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Nonsurgical Deep Vein Thrombosis (DVT) Treatment Vacuums Away Damaging Blood Clots and Restores Blood Flow in the Leg

Interventional Radiology's Drug-Device Technique Breaks Up and Removes Extensive Blood Clots to Help Prevent Permanent Leg Damage and Disability

Seattle, Washington (March 2, 2007) – A study presented today demonstrates that a new technique safely and effectively removes blood clots in the body faster, reducing patient risk for pulmonary embolism and disability. The interventional radiology treatment was also shown to have a positive impact on patients' quality of life, relieving symptoms such as pain and swelling, as well as greatly improving their ability to be active. The "rapid lysis" technique combines a clot-dissolving drug with a clot removal device, thus improving the breaking up and dissolving of the clot, which is then vacuumed out of the vein and into the catheter, nonsurgically clearing away the deep vein thrombosis (DVT). Blood flow is restored throughout the leg, resolving symptoms. Patients in the study had extensive, large volume DVT that commonly ran the length of the leg from the ankle to the pelvis, and often into the vena cava. Although the body may eventually dissolve clots, in the time needed to do so, permanent damage to the vein may occur, causing permanent disability and pain. In addition, previous studies have shown that clots in the larger veins will rarely clear on their own. The research was presented today at the Society of Interventional Radiology's 32nd Annual Scientific Meeting.

"The new combination technique offers a significant advancement in the treatment of DVT, often allowing the interventional radiologists to break up the clot in one treatment. It has worked on even the largest, most difficult clots and could become the new standard technique, potentially changing the way all DVT patients are treated," says Mark J. Garcia, M.D., interventional radiologist at Christiana Care Health System, Wilmington, DE.

This treatment worked on the largest, most difficult clots, allowing resolution of DVT quickly and safely while restoring blood flow in the vein. The treatment can reduce the length of a hospital stay, thus reducing costs. The current standard catheter-directed thrombolysis treatment uses a clot-dissolving drug only and, although highly effective, can take two to four days to work. This increases the patients' risk of bleeding as well as increasing their stay in the ICU. Although the catheter-directed thrombolysis technique has been available for about a decade, many DVT patients don't receive it. Instead, many patients are treated with blood thinners alone which can help prevent a life threatening pulmonary embolism, but do not help dissolve the clot. Long-term studies show that fifty percent of people with leg DVT treated with blood thinners alone develop the sequela of DVT, known as post-thrombotic syndrome. Post-thrombotic syndrome is caused by a combination of damage to the vein valves, as well as blocked blood flow in the vein from

residual thrombus (clot). This condition is characterized by chronic leg pain and swelling which can lead to skin thickening and ulceration.

"Post-thrombotic syndrome is a common complication of DVT that is under-recognized and potentially preventable if we are able to dissolve the clots early, before permanent damage to the vein occurs," says Garcia. "If we treat these patients within 14 days of their onset of symptoms, we are very successful in clearing the clot. Because the treatment is more rapid, safe and effective, patients are more likely to receive it and prevention of permanent damage is more likely to occur."

About the AngioJet® Rheolytic™ Thrombectomy System

The interventional radiologist uses imaging to guide a catheter and the device into the vein and advances it to the blood clot. The device then sprays a diluted clot-dissolving drug into the clot at high force, helping to break up the clot and deliver the drug to a larger surface area throughout the clot. This enables the drug to remove the clot more quickly and efficiently. A powerful saline jet within the device creates a vacuum that draws the clot into the catheter, thus removing it from the body as the catheter is withdrawn. The interventional radiologist pulls back the device in a spiral motion which allows for greater removal of clot.

About the Study

102 patients (sixty-two percent male and thirty-eight percent female) with a mean age of 47 were treated for 118 cases of large volume DVT. Fifty-one percent of the patients treated had complete clot removal as well as restoration of blood flow. Thirty-one percent of the patients had a substantial amount (fifty-nine percent) of the clot removed with blood flow restored. Eleven percent had partial and four percent had minimal clot removal. Forty-three percent of patients were completed at the initial setting and did not need further infusion of medicine to dissolve clot. Follow-up ultrasound exams at six months showed 78 percent veins to be open with no DVT and eighty-three percent open at 12 months with no DVT. The quality of life survey, up to one year, showed that since treatment, sixty-eight percent had no pain, sixty-seven percent had no more swelling and seventy-eight percent no longer had heat or burning discomfort. Abstract 52 can be found at www.SIRmeeting.org.

"Being able to restore blood flow once the clot is removed is imperative to ensuring the long-term success of this treatment. As long as the vein is open and blood freely flows, there is less likelihood the patient will develop another clot," added Garcia.

About DVT

Deep vein thrombosis occurs in the deep veins that lie near the center of the leg. These veins are surrounded by powerful muscles that contract and force deoxygenated blood back to the lungs and heart. One-way valves prevent the back-flow, or reversal of blood flow, between the muscle and heart 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 dissolve the existing clot.

About the Society of Interventional Radiology

Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-rays, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease nonsurgically. As the inventors of peripheral angioplasty and the catheter-delivered stent, interventional radiologists pioneered minimally invasive modern medicine, and provide treatments that offer less risk, less pain and less recovery time compared to open surgery. More information can be found at www.SIRweb.org.

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