Catheter-Directed Therapy Options for Iliofemoral Venous Thrombosis

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KEYWORDS

• Deep vein thrombosis • Pulmonary embolism • Postthrombotic syndrome
• May Thurner syndrome • Iliac vein compression

KEY POINTS

- Proximal deep venous thrombosis (DVT) is linked to a 50% risk of pulmonary embolism and postthrombotic syndrome.
- Catheter-directed thrombolysis (CDT) can be a useful adjunct to anticoagulant therapy for carefully selected patients with proximal acute DVT.
- CDT combined with mechanical thrombectomy allows for greater thrombus removal and decreased use of thrombolytics.
- An individualized approach to patient selection, with careful assessment of the risk for bleeding, is recommended.
- Risk of acute kidney injury from hemoglobinuria during pharmacomechanical thrombectomy can be reduced with periprocedural hydration, alkalinization of urine, and diuresis.

INTRODUCTION

Venous thromboembolism (VTE), which includes deep venous thrombosis (DVT) and pulmonary embolism (PE), is the third leading cause of cardiovascular death behind heart attack and stroke.[1] Up to one-third of patients diagnosed with VTE will die within 1 month of diagnosis, and nearly 25% of patients with PE will have sudden death as the presenting symptom.[2] Furthermore, VTE remains the leading cause of preventable hospital death.[3,4] Despite these sobering statistics, little is known by the general public about VTE and its long-term sequelae, including chronic thromboembolic pulmonary hypertension and the postthrombotic syndrome (PTS).

Disclosure Statement: Dr D. Sudheendra is a consultant for Boston Scientific and Teleflex. Dr S. Vedantham's institution receives research support from BSN Medical and Cook Medical for studies he conducts.

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Surg Clin N Am 98 (2018) 255–265
https://doi.org/10.1016/j.suc.2017.11.012
surgical.theclinics.com
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DVT is classified as distal (involving the calf veins) or proximal (involving the popliteal and/or more proximal veins) in nature. Although distal DVT tends to have a more benign disease course, proximal DVT is linked to an estimated 50% risk of PE and nearly 50% risk of PTS.[5,6] PTS, which consists of a medley of chronic symptoms including pain, leg swelling, skin discoloration, and sometimes progression to venous ulcers, is most commonly associated with iliofemoral DVT (which is defined as DVT involving the iliac and/or common femoral vein, with or without involvement of other veins) in particular. As a result, patients presenting with iliofemoral DVT have traditionally been considered the patients who may be most likely to experience long-term benefit from endovascular thrombus removal.

Presently, the standard of care for acute DVT is systemic anticoagulation. The purpose of systemic anticoagulation is to prevent thrombus propagation, thereby reducing the incidence of PE. However, it is the body's endogenous fibrinolytic system that plays the primary role in thrombus resolution. Even with systemic anticoagulation, the massive clot burden in iliofemoral DVT is overwhelming for the body's fibrinolytic system and usually results in incomplete clot dissolution. The remaining thrombus burden can predispose the patient to recurrent thrombosis and PTS secondary to ambulatory venous hypertension, which develops from the combination of venous obstruction and venous valvular dysfunction.

Endovascular treatment options with catheter-directed thrombolysis (CDT) and pharmacomechanical catheter-directed thrombolysis (PCDT) are often used for iliofemoral DVT to lessen the thrombus burden and expedite symptom resolution. They are also hypothesized to minimize valvular damage and thereby reduce the incidence and severity of PTS.

CLINICAL EVALUATION AND PATIENT SELECTION

Anticoagulation remains the standard of care for DVT treatment. CDT is a more aggressive treatment option requiring a thorough clinical evaluation and proper patient selection to ensure good outcomes and minimize complications. Although the vast majority of patients can be treated in a nonurgent manner, patients with a threatened limb (ie, phlegmasia cerulea dolens) warrant emergent thrombolysis and/or surgical thrombectomy for limb salvage.

Several factors must be considered in determining a suitable candidate for thrombolysis (**Fig. 1**). These factors include the following:

Age and Extent of Thrombus

Knowing the approximate age of the thrombus is critical in determining whether CDT or pharmacomechanical thrombectomy will be effective. At present, this assessment generally relies mainly on a careful medical history to document the onset date of symptoms. Noninvasive imaging with ultrasound (US) or computed tomography (CT) can lend additional information on whether the DVT is acute/subacute or chronic in nature. Thrombus that is acute ($\leq$14 days) has the highest likelihood of responding to thrombolytic therapy compared with older thrombus, which has become more organized and in some cases calcified.[7] In the authors' experience, there is no established role for thrombolytic therapy for chronic thrombus except in some situations of acute on chronic DVT. For extension of thrombus into the inferior vena cava (IVC) or free floating thrombus in the IVC, some practitioners consider the use of an IVC filter. However, the authors do not recommend this as a routine practice because available studies suggest that PE is rare with CDT. If an IVC filter is planned, the risks and benefits should be discussed with the patient.

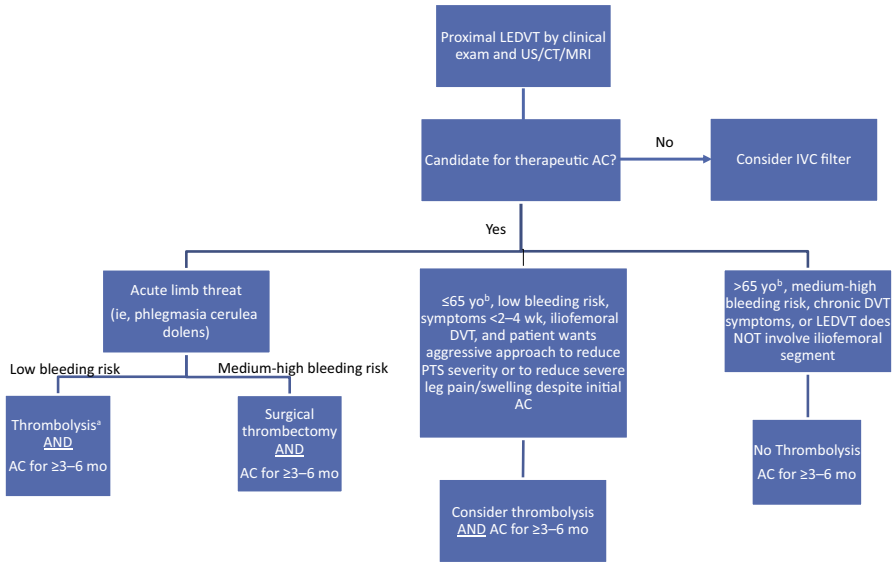


Fig. 1. Management algorithm for patients with acute proximal LEDVT. AC, anticoagulation; LEDVT, lower extremity deep vein thrombosis; PTS, postthrombotic syndrome; yo, years old. [a]Patients older than 65 years were shown to have a higher risk of bleeding from thrombolysis (as per ATTRACT study results). [b]Thrombolysis should be reserved as first-line treatment to speed symptom relief and reduce PTS in patients who want aggressive treatment (given ATTRACT study results).

Age of the Patient

Younger, healthier patients are more likely to benefit from aggressive therapy. Studies of thrombolytic therapy for multiple indications have shown that the risk of major bleeding is significantly higher for patients older than 65 years.[8]

Anatomic Abnormalities

Anatomic considerations that may increase the risk of the procedure, extend the duration of the procedure, necessitate further discussion of risk with the patient, or require more expertise include iliac vein compression (ie, May Thurner syndrome) and IVC stenosis and/or thrombosis.[9–11]

Presence of an Inferior Vena Cava Filter

The presence of an IVC filter is important in procedural planning because it will often need to be removed to prevent future complications (ie, filter fracture, IVC thrombosis) and recurrent DVT.[12] Removal of the filter may require complex IVC filter retrieval techniques necessitating referral to a more experienced center.

Patient Comorbidities Including Bleeding Diathesis

Absolute contraindications to CDT or pharmacomechanical thrombectomy include active bleeding or known bleeding diathesis; recent surgery, obstetric delivery, major trauma, or cerebrovascular event; the presence of a lesion that could bleed in a critical site (eg, central nervous system); and the presence of a contraindication to anticoagulation. Relative contraindications include pregnancy, uncontrolled hypertension, and

congestive heart failure.[8] Patients with chronic renal insufficiency may be at a higher risk for acute kidney injury from iodinated contrast administration and hemoglobinuria from mechanical thrombectomy; in some instances, renal protective agents may be considered for use before and during the procedure.[13]

PREPROCEDURE DIAGNOSTIC IMAGING

Noninvasive imaging with duplex US is the most common imaging modality used to diagnose DVT. However, US has limitations in evaluating the extent of DVT above the inguinal ligament because of body habitus or overlying bowel gas. CT or magnetic resonance venography may be used to quantify the extent of DVT and more importantly evaluate for other abnormalities such as structural lesions (ie, iliac vein compression from May Thurner syndrome), anatomic variation (ie, duplicated IVC), tumor compression, or caval thrombosis from an IVC filter. Cross-sectional imaging may also assist in determining the optimal access points for performing CDT.[14]

PREPROCEDURE PATIENT DISCUSSION AND PREPARATION

An honest and open discussion with the patient and their family about the risks and benefits of catheter-directed therapy options is essential given that these modalities are outside the standard of care. The risk of major hemorrhagic complications (3%–10%) should be discussed, including the risk of fatal or intracranial bleeding (0.5%).[15–17] In the Catheter directed Venous Thrombolysis in Acute Iliofemoral Vein Thrombosis (CaVenT) study, the risk of major bleeding was 3%, which suggests that careful patient selection is crucial in minimizing hemorrhagic complications.[17] Patients should be made aware that additional procedures may be needed in the future, and that currently available stents are permanent devices that are used off-label and for which there are limited data on long-term fate. In addition, there is the possibility that thrombolysis may be unsuccessful. Of paramount importance is that patients understand that anticoagulation will be needed for at least 6 months or possibly lifelong and that these procedures are not a replacement for anticoagulation. Although the goal of CDT or PCDT is to improve DVT symptoms and potentially minimize the long-term complications of PTS, it must be made clear that PTS may not be completely avoided and that the impact of CDT/PCDT on long-term outcome is still under study. Finally, adjunct therapies such as the use of compression stockings may be recommended to improve symptomatic swelling only with no potential benefit in preventing PTS.[18]

VENOUS ACCESS

Depending on the extent of DVT, the patient may be placed in either the supine or the prone position. Common sites of access include the internal jugular, common femoral, greater/smaller saphenous, popliteal, or calf veins. Preprocedural bedside US evaluation is important to determine the proper access site for thrombolysis. If possible, access should be obtained below the lowest point of occlusive thrombus and not within a thrombosed segment of vein. In order to minimize potential bleeding complications and inadvertent arterial injury, real-time US guidance should always be used. Once access has been established, the following steps may be performed as outlined in later discussion for CDT.

Catheter-Directed Thrombolysis

CDT involves the delivery of a thrombolytic agent through a multi-side-hole infusion catheter positioned within the occluded vein. This technique enables a higher

concentration of thrombolytic agent to be delivered locally within the thrombus while minimizing the systemic dose. At present, no fibrinolytic is approved by the US Food and Drug Administration for DVT therapy. Tissue plasminogen activator (TPA), the most commonly used agent, may be used at 0.01 mg/kg/h, not to exceed 1.0 mg/h. Treatment of unilateral iliofemoral DVT typically requires 24 to 30 hours of infusion.[15] After CDT, venography is performed to assess for thrombus resolution and exclude any underlying structural abnormalities that may contribute to DVT formation. Adjunctive maneuvers such as balloon maceration and/or mechanical thrombectomy can be performed to enhance thrombus removal (**Fig. 2**).

Catheter-Directed Thrombolysis Technique

CDT can be performed alone or in conjunction with mechanical thrombectomy. Because of the logistics involved with CDT, a firm understanding of the procedure is necessary by the medical and nursing staff to ensure that complications are avoided. Listed is a generalized technique for CDT:

1. Real-time US-guided access, ideally below the lowest point of occlusive thrombus
2. Lower extremity venogram performed to define thrombus extent
3. 0.035 hydrophilic guidewire and 4-F or 5-F catheter advanced through thrombus and into IVC. IVC venogram performed to evaluate for caval anomalies and patency
4. Multi-side-hole infusion catheter placed over wire with side-holes within the entire thrombosed segment
5. Recombinant TPA (eg, alteplase) infused through the catheter at 0.01 mg/kg/h not to exceed 1.0 mg/h. If both legs are being lysed, 0.5 mg/h of thrombolytic is used in each catheter for a total of 1.0 mg/h
6. Unfractionated heparin (UFH), usually targeted to subtherapeutic range, for example, activated partial thromboplastin time (aPTT) targeted 1.2–1.7 times (control) is started through the side arm of the access sheath (preferred) or through a peripheral intravenous line. If full-dose unfractionated heparin is used based on patient-specific considerations, close monitoring to prevent the partial thromboplastin time from becoming supratherapeutic is essential to avoid bleeding. Alternatively, full-dose, twice-daily injections of low-molecular-weight heparin (LMWH) may be used.
7. The patient is transferred to an intensive care unit or monitored bed for close observation, including every hour neurovascular checks to evaluate for any change in mental status that could signify a potential intracranial or other major hemorrhage. If the patient has severe head/neck pain or change in mental status, thrombolysis is stopped and an STAT noncontrast head CT scan is obtained. If nonintracranial major bleeding is suspected, thrombolysis is stopped and targeted clinical evaluation is performed urgently. Excellent communication between the physician team and nursing staff is paramount.
8. Hemoglobin and aPTT (if the patient is on unfractionated heparin) is checked every 6 hours while the patient is undergoing thrombolysis. Fibrinogen may also be checked, but it has not been established that doing so is associated with reduced bleeding complications.
9. To prevent acute kidney injury from potential hemoglobinuria caused by mechanical thrombectomy, aggressive fluid hydration with a goal urine output of 50 cc/h is performed overnight.

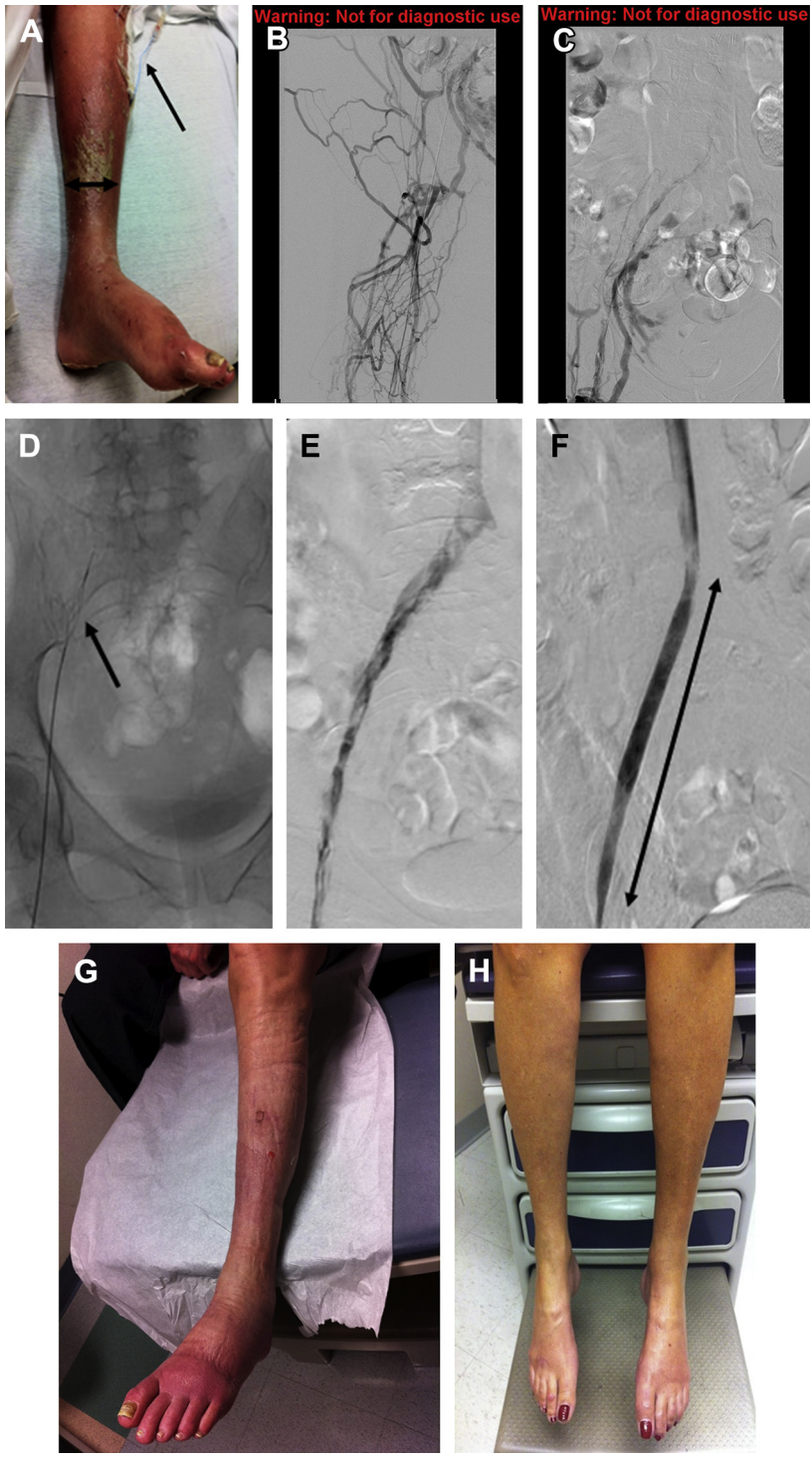


Fig. 2. A 62-year-old woman after pheochromocytoma resection presents with extensive subacute left iliofemoral DVT. (*A*) Photograph of the left leg at presentation shows

10. Repeat venography is performed. Depending on the amount and location of any residual thrombus, CDT may be continued or mechanical thrombectomy may be used to remove residual thrombus.

Pharmacomechanical Catheter-Directed Thrombolysis

PCDT has been used to accelerate thrombolysis and decrease the amount of thrombolytic used compared with conventional CDT. Devices for which case series have been published include the AngioJet Rheolytic Thrombectomy System (Boston Scientific, Marlborough, MA, USA), and the Arrow-Trerotola Percutaneous Thrombectomy device (Teleflex, Wayne, PA, USA). When used in aspiration mode, the AngioJet device uses the Bernoulli-Venturi effect to create a negative pressure gradient that results in thrombus being drawn into the catheter, where it is then fragmented and aspirated. Also, in power pulse-spray mode, dilute TPA can be sprayed under high pressure throughout the thrombus and allowed to dwell for approximately 30 minutes after which thrombus aspiration is performed. The Arrow-Trerotola Percutaneous Thrombectomy device does not aspirate thrombus but has a rotational mechanism that fragments thrombus, enabling its use to debulk thrombus in conjunction with CDT.[19]

Pharmacomechanical Catheter-Directed Thrombolysis Technique

The many variations of PCDT are beyond the scope of this article. To summarize, mechanical thrombectomy may be performed in conjunction with CDT or alone as a single-session PCDT for acute iliofemoral DVT (**Fig. 3**). Common side effects of mechanical thrombectomy that the physician must be aware of include hemoglobinuria and bradycardia if using the AngioJet device. Hemoglobinuria occurs as a result of intravascular hemolysis by the AngioJet catheter, resulting in the release of large amounts of free hemoglobin. Aggressive periprocedural hydration, urine alkalinization, and diuresis can reduce the occurrence of renal damage. Bradycardia during thrombectomy is usually self-limiting with temporary cessation of device activation; the mechanism of action is not well understood. One theory is that adenosine is released as a result of intravascular hemolysis and may result in transient bradycardia. A more plausible but still not substantiated theory is that stretch receptor activation in the right heart from cyclical high-pressure gradients by the device may play a more important role.[20] However, it is recommended that atropine be readily available should the patient become symptomatic from the bradycardia. Hemoglobinuria and bradycardia are not commonly seen with other thrombectomy devices.

significant swelling, erythema, and cellulitis (*double arrow*). Infusion catheter is in left popliteal vein (*arrow*). (*B*) Initial venogram from left popliteal vein access in the prone position shows occlusive thrombus in the left femoral and common femoral veins. A small amount of flow in the left external and common iliac veins is present. (*C*) Venogram after overnight CDT shows marginal thrombus reduction with small amount of flow in the external and common iliac veins. (*D*) Pharmacomechanical thrombectomy with AngioJet Rheolytic thrombectomy device (not shown) performed along with mechanical thrombectomy with Arrow-Trerotola thrombectomy device (*arrow*). (*E*) Significant improvement in flow in left iliac veins with persistent residual chronic thrombus. (*F*) An 18 mm × 9 cm Wallstent (*double arrow* shows length of stent) placed and angioplastied to 16 mm to increase length of stent. (*G*) Photograph of left lower extremity at 1-month follow-up shows improvement in swelling and cellulitis. (*H*) Photograph of left lower extremity at 4-year follow-up shows no evidence of recurrent DVT. (*Courtesy of* [D] Boston Scientific, Marlborough, MA and Teleflex, Wayne, PA; and [F] Boston Scientific, Marlborough, MA.)

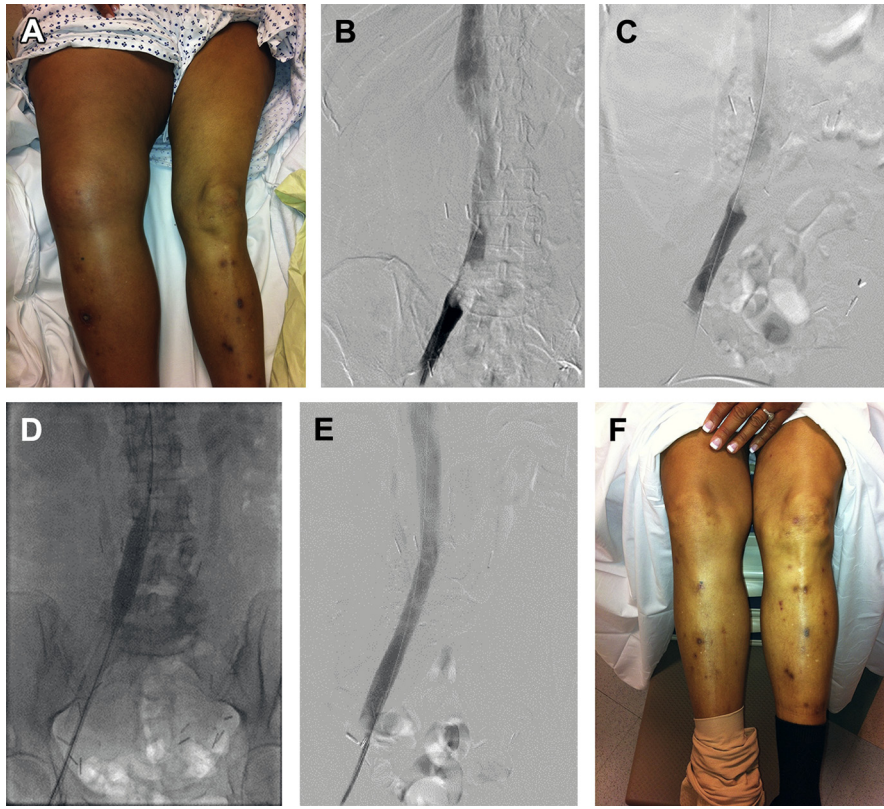


Fig. 3. A 54-year-old woman with recurrent urothelial cancer and right lower-extremity common iliac vein DVT. (*A*) Photograph of the right leg at presentation shows significant swelling. (*B*) Initial venogram from a right greater saphenous vein access shows occlusive thrombus in the right common iliac vein extending into the distal IVC. (*C*) Residual chronic thrombus of the right iliac vein is seen after pharmacomechanical thrombectomy with TPA (alteplase) and the AngioJet Rheolytic thrombectomy device (not shown). (*D*, *E*) A 16 mm × 9 cm Wallstent placed for maceration of chronic thrombus and for compressive effect of recurrent tumor on the iliac vein. (*F*) Photograph of legs 1 month after pharmacomechanical thrombolysis and stent placement shows resolution of initial swelling.

Stent Placement

Underlying venous stenoses that are uncovered after standard or PCDT are often treated with stenting. However, indications for stenting are not entirely clear, resulting in a wide range of stenting practices. According to current guidelines, stenoses in iliocaval vessels are appropriate for stent placement.[21] Femoral-popliteal stenoses are generally treated with angioplasty alone. The patency of stents in the venous system for acute DVT patients who have stent placement is excellent with 87% primary patency and 89% secondary patency at 1 year. Stent patency in nonthrombotic cases is extremely favorable with up to a 96% primary patency and 99% secondary patency at 1 year.[22–24] For acute DVT patients, stent placement is generally avoided across the inguinal ligament to prevent potential stent fracture and in-stent restenosis; however, for established PTS, stenting into the common femoral vein is often needed to maximize inflow.

CLINICAL RESULTS AND LITERATURE REVIEW

One rigorously conducted randomized controlled trial has shown improved thrombus reduction and reduced rates of PTS following CDT for proximal DVT. In the CaVenT trial, a 14.4% absolute reduction in PTS rate was seen in patients with iliac or femoral treated with infusion CDT compared with patients receiving anticoagulation alone at 24-month follow-up (41% vs 56%, $P = .047$).[15,17,25] However, there was no difference in 2-year health-related quality of life. Questions about the applicability of the CaVenT study to US practice relate to its small-medium size, lack of use of mechanical thrombectomy devices, and its performance in a geographically limited area (Southern Norway). The BERNUTIFUL (BERN Ultrasound-enhanced Thrombolysis for Iliofemoral Deep Vein Thrombolysis) trial compared US-assisted CDT (Ekowave catheter, EKOS Corporation, Bothell, WA, USA) for iliofemoral DVT versus standard CDT. However, no significant difference in important clinical outcomes, including thrombus load reduction and PTS, was found between the US-assisted CDT and conventional CDT groups.[26,27]

POSTPROCEDURE CARE AND FOLLOW-UP

After CDT or PCDT, the patient should remain on bed rest for 2 to 4 hours to allow for hemostasis. Sequential compression devices are encouraged to stimulate the calf muscle pump system. The patient is also encouraged to drink plenty of fluids in order to minimize the effects of hemoglobinuria. By the next day, the patient is encouraged to ambulate. Twenty to 30 mm Hg thigh-high compression stockings are recommended to help with lower-extremity edema. The patient should be discharged with a defined plan for anticoagulant therapy that is consistent with their risk of recurrence, and a follow-up office visit in 1 month with US or cross-sectional imaging to evaluate for deep venous and/or stent patency. Appropriate referral to hematology is warranted in patients with an unprovoked DVT or possible thrombophilia.

SUMMARY

CDT and PCDT are endovascular techniques that enable rapid recanalization of acute iliofemoral DVT, at the price of an increased risk of early bleeding. Although the long-term outcomes of these techniques continue to be studied, they are likely to be beneficial for selected patient groups provided careful pretreatment assessment and close monitoring are performed.

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