

Early Aggressive Thrombus Removal with Stenting is Better

Lori L. Pounds MD FACS
Professor Vascular Surgery
Program Director



UT Health
San Antonio

FLORIDA
VASCULAR
SOCIETY

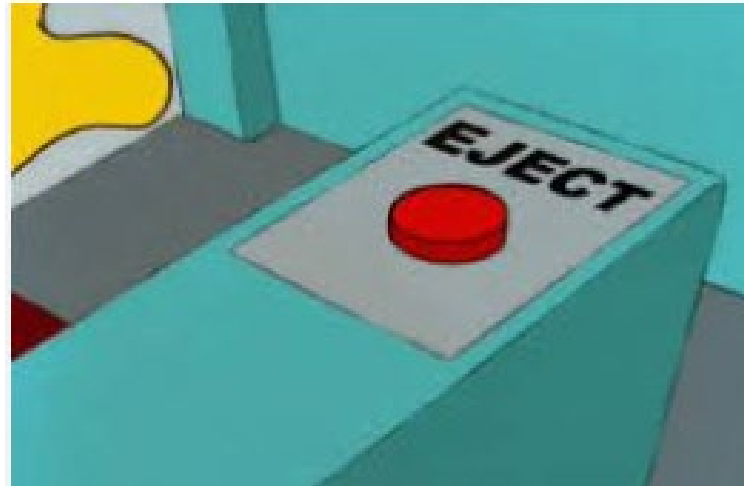
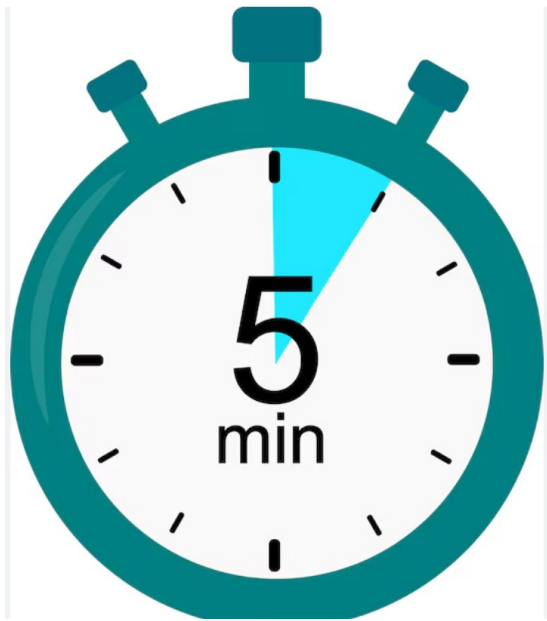
Objectives and Disclosure

- Patient value
- Procedure value
- Guidelines



I have NO disclosures other than I am Joe Dergan's Program Director

PRO: aggressive removal & Stenting



SVS & AVF Position 2012

SOCIETY FOR VASCULAR SURGERY® DOCUMENTS

Early thrombus removal strategies for acute deep venous thrombosis: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum

Mark H. Meissner, MD,^a Peter Gloviczki, MD,^b Anthony J. Comerota, MD,^c Michael C. Dalsing, MD,^d Bo G. Eklof, MD,^e David L. Gillespie, MD,^f Joann M. Lohr, MD,^g Robert B. McLafferty, MD,^h M. Hassan Murad, MD,ⁱ Frank Padberg, MD,^j Peter Pappas, MD,^k Joseph D. Raffetto, MD,^l and Thomas W. Wakefield, MD,^m *Seattle, Wash; Rochester, Minn; Toledo, Ohio; Indianapolis, Ind; Helsingborg, Sweden; Rochester and New York, NY; Cincinnati, Ohio; Springfield, Ill; Newark, NJ; West Roxbury, Mass; Ann Arbor, Mich*

Background: The anticoagulant treatment of acute deep venous thrombosis (DVT) has been historically directed toward the prevention of recurrent venous thromboembolism. However, such treatment imperfectly protects against late manifestations of the postthrombotic syndrome. By restoring venous patency and preserving valvular function, early thrombus removal strategies can potentially decrease postthrombotic morbidity.

Objective: A committee of experts in venous disease was charged by the Society for Vascular Surgery and the American Venous Forum to develop evidence-based practice guidelines for early thrombus removal strategies, including catheter-directed pharmacologic thrombolysis, pharmacomechanical thrombolysis, and surgical thrombectomy.

Methods: Evidence-based recommendations are based on a systematic review and meta-analysis of the relevant literature, supplemented when necessary by less rigorous data. Recommendations are made according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, incorporating the strength of the recommendation (strong: 1; weak: 2) and an evaluation of the level of the evidence (A to C).

Results: On the basis of the best evidence currently available, we recommend against routine use of the term “proximal venous thrombosis” in favor of more precise characterization of thrombi as involving the iliofemoral or femoropopliteal venous segments (Grade 1A). We further suggest the use of early thrombus removal strategies in ambulatory patients with good functional capacity and a first episode of iliofemoral DVT of <14 days in duration (Grade 2C) and strongly recommend their use in patients with limb-threatening ischemia due to iliofemoral venous outflow obstruction (Grade 1A). We suggest pharmacomechanical strategies over catheter-directed pharmacologic thrombolysis alone if resources are available and that surgical thrombectomy be considered if thrombolytic therapy is contraindicated (Grade 2C).

Conclusions: Most data regarding early thrombus removal strategies are of low quality but do suggest patient-important benefits with respect to reducing postthrombotic morbidity. We anticipate revision of these guidelines as additional evidence becomes available. (J Vasc Surg 2012;55:1449-62.)

Pharmaco-
Mechanical
Thrombectomy

early ileofemoral dvt removal and stenting

▼ Finished thinking

Early thrombus removal (ETR) with catheter-directed thrombolysis (CDT) or pharmacomechanical CDT (PCDT) should be considered for carefully selected patients with acute iliofemoral DVT, particularly younger patients with severe symptoms, good functional status, and low bleeding risk. Stenting is typically performed adjunctively when underlying venous stenosis is identified after thrombus removal. However, ETR does **not prevent** post-thrombotic syndrome (PTS) overall, though it may **reduce PTS severity** and improve early symptom relief. [Vascular and In... +1](#)

The **Society of Interventional Radiology (2023)** recommends adjunctive CDT/PCDT for nonelderly patients with acute iliofemoral DVT, moderate-to-severe symptoms, and low bleeding risk to enhance symptom relief, reduce PTS severity, and improve quality of life. The recommendation emphasizes that **therapeutic anticoagulation must not be delayed** while considering ETR. [Vascular and In...](#) For limb-threatening presentations (phlegmasia cerulea dolens), urgent CDT/PCDT is recommended for limb salvage. [Vascular and In...](#)

The **ATTRACT trial** iliofemoral subgroup analysis (391 patients) showed that while PCDT did not prevent PTS occurrence (49% vs 51%), it significantly reduced moderate-to-severe PTS (18% vs 28%, P=0.021), reduced early leg symptoms, and improved venous disease-specific quality of life over 24 months. Major bleeding occurred in 1.5% with PCDT versus 0.5% with anticoagulation alone.

ORIGINAL RESEARCH ARTICLE

Endovascular Thrombus Removal for Acute Iliofemoral Deep Vein Thrombosis

Analysis From a Stratified **Multicenter Randomized Trial**

Editorial, see p 1174

Anthony J. Comerota, MD,
MMath, Samuel Z. Goldhaber,
Mahmood K. Razavi, MD, A
MD, Mel Sharafuddin, MD, M
Lawrence V. Hofmann, MD,
For the ATTRACT Trial Invest

Clinical Perspective

What Is New?

- Outcomes are reported on a subgroup of 391 patients with acute iliofemoral deep-vein thrombosis (DVT) in whom pharmacomechanical catheter-directed thrombolysis (PCDT) was evaluated within a large multicenter, randomized, controlled trial (ATTRACT).
- In patients with acute iliofemoral DVT, PCDT does not influence the occurrence of the postthrombotic syndrome (PTS) or recurrent venous thromboembolism through 24 months.
- In patients with acute iliofemoral DVT, PCDT does appear to provide greater reduction in acute leg pain and swelling through 30 days follow-up, as well as reduced PTS severity, reduced moderate-or-severe PTS, and greater improvement in venous disease-specific quality of life through 24 months.

What Are the Clinical Implications?

- The findings support early use of PCDT in patients with acute iliofemoral DVT who have severe symptoms, low bleeding risk, and who attach greater importance to a reduction in early and late symptoms than to the risks, costs, and inconvenience of PCDT.

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

Table 1. Summary of Multicenter Randomized Controlled Trials of Endovascular Thrombus Removal for Acute DVT (16, 18, 19)

	Study		
	CAVENT (16)	ATTRACT (18)	CAVA (19)
Sample Size	200	200	154
Age Range	18-75yrs	18-75yrs	18-85yrs
Included Iliofemoral DVT	Yes	Yes	Yes
Included Fem-Pop DVT	Yes	Yes	No
Single Session Therapy	No	Yes (if open aspirator)	No
Flushing Dose	10-20	10-20	Unstated
Infusion Dose	0.05 mg/kg/hr	0.05 mg/kg/hr	100,000 IU/hr
Maximum Time	90min	30min	90min
Maximum Dose	80mg	35mg	8.85 million IU
Thrombolytic Doses	None	Angiatic Tissue	None
Ultrasound Catheter	No	Allowed (discouraged)	None
Venous Angiography	Yes	Yes	Yes
Iliac Vein Stenting	Yes	Yes	Yes



2023

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.

Review of Different Trials

	Study		
	CAVENT (18)	ATTRACT (8)	CAVA (19)
Sample size		692	184
Age range (y)		16–75	18–85
Included iliofemoral DVT		Yes	Yes
Included femoral-popliteal DVT	Yes	Yes	No
Single-session therapy	No		
Fibrinolytic drug	rt-PA		alteplase
Infusion dose	0.01 mg/kg/h	0.01 mg/kg/h	100,000 IU/h
Maximum time (h)	96	30	96
Maximum dose	80 mg	35 mg	9.85 million IU
Thrombectomy devices	None	AngioJet, Trellis	None
Ultrasound catheter	No	Allowed (discouraged)	Yes
Venous angioplasty	Yes	Yes	Yes
Iliac vein stent placement	Yes	Yes	Yes

	PTS	2yr	5 yr
AC	56%	71%	
PMT	41%	43%	

	PTS	2yr	Mod/Severe
AC	48%	24%	
PMT	47%	18%	

Society Guidelines

Society	Recommendation
National Institute of Healthcare Excellence, 2020 (110)	Consider catheter-directed thrombolytic therapy for people with symptomatic iliofemoral DVT who present with the following: symptoms lasting <14 d; good functional status; a life expectancy of ≥ 1 y; and a low risk of bleeding
National Institute of Healthcare Excellence, 2019 (111)	<p>Current evidence on the safety of percutaneous mechanical thrombectomy for acute DVT of the leg shows that there are well-recognized but infrequent complications</p> <p>For acute iliofemoral DVT, the evidence on efficacy is limited in quality and quantity; therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.</p> <p>For distal DVT that does not extend into the common femoral vein, the evidence on efficacy is inconclusive; therefore, this procedure should only be used in the context of research</p>
American Society of Hematology, 2020 (66)	<p>In most patients with proximal DVT, the American Society of Hematology guideline panel suggests anticoagulation therapy alone over thrombolytic therapy in addition to anticoagulation (conditional recommendation based on low certainty in the evidence of effects)</p> <p>Remarks: Thrombolysis is reasonable to consider for patients with limb-threatening DVT (phlegmasia cerulea dolens) and for selected younger patients at low risk of bleeding with symptomatic DVT involving the iliac and common femoral veins (higher risk of more severe PTS). Patients in these categories, who value rapid resolution of symptoms, are averse to the possibility of PTS and accept that 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</p> <p>For patients with extensive DVT in whom thrombolysis is considered appropriate, the American Society of Hematology guideline panel suggests using catheter-directed thrombolysis over systemic thrombolysis (conditional recommendation based on very low certainty in the evidence of effects)</p>
European Society of Vascular Surgery, 2021 (112)	<p>In selected patients with symptomatic iliofemoral DVT, early thrombus removal strategies should be considered (Class IIa, Level A)</p> <p>For patients with DVT limited to femoral, popliteal, or calf veins, early thrombus removal is not recommended (Class III, Level B)</p> <p>For patients with DVT treated by early thrombus removal, with or without stent placement, it is recommended that the duration of anticoagulation should be at least as long as if the patients were treated by anticoagulation alone and at the discretion of the treating physician (Class I, Level C)</p>
American College of Chest Physicians, 2021 (69)	<p>In patients with acute DVT of the leg, anticoagulant therapy alone is suggested over interventional (thrombolytic, mechanical, or pharmacomechanical) therapy (weak recommendation, moderate certainty evidence)</p> <p>Comments: In patients with very severe, limb-threatening DVT (such as those with phlegmasia or threatened venous gangrene), the benefits of more rapid thrombus resolution may outweigh the risk of harm</p>

Summary of Recommendations

3. Adjunctive CDT or PCDT (along with anti-coagulation) 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**).

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**).

6. When PCDT is performed for the purpose of achieving a long-term reduction in PTS severity and enhancement of long-term QoL, the optimal PCDT strategy to use has not been determined (**Level of Evidence E, Strength of Recommendation Weak**).

10. If a flow-limiting obstructive lesion is identified in the iliac vein after thrombus debulking and there is a good inflow from the leg veins, stent placement is recommended to reduce symptom severity and the risk of rethrombosis (**Level of Evidence C, Strength of Recommendation Moderate**).



Cardiovasc Intervent Radiol (2023) 46:1571–1580
<https://doi.org/10.1007/s00270-023-03509-8>

CLINICAL INVESTIGATION

VENOUS INTERVENTIONS

Six-Month Outcomes of Mechanical Thrombectomy for Treating Deep Vein Thrombosis: Analysis from the 500-Patient CLOUT Registry

Abdullah Shaikh¹ · Adam Zybulewski² · Joseph Paulisin³ · Mohannad Bisharat⁴ ·
Nicolas J. Mouawad⁵ · Adam Raskin⁶ · Eugene Ichinose⁷ · Steven Abramowitz⁸ ·
Jonathan Lindquist⁹ · Ezana Azene¹⁰ · Neil Shah¹¹ · James Nguyen¹² ·
Josh Cockrell¹³ · Bhavraj Khalsa¹⁴ · Vipul Khetarpaul¹⁵ · Douglas A. Murrey Jr.¹⁶ ·
Kalyan Veerina¹⁷ · Edvard Skripochnik¹⁸ · Thomas S. Maldonado¹⁹ ·
Matthew C. Bunte²⁰ · Suman Annambhotla²¹ · Jonathan Schor²² · Herman Kado²³ ·
Hamid Mojibian²⁴ · David Dexter²⁵ · the CLOUT Investigators

Received: 29 March 2023 / Accepted: 28 June 2023 / Published online: 14 August 2023

© The Author(s) 2023

CLOUT (NCT03575364) is a prospective, multi-center post-approval study designed to evaluate real-world outcomes following treatment of lower extremity DVT using mechanical thrombectomy sponsored by Inari Medical (Irvine, CA). All patients provided informed written consent pre-procedure and investigators obtained institutional review board approval at each site prior to enrolling patients.

Venous flow increased (30-90%)
Venous compressibility improved (30-90%)
Villalta improved 9 to 1 at 6 months
No bleeding events (vs CDT 7%)

8. The use of MT (with no fibrinolytic drug) cannot be recommended for most patients with acute iliofemoral DVT (Level of Evidence D, Strength of Recommendation Weak).

Conclusions

- In * Select patients IFDVT early treatment can decrease the risk of reoccurrence of DVT
- It can be performed with acceptable risks
- Choose the correct patient & correct method
 - Iliofemoral DVT
 - Younger
 - Functional
 - Less than 14 days old
 - Low bleeding risk
 - Patients that can understand the known risks and potential benefits

