Thrombectomy, post thrombotic syndrome and stenting

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Rane Center, Jackson MS

Objectives

1. Venous thromboembolism.
2. Role of thrombectomy in reducing post thrombotic syndrome.
3. Appropriate selection of patients for thrombectomy.
4. Role of iliofemoral venous stenting in alleviating signs and symptoms of post thrombotic syndrome.

Venous thromboembolism

- Third most common cardiovascular disorder, affecting up to 5% of the population.
- VTE commonly manifests as lower-extremity deep venous thrombosis or pulmonary embolism.
- Half of these events are associated with a transient risk factor.

Venous thromboembolism. Ann Intern Med. 2022;175(9):ITC129 – ITC144.

Venous thromboembolism

- Many patients with VTE will have a chronic disease requiring long-term anticoagulation.

- Specific venous thromboembolism risk factors described in popular literature include: prothrombotic genes, malignancy, pregnancy, trauma, and COVID-19.

Venous thromboembolism. Ann Intern Med. 2022;175(9):ITC129 – ITC144.

Venous thromboembolism

- Post thrombotic syndrome a common result of DVT, often manifesting several years following a DVT.
- Affects upto 40 – 50% of patients with DVT (at 2 years).
- Significantly impacts function and quality of life.
- Chronic pain, long term disability and venous ulceration.

Venous thromboembolism. Ann Intern Med. 2022;175(9):ITC129 – ITC144.

Venous thromboembolism

- Anticoagulation is the cornerstone of primary treatment for VTE.

- Main benefits: prevents clot propagation and prevents pulmonary embolism.

Venous thromboembolism

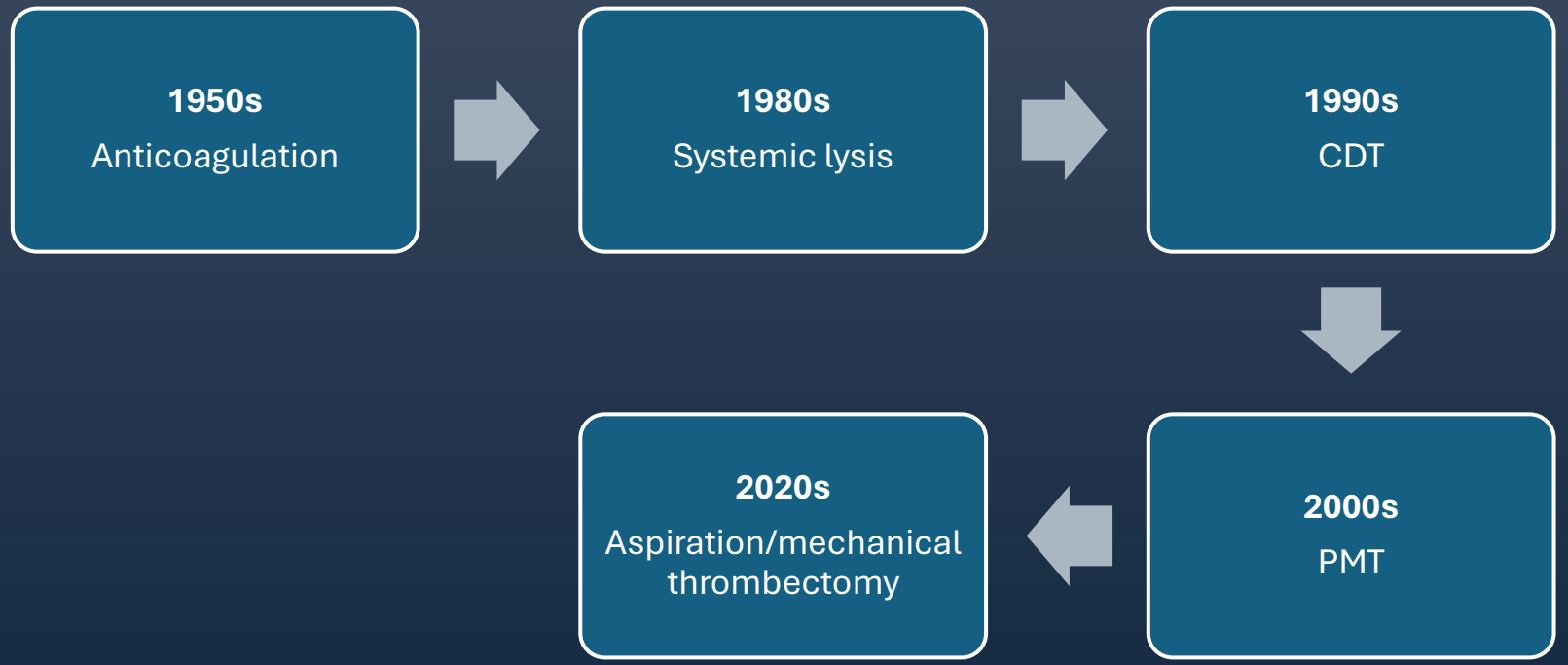
- However, some patients may develop progressive symptoms, thrombus extension, or severe activity limitation despite anticoagulation.

- Often, these patients have iliac – caval venous involvement.

- Thrombectomy: removes clot, rapidly improves symptoms, prevents PTS.

Dexter D. Frontiers in venous thrombectomy: Where is the data now? VuMedi.com

Evolution of DVT treatment strategies



Dexter D. Frontiers in venous thrombectomy: Where is the data now? VuMedi.com

ATTRACT trial

- A 56 center, RCT (2009 – 2014) that evaluated pharmaco-mechanical catheter directed thrombolysis (PCDT) for prevention of post-thrombotic syndrome (Villalta score > 5 or presence of an ulcer) in patients with acute proximal deep vein thrombosis.

- PCDT

(1) increased major bleeding;
(2) did not influence health related quality of life or recurrent VTE;
(3) improved leg pain and swelling over 30 days; and
(4) reduced the severity of PTS.

The ATTRACT Trial: a step forward for evidence based DVT care. European J Vasc Endovasc Surg. 2018;56:320-21.

Some prior shortcomings

- Long ICU stay – especially when using alteplase in PCDT
- Lytic therapy – risk of bleeding AND renal failure
- Lytic therapy – often not effective for chronic cases
- Emergency rooms full with DVT patients during pandemic – no hospital beds available
- Comprehensive treatment of DVT/PTS lacking in the community – close follow-up lacking

Saleem T, Raju S. Aspiration mechanical thrombectomy for treatment of acute iliofemoral and central deep venous thrombosis. Annals of Vasc Surg – Brief Reports and Innovations. 2021;1:100012.

Evolution of thrombectomy devices

- Our experience with Indigo Penumbra CAT 8 and CAT 12.
- Newer devices available, newer technology available -> safer, appears to be more effective
- No tpa used
- No associated ICU stay
- No perioperative pulmonary embolism
- Same day discharge possible!
- Single session treatment

Saleem T, Raju S. Aspiration mechanical thrombectomy for treatment of acute iliofemoral and central deep venous thrombosis. Annals of Vasc Surg – Brief Reports and Innovations. 2021;1:100012.

Who is most likely to benefit from thrombectomy – patient selection

- Thrombectomy should focus on patients who are highly symptomatic with acute iliofemoral caval DVT, including stented patients or patients with IVC filter associated DVT.

What is no longer a barrier to patient selection

- Advanced age (≥65 years),
- Baseline renal insufficiency (serum creatinine ≥ 1.5 mg/dL),
- History of recent major surgery (within 4 weeks of presentation),
- History of major spontaneous bleeding,
- History of recent major trauma (within 4 weeks of presentation)

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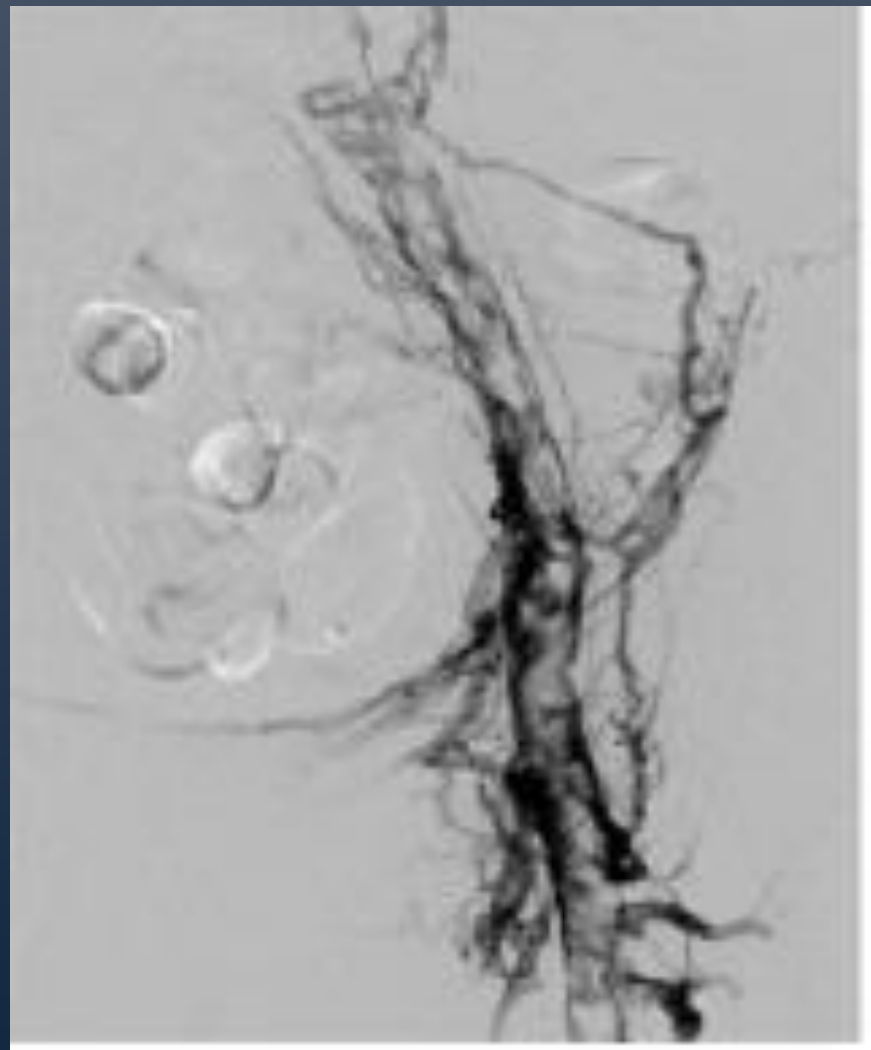

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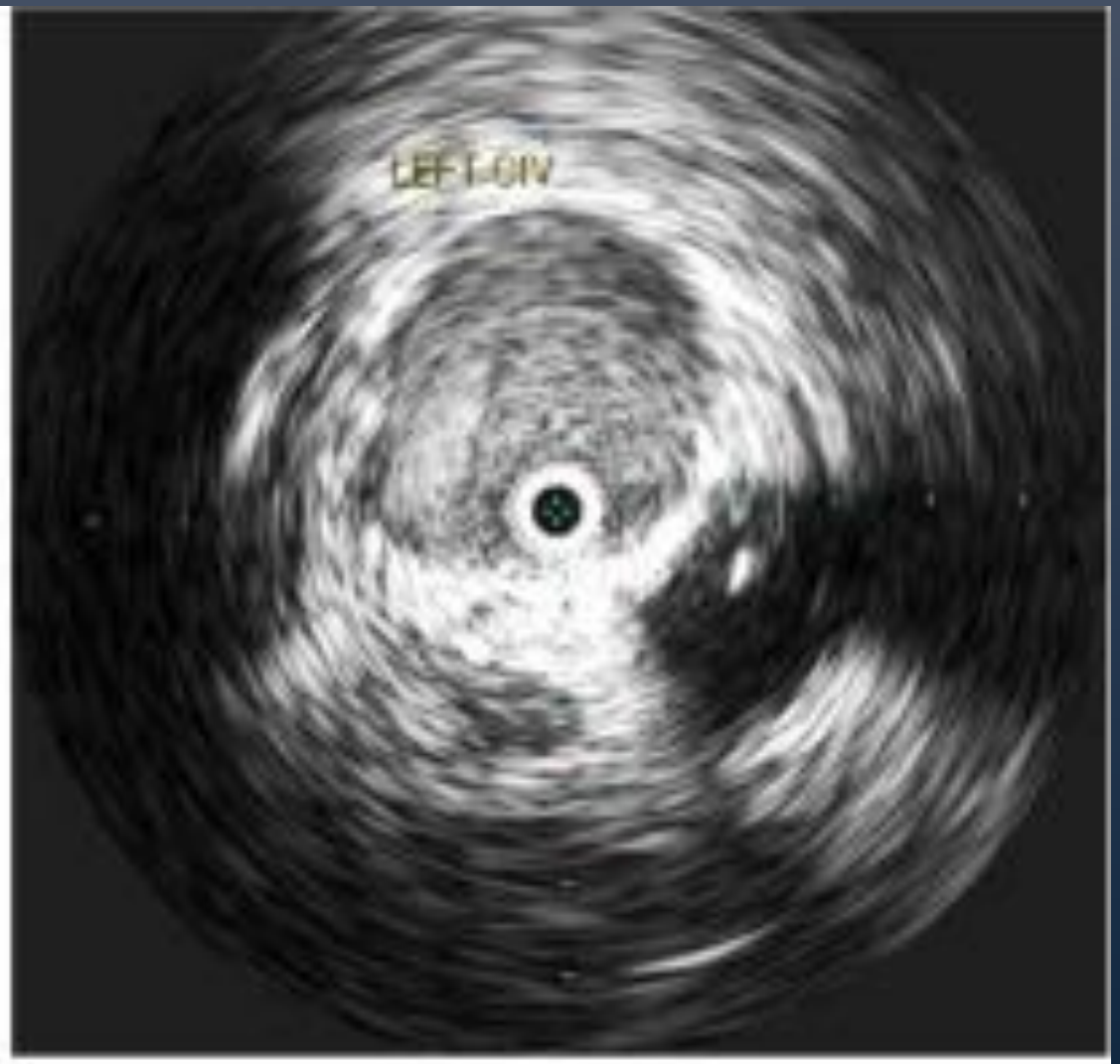

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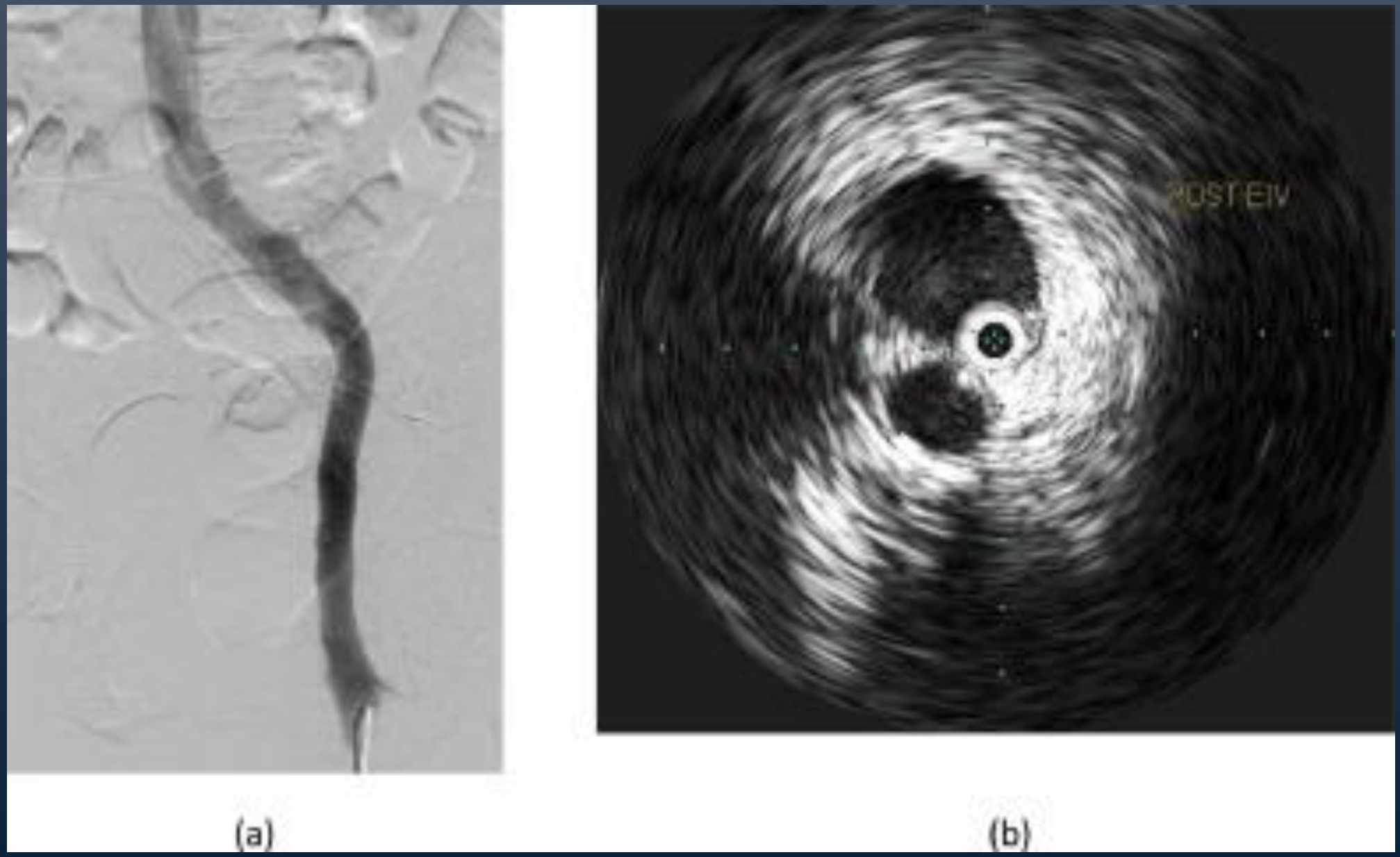
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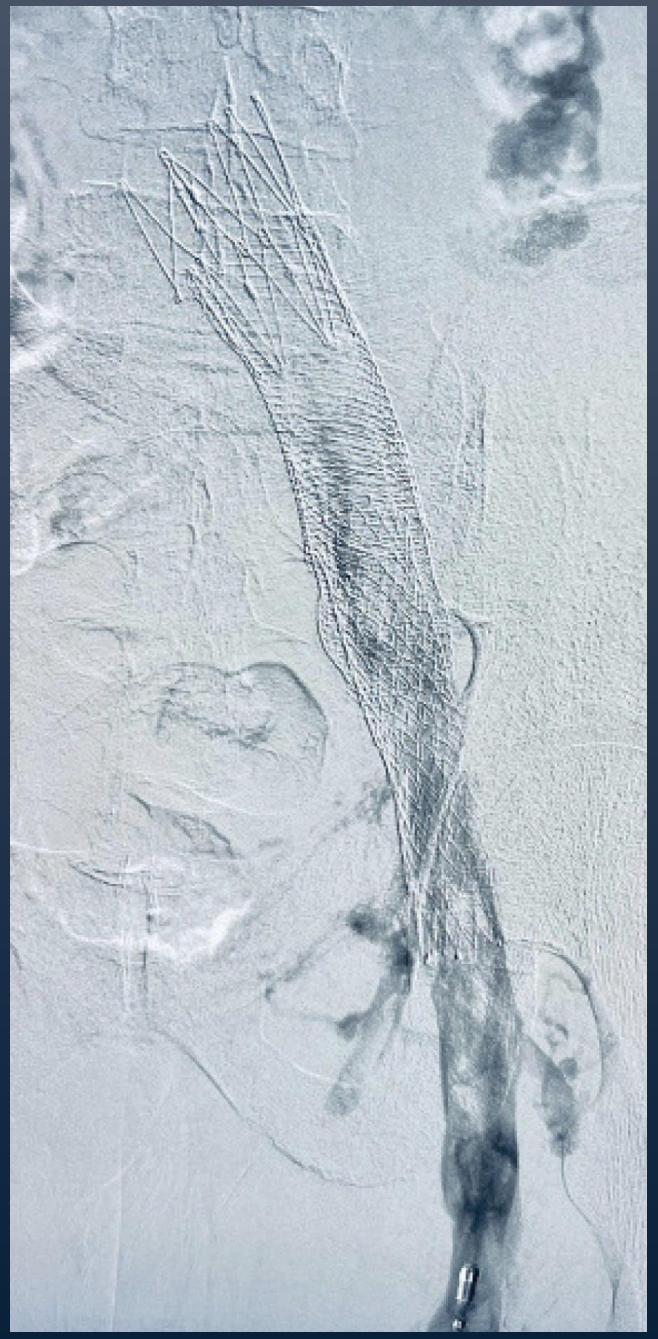

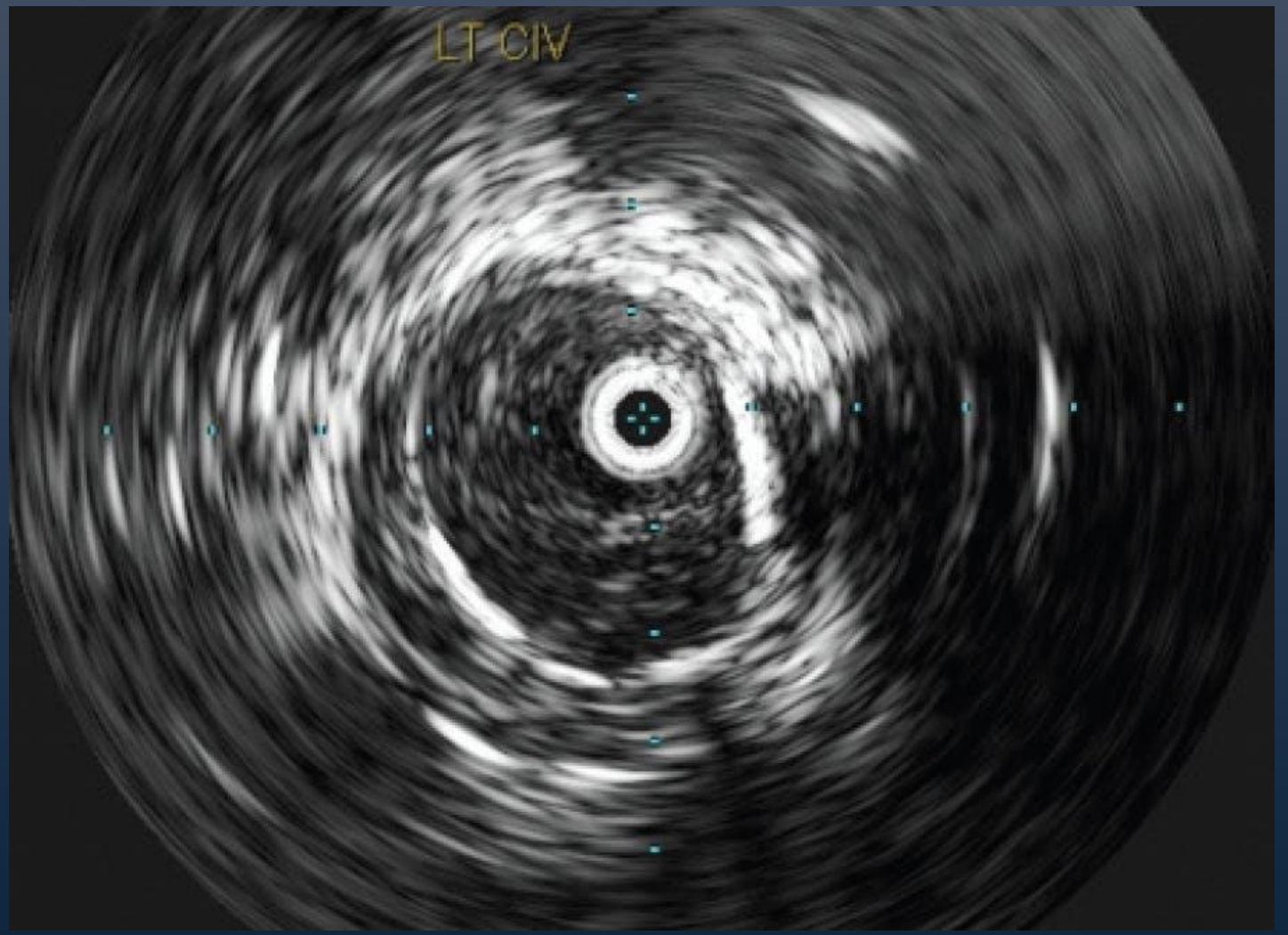
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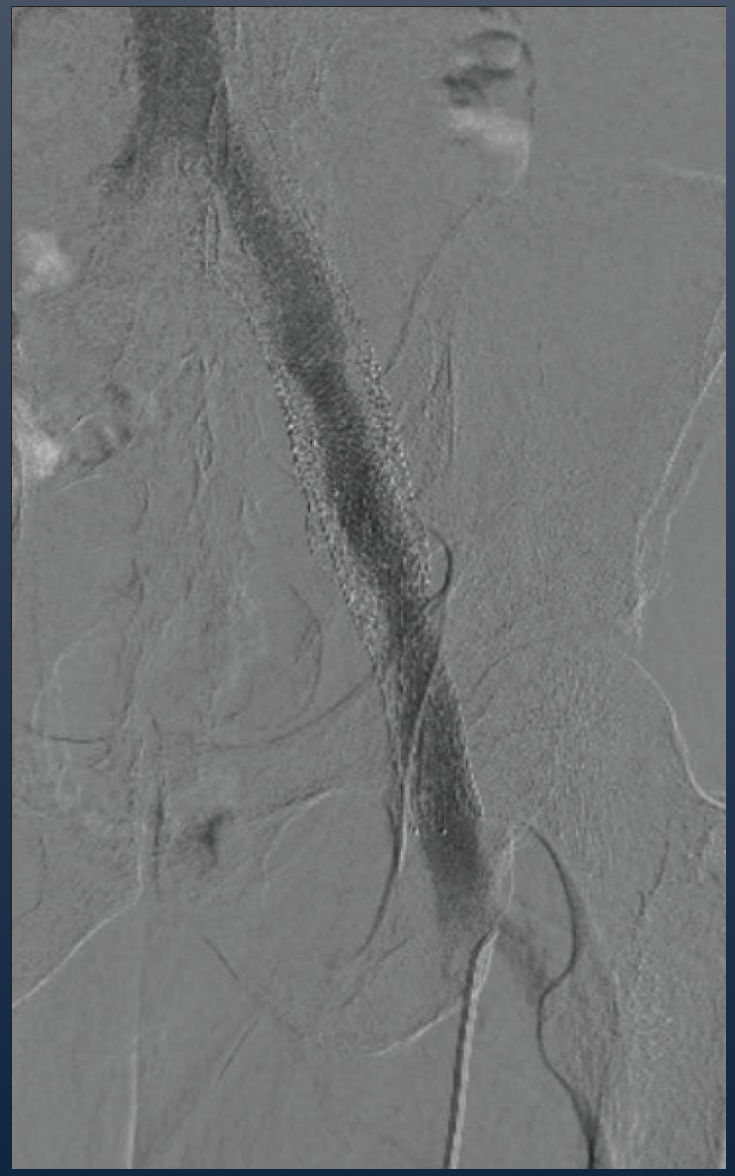
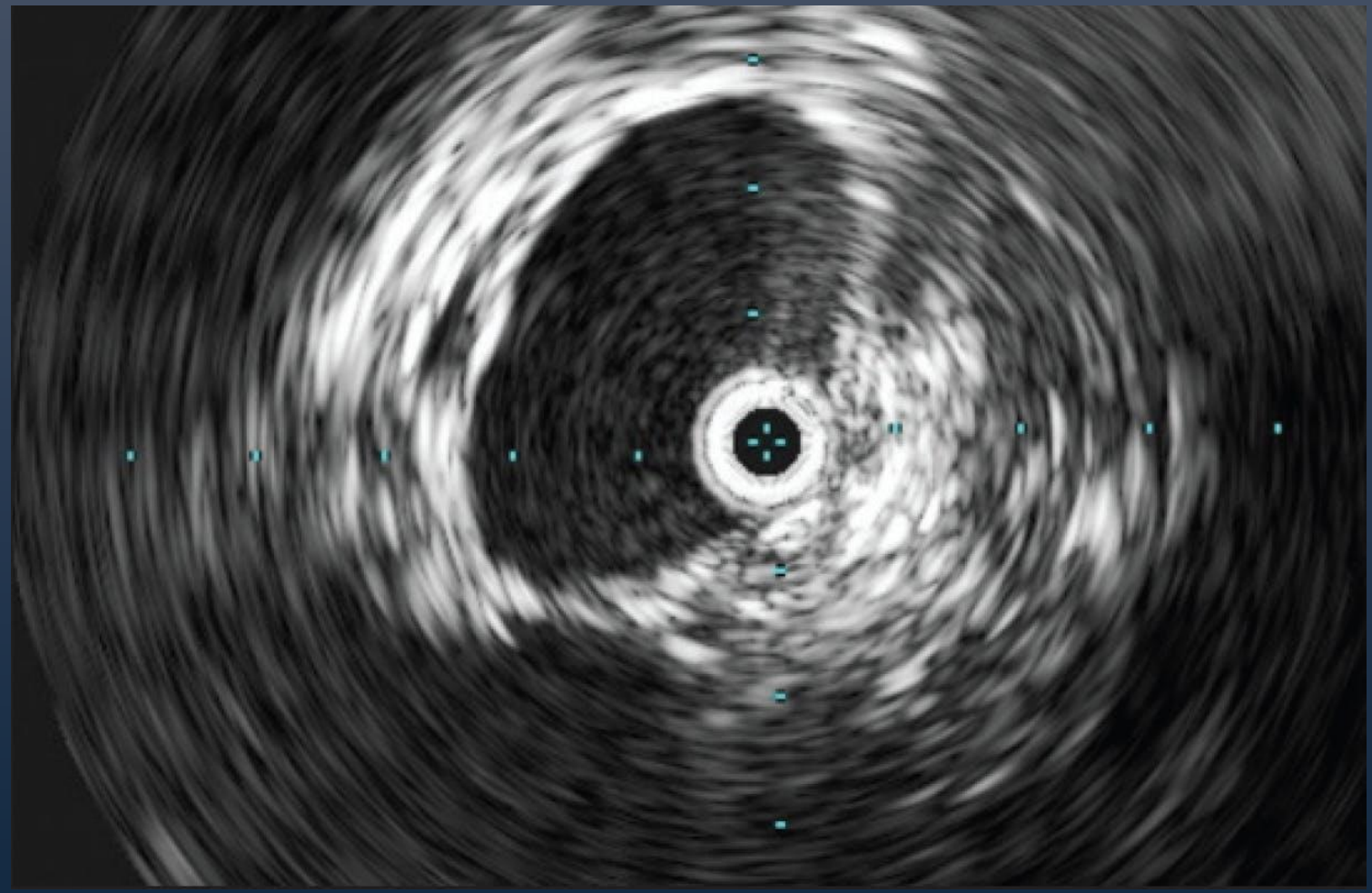




Are newer devices more effective at prevention of post thrombotic syndrome?

- 500 – patient CLOUT registry using ClotTriever system.
- Prospective, multicenter, single-arm registry.
- N=228, completed 2 year visit.
- Primary endpoint: complete or near complete (≥75%) thrombus removal by Marder score.
- Acute, subacute and chronic – all thrombus spectrum included.

Six-month outcomes of mechanical thrombectomy for treating deep vein thrombosis. Analysis from the 500-patient CLOUT registry. Cardiovasc Intervent Radiol. 2023;46:1571-1580.

Are newer devices more effective at prevention of post thrombotic syndrome?

- 31% patients with contraindications to thrombolysis.
- Mean age 62 years.
- 68% patients with iliofemoral AND femoral-popliteal DVT.
- Prior history of DVT: 25%.

Six-month outcomes of mechanical thrombectomy for treating deep vein thrombosis. Analysis from the 500-patient CLOUT registry. Cardiovasc Intervent Radiol. 2023;46:1571-1580.

Are newer devices more effective at prevention of post thrombotic syndrome?

- Serious adverse event rethrombosis/residual thrombus incidence: 4.8% at 30 days and 8.0% at 6 months.
- Median Villalta scores improved from 9.0 at baseline to 1.0 at 6 months ($P < 0.0001$).
- Device related pulmonary embolism: n=1.
- 9% patients reported moderate-severe PTS at 6 months.

Six-month outcomes of mechanical thrombectomy for treating deep vein thrombosis. Analysis from the 500-patient CLOUT registry. Cardiovasc Intervent Radiol. 2023;46:1571-1580.

Are newer devices more effective at prevention of post thrombotic syndrome?

- Single session: 99%.
- EBL: 40 cc.
- Technical success: 91%.

Six-month outcomes of mechanical thrombectomy for treating deep vein thrombosis. Analysis from the 500-patient CLOUT registry. Cardiovasc Intervent Radiol. 2023;46:1571-1580.

Our experience

- Lightning Flash (16 French); computer assisted vacuum mechanical thrombectomy system.
- Inclusion: Symptomatic acute or subacute (presentation within 6 weeks from symptom onset **AND** corresponding appearance of thrombus on ultrasound) iliofemoral-caval DVT including occluded venous stents and occluded IVC filters.
- Single session in all patients; n=20.
- No tpa, no ICU stay.
- No bleeding complications, no access site complications, no incidence of renal failure, no device related complications.

Our experience

- Significantly improved EBL over both Penumbra CAT 8 and CAT 12 systems used in the past.
- Mean EBL now 60 cc compared to 250 cc previously.
- Mean number of device passes with Lightning Flash: 4.
- Mean device dwell time in patient: 2 minutes.

Our experience

- Mean age: 60 years, range: 18 – 86 years.
- Contraindication to tpa: 50% patients.
- Baseline renal insufficiency: 40%.
- IVC extension: 50%.
- Occluded IVC filter: 30%.
- History of recent surgery: 30%.

- Intravascular ultrasound used in 100% of the patients.

Our experience

- Technical success based on IVUS.
- Defined as the resolution of ≥ 75% of the thrombus on IVUS after thrombectomy intraoperatively.
- Technical success: 100% with Lightning Flash, as noted by IVUS.
- Venous flow was restored immediately in 100% of patients.
- Incidence of perioperative PE: 0.
- No perioperative IVC filters placed for the purpose of thrombectomy.

Our experience

- 6-week outpatient ultrasound: 18/20 (90%) patients patent.
- Mean follow up duration: 12 months -> 90% patients remained patent by ultrasound.
- Incidence of recurrent DVT: 0.
- Symptomatic improvement noted at the time of discharge and persisted at long term follow up: 90% patients.
- 1 patient had developed HIT – noted to be re-occluded post procedure day 1 and remained occluded at follow-ups. Thrombectomy was not re – attempted.

Do you need 100% clot clearance every time?

- Symptom improvement was seen in all patients prior to discharge, even if residual thrombus noted by IVUS.
- 70% of treated limbs remained patent long term with CAT 8 and CAT 12 penumbra systems.
- Focus on creation of a flow channel with inline flow appears to be more important than percentage of residual thrombus, for symptomatic improvement in patients and for prevention of PTS.

Saleem T, Raju S. Aspiration mechanical thrombectomy for treatment of acute iliofemoral and central deep venous thrombosis. Annals of Vasc Surg – Brief Reports and Innovations. 2021;1:100012.
Jayaraj A, et al. Improvement following restoration of inline flow argues against comprehensive thrombus removal strategies and for selective stenting in acute symptomatic iliofemoral venous thrombosis. J Vasc Surg Venous Lymphat Disord. 2023;11:119-126.
Raju S, et al. Assessment of residual thrombus after venous thrombolytic regimens. J Vasc Surg Venous Lymphat Disord. 2014;2:148-154.

Clinical Trial > J Vasc Interv Radiol. 2020 Oct;31(10):1517-1528.e2. doi: 10.1016/j.jvir.2020.07.010
Epub 2020 Sep 15.

Correlation between Post-Procedure Residual Thrombus and Clinical Outcome in Deep Vein Thrombosis Patients Receiving Pharmacomechanical Thrombolysis in a Multicenter Randomized Trial

Mahmood K Razavi [1], Amber Salter [2], Samuel Z Goldhaber [3], Samantha Lancia [2], Susan R Kahn [4], Ido Weinberg [5], Clive Kearon [6], Ezana M Azene [7], Nilesh H Patel [8], Suresh Vedantham [9]

Affiliations + expand

PMID: 32948386 PMCID: PMC7541749 DOI: 10.1016/j.jvir.2020.07.010

Abstract

Purpose: To evaluate relationships between immediate venographic results and clinical outcomes of pharmacomechanical catheter-directed thrombolysis (PCDT).

Materials and methods: Venograms from 317 patients with acute proximal deep vein thrombosis (DVT) who received PCDT in a multicenter randomized trial were reviewed. Quantitative thrombus resolution was assessed by independent readers using a modified Marder scale. The physician operators recorded their visual assessments of thrombus regression and venous flow. These immediate post-procedure results were correlated with patient outcomes at 1, 12, and 24 months.

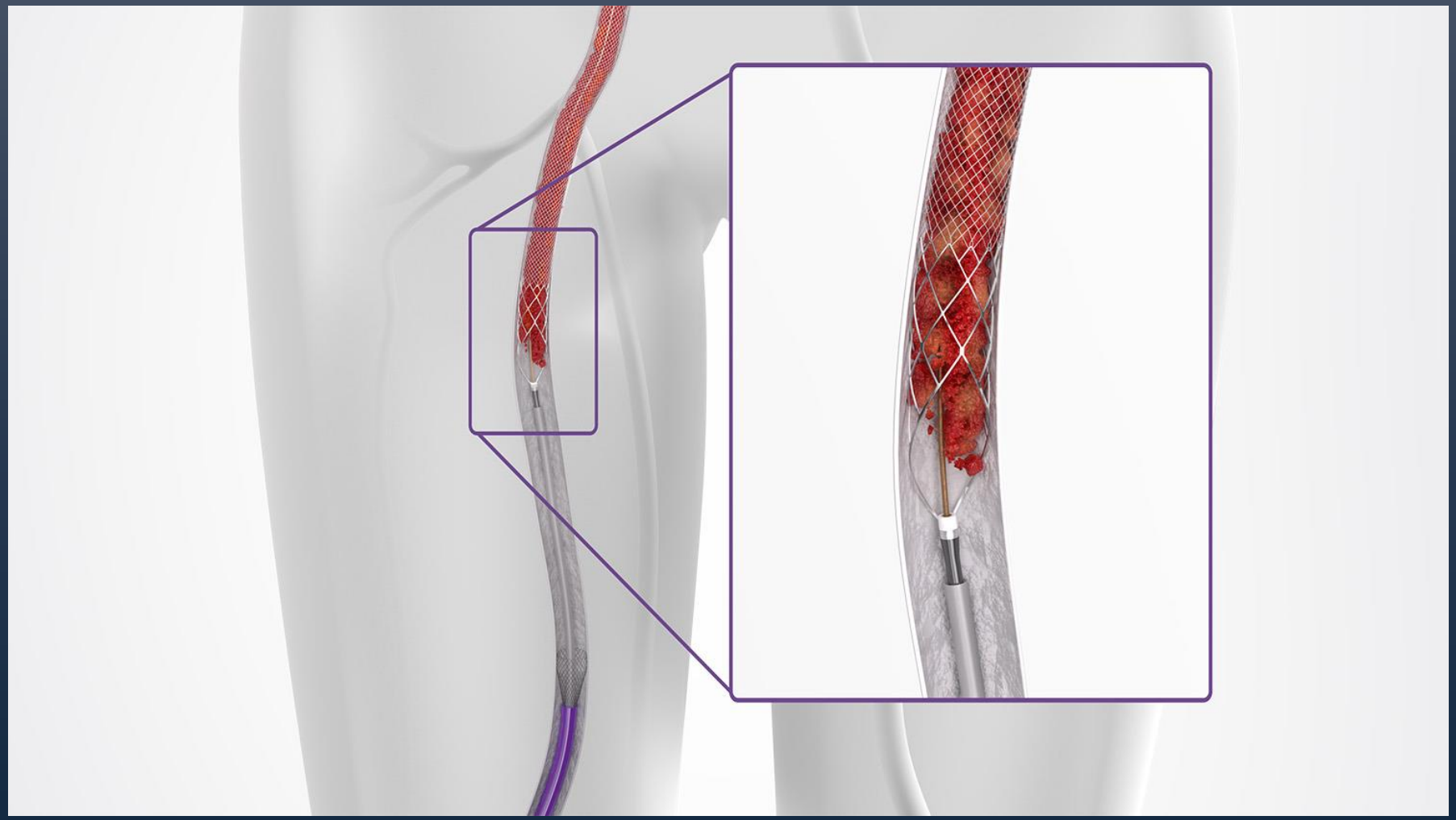
Results: PCDT produced substantial thrombus removal ($P < .001$ for pre-PCDT vs. post-PCDT thrombus scores in all segments). At procedure end, spontaneous venous flow was present in 99% o iliofemoral venous segments and in 89% of femoral-popliteal venous segments. For the overall proximal DVT population, and for the femoral-popliteal DVT subgroup, post-PCDT thrombus volume did not correlate with 1-month or 24-month outcomes. For the iliofemoral DVT subgroup, over 1 an 24 months, symptom severity scores were higher (worse), and venous disease-specific quality of life (QOL) scores were lower (worse) in patients with greater post-PCDT thrombus volume, with the difference reaching statistical significance for the 24-month Villalta post-thrombotic syndrome (PTS) severity score ($P = .0098$). Post-PCDT thrombus volume did not correlate with 12-month valvular reflux.

Conclusions: PCDT successfully removes thrombus in acute proximal DVT. However, the residual thrombus burden at procedure end does not correlate with the occurrence of PTS during the

Our experience

- Stenting performed selectively; not usually performed in acute setting.
- Only 2 patients were stented long term: 10%. In both patients, chronic occlusions were recanalized, angioplastied and stented.

Endovascular Today. Evtoday.com



Inari Medical. Inarimedical.com

Venous stenting and post thrombotic syndrome

- Wallstent initially used along with Zenith stent.

- Now, newer dedicated venous stents available for iliofemoral caval stenting.

A Brief Look at Outcomes

- The grade of swelling improved from 3 to 1 with newer stents and with Wallstent-Z stent.
- Visual analog scale for pain score improved from 7 to 2 in the newer stent group and from 5 to 0 in the Wallstent group (P = .007).
- At 12 months, ulcers healed in about 60% of both groups (P = .7).

Powell T, et al. Comparison between a dedicated venous stent and standard composite Wallstent-Z stent approach to iliofemoral venous stenting: intermediate term outcomes. J Vasc Surg Venous Lymphat Disord. 2023;11:82-90.e2.

A Brief Look at Outcomes

- QoL scores improved in majority of patients.
- Cumulative primary, primary-assisted, and secondary patency at 18 months was 81%, 97%, and 98% in the new stent group and 87%, 98%, and 100% in the Wallstent group, respectively (P > .4).
- No difference in the reintervention rates was noted between the two groups (P = .5).

Powell T, et al. Comparison between a dedicated venous stent and standard composite Wallstent-Z stent approach to iliofemoral venous stenting: intermediate term outcomes. J Vasc Surg Venous Lymphat Disord. 2023;11:82-90.e2.

ACADEMIC PRESS

Venous Ulcers (Second Edition)

2023, Pages 433-471

Chapter 25 - Iliac vein stenting in chronic venous leg ulcers

Taimur Saleem, Seshadri Raju

https://doi.org/10.1016/B978-0-323-90610-4.00011-2

Abstract

Chronic venous leg ulcers (VLUs) have been known since antiquity. Healing of chronic VLUs has been seen after iliac vein stenting in > 50% of limbs; highlighting the importance of obstructive pathology in venous ulceration. Iliac vein stent treatment has now largely replaced open surgery for the correction of deep vein obstruction with or without reflux in patients with chronic VLUs. The treatment is minimally invasive with low morbidity and mortality. Iliac vein assessment is carried out with transfemoral venography, intravascular ultrasound and two segment computed tomography.

Journal of *Personalized Medicine*

MDPI

Review

An Overview of Specific Considerations in Chronic Venous Disease and Iliofemoral Venous Stenting

Taimur Saleem

The RANE Center for Venous and Lymphatic Diseases, Suite 401, 971 Lakeland Drive, Jackson, MS 39216, USA; taimur@gmail.com

Abstract: Unlike arterial disease, chronic venous disease (CVD) is rarely life-threatening or limb-threatening. However, it can impose substantial morbidity on patients by influencing their lifestyle and quality of life (QoL). The aim of this nonsystematic narrative review is to provide an overview of the most recent information on the management of CVD and specifically, iliofemoral venous stenting in the context of personalized considerations for specific patient populations. The philosophy of treating CVD and phases of endovenous iliac stenting are also described in this review. Additionally, the use of intravascular ultrasound is described as the preferred operative diagnostic procedural tool for iliofemoral venous stent placement.

Keywords: intravascular ultrasound; iliofemoral vein stent; venous leg ulcers; quality of life; graduated compression stockings

1. Introduction

Unlike arterial disease, chronic venous disease (CVD) is rarely life-threatening or limb-threatening. However, it can impose substantial morbidity on patients by influencing their lifestyle and quality of life (QoL). The symptoms of CVD can range from mild discomfort to QoL-impairing lower extremity pain. The clinical signs of CVD can range across a spectrum from edema, varicose veins, cutaneous hyperpigmentation, and lipodermatosclerosis to venous ulceration [1].

Traditionally, venous symptoms have been managed with conservative therapies. These include compression, ambulation, elevation, and wound care/antibiotics, in the case of venous ulceration. However, with the advent of minimally invasive therapies, these have been utilized increasingly in patients with CVD. For superficial venous disease, these minimally invasive therapies include ablation of the incompetent vein by different modalities. For chronic deep venous obstructive disease, these minimally invasive therapies include iliofemoral caval venous angioplasty and stenting. Open venous bypass surgery has a limited, secondary role today. Minimally invasive therapies are associated with quicker recovery, lesser post-operative pain, and lesser incidence of infections [2].

CVD can manifest in a variety of ways in individuals. CVD manifestations can be

Citation: Saleem, T. An Overview of Specific Considerations in Chronic Venous Disease and Iliofemoral Venous Stenting. *J. Pers. Med.* **2023**, *13*, 331. https://doi.org/10.3390/jpm13020331

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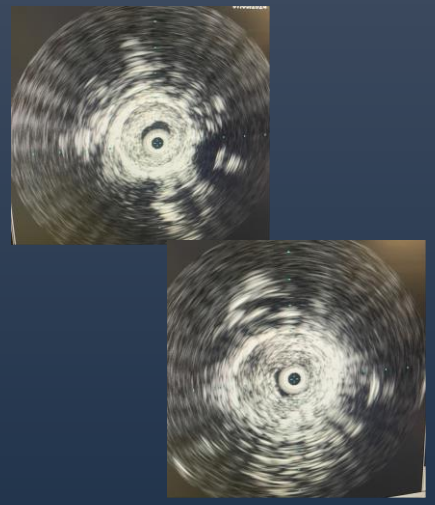
Patient History

- 49 yo Male
- Patient presented signs of chronic occlusion of left leg
- Patient brought in for follow-up venography and IVUS to assess stent
- Decision was made to intervene.

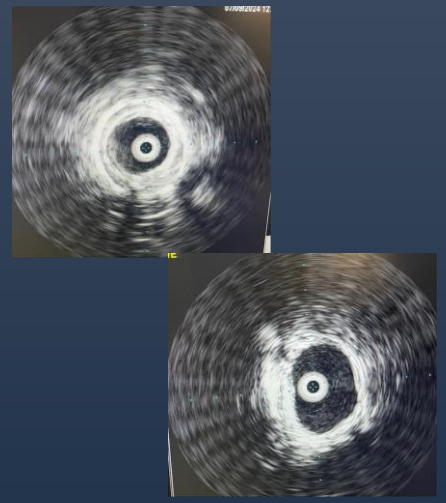
Procedural Notes

- ProTrieve sheath placed in IJ to collect thrombus liberated from within stent
- RevCore with venoplasty
- Minimal blood loss
- No need for TPA

IVUS Pre



IVUS Post



Venogram Pre

Venogram Post

Clot Removed

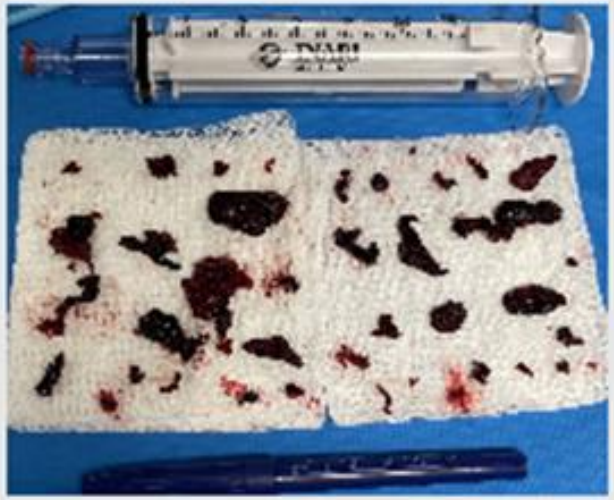
Patient History:

- 66yo male presents to ED with SOB, LLE swelling and pain; ~10 days
- CTA revealed minor PE, mostly distal/subsegmental and treated medically. Venous U/S study revealed extensive DVT extending from CFV-CIV
- Scheduled for mechanical thrombectomy

Procedural Notes:

- Patient placed prone and under general anesthesia
- Left popliteal vein prepped and accessed under U/S
- DVT traversed without complication and venogram performed, confirming U/S findings
- Stiff wire placed within R subclavian & sheath upsized to 13Fr ClotTriever sheath
- ClotTriever catheter placed in distal IVC, performing a total of 6 pullback passes
- Large amounts of acute & sub-acute thrombi extracted
- Post thrombectomy venogram and IVUS confirmed near 100% clearance of thrombus burden and laminar flow
- Successful, Single-Session DVT thrombectomy
- **ZERO** tPA utilized and no ICU stay required
- Minimal blood loss, <20mL

Case Images:



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Taimur Saleem, M.D.
Vascular Surgery

Endovascular Treatment of:

DVT

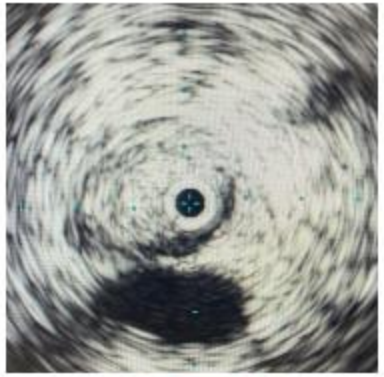
Inari Medical FlowTriever®

Procedure Date: 04/26/2021

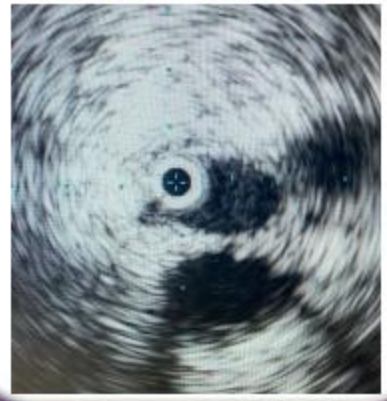
Procedure Notes

- 86yo female presents with sudden onset of leg swelling and pain
- Due to acuteness of clot, plan to use FlowTriever to extract thrombus
- Popliteal access & IVUS confirmed DVT (no contrast used)
- 5 passes with FlowTriever yielded large amounts of acute thrombus
- Single session treatment
- No tPA or ICU required

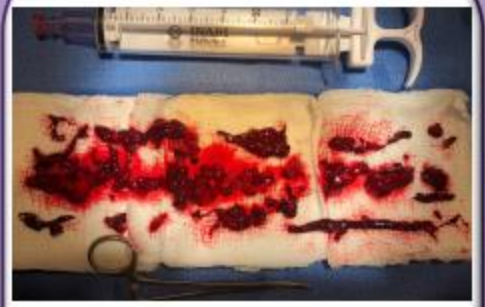
Pre IVUS



Post IVUS



Clot Removal



FlowTriever

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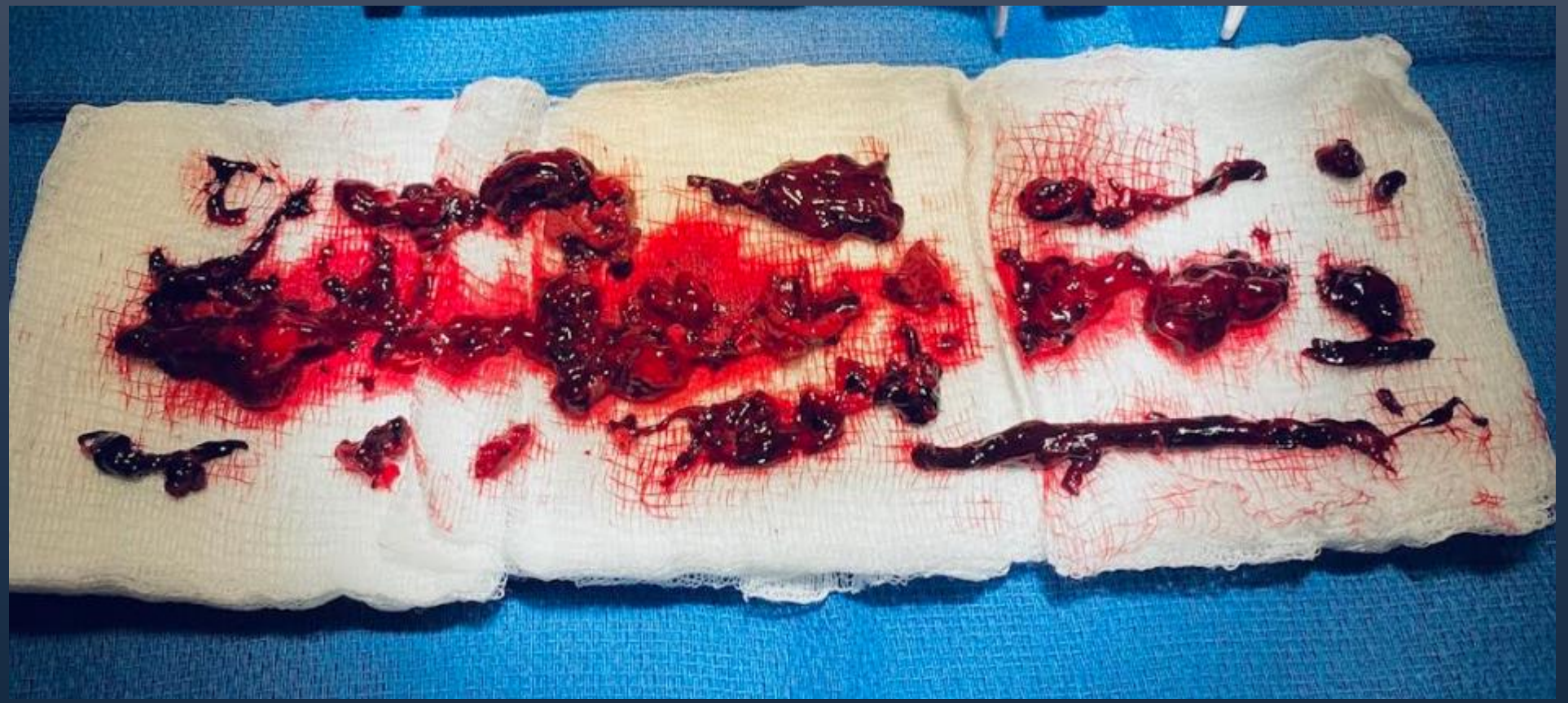

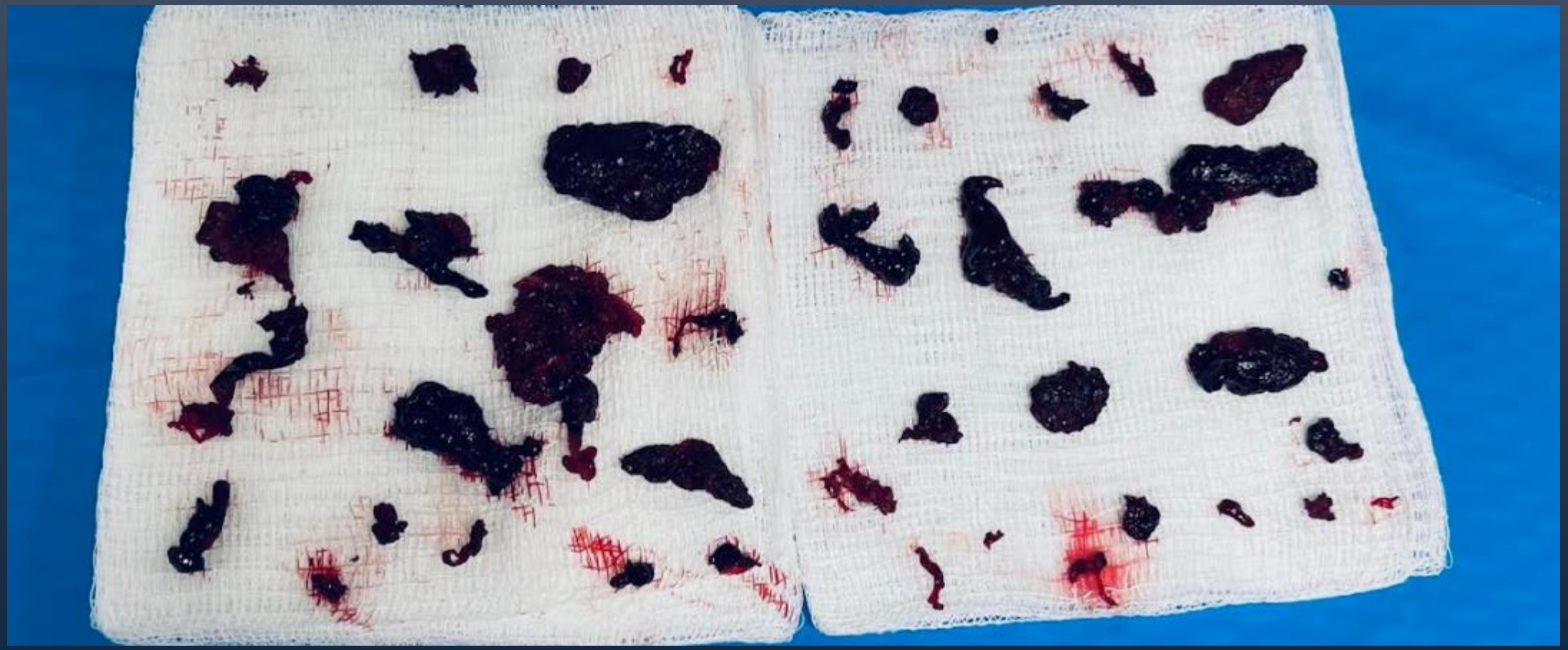


CM 1 2 3 4 5

A word of caution

- How to define PTS, and when to assess it?
- PTS was scored in the ATTRACT, CaVenT, and CAVA trials using the Villalta score, which includes a set of symptoms (patient reported) and signs (physician reported) of the leg.
- This score was never truly validated and only published as an abstract.
- While ATTRACT and CaVenT scored PTS according to the International Society of Thrombosis and Haemostasis (ISTH) consensus scoring method (venous ulceration or a Villalta score ≥ 5 after six months of follow up or later), CAVA used another definition (the development of venous ulceration or a Villalta score ≥ 5 on two separate occasions at least three months apart with the first assessment at least three months after the acute event).

Early thrombus removal in iliofemoral deep venous thrombosis to prevent PTS. European J of Vasc and Endovasc Surg. 2023. 65:169-170.

A word of caution

- Signs and symptoms used in Villalta score are non-specific.
- A symptom that is often reported by patients with an iliofemoral obstruction is venous claudication: severe thigh and leg pain while walking.
- This symptom is not included in the Villalta scale.
- Because it takes time for PTS to develop (often years), the effect of early thrombus removal on PTS should not be scored too soon after treatment.

Early thrombus removal in iliofemoral deep venous thrombosis to prevent PTS. European J of Vasc and Endovasc Surg. 2023. 65:169-170.

Conclusions

- Early thrombus removal in appropriately selected patients improves outcomes.
- Incidence of PTS and more importantly, severe PTS, appears to be impacted by thrombus removal strategies.
- Iliofemoral venous stenting alleviates signs and symptoms of post thrombotic syndrome in appropriately selected patients.

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