

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, ECS = elastic compression stocking, IVC = inferior vena cava, PCDT = pharmacomechanical catheter-directed thrombolysis, PE = pulmonary embolism, PMT = percutaneous mechanical thrombectomy, PTS = postthrombotic syndrome, PTT = partial thromboplastin time, VTE = venous thromboembolism

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate

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the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 North, Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents by using 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 for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, 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 by using a modified Delphi consensus method ([Appendix A](#)). For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is 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, and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION

Lower-extremity deep vein thrombosis (DVT) is a serious medical condition that can result in death or major disability as a result of

pulmonary embolism (PE), postthrombotic syndrome (PTS), paradoxical embolization, or limb amputation. Since the early 1990s, endovascular methods have been developed and refined by interventional radiologists to provide aggressive treatment for lower-extremity DVT (1). In 2006, SIR first published DVT treatment guidelines (2). The present, revised guidelines reflect a reassessment of the published literature through June 2013, and are intended to be used in quality-improvement programs to assess the treatment of lower-extremity DVT with endovascular thrombus removal procedures. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Disease Categorization

Venous thromboembolism (VTE) refers to the single common disease entity with two principal manifestations: (i) DVT refers to the presence of thrombus within a deep vein of the body as proven by diagnostic imaging; and (ii) PE refers to the intravascular migration of a venous thrombus to a pulmonary artery, as documented by a positive pulmonary angiogram, a positive helical computed tomography (CT) scan, a high-probability ventilation/perfusion scan, surgical observation, or autopsy. Episodes of DVT or PE can be symptomatic (the patient had symptoms and/or signs that prompted evaluation for DVT or PE) or asymptomatic (DVT or PE was detected on an imaging study in a patient without symptoms).

In some instances, extensive DVT can cause massive swelling, pain, and discoloration of the involved limb. Patients with phlegmasia alba dolens present with massive swelling and pale limb discoloration, but generally do not have acute arterial compromise. In contrast, patients with phlegmasia cerulea dolens have more extensive venous thrombosis and congestion, resulting in profound limb cyanosis and often acute arterial limb threat. This presentation has been associated with a high risk of subsequent compartment syndrome, venous gangrene, and limb amputation (3).

Although some patients' recall of the start date of their DVT symptoms can be unreliable, this parameter has prognostic value. Acute DVT refers to venous thrombosis for which symptoms have been present for less than 14 days or for which imaging studies indicate that thrombosis occurred within the previous 14 days. Subacute DVT refers to venous thrombosis for which symptoms have been present for 15–28 days as indicated by history or imaging studies. Chronic DVT refers to venous thrombosis for which symptoms have been present for more than 28 days as indicated by history or imaging findings. Acute-on-chronic DVT refers to venous thrombosis that has acute (< 14 d) and nonacute components as indicated by history or imaging findings.

Proximal DVT refers to complete or partial thrombosis of the popliteal vein, femoral vein, deep femoral vein, common femoral vein, an iliac vein, and/or inferior vena cava (IVC). Proximal DVT can be subclassified into femoropopliteal DVT (complete or partial thrombosis of the popliteal vein, femoral vein, and/or deep femoral vein) or iliofemoral DVT (complete or partial thrombosis of any part of the iliac vein and/or the common femoral vein, with or without other associated veins). Calf DVT refers to thrombosis of one or more deep calf veins, including the anterior tibial veins, posterior tibial veins, peroneal veins, and/or deep muscular veins.

Treatment Methods

During the past decade, there has been significant evolution in the methods of endovascular thrombus removal that are used in clinical DVT practice. Although it is not feasible to describe every distinct method of utilizing thrombolytic drugs and/or devices, the following categorization can be used to make sense of the published

literature and to define outcome expectations for endovascular DVT interventions:

1. *Pharmacologic thrombolysis* refers to administration of drugs with thrombolytic activity without use of mechanical thrombectomy devices, and is subcategorized as follows:
 - a. *Systemic thrombolysis* refers to thrombolytic drug delivery through an intravenous catheter located distant from the affected extremity.
 - b. *Flow-directed thrombolysis* refers to thrombolytic drug delivery through a pedal intravenous catheter placed within the affected extremity, with or without the use of tourniquets to direct the drug into the deep venous system.
 - c. *Catheter-directed intrathrombus thrombolysis* refers to thrombolytic drug delivery through an infusion catheter and/or wire which is embedded within the thrombosed vein. *Infusion-only catheter-directed thrombolysis* (CDT) refers to the slow intrathrombus infusion of a thrombolytic drug (eg, via a multiple-side-hole catheter). *Lacing* refers to use of a catheter to disperse a bolus dose of the thrombolytic drug in the thrombus. *Ultrasound (US)-assisted CDT* refers to thrombolytic drug administration via an infusion catheter that simultaneously emits US energy into the thrombus (eg, EkoSonic catheter; EKOS, Bothell, Washington).
2. Stand-alone *percutaneous mechanical thrombectomy* (PMT) refers to the percutaneous use of catheter-based mechanical devices that contribute to thrombus removal via fragmentation, maceration, and/or aspiration, without administration of a thrombolytic drug.
3. *Pharmacomechanical CDT* (PDCT) refers to thrombus dissolution via the concomitant use of pharmacologic CDT and PMT. PDCT many involve a combination of techniques, including the use of multiple-side-hole infusion catheters, pulse-spray technique manually (4) or via a device (eg, AngioJet Rheolytic Thrombectomy System; Medrad, Warrendale, Pennsylvania), and/or segmental isolation by using catheter-mounted balloons (eg, Trellis Peripheral Infusion System; Covidien, Mansfield, Massachusetts).

Commonly used adjunctive endovascular techniques include aspiration thrombectomy (use of a syringe to aspirate thrombus from the vein via a catheter, device, or sheath), balloon maceration (use of an angioplasty balloon to macerate or fragment thrombus), balloon angioplasty (inflation of a catheter-mounted balloon with the specific intent of enlarging the venous lumen), and stent placement (deployment of a metallic endoprosthesis to enlarge and maintain the venous lumen).

Surgical thrombectomy refers to the use of open surgical techniques, including venotomy, to remove thrombus from the deep veins of the body.

Outcomes

Major bleeding is defined as intracranial bleeding or bleeding severe enough to result in death, surgery, cessation of therapy, or blood transfusion (5). *Minor bleeding* is defined as less severe bleeding manageable with local compression, sheath upsizing, and/or dose alterations of a pharmacologic thrombolytic agent, anticoagulant, or antiplatelet drug.

Recurrent DVT is defined as imaging proven DVT involving a new venous segment or a previously involved venous segment for which symptomatic and imaging improvement had been obtained in a patient with at least one prior episode of DVT.

PTS refers to the specific form of chronic venous disease that is observed in many patients who have experienced one or more episodes of ipsilateral DVT. PTS is often characterized by limb swelling, heaviness, fatigue, pain, venous claudication, and/or limb hyperpigmentation, with a minority of patients developing severe manifestations such as venous ulceration. To ensure that PTS is distinguished from

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