**CRYOPLASTY OR CONVENTIONAL BALLOON POST-DILATION OF NITINOL STENTS FOR REVASCULARIZATION OF PERIPHERAL ARTERIAL SEGMENTS (COBRA TRIAL)**

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Background: In patients with diabetes mellitus endovascular treatment of superficial femoral artery (SFA) disease with nitinol self-expanding stent implants (nSES) is associated with high rates of in-stent restenosis (ISR).

Methods: We conducted a prospective multi-center randomized clinical trial of diabetic patients to investigate whether post-dilation of SFA nSES implants using cryoplasty (PolarCath®, Boston Scientific, Natick, MA) reduces ISR compared to conventional balloon angioplasty (CBA). Inclusion criteria included diabetes mellitus, lifestyle limiting claudication (Rutherford category ≥3), and SFA lesions requiring nSES >5 mm in diameter and >60mm in length. 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 ultrasonography.

Results: Seventy four patients with 90 SFA lesions were randomized to cryoplasty

(n=45 lesions) or 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±0.2 and 0.62±0.2 in the cryoplasty and CBA groups, respectively. Mean SFA lesion length was 148±98 mm; mean stented length was 190±116 mm; mean stent diameter was 6.1±0.4 mm and 50% of the lesions were total occlusions. The post-dilation balloon diameters were 5.2±0.51 vs. 6.8±9.8 mm and lengths 84±29 vs. 86±44 mm respectively, in the cryoplasty and CBA groups. At 12 months, binary restenosis was lower in the cryoplasty group (29.3% vs. 53.5%, p=0.03, odds ratio=0.36, 95% confidence intervals 0.15-0.89).

Conclusions: In diabetic patients, compared to CBA, post-dilation of nSES in the SFA using PolarCath® cryoplasty significantly reduced 12-month in-stent restenosis.