

The Coronary Sinus Reducer Stent for the Treatment of Chronic Refractory Angina Pectoris

El stent reductor del seno coronario para el tratamiento de la angina de pecho refractaria crónica

To the Editor,

We were very interested to read the article dealing with therapeutic options in patients with chronic refractory angina pectoris (RAP) signed by Cohen et al.¹ The authors presented an excellent review of the therapeutic options for such "no-option" patients suffering from chronic RAP caused by severe symptomatic and chronic coronary artery disease.

May we quote Dr. Cohen and colleagues: "Refractory angina is a major clinical challenge in contemporary cardiovascular medicine. . . Management strategies aimed at improving quality of life are fundamental in the management of these patients and may also be associated with a survival benefit." Dr. Cohen and colleagues are right, since chronic refractory angina pectoris has high social impact, making this a socio-medical issue that cannot be left without appropriate solution.

Dr. Cohen and colleagues discussed five invasive anti-anginal therapies for chronic RAP: spinal cord stimulation, percutaneous myocardial laser revascularization, transmyocardial laser revascularization, autologous CD34+ stem cells, and intramyocardial bone marrow stem cells injection; however, a very important, evolving innovation is missing: coronary sinus intervention.

We would ask for the opportunity to provide the readers with supplemental information about the Neovasc coronary sinus reducer stent (CSRS) for the treatment of chronic RAP. Coronary sinus intervention for the treatment of ischemic heart disease is an evolving innovation for patients with chronic angina who are not candidates for coronary artery revascularization. In the mid-1990 s we developed the upside-down strategy to support ischemic myocardium. This means: (1) catheterization of the coronary venous system instead of catheterization of the coronary arteries and (2) reduction of the effective cross area in the coronary sinus instead of expanding a narrowed coronary artery. Our initial studies in pig models proved that either acute permanent occlusion or constriction of the coronary sinus causes epicardial and intramyocardial neovascularization. This observation could be seen even at the macroscopic level. After a few years of development we came out with the first percutaneous intravenous CSRS and gave it the name "Neovasc", later known as Neovasc Medical, Inc.

The CSRS is a balloon-expandable stent, implanted by percutaneous transvenous approach through the right internal jugular vein or any other large peripheral vein. It has a unique shape that reduces the coronary sinus diameter to 3 mm; therefore, instead of increasing the coronary circulation input it reduces its output.

The first human study began in 2004.² This was a prospective, open-label, safety feasibility study. The CSRS was implanted in

15 patients with angina pectoris refractory to medical treatment. All patients underwent uneventful implantations without procedure-related complications. All patients were discharged from hospital 1-2 days afterward. No major adverse cardiac events were reported during follow-up period of 6 months. Six months after implantation, most of the patients had improved Canadian Cardiovascular Society (CCS) scores compared with baseline (3.07 versus 1.64; $P < .0001$). Improvements were also seen for stress-induced ST-segment depression and for the extent and severity of myocardial ischemia as shown by either dobutamine echocardiography or thallium single-photon emission computed tomography.

The 3-year follow-up ended with no deaths, no MI, no device-related adverse events, and persistence of the clinical improvements at 6 months follow-up, as measured by CCS.³ Eleven patients underwent computed tomography angiography after 3 years; all CSRS were patent and well located in the coronary sinus.

Further evaluation of coronary sinus interventions with the Neovasc reducer stent must be done, but initial findings suggest it may be a safe, feasible, comfortable, and effective option for many patients suffering from coronary artery disease. The Coronary Sinus Reducer for Treatment of Refractory Angina (COSIRA) study is a recent clinical multicenter study that will again assess CSRS efficacy.⁴ Patient enrollment began this past September. We hope that CSRS will be proved as an optional treatment to improve quality of life and survival for patients who suffer from chronic refractory angina pectoris.

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