New Angioplasty Procedure Improves Blood Flow in Blocked Arteries to Extremities

XCELL trial confirms nitinol stenting aids in wound healing, pain relief, and amputation-free survival

Patients with blocked arteries to their extremities, known as peripheral artery disease (PAD) or critical limb ischemia (CLI), may now find relief from lower leg pain and wounds caused by impaired leg artery circulation with the previously unproven therapy, percutaneous transluminal angioplasty (PTA). The XCELL trial results now available in Catheterization and Cardiovascular Interventions, a journal published by Wiley on behalf of the Society for Cardiovascular Angiography and Interventions (SCAI), reports that infrapopliteal nitinol stenting to treat CLI is safe and effective in improving wound healing, providing pain relief, and promoting amputation-free survival.

PAD is a disorder in which narrowed blood vessels restrict blood flow in the limbs. CLI affects close to 30 million people in Europe and North America, with most experiencing pain and ulcers with or without gangrene in the legs. Experts agree that current treatment options should aim to relieve pain, heal ulcers, prevent limb loss, improve quality of life and prolong survival. Previous research, however, show amputation rates are as high 40% in CLI patients in the first year following their diagnosis, with mortality rates approaching 20%. Moreover, prior studies estimate that 160,000 amputations due to PAD are performed each year in the U.S., of which a 25% reduction could save $29 billion in health care costs according to the Sage Group.

"With the obesity epidemic, we expect the incidence of diabetes to rise as well, and as these patients age this could sharply increase rates of CLI," explains Dr. Krishna J. Rocha-Singh, MD, FSCAI with Prairie Education & Research Cooperative in Springfield, Ill. "It is essential that we identify less invasive treatment strategies that are safe and effective in improving vascular disease."

One promising procedure for improving CLI outcomes is PTA with stenting of the infrapopliteal arteries. The multi-center trial of the "XpertTM Nitinol Stenting For Critically IschEmic Lower Limbs" (XCELL) evaluates the safety and effectiveness of this device in patients with CLI. The Xpert stent is manufactured by Abbott, a global health care company. The device was evaluated in 120 CLI patients with infrapopliteal lesions of 4-15 cm in length. A total of 140 limbs and 212 implanted devices were included in the study, with 12-month amputation-free survival (AFS), limb salvage, wound healing and pain relief determining the success of the procedure.

Results reveal that 12-month AFS was 78%. Further analysis confirmed that according to baseline Rutherford classes 4, 5, and 6, the 12-month AFS rates were

100%, 77%, 55%, respectively; freedom from major amputation were 100%, 91% and 70%, respectively. The investigators also determined that the 12-month freedom from major amputation rate and clinically driven target lesion revascularization were 90% and 70%, respectively. Six-month and 12-month wound-healing rates were 49% and 54%, respectively. Moreover, Rutherford class 4 patients had significant pain relief through 12 months.

"Our XCELL trial findings confirm that infrapopliteal nitinol stenting is safe and effective in treating CLI patients," concludes Dr. Rocha-Singh. "While there were a few major adverse events, such as death, heart attack, or major amputation that occurred in the first 30 days, at the first year post-procedure, limb preservation, wound healing and pain relief rates were excellent." The authors also point out that the 12-month wound healing with nitinol stenting was similar to the more invasive open surgery.

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