Update on Indications and Results with Cryoplasty Based on Real World Results

NOTES

Zvonimir Krajcer, MD, FACC, Houston, TX; Neil Strickman; Ali Mortazavi; Arup Achari; Kathy Dougherty

Background
Although endovascular techniques have gained widespread acceptance in the management of peripheral vascular disease, troubling issues such as arterial dissection, stent strut fracture and restenosis have generated a need for advancing technologies to treat complex, long, and occlusive and restenotic vascular disease. Cryoplasty has been developed to optimize interventional outcomes by simultaneously dilating and treating a diseased vessel by cooling it to a precise temperature. The PolarCath Peripheral Dilation System (CryoVascular Systems, Inc.) uses nitrous oxide to inflate and cool the angioplasty balloon to -10°C.

Objective
The purpose of this study is to assess the results of Cryoplasty and its impact on the treatment of complex peripheral vascular disease and restenosis.

Methods
A total of 70 patients (98 lesions) underwent Cryoplasty for the treatment of complex arterial lesions. Of those, 22 presented with restenosis after a previous stent implantation, seven had anastomotic lesions in their femoral-popliteal bypass, 40 had stenosis in the popliteal and tibial-peroneal trunk with limb-threatening ischemia, and the others had diffuse stenoses or total occlusion in the femoral artery.

Results
Procedural success was 100% with a reduction in stenosis to < 20% in all but one patient who required stent implantation for a suboptimal result. Ankle-brachial indices (ABI) improved significantly in all patients (Table 1). On follow-up (7 ± 3 months) 6 patients (8.6%) developed restenosis at the site of Cryoplasty.

Conclusions
Cryoplasty is a safe and effective therapy for the primary treatment of peripheral vascular disease as well as recurrent and in-stent restenosis. Further long-term results are needed.

Table 1. Study Results

Lesion Location	Pre-ABI	Post-ABI	p Value
Femoral	0.51 ± 0.10	0.82 ± 0.5	< .001
Popliteal	0.48 ± 0.31	0.78 ± 0.07	.008
Femoral-popliteal bypass	0.64 ± 0.02	0.82 ±.10	.02
Tibio-peroneal	0.3 ± 0.2	0.7 ± 0.2	< .001

ABI = ankle-brachial indices.