2022 MID-ATLANTIC CONFERENCE

10th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2022

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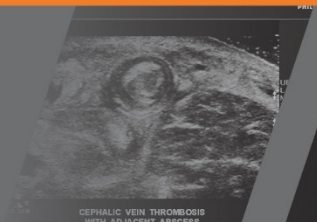
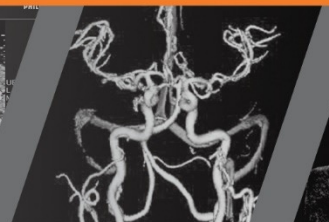
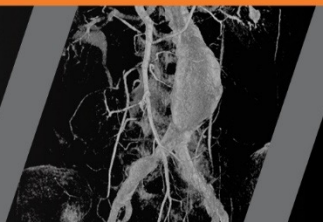
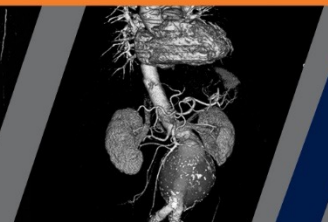
Virginia Beach, Virginia

APRIL 28-30









Sentara Vascular Specialists

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New Frontiers in Thrombectomy: Can We Do This Without Thrombolysis?

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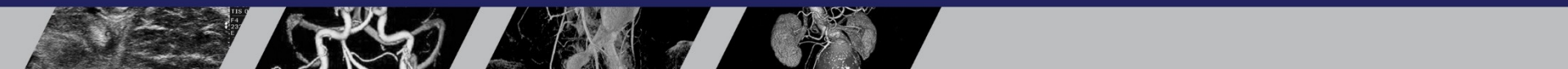
Sentara Vascular Specialists

- No Disclosures

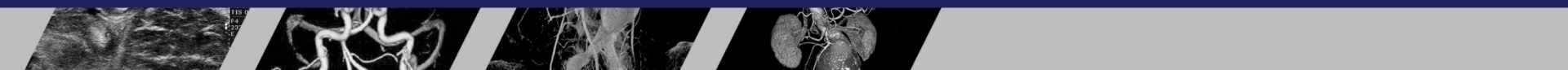
Background

- Deep venous thrombosis (DVT) affects approximately one in 1,000 patients yearly
  - 40–70% of these patients will develop **post-thrombotic syndrome** (PTS) in their lifetime.
- PTS: a constellation of symptoms and signs of chronic venous insufficiency including:
  - pain, swelling, varicose veins, and ulcerations
  - Pathophysiology: outflow obstruction, valvular damage leading to reflux, and chronic inflammation secondary to venous hypertension.
- PTS is associated with profound morbidity and cost, which justifies the attention it has received in recent years in the form of RCTs on how to decrease its incidence.
- The **‘open vein hypothesis’** recommends relieving the venous obstruction in order to improve flow and decrease the risk of reflux, thereby reducing the chance of developing PTS.



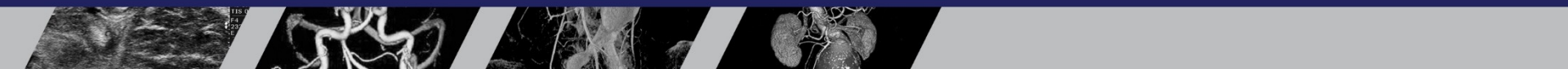
Background

- CHEST guidelines: Anticoagulation remains the primary treatment for DVT as it effectively prevents thrombus extension and recurrence.
    - ExACT (Extended Anticoagulation Treatment versus Standard Treatment for the Prevention of Recurrent Venous Thromboembolism (VTE) and Post-thrombotic Syndrome in Patients Being Treated for a First Episode of Unprovoked VTE) - RCT comparing standard and extended regimens of anticoagulation - no difference in the risk of PTS or in QOL
    - Anticoagulation does not dissolve DVT; venous patency is not its primary purpose.
    - Spontaneous recanalization of the iliac vein is rare after a DVT
- CaVenT (Catheter-directed Venous Thrombolysis) 2012 and 2016
    - Absolute risk reduction of PTS of 14.4% at 2 years and 28% at 5 years
- ATTRACT (Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-directed Thrombolysis) 2020:
    - Lower incidence of moderate (Villalta score >9) and severe (Villalta score >15) PTS, faster pain relief, and improved QOL for patients with iliofemoral DVT through 2 years
- CaVenT and ATTRACT trials were the first to establish benefit with catheter-based interventions in preventing or alleviating PTS in patients with first-time DVT.
- CAVA (Catheter-directed Thrombolysis versus Anticoagulation) 2020: ultrasound-assisted thrombolysis or anticoagulation
    - No difference in PTS at 1 year.



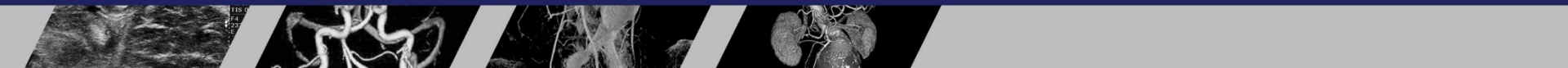
Background

- The conflicting results of the studies have raised criticism mainly with regard to incorrect patient inclusion or technical inappropriateness.
- Catheter-directed thrombolysis (CDT) is costly when compared to anticoagulation alone.
    - No difference in mortality has been shown
    - Is associated with higher rates of treatment associated blood loss requiring blood transfusion, pulmonary embolism requiring IVC filter placement, intracranial hemorrhage, and stroke
    - CDT is also associated with longer hospital stay and threefold higher hospital costs.



The role of catheter-directed thrombolysis in the current recommendations

- The revised guidelines of the American College of Chest Physicians: anticoagulation therapy alone instead of catheter-directed thrombolysis (CDT) for patients with acute proximal DVT.
  - However, CDT is likely to be offered to patients with low complexity and bleeding risk who have a high risk of post-thrombotic syndrome (PTS).
- European Society for Vascular Surgery guidelines: a selected group of patients with a low bleeding risk and symptomatic iliofemoral DVT could benefit from early thrombus removal strategies (class IIa; level of evidence A)
- Both societies have stated that thrombus removal techniques can be beneficial only for patients presenting with specific criteria:
  - Age (<75 years), type and onset of symptoms (<14 days), DVT location (iliofemoral), patient functional status and life expectancy (>1 year), and a low bleeding risk (ie, no current or recent bleeding diathesis, absence of cancer, renal or liver failure, thrombocytopenia, anticoagulant therapy, recent surgery or trauma, recent stroke, use of nonsteroidal anti-inflammatory drugs)



CaVenT Trial: Study Design

Eligibility (n = 209)

- **Age: 18-75 years**
- **First-time acute iliofemoral DVT**
- **Objectively verified DVT above midthigh level**
- **Symptom duration up to 21 days**
- **No increased risk of bleeding**

R

- **Conventional treatment only* (n = 108)**
- **CDT + conventional treatment (n = 101)**

* Initial low molecular weight heparin (LMWH) and warfarin followed by warfarin alone with target intensity international normalized ratio (INR) of 2.0-3.0

- Randomization was stratified for involvement of the pelvic veins.
- **Primary outcomes:**
  - Frequency of PTS at 24 months, assessed by the Villalta score
  - Iliofemoral patency after 6 months

Enden T et al. *Lancet* 2012;379(9810):31-8.

Villalta Scoring Scale

Five patient-related venous symptoms	Six clinician-rated signs
Pain	Pretibial edema
Cramps	Skin induration
Heaviness	Hyperpigmentation
Paresthesia	Pain during calf compression
Pruritus	Venous ectasia
	Redness

Scoring — Each sign or symptom is rated as:

0 = None
1 = Mild
2 = Moderate
3 = Severe

Summed-up ratings = total score:

- 0-4 = no PTS
- 5-9 = mild PTS
- 10-14 = moderate PTS
- ≥15/venous ulcer = severe PTS

Enden T et al. *Lancet* 2012;379(9810):31-8.

Outcomes: Additional CDT versus Standard Therapy

Outcome	Additional CDT (n = 90)		Standard therapy only (n = 99)		*p*-value
	n	% (95% CI)	n	% (95% CI)	
PTS after 6 mo	27	30.3 (21.8-40.5)	32	32.2 (23.9-42.1)	0.77
PTS after 24 mo	37	**41.1** (31.5-51.4)	55	**55.6** (45.7-65.0)	0.047
Iliofemoral patency after 6 mo*	58	**65.9** (55.5-75.0)	45	**47.4** (37.6-57.3)	0.012

* Five patients had inconclusive patency assessments, and 1 was lost to follow-up. At completion of 24 months of follow-up, 189 patients were available for analysis.

- PTS is defined as a Villalta score ≥5.
- *p*-values stated are from an unadjusted Chi-square test.
- Absolute risk reduction of long-term endpoint PTS at 24 months of follow-up in CDT versus standard therapy: 14.4% (95% CI 4-502).

Enden T et al. *Lancet* 2012;379(9810):31-8.

Adverse Events (AEs)

AEs	Additional CDT (n = 101)	Standard treatment (n = 108)
Bleeding complications	20	0
Major bleeding complications	3	0
Clinically relevant bleeding complications	5	0
Deaths	0	NR
Pulmonary embolisms	0	NR
Cerebral hemorrhages	0	NR
Nonbleeding complications	4	NR
Recurrent VTE at 24 mo	10	18

During follow-up, 28 patients had recurrent VTE and 11 had cancer; no significant difference between treatment groups ($p > 0.05$).

NR = not reported

Enden T et al. *Lancet* 2012;379(9810):31-8.

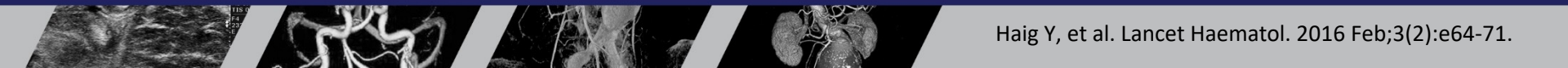
5-year CaVenT

	Adjunctive catheter-directed thrombolysis (n=87)		Standard treatment (n=89)		p value*	Risk difference (absolute risk reduction)
Post-thrombotic syndrome	37	42·5% (32·7–53·0)	63	70·8% (60·6–79·3)	<0·0001	28% (14–42)
Villalta severity category						
Mild (score 5–9)	31/37	83·8% (68·5–92·7)	49/63	77·8% (66·0–86·4)	..	..
Moderate (score 10–14)	2/37	5·4% (0·57–18·6)	13/63	20·6% (12·3–32·3)	..	..
Severe (score >14)	4/37	10·8% (3·7–25·3)	1/63	1·6% (0·0–9·3)	..	..
Iliofemoral patency†	68/86	79·1% (69·2–86·4)	61/86	70·9% (60·6–79·5)	0·218	–8% (–21 to 5)
Femoropopliteal reflux	54/87	62·1% (51·6–71·6)	75/89	84·3% (75·2–90·5)	<0·0004	22% (10–35)

Data are n, n/N, or % (95% CI), unless otherwise stated. *χ^2 test. †Four patients had inconclusive iliofemoral patency assessments at 5 years.

***Table 2*: Post-thrombotic syndrome 5 years after acute deep vein thrombosis**

Table 2: Post-thrombotic syndrome 5 years after acute deep vein thrombosis



Haig Y, et al. Lancet Haematol. 2016 Feb;3(2):e64-71.

5-year CaVenT

	Adjunctive catheter-directed thrombolysis (n=87)	Standard treatment (n=89)	p value*
Quality of life			
EQ-5D	0·78 (0·72–0·84)	0·79 (0·74–0·84)	0·874
Disease-specific quality of life			
VEINES-QOL	50·5 (49·0–52·0)	49·6 (48·2–50·9)	0·365
VEINES-Sym	51·0 (49·4–52·5)	49·1 (47·5–50·6)	0·086

Data are mean (95% CI). *χ^2 test.

Table 3: Quality-of-life scores 5 years after acute proximal deep vein thrombosis

	PTS (n=100)	No PTS (n=63)	p value*
Generic quality of life			
EQ-5D	0·71 (0·66–0·77)	0·88 (0·84–0·92)	<0·0001
Disease-specific quality of life			
VEINES-QOL	47·3 (45·8–48·8)	53·6 (52·7–54·5)	<0·0001
VEINES-Sym	46·6 (45·1–48·2)	54·4 (53·6–55·2)	<0·0001

Data are mean (95% CI). *Mann Whitney *U* test.

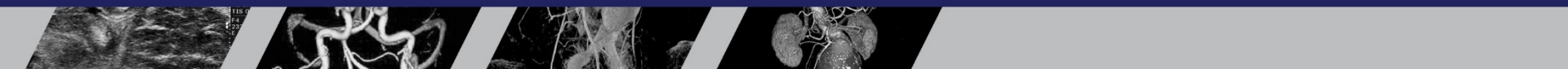
Table 4: Generic and disease-specific quality-of-life scores and symptom severity scores according to post-thrombotic syndrome (PTS) development

- **Allocation to adjunctive CDT vs. standard treatment did not lead to better quality of life.**
- **Patients who did not develop PTS reported higher quality of life scores.**

Haig Y, et al. Lancet Haematol. 2016 Feb;3(2):e64-71.

CaVenT Conclusions

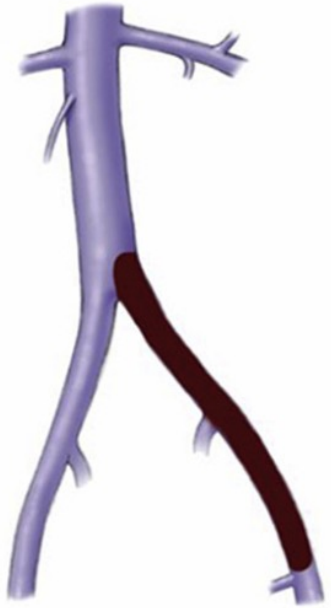
- CDT in addition to anticoagulation improved the clinically relevant 2- and 5- year outcome of decreasing PTS in patients diagnosed with iliofemoral DVT. In patients with a low a priori bleeding risk without contraindications, the addition of CDT should be considered.
  - No significant difference was observed in PTS between adjunctive CDT and conventional therapy at 6 months of follow-up ($p = 0.77$).
    - It takes longer than 6 mos to develop PTS, patients with a short life expectancy should not be offered CDT.
- CaVenT is the first relatively methodologically sound trial to show a statistically significant benefit of interventional therapy vs. anticoagulation alone in the risk of developing PTS
  - Even though the *p*-value of 0.047 was just under statistical significance of 0.05, ARR 14% in PTS as reflected by Villalta at 2 years is academically important as this result supports the **open vein hypothesis**.
- The CaVenT studies provided the foundational data for future investigations and innovations intended to restore venous patency to mitigate the risk of PTS.



Quality Of Life (QOL) After Pharmacomechanical Catheter-Directed Thrombolysis (PCDT) For Proximal Deep Vein Thrombosis (DVT)

ATTRACT Trial (Randomized Controlled Study)

691 patients with proximal (femoral-popliteal and iliofemoral) DVT



- ✓ **In patients with proximal DVT, PCDT resulted in greater improvement in disease-specific QOL than no PCDT, at 1 month and 6 months, but not later.**
- ✓ **In patients with iliofemoral DVT, PCDT led to greater improvement in disease-specific QOL during 24 months.**

JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Kahn et al. *J Vasc Surg Venous Lymphat Disord*, January 2020

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Catheter-Directed Thrombolysis

- CaVenT and ATTRACT support CDT to reduce PTS in patients with iliofemoral DVT
- Although beneficial, there are still significant risks associated with this therapy.
- **ATTRACT**:

Outcome	PCDT (n=336)	No PCDT (n=355)	P-Value
Major Bleeding (10 Days)	1.7%	.3%	.049
Any Bleeding (10 Days)	4%	2%	.03

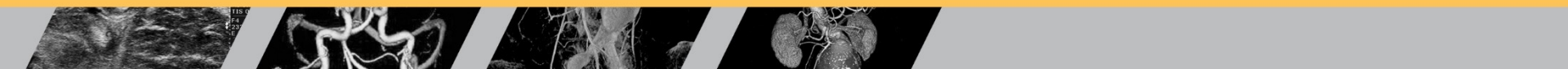
tPA is associated with **5×** higher bleeding risk

- **CaVenT**:

AEs	Additional CDT (n = 101)	Standard treatment (n = 108)
Bleeding complications	20	0
Major bleeding complications	3	0
Clinically relevant bleeding complications	5	0

tPA is associated with **3x** higher bleeding risk

- Alternative methods for rapid clot removal without lysis should be sought.



Catheter-Directed Thrombolysis (CDT) Versus Anticoagulation in Cancer Patients with Proximal Deep Vein Thrombosis (DVT)

Retrospective review of the NIS database

31,124 cancer patients with proximal DVT (4% treated with CDT)

CDT vs. Anticoagulation

No difference in In-Hospital Mortality

2.6% vs **1.9%**
p=.23

but

CDT increased the risk of :

Intracranial Hemorrhage	**1.3%** vs **0.4%**	P=.017
Blood Transfusion Rates	**18.6%** vs **13.1**	P<.001
Post-Procedure Hematoma	**2.4%** vs **0.4%**	P<.001

JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Brailovsky et al. *J Vasc Surg Venous Lymphat Disord, July 2020*

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Predictors of Intracranial Hemorrhage (ICH) in Patients Treated with Catheter-Directed Thrombolysis (CDT) for Deep Vein Thrombosis (DVT)

Review of National Inpatient Sample Database

7119 patients with proximal DVT treated with CDT

Rate of ICH with CDT

0.7%

Predictors of ICH

- History of Stroke
- CKD*
- Male Sex
- Age > 74 Years

*Chronic Kidney Disease

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Lakhter et al. *J Vasc Surg Venous Lymphat Disord, May 2021*

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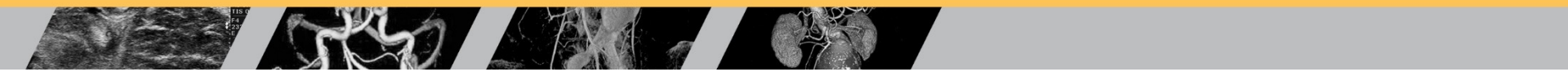
CDT outcomes

- Technical success rates with CDT alone range from 83% to 100%.
- Achieving thrombus clearance of >90% is of paramount importance.
- Primary patency of 85% is achieved with >50% clot removal compared to 36% primary patency in limbs with significant residual disease.
- CDT + stent, Avgerinos et al. 2019 demonstrated technical success in more 90% of patients with a 1-year primary stent patency of 83.1%.
  - Incomplete lysis (<50% thrombus clearance) predicts:
    - Stent thrombosis HR 7.41
    - Development of PTS within 5 years
- **Why is technical success not uniform?**

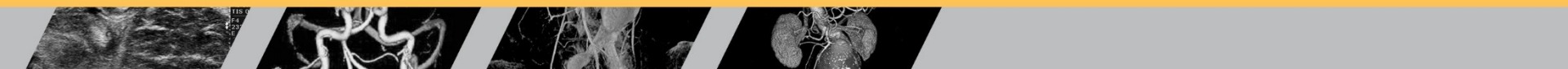
1. Park YJ, et al. Eur J Vasc Endovasc Surg 2008
2. Vedantham S, et al. N Engl J Med 2017
3. Comerota AJ, et al. Circulation 2019
4. Haig Y, et al. Lancet Haematol 2016
5. Mewissen MW, et al. Radiology 1999
6. Avgerinos E, et al. J Vasc Surg Venous Lymphat Disord 2019



The Composition of Thrombus Changes Over Time

- Thrombus composition changes over time [1]
  - Fibrin-rich matrix becomes more collagenic in nature
  - Thrombus becomes more resistant to thrombolytics
- Clinical symptoms are often used to estimate thrombus composition and determine effective treatment
- DVT may not be a singular event
  - Acute thrombus may occur along with chronic DVT
  - Leads to mixed-morphology thrombus and difficulty in assessing thrombus chronicity
- DVT can be asymptomatic for days to weeks, which may result in thrombus that is more chronic than expected [2,3]
- An effective DVT treatment for a range of thrombus chronicity is needed

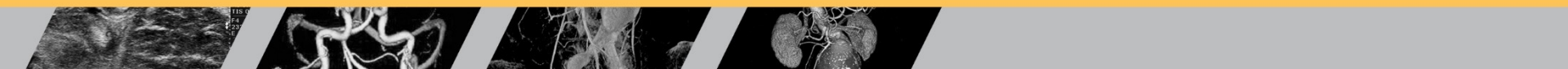
1. Czaplicki et al, Cardiovasc Diagn Ther. 2017
2. Silver et al, Catheter Cardiovasc Interv. 2021
3. Yuriditsky et al, J Vasc Surg Venous Lymphat Disord. 2022



Challenges with DVT and Chronic Thrombus

- Thrombus may be more chronic than anticipated
- Residual thrombus is predictive of long-term sequelae including PTS, rethrombosis, and reduced QoL
- Efficacy of catheter-directed therapy diminishes with thrombus age
  - Thrombolytics are known to be ineffective against collagen
  - 20% collagen content in thrombus at 1 week, 80% by 3 weeks[1]

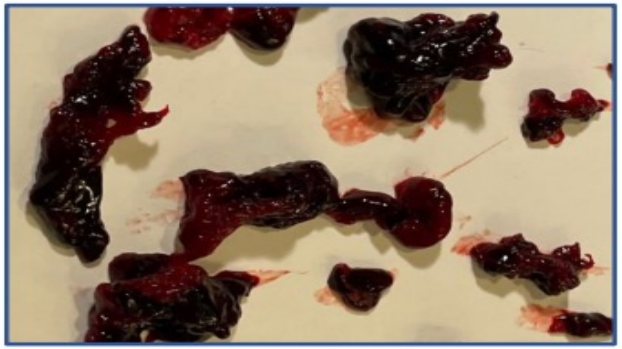
[1] Czaplicki C et al, 2017 Cardiovasc Diagn Ther 7: S186-S196.



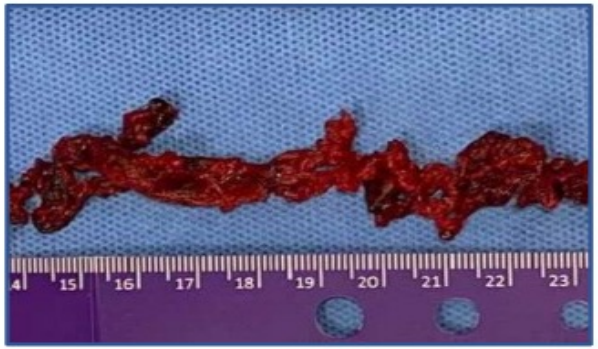
Thrombus Chronicity Assessed by Treating Physician*

- **Primary Measure:** Post-thrombectomy visual inspection of thrombus morphology
- **Additional Measures:** Pre-procedure medical history and intra-procedure imaging

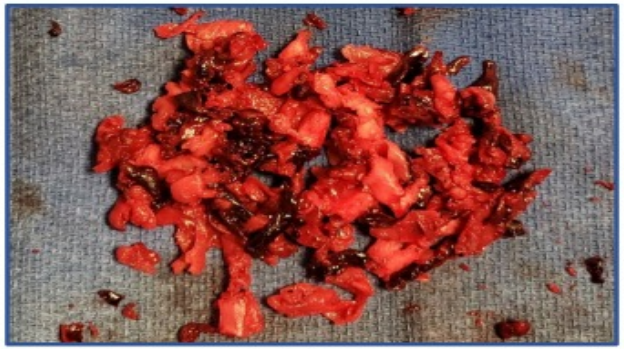
Post-Thrombectomy Thrombus Chronicity Definition



Acute
< 2 weeks; soft, dark red



Subacute
2-6 weeks; light red



Chronic
> 6 weeks; firm, white

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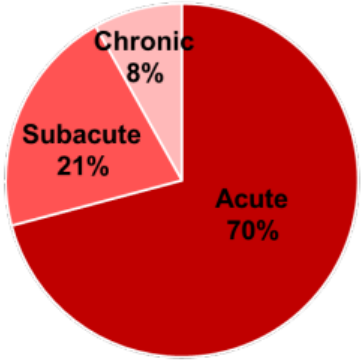
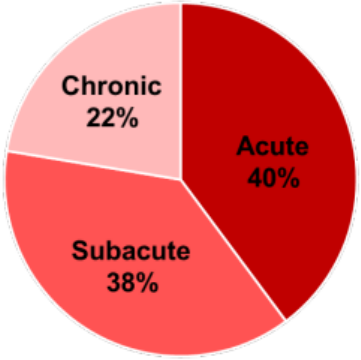
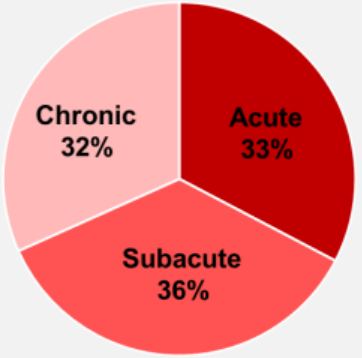
Thrombus Chronicity

Pre-Procedure Medical History	Intra-Procedure Imaging	Post-Thrombectomy Visual Inspection
		

With intra-procedure imaging and post-thrombectomy visual inspection, thrombus was found to be more often subacute and chronic

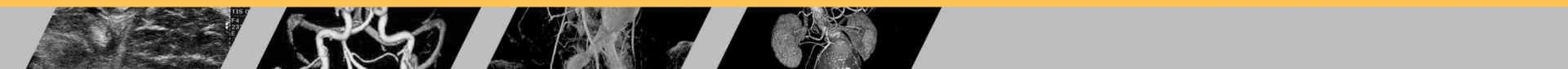
Dexter DJ. J Vasc Surg Venous Lymphat Disord. 2022

The Composition of DVT Changes Over Time

- Pre-history is not reliable
- Imaging is not reliable
- More often DVT composition is more fibrous, therefore thrombolysis will not be effective
- Catheter-directed thrombolysis is associated with **incomplete revascularization**, **bleeding complications, long procedural time,** and **significant morbidity**.
- To be optimally effective, we should use mechanical thrombectomy
  - Both venous and arterial indications

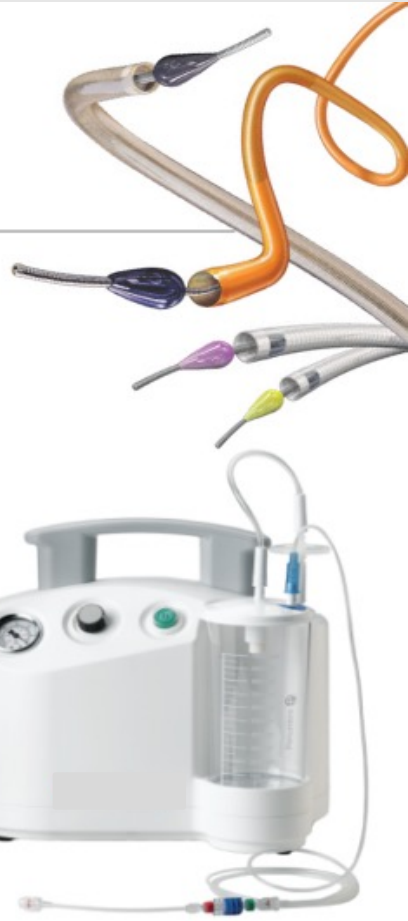
Mechanical Thrombectomy

- Extraction of Thrombus without the use of thrombolytic agents
- Advantages
  - Remove thrombi and emboli in one setting and treat the underlying stenosis
  - Able to treat large and small vessel sizes
  - Reduce the need for thrombolytic therapy
  - Still have other treatment options open, if needed
- Disadvantages
  - Catheters that pass into small vessels can be traumatic
  - Ineffective force to remove subacute thrombus



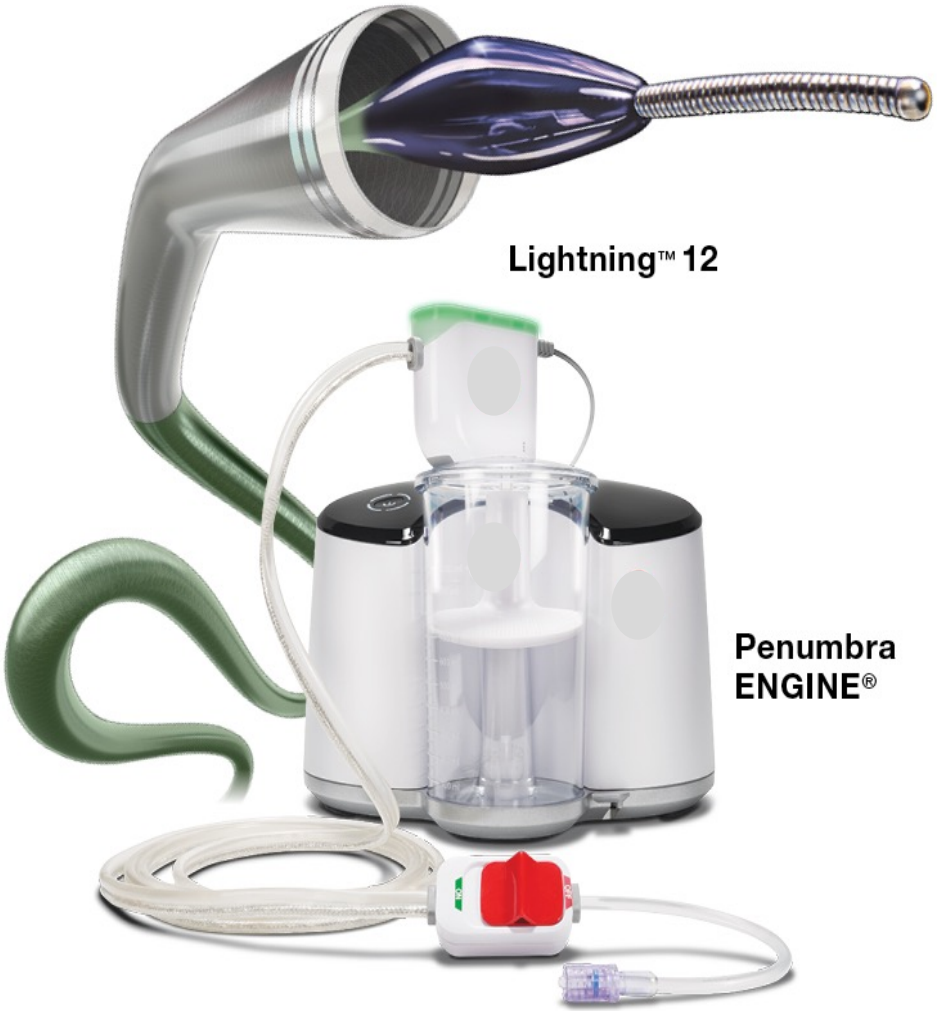
The Penumbra/Indigo System

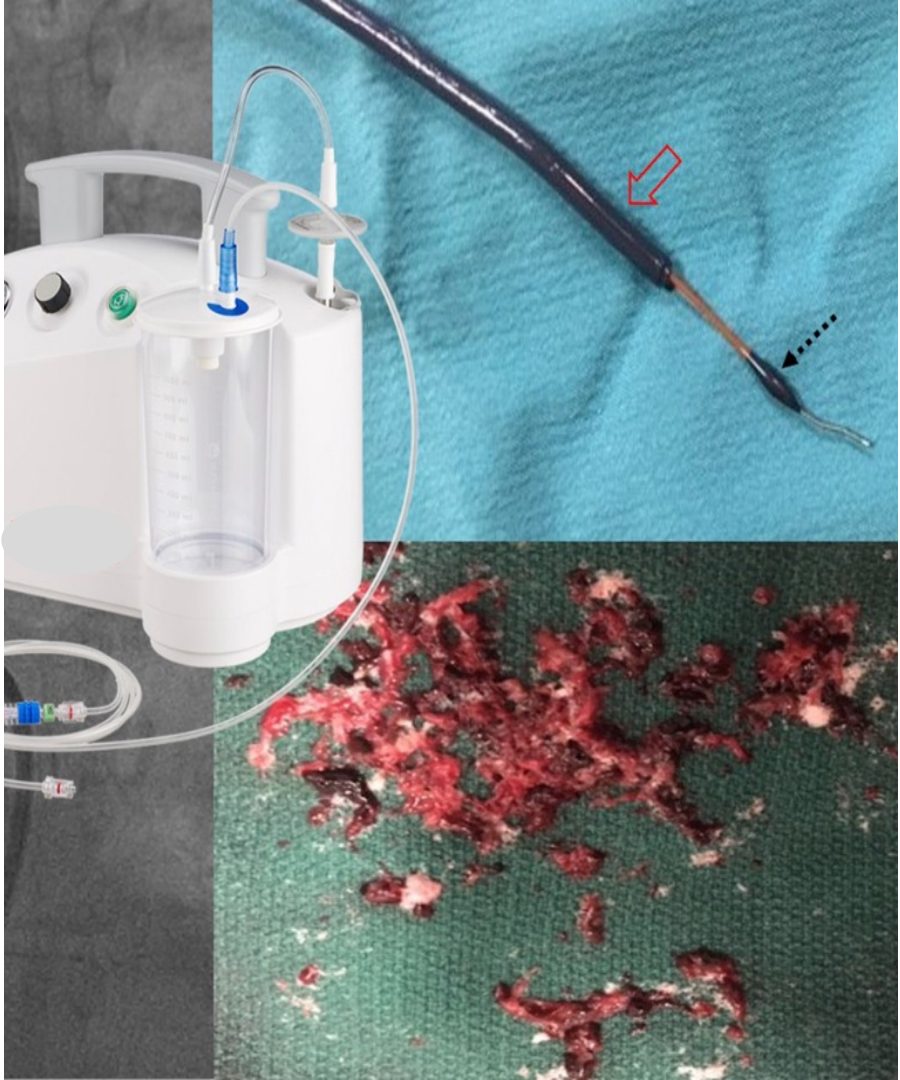
- The Penumbra/Indigo System, a highly trackable, effective aspiration system with a proven track record of success in ischemic stroke therapy, was designed for thrombi and emboli recovery in vessels of the periphery
- May help reduce overall procedural time and improve outcome while also minimizing complications



Indigo System Innovation of Catheters

	CAT 3	CAT 5	CAT 6	CAT 8	CAT D
					
Compatibility (Sheath/Guide)	**4.1 F** Compatibility	**6 F** Compatibility	**6 F** Compatibility	**8 F** Compatibility	**8 F** Compatibility
Working Length	**150 cm** Length	**132 cm** Length	**135 cm** Length	**85 & 115 cm** Length	**50 cm** Length
Wire Platform	Wire Platform **.014–.025"**	Wire Platform **.014–.038"**	Wire Platform **.014–.038"**	Wire Platform **.014–.038"**	Wire Platform **.014–.038"**
Compatible Penumbra Devices	Separator™ **3**	Separator **5**	Separator **6**	Separator **8**	Separator **D**
				Tip Shapes Straight *(85 cm)* Torq *(85 cm)* Xtorq *(115 cm)*	


Lightning™ 12
Penumbra
ENGINE®



JVIR
Journal of Vascular and Interventional Radiology
Society of Interventional Radiology

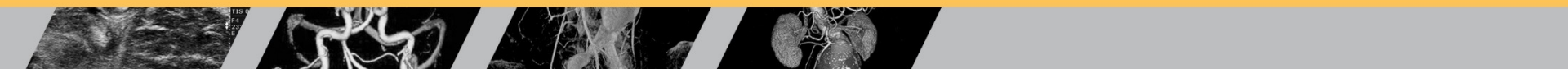
CLINICAL STUDY | VOLUME 29, ISSUE 1, P92-100, JANUARY 01, 2018

Utility of a Power Aspiration–Based Extraction Technique as an Initial and Secondary Approach in the Treatment of Peripheral Arterial Thromboembolism: Results of the Multicenter PRISM Trial

Richard R. Saxon, MD • James F. Benenati, MD • Corey Teigen, MD • George L. Adams, MD, MHS • Luke E. Sewall, MD • for the PRISM Trialists

Published: November 09, 2017 • DOI: https://doi.org/10.1016/j.jvir.2017.08.019 • Check for updates

- The multicenter, single-arm PRISM Trial sought to investigate the use of the Penumbra/Indigo® System for thrombectomy in the peripheral and visceral systems. Including patients with:
  - Peripheral occlusions with acute ischemia
  - Incomplete reperfusion after other interventions
  - Procedure-related distal emboli



BOLT: Study of the Indigo® Aspiration System When Used in Patients With Deep Vein Thrombosis

Study Description

Go to

Brief Summary:

The objective of this study is to demonstrate the safety and efficacy of the Indigo Aspiration system for percutaneous mechanical thrombectomy in a population presenting with obstruction due to deep vein thrombosis (DVT) who are eligible for treatment.

Condition or disease	Intervention/treatment	Phase
Deep Vein Thrombosis DVT	Device: Indigo Aspiration System	Not Applicable

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	400 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	BOLT: A Prospective, Multicenter Study of Patients With Deep Vein Thrombosis to Evaluate the Safety and Efficacy of the Indigo® Aspiration System
Actual Study Start Date :	September 30, 2021
Estimated Primary Completion Date :	July 2023
Estimated Study Completion Date :	September 2025

SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8

PATIENT HISTORY

A 25-year-old baseball player was evaluated for right arm pain and discoloration. Imaging confirmed right right axillosubclavian DVT due to venous thoracic outlet syndrome.

A two-stage treatment process was explained to the patient—first resolving the current clot and then surgical decompression of the underlying compression.

SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8

INTERVENTION

- A Turbo Pulse technique (Figure 1) was employed first to soften the DVT before removing it with a CAT8 catheter attached to the Penumbra ENGINE power aspiration system.
- Initial right upper extremity venography from a basilic vein access confirms the presence of thrombus in the axillosubclavian vein (Figure 2).

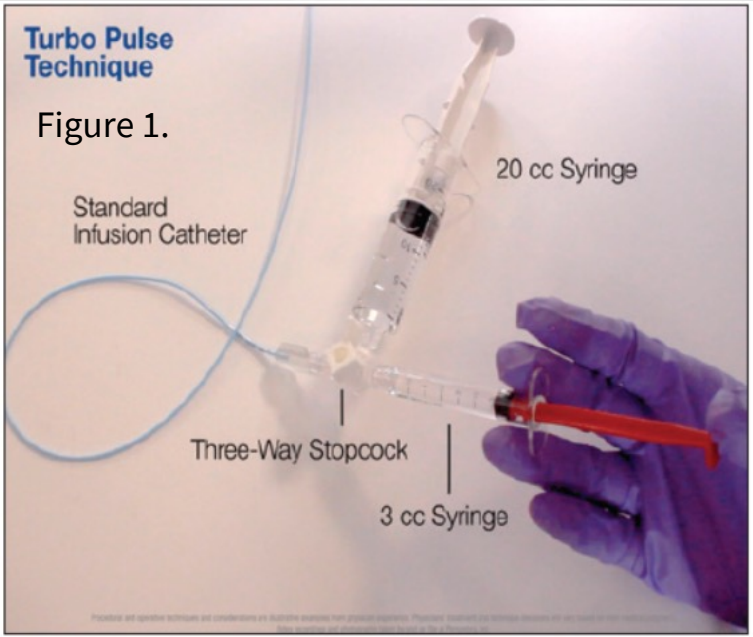


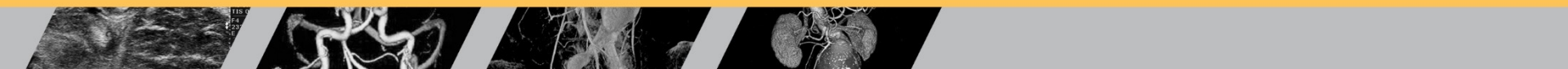
Figure 1.

Figure 2. Right UE venogram showing thrombus in the axillosubclavian vein with collaterals.

SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8

INTERVENTION

- Due to the subacute nature of the thrombus burden, the clot was infused with 8 mg of tPA using the Turbo Pulse technique through a 10-cm Unifuse™ infusion catheter (AngioDynamics) and allowed to dwell for 15 minutes.
- The Indigo System's CAT8 and Penumbra ENGINE achieved near-complete thrombus resolution.
- Completion venography after balloon venoplasty of the compression with a 10-mm Mustang™ balloon catheter (Boston Scientific Corporation) demonstrates persistent compression due to TOS, however, there is a patent channel from the upper arm through the superior vena cava (Figure 3).



SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8

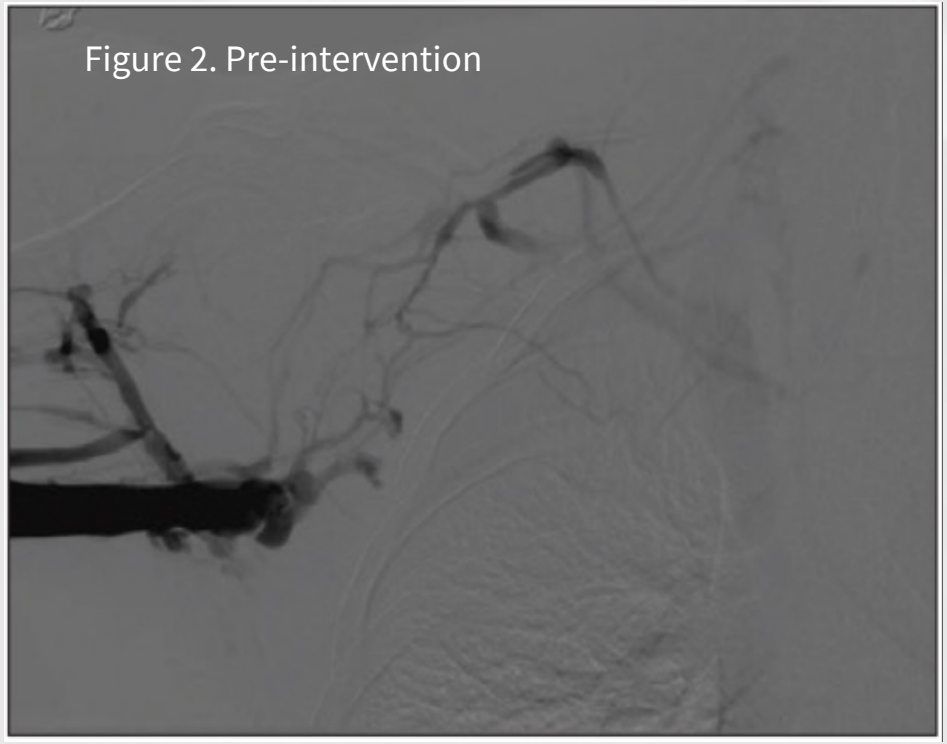


Figure 2. Pre-intervention

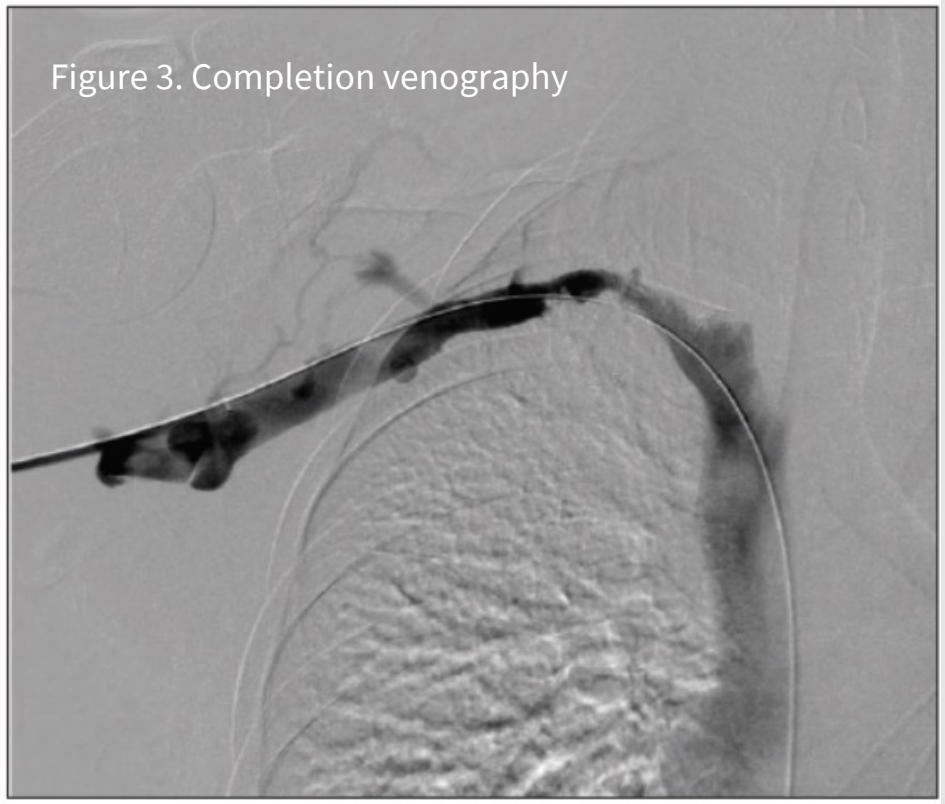


Figure 3. Completion venography

SINGLE-SESSION MANAGEMENT OF AXILLOSUBCLAVIAN DVT USING THE TURBO PULSE TECHNIQUE AND INDIGO SYSTEM CAT8

DISCUSSION

- This patient was effectively treated with thrombectomy and interval surgical decompression and is asymptomatic at 1 year.
- Single-session management of DVT using the Penumbra/Indigo System CAT8 with Turbo Pulse allows us to treat properly selected patients without ICU admission for overnight lysis thus reducing the dose and duration of tPA and its inherent risks. Data recently presented at VEITHsymposium showed a 100% technical success rate with venous patency until the day of rib resection and no distal embolization resulting in PE.[1]

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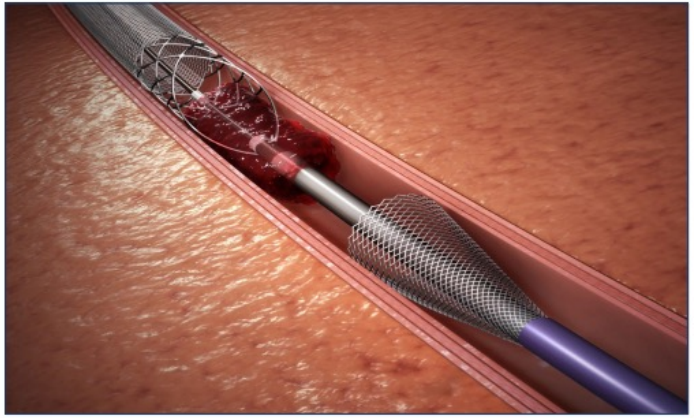
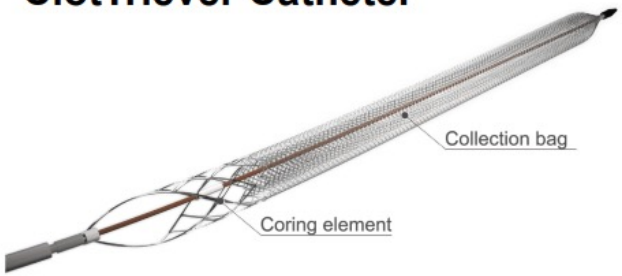
ClotTriever® Thrombectomy System

The ClotTriever System is a mechanical thrombectomy device designed to remove large thrombi from large vessels in a single session, without the need for thrombolytic drugs or consequent ICU stay

ClotTriever Sheath



ClotTriever Catheter



Intended for use in the peripheral vasculature, including DVT

Technical Success And Short-Term Outcomes After Treatment Of Lower Extremity Deep Vein Thrombosis (DVT) With The ClotTriever System

Retrospective cohort study

12 patients with DVT (11 iliofemoral, 1 femoropopliteal)

PROCEDURE

Percutaneous thrombectomy with ClotTriever® System*

*Inari Medical Inc., Irvine, California

Access:

Popliteal Vein	92%
Small Saphenous Vein	8%

Iliac vein stenting:

67% (8/12)

No Lytic therapy!

Mean Follow-up:

4 months (1 – 10)

RESULTS

- ☑ **Complete clot evacuation: 100%**
- ☑ **Average length of stay: 2 days**
- ☑ **ICU admission None**
- ☑ **30-day mortality: 8.3%**
  (1 death due to metastatic cancer)
- ☑ **Symptoms resolved or greatly improved 90%**
  (10/11)
- ❗ **Reocclusion 20%**
  (2/10)

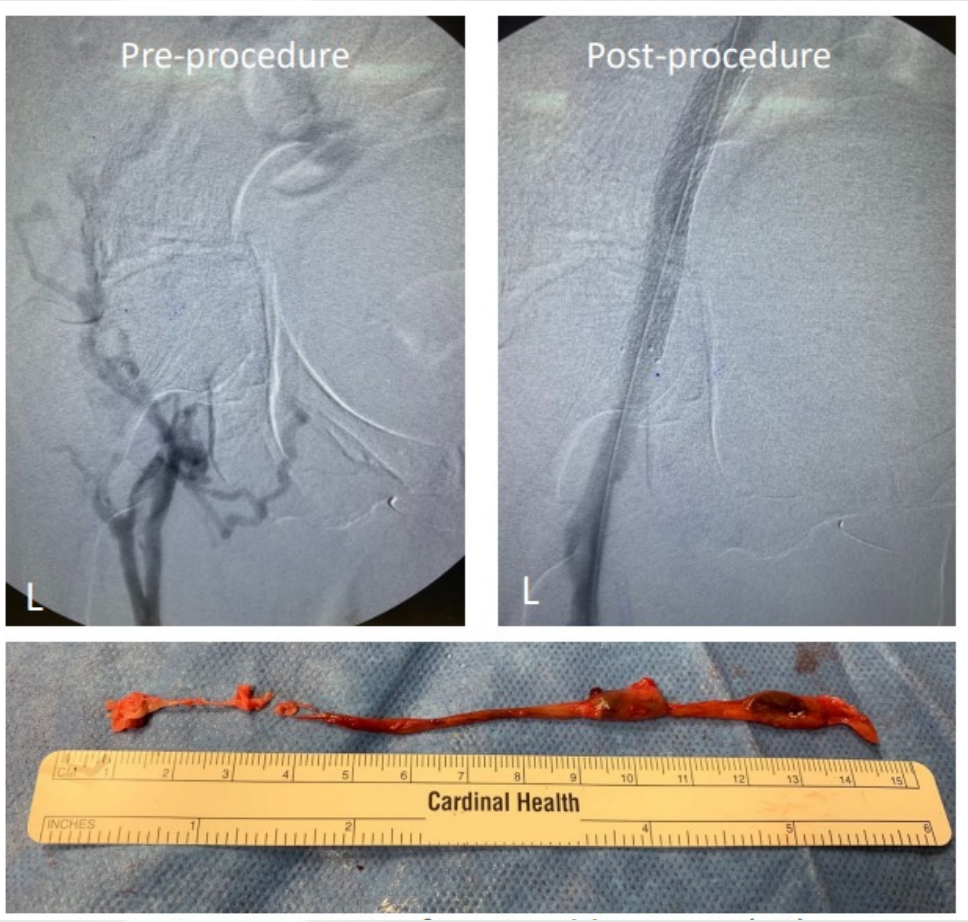
JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Benarroch-Gampel et al. *J Vasc Surg Venous Lymphat Disord, March 2020*

@JVascSurg @TheJVascSurg

Case Example

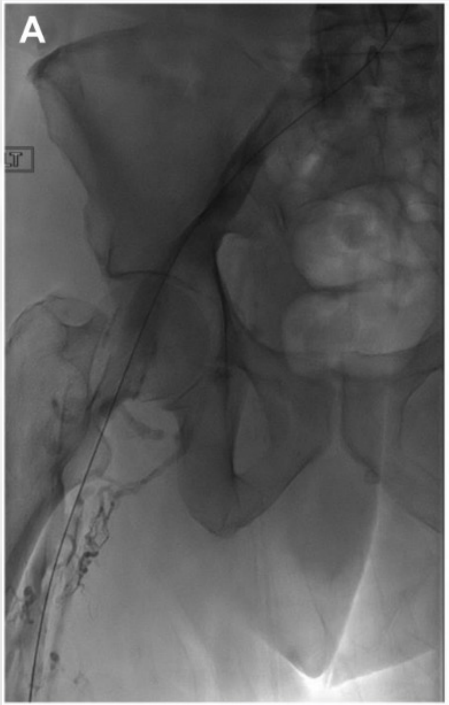
- A 73- year old female, history of DVT for 3 mos with persistent leg edema and treated with Eliquis
- Popliteal access
- 7 total ClotTriever passes with PTA
- Venovo stent in LEIV
- Discharged the same day

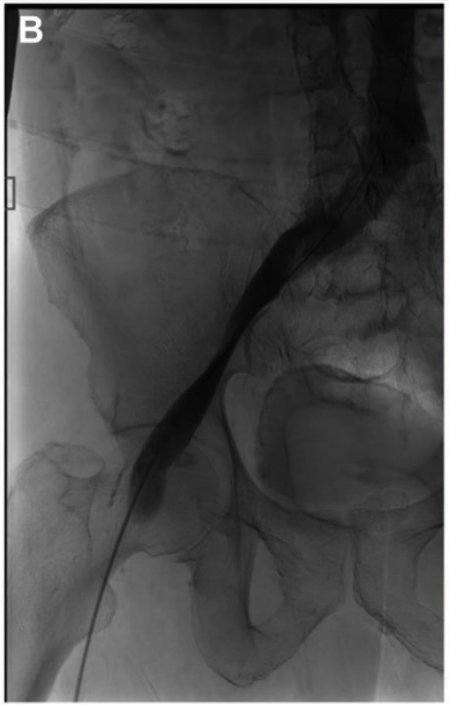


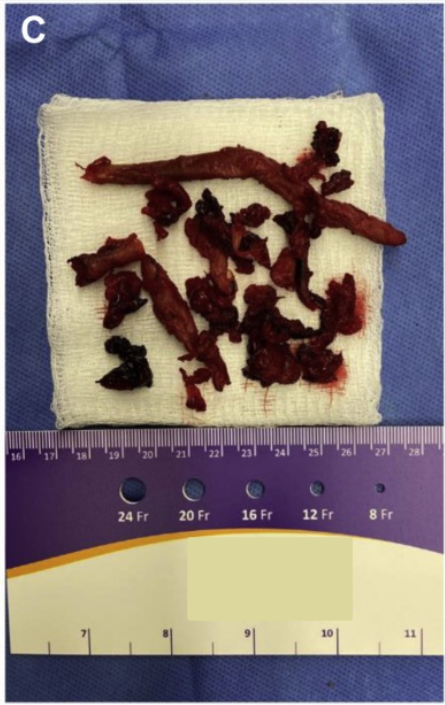
Case courtesy of Dr. Gerald Fortuna, Washington University, St. Louis, MO

Case Example

A 58-year-old man diagnosed with unilateral deep vein thrombosis (DVT) of the left lower extremity with complete occlusion of the external iliac and common femoral veins. ClotTriever was used with PTA resulting in 100% thrombus removal with an estimated blood loss of 10 mL. The patient avoided the intensive care unit (ICU) and was discharged after 48 hours. Venograms (A) before and (B) after thrombectomy show restoration of flow with the extracted thrombus (C and D).







Case images courtesy of Dr Hamid Mojibian, Yale University School of Medicine, New Haven, CT

CLOUT (ClotTriever Outcomes) Registry

Design	Objective	Enrollment
Prospective Multicenter Registry	Evaluate real world patient outcomes after treatment of acute, subacute, and chronic proximal lower extremity DVT with the ClotTriever System	Up to 500 patients with proximal lower extremity DVT at up to 50 sites

Primary Effectiveness Endpoint:

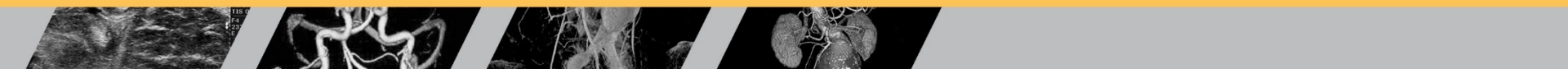
- Technical success
  - Complete or near complete (≥75%) removal of venous thrombus via core lab-adjudicated Marder score

Primary Safety Endpoint:

- Composite of Major Adverse Events through 30 days:
  - All-cause mortality
  - Major bleeding
  - New symptomatic PE documented by CTPA
  - Rethrombosis of a target venous segment

Variables Collected		
Baseline	**Procedure**	**Follow-up (30d, 6m, 1y, 2y)**
• Medical history • Duplex US • Villalta • rVCSS • EQ-5D QoL • NPRS pain scale • Edema	• Residual thrombus via core lab Marder score • Acute safety	• Duplex US • Villalta • rVCSS • EQ-5D QoL • NPRS pain scale • Edema

Interim analysis of acute outcomes (≤30 days) of 64 **chronic** (>6 weeks) thrombus DVT patients enrolled at 14 sites out of 189 total CLOUT patients



Interim outcomes of mechanical thrombectomy for deep vein thrombosis from the All-Comer CLOUT Registry

David J. Dexter, MD,[a] Herman Kado, MD,[b,c] Jonathan Schor, MD,[d] Suman Annambhotla, MD,[e] Brandon Olivieri, MD,[f] Hamid Mojibian, MD,[g] Thomas S. Maldonado, MD,[h] Sagar Gandhi, MD,[i] Joseph Paulisin, DO,[j] Matthew C. Bunte, MD, MS,[k] Wesley Angel, MD,[l] Jon Roberts, MD,[l] Kalyan Veerina, MD,[m] Steven Abramowitz, MD,[n] Fakhir Elmasri, MD,[o] Jeffrey Hnath, MD,[p] Matthew Jung, MD,[q] Daniel Long, MD,[r] Luis Sanchez, MD,[s] Octavio Cosme, MD,[t] Edvard Skripochnik, MD,[u] Ankur Lodha, MD,[v] Abdullah Shaikh, MD,[w] Christopher King, MD,[x] Mohannad Bisharat, MD,[y] *and and* Robert E. Beasley, MD,[z] for the CLOUT Investigators,

Norfolk, VA; Farmington Hills and Royal Oak, MI; Staten Island, NY; Gainesville, GA; Miami, FL; New Haven, CT; New York, NY; Greenville, SC; Bay City, MI; Kansas City, MO; Germantown, TN; Opelousas, LA; Washington, DC; Lakeland, FL; Albany, NY; Louisville, KY; Cincinnati, OH; St. Louis, MO; Tampa, FL; Lafayette, LA; Pittsburgh, PA; Birmingham, AL; Jacksonville, FL; and Miami Beach, FL

ABSTRACT

Objectives: The multicenter, prospective, single arm CLOUT registry assesses the safety and effectiveness of the Clot-Triever System (Inari Medical, Irvine, CA) for the treatment of acute and nonacute lower extremity deep vein thrombosis (DVT) in all-comer patients. Reported here are the outcomes of the first 250 patients.

Methods: All-comer patients with lower extremity DVT were enrolled, including those with bilateral DVT, those with previously failed DVT treatment, and regardless of symptom duration. The primary effectiveness end point is complete or near-complete (≥75%) thrombus removal determined by independent core laboratory-adjudicated Marder scores. Safety outcomes include serious adverse events through 30 days and clinical outcomes include post-thrombotic syndrome severity, symptoms, pain, and quality of life through 6 months.

Results: The median age was 62 years and 40% of patients had contraindications to thrombolytics. A range of thrombus chronicity (33% acute, 35% subacute, 32% chronic) was observed. No patients received thrombolytics and 99.6% were treated in a single session. The median thrombectomy time was 28 minutes. The primary effectiveness end point was achieved in 86% of limbs. Through 30 days, one device-related serious adverse event occurred. At 6 months, 24% of patients had post-thrombotic syndrome. Significant and sustained improvements were observed in all clinical outcomes, including the Revised Venous Clinical Severity Score, the numeric pain rating scale, and the EuroQol Group 5-Dimension Self-Report Questionnaire.

Conclusions: The 6-month outcomes from the all-comer CLOUT registry with a range of thrombus chronicities demonstrate favorable effectiveness, safety, and sustained clinical improvements. (J Vasc Surg Venous Lymphat Disord 2022;■:1-9.)

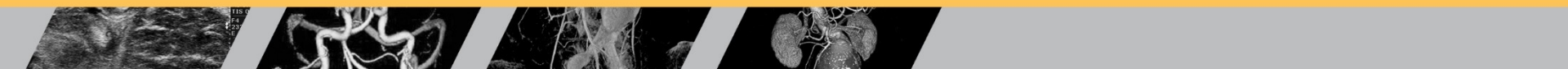
Keywords: Deep vein thrombosis; Mechanical thrombectomy; Post-thrombotic syndrome

Safety Results (≤30 days)

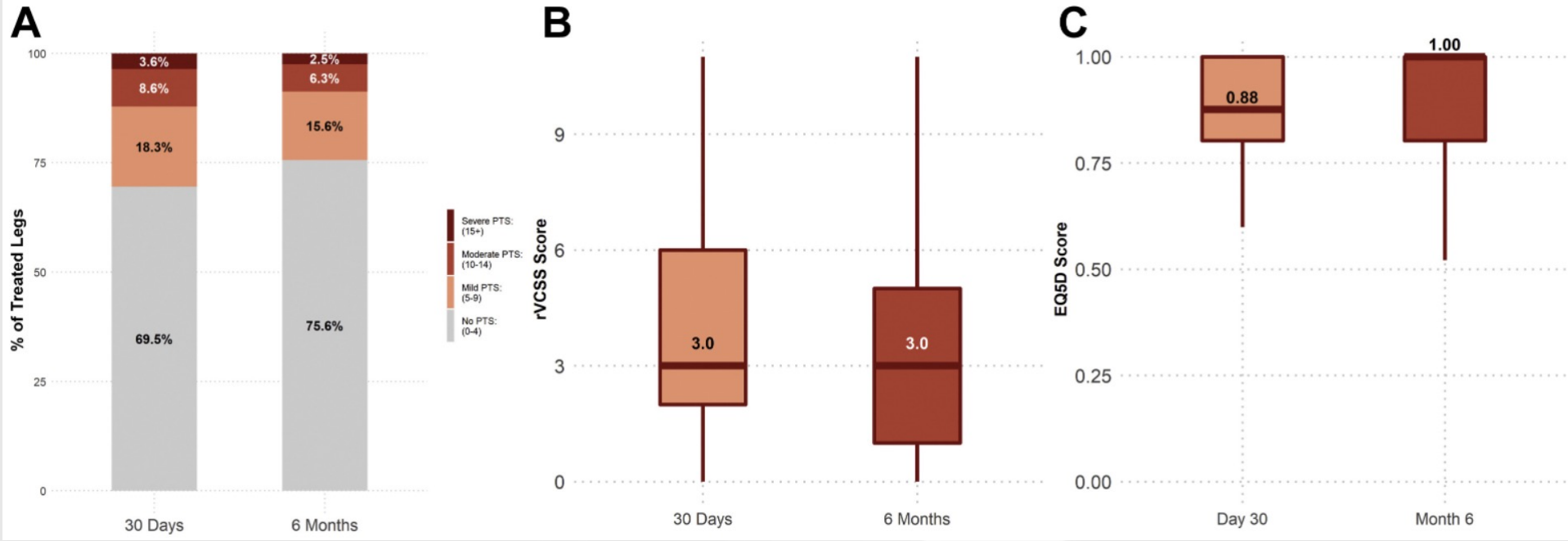
Characteristic	n (%)
SAE through 30 days	5 (7.8%)
Rethrombosis of target venous segment	3 (4.5%)
Major bleeding complications	1 (1.6%)
Pulmonary Embolism	1 (1.6%)
Acute renal injury	0 (0%)
Deaths	0 (0%)

N = 64

- No device-related SAEs
- Rethrombosis events
  - 1 day post-procedure from untreated inflow lesion
  - 9 days post-procedure
  - 13 days post-procedure
- 1 major access site bleed precipitated by patient ambulation
- 1 symptomatic PE, 1 day post-procedure

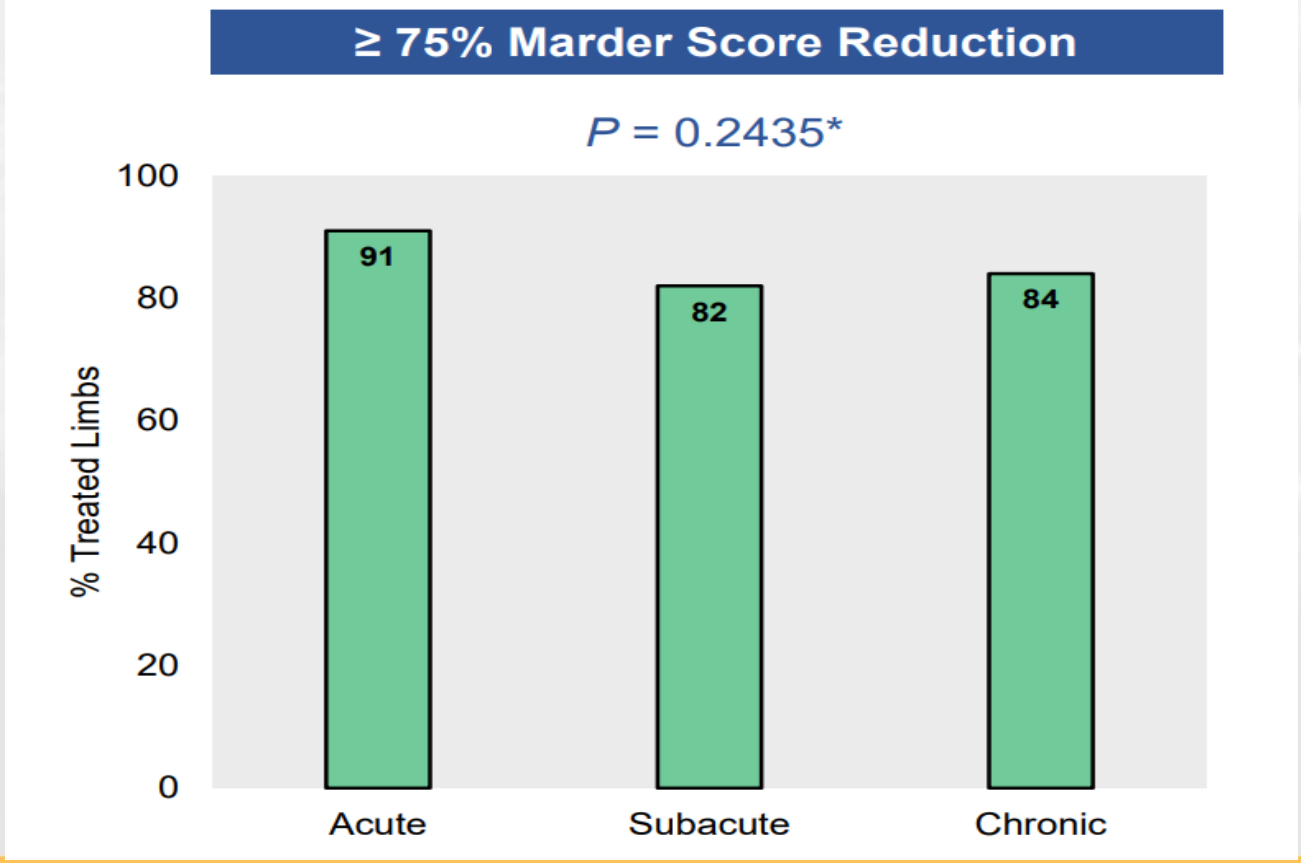


6-month CLOUT Results



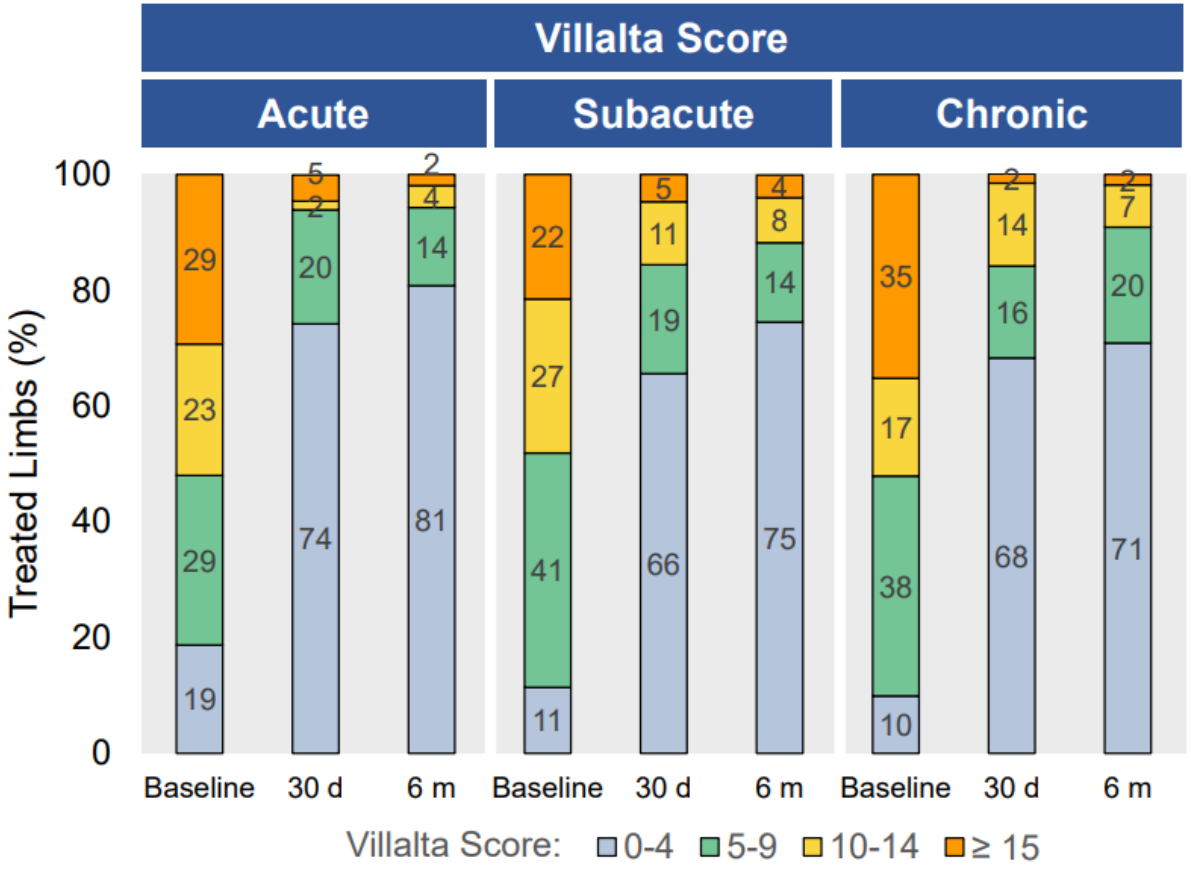
Other clinical outcomes through 6 months. Percentage of treated limbs categorized using Villalta scores at 30 days and 6 months after the procedure. Villalta score categories: no post-thrombotic syndrome (*PTS*): Villalta of <5; mild PTS, Villalta of 5-9; moderate PTS, Villalta of 10-14; and severe PTS, Villalta of ≥15. (A) Box-and-whisker plots showing Revised Venous Clinical Severity Score (*rVCSS*) (B), and EuroQol group 5-dimension self-report questionnaire (*EQ-5D*) Quality of life score (C) (n = 159-197 limbs and 157-196 patients).

Effective thrombus removal in all subgroups



Dexter DJ. J Vasc Surg Venous Lymphat Disord. 2022

Sustained Villalta Score & PTS Improvements



PTS

Any PTS at 6 m

P = 0.4987*

- Acute: 19.2%
- Subacute: 25.5%
- Chronic: 29.1%

Mod to Sev PTS at 6 m

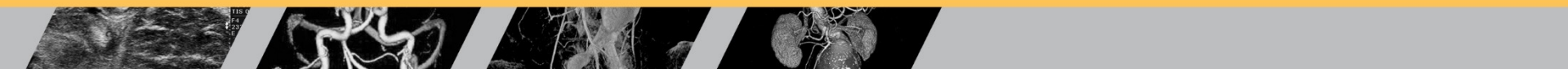
P = 0.5702*

- Acute: 5.8%
- Subacute: 11.8%
- Chronic: 9.1%

Dexter DJ. J Vasc Surg Venous Lymphat Disord. 2022

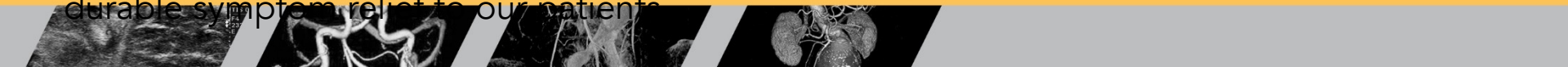
CLOUT Conclusions

- In this interim analysis from the CLOUT registry, the ClotTriever System demonstrated successful treatment of a range of thrombus chronicities within an all-comer DVT patient population with a favorable efficacy and safety profile without the need for thrombolytic drugs or consequent ICU stay
- The primary effectiveness end point of complete or near-complete (≥75%) thrombus removal was achieved in 85.8% of treated limbs.
- Mechanical thrombectomy with the ClotTriever System is a safe procedure with a low 0.4% rate of device-related SAEs through 30 days.
- Clinically and statistically significant improvements in outcome measures
  - Substantial improvements in Villalta scores, PTS rates, NPRS pain scores, rVCSS, and EQ-5D QoL through 6 months
  - Only 24% of treated limbs had PTS at 6 months, with moderate to severe PTS seen in less than 9%
- In the CLOUT registry, patient follow-up will continue out to 2 years to further examine the long-term clinical outcomes after mechanical thrombectomy using ClotTriever System.



Summary

- Multiple RCTs have found symptomatic benefit of early percutaneous DVT debulking in accordance with the open vein hypothesis.
- Multiple academic and clinical venous societies have incorporated percutaneous treatment recommendations into clinical guidelines for the treatment of DVT.
- Although anticoagulation and compression remain the mainstay of treatment, patients with moderate to severe swelling and pain, low bleeding risk, and good life expectancy could potentially be treated with a combination of pharmacological and mechanical thrombectomy methods.
- CDT procedures are generally safe but do confer an increased risk of bleeding.
- Mechanical thrombectomy is safe, effective across all thrombus subtypes, and yields improvement in all clinical outcomes assessed without the morbidity associated with tPA.
- Regardless of the treatment modality, physicians should strive for complete thrombus clearance assessed using IVUS, and residual disease should be stented to mitigate the risk of PTS.
- With the increasing popularity of percutaneous thrombus removal, it is essential to familiarize oneself with the who, when, and how of venous thrombosis treatment to provide effective and durable symptom relief to our patients.



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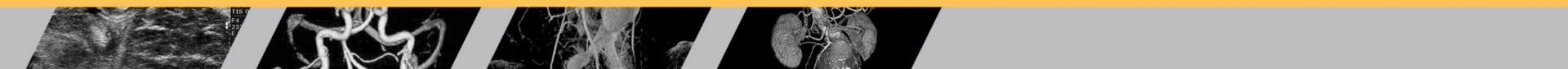

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Conclusion

Can We Do This Without Thrombolysis?

YES.

Thank you.