Coronary sinus reducer relieves angina, but how it works remains unclear

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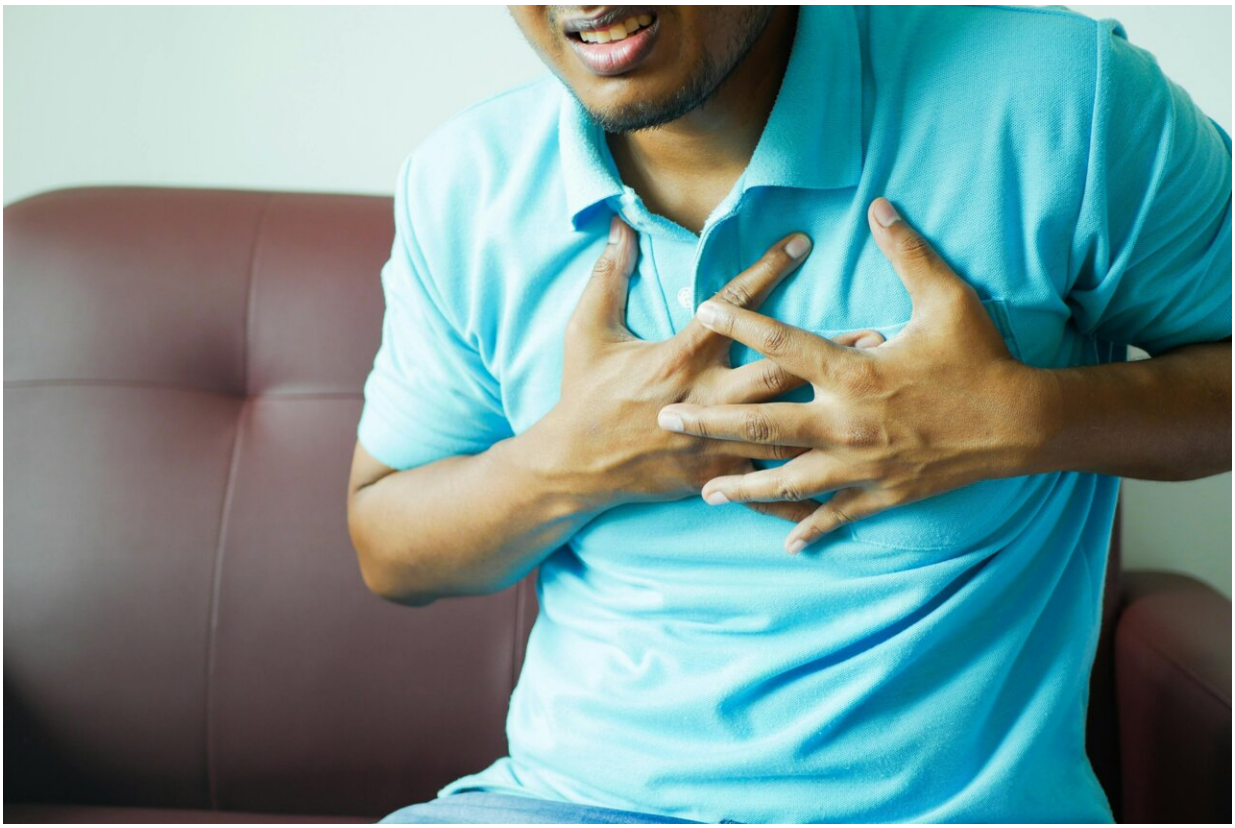

Credit: Towfiqu barbhuiya from Pexels

People with chronic chest pain who received a coronary sinus reducer (CSR)—a stent thought to increase the amount of oxygen-rich blood flowing to the heart muscle—experienced significant reductions in the daily number of chest pain episodes but did not show evidence of increased overall blood flow to the heart compared with patients who received a placebo procedure, according to six-month results from a study presented at the American College of Cardiology's Annual Scientific Session.

The ORBITA-COSMIC study met one of its primary endpoints by showing symptom improvements with the CSR but did not meet the main primary endpoint that was designed to determine the mechanism by which the CSR might work. The findings show no difference between groups in terms of an MRI-based assessment of overall blood flow to the heart tissue.

"We don't have a positive endpoint in terms of the primary hypothesis of how this device works, but it does seem to reduce angina frequency in patients with refractory angina," said Rasha Al-Lamee, MBBS, Ph.D., clinical academic interventional cardiology consultant at Imperial College Healthcare NHS Trust, clinical reader at Imperial College London and the study's senior author. "This is a population of patients who are very symptomatic and have no further options for treatment."

The trial focused on patients with angina, or chest pain due to plaque buildup in the coronary arteries, that is not adequately controlled with available treatments. The CSR is an hourglass-shaped stent designed to narrow the vein that collects blood from the heart muscle (the coronary sinus) and drive oxygen-rich blood back into areas of the heart muscle that may not be receiving enough blood.

ORBITA-COSMIC was designed to build on previous studies, which suggested that the CSR can improve angina symptoms by using more robust placebo-controlled methodology and endpoints assessing the impact of the device on blood flow. The researchers randomized 51 patients at six U.K. hospitals to receive either a CSR implant or a placebo procedure, which involved sedation but no implant.

All participants had symptomatic angina, ischemia and coronary artery disease with no further medical or interventional options at the start of the study. Participants underwent a cardiac MRI and treadmill exercise test before their procedure and at the end of a blinded six-month follow-up period. Patients also recorded their angina symptoms daily with a smartphone application.

The trial had two primary endpoints: angina symptoms as assessed with the smartphone application and blood flow to the heart assessed with a cardiac MRI. At six months, participants who received the CSR implant were 40% more likely to report a reduction in the number of daily angina episodes than those who received the placebo procedure; however, they showed no difference in terms of overall blood flow to the heart.

Results for the trial's secondary endpoints followed a similar pattern. Angina frequency lessened among those who received CSR across several measures, including the Seattle Angina Questionnaire, although no difference was found for other measures such as treadmill exercise time.

Patients who received CSR also saw an improvement in subendocardial to subepicardial ratio of stress myocardial blood flow, which may suggest some redistribution of myocardial blood flow but no difference in terms of other factors assessed with the cardiac MRI.

Most of the patients who received the CSR implant did not experience complete elimination of angina symptoms but did report reductions in the number of daily pain episodes and the number of days on which they experienced pain.

"For a patient, what they want to know is whether the device will help them to feel better. With the results of this placebo-controlled trial, we can tell them that their symptoms are more likely to improve with the reducer," Al-Lamee said. "However, we still need to work out why."

The CSR device was found to be generally safe. Two patients in the CSR group experienced blood clots, but no heart attacks or deaths occurred. The CSR device is already approved for use in Europe and the U.K., so the findings could potentially increase its use there, Al-Lamee said.

The device is not yet approved by the U.S. Food and Drug Administration (FDA) for use in the U.S., although an FDA-approved trial is currently underway.

The researchers plan to conduct further analyses to determine whether particular groups of patients may be more likely to benefit from CSR implantation. They also plan to conduct more detailed analyses to further investigate the mechanism of action involved.

This study was simultaneously published online in *The Lancet* at the time of presentation.

More information: Michael J Foley et al, Coronary sinus reducer for the treatment of refractory angina (ORBITA-COSMIC): a randomised, placebo-controlled trial, *The Lancet* (2024). DOI: 10.1016/S0140-6736(24)00256-3

Michael Foley, MBBS, clinical research fellow at Imperial College London, will present the study, "Coronary Sinus Reducer for the Treatment of Refractory Angina: A Randomised, Placebo-controlled Trial (ORBITA-COSMIC)," on Monday, April 8, 2024.

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