New Alternative To Amputation

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.

“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.

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, said Lookstein. Freedom from major amputation at follow-up was 90.6 percent for the entire group and 100 percent 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.

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. 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 re-growth, thus inhibiting restenosis.

Over a four-year period, Lookstein's group studied patient who underwent implantation of drug-eluting stents to treat a suboptimal angioplasty result in an infrapopliteal artery. All patients had symptoms of critical limb ischemia with Rutherford grade 4, 5 or 6 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, 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.

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