

CONTACT

Maryann Verrillo, (703) 460-5572
Diane Shnitzler, (703) 460-5582
March 11–12, Lisa Tadge, (212) 453-2137
March 11–12, Don Murphy, (212) 453-2462
March 11–12, Neil Hochman, (212) 453-2067
March 13–18, Tampa Press Room, (813) 276-6905,
(813) 276-6906 or (813) 276-6912
comm@SIRweb.org

EMBARGOED FOR RELEASE UNTIL MONDAY, MARCH 15, 2010, 9 A.M. (Eastern)

Emerging Interventional Radiology Treatment With Drug-eluting Stents Saves Limbs

New Technology Offers Set of Peripheral Arterial Disease (PAD) Patients With Critical Limb Ischemia Excellent Way to Avoid Amputation; Results Rival Bypass Surgery and Are Superior to Balloon Angioplasty Alone

TAMPA, Fla. (March 15, 2010)—In the United States, more than 100,000 amputations are performed each year on individuals with critical limb ischemia, the most severe form of peripheral arterial disease (PAD). The number one priority in treating these patients is to re-establish blood flow to avoid limb amputation. Interventional radiologists have found that a subgroup of patients with critical limb ischemia may avoid amputation through the use of drug-eluting stents on the smaller arteries below the knee, according to a study released at the Society of Interventional Radiology's Annual Scientific Meeting in Tampa, Fla.

"Drug-eluting stents are an emerging technology that offers hope to PAD patients with critical limb ischemia and freedom from major amputations. The placement of drug-eluting stents in the infrapopliteal leg arteries is safe and effective and can significantly impact their care. Our results rival bypass surgery and are better than balloon angioplasty alone," said Robert A. Lookstein, M.D., an interventional radiologist and associate director of the division of interventional radiology at Mount Sinai Medical Center in New York, N.Y. Primary patency (length of time the blood vessels stayed open and moved blood flow efficiently) for the 53-patient study at 12 months was 81.8 percent (45/55), said Lookstein, who is also an associate professor of radiology and surgery at Mount Sinai School of Medicine. Freedom from major amputation at follow-up was 90.6 percent (48/53) for the entire group and 100 percent (44/44) for patients with Rutherford category 4 (ischemic pain at rest) and 5 (lower-extremity ischemia associated with minor tissue loss) disease. The Rutherford categories are a severity classification scale for PAD that can be used to evaluate clinical improvement. Patients were followed for an average of 17 months.

About 10 million people in the United States are affected by PAD, but only about one in four is diagnosed and receives treatment. PAD is caused by plaque buildup that hardens inside the arteries to block and reduce blood flow to the legs, arms, brain and other organs. Critical limb ischemia is the most serious stage of PAD. If a person has critical limb ischemia, it means he or she is at great risk of tissue death due to lack of blood flow, which carries oxygen and nutrients to the cells. The restricted blood flow results in severe pain in the feet or toes, even while resting, and sores and wounds that will not heal. Tissue death (gangrene) and amputation are imminent at this advanced stage of PAD. Besides increasing the risk for an amputation, critical limb ischemia also greatly increases the likelihood for heart attack and stroke.

Surgical bypass remains the mainstream therapy for tiny blocked infrapopliteal arteries, but there are a growing number of patients who are unable to undergo this treatment because of their medical problems, said Lookstein. Attempts to treat critical limb ischemia in PAD patients with below-the-knee angioplasty are hindered by high rates of restenosis, the need for repeat treatments and the continued progression of atherosclerotic disease. Drug-eluting stents are a potential solution to the limitations of endovascular treatment. An interventional radiologist performs a balloon angioplasty to open a narrowed blood vessel and then places a drug-eluting stent in that artery. The stent acts as scaffolding to hold the narrowed artery open. Drug-eluting stents slowly release a drug for several weeks to block cell proliferation and regrowth, thus inhibiting restenosis.

Over a four-year period, Lookstein's group at Mount Sinai Medical Center in New York studied 53 patients (32 men, 21 women) ranging in age from 43 to 93 who underwent implantation of 94 drug-eluting stents (80 sirolimus, 12 evirolimus, 2 paclitaxel) to treat a suboptimal angioplasty result in an infrapopliteal artery. All patients had symptoms of critical limb ischemia with Rutherford grade 4 (15), 5 (29) or 6 (9) disease at presentation prior to treatment. Initial technical success rate was 100 percent with all treated lesions having less than 10 percent residual angiographic stenosis at completion of the procedure. The

mean number of stents placed per patient was 1.62 (range, 1–5), with the stent diameter ranging from 2.5 to 4 millimeters. Angiographic, clinical and noninvasive vascular examination results were collected prospectively at regular intervals. Primary endpoints, including technical success of the revascularization procedure, primary patency, freedom from major amputation and survival at follow-up, rival those of conventional bypass surgery.

“Our study reinforces the fact that when it comes to treating cardiovascular disease, there is a wide range of safe and effective treatments,” said Lookstein. Multicenter randomized trials are necessary to support such promising results of the value of infrapopliteal drug-eluting stents in critical limb ischemia treatments, he added. In the United States, drug-eluting stents are FDA-approved for the coronary arteries but not for infrapopliteal arteries.

More information about the Society of Interventional Radiology, interventional radiologists and peripheral arterial disease (PAD) can be found online at www.SIRweb.org.

Abstract 208: “Single Center Experience With Drug-eluting Stents for Infrapopliteal Occlusive Disease in Patients With Critical Limb Ischemia,” A.M. Fischman, S.S. Shah, E. Kim, P. Stangl, F. Nowakowski, J.L. Weintraub, R. Lookstein, all at Mount Sinai Medical Center, New York, N.Y., SIR 35th Annual Scientific Meeting March 13–18, 2010, Tampa, Fla. This abstract can be found at www.SIRmeeting.org.

###

About the Society of Interventional Radiology

Interventional radiologists are 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-ray, MRI and other imaging to advance a catheter in the body, such as in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine. Today, interventional oncology is a growing specialty area of interventional radiology. Interventional radiologists can deliver treatments for cancer directly to the tumor without significant side effects or damage to nearby normal tissue.

Many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. Visit www.SIRweb.org.

The Society of Interventional Radiology is holding its 35th Annual Scientific Meeting March 13–18 in Tampa, Fla. The theme of the meeting is “IR Innovation,” celebrating the remarkable inventiveness of SIR members and highlighting the contribution made to both creating the field of interventional radiology and to improving patient care.

Local interviews and high-resolution peripheral arterial disease images are available by contacting SIR’s communications department via e-mail at mverrillo@SIRweb.org or by phone at (703) 460-5572.