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MYOCARDIAL ISCHEMIA AND INFARCTION

LONG-TERM FOLLOW-UP TO EVALUATE THE SAFETY OF THE NEOVASC REDUCER A DEVICE-BASED THERAPY FOR CHRONIC REFRACTORY ANGINA

ACC Oral Contributions
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Session Title: Factors Associated with Outcome in Acute and Chronic Ischemia
Abstract Category: Stable Ischemic Syndrome
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Background: The Neovasc Reducer is a device designed to modulate flow and to elevate pressure in the coronary sinus (CS) by establishing a narrowing. Increased CS pressure can reduce myocardial ischemia by redistribution of blood from non ischemic to ischemic myocardium. In preclinical and clinical experiments, implantation of the Reducer was proven to be safe and was associated with improved ischemic parameters. The 6 months follow up results were previously reported. Here we present the 3 years follow up **Results:**

Methods: 14 patients with severe angina and reversible myocardial ischemia, who were not candidates for revascularization, were electively treated with percutaneous trans-venous implantation of the CS Reducer. Clinical evaluation was performed before, and 6 months and 3 years after implantation.

Results: No death or MI and no device or procedure-related adverse events occurred during the follow-up periods. CT angiography (n=11) after 3 years showed that all Reducers were patent and well located in the CS. Angina score (CCS class) and objective ischemia parameters improved 6 months after Reducer implantation and the improvement was maintained at 3 years:

	Baseline	6 months	3 years	P value
CCS class	3.07±0.11	1.73±0.22	1.57±0.23	0.006
Dobutamine Echo ischemia severity	1.33±0.28	0.55±0.25	0.45±0.16	0.02
Thallium SPECT ischemia severity	1.93±0.06	1.47±0.13	0.82±0.26	0.03
Maximal ST segment depression	1.67±0.33	0.78±0.22	0.67±0.33	0.03

Conclusions: The safety and performance of the Neovasc Reducer is maintained 3 years after implantation. There were no deaths MI or adverse events. Reducers were patent and located at the exact site of deployment. The improvement in angina and ischemia severity observed 6 months after implantation of the Reducer was maintained for 3 years.