

New blood pressure treatment tries fooling brain

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While dozens of medical device makers are racing to treat medication-resistant hypertension by burning nerves inside arteries in the kidneys, Minneapolis firm CVRx is coming at the problem from a different direction.

Its implantable pacemaker-type device stimulates pressure sensors in the carotid arteries - essentially fooling the brain into [lowering blood pressure](#). The system is minimally invasive, adjustable and reversible - and the results from it are dramatic, said CVRx President and CEO Nadim Yared.

"It's a beautiful system because, at the end of the day, we do not decide how to lower [blood pressure](#)," he said. "We let the brain decide."

The device has been approved to treat hypertension in Europe. CVRx is hoping to win U.S. approval. But CVRx also is hoping to show the U.S. Food and Drug Administration that its Barostim Neo device is safe and effective in treating [heart failure](#) as well. Early data are encouraging and clinical trials in Europe, Canada and the United States are continuing or getting underway, he said.

"It works," said Yared, who came to CVRx five years ago from GE Medical.

The human body has a system for sensing changes in blood pressure and other [blood flow](#). While much of this system is located in the brain,

there are also pressure sensors within the walls of the carotid arteries, [blood vessels](#) in the neck that supply blood to the brain. Called baroreceptors, these sensors measure and report blood flow to the brain, which then make adjustments depending on the body's needs.

For example, higher blood pressure is good for exercising, while lower blood pressure is appropriate during sleep or other periods of reduced activity.

In much the same way that holding a match to the thermostat on the wall can make your home's furnace lower the heat, the Barostim Neo stimulates the baroreceptors to get the brain to lower blood pressure, Yared said.

A small device, like a pacemaker, is implanted under the [collar bone](#). A thin wire runs from the device along the [carotid artery](#) with an electrode about the size of the head of a nail. Doctors then use an external system to program and customize therapy settings.

Implanting the device usually takes an hour or two and can be done on an outpatient basis, although some patients stay overnight at the hospital.

Blood pressure is measured in millimeters of mercury (mm Hg) and recorded with the systolic number first, followed by the diastolic number. A normal blood pressure would be recorded as something under 120/80 mm Hg. About 1 in 3 American adults - nearly 70 million - have high blood pressure.

Yared said patients in the Barostim Neo studies have averaged a systolic pressure of 183; the device lowered the pressure of about half those patients to below 140.

Dr. Eric Irwin, a vascular surgeon at North Memorial Medical Center in

Robbinsdale, Minn., has been involved with the CVRx technology for several years and holds stock options in the company.

"It is a big step forward," he said. "This has taken a group of patients who were 100 percent failing to respond to the best medical care and has gotten a 10-20 point drop in pressure. We're talking changes that are really significant."

At a time when med-tech giants Medtronic, St. Jude Medical and Boston Scientific are part of a stampede of firms developing renal denervation systems, Yared and others say CVRx might be on to a better approach. Renal denervation is a one-time treatment for hypertension in which a device burns - or ablates - nerves in the renal artery. That approach is available in Europe, although not yet in the United States.

But, Yared said, renal denervation is imprecise and irreversible. The Barostim Neo can be set at different stimulation settings for different times of the day and can be removed if necessary.

"This is more controllable and adjustable," Irwin said.

Said Yared: "We've had some patients and physicians who prefer the elegance of this approach."

Barostim Neo already is being sold for treating hypertension in Europe. CVRx is expected to earn about \$2 million in 2012, Yared said. It continues to be studied for treating medication-resistant hypertension in the United States, as well as for treating heart failure in the United States, Canada and Europe. Yared said he expects the company to become profitable before FDA approval.

Thomas Gunderson, a senior analyst with Piper Jaffray Co., said its technology gives CVRx a unique place in the market for treating high

blood pressure. In fact, the technology has even been shown to help patients for whom denervation was ineffective.

"When you see a big market opportunity with a clear benefit for the patients and the payers, you are going to have a lot of investment interest," he said of CVRx's potential.

The results of initial studies and earlier clinical trials have been promising enough that CVRx has to date attracted \$209 million in financing and the enthusiastic support of venture capital firms New Enterprise Associates, or NEA, and Johnson & Johnson Development Corp.

Despite the uncertainties of the regulatory climate for medical devices, John Nehra, a special partner with NEA, said the large hypertension market - and CVRx's technology - makes it a good bet.

"We think the technology works," Nehra said. "Because of its programmability and adjustability, it works better than surgical intervention."

Nehra and Yared said the Barostim Neo could be approved for use in the United States in three or so years. In the meantime, Nehra said, a goal is for CVRx to reach \$100 million in revenue in Europe and elsewhere.

"We feel very good about the company and its position," he said. "Although it has taken longer and more capital, the opportunity is still very much in front of us."

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