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New Study Shows Subintimal Angioplasty and Selective Stenting Restores Blood Flow and Prevents Amputation in Severe Peripheral Arterial Disease

Interventional Radiology Technique Effective in Treating Very Long Lesions in Small Vessels of the Legs and Feet

NEW ORLEANS, Louisiana (April 2, 2005) – This study, presented today at the 30th Annual Scientific Meeting of the Society of Interventional Radiology, shows that treating long segments of the blocked artery with subintimal angioplasty, followed by stenting as needed, is highly successful in restoring blood flow nonsurgically and preventing amputation. Subintimal angioplasty differs from the usual intraluminal angioplasty because subintimal angioplasty is performed in the wall of the artery to create a new nondiseased channel underneath the diseased lumen area, whereas traditional angioplasty opens the narrowed lumen. The study examines treating long segments of small vessels in the legs and feet (the superficial femoral arteries and tibial arteries) in patients with chronic critical limb ischemia. These patients had such restricted blood flow to their feet from peripheral arterial disease, that most were not candidates for arterial bypass surgery, the treatment frequently offered to patients with chronic critical limb ischemia, and were facing amputation of their foot and leg.

Peripheral arterial disease, or clogged arteries from fatty plaque buildup, can be a very serious condition that causes decreased blood flow to the legs, which can result in pain when walking, and eventually gangrene and amputation. These patients already had tissue loss or rest pain (pain even when not walking) from the lack of blood, known as chronic critical limb ischemia.

"This study shows that we can treat very severe peripheral arterial disease in the smallest vessels, even those with long lesions, with subintimal angioplasty and stenting, potentially saving these patients from amputation. This finding is significant because patients with severe critical limb ischemia typically have poor wound healing and increased risk of infection following bypass surgery in the leg. Subintimal angioplasty can offer a less invasive treatment in both patients who are candidates for bypass surgery and in those who may not be," says lead author David Spinosa, MD, interventional radiologist, Fairfax Radiology.

The superficial femoral arteries, and the even smaller tibial arteries in the feet, are difficult to treat and more likely to reclog than larger vessels. The longer the length of

the segment clogged with plaque, the more difficult it is to treat and to keep open. "The results of this study are particularly exciting because these patients are clinically difficult to treat with angioplasty or surgery, and many go on to amputation. Knowing that we can offer potentially successful treatment for these long lesions in patients who typically have few options other than amputation is important," explained Spinosa.

About the Study (Abstract 86)

The study involved 79 patients with chronic critical limb ischemia; 77% had tissue loss and 23% had rest pain alone. Reestablishing straight line blood flow to the foot was accomplished in 100 percent of the patients. The patients were divided into two groups, both of which had the superficial femoral artery/popliteal segments treated. Group one, who had lesions <200 mm long, received subintimal angioplasty with stenting as needed. Group two had lesions longer than 200 mm, and all received subintimal angioplasty and stenting, to determine if routine stenting was beneficial. The six-month limb salvage rates in group one were 86 percent, and 90 percent for group two. Stenting the longer segments over 200 mm did not appear to improve limb salvage compared to stenting as needed after subintimal angioplasty, and long segment treatment was highly successful.

About Subintimal Angioplasty and Stenting

Using imaging for guidance, the interventional radiologist threads a catheter through the femoral artery in the groin, to the blocked artery in the legs. He then intentionally passes through the layers in the blocked artery wall (the subintimal space) and then back into the lumen (the interior channel of the blood vessel through which blood flows) of the artery. Then he inflates a balloon to open a channel in the wall of the blood vessel where it is narrowed or blocked. In some cases, this is then held open with a stent, a tiny metal cylinder. This is a minimally invasive treatment that does not require surgery, just a nick in the skin the size of a pencil tip. Subintimal angioplasty differs from the usual intraluminal angioplasty because subintimal angioplasty is performed in the wall of the artery rather than in the lumen (center opening) of the artery like traditional angioplasty.

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