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New Nonsurgical Techniques Spray, Chew and Vacuum Away Damaging Deep Vein Thrombosis (DVT) in the Leg

Interventional Radiology's Combination Drug-Device Technique Clears Clots to Prevent Permanent Leg Damage and Disability

NEW ORLEANS, Louisiana (April 1, 2005) – Studies presented today show that three new pharmacomechanical thrombolysis techniques are highly effective and enable DVT treatment with less risk, less medication, and less cost than the current catheter-directed thrombolysis technique, which uses drug alone. The new techniques combine the use of clot busting drugs with clot macerating devices to break up the clot in the leg. The research was presented today at the Society of Interventional Radiology's 30th Annual Scientific Meeting. These devices provide interventional radiologists with physical assistance to break up the clot faster. By using pulsing spray or a macerating motion, the devices mechanically break up the clot, allowing the clot dissolving drugs to work much quicker. This nonsurgical treatment is performed by using imaging to guide and advance the device inside the vein directly to the clot.

"The new combination techniques offer a very significant advance in treating DVT. With these techniques, interventional radiologists can often break up the clot in one day, often in a single session. This has the potential to become a standard outpatient treatment and could really change the way DVT patients are treated," says Suresh Vedantham, MD, interventional radiologist, Washington University, St. Louis. The current catheter-directed thrombolysis treatment is highly effective but generally takes one to two days and few DVT patients receive it, although it has been available for about a decade.

Removing these clots is important because about 50 percent of the time, untreated clots will cause post-thrombotic syndrome, a condition characterized by chronic leg pain and swelling. Post-thrombotic syndrome is caused by a combination of vein valve damage and blocked blood flow in the vein from residual thrombus (clot). "The new treatments offer hope that interventional radiologists could greatly reduce the number of patients who develop post-thrombotic syndrome from DVT. This is a common complication from DVT that is under-recognized," says Vedantham.

About the Combination Techniques and Studies

In both the Power Pulse Spray and Trellis studies, over 80 percent of patients were treated in a single session, without the need for overnight infusion. In the Helix study, which compared the pharmacomechanical technique to catheter-directed thrombolysis (CDT), the treatment time also was significantly shorter than CDT, and there was a trend toward fewer bleeding events.

Power Pulse Spray, **Abstract 33 –** The power pulse spray injects a diluted clot-dissolving drug throughout the clot at high force. This helps break up the clot and deliver the drug to more surface area throughout the clot. After waiting approximately half-an-hour to allow the clot to partially dissolve, powerful saline jets create a vacuum that draws the clot (thrombus) into the catheter where it is removed from the body. The power pulse spray technique is a new method of using the already existing Angiojet device.

Over 80 percent of the patients were treated in a single session, without the need for overnight infusion. Of the 14 patients reviewed in this multi-center retrospective study, the Power Pulse Spray technique led to complete removal of the DVT in 10 cases (71 percent), substantial removal in 3 cases, and 1 case of only partial removal. Nine of the 14 patients underwent angioplasty to treat underlying venous lesions, and five of the nine also had a stent placed to keep the vein open and help prevent future clots. After completion of therapy, all patients had resolution of their symptoms. The authors conclude that the technique as well as treatment of underlying conditions, such as vein narrowing, that predispose patients to DVT, should be considered for treating acute iliofemoral DVT.

Trellis, Abstract 37 – The Trellis®-8 Infusion System is positioned at the site of the clot and a balloon is inflated on both sides of the clot to prevent pieces of the clot from traveling to other parts of the body and to isolate the treatment zone, so that there is less chance the infused drug will cause bleeding. Then a "wire filament" is fed through the clot. The wire begins to whip around, chewing the clot into pieces that are pulled/aspirated into the catheter and removed from the body. The Trellis was recently FDA approved as a drug infusion catheter for vascular clots.

The study compared the DVT treatment using the Trellis to catheter-directed thrombolysis. Technical success, bleeding complications, and cost for 66 DVT patients treated with the Trellis were reported through a company sponsored registry.

The results showed the Trellis technique to have a high rate of success, with a lower risk of bleeding, lower dose of drug, and lower costs to the hospital compared to traditional catheter-directed thrombolysis treatment. Eighty-one percent of the patients were treated in a single setting. Thrombus was acute in 58 percent, chronic in 30 percent, and acute on chronic in 12 percent. [Acute, fresh clots are more easily treated.]

Helix, Abstract 38 – The HELIX™ Clot Buster® Thrombectomy Device is a mechanical thrombectomy catheter that macerates the clot. A drive shaft, extending the length of the catheter, rotates an encapsulated impeller housed at the distal end of the device. This miniature impeller creates a re-circulating vortex that homogenizes the thrombus. The Helix is approved for dialysis graft clots and is being investigated for DVT.

This new study compared the Helix treatment to conventional catheter-directed thrombolysis. Over an 8-year period, 36 patients were treated with catheter-directed thrombolysis (CDT) using the clot-dissolving drug urokinase. The first 11 patients (14 limbs) had conventional CDT, with urokinase and full dose heparin, an anticoagulant (blood thinner), followed by stent placement to keep the vein open if their vein was stenosed (blocked or narrowed) after thrombolysis. The other 25 patients (36 limbs) were treated with the Helix device in combination with urokinase and subtherapeutic heparin dose, followed by stent placement for stenosis or short-segment residual thrombus.

Technical and clinical success was achieved in 86 percent of the treatments (43 of the 50 limbs) and did not differ significantly between the two groups. Significant (complete or partial) thrombolysis was more frequent in the Helix group (94 percent), versus the CDT group (71 percent). In the Helix group, treatment time was significantly shorter, the total urokinase dose needed was cut in half, and there was a trend toward fewer bleeding events.

About DVT

Deep vein thrombosis occurs in the deep veins that lie near the center of the leg and are surrounded by powerful muscles that contract and force deoxygenated blood back to the lungs and heart. One-way valves prevent the back-flow of blood between the contractions. When the circulation of the blood slows down due to illness, injury or inactivity, blood can accumulate or "pool," which provides an ideal setting for clot formation. The standard initial treatment with blood thinners is important to prevent a life-threatening pulmonary embolism, but does not treat the existing clot.

About Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology's 30th Annual Scientific Meeting in New Orleans. Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat diseases nonsurgically through the blood vessels or through the skin. By combining diagnostic imaging expertise with advanced procedural skills, interventional radiologists perform minimally invasive treatments that have less risk, less pain, and less recovery time than open surgery. Interventional radiologists pioneered minimally invasive modern medicine with the invention of angioplasty and the catheter-delivered stent, which were first used to treat peripheral arterial disease. More information can be found at www.SIRweb.org.

Interviews, medical illustrations and broadcast quality video footage are available. Abstracts can be found at www.SIRmeeting.org in the program section and click on scientific sessions.

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