Venous Issues

Mechanical Thrombectomy for DVT

Should mechanical thrombectomy play a significant role in treating DVT?

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eep venous thrombosis (DVT) continues to be a life-threatening disorder and is the source of major morbidity both acutely and over time. DVT affects hospitalized patients and healthy individuals alike, 1.2 and it has been estimated that the yearly incidence of DVT is as high as 250,000 cases in the US alone. 3-5 Although as many as 100,000 patients die annually from pulmonary embolism, 6 late morbidity may arise from recurrent thrombosis and the sequelae of the postthrombotic syndrome. 7-11

The management of venous thromboembolism has evolved in recent years to encompass the use of low-molecular-weight heparin for outpatient treatment. Although anticoagulation alone is appropriate for minimally symptomatic thromboses, more extensive processes are associated with the development of the postthrombotic syndrome in many cases. As such, patients with large, proximal DVT are likely to benefit from early recanalization of the occluded veins with extraction or dissolution of the thrombus. This article will be limited to a discussion of proximal DVT involving the iliofemoral venous segments in the thigh and pelvis.

THE GOALS OF DVT THERAPY

The goals of therapy for DVT are to diminish the severity and duration of acute lower-extremity pain and edema, prevent pulmonary embolism, minimize the risk of recurrent venous thrombosis, and limit the development of the postthrombotic syndrome

Although small, distal DVT can be minimally symptomatic, proximal DVT is usually associated with sudden onset of leg edema, pain, and impaired ambulation. These symptoms arise from the immediate venous hypertension associated with outflow obstruction. Although the symptoms usually subside over a period of days to weeks as collateral venous channels enlarge, many patients continue to experience some element of outflow obstruction. The symptoms of obstruction are especially severe during exercise, when total lowerextremity blood flow can rise five-fold. 13 With these considerations in mind, one of the primary goals of therapy for proximal DVT is the relief of outflow obstruction. Such relief is rarely obtained with anticoagulation alone, with partial regression of thrombus in only 50% of patients treated with anticoagulants. 14,15 The rate of complete venous recanalization is much lower, occurring in a small minority of patients treated with anticoagulants.¹⁶

During long-term follow-up, the postthrombotic syndrome is the consequence of the destruction of venous valves and the resulting valvular reflux. In addition to valve incompetence, venous hypertension and stasis compound the problem.⁸ Postthrombotic symptoms can include chronic leg heaviness, leg aching, and venous claudication, edema, varicosities, hyperpigmentation, and nonhealing ulcers. The syndrome develops in 20% to 50% of patients with DVT, with an increasing prevalence over long-term follow-up.⁷ Some studies suggest that the majority of patients with DVT develop

some postthrombotic symptoms if followed for longer than 5 years. ¹⁰ The combination of venous obstruction and valvular reflux is associated with more severe symptoms, and persistent venous outflow obstruction portents the greatest risk for the late development of postthrombotic symptoms. ¹⁷ The syndrome appears to occur more frequently with extensive, multilevel DVT, in patients with recurrent DVT, and when an inadequate oral anticoagulant regimen is employed. ^{10,18,19} These findings raise the possibility that early removal of thrombus with the use of mechanical thrombectomy and/or pharmacologic thrombolysis may protect against distal valvular incompetence and limit the development and severity of postthrombotic syndrome. ²⁰

OPEN SURGICAL THROMBECTOMY

Historically, iliofemoral venous thrombectomy combined with ligation of the femoral vein was the treatment of choice for DVT.^{21,22} The thrombectomy was performed to improve venous outflow from the leg, whereas femoral vein ligation was done to prevent subsequent pulmonary embolism. Although the utility of femoral vein ligation is doubtful, studies going back more than 50 years attest to the benefits of an open surgical approach to acute DVT.^{23,24} The development of balloon thrombectomy catheters by Fogarty in the 1960s facilitated surgical venous thrombectomy.²⁵ Some investigators have recommended the addition of a temporary arteriovenous fistula to augment blood flow across the thrombectomized, thrombogenic luminal venous surface.²⁶ More recently, percutaneous techniques have been used to close the fistula once venous re-endothelialization has occurred.²⁶

In 1984, Plate et al compared conventional anticoagulation to surgical venous thrombectomy and temporary arteriovenous fistula in patients with acute iliofemoral DVT.²⁷ After 6 months of follow-up, postthrombotic symptoms of leg edema, varicose veins, and venous claudication were more frequent in the group treated with anticoagulation alone (42% and 7%, respectively; P=.005). Venographically documented patency of the iliofemoral venous segment was more than two-fold higher in the thrombectomy group than in those given anticoagulants alone (76% and 35%, respectively; P=.025). Patent femoropopliteal veins with competent valves were observed in 52% of those subjected to thrombectomy and 26% in the anticoagulated group (P=.05).

Of greatest importance, this group published 10-year follow-up data from the cohort of patients in the original randomized trial.²⁸ At long-term follow-up, lower-

extremity edema was more frequent in the group that received anticoagulation alone (71% vs 46%), as were leg ulcerations (18% vs 8%). Long-term patency of the iliofemoral venous segment was demonstrated by radionuclide angiography in 41% of the anticoagulated patients compared with 83% of the patients who underwent thrombectomy. Duplex ultrasound confirmed a slightly greater degree of venous valvular incompetence in the femoral and popliteal veins of the anticoagulated group. These clinical and anatomic findings suggest that extraction of the occluding venous thrombus is important in limiting the acute and longterm complications from acute proximal DVT. Noting the morbidity and blood loss associated with open surgical thrombectomy, however, the procedure is now reserved for patients with contraindications to percutaneous interventions or for those in whom other modalities have failed.

PHARMACOLOGIC THROMBOLYSIS

The advent of plasminogen activators to dissolve intravascular thrombi provided a less-invasive strategy to restore venous patency after DVT. At first, systemic administration of agents such as streptokinase (was employed, but results were unsatisfactory.^{29,30} When thrombolytic agents are given systemically, complete (50%-100%) thrombus dissolution occurs in approximately 50% of venous segments with nonobstructive thrombi and in only 10% of fully obstructed segments.31,32 There are numerous contraindications to thrombolytic therapy, most of which focus on factors that increase the risk of bleeding complications. These include recent surgery, stroke, or gastrointestinal bleeding. Unfortunately, only 20% of patients with DVT are appropriate candidates for thrombolytic therapy.³³ Experimental and clinical evidence suggests that systemic administration of thrombolytic agents, which is effective for dissolution of small thrombi in arteries such as the coronaries, is ineffective for treatment of DVT, likely because of the inefficient diffusion of these agents into the substance of large venous thrombi.³⁴⁻³⁶ Furthermore, systemic thrombolysis for DVT is associated with an increased risk of bleeding compared with that observed with anticoagulation alone. 29,30,37 These observations prompted studies of catheter-directed, local infusion of thrombolytic agents, in an effort to minimize bleeding complications and to enhance the efficiency of clot dissolution.38

The largest published results with catheter-based therapy have come from the National Venous Thrombolysis Registry.³⁹ This multicenter database included 287 patients treated with urokinase and fol-

lowed for 1 year. Overall, 71% of the patients were treated for iliofemoral DVT. Complete dissolution of thrombus was achieved in 31% of cases, and partial (50%-99%) thrombus dissolution was reported in an additional 52% of patients. Primary patency at 1 year was 60%. Patency was higher in iliofemoral segments than in femoropopliteal segments and in patients whose thrombus underwent complete dissolution during the initial hospitalization. Preservation of valvular competence was demonstrated in 72% of patients in whom complete thrombolysis was obtained. In a subsequent study that focused on quality of life in a subset of patients entered into the National Venous Thrombolysis Registry, Comerota et al demonstrated better functioning and well being in patients whose iliofemoral DVT was treated with catheter-directed thrombolysis than in those treated only with anticoagulants.40

In a randomized clinical trial comparing thrombolysis with anticoagulation to anticoagulation alone in patients with iliofemoral DVT, thrombolysis was associated with improved patency rates (72% and 12%, respectively; P<.001) and better preservation of venous valvular competence (89% and 59%, respectively; P=.04) at 6 months.²⁰ Although most studies of venous thrombolysis have employed urokinase, recent studies suggest that recombinant tissue-type plasminogen activator (0.5 to 1 mg/h)⁴¹ or reteplase (0.5 to 1 U/h)⁴² can also be used with success.

Potential complications associated with catheterdirected thrombolysis for DVT include hemorrhage and pulmonary embolism. Of these, bleeding is the most feared complication. The National Venous Thrombolysis Registry reported bleeding severe enough to require blood transfusion in 11% of patients and an intracranial bleeding rate of 0.2%. Minor bleeding occurred in 16% of patients. Pulmonary embolism occurs in approximately 1% of patients receiving catheter-directed thrombolytic therapy. However, most emboli occur prior to diagnosis of DVT, and the incidence of pulmonary embolism is sufficiently low that most centers do not advocate routine placement of an inferior vena caval filter prior to instituting catheter-directed thrombolysis. The recent introduction of removable caval filters may change practice, but more information is needed.

PERCUTANEOUS MECHANICAL THROMBECTOMY

Percutaneous mechanical retrieval of venous thrombi is a logical extension of open surgical thrombectomy. Potentially, these devices offer one advantage over phar-

macologic thrombolysis; the possibility of rapid clearance of thrombus from the occluded venous seqments. 43,44 In its simplest form, percutaneous venous thrombectomy can be accomplished through the use of large bore sheaths; an approach that is cumbersome and infrequently associated with complete thrombus extraction.⁴⁵ The introduction of a variety of motorized thrombectomy devices represents an advance over earlier techniques. Except in patients with bleeding diatheses, mechanical thrombectomy devices are usually used in conjunction with adjuvant pharmacologic thrombolysis. 46,47 Combining these two treatment modalities offers the best opportunity for rapid clearance of thrombus, thereby decreasing the duration and dose of thrombolytic agent. Although promising, experience is limited and there are few published reports documenting the utility of this approach for treatment of acute

Mechanistically, thrombectomy devices fall within two categories; hydrodynamic recirculation devices and rotational recirculation devices. Rotational thrombectomy devices use a high-speed rotating basket or impeller to fragment the thrombus. In most cases, the resultant small particles travel to the pulmonary circulation.⁴⁸⁻⁵⁰ Examples of this type of device are the Amplatz thrombectomy device (ev3, Plymouth, MN), the Arrow-Trerotola percutaneous thrombolytic device (Arrow International, Reading, PA), and the Cragg-Castaneda thrombolytic brush (Micro Therapeutics, Inc., Aliso Viejo, CA). Rotational, or "wall contacting," devices have the potential to damage the endothelium lining the vein. Although wall-contact devices are likely to be safe in the setting of a prosthetic dialysis access graft or even a prosthetic peripheral arterial graft, it is probable that their use for venous thrombectomy will result in vascular wall damage. For this reason, the use of such devices in the peripheral veins remains infrequent. In an attempt to circumvent this potential problem, the Bacchus Fino device (Bacchus Vascular, Santa Clara, CA) employs a rotating Archimedes screw that is protected from wall contact by a helically oriented nitinol framework. The screw fragments the thrombus, extracting much of it into a sheath through its rotational actions. No clinical data with this device are available.

The Bacchus Trellis device (Bacchus Vascular, Santa Clara, CA) is a relatively recent introduction into the armamentarium of devices for removal of venous thrombus. This device is composed of a catheter with proximal and distal occlusion balloons, and a sheath that can be used to aspirate contents between the inflated balloons. A nitinol sinusoidal-shaped wire is placed within the catheter such that, when rotated,

there is mixing of the blood between the balloons. The Trellis device, which has been used with some success in patients with DVT,⁵¹ has the potential to remove thrombus by combining high concentrations of thrombolytic agent with mechanical disruption of the clot. The occlusion balloons limit leakage of thrombolytic agent into the systemic circulation; thereby potentially reducing the risk of bleeding complications. In addition, the proximal balloon reduces the risk of embolization of particulate debris to the pulmonary circulation.

Hydrodynamic ("rheolytic") recirculation devices are based on the Venturi effect, created by high-speed saline jets directed in a retrograde fashion. The jets fragment the thrombus and the material is then aspirated into the device. Theoretically, devices using this mechanism of action may produce less valvular or endothelial damage than rotational thrombectomy devices, but this concept has yet to be proved in clinical trials. Examples of hydrodynamic recirculation devices include the AngioJet device (Possis Medical, Inc., Minneapolis, MN), Hydrolyser (Cordis Corporation, a Johnson & Johnson company, Miami, FL), and the Oasis Thrombectomy System (Boston Scientific Corporation, Natick, MA). In a study of 37 patients treated with these devices, Kasirajan reported extraction of more than 50% of the thrombus in 59% of the cases and symptom improvement in 82% of patients.⁴⁶

In 1992, Drasler et al first described the use of a rheolytic system for percutaneous thrombectomy.⁵² The device (the Possis Angiolet system) uses high-velocity jets of saline to fragment the thrombus into tiny particles and extract them through the catheter. The catheters spray jets of saline from exhaust ports at the end of the catheter at a pressure of 10,000 lbs/in² or more. Using the Venturi effect, the thrombus is fragmented and aspirated through the catheter. The initial clinical study was published in 1998, representing a multicenter experience with 21 subjects presenting with a 2-week or less history of limb-threatening ischemia.⁵³ Subsequently, the Possis device was evaluated in both in the arterial and venous sides of the circulation and was approved for human peripheral arterial use in 2000.

Kasirajan published the Cleveland Clinic experience with the Angiolet thrombectomy device for extensive DVT; reporting a 17-patient experience. Among these, 14 were in the lower-extremity veins and three were in the upper-extremity veins. With use of Angiolet alone, four patients (24%) had essentially complete (>90%) thrombus removal, six (35%) had between 50% and 90% thrombus removal, and seven (41%) had less than 50% thrombus removal. Adjunctive pharmacologic thrombolysis was subsequently administered in nine of

13 patients who had incomplete thrombus removal with the AngioJet; complete clearance of thrombus was achieved thereafter in seven (78%) of these cases. Overall, use of the AngioJet percutaneous thrombectomy device with or without pharmacologic thrombolysis resulted in 90% or greater thrombus removal in 11 of the 17 cases (65%). Excluding patients with contraindications to pharmacologic thrombolysis, complete thrombus removal was observed in fully 11 of 13 cases (85%).

A new method of combing Angiolet thrombectomy with thrombolysis was reported by Allie et al.⁵⁴ Using the AngioJet RT system, and the 6-F Xpeedior RT catheter, tenecteplase or urokinase was dissolved in 50 mL of normal saline. The solution is used for the saline prime and a stopcock is added to occlude the outflow port, converting the system to a "power-pulse" mode. A 0.6-mL bolus of thrombolytic solution is delivered with each pedal pump, using system as a high-pressure infusion catheter without extraction. Allie et al advise a single antegrade and retrograde pass. After a 20-minute period to allow thrombolysis dissolution to occur, the residual thrombolytic agent is evacuated, the AngioJet catheter is reintroduced, a single antegrade pass is made, and angiography is performed. Although this procedure has not been described specifically for the DVT indication, the results in acute limb ischemia suggest that such use may be warranted.

ADJUVANT VENOUS ANGIOPLASTY AND STENTING

DVT can occur in the setting of underlying venous pathology. Most significant is left common iliac vein stenosis, located where the vein crosses beneath the right common iliac artery. This entity, which was originally described in separate reports by May and Thurner, is now known as the May-Thurner syndrome.⁵⁵ Prior to the widespread use of postinterventional imaging studies, this anomaly often went undetected, which may account for the high rate of rethrombosis reported in the earlier studies of open surgical venous thrombectomy.²⁴ With the use of postintervention angiography in patients undergoing percutaneous thrombolytic and thrombectomy procedures, it is now possible to identify a culprit lesion in some patients. Once identified, these lesions can usually be treated with percutaneous angioplasty and stenting. 38,56-58 Patency rates for metallic stents placed in the venous circulation appear to be high. Although long-term anticoagulation in such patients seems reasonable, objective data are lacking.

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