

# DVT Requires Aggressive Tx To Avoid Chronic Syndrome

BY BRUCE JANCIN  
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ROME — Many physicians outside of interventional radiology are inappropriately complacent regarding the long-term sequelae of deep vein thrombosis in the lower extremities, speakers said at the annual meeting of the Cardiovascular and Radiological Interventional Society of Europe.

Deep vein thrombosis (DVT) occurs in more than 250,000 U.S. patients per year. Standard medical management—that is, anticoagulation, compression stockings, and leg elevation—is all about preventing pulmonary embolism, a dreaded acute complication with roughly a 13% in-hospital mortality.

But often, anticoagulation only partially clears the thrombus, and it doesn't fix the delicate venous valves threatened by low or absent blood flow. As a result, many patients develop chronic post-thrombotic syndrome

(PTS), or "heavy leg," marked by ruptured valves, lifelong chronic deep venous insufficiency, painful leg swelling, and stasis ulceration, according to Dr. Kenneth R. Thomson of the Alfred Hospital, Melbourne.

"No patient I've ever met who's had heavy leg syndrome or PTS after DVT thinks it's any good at all," Dr. Thomson said. "We need to educate clinicians to think of [deep venous] thrombus as a valve attack, like a brain attack or a heart attack, and have a more rapid and aggressive treatment."

That will require more accurate diagnosis. Even in premier medical centers, the radiologist continued, it's surprising how often patients who present to the emergency department with a swollen leg get an ultrasound exam that stops at the groin and doesn't include the iliac veins or inferior vena cava.

Dr. Stephen T. Kee stressed that PTS can be as disabling as severe peripheral arterial disease. The direct medical costs of PTS in the United States are estimated at \$300 million annually.

"When venous disease is extensive, it is essentially beyond medicine's ability to treat. Anticoagulation alone is not enough. They need our help. Lysis in correct doses is very safe, although in most cases it must be combined with other endovascu-

lar techniques with which we are very familiar," said Dr. Kee, chief of interventional radiology at the University of California, Los Angeles, Medical Center.

Interventional radiologists perform catheter-delivered thrombolysis (CDT) for DVT. It provides more complete clot lysis than the systemic infusion used in acute MI, and with much lower risk of bleeding complications. In roughly 90% of cases, there is an underlying anatomic defect that requires adjunctive angioplasty in order to maintain patency, along with stenting in the case of suprainguinal disease, he explained.

These procedures are most effective in acute DVT. Ideally, Dr. Thomson said, CDT ought to be done in the emergency department. The reality is most patients aren't referred for this more aggressive therapy until at least several months of anticoagulant therapy have gone by and the leg remains swollen. By then the thrombus is hardened and desiccated, crosslinked to fibrin, tightly adherent to the vein wall—and the valves are destroyed.

Dr. Thomson is a coinvestigator in a Cook Inc. project aimed at developing percutaneous bio-prosthetic venous valves for use in DVT patients who have experienced "valve attack." The 1-year clinical outcomes reported at the meeting are promising, but better biomaterials are needed to improve valve longevity.

CDT for DVT is an off-label use of lytics. Nonetheless, the Society for Interventional Radiology (SIR) this year issued a position statement declaring CDT as an adjunct to anticoagulation an acceptable initial treatment strategy for carefully selected patients with acute DVT of less than 14 days' duration.

The SIR statement cited registry data suggesting CDT has better outcomes than those obtained with anticoagulation alone, which results in PTS in up to 50% of patients if compression stockings aren't used and 25% if they are.

A SIR research consensus panel concluded that if more aggressive treatment of DVT is to become a multidisciplinary national priority, there is a pressing need for persuasive A-level supporting data.

Toward that end, the society has submitted to the National Institutes of Health a detailed protocol for a large randomized trial to be called Acute Venous Thrombosis Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT). The trial will compare anticoagulation alone to thrombolysis with or without angioplasty and stenting. The primary end point will be the cumulative 12-month PTS incidence.

"The trial will by protocol get interventional radiologists doing the same thing. One of the big problems with DVT is that each of the 250 of us in this room now do things in our own tweeky way. It makes it hard to get the point across to the physician who's referring patients that there's a standard method of treatment for this disease. I think if we can somehow or another get a consensus on the right way for interventionalists to treat DVT, it will help us to get data that's reproducible," Dr. Kee said.

If approved by NIH, ATTRACT will start in April 2007 and be led by Dr. Suresh Vedantham of Washington University, St. Louis. ■

# Facilitated Thrombolysis Devices Speed DVT Therapy, Reduce Costs

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ROME — Several relatively new percutaneous pharmacomechanical devices may have a major impact on the treatment of deep vein thrombosis, speakers predicted at the annual meeting of the Cardiovascular and Radiological Interventional Society of Europe.

Devices such as Bacchus Vascular Inc.'s Trellis and the EKOS Lysis System render tough clots more amenable to low-dose lytic therapy, albeit through very different mechanisms. The thrombus clears dramatically faster than with conventional catheter-delivered thrombolysis (CDT), which often takes 24-50 hours or more of continuous infusion conducted in an ICU or step-down unit.

And the faster thrombus clearance translates into lower hospital costs and—in the view of many interventionalists—less risk of lytic-related hemorrhage as well.

Dr. Thomas O. McNamara said both the Trellis and Lysis devices are so new to the marketplace that their optimal roles aren't defined yet. Outcome data remain scarce. But he has used both devices, and it's his impression they are particularly well-suited for treating subacute DVT of about 8-90 days' duration.

Fresh thrombus not more than a week old is often readily cleared using slow-drip CDT. But subacute clot that has begun to harden and cross-link with fibrin is much more resistant to conventional CDT. The pharmacomechanical devices thus broaden the spectrum of DVT amenable to lysis, explained Dr. McNamara, professor of radiology at the University of California, Los Angeles.

The Trellis device consists of a lytic-infusion catheter with an oscillating wire and occluding balloons at either end. The catheter is passed across the clot, the balloons above and below the thrombus are inflated, and the oscillating wire is activated for 15 minutes, during which a small quantity of a thrombolytic agent is administered at 5-minute intervals.

The oscillating wire macerates the clot, breaking it up into smaller fragments with far greater surface area. This enhances the effectiveness of lytic therapy. Meanwhile, the bal-

loons trap the clot so it can't embolize. They also theoretically trap the lytic so it can't become systemic and cause bleeding. "I think the device does that, but not completely," Dr. McNamara commented.

After the oscillating wire has been fired up for several 15-minute bursts, the dissolved clot is sucked out through the catheter and the balloons are deflated.

Dr. Stephen T. Kee noted that total Trellis procedure time, from access site puncture to sheath removal, is typically 1 hour to just over 2 hours, even when stenting or other adjunctive procedures are performed.

"This is a revolutionary way of treating patients that we haven't previously had. It means you can get in, get out, and go home. You don't have to keep these patients in the hospital overnight if you don't want to," said Dr. Kee, chief of interventional radiology at UCLA Medical Center.

Dr. McNamara characterized the Trellis as "a lovely idea." Interventionalists who have difficulty getting patients into the ICU for lengthy CDT may use it routinely as a single-session treatment. But he added that the Trellis system is too expensive to use as initial therapy for most of his patients.

One situation where the device is clearly justified, though, is in the postop patient with DVT, he continued. He has used the Trellis in 24 such patients and found it quite effective. It's not foolproof, however: One spinal fusion surgery patient required transfusion after bleeding into the buttock that was believed to be caused by systemic escape of the lytic triggering bleeding at the donor bone site.

The Lysis System combines high-frequency, low-power ultrasound with simultaneous CDT. The system includes a catheter with multiple ultrasound transducers placed 1 cm apart. The same catheter emits a thrombolytic agent in a continuous infusion through a separate channel.

The radially delivered ultrasound waves loosen the clot while driving the lytic agent deep within it. The result is accelerated thrombolysis, with an average infusion time of 24 hours or less, and lower lytic doses than in conventional CDT, said Dr. McNamara, who is a consultant to EKOS. ■

## Peripheral Arterial Disease Education

The "Stay in Circulation: Take Steps to Learn About PAD" campaign offers educational materials in English and Spanish, including fact sheets, posters, and a DVD about living with peripheral arterial disease.

The campaign was launched by the National Heart, Lung, and Blood Institute, in cooperation with the PAD Coalition, which includes 45 organizations and specialty societies, including the American College of Cardiology, the American College of Physicians, and the American Diabetes Association, and the American Heart Association.

More information is available at the campaign Web site, [www.aboutpad.org](http://www.aboutpad.org).