

# Coronary sinus intervention for the treatment of refractory angina pectoris

Yoav Paz<sup>1,3</sup>  
Amihay Shinfeld<sup>2,3</sup>

<sup>1</sup>General Intensive Care Unit, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel; <sup>2</sup>Department of Cardiac Surgery, Chaim Sheba Medical Center, Tel Hashomer, Tel Aviv, Israel; <sup>3</sup>Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

We read with great interest the article “Recent advances in the management of chronic stable angina II. Anti-ischemic therapy, options for refractory angina, risk factor reduction, and revascularization” by Dr Richard Kones.<sup>1</sup>

Dr Kones presents an excellent review in which he describes some invasive anti-anginal therapies for the treatment of those ill-fated patients who suffer from refractory angina pectoris (RAP), a type of angina pectoris that persists despite optimal medical therapy, in patients who are not candidates for revascularization.

Dr Kones discusses five invasive antianginal therapies for refractory angina: spinal cord stimulation, enhanced external counterpulsation, transmyocardial laser revascularization, stem cell/gene therapy, and percutaneous coronary intervention (PCI), all of which are options for a selected group of patients only. However, one emerging innovation for the treatment of patients suffering from RAP has been overlooked, namely that of coronary sinus intervention.

We would like to add a comment to Dr Kones’ excellent review and present some historical facts and medical information about the Neovasc coronary sinus reducer stent (CSRS) for the treatment of patients with RAP who are not candidates for coronary artery revascularization, either coronary artery bypass grafting or PCI. In the mid 1990s we initiated an unusual, novel approach to support the ischemic myocardium, which we called “the upside-down strategy”. This means we initially catheterized the coronary venous system instead of the coronary arteries, arriving at the coronary sinus, and secondly reduced the coronary sinus effective cross area instead of expanding a narrowed coronary artery. We were very surprised with the results of our initial studies in pig models, since we noticed that permanent constriction of the coronary sinus caused some kind of epicardial and intramyocardial neovascularization/angiogenesis of medium-size blood vessels, compared with untreated pigs. These new or dormant blood vessels could be seen even at the macroscopic level. Following several developmental stages, we produced the first percutaneous intravenous CSRS, which we called “Neovasc”, and which later became known as Neovasc Medical, Inc (Richmond, Canada).

The CSRS is a balloon-expandable stent, implanted by a 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, thereby reducing, rather than increasing, coronary circulation output.

The first human study, a prospective, open-labeled, safety feasibility study, began in 2004.<sup>2</sup> The CSRS was implanted in 15 patients with angina pectoris refractory

Correspondence: Yoav Paz  
General Intensive Care Unit, Tel Aviv Sourasky Medical Center, 6 Weizman St, Tel Aviv 64239, Israel  
Email pazyoav@bezegint.net

to medical treatment. All patients underwent uneventful implantations without procedure-related complications, and were discharged from hospital 1 to 2 days later. No major adverse cardiac events were reported during a follow-up period of 6 months, at which time most of the patients had improved Canadian Cardiovascular Society (CCS) scores compared with baseline (3.07 versus 1.64;  $P < 0.0001$ ). Improvement was also seen for stress-induced ST-segment depression, as well as for the extent and severity of myocardial ischemia, as shown either by dobutamine echocardiography or by thallium single-photon emission CT.

Three years follow-up of the patients has now been completed without mortality, myocardial infarctions, or device-related adverse events, while clinical improvements remain constant, as measured by CCS at 6 months of follow-up.<sup>3</sup> Eleven patients underwent CT angiography after 3 years and all CSRSs were patent and well located in the coronary sinus. These findings suggest that the Neovasc reducer stent 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 trial that will reassess the efficacy of the CSRS.<sup>4</sup> Patient enrollment began in September 2010. On September 27, 2010, the Neovasc CSRS was featured in a “live case” performed in the Antwerp Cardiovascular Institute/ZNA Middelheim in Belgium and broadcast to the main arena

of the Transcatheter Cardiovascular Therapeutics 2010, the 22nd Annual Scientific Symposium sponsored by the Cardiovascular Research Foundation.<sup>5</sup> The Neovasc CSRS was successfully implanted by the COSIRA trial principal investigator into the coronary sinus of a patient suffering from refractory angina pectoris.

We hope that by improving quality of life and survival, implantation of the Neovasc CSRS will prove to be the optimal treatment for those patients who suffer from chronic RAP.

## Disclosure

The authors report no conflicts of interest in this work.

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