Veith Symposium 2024

Have Venous Trials Changed The Management of Ilio-Femoral DVT in 2024?

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Faculty Disclosure

- None

Ilio-Femoral DVT: Endovascular Intervention

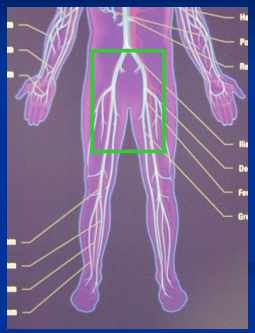
Venous Thromboembolism (DVT & PE)

- >2 million Deep vein thrombosis
- >200,000 deaths from pulmonary embolism
- Even after 6 months of anticoagulation following first VTE event, risk of subsequent VTE is increased by 5-12% annually.

Ilio-Femoral DVT

Endovascular Specialists:

- View ilio-femoral DVT as fundamentally different from physiologic/anatomic considerations as well as more severe disease manifestation
- BUT it is rarely distinguished from other forms of DVT by other physicians.



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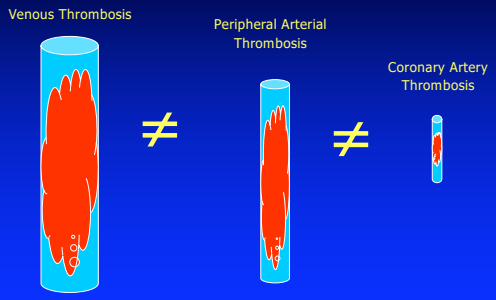
Not All Clots Are Created Equal



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Post thrombotic syndrome

- Most physicians treat all cases of proximal DVT the same.
- MUST differentiate between iliofemoral DVT and infrainguinal DVT.
- Iliofemoral DVT ⟶ Virulent post-thrombotic morbidity.

20 -60% of Pts with DVT
800,000/Yr cases of Post-Thrombotic Syndrome

Incidence and cost burden of post-thrombotic syndrome.
AU
Ashrani AA, Heit JA
J Thromb Thrombolysis. 2009 Nov;28(4):465-76.

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Ilio-Femoral DVT
Long Term Clinical Status and QOL

- ***Conclusions***
- Venous claudication developed in almost 50%
- Limited ambulation in 15%
- Marked hemodynamic impairment
- Markedly reduced QOL

Delis KT et al
Ann Surg 2004;239(1):118

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Anticoagulation

DOES

- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis

DOES NOT

- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function

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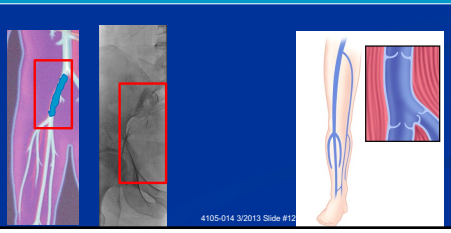
Ilio-Femoral DVT
Ambulatory Venous Hypertension

Combination of Obstruction + Valvular Incompetence

Highest Venous Pressure and most severe morbidity



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Ilio-Femoral DVT
Improved Outcome with Early Resolution

Randomized Trial: Iliofemoral DVT
Venous Thrombectomy vs. Anticoagulation
(Follow-up @ 6 mos, 5 yrs, 10 yrs)

- Patients randomized to thrombectomy showed:
  1. Improved patency — $P < 0.05$
  2. Lower venous pressures — $P < 0.05$
  3. Less leg swelling — $P < 0.05$
  4. Fewer post-thrombotic symptoms — $P < 0.05$

Compared to anticoagulation

Plate G, et al. *JVS*, 1984
Plate G, et al. *Eur J Vasc Surg*, 1990
Plate G, et al. *Eur J Vasc Endovasc Surg*, 1997

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Management of Ilio-Femoral DVT

Anticoagulation
⟶
Surgical Thrombectomy
⟶
Catheter Directed Thrombolysis
⟶
PharmacoMechanical/Aspiration MechanicalThrombectomy

PEARL Comparison

Treatment of LE DVT

		PEARL	Venous Registry*	CaVenT**	
				CDT	STD
Onset of DVT Symptoms	Acute	67% (≤14 days)	66% (≤10 Days)	100% ≤21 days	
	Chronic	33% (>14 days)	16% (>10 Days)	NA	
	Acute & Chronic	NA	19%	NA	
Primary Lytic		TPA	Urokinase	TPA	NA
CDT Drip Times *(mean)*		17 hrs	48 hrs	57.6 hrs (2.4 days)	NA
Procedure Times	CDT (N=29)	40.9 hrs	NA	NA	NA
	CDT+PPS/RL (N=172)	22.0 hrs	NA	NA	NA
	PPS/RL (N=113)	2.0 hrs	NA	NA	NA
Bleeding Complications		5% (major & minor combined)	11% (major); 16% (minor)	22% (major & minor combined)	0%

*Mewissen MW, Seabrook GR. Radiology 1999;211:39-49
**Enden , Haig Y. . Lancet 2012;379:31-38

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PEARL Comparison

Treatment of LE DVT

		PEARL	Venous Registry*	CaVenT**	
				CDT	STD
Overall % Thrombus Removal		96%	83%	89%	NA
By Lytic Groups: % thrombus Removal	CDT (N=28)	93%	NA	NA	
	CDT+PPS/RL (N=167)	97%	NA	NA	
	PPS/RL (N=113)	95%	NA	NA	
Acute: % Thrombus Removal		97%	86%	89%	
Chronic: % Thrombus Removal		95%	68%	NA	
Acute & Chronic: % Thrombus Removal		NA	76%	NA	
Primary Patency		NA	6 Mon=65%; 12 Mon=60%	6 Mon = 65.9%	6 Mon = 47.4%
Freedom from Rethrombosis		6 Mon= 87%; 12 Mon=83%	NA	NA	NA

*Mewissen MW, Seabrook GR. Radiology 1999;211:39-49
**Enden , Haig Y. . Lancet 2012;379:31-38

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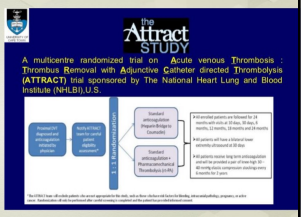
The "Open Vein Hypothesis"

- Development of PTS is associated with persistent venous thrombosis
- Does active elimination of DVT prevent PTS?
- Support comes from studies linking:
  - Poor thrombus clearance to venous valve dysfunction and recurrent VTE[8,9]
  - Residual venous thrombus or valve incompetence and PTS[10]
  - Systemic thrombolysis, surgical thrombectomy or CDT to reduced incidence of PTS[11-14]



Good News

- Leg pain and swelling significantly improved in PCDT vs. no-PCDT out to 30 days (p=0.019 and p=0.05)
  - PCDT helpful for acute symptoms
- 25% fewer patients in PCDT arm developed moderate or severe PTS vs no-PCDT (17.9 % vs 23.7%; p=0.035)
  - "Open Vein hypothesis"

Good News

- In IFDVT mod-severe PTS was 18.4% vs 28.2% in PCDT vs no-PCDT
- In FPDVT little difference (17.1% vs 18.1% moderate to severe PTS)
- PCDT was less effective in patients ≥ 65 y/o

ATTRACT Summary and Learning Points

- Ambitious well-designed RCT, failed primary endpoint, but not the end
- Helps us strategize for appropriate care
- Who to and not to treat
  - Same as CaVenT: iliofemoral DVT, younger and functional patients
  - Femoropopliteal DVT alone patients do not derive same benefit
  - Older patients do not derive same benefit
  - Prevent bleeding and cost in inappropriate patients

CLINICAL PRACTICE GUIDELINE DOCUMENT

Editor's Choice – European Society for Vascular Surgery (ESVS) 2021 Clinical Practice Guidelines on the Management of Venous Thrombosis☆

Stavros K. Kakkos [a,*], Manjit Gohel [b,*], Niels Baekgaard [c], Rupert Bauersachs [d], Sergi Bellmunt-Montoya [e], Stephen A. Black [a], Arina J. ten Cate-Hoek [f], Ismail Elalamy [g], Florian K. Enzmann [f], George Geroulakos [h], Anders Gottsäter [i], Beverley J. Hunt [j], Armando Mansilha [k], Andrew N. Nicolaides [l], Per Morten Sandset [m], Gerard Stansby [n]

ESVS Guidelines Committee [o], Gert J. de Borst, Frederico Bastos Gonçalves, Nabil Chakfé, Robert Hinchliffe, Philippe Kolh, Igor Koncar, Jes S. Lindholt, Riikka Tulamo, Christopher P. Twine, Frank Vermassen, Anders Wanhainen

Document reviewers [r], Marianne G. De Maeseneer, Anthony J. Comerota, Peter Gloviczki, Marieke J.H.A. Kruip, Manuel Monreal, Paolo Prandoni, Melina Vega de Ceniga

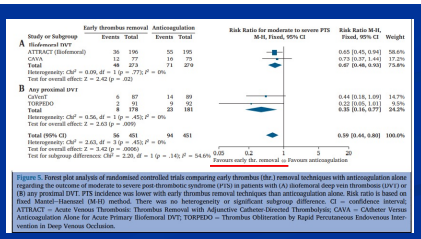


Figure 5. Forest plot analysis of randomised controlled trials comparing early thrombus (thr.) removal techniques with anticoagulation alone regarding the outcome of moderate to severe post thrombotic syndrome (PTS) in patients with (A) iliofemoral deep vein thrombosis (DVT) or (B) any proximal DVT. PTS incidence was lower with early thrombus removal techniques than anticoagulation alone. Risk ratio is based on fixed Mantel–Haenszel (M-H) method. There was no heterogeneity or significant subgroup difference. CI = confidence interval; ATTRACT = Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis; CAVA = CAtheter Versus Anticoagulation Alone for Acute Primary Iliofemoral DVT; TORPEDO = Thrombus Obliteration by Rapid Percutaneous Endovenous Intervention in Deep Venous Occlusion.

CLINICAL GUIDELINES

blood advances

American Society of Hematology 2020 guidelines for management of venous thromboembolism: treatment of deep vein thrombosis and pulmonary embolism

Thomas L. Ortel,[1] Ignacio Neumark,[2] Walter Ageno,[3] Rebecca Beyth,[4,5] Nathan P. Clark,[6] Adam Cuker,[7] Barbara A. Hutten,[8] Michael R. Jaff,[9] Veena Manja,[10,11] Sam Schulman,[12,13] Caitlin Thurston,[14] Suresh Vedantham,[15] Peter Verhamme,[16] Daniel M. Witt,[17] Ivan D. Florez,[18,19] Ariel Izcovich,[20] Robby Nieuwlaat,[19] Stephanie Ross,[19] Holger J. Schünemann,[19,21] Wojtek Wiercioch,[19] Yuan Zhang,[19] and Yuqing Zhang[19]

Remarks: Thrombolysis is reasonable to consider for patients with limb-threatening DVT (phlegmasia cerulea dolens) and for selected younger patients at low risk for bleeding with symptomatic DVT involving the iliac and common femoral veins (higher risk for more severe postthrombotic syndrome [PTS][3]). Patients in these categories who value rapid resolution of symptoms, are averse to the possibility of PTS, and accept the added risk of major bleeding may prefer thrombolysis. The use of thrombolysis should be rare for patients with DVT limited to veins below the common femoral vein.

STANDARDS OF PRACTICE

Society of Interventional Radiology Position Statement on the Endovascular Management of Acute Iliofemoral Deep Vein Thrombosis

Suresh Vedantham, MD, Kush R. Desai, MD, Ido Weinberg, MD, William Marston, MD, Ronald Winokur, MD, Sheena Patel, MPH, Kanti Pallav Kolli, MD, Ezana Azene, MD, and Kari Nelson, MD

ABSTRACT

Purpose: To establish the updated position of the Society of Interventional Radiology (SIR) on the endovascular management of acute iliofemoral deep vein thrombosis (DVT).

Materials and Methods: A multidisciplinary writing group with expertise in treating venous diseases was convened by SIR. A comprehensive literature search was conducted to identify studies on the topic of interest. Recommendations were drafted and graded according to the updated SIR evidence grading system. A modified Delphi technique was used to achieve consensus agreement on the recommendation statements.

Results: A total of 84 studies, including randomized trials, systematic reviews and meta-analyses, prospective single-arm studies, and retrospective studies were identified and included in the review. The expert writing group developed 17 recommendations that pertain to the care of patients with acute iliofemoral DVT with the use of endovascular venous interventions.

Conclusions: SIR considers endovascular thrombus removal to be an acceptable treatment option in selected patients with acute iliofemoral DVT. Careful individualized risk assessment, high-quality general DVT care, and close monitoring during and after procedures should be provided.

3. Adjunctive CDT or PCDT (along with anticoagulation) is reasonable to use in carefully selected patients with acute iliofemoral DVT after consideration of presenting clinical severity, bleeding risks, symptom duration, pre-DVT functional capacity, comorbidities, and patient preferences **(Level of Evidence B, Strength of Recommendation Moderate)**.

b. For nonelderly patients with initially presenting acute iliofemoral DVT, nonthreatened limbs, good pre-DVT functional status, moderate-to-severe symptoms, and low risk of bleeding, adjunctive CDT/PCDT should be strongly considered for use as part of the first-line treatment approach (along with anticoagulant therapy) to enhance relief of presenting symptoms, reduce PTS severity, and improve health-related QoL **(Level of Evidence B, Strength of Recommendation Moderate).**

c. For patients with acute iliofemoral DVT who continue to have moderate-to-severe symptoms or impaired ambulation despite initial anticoagulation, **who are at low risk of bleeding, and whose thrombus is believed to have formed within the past 14 days, adjunctive CDT/PCDT should be considered to alleviate symptoms and improve ambulatory capacity (Level of Evidence C, Strength of Recommendation Moderate).**

4. The use of CDT/PCDT is not recommended for most patients with DVT that is limited to the tibial, popliteal, and femoral veins; for patients with clinical factors that confer a moderate or high risk for bleeding (including advanced age); and for patients with only mild lower extremity symptoms **(Level of Evidence B, Strength of Recommendation Strong).**

EVeR

- ESVS will initiate a registry of international repository of DVT treatment data.
- Collect information on the outcomes of venous interventions.
- Although it is not randomized, it will provide evidence-based date to show practice patterns, various interventions, devices and outcomes.

Summary: Acute Ilio-Femoral DVT

- Medical management is associated with higher PTS compared to endovascular management
- There is increasing evidence that early thrombus resolution with endovascular intervention is associated with improved outcome with decrease in pain and swelling
- Pharmacomechanical/Suction Aspiration Thrombectomy decreases procedure time, decrease amount of thrombolytic used