Aggressive Percutaneous Mechanical Thrombectomy of Deep Venous Thrombosis

Early Clinical Results

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Objective: To evaluate percutaneous mechanical thrombectomy for deep venous thrombosis (DVT).

Design: A retrospective analysis.

Setting: Tertiary academic medical center.

Patients: Thirty patients with DVT who underwent percutaneous mechanical thrombectomy.

Interventions: Percutaneous mechanical thrombectomy of upper or lower extremity DVT.

Main Outcome Measures: Thrombus removal, patency, and valvular function. Venography and intravascular ultrasonography assessed periprocedural lysis. Duplex ultrasonography assessed patency and valvular function before and after the procedure.

Results: Fourteen patients had iliofemoral, 6 had iliofemoropopliteal, 5 had femoropopliteal, and 5 had subclavian vein thromboses. Mean age was 50.9 years (range, 15-78 years); 10 patients (33%) had a documented hypercoagulable state. There was 100% technical success in crossing the DVT, with treatment performed in a single setting in 24 patients (80%). Mean±SD procedural time was 145±35 minutes; range, 55-210 minutes. Mean thrombolytic dose was 6.2 mg of tenecteplase with the Trellis-8 and 10 mg with the AngioJet. Adjunctive procedures were required in 28 patients (percutaneous transluminal angioplasty and stent placement in 17 and percutaneous transluminal angioplasty alone in 11). Recoverable inferior vena cava filters were placed in 21 patients and retrieved within 4 weeks. There were no clinically significant periprocedural pulmonary emboli; however, 5 patients (17%) had evidence of pulmonary embolism on computed tomographic angiography (all in patients without inferior vena cava filters). Venous patency was maintained in 27 patients (90%) and lower extremity valvular function was maintained in 22 (88%) of 25 treated lower limbs, with a mean follow-up of 6.2 months (range, 3-24 months).

Conclusions: Percutaneous mechanical thrombectomy is effective in the treatment of acute DVT in the upper and lower extremity to restore venous patency. In the lower extremity, valvular function is maintained acutely. Continued surveillance and follow-up will be necessary to determine whether valvular function is maintained long-term.

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Deep venous thrombosis (DVT) is a highly prevalent clinical problem, ranking as the third most common cardiovascular disease in the United States.1 The incidence of morbidity and mortality associated with DVT carries a tremendous economic impact, with more than 600 000 hospitalizations or outpatient treatments per year, and accounts for approximately 100 000 deaths.2 For severe DVT, hospitalizations can last 1 to 2 weeks.3

Current treatment options include anticoagulation therapy alone, designed to address acute symptoms and prevent clot propagation and pulmonary embolism; thrombolytic therapy to lyse the thrombus; surgical thrombectomy; and, more recently, nonsurgical mechanical thrombectomy using devices that are designed to mechanically macerate and remove a flow-obstructing thrombus. Thrombus-removing strategies promote early restoration of patency and improved venous return.4,5 Anticoagulation therapy alone is
currently accepted as the standard of care for most patients with DVT; however, thrombolytic therapy is becoming more widely used for a subset of patients who fail or are ineligible for anticoagulation therapy alone, supplementing surgical thrombectomy as the conventional means of thrombus removal. A growing body of evidence supporting the potential merits of early thrombus removal has inspired new product and procedure development aimed at safe, effective mechanisms for rapid restoration of patency via thrombus extraction without the bleeding risks associated with thrombolysis.

The purpose of this study was to evaluate percutaneous mechanical thrombectomy (PMT) for DVT of both the upper and lower extremities for safety and efficacy in restoring venous patency, for recurrent ipsilateral DVT, and for clinical symptomatic improvement. We also evaluated valvular competence in the lower legs following treatment.

METHODS

PATIENTS

Between October 1, 2002, and December 31, 2005, 30 patients with DVT in the upper or lower extremity were treated at our tertiary academic medical center with PMT using either the Trellis-8 infusion system (Bacchus Vascular, Santa Clara, Calif) or the AngioJet (Foss Medical, Inc, Minneapolis, Minn). The patients’ medical records were captured prospectively in a vascular registry and retrospectively reviewed. Data collected included patient demographics, results of a hypercoagulability workup, periprocedural data, the lytic agent used, adjunctive interventions, and clinical outcomes. Primary end point analysis of the clinical outcomes included the efficacy of the device in removing the thrombus within the treatment area, as well as maintenance of patency at 1 and 6 months after treatment.

DVT DIAGNOSIS

Deep venous thrombosis was diagnosed by means of patient history and physical examination and was confirmed with duplex ultrasonography (US) in all cases. Diagnostic US imaging was performed before and after thrombectomy (HDI 5000 SonosCT; Philips Medical Systems, Bothell, Wash). Vein wall compression was performed using a linear transducer in transverse orientation from the distal external iliac vein at the groin and throughout the entire length of the common femoral, superficial femoral, popliteal, posterior tibial, and peroneal veins. The greater saphenous and lesser saphenous veins were assessed in a similar fashion. Regions of noncompression or partial compression were evaluated in the transverse and sagittal planes in gray scale and color Doppler imaging to delineate the residual lumen. The same technique was used in the upper extremity to assess the cephalic, basilic, brachial, axillary, subclavian, and internal jugular veins. Doppler spectral waveforms were obtained to demonstrate venous flow dynamics. Pulsed wave samples were obtained in a sagittal plane, and calf augmentation maneuvers were performed to assess the valvular function of the deep veins at the lower superficial femoral vein and the popliteal vein. (Augmentation maneuvers were not performed in the presence of acute DVT.)

ANTICOAGULATION REGIMEN

At the time of the initial diagnosis of DVT, all patients underwent anticoagulation therapy with subcutaneous low-molecular-weight heparin (n=26), intravenous heparin (n=3), or argatroban (Texas Biotechnology Corporation, Houston, Tex) (n=1; in a patient with heparin-induced thrombocytopenia) followed by warfarin sodium to maintain an international normalized ratio of 2 to 3. Patients were treated within 14 days of symptom onset and diagnosis. All patients underwent a hypercoagulability screening before treatment that included determination of protein C and S deficiency and levels of antithrombin III, lupus anticoagulant, antiphospholipid antibody, factor V Leiden (determined by polymerase chain reaction), prothrombin 20210A (determined by polymerase chain reaction), and homocysteine.

PROCEDURE DETAILS

The procedure was performed using US guidance to access the popliteal vein for iliofemoral thrombosis and the cephalic vein for subclavian vein thrombosis. A 6F or 8F sheath was placed and a 0.035-in guidewire and catheter (Glidewire and Glidcatheter, respectively; Boston Scientific, Natick, Mass) were used to pass through the clot. Venography was performed to confirm the presence of DVT. Patients were treated with a localized infusion of thrombolytics (tenecteplase) (Genentech Inc, South San Francisco, Calif) using the Trellis-8 or the AngioJet with the power-pulse spray technique.

TRELLIS-8

The catheter is introduced through a percutaneous approach using an 8F sheath. The system consists of a single-use catheter, a dispersion wire, and an integral drive unit. The Trellis-8 is advanced over a guidewire and through the thrombus. The catheter consists of a proximal and a distal balloon that are inflated prior to infusion of thrombolytics. With the balloons inflated, the thrombolytic agent is infused and theoretically contained between the balloons. A sinusoidal dispersion wire connected to the integral drive unit is inserted within the catheter and rotates up to 3500 rpm, causing a localized pharmacomechanical lysis. After 10 minutes of dispersion, an aspiration port is used to remove any small particulate matter.

ANGIOJET

The catheter is introduced through a percutaneous approach using a 6F sheath. The system consists of a single-use catheter, a pump set, and a drive unit. The power-pulse spray technique was used. The AngioJet catheter is advanced over a guidewire and through the thrombus. Adjunctive thrombolytic was added to the infusion solution, and 10 mg of thrombolytic in 50 mL of isotonic sodium chloride solution was used to infuse the clot as the catheter was slowly withdrawn. The lytic is allowed to work for 10 minutes. Following the infusion of the lytic, the system is used in the standard fashion. The drive unit generates pressure up to about 10,000 psi of pulsatile isotonic sodium chloride solution flow. These high-velocity jets create a localized low-pressure zone, which leads to thrombus maceration and aspiration.

ASSESSMENT OF THROMBUS REMOVAL

Venography and intravascular US were used during the procedure to assess lysis and thrombus reduction. Duplex US was used 1 and 6 months after the procedure and then annually to assess patency (in all veins) and valvular function (in the lower extremities).
RESULTS

PATIENT DEMOGRAPHICS

The patients had a mean±SD age of 50.9±18.0 years (range, 15-78 years) and consisted of 17 men and 13 women. Ten of the patients (33%) had a hypercoagulable state. Fourteen patients had iliofemoral, 6 had iliofemoropopliteal, 5 had femoropopliteal, and 5 had subclavian vein thromboses. The mean time to intervention was 5.7 days (range, 3-14 days) after the diagnosis was made. Eighteen patients were treated with the Trellis-8 and 12 with the AngioJet.

PERIPROCEDURAL DATA

Twenty-one patients (84%) of the 25 patients with lower extremity DVT had optional recovery inferior vena cava filters (Bard Peripheral Vascular Inc, Tempe, Ariz) placed for distal protection before the intervention. Technical success in crossing and recanalizing the venous segment was achieved in all patients with lower or upper extremity DVT. In 24 patients (80%), treatment was performed at a single setting with a mean±SD procedural time of 145±35 minutes (range, 55-210 minutes); complete thrombus removal was confirmed by venography and intravascular US assessment. A single infusion and a run of 10 minutes was used with the Trellis-8 device. In patients treated with the AngioJet, a total of 400 mL of effluent was used. Six patients with partial thrombus removal required 12-hour infusions of tenecteplase to achieve complete thrombus removal as confirmed by venography and intravascular US. Four partial thrombus removals occurred after treatment with the AngioJet and 2 after the Trellis-8.

LYTIC AGENT USED AND DOSAGE

The mean thrombolytic dose used with the Trellis-8 was 6.2 mg of tenecteplase (range, 5-10 mg), whereas 10 mg of tenecteplase was used in all patients who underwent treatment with the AngioJet in a single setting. In the 6 patients who required 12-hour infusions, tenecteplase was administered at a rate of 0.25 mg/h.

ADJUNCTIVE PROCEDURES

Adjunctive procedures were required in 28 patients (percutaneous transluminal angioplasty and stent placement in 17 patients and percutaneous transluminal angioplasty alone in 11). Stent placement was performed with self-expanding wall stents (Boston Scientific) when there was evidence of May-Thurner syndrome of the left common iliac vein (Figure 1). No stents were placed in the femoropopliteal segments. Angioplasty of the subclavian and femoropopliteal veins was performed for any stenosis seen after thrombus removal. All optional filters were retrieved within 4 weeks of treatment; no evidence of clot was observed within the filters, and the patients experienced no complications.

CLINICAL OUTCOMES

There were no clinically significant periprocedural pulmonary emboli; however, 5 patients (17%) underwent computed tomographic angiography of the chest following the intervention and showed incidental findings of pulmonary embolism. None of the 5 patients had received inferior vena cava filters. There were no minor or major bleeding complications. Duplex US showed patent venous segments in 27 (90%) of the 30 patients at a mean follow-up of 6.2 months (Figure 2). Valvular function was maintained in 22 (88%) of the 25 lower extremities at a mean follow-up of 6.2 months (range, 3-24 months). Patients were treated with a minimum of 6 months of anti-coagulation therapy for primary DVT. Those receiving stents were treated with anti-coagulation therapy for 6 months followed by lifelong antiplatelet therapy. Patients with a known hypercoagulable state received lifelong anti-coagulation therapy.
An extraordinary number of patients experience long-term effects of DVT, including unresolved or worsening of symptoms, skin ulceration, recurrence of acute thrombosis, and postthrombotic syndrome. Venous hypertension due to insufficient valves that were damaged by the DVT process and/or poor venous return due to outflow obstruction from residual thrombus is typically the cause of these symptoms. Strong advocacy of early thrombus removal was led by Comerota et al., Mewissen, Meissner, and Bjarnason et al., who demonstrated the relationship between early restoration of patency and improved interim and long-term outcomes. However, it appears that the standard for most patients remains anticoagulation therapy alone.

Although the underlying pathology of the obstructive clot has been well studied, current clinical methods do not address complex thrombus, which consists of both acute and chronic substrates, or the significant morbidity sequelae of residual thrombus following standard anticoagulation therapy. Anticoagulation therapy decreases the incidence of symptomatic pulmonary embolism by preventing further propagation or recurrence of a thrombus. However, it is well accepted that anticoagulation therapy does not lyse the clot; therefore, the restoration of venous patency in the involved segment is dependent on intrinsic fibrinolytic mechanisms. Prior to thrombolysis, surgical thrombectomy was the sole option for the removal of flow-obstructing or limb-threatening thrombus. Embolectomy, developed by Fogarty et al., was the precursor to new, less invasive mechanical means of clot removal. Embolectomy was a highly effective treatment, as demonstrated by a series of landmark reports by Plate and colleagues describing the long-term outcomes of venous thrombectomy vs anticoagulation therapy. Their data, based on up to 10 years of follow-up, showed that 6-month patency results predict a positive trend of improved long-term clinical outcomes vs anticoagulation therapy alone. At 6 months, 16 (76%) of the 21 patients who had undergone thrombectomy had normal venogram results vs 9 (35%) of the 26 patients in the group that received anticoagulation therapy alone; similar dramatic differences between groups were seen for the clinical end points of pain, swelling, claudication, and varicose veins. At 5 years of follow-up, normal venogram results were demonstrated in 78% of the patients in the thrombectomy group and in 50% in the anticoagulation group; at 10 years, normal venogram results were demonstrated in 84% and 41% of the patients, respectively.

Although thrombolysis is effective for lysis of a thrombus, the use of systemic delivery is problematic because of the risk of bleeding. Catheter-directed thrombolysis (CDT) has demonstrated a safer, more efficient means to lyse the thrombus and restore venous patency. Mewissen et al demonstrated a strong relationship between the degree of clot removal and long-term patency and between the degree of clot removal and reduction of postthrombotic syn-
In the largest study published on thrombolysis, major bleeding complications occurred in 11% of patients. In that study, Ouriel et al compared CDT using urokinase (UK) vs CDT using recombinant tissue plasminogen activator in 653 patients and demonstrated bleeding at the insertion site in 21.9% of the patients in the UK group vs in 43.0% of the patients in the recombinant tissue plasminogen activator group; any bleeding requiring transfusion in 12.4% vs 22.2% of patients, respectively; and intracranial hemorrhage in 0.6% vs 2.8% of patients, respectively. Typically, most studies have shown that treatment times with CDT range between 36 and 72 hours of infusion. Wells and Forster argued that a randomized controlled trial comparing anticoagulation therapy with CDT is necessary to justify the role of CDT when the associated adverse events are taken into account.

AbuRahma et al reported on a series of 51 randomized patients in whom these 2 treatment modalities were compared and demonstrated superior long-term (90-day) results with CDT plus stent placement, although the bleeding rates were significantly higher in the thrombolysis group (6% vs 11%). The advent of catheter-driven mechanical thrombectomy devices used in conjunction with minimal intraoperative lytic doses (which avoids postprocedural infusions of thrombolytics) holds promise for safe, effective thrombus removal in a single setting without the risks associated with surgery or prolonged thrombolytic infusions. The types of PMT catheters that are commercially available generally fall into one of 2 categories. The first type causes microfragmentation of the thrombus as a result of direct maceration of the clot that is assisted by the addition of small doses of a lytic agent (eg, the Trellis-8 device). The second is based on thrombus aspiration (ie, the Venturi effect) in which high-velocity jets create a localized low-pressure zone, which leads to thrombus maceration and aspiration (eg, the AngioJet). The combination of lytics and PMT devices enables lower mean doses and shorter durations of lytic infusions. Reducing the dose of the lytic agent and the infusion time has been shown to reduce the morbidity (fewer hemorrhagic complications) and to increase cost savings.

In the present study, we evaluated the use of 2 PMT devices for the treatment of acute DVT. Technical achievement of the primary goal of venous patency was successful, with short-term follow-up for up to 6 months. At last follow-up, nearly 88% of the veins remained patent. All patients in whom thrombosis recur had an underlying hypercoagulable state. Furthermore, vessel patency was achieved in a single setting in most of the patients (27 [90%]). Although most of the patients were treated with adjuvant thrombolysis, the amount and duration were limited. By limiting thrombolysis to a single setting and by avoiding a prolonged duration of infusion, we have significantly decreased the incidence of bleeding complications in this study. There were no incidences of bleeding complications in this study and no patients required a blood transfusion. In contrast, hemorrhagic complications have ranged between 11% and 43% in other studies evaluating CDT. Pancreatitis has been reported as a complication of percutaneous mechanical rheolytic thrombectomy, which is increasingly being used, but this complication appears to be rare, with only 5 cases reported to date and all of those after use of the AngioJet. We have not seen this complication in any of our patients.

By removing the majority of the clot with the thrombectomy device, the amount of lytic required was markedly reduced in our series. Although this series was limited by the small number of patients, use of both devices appears to be safe and efficacious in achieving the desired outcome of immediately restoring vessel patency. The use of inferior vena cava filters was at the discretion of the primary treating interventionalist (F.R.A.). Optional filters are efficacious for preventing pulmonary embolism. Furthermore, all of the devices were passed through the clot and it was considered prudent to use distal protection for the safety of the patient. While the risk of pulmonary embolism with CDT is infrequent, its incidence with PMT is unknown. In this study, we saw no complications associated with filter use, and all filters were successfully removed.

Both devices tested were successful in removing clots from the femoral and popliteal segments. However, for clots in the common and external iliac segments, especially those on the left side and those associated with May-Thurner syndrome, there was often evidence of chronic thrombosis and stricture of the veins. Although the acute clot was removed, all of these patients required intervention with PTA and stent placement with 12- to 16-mm self-expanding stents. Patency of the vessel has been maintained in 13 (93%) of the 14 patients without evidence of recurrence. All patients with evidence of a hypercoagulable state will receive lifelong warfarin therapy. While it is not current practice or the standard of care at our institution to order laboratory studies to determine the hypercoagulability status in a patient with first-time DVT, we proceeded with a workup in all of our patients owing to the extension of their disease and failure to improve while receiving anticoagulation therapy. The other 4 patients were treated with a minimum of 6 months of anticoagulation therapy. Two of these patients had subclavian vein thrombosis and were treated with 6 months of anticoagulation therapy, and the 2 with lower extremity DVT were treated with 9 months of anticoagulation therapy. Although the length of follow-up was short, it is encouraging to note that the venous valves were still functioning at last follow-up imaging. Longer follow-up and a larger number of patients will be required to determine whether valvular function continues.

In conclusion, PMT can be used effectively and safely to restore venous patency in patients with acute DVT. Furthermore, this can be performed in a single setting with low doses of thrombolytics. Patency and valvular function were evident at an early follow-up visit, even in patients with a hypercoagulable state. Longer follow-up is necessary to determine whether chronic venous insufficiency can be prevented.

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Deep vein thrombosis is an entity that troubles all surgeons and internists. While the acute sequelae of the DVT, including pain, swelling, and potential for pulmonary embolism, are real, the long-term sequelae, as Dr Arko demonstrated, are much more important, including loss of valvular function, chronic swelling, lipodermatosclerosis, and potential for skin ulceration. While this does not often lead to limb loss, the countless number of office visits, wound care, and lost time at work make this an incredibly important problem. Past therapies have been adequate to treat the condition, but again result in a majority of these patients ending up, if followed long enough, with postphlebitic syndrome.

Newer techniques of thrombolysis, as has been demonstrated, are promising but not very often distributed among the entire population of DVT patients. The mechanical thrombectomy, as very well demonstrated today, offers all of us in vascular surgery, especially our clinical staff, the hope that we don’t have to see these patients for the rest of our careers. The other option it offers the folks down in Dallas [is that] there is more open deep venous segment, so that they can replace even more infected vascular conduits.

The authors have done a very nice job demonstrating the successful employment of mechanical thrombectomy with fantastic results. I won’t rehearse the very good presentation, but I am excited for long-term data to see if this will help the post-phlebitic syndrome.

Some of my questions:

1. While valve function was often mentioned, there seemed to be a majority of iliac vein thrombosis, demonstrated by 17 to 25 receiving stents in that area. Therefore, the valve patency may be a little bit lower if your denominator of valve segments looked at is changed.

2. The hypercoagulability workup was very good, and I was wondering if you could tell us which patients from the ‘get-go’ you should work up? Should you work up all of them, or did some of these have an explanation for DVT?

3. There were a significant number of inferior vena cava filters, and all of the computed tomographic scans postprocedure were few and scattered. The placement of the filter and the retrieval of the filter offer 2 more episodes of complications, costs. Should we not maybe evaluate in a randomized trial whether these patients really do have clinically insignificant pulmonary embolisms and maybe avoid placement of a filter in all of these patients? Some argue that, in valve segments alone, occlusion left alone is sometimes better than opening up the valve segment with residual incompetent valves. I didn’t know if any of your incompetent venous segments had a residual thrombus or whether you have addressed any of this.
4. Last, percutaneous transluminal angioplasty in valve segments has been notoriously poor for long-term outcome. I am looking forward to the long-term results of that. Have you noticed any restenosis and/or occlusion at this point?

**Dr Arko:** There was a preponderance of patients with DVT that included the superficial femoral vein and the iliofemoropopliteal segment. I do not think that the valvular patency will be lower, however, as a result of this. By opening the iliofemoral segment and placing a stent in the iliac vein—stenosis that is typically associated with May-Thurner syndrome—this should decrease the risk of venous hypertension within the affected limb and improve the long-term valvular patency.

Second, we included both upper and lower extremity DVT because we wanted to evaluate the efficacy and safety of clot removal, which was the primary objective of this study. When patients are treated as part of their subclavian vein thrombosis, this is usually associated with thoracic outlet syndrome. They usually get very good results from the mechanical thrombolysis, but they do usually require a first rib resection as well.

I routinely use optional inferior vena cava filters to protect against distal embolism during these procedures; while I feel the risk of symptomatic pulmonary embolism appears to be low, I would feel horrible if I gave them a pulmonary embolism that resulted in the ultimate demise.

The optional filters that are placed are typically quite simple to remove, especially if you get them out within the first 2 to 4 weeks. There are retrievability rates within that time period upwards of 94%, and we have been able to remove all the filters that we placed. This is a second procedure that I perform while they are in an anticoagulated state, and I use ultrasonographic guidance of the internal jugular vein.

Third, patients who rethrombosed were all found to have a hypercoagulable syndrome. So it appears that they are the ones at higher risk of recurrent DVT.

Furthermore, patients who had valvular insufficiency had evidence of multiple DVTs in the past. They could have had long-standing venous hypertension prior to our intervention that was not associated with the clot removal. The only way to tell that is to have those studies preprocedure and prior to their recurrent DVT, which were not available for this study.

With regard to the workup of a hypercoagulable syndrome, I tend to be fairly liberal in sending these patients to a hematologist to have this done, especially if they do not have any risk factors for DVT.

I just recently performed this procedure on a 16-year-old cross-country runner with severely symptomatic DVT. She was started on oral contraceptive pills for acne. She underwent a hypercoagulable syndrome workup and was factor V Leiden–positive, and she had May-Thurner syndrome. Here, DVT extended from the iliac vein to the popliteal vein. She was unable to walk and had not been in school in 3 weeks secondary to pain. She was anticoagulated, she was treated over a 2-day period, and she left the hospital completely pain-free with a marked decrease in the swelling of the leg.

These are some of the happiest patients I treat in my practice, and I have been quite happy with the results.

**R. Stephen Smith, MD, Wichita, Kan:** Preclinical trials, as well as a small group of clinical trials, have shown that low-frequency, relatively high-intensity ultrasound energy administered either through an intravascular transducer or even transcutaneously can help with the rapid resolution of DVT. I just wonder if you had any opinions or experience with this potentially less invasive technique.

**Dr Arko:** I have had some experience with both of those. ImaRx Therapeutics, Inc (Tucson, Ariz) has microbubbles fragment with external ultrasound energy and fragment the clot. However, it is somewhat limited by the penetration of the ultrasound, especially with the iliac veins. EKOS Corp (Bothell, Wash) and Omnionics Medical Technologies (Wilmington, Mass) also have technologies that use ultrasound energy to fragment a clot from within the vessel. There are other companies, especially EKOS Corp and Omnionics Medical Technologies (both of which have catheters), that apply ultrasound energy from within the vessel. Both of those are promising technologies that we hope to evaluate in the future.

**Walter J. McCarthy, MD, Chicago, Ill:** We have used the Angiojet and the Trellis-8 and been pretty impressed with them. The “holy grail” of these procedures is to preserve the valvular function between the groin and the knee for future competency.

My question is: Do these devices tear or otherwise damage the valves? What is your experience?

**Dr Arko:** If you look at animal studies with either of those devices and evaluate valvular function, the valves are still functioning following the procedure. The question is not whether they are functioning right afterwards, but what their function is 6 months, 1 year later, or 3 years later. I have not yet seen any valvular damage in the short term. We continue to follow these patients long term, and I hope to present results on what their long-term valvular function is, because that is really what we are trying to preserve.

**Bruce L. Gewertz, MD, Los Angeles, Calif:** Bill Fry, one of Dick Thirlby’s heroes, always told me you never give a talk about infected grafts or venous disease, and Dr Arko has blown that out of the water.

I really very much enjoyed the presentation and think it is a promising treatment. I have to ask, though, if we have a sense of who really will benefit from this. What you described today was an exciting technique applied to a very heterogeneous population—patients with and without coagulopathies, patients with and without anatomic reasons to get venous thrombosis. They ranged from a 16-year-old and a 26-year-old marathoner to older people.

The questions raised by this initial experience cry out for a randomized study that would be tiered so that you could look at these different patient populations individually, because it is my sense that certainly major iliofemoral thrombosis merits this type of aggressive response. I am not so certain that the natural history of mid–superficial femoral vein or infrapopliteal venous thrombosis would change substantially. I wonder how you could better define the population that might benefit from this technique.

**Dr Arko:** First, I will comment on the age of patients. I am not sure, if you ask the people in this audience, that they would agree that 51 years is old. I think 51 years is a reasonable age. But certainly the younger you are and the more symptoms you have, the better the results you are going to get.

With regard to the location of the disease, it has clearly been shown that patients with iliofemoral DVT, when treated with CDT, have a better quality of life and a better long-term outcome.

Those patients with DVT in the femoral popliteal segment do have better outcomes, but some investigators feel that the risks of minor and major bleeding complications may outweigh the risks of CDT. So, in that population, it is still uncertain what is going to be better.

However, if you can open up the veins and preserve valvular function within the femoropopliteal segment, these patients will have a lower incidence of postphlebitic syndrome and long-term complications.

A randomized controlled study to evaluate percutaneous mechanical thrombectomy in patients with DVT would be helpful to determine the appropriate treatment for these patients. Based on our data, these devices do appear to be safe and efficacious in removing the clot. What their results are long term, we will have to wait and see.

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