Promising 3-year data: Saving limbs with drug-eluting stents

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Attempts to treat critical limb ischemia in peripheral arterial disease (PAD) patients with below-the-knee angioplasty are still thwarted by restenosis (the re-narrowing of the artery at the site of angioplasty or stenting), the need for repeat treatments and the continued progression of atherosclerotic disease, leading to tissue death (gangrene) and amputation. Interventional radiologists have been studying a potential solution—the use of drug-eluting stents—and have found that these types of stents lessened the rate of repeat procedures to open these small arteries, according to results presented at the Society of Interventional Radiology's 34th Annual Scientific Meeting.

"This is encouraging news for PAD patients with critical limb ischemia. The smaller blood vessels below the knee are more difficult to treat due to their size (3 millimeters) and are more prone to reclog than larger vessels. The use of drug-eluting stents in the tiny infrapopliteal arteries of the leg may significantly impact their care," said Dimitris Karnabatidis, M.D., assistant professor of interventional radiology at Patras University Hospital in Rion, Greece. "Drug-eluting (or drug-coated) stents have emerged as a potential solution to the limitations of endovascular treatment of PAD patients with critical limb ischemia," he added. An interventional radiologist performs a balloon angioplasty to open a clogged 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 or regrowth, thus inhibiting restenosis.

Researchers from a single center studied 103 patients in a double-arm prospective registry who had critical limb ischemia and who underwent infrapopliteal revascularization with angioplasty and placement of either a drug-eluting stent (with sirolimus, an immunosuppressant drug) or a bare-metal stent (without a drug coating). The patients had regular follow-ups up to three years, and researchers studied how they did by stent type. In the first group, 41 patients (75.6 percent diabetics) were treated with bare-metal stents, and in the second group 62 patients (87.1 percent diabetics) were treated with drug-eluting stents.

At three years, those patients with drug-eluting stents had "significantly higher patency" (length of time the blood vessels stayed open and moved blood flow efficiently); reduced restenosis of the vessels; and consequently less clinical recurrence requiring repeat angioplasty, said Karnabatidis. "In the drug-eluting stent group, an estimated 60 percent of the treated arteries remained open at three years. This is significantly longer than the bare-metal stent group, where the arteries remained open only approximately 10 percent at 3 years," said Karnabatidis. "This corresponds to a more than 5 times increased risk of vessel reclogging when bare metal stents were used," he added. "Because of the reduced vessel restenosis, repeat angioplasties were necessary in only 15 percent of the patients in the drug-eluting stent group versus almost 35 percent in the bare-metal stent group up to 3 years—this being the equivalent to an almost 2.5-fold risk of repeat procedures in the case of bare metal stents," noted Karnabatidis. "These statistical results are based on three-year adjusted survival analysis after application of a Cox model for multivariable analysis," he explained.

If a person has critical limb ischemia, it means he or she is at great risk for tissue death due to lack of blood flow, which carries oxygen and nutrients to the cells. The severely 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, which is caused by atherosclerosis, the hardening and narrowing of the arteries over time due to the buildup of fatty deposits called plaque.

"Multicenter randomized trials are necessary to support these promising results and build on the level of clinical evidence supporting the integral value of infrapopliteal drug-eluting stents in critical limb ischemia treatment," he added. In the United States, drug-eluting stents are FDA-approved for the coronary arteries but not for infrapopliteal arteries. In Europe, drug-eluting stents have CE Mark approval for below-the-knee use.

Source: Society of Interventional Radiology