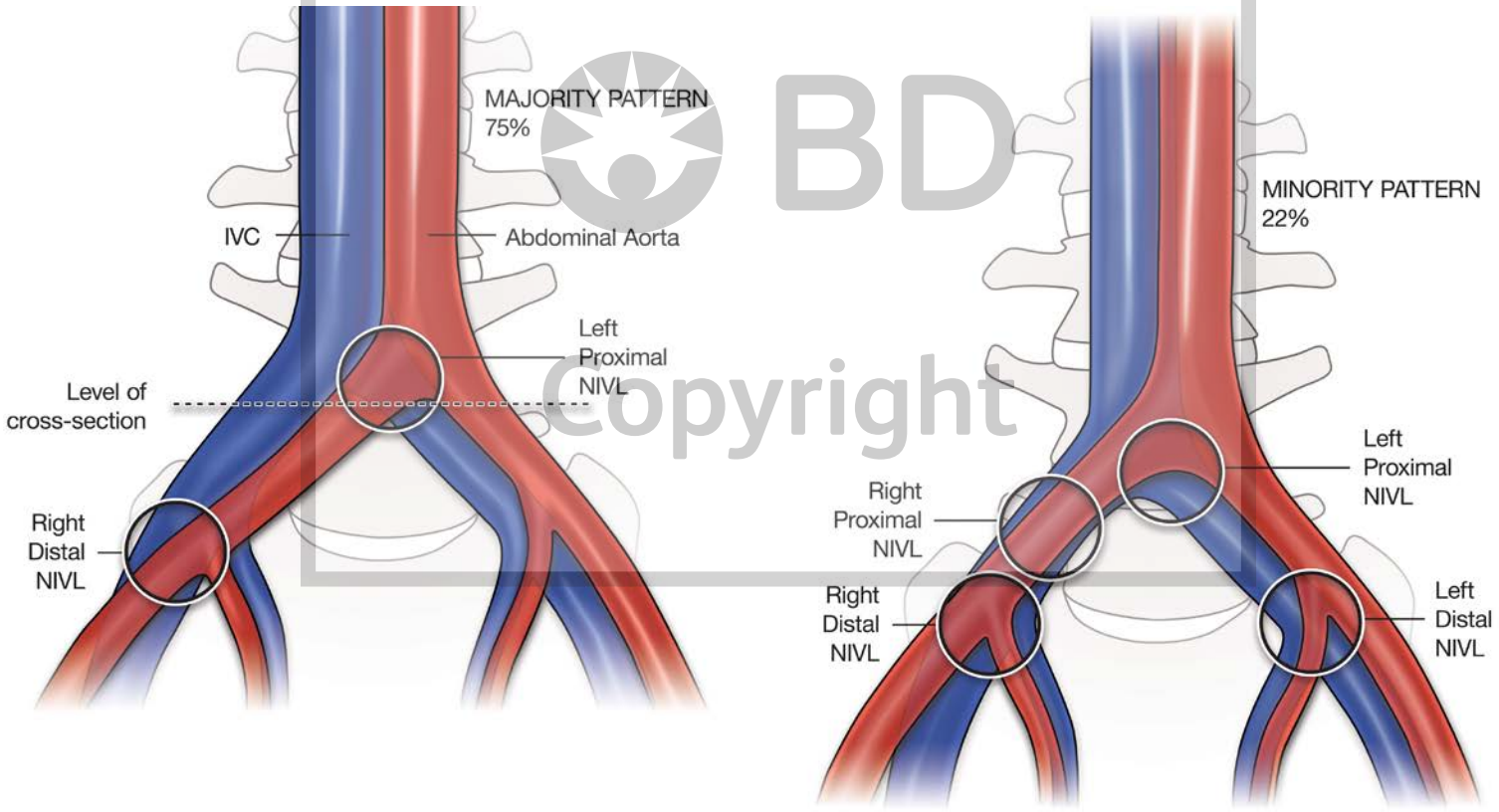
Non-Thrombotic Iliac Vein Lesion (NIVL)

NIVL lesions are venous compressions caused by anatomical abnormalities. They limit and restrict blood flow and can result in narrowing of the vein.



Venous Compressions

Compression points caused by the artery on the vein



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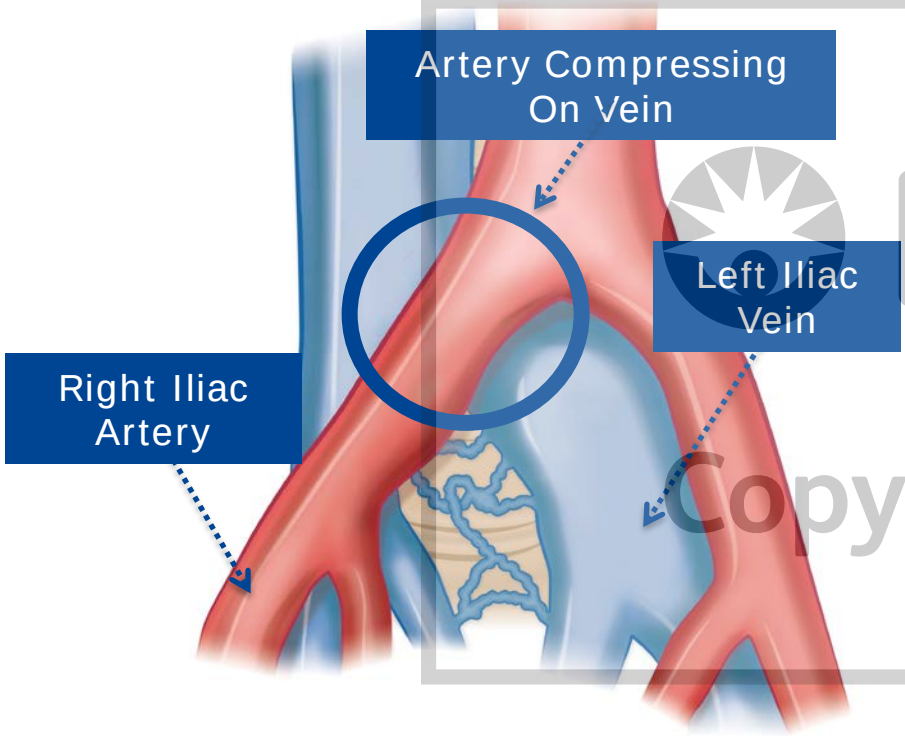
May-Thurner Syndrome



Overview: Type of venous compression that occurs when the right iliac artery compresses the left iliac vein

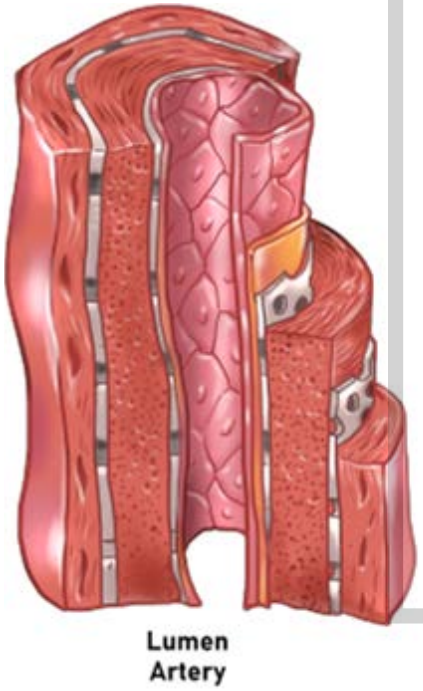
Symptoms: Often none, unless it has caused DVT. In this case, some symptoms of DVT may be present such as leg swelling, particularly on the left side.

Risk Factors:

- 22-32% of the population
- Left-side lower extremity DVT
- Females ages 20-40
- Pregnancy
- Immobility

Arterial vs. Venous

Arteries vs. Veins



Arteries
- More muscular, thicker walls
- Smaller lumens
- No valves
- Not elastic or compliant
- Higher blood flow rate

Veins
- Thinner walls
- Larger lumens
- Bicuspid valves
- Less elastic, more compliant
- 70% of the body's blood
- Lower blood flow rate
- Higher degree of variability

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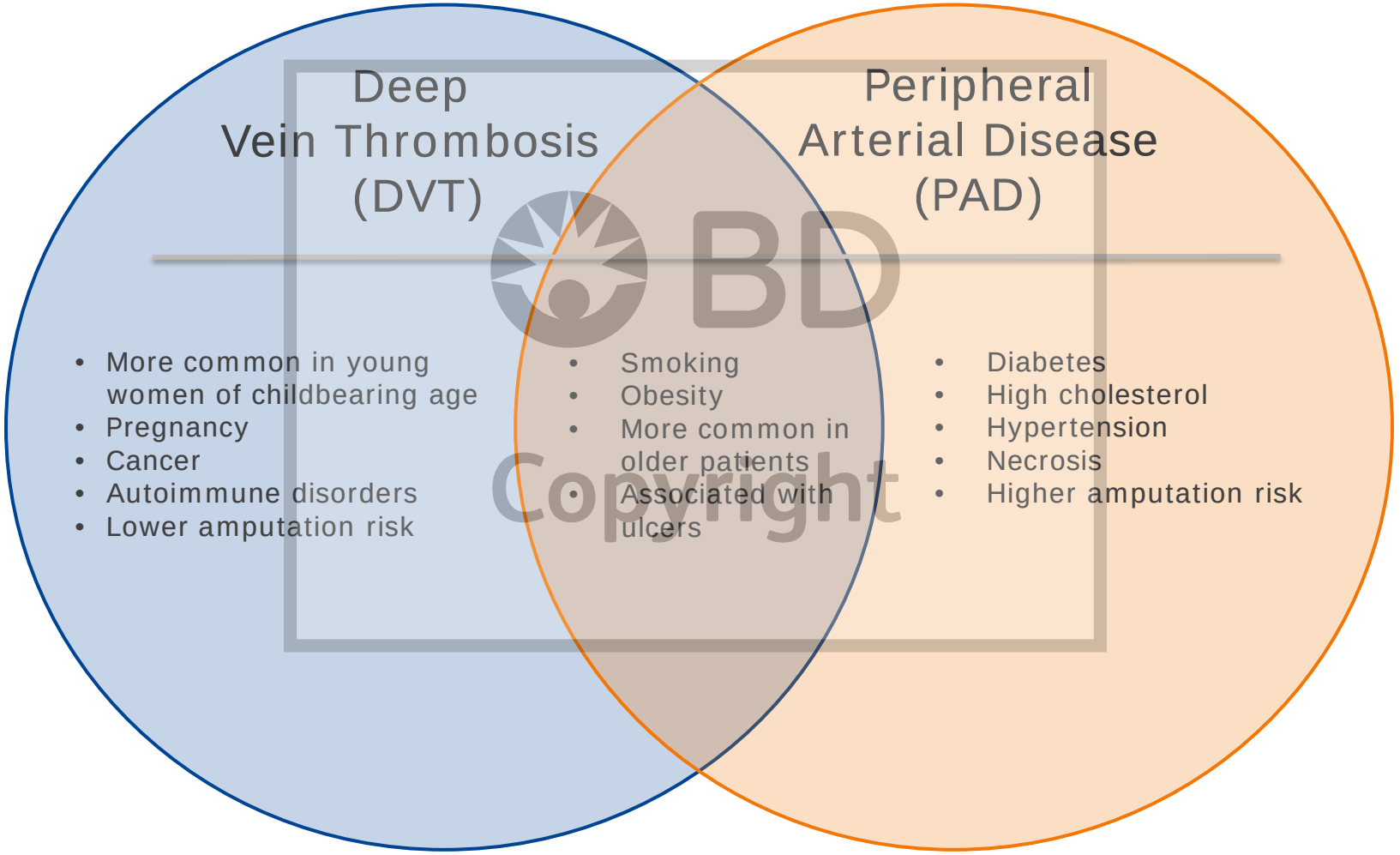
What is the Difference?



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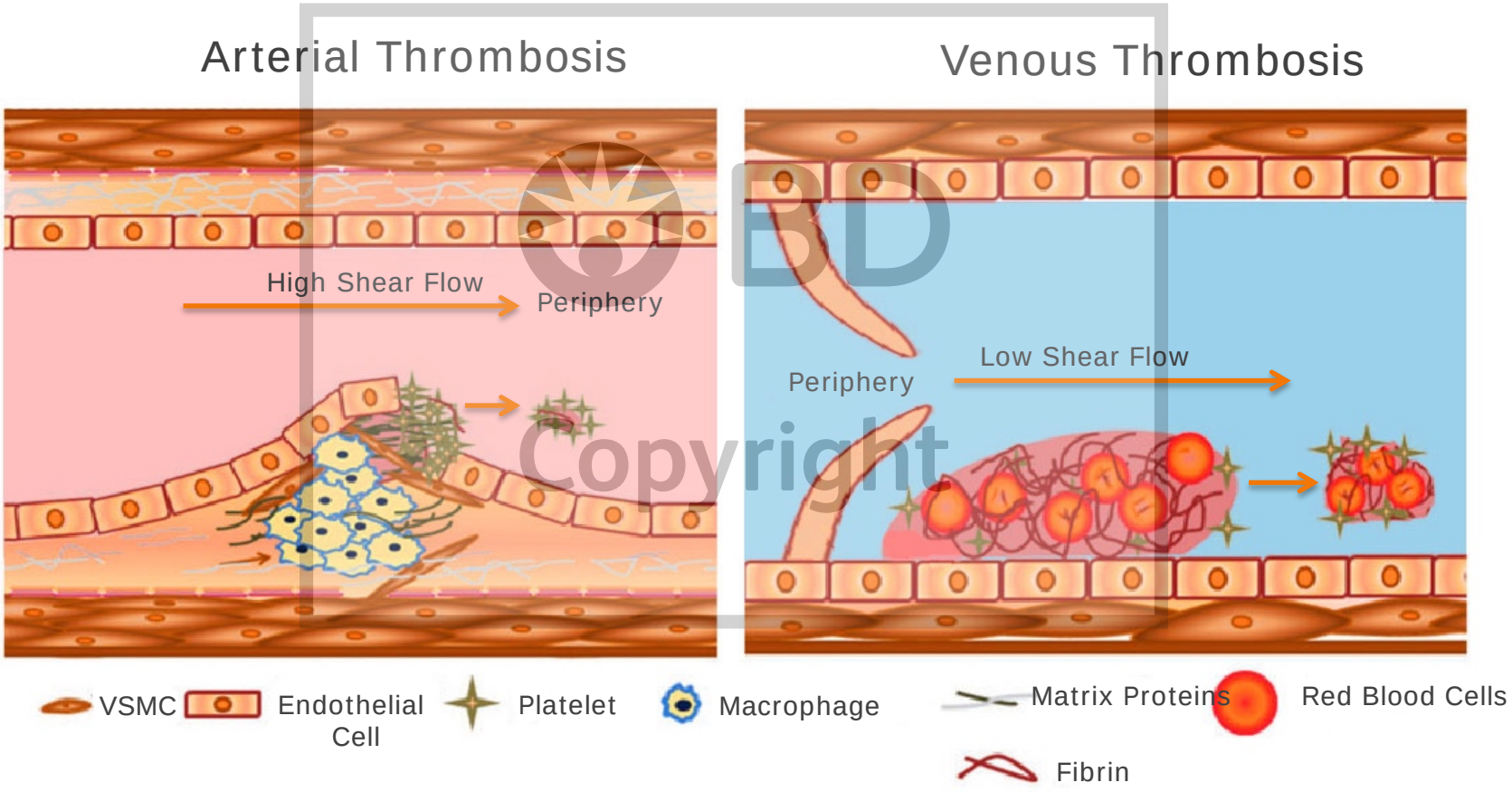
Formation of Venous Thrombus



Leg Presentation DVT vs. PAD

Image provided by Dr. Shammas

DVT

Image by James Heilman, MD

PAD

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Leg Characteristics DVT vs. PAD

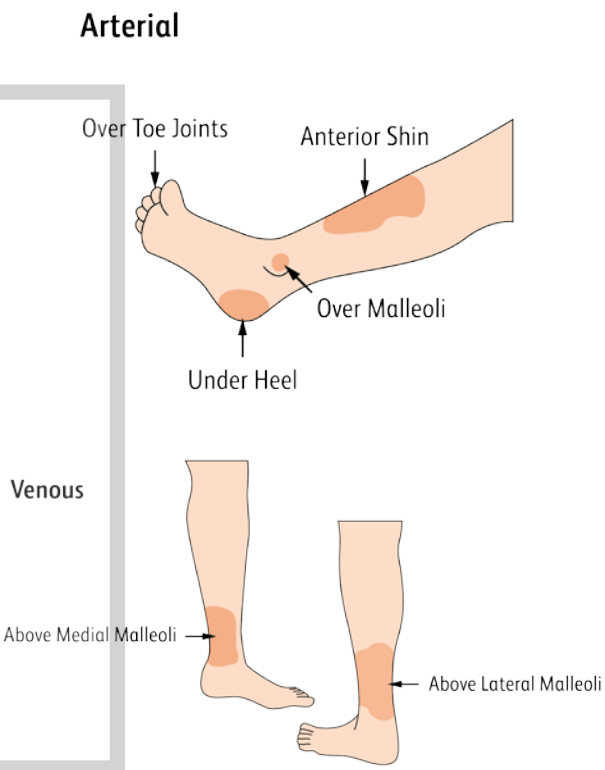
Venous Ulcer
Note hemosiderosis, classic location at medial malleolus, crusting, edema, and shallow irregular borders.

Arterial Ulcer
Note the dry, rubor, scaly, necrotic skin, causing ischemia.

Star, A. (2018, December). Differentiating Lower Extremity Wounds: Arterial, Venous, Neurotrophic. In Seminars in interventional radiology (Vol. 35, No. 05, pp. 399-405). Thieme Medical Publishers.

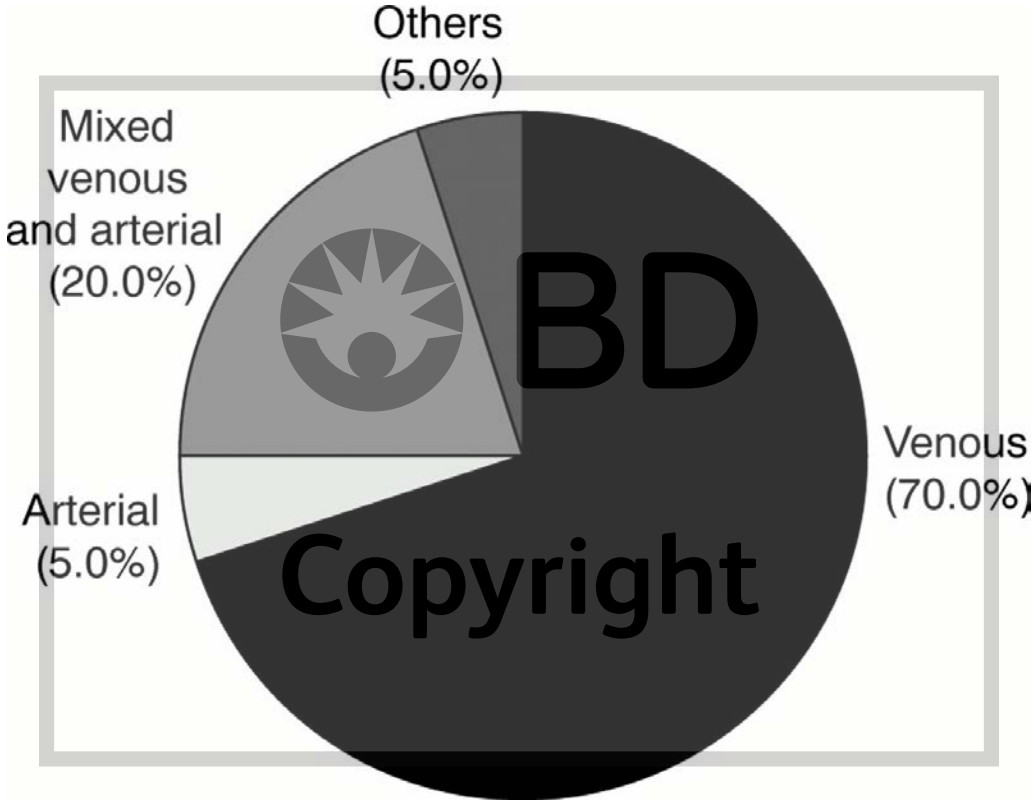
Differences in Wound Characteristics

	Arterial	Venous
Cause	Insufficient blood supply to area, causing ischemia (tissue death)	Pooling of blood causing increased pressure in the veins
Risk Factors	Vascular insufficiency, uncontrolled blood sugars in people with diabetes melitus, limited joint mobility or mobility problems, improper footwear	Varicose veins, deep vein thrombosis, incompetent valves, muscle weakness in the legs, immobility, pregnancy
Skin changes	Shiny, thin, flaky, hair loss, rubor (pinkish red)	Hyperpigmented (hemosiderosis—purple, dark reddish brown), telangiectasias, thickening (lipodermatosclerosis), peri-wound maceration, scaling/crusting
Location	Foot more often than leg	Lower leg, almost never foot
Laterality of leg	Usually lateral	Usually medial
Distribution	Angiosomal	Gaiter
Wound edges	Well defined	Irregular, poorly defined
Wound bed	Pale or necrotic	Dark red, fibrinous slough
Eschar	Common	Never
Exudate	Rare	Always
Odor	If infected (gangrene)	Usually none
Pain (in ulcer)	Uncommon unless infected or acute ischemia	Uncommon unless infected
Preceding trauma	Common	Uncommon
Edema	No	Yes
Sensation	Normal	Normal
Temperature	Cold	Normal
Pulses	Abnormal	Normal
Delayed capillary refill	Sometimes	Only if arterial component
Elevational pallor	Present	Absent
Dependent rubor	Present	Absent
Pain with leg raise	Increased	Decreased



Star, A. (2018, December). Differentiating Lower Extremity Wounds: Arterial, Venous, Neurotrophic. In Seminars in interventional radiology (Vol. 35, No. 05, pp. 399-405). Thieme Medical Publishers. http://www.samfratesi.org/markdown/styled-5/

Venous Ulcers



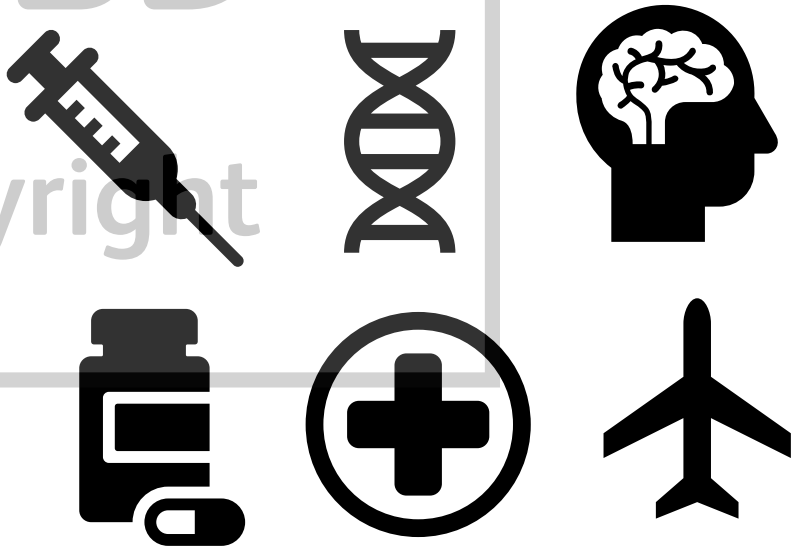
Sarkar, P. K., & Ballantyne, S. (2000). Management of leg ulcers. Postgraduate medical journal, 76(901), 674-682.

Risk Factors / Signs and Symptoms

Risk Factors

Identifying risk factors earlier is the first step towards getting diagnosed and treated. This is important, as these risk factors could cause a DVT and potentially lead to chronic venous disease.

- ✓ Trauma
- ✓ Obesity
- ✓ Pregnancy
- ✓ Surgery
- ✓ Smoking
- ✓ Cancer
- ✓ Venous Compression
- ✓ Genetic Clotting Disorders
- ✓ Oral Contraceptives
- ✓ Hormone Therapy
- ✓ Prolonged Travel/Immobility



Signs and Symptoms

Every venous case is different; some may experience more swelling in the left leg or notice leg pain when standing.

- ✓ Leg Swelling
- ✓ Leg Pain When Standing
- ✓ Leg Discoloration
- ✓ Leg Wounds

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Clinical Manifestations or Presentations

Venous Insufficiency can present in various ways for each patient, it's important to note which of the below experiences occurs in order to properly diagnose and treat patients.

- ✓ Leg pain, itching, cramps, heaviness, throbbing
- ✓ Restless legs or skin changes
- ✓ Location of swelling
- ✓ Unilateral vs. bilateral
- ✓ Hemorrhage
- ✓ Unexplained LE Edema
- ✓ Large calf diameter or dilated superficial veins
- ✓ Non healing wounds/ulcerations

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Chapter 2: Classification/Diagnostic Tools and Treatment Options

CEAP Score

Clinical Etiological Anatomical Pathophysiological

C1 C2 C3 C4 C5 C6

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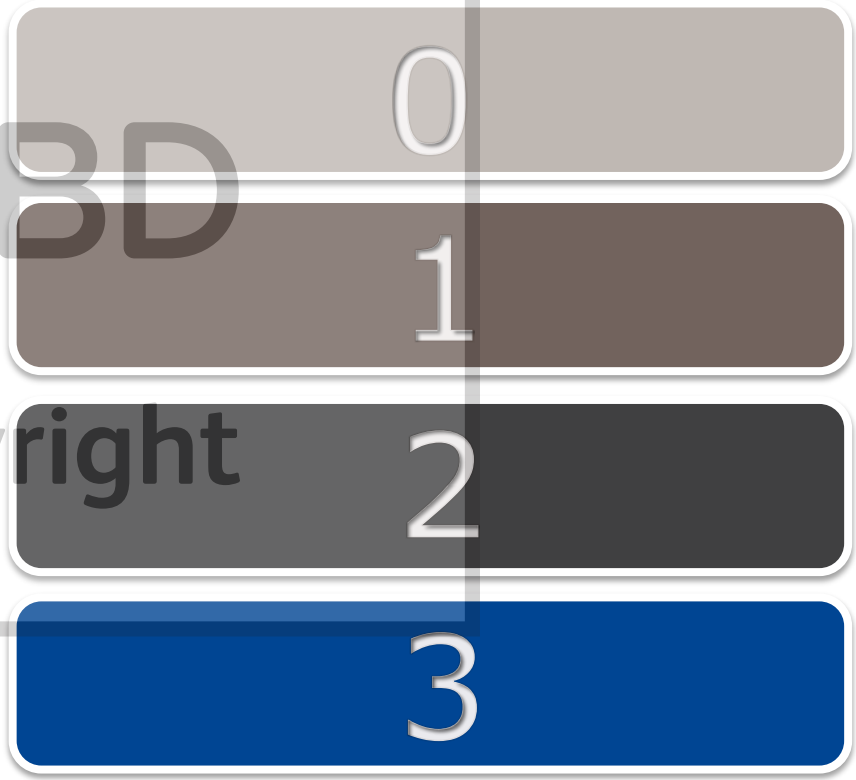
VCSS

Venous **C**linical **S**everity **S**core

- ✓ Pain
- ✓ Varicose veins
- ✓ Venous edema
- ✓ Skin pigmentation
- ✓ Inflammation
- ✓ Induration
- ✓ Number of active ulcers
- ✓ Active ulcer size
- ✓ Ulcer duration
- ✓ Compression therapy



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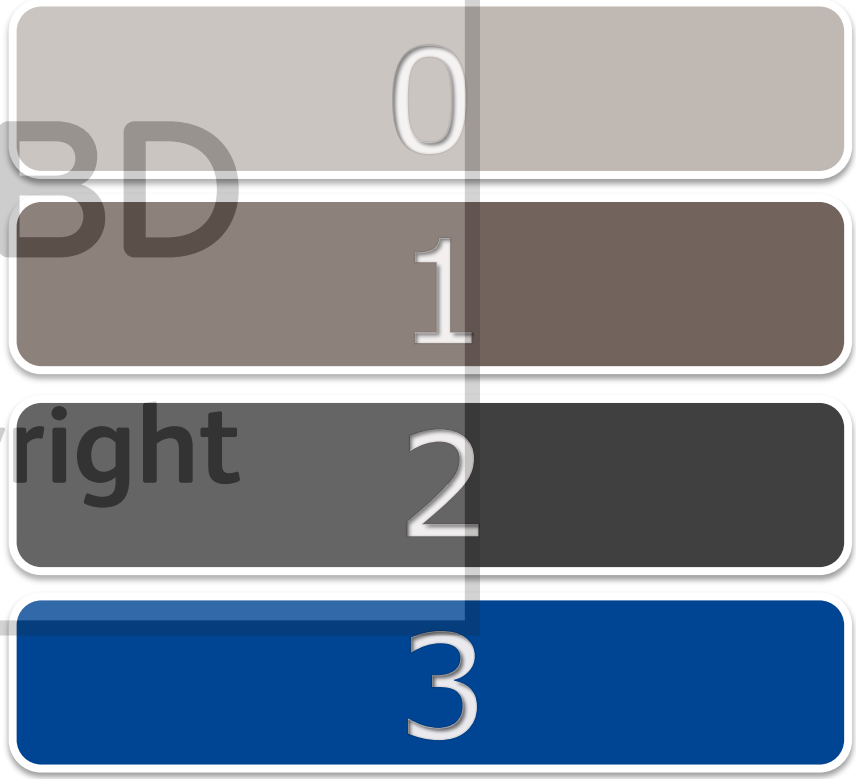
Villalta

Symptom severity scale specifically for **PTS**

- ✓ Pain
- ✓ Cramps
- ✓ Heaviness
- ✓ Paresthesia
- ✓ Pruritus
- ✓ Pretibial edema
- ✓ Skin induration
- ✓ Hyperpigmentation
- ✓ Redness
- ✓ Venous ectasia
- ✓ Pain on calf compression
- ✓ Venous ulcer



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CIVIQ-20

Chron**I**c **V**enous **I**nsufficiency **Q**uestionnaire

Example:

1.) During the past four weeks, have you had any pain in your ankles or legs, and how severe has this pain been? *Circle the number that applies to you.*

1	2	3	4	5
No pain	Slight pain	Moderate pain	Considerate pain	Severe pain

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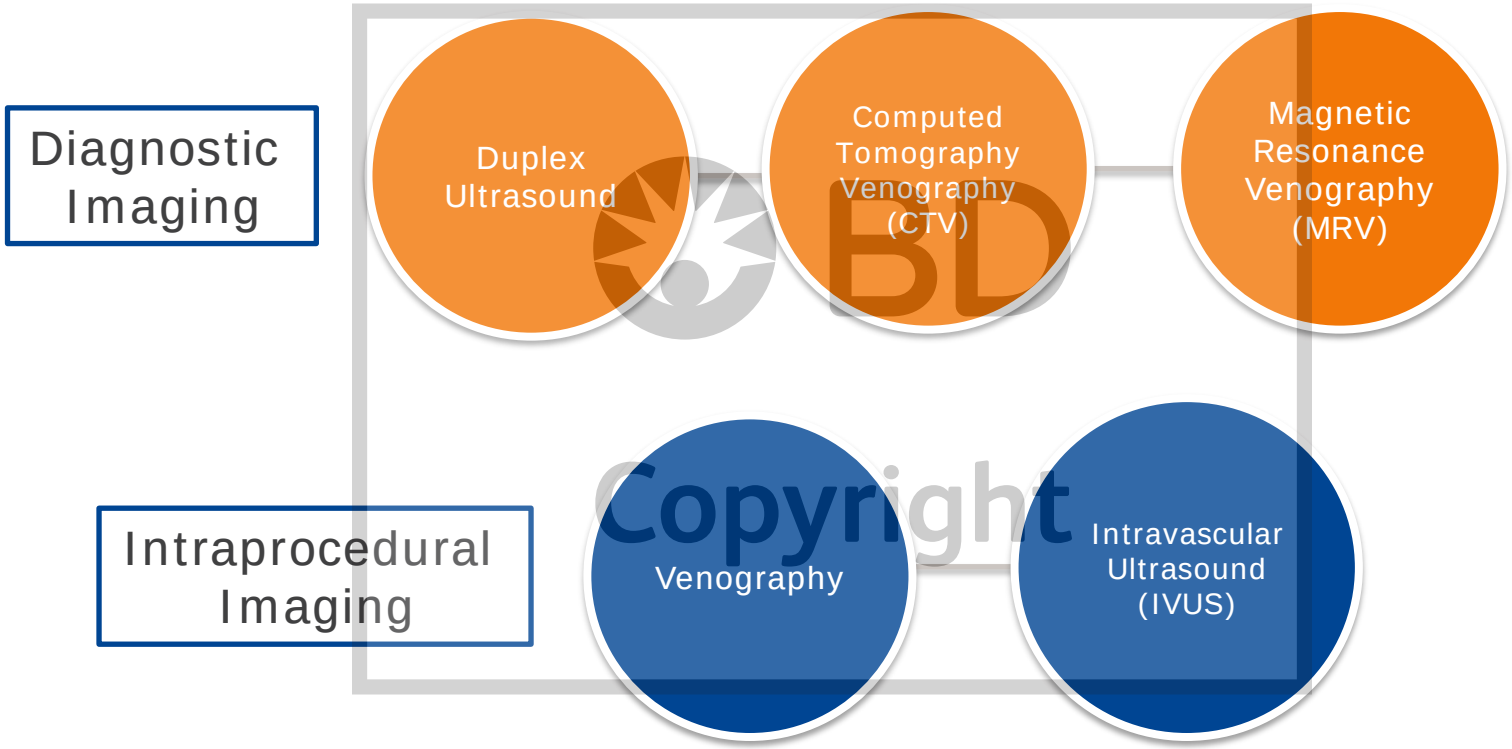
Diagnostic vs. Intraprocedural Imaging



May-Thurner Syndrome: MRV

Diagnosed if the veins are compressed and the outflow in obstructed blood flow is redistributed and collaterals are activated and/or formed

Image by Dr. Shammas

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Intraprocedural: Venography

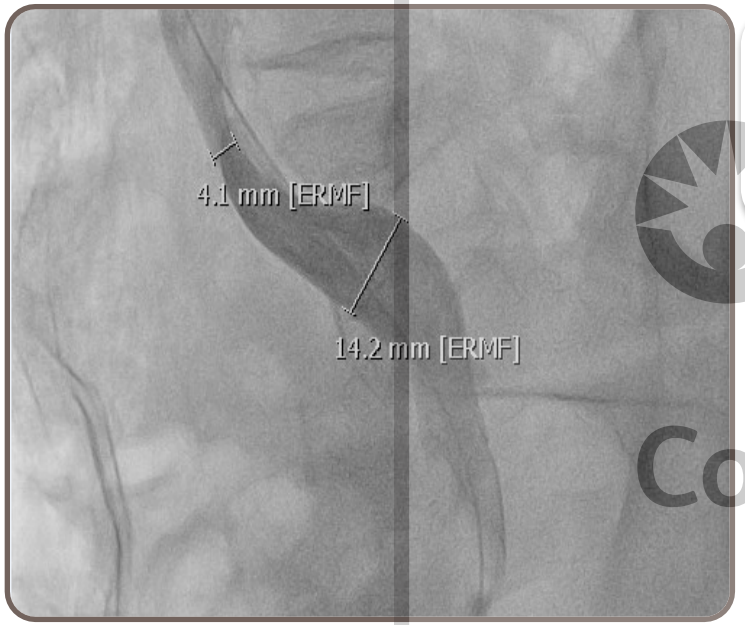

Image by Dr. Shammas

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- Can be used for both diagnostic and intraprocedural imaging
- Can be used to locate blood clots

–

- High radiation
- Less sensitive to lesion severity
- Less accurate for stent sizing compared to IVUS
- Difficult to visualize compressive lesions

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Intraprocedural: IVUS

Overview: Used to assess presence and extent of disease, examine plaque geometry and morphology, and position guidewire and stent.

Placing a Stent

Take the average value of the min and max diameters and oversize by 1-2 mm

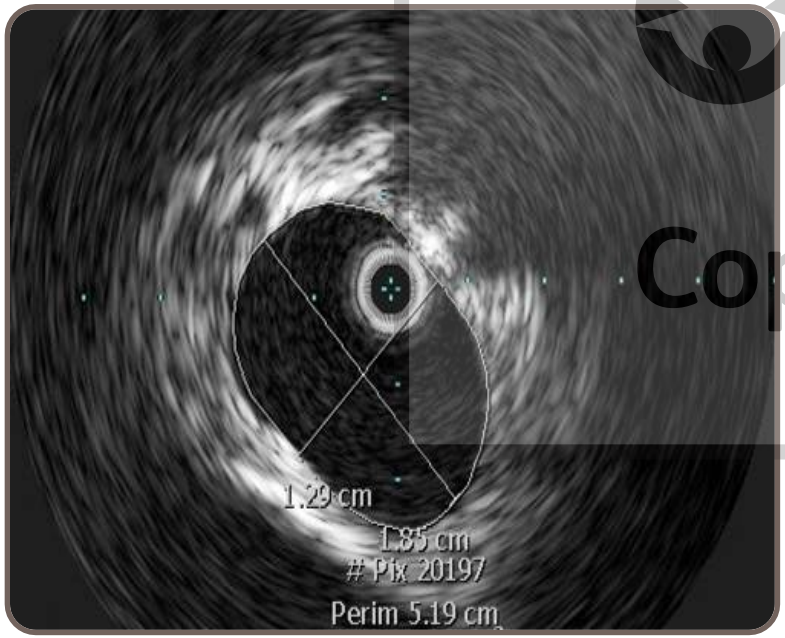

Image by Dr. Shammas

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- Advanced diagnosis
- Ability to measure diameters/areas
- Accuracy identifying lesion location
- No radiation

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- Invasive
- Additional procedural cost

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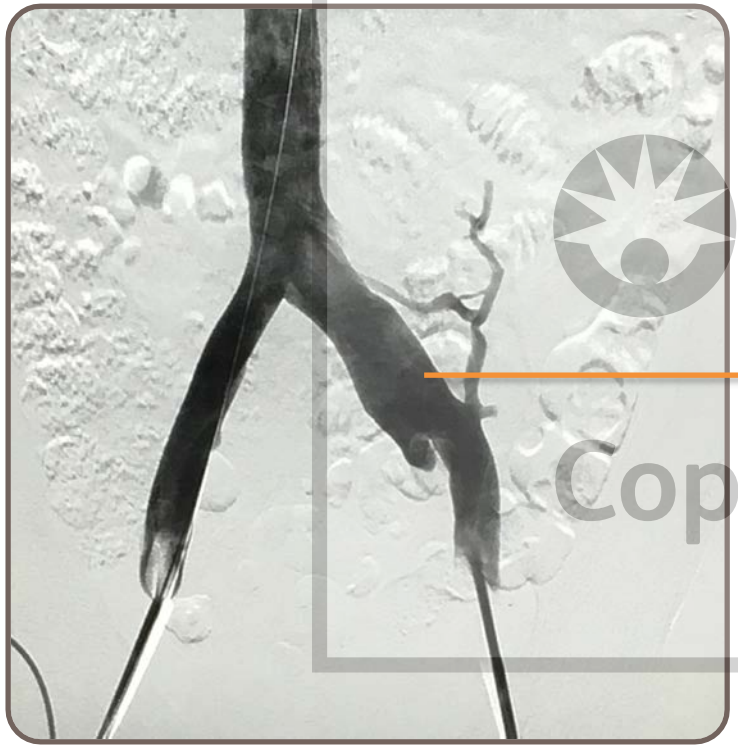
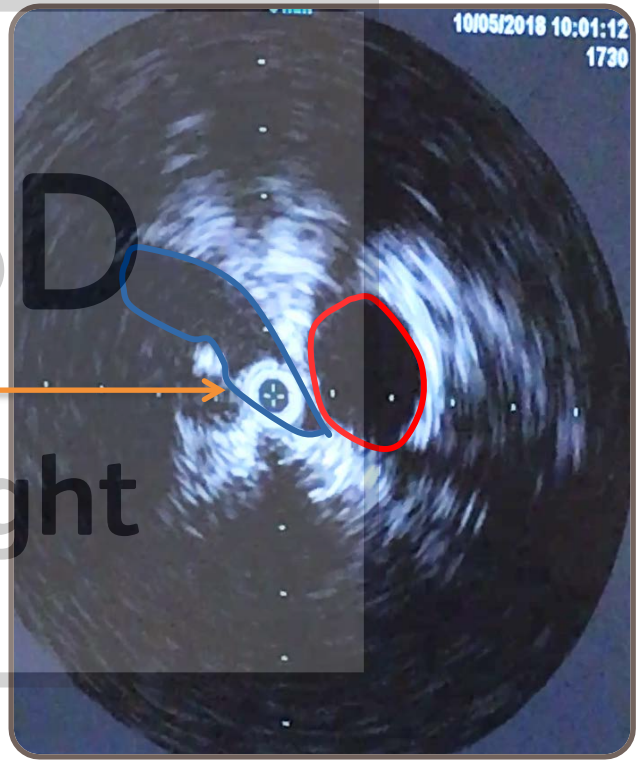
May-Thurner Syndrome: IVUS



Images by Maria Vega



Images by Maria Vega

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VIDIO Trial

100 Patients

+

14 Locations

IVUS

81%

Identified Lesions

- Identified lesions in 32% of patients venography missed
- Measurements changed the treatment plan of 57 patients

Key Takeaways

- VIDIO Trial shows that IVUS is **particularly useful** for evaluating lesion severity and accurate stent placement compared to venography
- Venography underestimated lesion severity by 11+/-22%

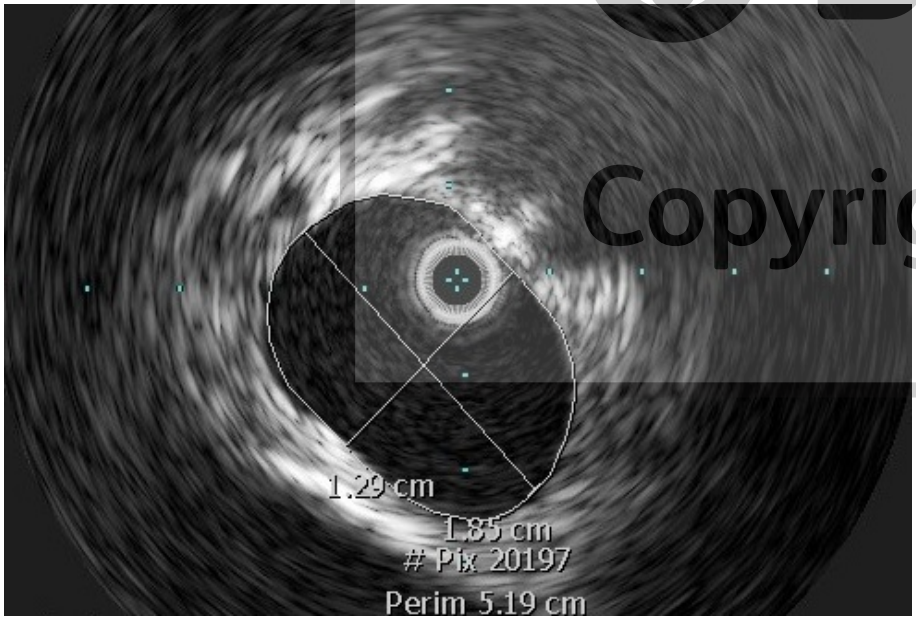
Gagne, P. J., M. D. et al. (2017). Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. Journal of Vascular Surgery: Venous and Lymphatic Disorders, 5(5), 678-687.

Review

QUIZ

Which stent size is most appropriate for the vessel on the left?

a) 14mm
b) 16mm
c) 18mm
d) 20mm
e) 22mm



To calculate the stent size, take the average of the two diameters, then oversize by 1-2 mm per the Venovo™ Venous Stent IFU.

Average of the two diameters:
(1.29 cm + 1.85cm) / 2 = 1.57cm
1.57cm = 15.7mm
15.7mm+2mm = ???

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Interventional Treatment Options

Goals of Interventional Treatment

- Relive acute pain and edema
- Prevent PE
- Prevent PTS
- Restore vessel patency
- Preserve valve function
- Correct underlying anatomic lesions

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Thrombolysis and Thrombectomy

Medical-Surgical Interventions to Treat Deep Vein Thrombosis		
Approaches	**Indications for DVT**	**Technical Purposes**
Systemic anticoagulation	Accepted conservative gold standard for all DVT	Prevents further propagation of thrombus or PE
Systemic thrombolysis	No indication for isolated DVT (useful in PE)	Accelerates thrombus lysis indiscriminately throughout body
Surgical thrombectomy (open venous, balloon)	Cases refractory to less invasive interventions	Removes thrombus
CDT (simple, ultra-sound assisted)	Serious DVT and/or PE	Direct iv. thrombolytic agent physically within thrombosed area
Percutaneous mechanical thrombectomy	When throbolytics are absolutely contraindicated	Removes thrombus with action of rotary. Scraping, or high-powered water jets
Pharmacomechanical thrombolysis	Single-session treatment of DVT	High-powered water jets incresae action of iv. Thombolytic agent directed to the site of the thrombus
Isolated pharma-comechanical thrombolysis	Single-session treatment of DVT	Macerating wire increases action of iv. thrombolytic aged directed to the site of the thrombus

OSullivan, G. J. (2011). Thrombolysis versus thrombectomy in acute deep vein thrombosis. Interventional Cardiology, 3(5), 589-596.

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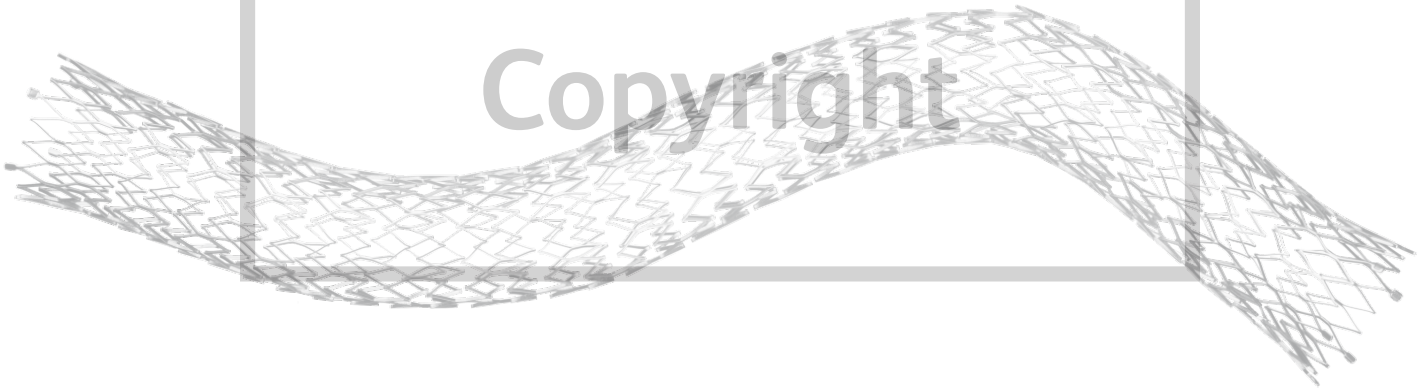
Iliofemoral Venous PTA

- Iliofemoral venous lesions are composed of highly resistant, fibrinous scar-like tissue
- More compliant balloons may not be able to fully efface the lesion, which can be seen as “waisting” on venography
- Ultra non-compliant PTA is needed for maximum stent expansion

Deep Venous Stenting

- Treatment with POBA alone demonstrates poor long-term patency as compared to POBA and stenting together for **improved patency**
- Veins and venous lesions are **different** from arteries and arterial lesions
- IVUS imaging is vital for accurate stent placement
- Treatment algorithm differs between PTS and NIVL



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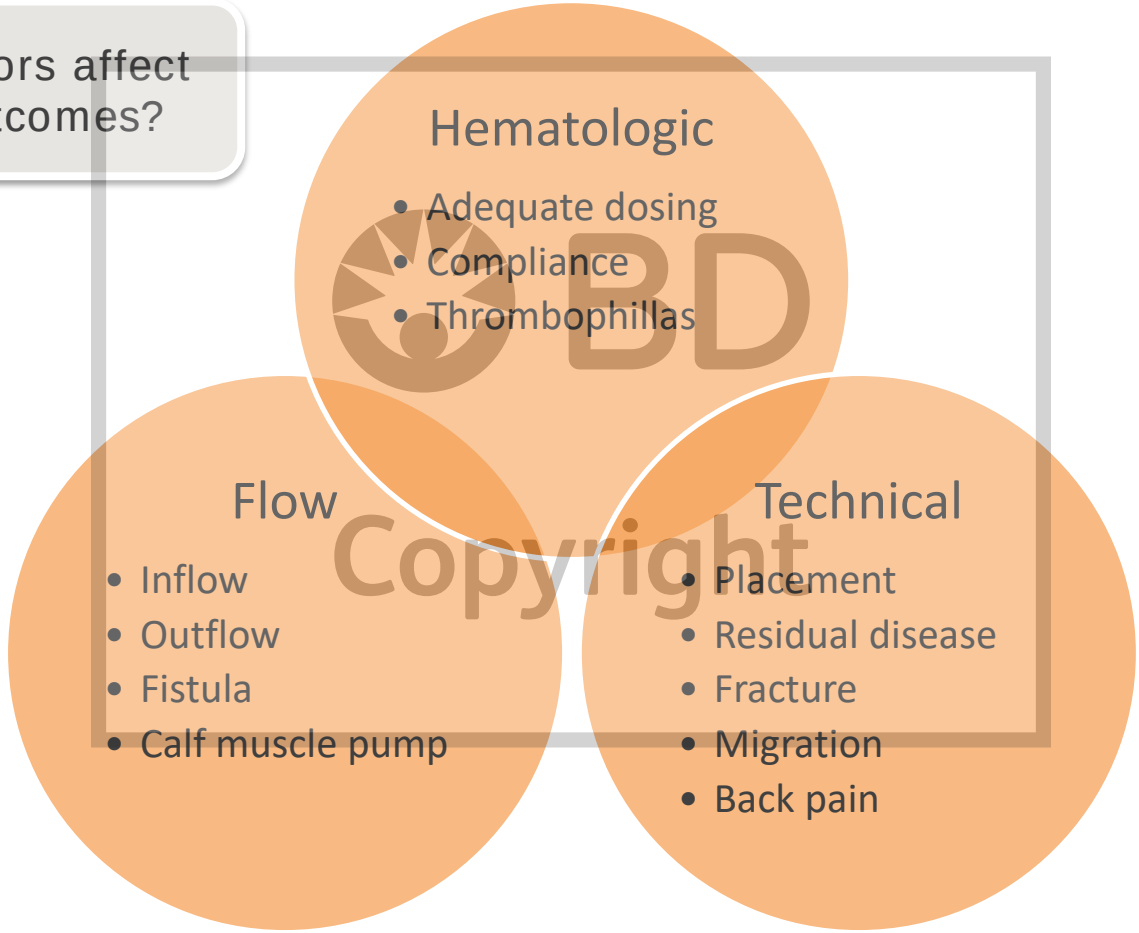
Venous Stenting Technical Considerations

Deep Venous Stenting

What factors affect stent outcomes?



Black, S. et all. (2019, July). The Unknowns of Venous Stenting: Why Do Good Cases Go Bad? ENDOVASCULAR TODAY. Vol. 18, No. 7, pp. (65-69).

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Technical Considerations

"Technical failure is likely the single largest cause of early stent failure"

Placement
- Cranial bony landmark
  - Iliac confluence & proximal extent of stenting in the left-sided disease
    - Spinous process when the spine is viewed in AP
  - The outer border of the spinal body serves as a good marker for the contralateral IVC wall
  - Ensure the stent extends beyond the left edge of the spinous process when viewed AP is a good indicator that the stent is beyond the compression point of the left CIA
- Caudal bony landmark
  - Profunda and femoral vein confluence from the CFV
    - Lesser trochanter

Residual
- Inflow and outflow
  - Extend the stent caudally enough to manage disease in the CFV
  - Extend the stent cranially to treat outflow disease

Black, S. et all. (2019, July). The Unknowns of Venous Stenting: Why Do Good Cases Go Bad? ENDOVASCULAR TODAY. Vol. 18, No. 7, pp. (65-69).

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Technical Considerations

Fracture

- Overlap of stents 1 cm on either side of the ligament should be avoided
- If overlap is needed, have the stent overlap in the EIV (less movement/compression)
- If stent extension is needed below the ligament to the confluence of the product and femoral veins ideal configuration is 2 stents with a single overlap point in the EIV
- Typically requires a stent length of 150 mm
- For long lesions, the longest available stent should be used to avoid overlapping

Black, S. et all. (2019, July). The Unknowns of Venous Stenting: Why Do Good Cases Go Bad? ENDOVASCULAR TODAY. Vol. 18, No. 7, pp. (65-69).

BD

Technical Considerations

Migration

- Avoid short-length stents just across the compressive lesion
  - Valsalva maneuver post-procedure may result in stent movement
- Place longer-length stents with extension into the EIV to minimize risk of migration
- Higher risk of stent migration in NIVL vs. PTS lesions

Back pain

- Back pain resolves after 2 – 3 weeks in most patients
- May occur due to compression of the lumbosacral nerves as the stent traverses the spine and sacrum to the pelvis
- Ensure appropriate stent sizing to minimize back pain

(see general and Venovo™ Venous Stent sizing details on next slide)

Black, S. et all. (2019, July). The Unknowns of Venous Stenting: Why Do Good Cases Go Bad? ENDOVASCULAR TODAY. Vol. 18, No. 7, pp. (65-69).

Selecting Stent Sizes

Vessel	Average Diameter (mm)	Average Area (mm²)
Common femoral vein	12	125
External iliac vein	14	150
Common iliac vein	16	200
Inferior vena cava	18-24	300-400

Venovo™ Venous Stent Size Selection	
Reference Vessel Diameter	Unconstrained Stent Inner Diameter
7-9 mm	10 mm
9-11 mm	12 mm
11-13 mm	14 mm
13-15 mm	16 mm
15-17 mm	18 mm
17-19 mm	20 mm

Flow Considerations

"Flow is the single most difficult factor to account for, and in many respects, this becomes more an issue of patient selection"

- Close attention needs to be paid to the **quality of the inflow vessels**
- Selecting a **good target vessel for inflow** at the index procedure is vital
- Patient with normal inflow to the CFV and good flow into the stents will likely do well regardless of the length of the stent cranial to this

Black, S. et all. (2019, July). The Unknowns of Venous Stenting: Why Do Good Cases Go Bad? ENDOVASCULAR TODAY. Vol. 18, No. 7, pp. (65-69).

Hematologic Considerations

"Anticoagulation strategies are vital after stent placement to reduce the risk of early stent thrombosis"

- Anticoagulation protocol for patients with Post-Thrombotic disease is especially important in the context of acute and chronic post-thrombotic disease
- Animal studies have indicated that it takes approximately 56 days for the newly placed stent to epithelialize
- Data on stent thrombosis state that the risk of thrombosis is higher in the first 6 weeks after stent placement, although it may still occur later
- Patient education on anticoagulation is vital
- A multidisciplinary team including a hematologist with an interest in thrombosis

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Follow-up Protocol

Post-procedure anticoagulation and follow-up

Anticoagulation

- Post-op anticoagulation and antiplatelet therapy protocol is largely tailored to each individual and there are no standard guidelines
- Example:
  - MTS = Plavix (clopidogrel) / Eliquis (apixaban) for 1 month → Aspirin for 6 months
  - MTS + DVT = Eliquis/Aspirin for 6 months
  - PTS = Aspirin or Plavix for 3-6 months

Note: All recommendations that appear on this slide are individual physician examples. Actual post-procedure protocol will vary.

Follow-up

- Follow-up protocol varies, but some physicians recommend first month, 3 month, 6 month and annual visits.
- Duplex ultrasound may be considered during follow-up + clinical symptom assessment
- Patients should expect back pain for 2-4 weeks
- Possible stent failures due to:
  - Patient non-compliance
  - Inflow/outflow not established
  - Incorrect stent size/location
  - Pharmacotherapy transition

BD

Multidisciplinary Venous Teams

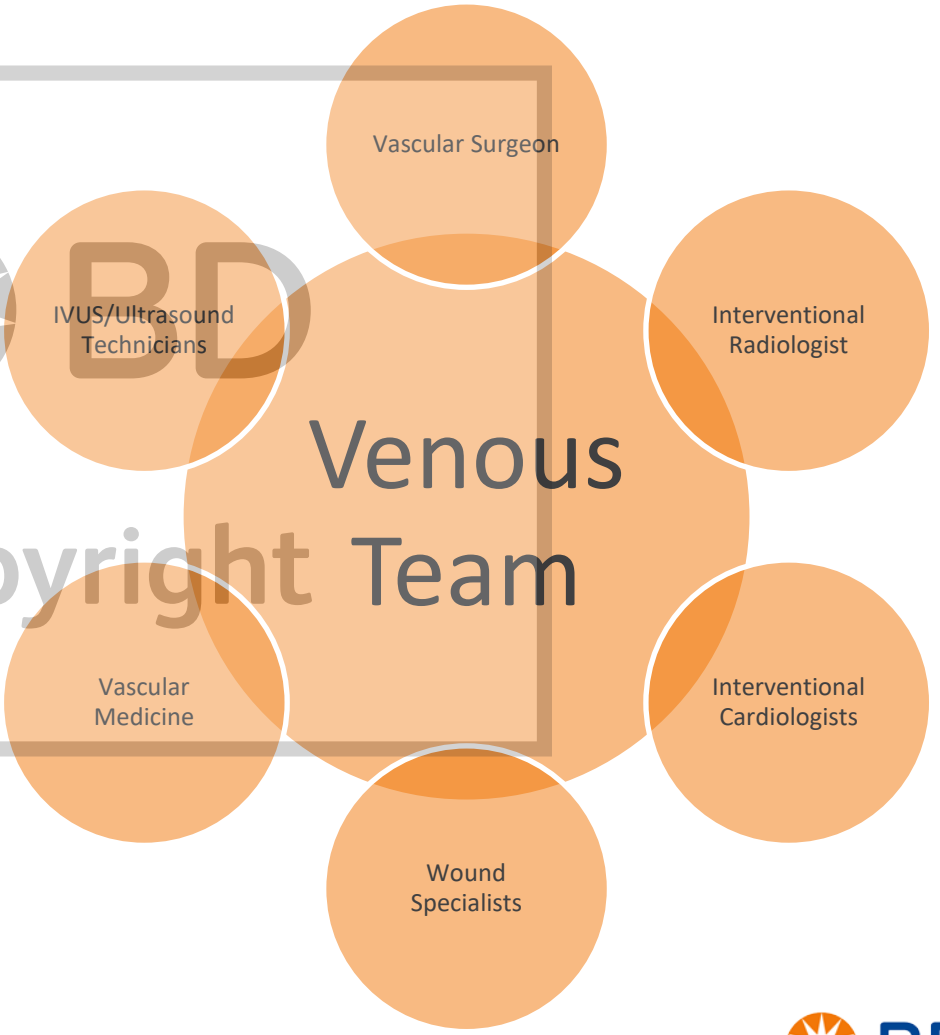
Successful Venous Program

Working together across a continuum of care, from awareness, early detection, wound treatment and ongoing management, a venous program can bring attention to long-term needs of patients. With a focus on preventing future events, developing a program can help improve the quality of life for your patients.

- ✓ Determine scope of your intervention program
  - ✓ Varicose veins
  - ✓ Acute or chronic DVT and/or PE
- ✓ Train staff on venous education
  - ✓ Venous anatomy/pathophysiology
  - ✓ Access considerations
  - ✓ Diagnostic tools
  - ✓ Interventional tools/techniques
- ✓ Identify and utilize various resources
  - ✓ Medical industry
  - ✓ Conferences
  - ✓ Journals
  - ✓ Field peers

Collaborative Venous Team

To ensure comprehensive care, it is important to have a multidisciplinary team of experts in venous disease management and treatments. Treatment plans can include lifestyle changes, medication, minimally invasive endovascular and surgical options, which means patients get comprehensive, expert care.



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Chapter 3: Patient Case Reviews

The opinions and clinical experiences presented herein are for informational and educational purposes only. The results presented may not be predictive for all studies and patients.

Venovo™ Venous Stent PTS Case

History / Presentation:

- 65-year-old female with left lower extremity DVT after obstetrical procedure in 1995
- Developed left lower extremity edema, daily pain with activity
- Significant varicosities in left leg, pubic region/abdominal wall
- No ulceration
- Progressive right lower extremity edema, corona phlebectatica
- Compliant with left lower extremity compression
- Left lower extremity VCSS: 15
- On anti-coagulants

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
Northwestern University

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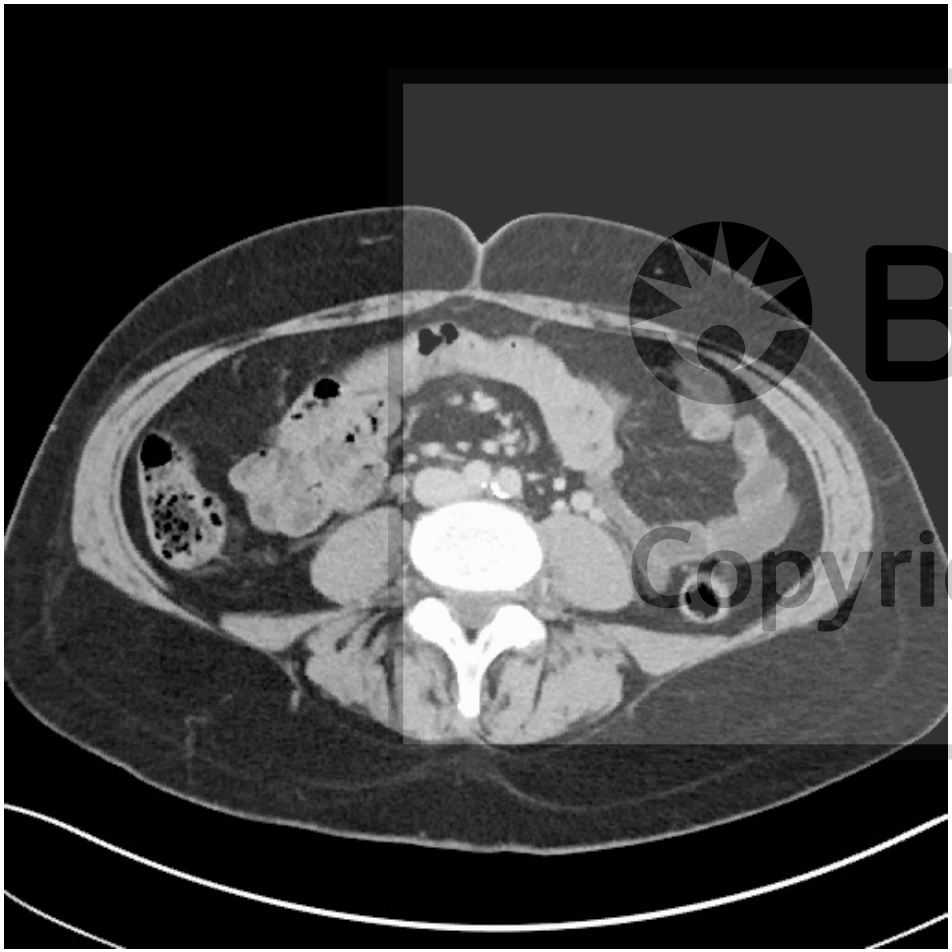
Imaging/CT Findings



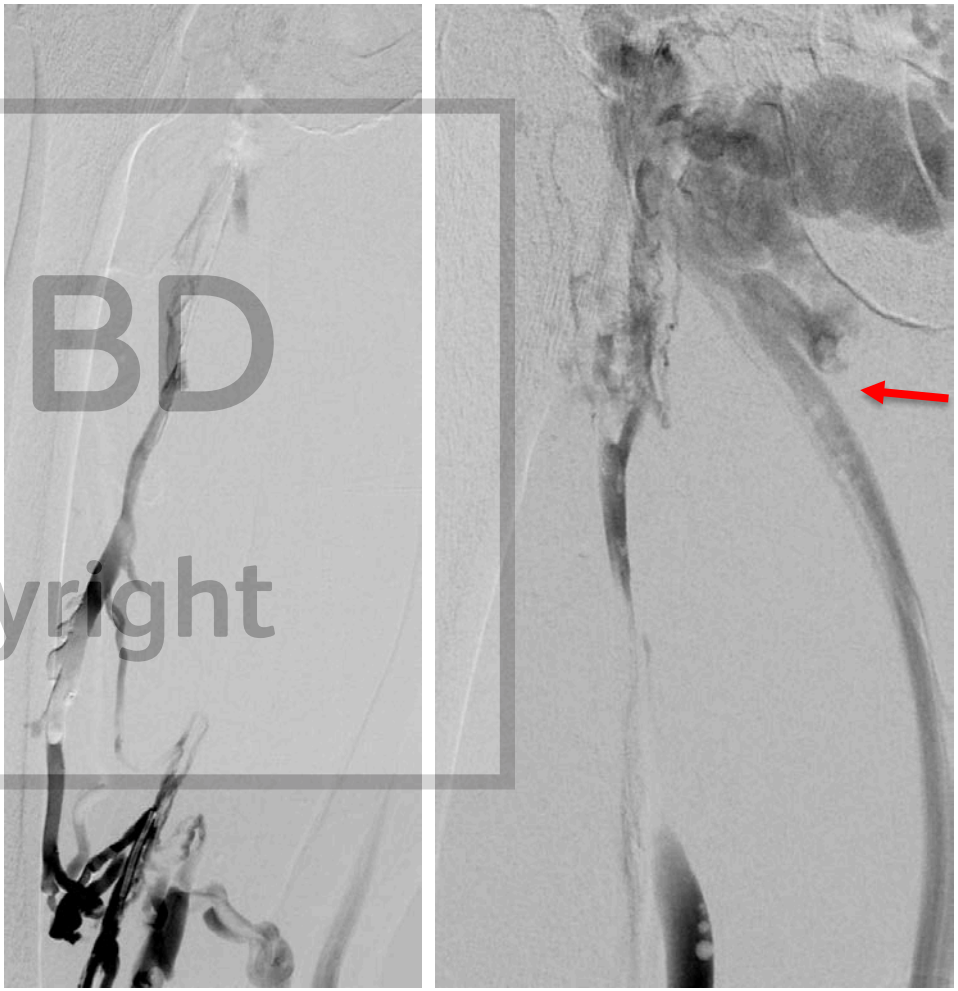
- Duplex: Chronic common femoral and femoral vein occlusion on left. Right side normal
- CT obtained

- Post-thrombotic occlusion of the left external through common iliac veins
- Large saphenous-saphenous collateral acting as a pseudo “bypass” to the right leg
- Causing mild right leg symptoms → right leg is overwhelmed with flow form both

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
Northwestern University

Procedure

- Prone positioning
- PTV access
- 10 Fr sheath
- Fully heparinized, keep on anti-coagulation through procedure
- Difficult to identify precise location of occluded CFV due to overlying collaterals
- Obtained left GSV (red arrow) access at mid thigh to provide target (i.e. saphenofemoral junction)



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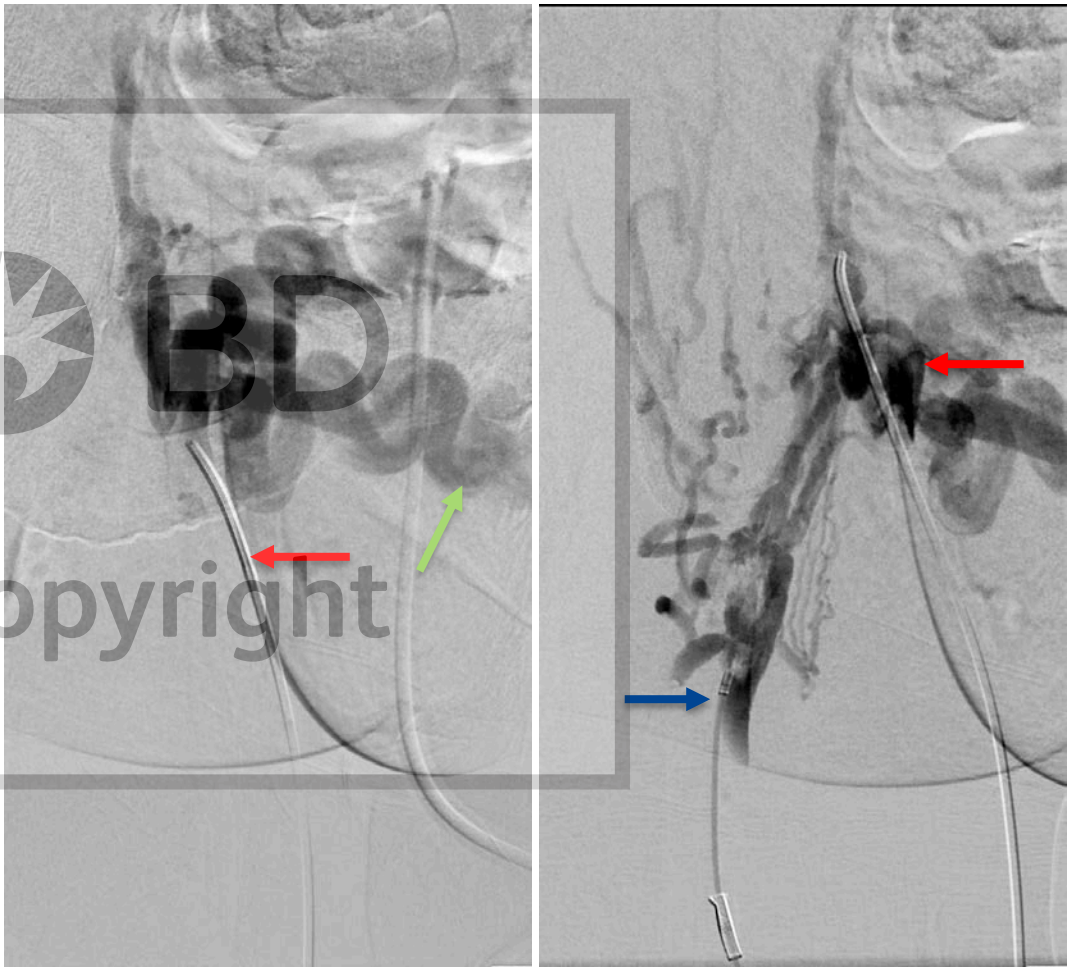
Procedure

- Angle tip catheter in GSV (red arrow) provides target at saphenofemoral junction
- Lesion crossed with a crossing wire (blue arrow)
- Saphenous ”bypass” collateral identified, as previously seen on CT (green arrow)



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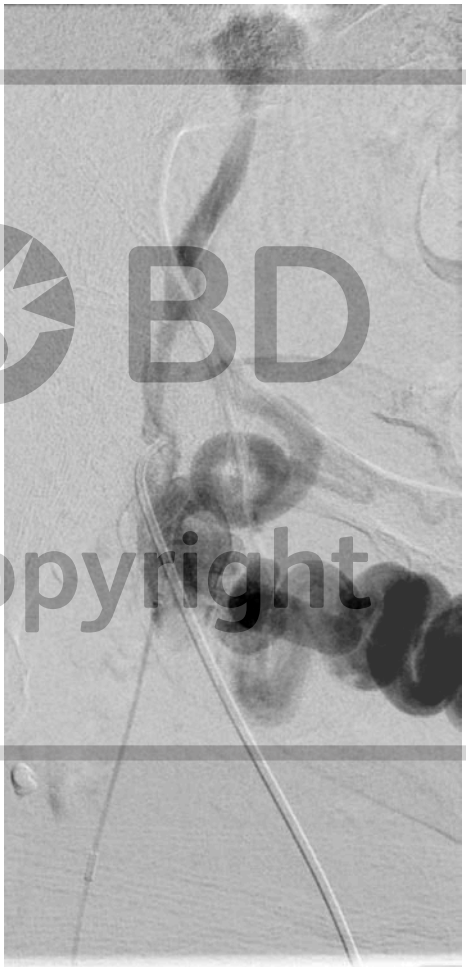
Procedure

- Red arrow denotes occluded left iliac vein (string sign of a chronic occlusion)



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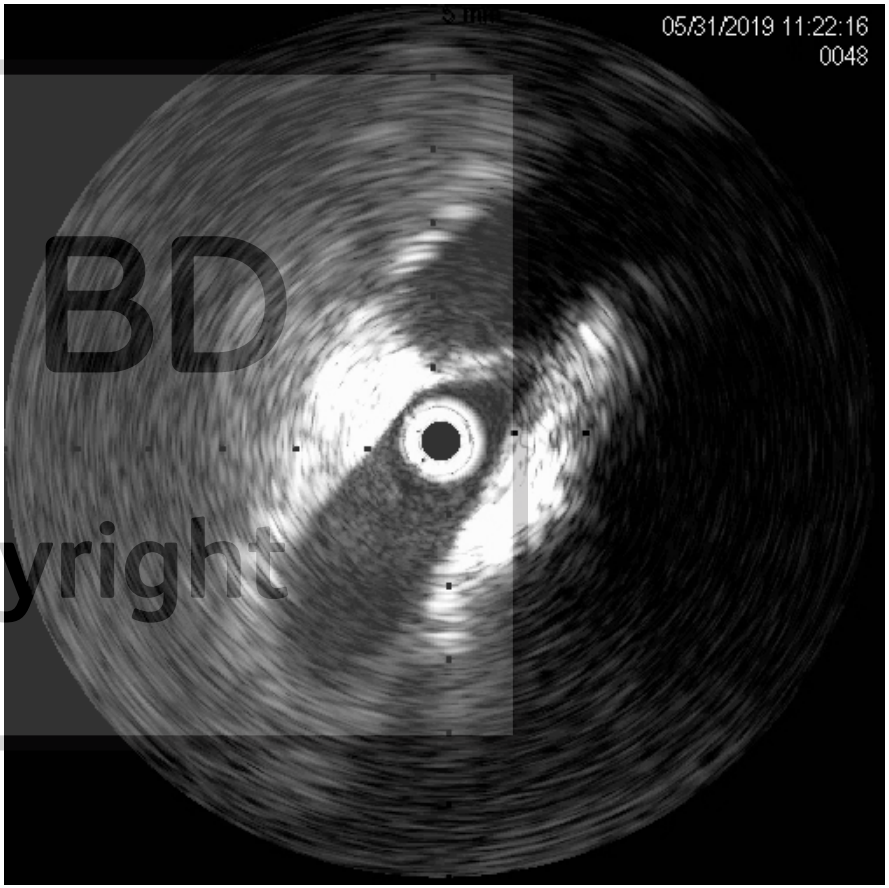
Procedure

- IVUS confirms chronic, post-thrombotic occlusion
- Use markers on IVUS to measure stent length
- Pre-dilate sequentially with 8 mm x 150 mm PTA balloon followed by 14 mm x 60 mm (iliac segment and 12 mm x 40 mm (CFV segment) Atlas™ Gold PTA Dilatation Catheter



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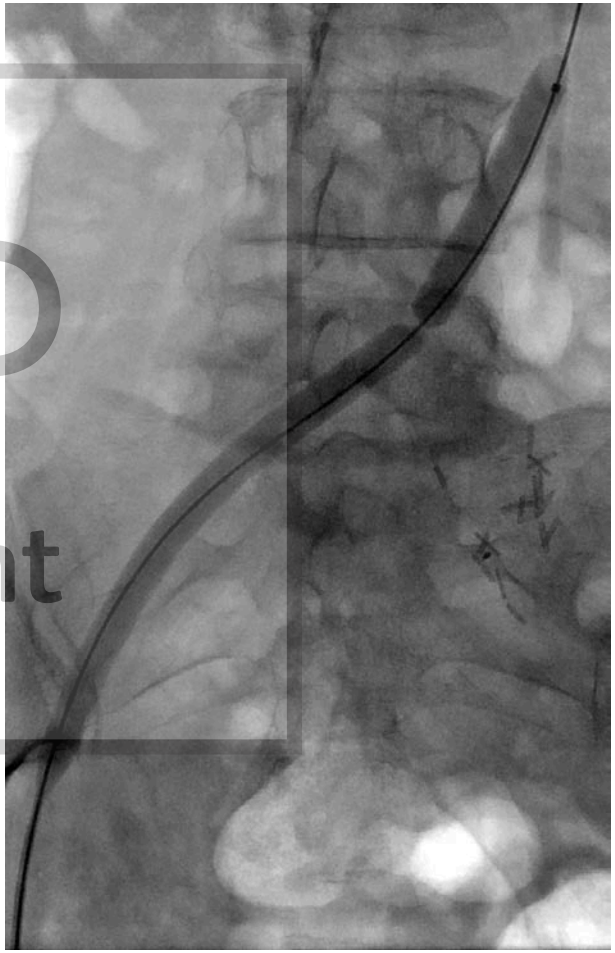
Procedure

- 14 mm x 160 mm Venovo™ Venous Stent in left iliac vein, covers entire common and external iliac lesion
- 12 mm x 80 mm Venovo™ Venous Stent in common femoral vein, only stent to origin of profunda (typically at lesser trochanter)
- Post-dilate with 14 mm ultra non-compliant PTA balloon to rated stent diameters



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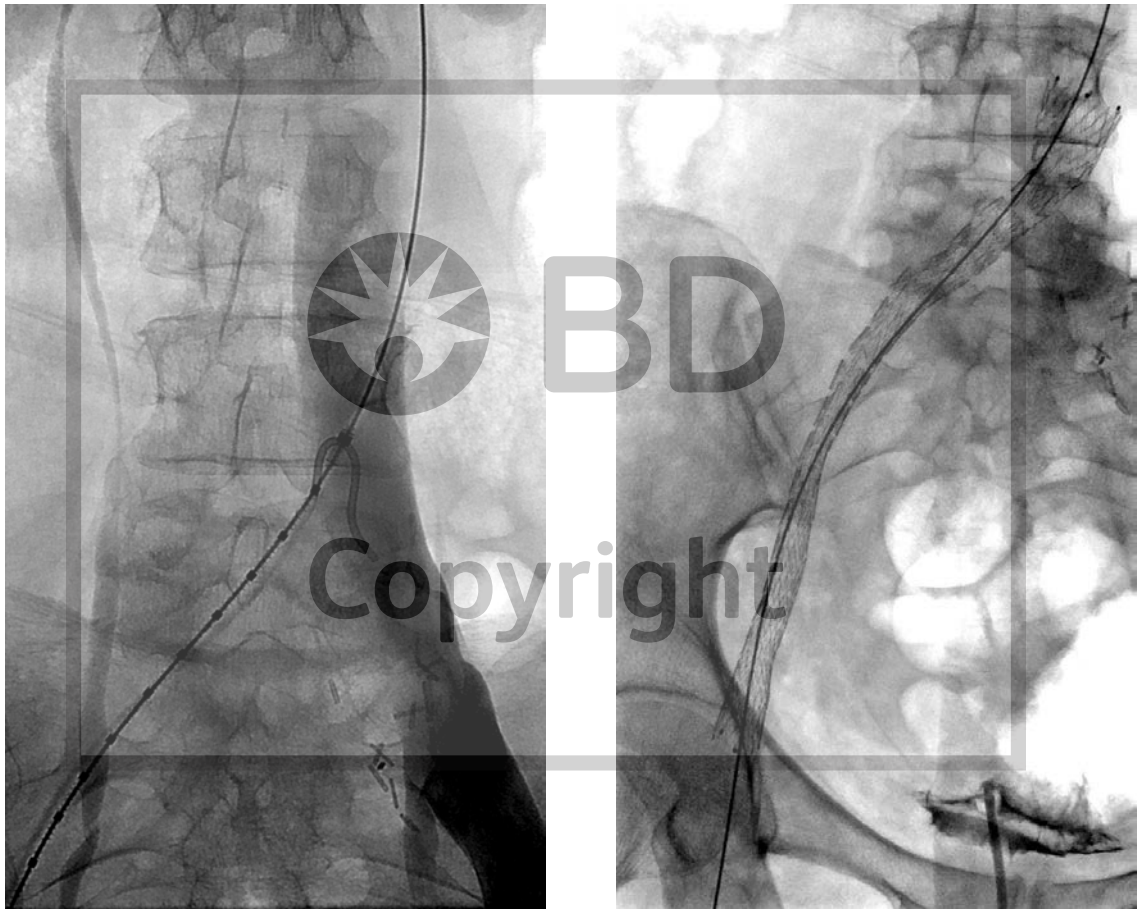
Procedure



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Procedure

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
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Procedure

- Excellent flow on final venogram
- Post-stent IVUS demonstrates coverage of diseased segments

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Post-procedure

- Started on clopidogrel for 3 months, then transitioned to aspirin 81 mg
- Swelling improved, pain entirely resolved at 1 week
- Able to play tennis for first time in 20+ years

6-month follow-up

- On anti-coagulation and aspirin
- Clinical improvement remains, no worsening of symptoms
- All RIGHT lower extremity symptoms resolved
- Abdominal wall collaterals gone
- 7-point reduction of VCSS
- Duplex demonstrates patent stent

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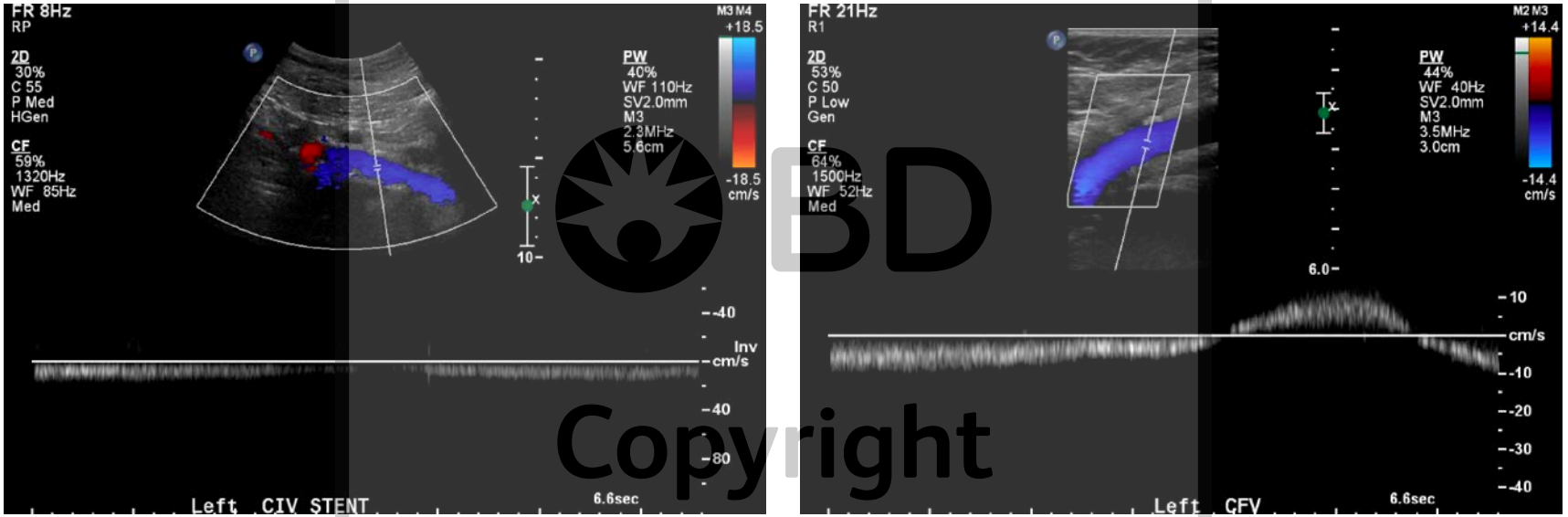
Post-procedure



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Venovo™ Venous Stent
NIVL/Pelvic Case

History/Presentation:

- 56-year-old female with 1-year history of constant left groin/pelvic pain
- Also has back pain aggravated by prolonged sitting or intense activity
- Intermittent left leg heaviness, no edema, no history of DVT
- Has been told she has “nutcracker syndrome”
- No flank pain or hematuria
- No lower extremity/vulvar varicosities
- Exam unremarkable

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
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Procedure

- Axial post-contrast CT venogram of the abdomen demonstrates apparent narrowing of the left renal vein (red arrow) between the abdominal aorta and superior mesenteric artery

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
Northwestern University

Procedure

- Coronal reconstructions from abdominopelvic CTV demonstrates dense contrast column in left ovarian vein (red arrow) and pelvic venous plexus (blue arrow), consistent with delayed emptying

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Procedure

- 8 Fr sheath
- 7 Fr gonadal guiding catheter
- 5 Fr glide catheter

- Left renal venogram demonstrates hilar collaterals and dilated left ovarian vein with reflux. However, there is partial emptying of contrast into IVC

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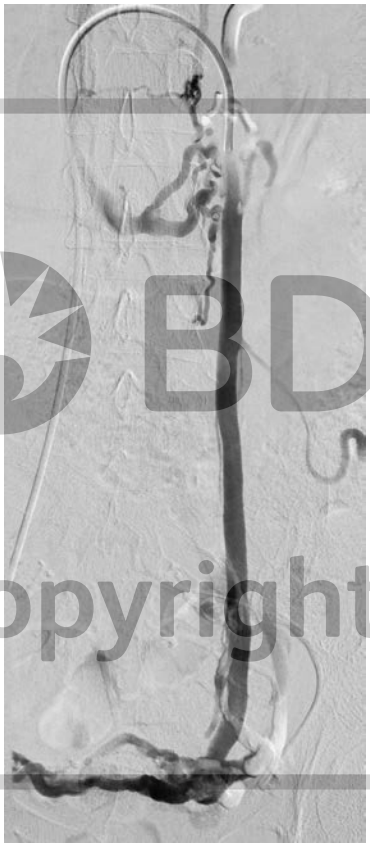
Procedure

- Left ovarian venograms demonstrate venous dilation and reflux into the dilated pelvic venous plexus



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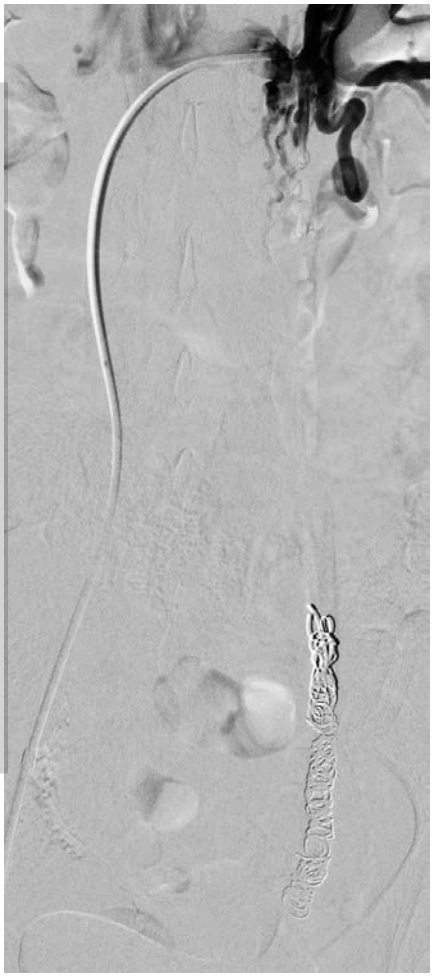
Treatment

- 3% STS foamed with CO2
- 12 mm coils

- Left ovarian venogram (left image) demonstrates occlusion and stasis of left ovarian vein
- Left renal venogram demonstrates cessation of left ovarian reflux.



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Treatment

- Left external iliac venogram demonstrates pre-stenotic dilation of left common iliac vein on the basis of left CIV compression (red arrow)

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Post-procedure 1

- Discharged with pain medicine
- Returned at 1 month for follow-up, symptoms have progressed and left groin/pelvic pain now more severe
- Intermittent left leg heaviness continues
- Plan for left iliac venogram/IVUS

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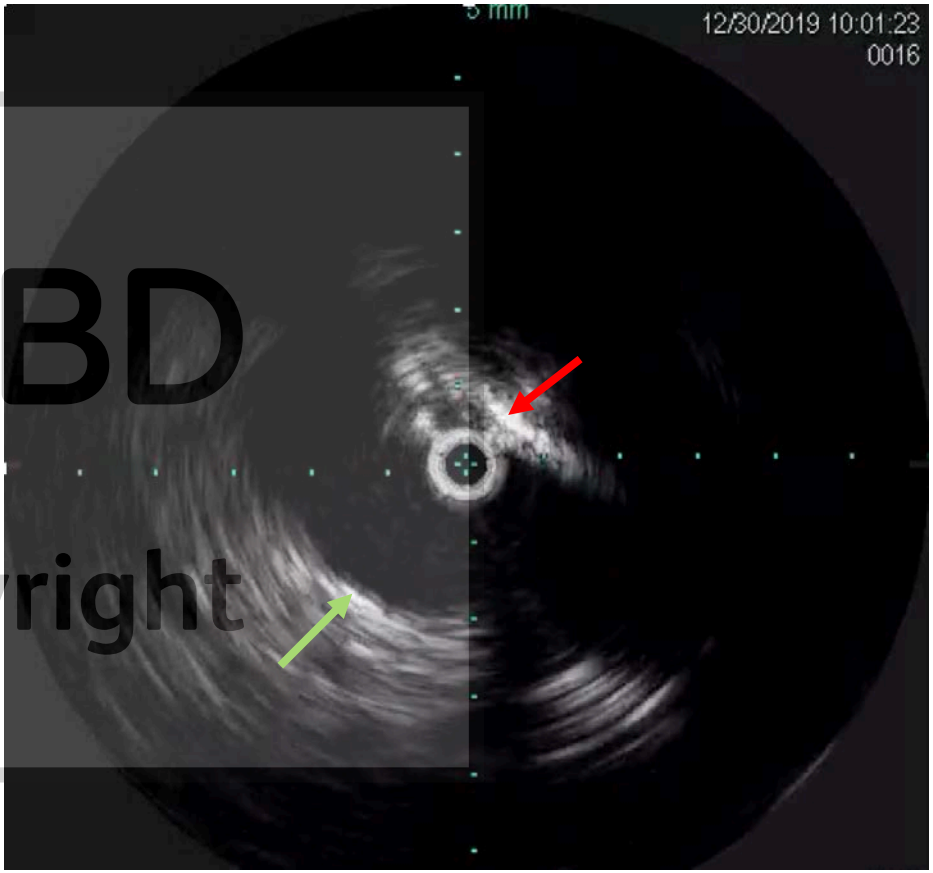
Post-procedure 2

- Left iliac IVUS demonstrates left common iliac vein compression (red arrow) by the right common iliac artery (green arrow)



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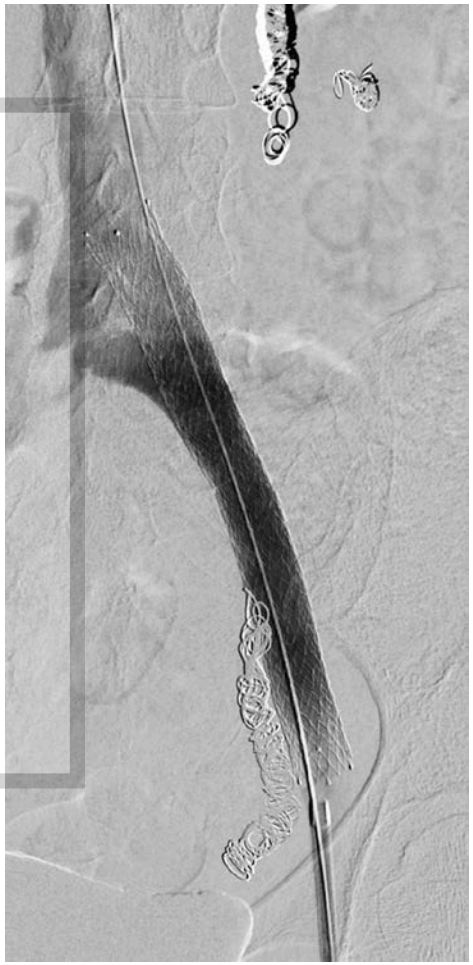
Post-procedure 2

- IVUS confirms compression seen on venogram
- 14 mm x 140 mm Venovo™ Venous Stent placed

- Left external iliac venogram following left common/external iliac vein stent placement demonstrates no flow-limiting stenosis



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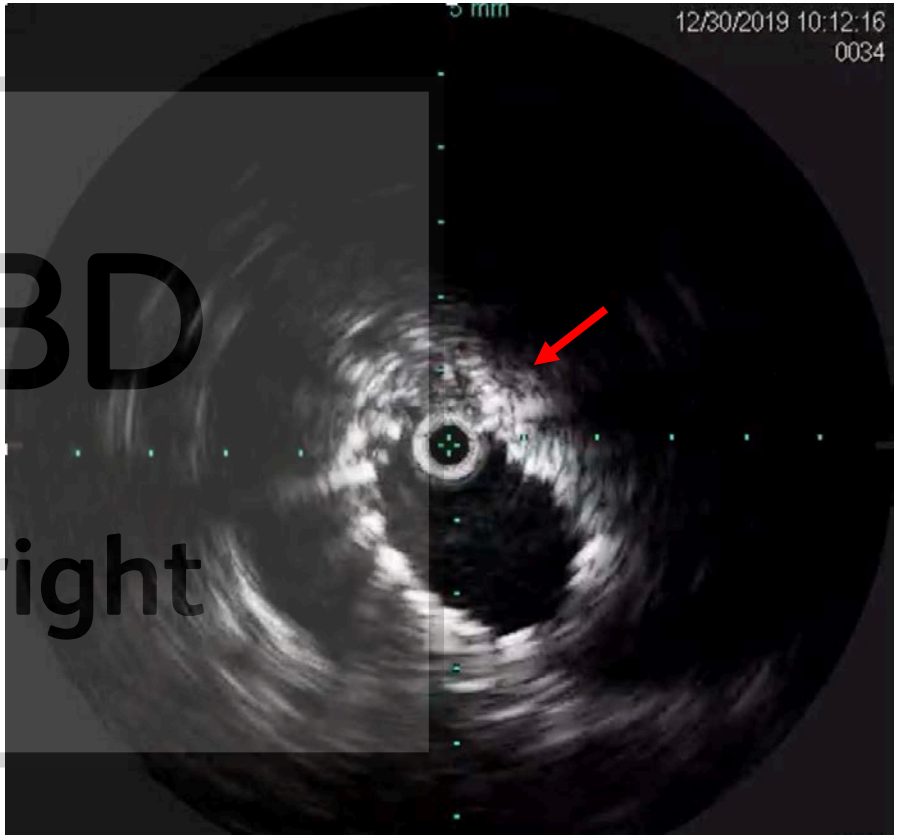
Post-procedure 2

- IVUS following stent placement demonstrates left common iliac vein luminal restoration (red arrow) following stent placement



- Left groin/pelvic pain resolved
- Back pain following stent placement resolved after 1 week

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Venovo™ Venous Stent ACUTE DVT Case

History/Presentation:

- 63-year-old female presenting with 3 days of left leg edema and pain
- Pain severe enough to wake her up
- Noted that left leg was red/purple in color, nearly doubled in size relative to right leg
- Duplex and CT obtained

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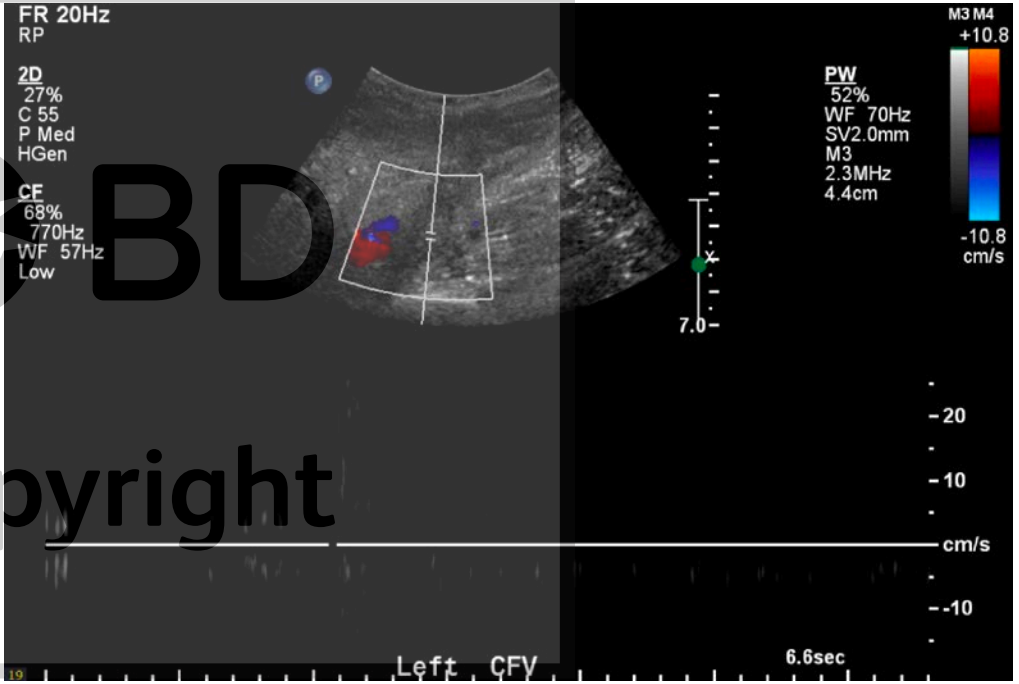
Procedure

- Color and spectral Doppler US of the left common femoral vein demonstrates occlusive thrombus in the left common femoral vein, which extended caudally through the infrapopliteal tibial veins



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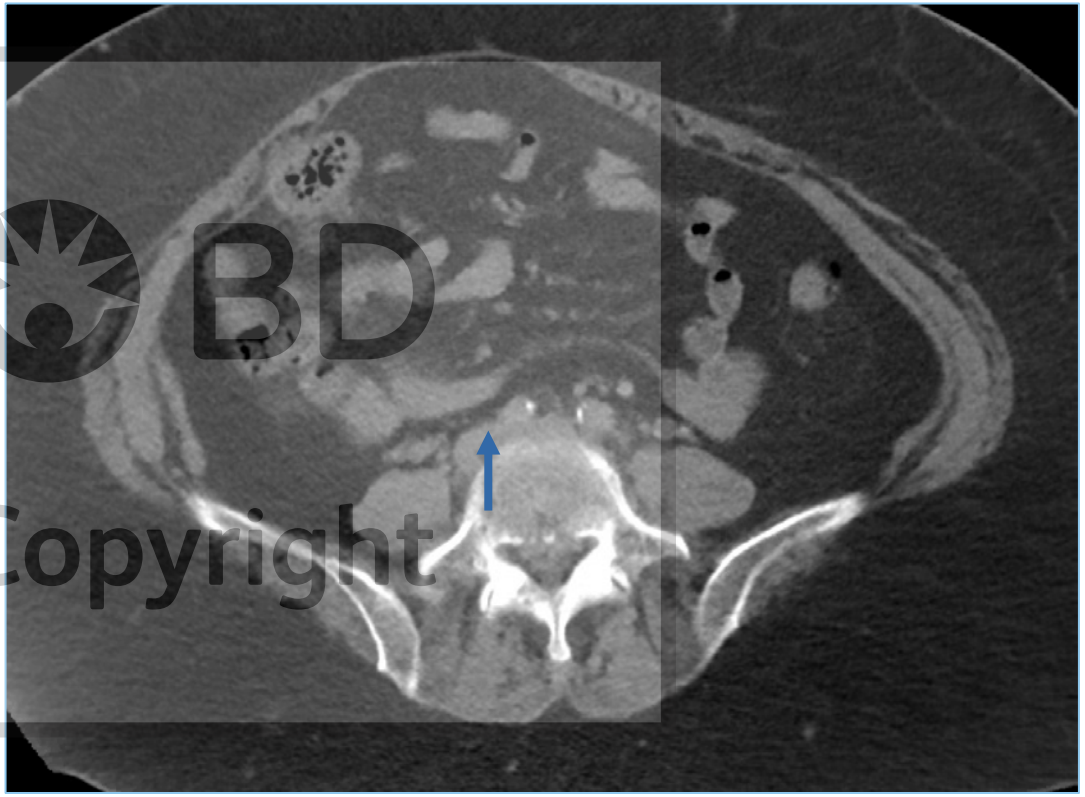
Procedure

- Axial post-contrast CT of the abdomen/pelvis demonstrates compression of the L CIV by the R CIA (blue arrow)



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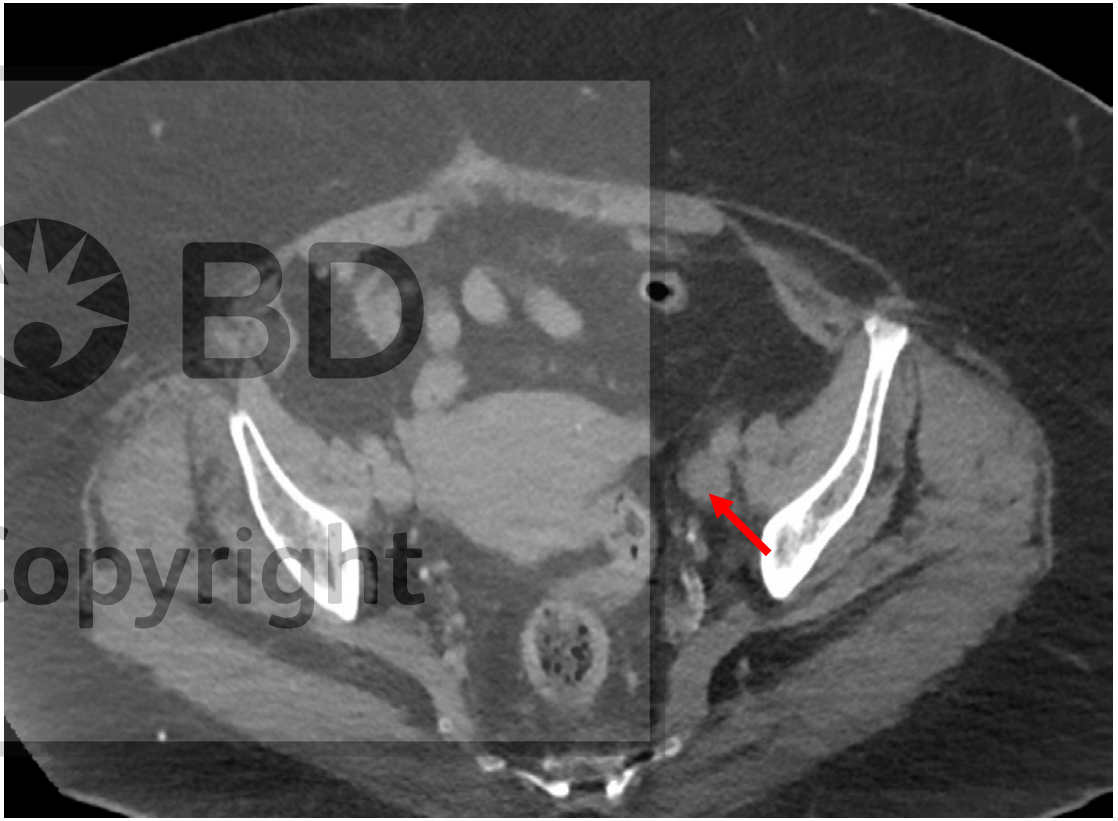
Procedure

- A caudal image from the same CT demonstrates an expanded left external iliac vein with perivenous stranding, consistent with thrombus



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Procedure

History/Presentation:

- No history of travel or hospitalization/surgery
- Noted cough/shortness of breath 17 days prior
- Tested COVID-19+
- Asymptomatic now – decision based on guidance at that time was to postpone
- Started on compression and enoxaparin

Subsequent Presentation

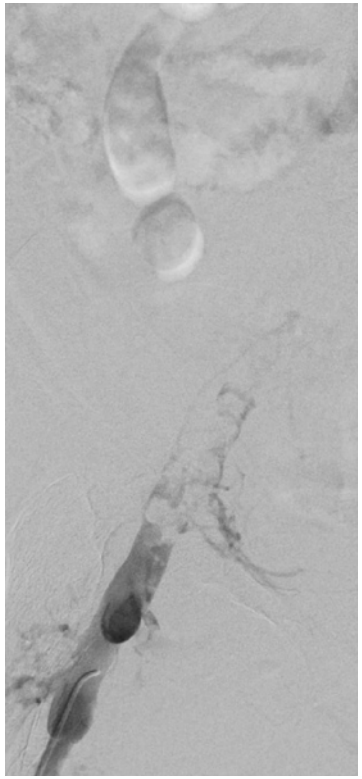
- Returns 10 days later – 13 days after onset of symptoms
- Now wheelchair bound

Case Courtesy of Kush Desai, MD FSIR
Associate Professor of Radiology, Surgery, and Medicine
Northwestern University

How I Do It

- Small saphenous, posterior tibial, or popliteal access Venography to confirm extent of thrombus
- 10Fr sheath for broad device compatibility

- Left external iliac venogram demonstrates complete, acute thrombotic occlusion of the left external through common iliac veins



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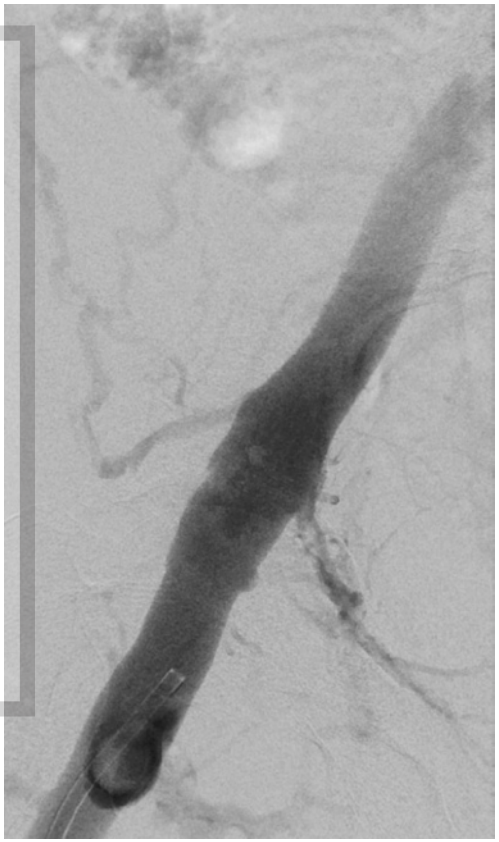
How I Do It

- 10 mg tPA in 50 mL power pulse, dwell 30 min
- Rheolytic thrombectomy for 90-120 seconds

- Left common iliac venograms demonstrate persistent, adherent common femoral thrombus (left image) that was aspirated through a 9Fr guide catheter (right image)



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How I Do It

- Post thrombectomy venography followed by “touch up”
- Embolectomy balloon catheter to peel adherent thrombus off wall, as needed, or localized guide catheter suction thrombectomy
- Stent placement
- IVUS
- Measurement of stent length
- Lock table once landing zone determined
- Pre-dilate to stent diameter

- Final left common femoral venogram demonstrates brisk flow through the recanalized segments and clearance of thrombus from the left CFV and EIV

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Northwestern University

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Questions?

United States

Indications for Use: The Atlas™ Gold PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the peripheral vasculature, including the iliac arteries and iliac and femoral veins, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Contraindications: None known.

Warnings: The Atlas™ Gold PTA Dilatation Catheter is supplied sterile using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Single patient use only. Do not reuse, reprocess, or re-sterilize. This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. To reduce the potential for stent or stent graft damage and/or vessel damage from the stent or stent graft, the diameter of the balloon should be no greater than the diameter of the stent or stent graft. Refer to the stent or stent graft IFU for safety information including the WARNINGS, PRECAUTIONS, and potential ADVERSE EFFECTS regarding the use of balloon post-dilatation. When thecatheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip breakage or balloon separation. Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over pressurization, use of a pressure monitoring device is recommended. After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.

Precautions: Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape, and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. The Atlas™ Gold Catheter shall only be used by physicians trained in the performance of Percutaneous Transluminal Angioplasty. The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label. Do not remove the guidewire in situ to shoot contrast through the wire lumen or perform a wire exchange. If the wire is removed while the balloon catheter is situated in tortuous anatomy, the risk of kinking the catheter is increased. Use the recommended balloon inflation medium (a range of 30-50% contrast medium / a range of 50-70% sterile saline solution). It has been shown that a 30/70% contrast/saline ratio has yielded faster balloon inflation / deflation times. Never use air or other gaseous medium to inflate the balloon. If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon. If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit. Do not continue to use the balloon catheter if the shaft has been bent or kinked. Prior to reinsertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire.

Potential Adverse Reactions: The complications which may result from a peripheral balloon dilatation procedure include: acute thrombotic occlusion, additional intervention, allergic reaction to drugs or contrast medium, aneurysm or pseudoaneurysm, arrhythmias, balloon rupture, balloon getting stuck on stent, distal embolization (PE), hematoma, hemorrhage, including bleeding at the puncture site, hypotension/hypertension, inflammation, leg edema, occlusion, pain or tenderness, pneumothorax or hemothorax, sepsis/infection, shock, short term hemodynamic deterioration, stent disruption or dislodgement with balloon insertion, stroke, thrombosis, vessel dissection, perforation, rupture, or spasm.

United States
Indication for Use: The Venovo™ Venous Stent is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction

International
Indication for Use: The Venovo™ Venous Stent System is indicated for the treatment of stenoses and occlusions in the iliac and femoral veins.

Contraindications: The Venovo™ Venous Stent System is contraindicated for use in patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum, who cannot receive recommended antiplatelet and/or anti-coagulation therapy, or who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system

Warnings: The Venovo™ Venous Stent System is supplied sterile and is intended for single use only. Do not resterilize and/or reuse the device. Do not use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. Do not use the device with contralateral access. Do not use if pouch is opened or damaged. Do not use the device after the “Use By” date specified on the label. Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. Do not expose the delivery system to organic solvents, e.g., alcohol. The stent is not designed for repositioning or recapturing. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. If a long lesion needs to be stented consider using the longest available stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). The long-term outcomes following repeat dilatation of endothelialized stents are unknown. The safety and effectiveness of this device for use in the arterial system have not been established.

Precautions: The device is intended for use by physicians who have received appropriate training. During system flushing, observe that saline exits at the catheter tip. The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. Store in a cool, dark, dry place. Do not attempt to break, damage, or disrupt the stent after placement.

Potential Complications and Adverse Events: Allergic/anaphylactic reaction; Amputation; Aneurysm; Arteriovenous fistula; Death related/unrelated to procedure; Dissection; Embolization; Extravasation; Fever; Hemorrhage/bleeding requiring a blood transfusion; Hematoma; Hypotension/hypertension; Incorrect positioning of the stent requiring further stenting or surgery; Intimal injury/dissection; Ischemia/infarction of tissue/organ; Local infection; Malposition (failure to deliver the stent to the intended site); Open surgical repair; Pain; Pulmonary embolism; Pseudoaneurysm; Renal failure; Respiratory arrest; Restenosis; Rupture; Septicemia/bacteremia; Stent Fracture; Stent Migration; Vasospasm; Venous occlusion/thrombosis/restenosis

Please consult package insert for more detailed safety information and instructions for use.

Thank you!