Device drops blood pressure in patients with difficult-to-treat hypertension

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A device designed to treat people with resistant hypertension helped lower blood pressure by 33 points, a substantial drop that would otherwise require patients to take an additional three or four drugs, on top of this subgroup's usual regimen of up to five drugs, to control their difficult-to-treat condition.

The device, called the Rheos System, was tested in a pivotal Phase III study presented today as a late-breaking clinical trial at the American College of Cardiology's Annual Scientific Sessions. It is the first device to be tested in a large-scale clinical trial for the treatment of hypertension and works by activating the body's natural blood flow regulation mechanism to reduce high blood pressure.

Though the therapy led to a considerable drop in blood pressure and had a good safety profile, it did not meet all of the study goals. Another, more focused trial testing the device is needed before the U.S. Food and Drug Administration will consider approving the treatment, according to physicians who led the study.

"The device works extremely well and there is a large group of patients who would benefit from this therapy, but we need to go back and identify this group more clearly," said John Bisognano, M.D., Ph.D., a lead study investigator from the University of Rochester Medical Center. "This outcome is not uncommon. While the initial results are not as crisp as we would expect, it is clear from looking at the data that there are therapeutic benefits to pursue."

The pivotal trial included 265 patients with resistant hypertension treated at 40 medical centers in the United States and two in Europe, and is the latest in a series of studies that have shown the device is beneficial.

People who do not respond to the typical treatment regimen for high blood pressure, which includes one to three medications, coupled with improved nutrition and exercise, have resistant hypertension. These patients are at a far greater risk for stroke, heart attack, heart failure, kidney disease and death, which is why new therapies like Rheos are needed.

"Current drugs and lifestyle modifications can only do so much. I treat a huge number of people who are doing everything right – taking their medications, maintaining a healthy diet, working out – and they still develop resistant hypertension," noted Bisognano, Professor of Medicine and Director of Outpatient Cardiology at the Medical Center.

The prevalence of resistant hypertension is unknown, but current estimates suggest that between 10 and 15 percent of people with high blood pressure are in the truly resistant group. Many people with a family history of high blood pressure have the condition. Older age is also associated with the disorder.

The Rheos System, developed by CVRx Inc. of Minneapolis, regulates blood pressure much like a pacemaker regulates heart rhythm. A battery-powered implantable generator is inserted under the skin near the collarbone and two leads, or wires, run from the generator to the carotid arteries, the two main arteries that supply blood to the head. The device triggers specific receptors on these arteries, known as carotid baroreceptors – key regulators of blood flow in the body.

These receptors then send signals that are interpreted by the brain as a rise in blood pressure. The body responds to this phantom rise in blood

pressure by taking action to lower it, including relaxing the blood vessels and reducing the heart rate.

Rheos was first implanted in the United States in 2005 by physicians at the University of Rochester Medical Center. According to Bisognano, the next trial will include a different selection of patients and use a slightly different implantation technique. He believes the study will likely show that the device, in combination with drug therapy and lifestyle changes, provides major benefit for people with resistant hypertension.

In a separate sub-analysis from the pivotal Phase III study, researchers found that the Rheos device also leads to positive changes in the structure and function of the heart. Years of high blood pressure can damage the heart, resulting in the thickening and enlargement of the heart. Rheos reversed this damage in patients, improving the overall pumping action of the heart – an outcome that doesn't always result from drug therapy.

"The device lowers blood pressure in a way that actually benefits patients beyond changing their numbers – it improves the structure of the heart which in turn improves overall cardiac function," said Bisognano.

Provided by University of Rochester Medical Center

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