## **CORONARY ARTERY DISEASE**

## Interventional narrowing of the coronary sinus in refractory angina

Percutaneous implantation of a balloon-expandable device in the coronary sinus improves symptoms and quality of life in patients with drug-refractory angina who are not candidates for revascularization. This finding comes from the phase II COSIRA trial now published in *The New England Journal of Medicine*.

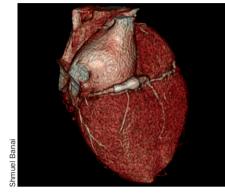
The Reducer device (Neovasc, Canada) is a stainless-steel, hourglass-shaped device that can be percutaneously implanted in the coronary sinus. By artificially narrowing the vessel, pressure is increased upstream in the coronary sinus, which is thought to redistribute blood flow to the coronary collateral vessels that supply ischaemic myocardium.

In the multicentre, double-blind COSIRA trial, sponsored by Neovasc, 104 patients were randomly allocated to receive the Reducer device, or undergo a sham procedure. All participants had Canadian Cardiovascular Society (CCS) class III or IV angina and myocardial ischaemia, and were ineligible for revascularization. The primary end point

was an improvement of two or more CCS angina classes after 6 months of follow-up.

Overall, 35% of the patients who received the Reducer device, compared with 15% of those in the sham group, achieved the primary end point (P = 0.02). A total of 71% and 42% of patients in each group, respectively, improved by at least one CCS angina classification (P = 0.003). Quality of life measured using the Seattle Angina Questionnaire improved by 17.6 points in patients who received the device and by 7.6 points in those who did not (P=0.048). Improvement in mean exercise duration was numerically, but not significantly, higher in patients with the Reducer device than in the sham group (59 s versus 4 s; P = 0.07). Wall-motion index assessed using dobutamine echocardiography did not differ significantly between the two groups.

The results of this small, phase II trial indicate that the implantable Reducer device can improve quality of life and symptoms in patients with refractory angina. In an accompanying editorial, Christopher Granger and Bernard Gersh



welcome this "high-quality trial", but caution that with only 26 patients achieving the primary end point, "this positive outcome is not sufficient for a reliable estimation of modest treatment effects". A large-scale, phase III trial is needed to validate the results.

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