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 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

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pulmonary embolism (PE), postthrombotic syndrome (PTS), paradoxic 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. PCDT 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 resolving sequelae of acute DVT, PTS should not be diagnosed until at least 3 months after the DVT episode (6).

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator which should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of major bleeding is one measure of the quality of endovascular thrombus removal for DVT, values in excess of the defined threshold (in this case 7%) should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication. 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. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; **Appendix B**). The complication rates and thresholds in this document refer to major complications.

INDICATIONS

All patients in whom endovascular DVT therapy is planned should undergo a rigorous, individualized assessment that incorporates information from medical history, physical examination, and diagnostic imaging. Patients should be routinely queried about known VTE risk factors, details of previous VTE episodes and treatments, the nature and duration of preexisting and more recent limb symptoms, and comorbidities. Patients with acute DVT often experience limb swelling and/or pain, which may be accompanied by cramping, tingling, or discoloration. It is important to ensure that the providers and patient understand the potential for clinical benefit relative to the individualized risk of harm via consideration of the following attributes.

Clinical Severity

Patients undergoing endovascular DVT thrombolysis should have an imaging-confirmed diagnosis of DVT. For patients with acute limb threat as a result of DVT, small case series attest to the ability of urgent endovascular therapy to provide limb salvage without the need for open surgery (7–9). Given the high rates of limb amputation and death with other therapies in this subpopulation, the benefits of thrombolysis are likely to outweigh the risks for patients in whom major bleeding-related contraindications are not identified. DVT patients for whom elective endovascular DVT therapy is being considered should generally be symptomatic, as asymptomatic DVT is associated with very low rates of PTS and would not generally justify incurring the risks of endovascular therapy (10).

Anatomic Severity

Patients with iliofemoral DVT tend to be highly symptomatic and are at particularly high risk for recurrent DVT, PTS, and late disability (11–14). Because these patients have a relatively poor prognosis when treated with anticoagulation alone, and because endovascular thrombolysis can remove acute venous thrombus, provide immediate symptom relief, and facilitate stent treatment of underlying venous stenoses (1,15–17), the iliofemoral DVT subgroup is believed to be the best subgroup for endovascular intervention. Patients with IVC thrombosis are also good candidates for aggressive therapy, as they tend to be highly symptomatic and are at risk for major PE and sometimes renal or hepatic compromise if the thrombus extends in a cephalad direction (18).

It should be noted that patients with DVT extending only into the cephalad half of the femoral vein were included along with patients with iliofemoral DVT in a recent multicenter randomized clinical trial (19), the Catheter-Directed Venous Thrombolysis Trial (CaVenT) study, which found significant reduction in the 2-year PTS rate with use of infusion-only CDT. Therefore, CDT may also be justified for selected patients with femoral DVT. However, the proper threshold for the use of CDT for femoral DVT should probably be higher than for iliofemoral DVT, with patients with severe symptoms, long life expectancy, and good performance status being the better candidates. On the contrary, the risks of thrombolysis cannot generally be justified in patients with isolated calf DVT or for patients whose DVT extends no higher than the popliteal vein.

Likelihood of Successful Thrombolysis

Successful endovascular thrombus dissolution is most likely for patients whose DVT symptoms began within the preceding 2 weeks (15). A careful history should be taken from patients with symptoms for 2–4 weeks to discern if there may be an acute (< 2 wk) component. Patients with chronic-only DVT (> 4 wk symptom duration) may be amenable to other endovascular treatment methods that do not involve thrombolytic therapy. In patients with chronic DVT, endovascular thrombolytic therapy can occasionally be helpful to manage superimposed acute thrombosis causing new symptoms, or to eliminate thrombus that forms during another endovascular procedure.

Risk of Complications

Because the vast majority of thrombolytic DVT interventions are performed for nonurgent indications, treatment should be avoided in patients with a hemorrhagic disorder, an anatomic lesion in a critical location that is prone to bleeding, or a strong contraindication to anticoagulant therapy. A list of contraindications to CDT is provided in **Table 1**. Before thrombolysis, patients with malignancies known to frequently metastasize to the central nervous system should undergo brain imaging (or have a recent study reviewed) to exclude metastatic lesions. The patient should be assessed for overall clinical stability, life expectancy, and amenability to undergo a procedure with conscious sedation. The hematocrit level, platelet count, International Normalized Ratio, PTT, creatinine level, and pregnancy test result (in women with childbearing potential) should be known before the initiation of therapy.

Patient-Centered Factors that Influence Benefit and Risk

The benefits of aggressive therapy are not likely to outweigh the risks for patients who are chronically nonambulatory for reasons beyond the acute DVT (eg, paralysis, lumbar spine disease). In addition, because there is significant uncertainty surrounding published estimates of benefit relative to risk for most CDT indications, it is important to incorporate each individual patient's values and preferences into the decision-making process. Some patients will be inclined to pursue endovascular therapy to optimize long-term benefit, whereas others may be concerned about procedural risks or other factors of importance to them (eg, need for hospitalization). Acceptable indications for performing endovascular thrombus removal in the treatment of lower-extremity DVT are summarized in **Table 2**.

Table 1. Contraindications to Pharmacologic Catheter-Directed DVT Thrombolysis

Absolute contraindications
Active internal bleeding or disseminated intravascular coagulation
Recent cerebrovascular event (including TIA), neurosurgery (intracranial, spinal), or intracranial trauma (< 3 mo)
Absolute contraindication to anticoagulation
Relative contraindications
Recent cardiopulmonary resuscitation, major surgery, obstetrical delivery, organ biopsy, major trauma, or cataract surgery (< 7–10 d)
Intracranial tumor, other intracranial lesion, or seizure disorder
Uncontrolled hypertension: systolic BP > 180 mm Hg, diastolic BP > 110 mm Hg
Recent major gastrointestinal bleeding or internal eye surgery (< 3 mo)
Serious allergic or other reaction to thrombolytic agent, anticoagulant, or contrast media (not controlled by steroid/antihistamine pretreatment)
Severe thrombocytopenia
Known right-to-left cardiac or pulmonary shunt or left heart thrombus
Severe dyspnea or severe acute medical illness precluding safe procedure performance
Suspicion for infected venous thrombus
Renal failure (estimated GFR < 60 mL/min)
Pregnancy or lactation
Severe hepatic dysfunction
Bacterial endocarditis
Diabetic hemorrhagic retinopathy

BP = blood pressure, DVT = deep vein thrombosis, GFR = glomerular filtration rate, TIA = transient ischemic attack.

Table 2. Indication for Endovascular Thrombus Removal for Lower-Extremity DVT

Indication	Threshold (%)
Imaging-proven symptomatic DVT in IVC or iliac, common femoral, and/or femoral vein in a recently ambulatory patient with DVT symptoms for < 28 d or in whom there is strong clinical suspicion for recently formed (< 28 d) DVT	> 90

DVT = deep vein thrombosis, IVC = inferior vena cava.

The suggested threshold for this indication is 90%. When fewer than 90% of endovascular thrombus removal procedures for lower-extremity DVT are performed for this indication, the department should review the process of patient selection.

SUCCESS RATES

Although we have grouped endovascular thrombus removal methods as detailed earlier, it is recognized that treatment outcomes may be largely device- or technique-specific even within a particular category. We acknowledge that treatment outcomes associated with a particular category may not necessarily reflect the outcomes that can be expected with use of any specific technique or device, but there is currently insufficient data to support device- or method-specific thresholds.

For patients undergoing emergent endovascular thrombus removal for treatment of DVT causing acute limb threat, the goals of therapy are limb salvage, preservation of visceral organ function, and survival. Although comparison with historical studies suggests that endovascular therapy is effective relative to other approaches, these data are derived solely from case reports and small retrospective case series; in addition, there is significant potential for publication bias. We therefore conclude that there is insufficient evidence to support a specific numerical threshold for clinical success rate when thrombolysis is performed to manage DVT causing acute limb threat. It should be recognized that, because these patients are often at immediate risk of irreversible harm (ie, limb loss or death), endovascular thrombus removal is often performed even when relative contraindications are present. Because higher rates of complications are likely to be observed in this subpopulation, we recommend that their complication rates be considered separately from those of patients undergoing DVT thrombolysis electively for nonurgent indications.

The literature describing the elective use of endovascular thrombus removal for patients with extensive DVT in nonthreatened limbs is more substantial. An important positive trend is the fact that clinical follow-up beyond 1 year after the procedure was documented in 25 (19,21,22,25–32,36–41,43–50) of 28 (19,21,22,25–32,34–50) studies for which this was relevant (excluding two studies that narrowly focused on specific procedural questions), encompassing 1,499 of 1,637 (91.5%) patients in the 22 (19,21,22,26,28–32,34,36,37,40,41,43–50) studies that provided an accounting of all patients' follow-up. In these studies, the follow-up visits enabled identification of many patients with ongoing symptoms, which prompted modifications of therapy and, in some cases, additional endovascular procedures to restore patency. We therefore conclude that it is important and feasible to perform longitudinal follow-up in DVT thrombolysis populations.

However, long-term efficacy outcomes data are available from only one rigorously conducted multicenter randomized trial (the CaVenT study [19]). In that study, the use of infusion-only CDT with anticoagulant therapy in patients with DVT involving the iliac and/or upper femoral venous system was associated with a 26% relative reduction in the risk of PTS over 2 years of follow-up (41.1% vs 55.6%; $P = .04$) compared with anticoagulant therapy alone (19). The amount of residual thrombus after CDT correlated with venous patency rates at 24-month follow-up ($P = .04$), and venous patency at 6 and 24 months correlated with freedom from PTS ($P < .001$) (20). These findings parallel those of other studies in which residual thrombus burden was correlated with the risk of PTS (21,22). However, factors that limit the generalizability of the CaVenT study (19) findings include its modest sample size (outcomes reported in 189 patients, of whom 92 received CDT), geographic limitation (four treatment centers in southern Norway), the use of infusion-only CDT without PMT in all patients but one, and the limited use of stents compared with other studies. Therefore, although physicians should track their long-term outcomes, the level of uncertainty surrounding long-term rates of PTS and valvular reflux is still significant, precluding any assignment of threshold values for these important efficacy outcomes. It is hoped that data from the National Institutes of Health–sponsored Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis study, and others, will permit more precise estimates of the long-term efficacy of PCDT (23).

Early treatment outcomes of endovascular DVT thrombolytic procedures that have been reported with reasonable consistency in the published literature include the percentage of thrombus removed, the proportion of limbs experiencing immediate restoration of venous patency, and freedom from early (< 1–3 mo) recurrence of thrombosis. In using the available information and suggested thresholds, it is important to recognize the heterogeneity of different studies in terms of patient cohorts, methods of endovascular treatment, and endpoint evaluation. One should realize that the common practice of reserving endovascular therapy for DVT cases in which first-line anticoagulant therapy fails may essentially preselect "poor responders" for endovascular therapy, and that this may be reflected in the data from most retrospective studies and prospective registries. In contrast, patients treated in randomized trials are rigorously preselected for safety but are more likely to receive thrombolytic therapy as first-line treatment.

Anatomic success has been defined in most published studies as the percentage of thrombus removed. In the patients who received CDT in the CaVenT Study (20), the mean thrombus removal was 82% ± 25. Removal of more than 50% of the thrombus was achieved in 90% of patients, which is largely consistent with the remainder of the published literature. To determine safety and efficacy thresholds for this review, the committee reviewed more than 200 articles and ultimately selected 30 studies that met the following criteria: (i) English-language publication from 2004–2013; (ii) reported on the endovascular thrombolytic treatment of patients with lower extremity DVT using pharmacologic CDT or PCDT; (iii) included mainly acute DVT cases; and (iv) included a prospective data collection or a retrospective review of data on at least 25 treated patients (19–22,24–50). Of these 30 studies, 17 reported thrombus removal as a percentage based on review of pre- and posttreatment venograms (19,20,23,28–32,35,38,40–42,45–47,50). In these studies, removal of more than 50% thrombus was reported in 91.8% of the 1,046 treated patients. Considering also an additional nine studies that reported the number of patients with restoration of iliofemoral venous flow on venography, anatomic success has been observed in 91.0% of 1,474 treated patients (25–27,33,34,36,39,43,44).

In the CaVenT study (16), the use of additional CDT did not influence rates of recurrent VTE over 2 years of follow-up (11% vs 19%; *P* value not significant). However, substantial rates of early recurrent thrombosis have been reported in nonrandomized studies. In the committee's review, 14 studies (19,25,26,29,35,37–39,42–44,46,48,50) directly reported the frequency of early (1–3 mo after treatment) recurrent thrombosis, and this information could be closely estimated from an additional six studies (30–32,40,45,47). Early recurrent thrombosis was observed in 9.1% of the 1,131 patients treated in these 20 studies. The early recurrent thrombosis threshold value we propose (20%) reflects the great uncertainty inherent in these estimates from studies with heterogeneous study populations and reporting. The committee recommends that a lower threshold be used when CDT or PCDT is used in an unselected population as a component of first-line DVT therapy. In contrast, a higher rate of recurrent thrombosis may be reasonably expected when CDT or PCDT is performed in patients who have been preselected for salvage therapy after failure of initial anticoagulant therapy (**Table 3**).

When the observed rate of early treatment success prompts an internal quality review, we suggest attention to the following items: it should be confirmed that (i) the treated population consisted primarily of patients with acute DVT; (ii) intrathrombus drug delivery was accomplished, as systemic thrombolysis and flow-directed thrombolysis are not as effective as intrathrombus CDT (51); (iii) therapeutic-level anticoagulation (heparin-based therapy for patients without contraindications) was provided during the on-table procedural manipulations and after procedure completion (unfractionated heparin may be continued or halted briefly for sheath removal, but complete reversal of its effect is rarely desired) and that heparin-based therapy was given during the infusion CDT component of the treatment (if applicable); and (iv) flow-limiting obstructive lesions (eg, stenosis from iliac vein compression syndrome or other cause, or residual thrombus) were sought and appropriately treated with balloon angioplasty and/or stent placement (1,15,38,52,53). Failure to address such lesions has been associated with high rates of treatment failure or early recurrent thrombosis after thrombus removal procedures, and improved outcomes have been observed in patients treated with left-sided DVT in whom stents were placed (15,19,20,52).

Table 3. Suggested Efficacy Thresholds for Endovascular Thrombus Removal for DVT

Efficacy Outcome	Published Literature (19,21,22,24–50) (%)	Suggested Threshold (%)
Elimination of > 50% thrombus with restoration of iliofemoral venous flow	91	> 80
Freedom from early rethrombosis of treated segment (≤ 1–3 mo)	91	> 80
Completion of (or documentation of attempts to arrange) at least two follow-up visits with treating physician within 12 mo after the procedure, with at least one visit beyond 6 mo	92	> 80
For patients in whom an IVC filter was placed for periprocedural PE prophylaxis, completion of (or documentation of attempts to arrange) clinical reassessment for appropriateness of filter removal	99	> 95

DVT = deep vein thrombosis, IVC = inferior vena cava, PE = pulmonary embolism.

When the observed rate of recurrent thrombosis prompts an internal quality review, it should be confirmed that patients received careful monitoring of anticoagulation during the initial weeks after the procedure, and that long-term anticoagulant therapy of a type and duration consistent with each patient's individualized risk for recurrence was provided. In general, patients with DVT provoked by a major reversible risk factor (eg, major surgery, trauma) with no other identifiable risk factors should receive at least 3 months of anticoagulant therapy; patients with unprovoked DVT should receive at least 12 months of anticoagulant therapy; patients with cancer should receive long-term anticoagulation with low molecular weight heparin (rather than warfarin); and patients with recurrent thrombosis should be considered for indefinite therapy, subject to periodic reassessment of whether the risk of recurrence outweighs the risk of bleeding (54). It should also be confirmed that patients with retrievable IVC filters have been clinically reassessed and the filters removed when appropriate, as has been done in randomized DVT trials (19,37).

Relief of presenting DVT symptoms (eg, limb swelling, pain) is expected to parallel successful thrombus removal, restoration of venous flow, and freedom from recurrent thrombosis. The use of compression bandage wrapping of the limb may help to provide faster reduction of limb swelling during the acute phase, and the use of elastic compression stockings (ECSs) clearly can help some patients manage long-term symptoms of PTS. Until recently, it was believed that the daily use of ECSs for 2 years after a proximal DVT episode would reduce the risk of PTS, based on two single-center randomized, controlled trials (55,56). However, in the recently completed SOX trial (57), a multicenter, placebo-controlled, double-blind North American study in which the use of ECSs was compared with the use of placebo stockings (with no ankle pressure) in patients with proximal DVT, no difference in PTS rates was observed between the two treatment arms (57). Given that the SOX trial is by far the largest (806 patients, which is more than four times the size of each of the other studies) and most methodologically rigorous study, it seems likely that the previous studies yielded a biased estimate of the effect of ECSs, likely because of a placebo effect. Hence, although many patients may benefit from ECSs, pending further study, their use in the general population of patients with proximal DVT is not expected to reduce the occurrence of PTS.

COMPLICATIONS

Major bleeding is the most frequent major complication of endovascular DVT thrombus removal, and was observed in 2.8% of patients undergoing treatment in randomized trials and in our review of 30 studies (including 1,531 patients in whom safety outcomes were reported) published within the past decade (19–22,24–50). However, observed major bleeding rates may be expected to vary based on differences in patient populations, so a threshold value of 7% is suggested for this parameter. Intracranial bleeding, symptomatic PE, and death represent the most feared complications of endovascular thrombus removal procedures. However, analysis of the published literature indicates that each of these complications is rare. Suggested thresholds for these indicators and the overall major complication rate are presented in Table 4.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed here. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality improvement program. All values in Table 4 are supported by the weight of literature evidence and panel consensus.

Table 4. Complication Rates for Endovascular Thrombus Removal for DVT

Complication	Published Literature (19,21,22,24–50) (%)	Suggested Threshold (%)
Major bleeding	2.8	< 7
Symptomatic PE	0.5	< 2
Intracranial bleeding	0	< 1
Overall major complications	3.9	< 10

DVT = deep vein thrombosis, PE = pulmonary embolism.

Prevention of Bleeding

When bleeding rates are the subject of an internal quality review, attention may be given to the following aspects of care. (i) It should be confirmed that venous access was routinely obtained with US guidance and a micropuncture needle. The popliteal vein may be used as the preferred access site for most patients (20). (ii) When recombinant tissue plasminogen activator is used, weight-based dosing at 0.01 mg/kg/h (not to exceed 1.0 mg/h) is recommended (19). (iii) The presence of careful monitoring of patients undergoing thrombolysis should be confirmed. This should include placement of patients at bedrest with immobility of the catheter-bearing extremity, frequent contact with nursing staff, and blood draws for hematocrit, platelet count, and PTT at least every 12 hours. Although a conclusive relationship between fibrinogen levels and bleeding has not been established, the consensus opinion of the committee members is that serial monitoring of fibrinogen levels during venous CDT may help to prevent complications (58). However, other findings should also be considered potential markers of impending bleeding, such as marked pericatheter oozing, minor sentinel bleeds (eg, epistaxis), and elevated PTT. (iv) It should be confirmed that arterial punctures and intramuscular injections did not occur during thrombolysis (except under dire circumstances). Finally, (v) it should be confirmed that thrombolytic progress was assessed by venography at least every 24 hours to enable cessation of the infusion as soon as possible.

Proper matching of the type and level of anticoagulation to each patient's individualized bleeding risk should be considered when evaluating the frequency of bleeding events. Young, healthier patients can tolerate more robust heparin and recombinant tissue plasminogen activator dosing than elderly or debilitated patients. It should be confirmed that the effect of any long-acting anticoagulants (eg, warfarin, rivaroxaban) was allowed to become subtherapeutic by the time of thrombolysis. For patients receiving unfractionated heparin, it should be confirmed that PTT values were not supratherapeutic during thrombolysis (the optimal PTT target range has not been established, though subtherapeutic dosing—1.2–1.7 times the control PTT—was reasonably effective and safe in one multicenter randomized, controlled trial [19]). The consensus opinion of the committee members is that low molecular weight heparin at twice-daily, weight-based, Food and Drug Administration–approved dosing may also be a safe method of anticoagulation during CDT/PCDT, but there are few data to substantiate this. One small study (50) suggests that the use of argatroban for this purpose may also be safe, but heparin-based therapy should be preferred in patients without contraindications until larger studies are available.

Prevention of Symptomatic PE

The best ways to prevent procedure-associated symptomatic PE are to ensure adequate anticoagulation before, during, and after the endovascular procedure and to avoid the use of stand-alone PMT in patients who are eligible to receive pharmacologic thrombolysis (59,60). The incidence of symptomatic PE during pharmacologic CDT does not appear to exceed that observed in patients who receive anticoagulant therapy alone (15,19,37). In a multicenter randomized, controlled trial in which 92 patients received infusion-only CDT (19), there were no cases of procedure-related symptomatic PE. Therefore, the routine placement of IVC filters before infusion-only CDT or infusion-first PCDT is not recommended. Whether an IVC filter enhances safety for patients undergoing single-session PCDT is not clear (61). The long-term risks of retrievable filters include device migration, embolization, and fracture, and recurrent DVT (62). Placement of a retrievable filter may be a reasonable solution for certain patients at particularly high risk of major morbidity as a result of clinical PE during CDT, such as patients with poor cardiopulmonary reserve and the rare patient treated with stand-alone PMT without pharmacologic CDT (63). When PCDT has been completed, IVC filters should be removed as soon as possible—if this cannot occur soon after the procedure, the interventional physician should take responsibility for ensuring that the patient is clinically reevaluated and has the filter removed as soon as possible.

Additional Safety Measures

Additional measures to ensure patient safety are to (i) ensure that patients with preexisting renal insufficiency receive appropriate preprocedure hydration; (ii) premedicate patients with contrast medium allergies with steroids and antihistamine agents; (iii) routinely monitor vital signs and oxygen saturation during therapy; and (iv) use meticulous sterile technique. The development of bradycardia, which can occur with use of the AngioJet device, is poorly understood, but the consensus opinion of the committee is that such occurrences are usually transient and can be limited by use of pause periods during use, especially when used in the iliac vein and/or IVC.

CONCLUSIONS

This article summarizes the available published literature and expert consensus on endovascular thrombus removal procedures for the treatment of lower-extremity DVT. It is hoped that this summary will serve as a useful tool for local quality improvement programs that seek to enhance outcomes in patients with DVT through provision of optimal, evidence-based care.

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APPENDIX A: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database. Consensus on statements in this document was obtained by using a modified Delphi technique (1,2).

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APPENDIX B: SOCIETY OF INTERVENTIONAL RADIOLOGY STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. No therapy, no consequence
B. Nominal therapy, no consequence; includes overnight admission ($\leq$ 23 h) for observation only

Major Complications

C. Require therapy, minor hospitalization ($\geq$ 24 h but $<$ 48 h)
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization ($>$ 48 h)
E .Cause permanent adverse sequelae
F. Result in death

SIR DISCLAIMER

The clinical practice guidelines of SIR attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.