

# Current Trends in Interventional DVT Management

A roundtable discussion of the challenges faced in treating deep vein thrombosis and the benefits of endovascular therapy.

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**A**lthough the number of deep vein thrombosis (DVT) patients treated with proactive endovascular therapies is increasing, and the data from small studies and registries generally show significant benefit to

the patient and cost reduction, the adoption of venous thrombectomy and catheter-directed lysis is slower than might be expected.

*Endovascular Today* assembled a roundtable of leading practitioners to discuss the advantages, challenges and potential pathways to increased utilization of interventional treatment for DVT.

## What benefits do you see in using an endovascular approach versus anticoagulation therapy in treating your DVT patients?

**Dr. Garcia:** As we all know, anticoagulation is still the mainstay of therapy in patients with acute DVT. However, there are patients, particularly those with extensive DVT, who, despite anticoagulation, will still develop chronic DVT and ultimately postthrombotic syndrome (PTS). The endovascular approach allows us to address patients we can identify as being at high risk for PTS. We can treat them before their clot hardens and causes permanent damage to the vein, saving them from the lifestyle limitations caused by PTS.

**Dr. Wang:** I view anticoagulation as a requirement for all patients. If you use endovascular therapy to remove thrombus, you still need to leave the patient on some form of anticoagulation afterward. Without it, I would not have high hopes for long-term patency. The primary goal of both treatments is to prevent additional thrombus and fatal pulmonary embolism (PE). The endovascular approach to remove the thrombus has not been proven to prevent fatal PE, but it has been proven to prevent PTS. However, anticoagulation has been proven to prevent fatal PE. If you choose to intervene with endovascular therapy, in my opinion, you still need to administer anticoagulation.

**Dr. Lookstein:** The major benefit I see to endovascular therapy for DVT in my practice is the alleviation of a patient's acute symptoms. I don't think that patients who are mildly symptomatic benefit from endovascular therapy. In those cases, it's not prudent to do an invasive treatment, and I would just do anticoagulation alone.

Conversely, severely symptomatic patients who are in pain, have leg swelling, and can't walk do not do well with anticoagulation alone. Their symptoms do not improve enough with medical therapy to achieve a meaningful outcome. I consult with them regarding the benefits of endovascular options, and they usually choose that path because they have exhausted other options.

**Dr. Shishehbor:** Anticoagulation prevents additional clots from forming; it does not dissolve clots, it only prevents more. The existing clot has to dissolve on its own. This can take a long time, and the veins can get damaged, leading to PTS. With the devices that have been developed in the last 10 or 15 years, we can treat patients with DVT in a more directed manner. So rather than waiting for the body to dissolve the clot, which can take months or years or maybe never happens, we can try to help by removing as much of the clot as we can in a safe way. Obviously, this will only work in appropriately selected patients with significant clot burden and symptoms. Each patient should be evaluated individually, addressing the risk and benefit of endovascular therapy versus anticoagulation alone.

**Dr. Garcia:** Absolutely—pharmacomechanical thrombolysis (PMT) has been a significant step forward in our ability to treat these patients. The real benefit is that you can eliminate the clot early, maintain the valves, maintain the vein function, and potentially ward off PTS.

### How would you describe the role of endovascular therapy in treating DVT, and what are some of the considerations you make in choosing an interventional approach?

**Dr. Shishehbor:** Every patient is different, of course. The decision of which treatment to use must be a dynamic process, and you have to talk about the risks and benefits of each approach. If I have a very young, active, female patient who wants to walk and run and for whom cosmetic issues may be a problem, I will be more aggressive doing endovascular therapy and trying to remove as much clot as possible. However, this may be different in a fragile, elderly, nursing home patient. In this case, the risks may outweigh the benefits, and I will be more hesitant to use the endovascular procedure.

**Dr. Wang:** I agree. If a patient's life expectancy is less than 2 years, I would not subject him or her to an endovascular procedure. Also, if the patient had a hard indication against lytic therapy, I would be less likely to use an endovascular option requiring use of lytic.

I will essentially consider treating any DVT as long as it extends through the common femoral or higher. Of

course, I prefer to treat them pharmacomechanically, but there are always certain exceptions. In terms of being able to tolerate anticoagulation, if the patient can't but it's for a transient reason, such as recent surgery or bleeding hemorrhoids, I would consider treating him or her. But if someone had truly long-term reasons to not have anticoagulation, such as a recent brain hemorrhage or high fall risk, I would not treat that patient with catheter-directed thrombolysis (CDT).

**Dr. Shishehbor:** I select my patients for endovascular intervention using three points: the comorbidities of the patient, the functional status of the patient, and the extent of the clot. To me, the more clot there is, the more helpful endovascular intervention is because you are helping the body to do its work faster.

**Dr. Lookstein:** I choose my approach based on symptoms, but it usually corresponds with the anatomy and the site of the thrombus. For example, patients with isolated calf vein DVT seem to be the least symptomatic, and I almost never advocate for endovascular therapy to treat them. Patients with extensive iliofemoral DVT are typically the most symptomatic and, in my opinion, can benefit the most from interventional options.

The major issue for me is whether the patient can tolerate the procedure the way it is performed at my institution. The patient must be able to lie prone for more than 2 hours in some cases, and I heavily factor in whether there are any predisposing factors for an adverse event. I have to say, though, that we have not performed overnight CDT in more than 6 years. When thrombectomy catheters were first introduced, we experimented with protocols to initiate the same-day treatment concept without the need for overnight infusion. It took us about two dozen cases. We have used the same technique with subtle modifications since 2006, and we have well over 100 cases now.

**Dr. Garcia:** We don't use overnight CDT much anymore, either. If you look at the data on CDT before PMT really came around, it was 2 to 3 days of intensive care unit stay, with higher cost and higher risks. Any time a patient has tissue plasminogen activator (tPA) circulating through the body, there is a risk for a potential bleed. With PMT, you can significantly reduce the time of tPA infusion and thus minimize the bleeding risks.

When deciding on which patient to treat and choosing an approach, I not only evaluate the extent (and anatomic location) of the clot, but also the effect on the quality of life and the risk-benefit of treatment. Clearly, if anticoagulation fails in someone who is young, active, and has significant lifestyle limitations, he or she should be considered for endovascular treatment sooner than

somebody who may be elderly, incapacitated, and bedridden.

### What discussions do you typically have with patients regarding treatment strategies?

**Dr. Garcia:** I attempt to educate these patients on the potential risks of anticoagulation therapy alone, PTS, as well as the potential benefits of treatment so that they have no surprises. If the benefit of endovascular intervention is clearly greater than the risk, then I will go over the procedure, discussing exactly what they are going to have done and what to expect. We talk about the follow-up, what recuperation will be like, what they will do when they go home, and how we are going to follow them long-term.

I discuss postthrombotic morbidity and what it may lead to if the patients don't have anything done and the clot persists. I think they need to know the sequelae of both anticoagulation alone versus pharmacomechanical or catheter-directed lytic therapy, whichever treatment is chosen. Patients need to know their potential risks, for both standard anticoagulation therapy and lytic therapy. You need to give them the best information you can.

I will talk to patients about all possible treatment options available. Not every patient gets PMT. For example, in someone who may have a transplant kidney or underlying renal issues, we may elect to perform CDT using either standard infusion catheters or the Ekos system (Ekos Corporation, Bothell, WA) to resolve the clot rather than using a mechanical thrombectomy device that may create hemolysis and further worsen renal function.

**Dr. Wang:** I tell patients, "You have a thrombus in this location, and as extensive as you have it, two-thirds of patients will do fine on anticoagulation, but one-third will have a chronically swollen or even ulcerated leg." I explain that endovascular therapy can reduce the chance that they will develop chronic pain or ulcerations, but there is some risk with the procedure. I tell them that approximately 2% will bleed from the procedure. I tell them that the bleeding can happen anywhere; if it happens at the access point, that is easily controlled. However, if you bleed into your head, that can be a potentially fatal situation. I also tell them that even though there are risks to endovascular therapy, your risk of bleeding on long-term anticoagulation alone is higher. I tell all my patients this, and their reaction and decision depends on how painful or swollen their legs are. If a



**Figure 1.** Distal tips of the AngioJet Solent Dista, Proxi, and Omni peripheral thrombectomy catheters (Bayer Radiology and Interventional, Indianola, PA).

patient's leg is not terribly swollen, he usually is more inquisitive. But 90% of them ultimately want to have the procedure.

**Dr. Lookstein:** We discuss improvement in their immediate quality of life in that we will try to alleviate their pain, swelling, and difficulty walking. We also discuss the potential benefit of reducing the long-term risk of PTS. Opening up the thrombosed segment will allow a significant number of patients to go for the rest of their lives without any further problems. When you treat the thrombosed segment with anticoagulation alone, it's rare that patients will recanalize or lyse their clots spontaneously. As a result, the clot that remains will be replaced by scar tissue within the

vein. This will frequently cause permanent damage to the valves leading to higher pressures. Extracting the clot and making the vessel widely patent means the pressure should never get that high. Moving forward, the patient should have relatively normal pressures in that limb.

**Dr. Shishehbor:** In my opinion, endovascular options are relatively safe, and I tell my patients that. The most common complication from the procedure is bleeding from the access site. The decision to do it is more related to how active they are and how devastating potential PTS would be for them. Here is a perfect example: A 19-year-old patient with a genetic abnormality at risk for DVT took a long drive and was diagnosed with extensive iliofemoral DVT. Her doctor decided to treat her medically, and she got severe PTS, to the point that she cannot perform the activities that she was performing before. She was a soccer player and a runner, with a twin sister who did all of the same activities. With the PTS, she became very depressed and this has affected her whole family. They felt they had not been aggressive enough. The problem now is the DVT has been there for 8 or 9 months; there are very limited options for her. So I also address the fact that the opportunity to treat the DVT successfully is higher when it happens acutely. The chance of being successful is much higher in the first 2 to 4 weeks. When you wait to use endovascular therapy, the odds go down exponentially.

### What is your typical approach to DVT treatment, including device selection, lytic use, postprocedure treatment, etc.?

**Dr. Shishehbor:** After assessing a patient's risk of bleeding and obtaining consent, we identify the access

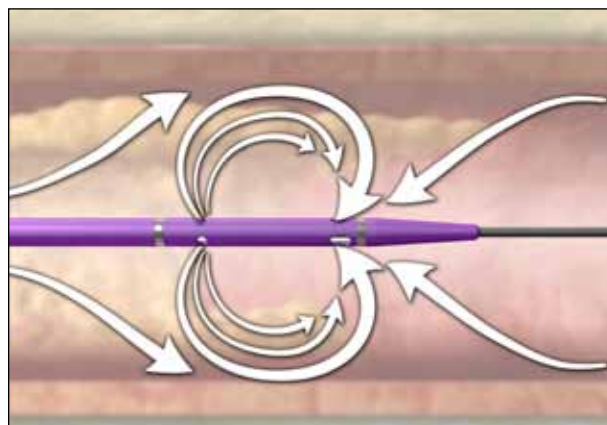
site. For iliofemoral DVT, we typically use the popliteal approach, and we obtain access with the patient in the prone position using ultrasound guidance and micro-puncture. We then typically traverse the occlusion all the way to the inferior vena cava (IVC) using a hydrophilic guidewire. After confirming luminal position, we then use the Power Pulse Delivery Kit on AngioJet (Bayer Radiology and Interventional, Indianola, PA) and spray lytic directly into the clot. We usually use 1 mg of tPA for every 3 cm of clot. After waiting 20 to 30 minutes, we start mechanical thrombectomy. For iliofemoral DVT, I normally use the AngioJet Solent or the DVX catheter. We start distal (near the popliteal artery) and move up. Passes should be slow. We monitor the color of blood in the AngioJet tubing. Darker color in general indicates active thrombectomy. After several passes, we obtain images and reassess.

**Dr. Garcia:** We start with a venous Doppler exam of the leg and make sure it is a thrombotic event. If you suspect something more central, such as May-Thurner syndrome, or if the patient had an IVC filter in the past and now has bilateral leg swelling, you must suspect that thrombus extends up into the IVC/filter.<sup>1</sup>

If so, we'll perform either computed tomography venography or magnetic resonance venography and look at the central anatomy to make sure that the approach we are planning will be adequate in treating this patient. For example, we may decide that access from the jugular vein may be more beneficial than popliteal access.

In our institution, I like to get hematology involved for not only the acute care but long-term follow-up, including evaluation of hypercoagulable state. As far as filter use, we usually do not place filters before therapy, as the risk for PE is quite low. We use the "rapid lysis" technique that we designed and have been using now for nearly 14 years. It's a combination therapy using AngioJet with tPA where we use the AngioJet from the central clot to the peripheral clot using a spiraling technique to gain wall-to-wall apposition. Using this technique, we have had no PE issues in hundreds of patients without using any filters.

**Dr. Wang:** I have converted my approach to endovascular DVT therapy into an ambulatory one. If a patient has a DVT that we've determined needs treatment, they are placed into a prone position, and the popliteal vein is accessed. We obtain a venogram and pass the wire through. You know you can get a lot of information from just putting the guidewire in. If it traverses to the IVC easily, it's fresh clot; if it takes effort to push through, you know you are likely dealing with mixed or more chronic thrombus, or even scars or webs. In most cases



**Figure 2.** Cross-stream technology applied to the AngioJet thrombectomy catheters creates a low-pressure zone at the inflow ports of the catheter tip, entraining and removing thrombus from the occluded vessel.

I place a filter in the IVC, although recently I have been using them less. For a single-limb DVT, I Power Pulse in 10 mg of tPA with the AngioJet catheter. My problem with catheter-directed lysis is that once there is a channel in the thrombus, a lot of the dripped lytic just flows right through the center and becomes systemic. Using the AngioJet Power Pulse, the drug penetrates a wider area of thrombus. Then I'll put a lytic therapy catheter in, not really to deliver lytic, because I've already done that with Power Pulse to penetrate the thrombus. This catheter is to hold my place for later so I do not have to retrace the vein.

The half-life of tPA is 6 to 15 minutes, so you need to give the drug five half-lives to work. This is where it could get logistically difficult, but I have figured out a way to do it. I take the patient off the table and put him in the holding area, all the while still getting a minimal drip and access in the back of the knee. I then bring in another case or two, as long as the total time is more than 1.5 hours. Then I bring the first patient back and use the AngioJet in thrombectomy mode to suck out as much thrombus as I can. I obtain another venogram and make liberal use of angioplasty. Often there is some residual scar or older DVT, so I perform angioplasty throughout the diseased segment and, if necessary, stent. I have found that stents in the iliac segment have very good patency, and usually the problem is in the iliofemoral segment. I have put a few stents in the superficial femoral and even the popliteal, but their patency is much less than in the iliofemoral segment.

AngioJet System users have told Bayer that their general practice is to Power Pulse lytic, wait approximately 20 to 30 minutes and then perform mechanical thrombectomy.

If you give the drugs longer to work, however, I believe

1. The AngioJet Thrombectomy System is not indicated for use in the IVC. Please refer to *AngioJet Peripheral Catheter Information for Use* for complete indication and prescribing information.



you get a better result because they have more time to break down the thrombus. The problems with this are, first, if you take 2 hours to do one case, you need to find a better use of your time. Second, the cath lab staff will get upset with you for leaving a patient on the table for that long. My “ambulatory” technique of moving patients to a holding area and then back to the table for secondary intervention and subsequent same day discharge allows me to control my time and the situation more efficiently. I get the amount of time I need for lytic infusion and good results for thrombus removal. Also the patient can be treated in an ambulatory fashion.

I do use Ekos catheters and other devices as well, but the mainstay of this treatment is the AngioJet catheter with Power Pulse. For lytic, I use tPA because it's the least expensive and we are somewhat limited in a community practice. I use enoxaparin and warfarin for long-term oral anticoagulation.

**Dr. Garcia:** We rarely go to catheter-directed lysis, but if we do, I consider Ekos, too. It does appear that the ultrasound enhancement improves the ability to lyse clot and therefore reduces the time patients may be on the lytic therapy.

**Dr. Lookstein:** We do not routinely use filters in my practice. The risk of an embolic complication is exceedingly low, especially with good screening, so we only use filters selectively. It's just another risk and an added procedure with added cost. The majority of patients I see in my office, approximately 90% to 95%, will get screened with CT or MRI to document if there is an extrinsic narrowing on the venous segment that is thrombosed. If there is a narrowing, that works like an intrinsic filter. Those patients will not get filters, the clot will be completely extracted, and in the last stage of the procedure, the narrow segment will be angioplastied and stented. If the segment is patent but filled with clot, they will have no intrinsic filter and so they are potentially at risk for a clot in their central circulation. They get a filter, but that's 5% or fewer patients.

**Dr. Shishehbor:** There are little data regarding embolization to the lungs during endovascular therapy. I typically do not use an IVC filter because the risk of PE is low and because of the risk and cost associated with the filter (with no proven benefit). After the procedure, we wrap the legs and keep them elevated. Patients are usually



**Figure 3.** The AngioJet Thrombectomy System console energizes the thrombectomy catheter, displays run times for thrombectomy procedures, and shows infusion amounts for Power Pulse delivery.

hydrated aggressively given the possibility of hemolysis. The kidney function should be checked the next day. It is not unusual to have hematuria after these cases, but the condition improves after hydration and eventually completely clears. Patients are then discharged on warfarin and enoxaparin until their international normalized ratio (INR) is somewhere between 2.5 to 3.5.

**Dr. Lookstein:** We have a routine post-procedure protocol. Patients are on anticoagulation for at least 12 months, especially if they have had venous angioplasty and stenting. We combine this with elastic graded compression stockings for the lower extremities; we do this bilaterally because most patients won't tolerate wearing just one stocking (it's a psychological thing). At 1 year, we transition them from warfarin to one 81-mg aspirin a day for life. If they have multiple biomarkers or intrinsic coagulopathies, and especially if they had angioplasty, we maintain them on anticoagulation for life. Mostly we use warfarin.

There are newer drugs currently in trials, which may offer potential safety and efficacy benefits for patients. Our follow-up consists of venous duplex of the previously treated segment at 1, 6, and 12 months, and annually thereafter.

**Dr. Garcia:** I like putting patients on enoxaparin before the procedure, getting them on the table, and continuing enoxaparin into the postprocedure arena. Postprocedure, we usually will try to stay with enoxaparin for 1 month in the acute patients before transitioning them over to warfarin. This also may allow the hematologist, if they haven't been able to get the hypercoagulable workup previously, to get their workup done prior to putting them on warfarin. In the chronic DVT patient, we will actually extend the enoxaparin for 3 months before switching to warfarin. We found that enoxaparin allows for a more accurate anticoagulant level, with less variability than warfarin, which can have wide fluctuations in the INR. The patients on enoxaparin have anecdotally had much better long-term patency rates than patients put on warfarin, who may have dips in their INR below therapeutic levels and thus develop some recurrent thrombus. Posttreatment, we follow them in the office with Doppler exams, a physical exam, and a questionnaire at 1, 3, 6, and 12 months, and then usually every 6 months or yearly.

**Dr. Wang:** For follow-up, I see patients 2 weeks after the procedure. By that time, their leg or legs will have significantly shrunk in size. I do not do an ultrasound if

their legs are shrinking, which is about 95% of the time. I take the filter out between weeks 3 and 4. I see them every 3 months for the first year for a repeat duplex, then every 6 months after that. If they have stents, it's every 6 months for life; if no stents were placed, they may go to yearly or as needed.

### How do you mitigate potential complications of DVT treatment?

**Dr. Lookstein:** The best way to avoid complications is proper screening, trying to identify high-risk patients early on. Any experienced operator has a sense of who is at high risk for bleeding and as such should not be offered this therapy unless it is urgent. We perform periprocedural hydration to prevent any contrast-induced nephropathy; this also addresses hemolysis and hemoglobinuria, which may be side effects of the AngioJet. If a patient is dehydrated and receives intravenous contrast, and then has fragmented red blood cells from thrombectomy, all of this in combination can have adverse effects on the kidneys. The best way to address that is to use aggressive periprocedural hydration. Patients get from 0.5 to 1 L of normal saline and a drip continuing until discharge. We have not seen any negative effects in years since we adopted this approach.

**Dr. Shishehbor:** The most common complication to me is access-site bleeding or bleeding in general. Second, there is sometimes renal insufficiency and hematuria. We perform lysis and remove as much clot as possible, then put the patient on warfarin to be sure additional clots don't form. Depending on the etiology of the clots, we put patients on warfarin for the duration necessary. If the clot was provoked, 3 to 6 months. The unprovoked clots are the ones we worry about and treat longer, sometimes with lifelong anticoagulation.

To prevent access-site complications I use ultrasound guidance. If feasible, I use Power Pulse delivery rather than infusion over 2 or 3 days, as this decreases the amount of lytic needed and further reduces the risk of bleeding. I hydrate the patient to protect the kidneys, and we monitor urine output after the procedure. Typically we wrap the leg and keep it elevated after the procedure, and patients stay with us for 24 hours.

**Dr. Garcia:** The risk of bleeding may be the most significant complication of thrombolytic therapy. Proper screening of at-risk patients can limit the risk, however. Because we primarily use pharmacomechanical techniques, we limit that risk. Regarding PMT with AngioJet, we try to hydrate well prior to using it, and if I use it more than 1000 mL volume, I'll give furosemide to help "flush" the kidneys. In somebody who has diabetes or any sign of chronic renal insufficiency or potential of

underlying renal issues, we again hydrate well. We do that for anybody with concerns of renal insufficiency. In the normal population, I can safely use the AngioJet up to 1,000 mL of solution. If, following PMT there is residual clot, we'll place an infusion catheter to resolve the remaining thrombus.

Our post-PMT order sheet has a line stating that hematuria/hemoglobinuria is expected with patients who receive AngioJet, so that the nurses don't think that the patient is bleeding and that we need to stop the anticoagulation and/or thrombolysis.

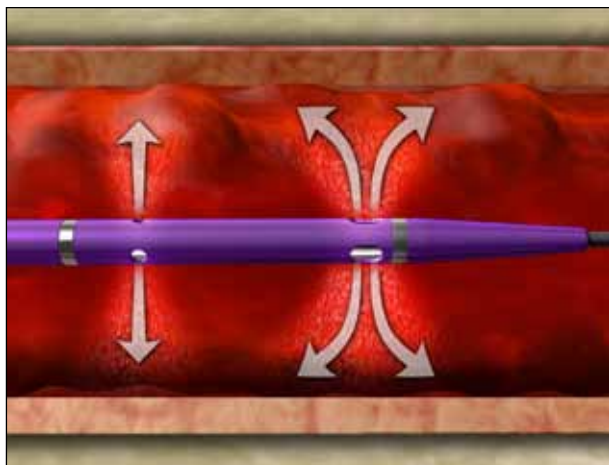
**Dr. Wang:** I find that men are much more concerned about hemoglobinuria than women. I give all patients a liter of fluid in the cath lab when they are waiting to go home. Then I tell everyone, "Your urine is going to turn brown or red, you need to drink a cup of water every hour while awake, and it will clear up after 48 hours, which it always does. If it is brown or red that is fine, but if there are clots, you need to come back to our office or hospital." That has never occurred; however, even after you tell people, you will still get calls. I typically get one call from a female patient for every three calls from a male patient. You can make of that what you will.

I try to keep my AngioJet run times shorter than 150 seconds; that's probably less than what others do. I do hydrate during and after, but I don't do prehydration due to the fact that these patients are coming in that morning. I have never had to take anyone off of anticoagulation because of hemoglobinuria. It may be because my ambulatory technique lets the drugs melt the thrombus more, so I need to chop it up less.

### How has your approach to patient preoperative assessment and DVT treatment evolved, and what activities specific to developing new treatment pathways have you found to be successful?

**Dr. Lookstein:** Here are my top three tips. First, identify what you can do for patients to have an optimal experience; if patients are happy, their doctors will be happy. Our greatest limitation in the past was the overnight requirement of therapy. Now, with a technique that eliminates that, we have more uniform patient and doctor satisfaction, leading to more interest with this approach. Patient satisfaction and ease are paramount. There is a constant quality assurance piece that goes with any venous practice to make sure patients are happy and that any issues are addressed. For example, surveying your patients afterward shows your willingness to improve and learn.

Second, know that there is an Internet presence for this disease entity, and use that to your advantage. People find me on the web or via word of mouth. The



**Figure 4.** The AngioJet Thrombectomy System includes select catheters that are enabled for Power Pulse delivery of physician-specified fluids directly into the thrombus.

branding that goes with modern techniques allows for more uniform education of patients. For doctors, that branding improves their understanding as well. The venous interventional specialist needs to offer comprehensive care—not just treatment for venous thrombosis, but also for those with superficial venous problems. Your branding should be as a venous specialist and not just procedurally based; this approach goes a long way toward improving your own identity.

Third—and this is absolutely critical—excellent patient education. They need to know not just what a deep vein intervention entails, but what their prognosis is and what the follow-up will be. This is not just for the patient, but for family and for the doctor as well. From when patients arrive to when they go home, this kind of communication demystifies the treatment of DVT and allows for broader acceptance of what the therapies can do.

**Dr. Garcia:** Our preoperative assessment and DVT treatment evolution really stemmed from doing cases that were very complex with tremendous risk. These patients were high-risk for catheter-directed thrombolysis, so we convinced the hematologists and vascular surgeons to allow us the opportunity to use the pharmacomechanical device. After having fantastic results, we were able to go from the high-risk patient to those who were standard risk but were suffering from PTS. Once we started doing those cases and getting great results, it evolved from there. We started seeing patients who were known to be at high risk of developing long-term PTS or who had severe pain and swelling despite therapeutic anticoagulation. Like any practice, the more great outcomes you have, the more patients you'll see. That led to patients who had chronic DVT.

Over the last 5 or 6 years, we've actually taken on more and more of those patients, and we've now started to present and publish at national meetings information on the outcomes of treating chronic DVT, showing that we can change the outlook for the chronic DVT population.

We are fortunate that at our institution, hematologists and vascular surgeons who see patients with significant symptoms despite anticoagulation recognize the value of proactive endovascular treatment. It has been an evolution over time, having good outcomes, talking at medical and surgical grand rounds, and presenting at national meetings. If you can do it safely in the high-risk population, people realize you can do it in the low-risk population, too.

**Dr. Wang:** As a young surgeon, I spoke with primary and ER physicians in the hospital to let them know about the treatment I was able to provide, but they were not clear about when to consider proactive treatment for a DVT patient until I came up with a DVT treatment protocol. Literally, in stepwise fashion, when you have a suspected diagnosis of DVT or PE, it tells you the boxes you check off to get them tested, what you need to do to get them treated for DVT or PE, and the extent of the DVTs that you need to call for (the thrombus needs to involve the common femoral vein or a more proximal vein). Otherwise you will get too many calls. I gave this tool to the hospitalists and the emergency department staff, and it's now part of our electronic order entry. The protocol streamlines the process and gets more buy-in from the hospitalists. You have to engage with them and tell them you can prevent these ulcers that otherwise would need to be sent to wound care or admitted to long-term skilled nursing. You have to get the word out, at least very basically, about PTS. In our case, we just needed to give those doctors a tool.

We also have a support group with quarterly speakers for patients with DVT and PE. We bring out dietitians and other practitioners to educate our patients, for example, with diet information while on anticoagulation or physical therapy tips for residual swelling.

At least in my facility, if you treat DVT in an ambulatory setting, it makes better use of facilities, staff, and equipment. I am working the whole time, not waiting around. The patient is treated quickly and returned home the same day. This approach allows the patient, the physician, and the hospital system to do well.

**Dr. Shishehbor:** I also do outreach. I try to emphasize the safety of the endovascular approach. Many of the physicians who encounter patients with DVT are reluctant to send patients for any kind of endovascular treatment because they associate this treatment with the

older concept of systemic lytic and its complications.

I try to educate them about the endovascular approach; I tell them it is local therapy in the clot, using much lower doses of drugs than before. I do it one-on-one, I do it by feedback and lectures, I do it any way I can. This education pays off for the patients, and that resonates.

### What do you believe are some of the important initiatives and studies currently underway looking at DVT treatment options?

**Dr. Wang:** The clinical trials I am very interested in have to do with anticoagulants. I hate to say it because I am a surgeon, but my main concern is not what I am doing while they are sedated, but what happens later, in their day-to-day lives. Warfarin is a huge issue. The hematologist tells patients that their biggest bleeding risk is from the drugs, and that they need frequent lab checks. Patients complain about this required maintenance and are very interested in the oral anticoagulants that are coming out. Hopefully they will be approved in the United States. Taking one pill in the morning and one at night and being done—that would be a huge change.

**Dr. Garcia:** The NIH-sponsored and industry-supported ATTRACT trial compares acute DVT treated with anticoagulation alone versus anticoagulation combined with PMT, or thrombolytic therapy and the incidence of PTS. I think the majority of us believe that the treated arm will be less symptomatic in long-term follow-up for PTS sequelae than the patients who get anticoagulation alone. This may be the biggest marketing tool that we will have to convince our medical colleagues that they should be looking at early intervention and that anticoagulation alone shouldn't be the standard of care, given

the newer techniques and devices that are available. We are hoping to complete enrollment by the end of 2013, I believe, with follow-up completion in 2015.

The CAVENT trial in Europe looked at thrombolytic therapy versus anticoagulation and showed that there was a benefit to thrombolytic therapy, although the design wasn't optimal. It was a randomized, single-center trial, but they didn't use PMT. They used catheter-directed lytic therapy, but they still showed a trend toward improved outcomes over anticoagulation alone. There really isn't any other study out there with the robust nature that ATTRACT will have.

**Dr. Lookstein:** I totally agree. Most people who are reluctant to embrace the technique say their main criticism is that there is not yet level 1 evidence to support its use. ATTRACT will give us that level 1 evidence.

It's also worth mentioning the PEARL multicenter registry for AngioJet usage, which is sponsored by Bayer to capture modern usage patterns. PEARL looks at acute outcomes, quality-of-life, and patency outcomes out to 12 months. The preliminary data show three things. First, the majority of people are using it in combination therapy—using alteplase in the veins and then extracting the lysed clot with the AngioJet. Second, 75% of patients can be treated in less than 24 hours compared to historical controls. Third, this treatment offers a dramatic improvement in quality-of-life measures in patients treated, which is very encouraging for the technique.

The bottom line: This is a transformative technology that allows symptomatic patients who formerly did not have any palatable choices to have a realistic treatment option they can understand. It's changing the treatment paradigm for DVT. ■

#### AngioJet® Thrombectomy Systems for Peripheral Use

##### Use Indications/Contraindications

AngioJet and AngioJet Ultra Systems are indicated for breaking up and removing thrombus from infrainguinal peripheral arteries, upper and lower extremity peripheral arteries, upper extremity peripheral veins, iliofemoral and lower extremity veins, A-V access conduits, and for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. Do not use in patients: who are contraindicated for endovascular procedures, who cannot tolerate contrast media, and in whom the lesion cannot be accessed with the wire guide.

##### Warnings and Precautions

The system has not been evaluated for treatment of pulmonary embolism or for use in the carotid or cerebral vasculature. Some AngioJet devices have not been evaluated for use in coronary vasculature. Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Cardiac arrhythmias may occur and cardiac rhythm should be monitored during catheter use and appropriate management employed, if needed. Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. Operation of the system causes transient hemolysis. Large thrombus burdens may result in significant hemoglobinemia which should be monitored. Consider hydration, as appropriate.

##### Potential Adverse Events

Potential adverse events (in alphabetical order) which may be associated with use of the system include, but are not limited to, the following: abrupt closure of treated vessel, acute myocardial infarction, acute renal failure, bleeding from access site, cerebrovascular accident, death, dissection, embolization (proximal or distal), hematoma, hemolysis, hemorrhage requiring transfusion, hypotension/hypertension, infection at access site, pain, pancreatitis, perforation, pseudoaneurysm, reactions to contrast medium, thrombosis/occlusion, total occlusion of treated vessel, vascular aneurysm, vascular spasm, and vessel wall or valve damage.

Refer to product labeling for device-specific indications, contraindications, warnings/precautions, and adverse events. Rx only. PER – October 2010