

Quality Improvement Guidelines for the Treatment of Lower Extremity Deep Vein Thrombosis with Use of Endovascular Thrombus Removal

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Abbreviations: CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, FDA = Food and Drug Administration, IVC = inferior vena cava, PE = pulmonary embolus, PMT = percutaneous mechanical thrombectomy, PTS = post-thrombotic syndrome, PTT = partial thromboplastin time, VTE = venous thromboembolism

LOWER extremity deep vein thrombosis (DVT) is a serious medical condition that can result in death or major disability due to pulmonary embolism (PE), post-thrombotic syndrome (PTS), paradoxical embolization, or limb loss. Since the early 1990s, endovascular

methods have been used by interventional radiologists to provide aggressive treatment for lower extremity DVT (1). However, there currently exist no published guidelines for the appropriate utilization of these techniques. The Society of Interventional

Radiology (SIR) strongly believes that active participation of the interventional radiologist in the patient selection, pretreatment evaluation, patient selection, periprocedural monitoring, and postprocedural care of the DVT patient will improve the safety and effectiveness of these procedures.

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METHODOLOGY AND LIMITATIONS

SIR creates its Standards of Practice documents with use of the following process: Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author, with additional authors assigned depending on the project's magnitude.

An in-depth literature search is performed with use of electronic medical literature databases. A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that

it contains evidence-based data with respect to content, rates, and thresholds. When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with use of a Modified Delphi Consensus Method (2). For the purpose of these documents, consensus is defined as 80% participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members in either a telephone conference call or face-to-face meeting. The revised draft is then sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee members and appropriate revisions are made to create the finished Standards document. Before its publication, the document is endorsed by the SIR Executive Council.

The current guidelines are written to be used in quality improvement programs to assess the endovascular treatment of lower extremity DVT. The most important elements of care are (a) pretreatment evaluation and patient selection, (b) performance of the procedure, and (c) postprocedure follow-up care. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Although practicing physicians should strive to achieve perfect outcomes, in practice all physicians will fall short of ideal outcomes to a variable extent. Therefore, in addition to quality improvement case reviews conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess treatment safety and efficacy in ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator which, when reached or crossed, should prompt a review of departmental policies and procedures to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult and each department is urged to adjust the thresholds as needed to higher or lower

values to meet its specific quality improvement program situation.

The SIR is committed to the basic principles of outcomes-focused, evidence-based medicine. Ideally, every Standards of Practice Committee recommendation would be based on evidence derived from multiple prospective randomized trials of adequate statistical power. Unfortunately, there currently exist no published multi-center randomized trials of significant size that evaluate image-guided endovascular DVT therapies. In evaluating the existing publications, several major limitations are evident: (a) extreme variation in patient selection parameters, definitions of short-term efficacy, and definitions of complications; (b) reliance on surrogate measures of treatment success instead of scientifically rigorous assessment of clinically meaningful outcomes; and (c) absence of systematic assessment of long-term efficacy. For these reasons, the U.S. Food and Drug Administration (FDA) does not currently label any drug or device for endovascular DVT treatment. Streptokinase (administered systemically) did receive FDA approval for DVT in 1980, but a National Institutes of Health consensus panel later recommended against the use of systemic thrombolysis for DVT (3).

The SIR recognizes the potential pitfalls of developing evidence-based DVT standards and of making recommendations regarding the off-label use of drugs and devices based on studies of suboptimal design. However, these difficulties are far outweighed by the potential improvements in safety and treatment efficacy that may be gained by implementing the key lessons learned from the peer-reviewed scientific literature that has evaluated these procedures. The current document was drafted by the DVT Standards and DVT Research Committees of the SIR Venous Forum with further modification by the SIR Standards of Practice Committee and therefore reflects the consensus experience of interventional radiologists with extensive expertise in treating DVT using endovascular means. Given the limited scientific foundation, however, most of the recommendations presented in this document are intended to guide clinical practice rather than to mandate the use of specific methodologies. The authors fully anticipate that

these guidelines will be appropriately revised when future studies of greater scientific rigor are available.

DEFINITIONS

Disease Processes

Venous thromboembolism (VTE) refers to the single common disease entity with two principal manifestations: DVT and PE. A patient with a proved episode of DVT and/or PE is said to have had an episode of VTE.

Pulmonary embolism (PE) refers most commonly to the intravascular migration of a venous thrombus to the pulmonary arterial circulation. *Proved PE* refers to PE that is documented by a positive pulmonary angiogram, an unequivocally positive helical CT scan, a high probability ventilation-perfusion scan, surgical observation, or autopsy. *Proved PE* can be *symptomatic* (patient had clinical PE symptoms and/or signs such as chest pain, dyspnea, hemoptysis, palpitations, or tachycardia) or *asymptomatic* (PE was detected on an imaging study in a patient without suggestive symptoms). *Suspected PE* refers to PE that is suspected based on clinical symptoms and/or signs but for which definitive diagnosis has not been made by imaging or autopsy.

Deep vein thrombosis (DVT) refers to the presence of thrombus within a deep vein of the body as proved by diagnostic imaging.

Phlegmasia refers to a characteristic clinical picture in which DVT causes massive swelling of the entire extremity. Patients with *phlegmasia alba dolens* do not have associated cyanosis. Patients with *phlegmasia cerulea dolens* have more extensive thrombosis with associated cyanosis of the affected limb. This disorder can lead to arterial insufficiency, compartmental compression syndrome (compartment syndrome), and/or venous gangrene and has been associated with a high rate of limb amputation (4).

Duration of Symptoms

Acute DVT refers to venous thrombosis for which symptoms have been present for 14 days or less or for which imaging studies indicate that venous thrombosis occurred within the last 14 days.

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