One-Step Treatment of DVT With the Trellis-8 Device

Preliminary data reveal a safe, effective, and expeditious treatment option.

BY ZVONIMIR KRAJCER, MD, AND SATYA REDDY ATMAKURI, MD

Venous thromboembolic disease is a common disease that affects 15 million Americans at the rate of 48 per 100,000 annually.[1] The most feared complication of deep venous thrombosis (DVT) is pulmonary embolism (PE); the number of DVTs per year is 600,00 and the number of PE deaths is 200,000. DVT of iliofemoral veins has a high incidence of propagation of thrombus to cause PE (50%) and postphlebitic syndrome.[2,3] Furthermore, thrombosis in the iliofemoral veins rarely undergoes spontaneous lysis and leads to development of postphlebitic syndrome in 90% of cases.[3] Other long-term sequelae include venous ulcers (81%) and venous claudication (50%), leading to disability (86%).[3] Currently, traditional methods of anticoagulation are commonly used to treat DVT.[4] Unfortunately, although anticoagulation reduces future thromboembolic events, it does not consistently prevent late complications and disability in a majority of patients.[4] Previous studies have revealed that thrombolytics are more effective than heparin in achieving complete or partial thrombolysis.[5] Several thrombolysis strategies have been used to treat DVT (Figure 1).

Endovascular therapies are typically prescribed for patients who present with life-threatening complications.[5] Systemic thrombolysis has, however, shown suboptimal results and has been essentially abandoned.[4] The problems with systemic thrombolysis are related to the inability to achieve a predictable result. This mode of treatment frequently requires large doses

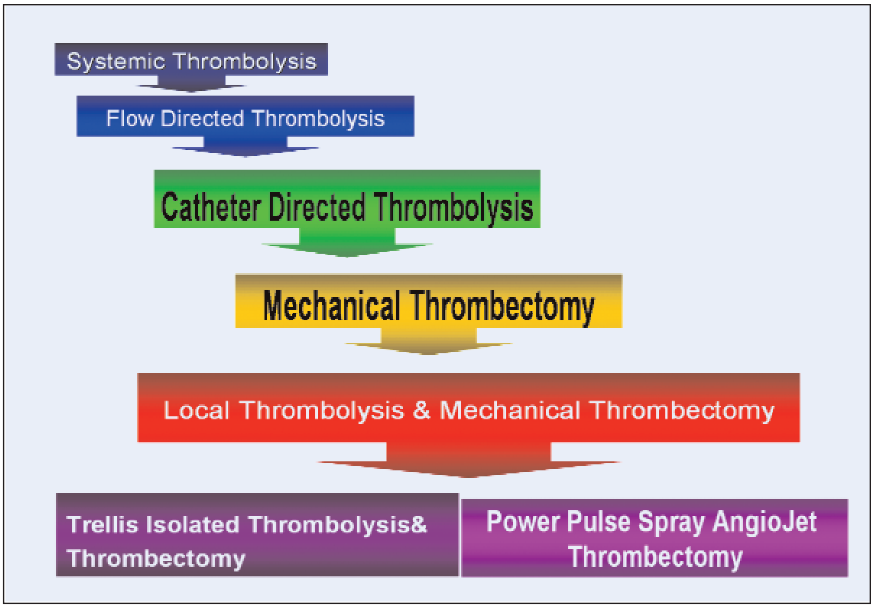

Figure 1. The history of interventional strategies for treatment of DVT.

Figure 2. The Trellis-8 system (Bacchus Vascular, Santa Clara, CA) consists of proximal and distal balloons, with balloon inflation syringes, a thrombolysis infusion port, the thrombus aspiration syringe, and a drive unit for mechanical dispersion of the thrombolytic agent.

TABLE 1. POTENTIAL BENEFITS OF COMBINATION ENDOVASCULAR THERAPY FOR DVT

Potential Advantages of Local Thrombolysis and Mechanical Thrombectomy

- Local delivery of thrombolytic agent
- Smaller doses of thrombolytic agent
- Shorter duration of thrombolysis
- Avoid risks of systemic effects of thrombolytic agents
  - Can be used in patients with relative contraindications to thrombolysis
  - Decreases bleeding complications
- Less costly

of thrombolytics that are infused over several days, which increases the risk of bleeding and procedure costs. The traditional endovascular treatment of DVT is typically done by catheter-directed thrombolysis. The National Venous Thrombolysis Registry[6] included 473 patients undergoing catheter-directed thrombolysis with urokinase from 63 sites; 83% of patients achieved at least 50% thrombolysis, with complete lysis in 31% of patients. The mean duration of infusion was 53.4 hours. However, the incidence of bleeding was 27% (major 11%, minor 16%), with the majority of bleeding occurring at the access site (39% had major bleeding, and 52% had minor bleeding). Therefore, some of the drawbacks of this procedure include a higher risk of bleeding than with conventional therapy, higher cost secondary to the time of infusion and the repeated visits to the angiographic suite after thrombolysis of thrombus, and lack of immediate resolution of thrombus in conditions requiring emergent therapy.

MECHANICAL THROMBECTOMY DEVICES

Mechanical thrombectomy devices were developed to overcome the bleeding complications associated with thrombolysis and to achieve faster resolution of thrombus. There are multiple devices currently available for mechanical thrombectomy. Two of the most commonly used thrombectomy devices are AngioJet (Possis Medical, Minneapolis, MN) and the Trellis-8. The potential benefits of combining thrombolytic therapy with mechanical thrombectomy are shown in Table 1.

Kasarajan et al reported their experience in 44 patients with DVT who underwent AngioJet thrombectomy.[7] In their series, 54.5% of patients received thrombolysis prior to Angiojet thrombectomy. They found no major complications related to the use of the AngioJet. Complete lysis was achieved in 50% of the patients, and another 25% of the patients had 50% to 90% thrombus removal.

More recently, Allie et al have reported on the new method of combining the 6-F Xpeedior RT AngioJet thrombectomy catheter with thrombolysis.[8] The benefits of the AngioJet thrombectomy catheter in a Power-Pulse Spray mode is that the thrombolytic is dispersed directly in the area of thrombus and aspirated after 20 minutes, reducing the procedure's duration and the risk of bleeding.

The Trellis-8 system is a novel device that is designed to achieve DVT lysis and aspiration of a thrombus over a period of 15 to 20 minutes. This technique alleviates the need for prolonged infusion of the thrombolytic agent and repetitive returns to the angiography suite to assess the results. Removal is accomplished with an infusion and mechanical dispersion of a thrombolytic agent within the area of a thrombosis. The treatment area is contained within the occluding balloons. Aspiration of the lysed thrombus is usually achieved after 5 to 20 minutes of treatment.

The Trellis-8 peripheral infusion system consists of a

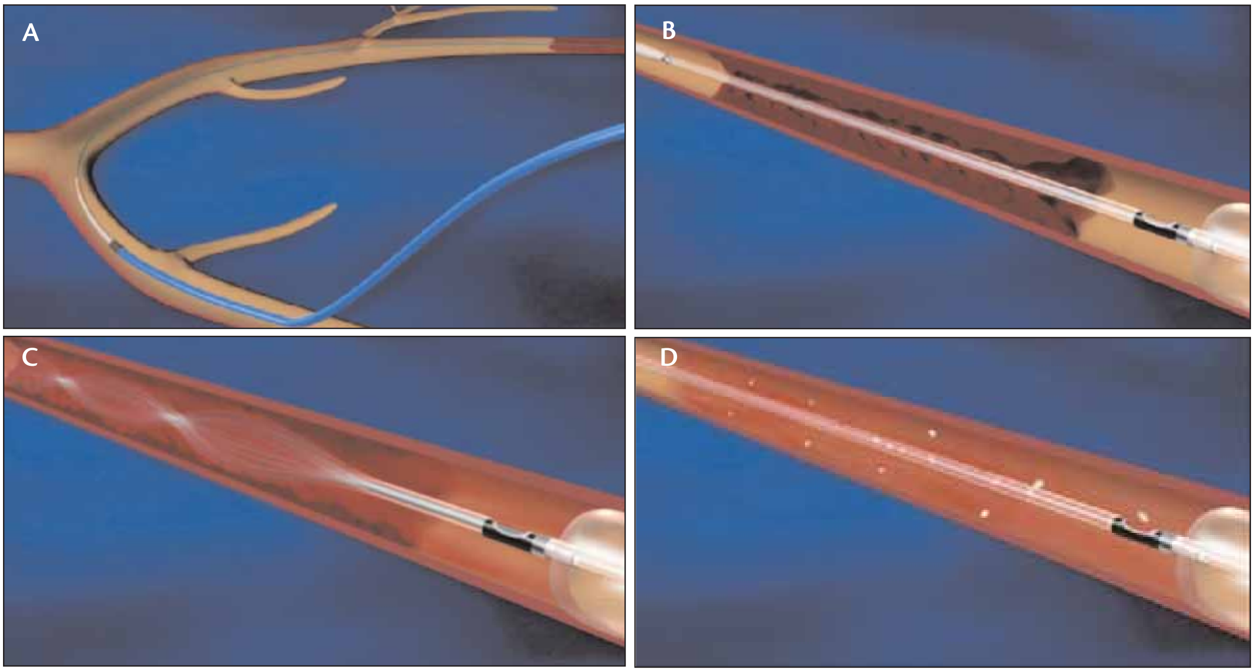

Figure 3. Artistic rendering showing the technique of introduction of a Trellis-8 device via contralateral femoral vein approach through a contralateral sheath (A). The rendering illustrates the position of the device across the area of thrombus with proximal and distal balloons positioned outside the thrombus (B). The wire oscillates after the drive unit is activated at the speed of 3,000 rpm, facilitating the dispersion of a thrombolytic agent within the thrombus (C). The removal of the thrombus during the aspiration phase of the procedure (D).

catheter with proximal and distal balloons with drug infusion holes between the two balloons (Figure 2). The catheter is delivered through an 8-F sheath, and length varies from 80 cm to 120 cm (Figure 3A). The

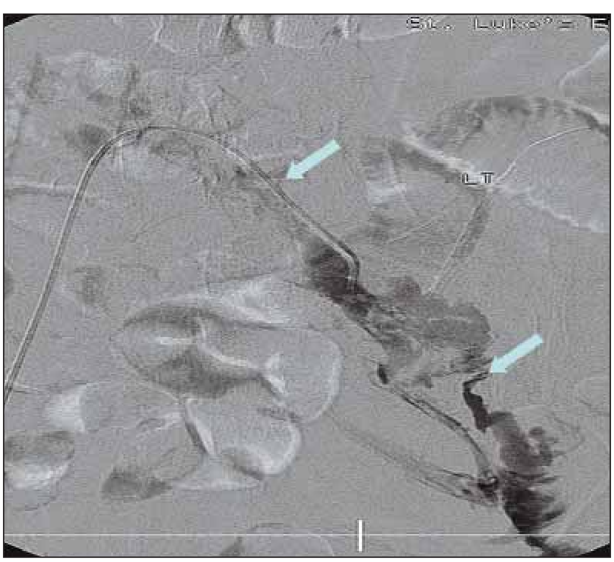

Figure 4. Left common iliac vein angiogram via contralateral femoral vein approach reveals thrombosed left iliac and femoral veins (arrows).

balloon size varies from 5 mm to 16 mm, and the length of treated segment is between 15 cm to 30 cm. Placing a dispersion wire in the catheter, which is activated by the electrically powered drive unit, enables the catheter to vibrate at 500 rpm to 3,000 rpm, mechanically dispersing the thrombolytic agent (Figure 3B,C). The mechanical action of vibration and thrombolytic dispersion locally in the thrombus leads to rapid resolution of the thrombus. The advantage of this technique is the delivery of the thrombolytic agent to the isolated segment of the vessel containing thrombus. After activating the dispersion wire for 5 to 15 minutes, the proximal balloon is deflated, and the thrombus is aspirated from the distal port (Figure 3D). The risk of embolization during aspiration of the thrombus is avoided by distal balloon occlusion until aspiration of the thrombus is completed.

CASE STUDY

A 55-year-old woman with previous DVT was referred for endovascular therapy after a failed attempt to relieve the pain, swelling, and to recanalize her left lower-extremity venous system with low-molecular-weight heparin and warfarin. The patient had persistent left leg pain and swelling, interfering with activities of

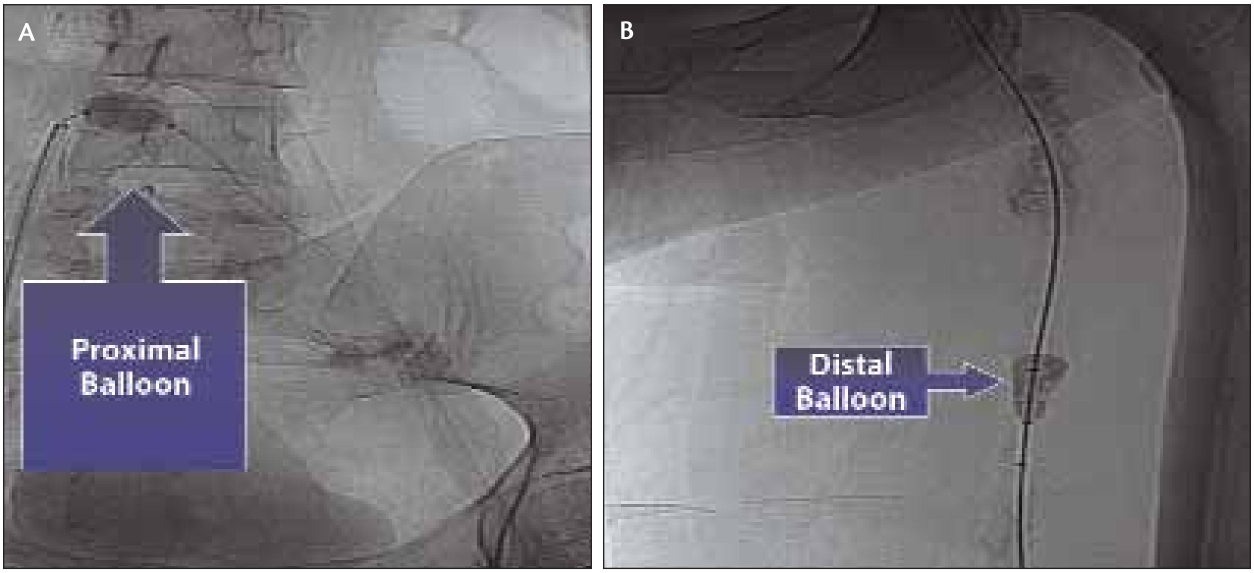

Figure 5. Cineangiogram showing the Trellis-8 thrombectomy device with the position of the proximal and distal balloons in the left iliac (A) and left femoral veins (B), respectively.

daily living. Because the patient had severe swelling of her left lower extremity that limited access to the ipsilateral popliteal vein, a contralateral approach was utilized with percutaneous access from the right femoral vein. A .035-inch SS Glidewire (Terumo Medical Corporation, Somerset, NJ) was used to cannulate the left iliac and femoral veins. The initial angiogram shows extensive thrombus in the left iliac, femoral, and popliteal veins (Figure 4). The Trellis-8 device was advanced over a Glidewire, and the distal balloon was positioned and inflated in the distal left popliteal vein (Figure 5). After inflating the proximal balloon in the iliac vein, 400,000 units of urokinase (Abbott Vascular, Abbott Park, IL) was infused between the balloons. The dispersion wire was activated for 5 minutes, and the thrombus was aspirated (Figure 6). An angiogram obtained after the aspiration revealed stenosis of the left common iliac vein suggestive of May-Thurner syndrome (compression of the left common iliac vein caused by crossover of the right common iliac artery) (Figure 7A). Percutaneous angioplasty and stenting was accomplished with 12-mm X 80-mm and 12-mm X 60-mm self-expandable nitinol stents (Figure 7B). The patient was discharged from the hospital 2 days later on oral anticoagulants with a complete resolution of the left leg edema and pain. The successful thrombolysis and thrombus aspiration, however, does not prevent the reoccurrence of DVT in patients with May-Thurner syndrome. Prevention of thrombosis in patients with this condition frequently requires left common iliac vein angioplasty and stenting as well as long-term treatment with oral anticoagulants.

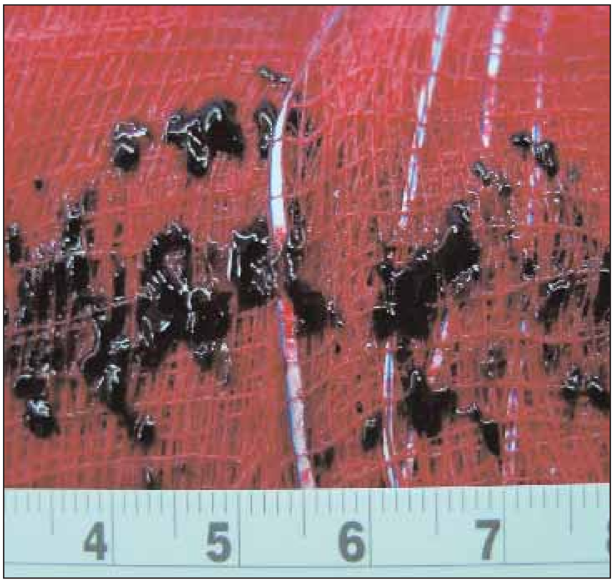

Figure 6. An aspirated thrombus after isolated thrombolysis and mechanical thrombectomy with the Trellis-8 device.

SUMMARY

DVT is a common problem that, when treated aggressively, will relieve a patient's acute symptoms and prevent potential lethal consequences, such as PE, and long-term sequelae, such as chronic venous insufficiency. Our preliminary experience with isolated thrombolysis and thrombectomy with the Trellis-8 device appears to be safe and effective treatment that ensures rapid

Figure 7. A left iliac vein angiogram reveals stenosis of the proximal left common iliac vein (arrow), suggestive of May-Thurner syndrome (A). Final angiogram of the left iliac vein after stent deployment reveals complete resolution of thrombus and stenosis (arrows) (B).

resolution of a potentially life-threatening condition. As shown in our case, this one-step approach for treatment of DVT can be successfully used when other conventional treatments have failed. This method significantly reduces the risk of bleeding by preventing systemic absorption of the thrombolytic agent as the drug is aspirated along with the thrombus. Currently, published case reports show complete resolution of thrombus leading to rapid relief of symptoms.[9,10] In a recent case series of 66 patients by Razavi et al (on file with Bacchus Vascular), grade 1 and 2 lysis was obtained in 88% of patients without major bleeding complications. In addition, they estimated that the cost savings from using the Trellis-8 system was $2,970 when compared with catheter-directed thrombolysis.

The preliminary data indicate that this procedure offers safe, effective, and expeditious treatment of acute and subacute DVT at a lower cost than catheter-directed thrombolysis. This technique offers physicians who were previously reluctant to treat DVT a simple, rapid, one-step solution to a complex problem. To further evaluate the efficacy of this treatment modality of DVT, randomized trials or registries should be undertaken. ■

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1. Jantet G. Chronic venous insufficiency. Angiology. 2002;53:245.
2. Anderson FA Jr, Wheeler HB, Goldberg RJ, et al. A population based perspective of the hospital incidence and case-fatality rates of deep vein thrombosis and pulmonary embolism. The Worcester DVT Study. Arch Intern Med. 1991;151:933-938.
3. O'Donnell TF Jr, Browse NL, Burnand KG, et al. The socioeconomic effects of an ileofemoral venous thrombosis. J Surg Research. 1977; 22:483-488.
4. Bates SM, Ginsberg JS. Treatment of deep-vein thrombosis. N Engl J Med. 2004;351:268-277.
5. Comerota A, Aldridge SC. Thrombolytic therapy for venous thrombosis: a clinical review. Can J Surg. 1993;36:359-364.
6. Mewissen MW, Seabrook GR, Meissner MH, et al. Catheter-directed thrombolysis for lower extremity deep venous thrombosis: report of a National Multicenter Registry. Radiology. 1999;191:487-494.
7. Kasarajan K, Arata M, Swischuk S, et al. Rheolytic thrombectomy for management of venous thrombosis: results of multicenter venous registry. J Vasc Interv Radiol. 2003;14(Suppl):16.
8. Allie DE, Hebert CJ, Khan MH, et al. The power-pulse spray technique. Endovasc Today. 2003;2:25-30.
9. Ramaiah V, Del Santo PB, Rodriguez-Lopez JA, et al. Trellis thrombectomy system for the treatment of iliofemoral deep venous thrombosis. J Endovasc Ther. 2003;10:585-589.
10. Sarac TP, Hilleman D, Arko FR, et al. Clinical and economic evaluation of the Trellis thrombectomy device for arterial occlusions: preliminary analysis. J Vasc Surg. 2004;39:556-559.