Catheter-directed thrombolysis for the treatment of acute deep venous thrombosis

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Deep venous thrombosis (DVT) is a major medical problem with significant morbidity and mortality from its associated complications, such as pulmonary embolism, post-thrombotic syndrome, and phlegmasia cerulea dolens. Catheter-directed thrombolysis is a promising and relatively new technique to treat acute DVT and to relieve its symptoms rapidly. The recent unavailability of urokinase has resulted in an increased demand for other thrombolytic agents. Alteplase has demonstrated similar success and complication rates, but with the added benefits of a shorter infusion time and lower cost. Reteplase is a newer thrombolytic agent, and preliminary results have been encouraging, especially when reteplase infusion is combined with the administration of glycoprotein IIb/IIIa inhibitors. Mechanical thrombectomy, particularly when used in conjunction with catheter-directed thrombolysis, is an encouraging technique to further improve the interventionalist's ability to treat DVT and is undergoing continued investigation. This article will review recent advances in the area of catheter-directed thrombolysis for DVT, including several abstracts presented at the recent Society of Cardiovascular and Interventional Radiology 2001 Annual Meeting.

Deep venous thrombosis (DVT) of the lower extremity is the most common manifestation of venous thrombosis in the body. The incidence of lower-extremity DVT in the United States has been estimated at 300,000 cases annually.[1] Virchow's triad refers to the existence of several factors predisposing to the occurrence of venous thrombosis, and includes venous stasis, hypercoagulability, and vessel injury. One or more of these predisposing factors are commonly identified in patients with DVT. Clinical risk factors for DVT include malignancy, prolonged immobilization, and prior venous thrombosis, among others.

In most patients, thrombus originates and remains in the calf veins, and the clinical significance of isolated calf thrombosis is controversial, as an associated high risk for pulmonary embolism has not been identified.[2] Thrombus involving the popliteal and iliofemoral veins is of considerably greater clinical concern due to the higher risk for pulmonary embolism and is the focus of most treatment strategies. Symptoms of acute DVT include leg swelling, tenderness, and pain. Homans' sign, although classically associated with DVT, is observed infrequently, and is described as the onset of calf pain with forced dorsiflexion of the foot.[3] Pulmonary embolism is the major complication of DVT, and the lower extremity veins are the source of pulmonary embolism in at least 80% of patients.[2,3] Furthermore, pulmonary emboli associated with proximal DVT are larger and more frequent compared with calf vein thrombosis, and are more likely to be fatal.[4]

The natural history of acute DVT includes several possibilities occurring over the course of approximately 6 months. The thrombus may undergo complete lysis; organization with venous occlusion; or recanalization resulting in narrowing of the vein lumen, thickening of the vein walls, and destruction of the valves. Up to 50% of veins demonstrate residual disease after acute DVT.[5] These

Table 1. Preliminary consensus recommendations for catheter-directed thrombolysis with alteplase[19]

Alteplase dose
- 0.12 to 2.0 mg/hr
- Recent consensus is to discourage a weight-based formula
- Total dose not to exceed 20 to 40 mg, with infusion for deep venous thrombosis toward higher end of range
- Minimum dose for effective thrombolysis is unknown

Heparin dose
- 500 U/hr, with prothrombin time 1.25 to 1.5X control
- Separate infusion

chronic venous changes may lead to incompetency of the venous valvular system, with secondary venous hypertension. This has been termed the post-thrombotic syndrome.[6] The clinical symptoms of the post-thrombotic syndrome include limb edema, pain, hyperpigmentation, and chronic venous stasis ulcers.[7] Phlegmasia cerulea dolens is a condition seen in a small percentage of patients with chronic DVT in whom marked venous insufficiency leads to severe pain and leg swelling, followed by signs of arterial insufficiency. Complications include gangrene of the affected extremity, pulmonary embolism, and even death.[8] In addition, the elevated pressure in the deep venous system may result in reversal of flow in the superficial veins, leading to the development of varicose veins.

Treatment

Standard treatment for DVT is anticoagulation and supportive care, including bed rest, leg elevation, and compression stockings. Anticoagulation is typically started with approximately 5 days of intravenous unfractionated heparin administration followed by the conversion to long-term oral warfarin sodium. The recent introduction of subcutaneously administered low molecular-weight heparin compounds has permitted outpatient management of acute DVT in select cases.

The benefits of anticoagulant therapy include the prevention of thrombus propagation, reduction in the rate of new thrombus formation, and reduction in the rate of pulmonary embolism. However, anticoagulation does not eliminate the existing thrombus. This relies upon the patient's own fibrinolytic system, which can recanalize the lumen of the occluded vein, thereby permitting re-establishment of venous patency.[9] Johnson et al[6] have shown that in veins >8 mm in diameter (such as the iliofemoral veins), the endogenous fibrinolytic system may be unable to completely recanalize the vessel lumen, ultimately predisposing patients to the post-thrombotic syndrome.

Thrombolysis

Systemic administration of thrombolytic agents has been reported in the literature and has been shown to be clinically superior to heparin administration alone. However, systemic thrombolytic delivery is usually not successful with extended areas of thrombosis.[10,11]

Catheter-directed thrombolysis was initially reported in the early 1990s as an alternative to anticoagulation and systemic thrombolytic administration.[12-14] The primary goals of catheter-directed thrombolysis include rapid clot lysis that produces rapid symptomatic relief, and improved therapeutic efficiency with local delivery of the thrombolytic agent. Urokinase had been the primary thrombolytic agent until late 1998, with technical success rates reported at 80% to 90% for iliofemoral DVT.[15-16] In late 1998, the U.S. Food and Drug Administration passed a ban on further use of urokinase due to concerns about sterility.[17] Alteplase (rt-PA; Activase, Genentech, Inc., South San Francisco, CA) has now become the most commonly used agent for catheter-directed thrombolysis. Alteplase is a recombinantly engineered analog of human tissue plasminogen activator. Current indications for alteplase include bolus administration for acute myocardial infarction, pulmonary embolism, and acute nonhemorrhagic stroke, but it has been used with success for DVT thrombolysis.[11]

At the 2001 Society of Cardiovascular and Interventional Radiology (SCVIR) Annual Meeting, Sugimoto et al[18] reported on the treatment of a total of 93 affected limbs (54 DVT, 39 acute peripheral arterial obstruction) with either alteplase with subtherapeutic heparin, or urokinase with full heparin. The investigators found that compared with urokinase, alteplase (at <2 mg/hr) with subtherapeutic heparin was equally efficacious with a similar complication rate, yet significantly (P <0.05) faster and less costly. Recently, the SCVIR Advisory Panel on Catheter-Directed Thrombolytic Therapy published preliminary guidelines for alteplase dosing to minimize the associated risk of bleeding (Table 1).[19] Further recommendations for alteplase for catheter-directed thrombolysis are being developed.

Reteplase (r-PA; Retevase, Centocor/Johnson & Johnson, Malvern, PA) is a more recently investigated recombinant analog of alteplase, and is presently approved for acute myocardial ischemia. Reteplase demonstrates an increased circulating half-life (15 versus 5 minutes) and a decreased fibrin affinity when compared with alteplase. The reduced affinity for fib-

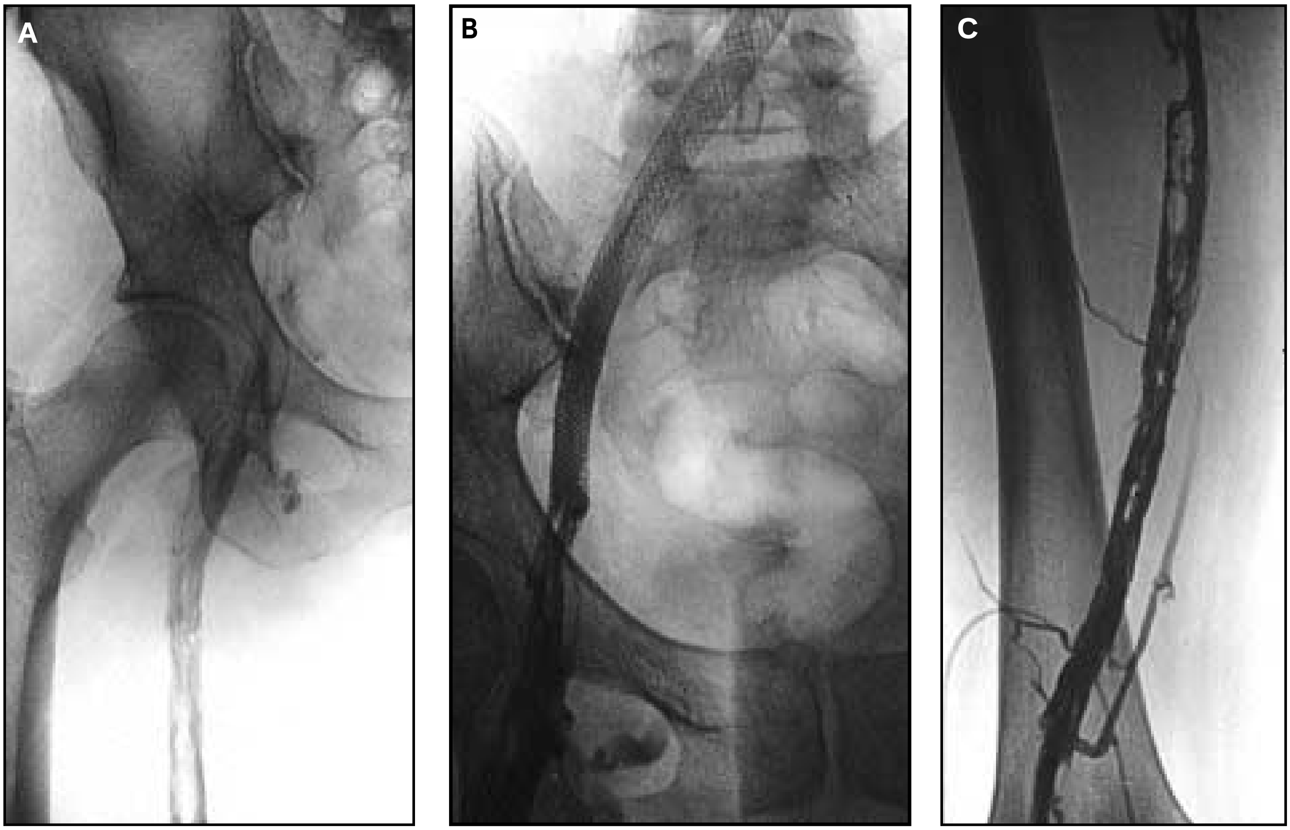


__FIGURE 1.__ A 46-year-old woman with progressively worsening left leg swelling over 6 weeks while on oral anticoagulation. (A) Venogram performed via the antegrade popliteal vein access demonstrates nearly occlusive deep venous thrombosis (DVT) within the left common iliac vein. Nonocclusive DVT was identified from the superficial femoral vein to the popliteal vein (not shown). Patient was started on continuous alteplase infusion via a multi-sidehole coaxial infusion catheter placed into the iliofemoral veins. (B) Venogram after 12 hours of thrombolysis. Severe stenosis and mural irregularity extending from left common iliac to superior external iliac veins, across which two self-expandable stents were deployed (Wallstent, Boston Scientific Corp., Natick, MA) with good results. (C) Venogram after 2 days of thrombolysis. Persistent superficial femoral vein thrombus, presumably chronic. Patient's symptoms improved significantly, and thrombolysis was discontinued.

rin may allow improved absorption by the thrombus compared with alteplase, although its true clinical significance has not been demonstrated. Recently, investigators have reported the use of reteplase for peripheral DVT. Castaneda et al,[20] at the 2001 SCVIR Annual Meeting, described preliminary results in 25 patients with acute DVT treated with reteplase. More than 90% of patients were treated with infusion rates of 0.5 to 1.0 U/hr. Success was obtained in 89% of patients, and there was no significant difference in success with the lower 0.5 U/hr infusion rate. Further research with reteplase comparing its efficacy with other thrombolytic agents is being conducted. In addition, recent research has suggested that reteplase in combination with abciximab, a glycoprotein IIb/IIIa receptor antibody, may improve the time to achieve thrombolysis and reduce the dose of the thrombolytic compared with reteplase alone.[21]

Patients with acute iliofemoral DVT, with <10-day duration of symptoms, documented by venography or color Doppler ultrasound, and without contraindications for thrombolysis and chronic anticoagulation therapy, may be considered suitable candidates for catheter-directed thrombolytic therapy.[16] Contraindications to thrombolysis include prior cerebrovascular accident, active internal bleeding, a neurosurgical procedure (intracranial or spinal) within the last 12 months, pregnancy, or coagulopathy.[16] Typically, a multiple side-hole infusion catheter is placed across the thrombus via the ipsilateral popliteal vein, which is punctured under ultrasound guidance to avoid inadvertent popliteal artery puncture. Although the femoral vein can also be used as a venous access site, retrograde placement of the infusion catheter may result in injury to the valve leaflets. Venography is performed at selected intervals at the discretion of the physician to monitor the progress of thrombolysis. Thrombolysis is discontinued when venography shows resolution of

Table 2. Mechanical thrombectomy devices

Device	Manufacturer	Price ($)	Sheath Size (F)	Aspiration	Over the Wire	Immediate Technical Success (Ref.)
Rotational						
ATD	Microvena White Bear Lake, MN	550	6/8	N	N*	89%[25]
PTD	Arrow International Reading, PA	600	5	N	N*	95%[26]
EndoVac	NeoVascular Technologies Brooklyn, NY	350	6	Y	N	N/A
Hydrolysing						
AngioJet	Possis Medical Minneapolis, MN	600	5	Y	Y	88%[27]
Oasis	Boston Scientific Natick, MA	600	6	Y	Y	71%[28]
Hydrolyser	Cordis Endovascular Warren, NJ	600	6/7	Y	Y	87%[29]

* Newer versions of these devices will have over-the-wire capabilities.

ATD= Amplatz Thrombectomy Device; PTD= Arrow-Trerotola Percutaneous Thrombolytic Device.

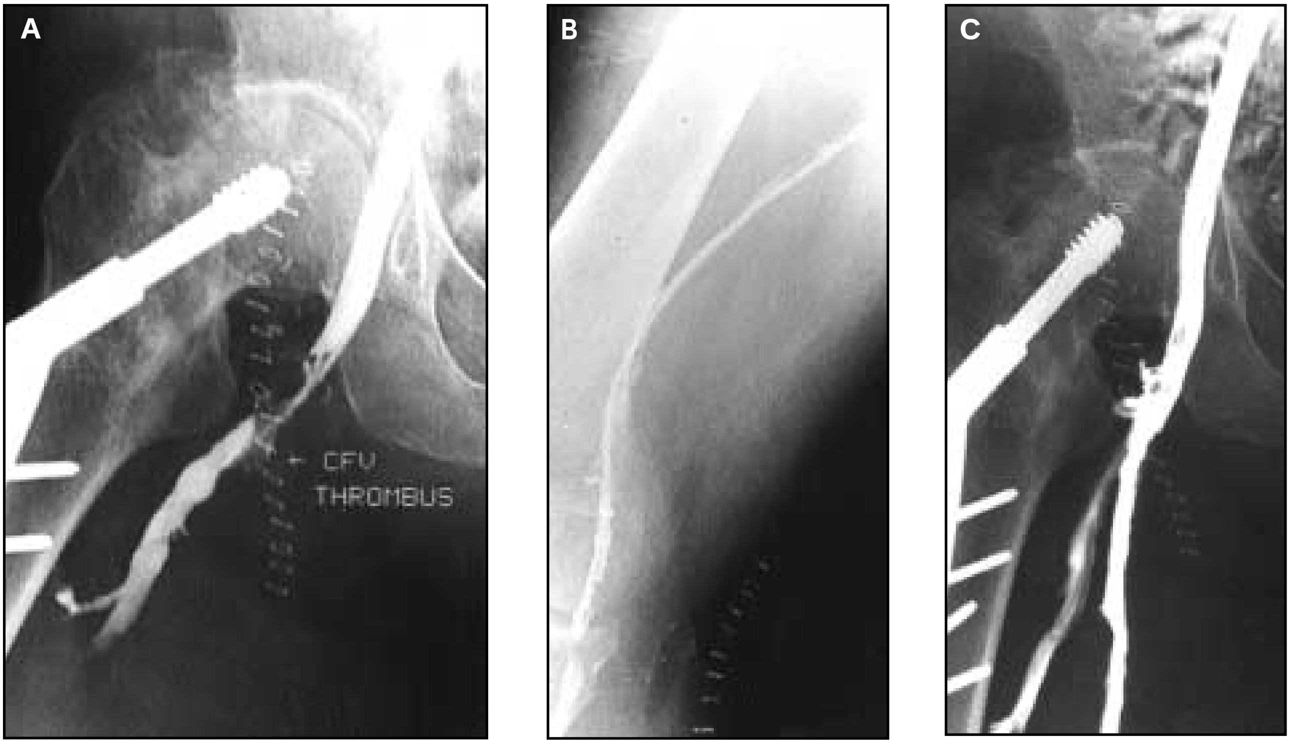
thrombus, or when no additional improvement is noted after further infusion over 12 hours. Balloon angioplasty may be performed to macerate residual thrombus, and stent placement may be used to treat venous wall elastic recoil, venous rupture, or residual stenosis. Often, successful DVT thrombolysis may uncover the primary cause of the patient's DVT, such as iliac vein compression (May-Thurner) syndrome, which can be treated with additional procedures such as stent placement[22] (figure 1). Inferior vena cava filters are indicated infrequently because the occurrence of significant pulmonary embolism during catheter-directed thrombolysis is uncommon.[14] Filter placement may be considered if there is a history of recurrent pulmonary emboli despite adequate anticoagulation, or if a "free-floating" thrombus in the iliac veins or inferior vena cava has been identified.[15,23] The most significant potential complication of thrombolysis is bleeding, either major (venous entry site, intracranial, retroperitoneal, gastrointestinal, genitourinary, or musculoskeletal) or minor (venous entry site). In the series of 473 patients reported by Mewissen et al,[16] 11% had major bleeding complications and 16% had minor bleeding complications. Pulmonary embolism is another major complication reported in the literature, and in the same series by Mewissen et al, a total of 6 patients experienced pulmonary embolism, one of which was fatal.

Various investigators have attempted to devise methods to "stage" DVT to predict the potential success of thrombolysis. At the 2001 SCVIR Meeting, Roh et al[24] reported results assessing the value of selected CT findings from 24 patients with DVT in predicting the success of catheter-directed thrombolysis. Patients who responded favorably to thrombolysis had significantly higher thrombus attenuation coefficients (measured as Hounsfield units) compared with those of patients who responded poorly (66.1 ± 8.7 versus 45.9 ± 9.6, P <0.0001). The attenuation coefficient was found to be the most significant of several CT variables by multivariate regression analysis.

Mechanical thrombectomy

Mechanical thrombectomy for lower extremity DVT, either exclusively or in combination with thrombolysis, remains controversial and the focus of ongoing investigation (figure 2). Table 2 reviews six presently available mechanical thrombectomy devices that are approved for use in polytetrafluoroethylene hemodialysis grafts. These devices can be classified into two categories, based upon their mechanism of action. Rotational devices employ a mechanical device such as a wire basket (Arrow-Trerotola Percutaneous Thrombolytic Device, Arrow International, Reading, PA) or helical propeller (Amplatz Thrombectomy Device, Microvena, White Bear Lake, MN) to macerate the clot. Hydrolysing devices create a hydrodynamic vortex to homogenize the clot into a slurry, which may be aspirated, depending upon the specific device. A major disadvantage of hydrolysing devices is that they are limited to relatively acute thrombus (within 10 days old) for maximum efficacy.

Vedantham et al[30] reported the outcomes of 13 patients with 17 symptomatic limbs over 3 years with iliofemoral, caval, or femoropopliteal DVT treated with both thrombolysis and various mechanical thrombectomy devices, including the Amplatz Thrombectomy Device (ATD; n=9),



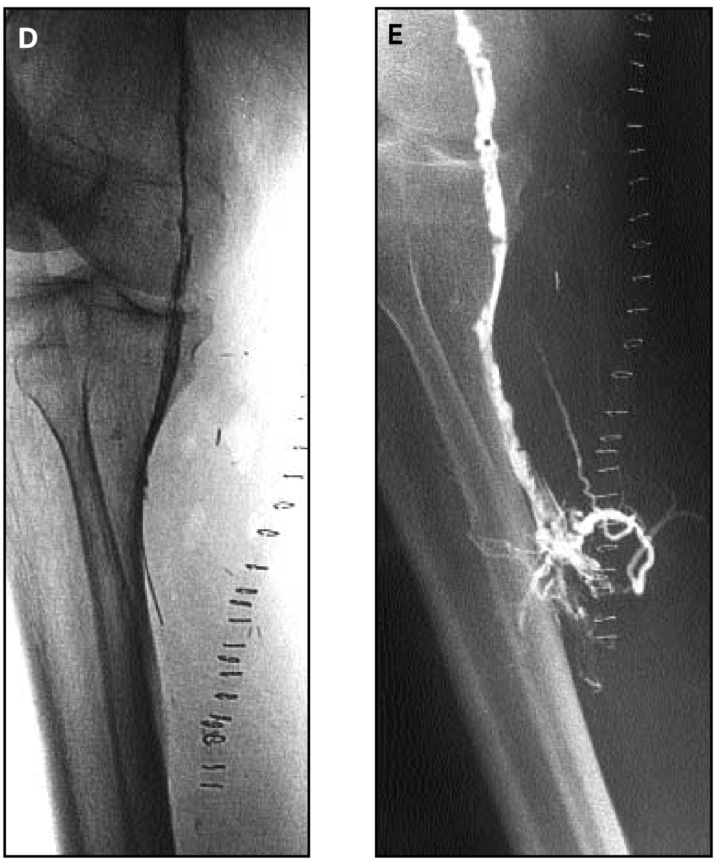


FIGURE 2. *A 63-year-old man following right-leg arterial bypass. Right-leg swelling started 2 days after surgery, and ultrasound examination demonstrated extensive deep venous thrombosis (DVT). On the third postoperative day, the right lower leg was found to be cold and discolored, and arterial compromise was suspected. (A) Venogram performed from contralateral femoral vein access demonstrates nonocclusive thrombus within the left common femoral vein, and occlusive thrombus from the proximal superficial vein inferiorly. (B) Venogram performed following three passes with the AngioJet mechanical thrombectomy device shows thin lumen along path of thrombectomy. Patient was started on continuous alteplase infusion via a multi-sidehole coaxial infusion catheter. (C) Venogram after 18 hours of thrombolysis demonstrates common femoral and iliac veins without residual DVT. (D) After 18 hours of thrombolysis, nonocclusive DVT from superficial femoral vein to infrageniculate popliteal vein. Calf veins do not opacify. (E) After 2 days of thrombolysis, popliteal vein (and superficial femoral vein, not shown) is irregular in appearance but patent. There is persistent thrombus within the peroneal vein. Infusion was stopped at this point. The patient's right leg had improved significantly with restoration of normal color and resolution of swelling, except for the forefoot and midfoot, which were gangrenous and were amputated surgically.*

AngioJet (n=6), Oasis (n=1), and the Arrow-Trerotola Percutaneous Thrombolytic Device (PTD; n=1). Nine cases were acute or subacute, and 4 were chronic. Six patients were treated with urokinase (with full heparin), 4 with alteplase, and 3 with retavase (both with subtherapeutic heparin). Clinical success was obtained in 14 of 17 limbs; in 9 patients, patency was fully restored, and in 6 patients, iliac vein stents were required for residual stenosis (1 patient experienced pectineus muscle bleeding that required transfusion). Of those limbs not treated for freshly formed intraprocedure thrombus, mechanical thrombectomy cleared at least one venous segment of thrombus in 4 of 7 when used before thrombolysis, and in 8 of 8 cases when used after thrombolysis. However, in only one of these cases was mechanical thrombectomy able to clear thrombus over the entire occlusion; the remainder demonstrated only partial clearing. Mean thrombolysis doses and times were less than those reported by other investigators who used different thrombolytic agents but who did not use mechanical thrombectomy.[15,16,18,22,31,32] In a recent paper by Delomez et al,[33] mechanical thormbectomy with the Amplatz Thrombectomy Device was performed on a total of 18 patients with iliofemoral or IVC DVT, with technical success in 83%. Of 11 living patients followed-up on average at 30 months, 10 had no or minimal sequelae.

A significant concern about mechanical thrombectomy that has limited its widespread use is the risk for pulmonary embolism during the procedure. The use of temporary IVC filtration to prevent intraprocedure pulmonary embolism was reported by Trerotola et al.[34] In this investigation, mechanical thrombectomy with the Arrow-Trerotola Percutaneous Thrombolytic Device was performed in 12 canine models with subacute iliocaval thrombus after placement of a nitinol expandable sheath into the suprarenal IVC for temporary caval filtration. Results of pulmonary arteriography after thrombectomy were compared with another group who underwent the same procedure without caval filtration. A significant ($P < 0.002$) reduction in pulmonary emboli was noted after filtration, although pulmonary emboli were not entirely eliminated, as indicated by segmental and subsegmental emboli that were observed after the procedure in the filtered group. This report suggests that temporary caval filtration, although not a perfect solution, may represent a significant advance that improves the risk profile of mechanical thrombectomy for acute lower-extremity DVT.

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Conclusion

Catheter-directed thrombolysis is a safe and effective treatment for selected patients with symptomatic acute DVT, providing rapid relief of symptoms and a reduction in the incidence of complications associated with chronic DVT. The long-term benefits of catheter-directed thrombolysis have yet to be established, but should be accomplished with large randomized controlled trials comparing this therapy with other therapies for acute DVT, such as anticoagulation. Successful thrombolysis often may uncover an underlying primary etiology for the patient's DVT, and adjunctive procedures, such as angioplasty and stent placement, may increase the primary patency rate compared with thrombolysis alone.

Mechanical thrombectomy, when used in conjunction with catheter-directed thrombolysis, appears to be a promising procedure that may significantly reduce the thrombolytic dose and time of infusion. If, in fact, the thrombolytic dose can be reduced with mechanical thrombectomy, perhaps the incidence of the feared bleeding complications may be reduced even further. Temporary caval filtration is an interesting technique that may reduce the incidence of pulmonary emboli during mechanical thrombectomy, and it deserves further investigation. ❑

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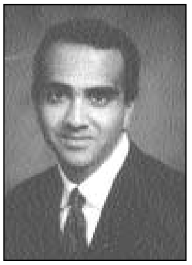

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