Results of the COBRA trial reported at TCT 2011

November 11 2011

A clinical trial of patients with diabetes has demonstrated that cryoplasty post-dilitation compared to conventional balloon angioplasty in the superficial femoral artery (SFA) decreased the risk of in-stent restenosis (ISR). Results from the COBRA clinical trial were presented today at the 23rd Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation (CRF).

Diabetes is associated with increased risk of in-stent restenosis after superficial femoral artery (SFA) stenting with nitinol self-expanding stents (nSES). The objective of the COBRA trial (Cryoplasty Or Conventional Balloon Post-dilation of Nitinol Stents For Revascularization of Peripheral Arterial Segments) was to determine whether cryoplasty post-dilation, when compared to conventional balloon angioplasty, decreases the risk of SFA nSES in-stent restenosis.

Researchers used a cryoplasty dilatation system that simultaneously dilates and cools the vessel wall. Cooling to -10oC was achieved by inflating the balloon with nitrous oxide instead of saline and contrast. The system induces smooth muscle cell (SMC) apoptosis, minimizes SMC necrosis (-5 to -15oC) and reduces ISR.

In this prospective, multi-center, randomized clinical trial, 121 patients with diabetes mellitus were enrolled between August 2008 and December 2010 in four clinical sites within the United States. Inclusion criteria included insulin or non-insulin dependent diabetic patients,

severe lifestyle limiting claudication (Rutherford category ≥3), chronic critical limb ischemia with rest pain (RB stage 4) or ischemic ulcers (RB stage 5), and SFA lesions requiring nSES ≥5 mm in diameter and ≥60mm in length.

Seventy-four patients with 90 SFA lesions were randomized to cryoplasty (n=45 lesions) or conventional balloon angioplasty (CBA) (n=45 lesions). Mean age was 64±11.4 years, and 88% were men. Mean hemoglobin A1C was 7.4±1.6 g/dL. The baseline ankle-brachial index (ABI) was 0.59±0.21 and 0.62±0.19 in the cryoplasty and CBA groups, respectively.

The primary endpoint was 12 month SFA nSES binary in-segment restenosis, defined as a ≥2.5 times increase in peak systolic velocity by duplex ultrasound. The rate of occurrence was 55.8% for the conventional balloon group and 29.3% for the cryoplasty group.

"In patients with diabetes mellitus presenting with life-style limiting claudication, post-dilation of nitinol self-expanding stents in the superficial femoral artery using cryoplasty significantly reduced 12-month in-stent restenosis compared to conventional balloon post-dilation," said Subhash Banerjee MD. Dr. Banerjee is Chief of Division of Cardiology at VA North Texas Health Care and Associate Professor of Medicine at The University of Texas Southwestern Medical Center in Dallas, Texas.

"These results indicate the potential impact of stent post-dilation strategies on endovascular treatment of symptomatic peripheral arterial disease," Dr. Banerjee said.

Provided by Cardiovascular Research Foundation