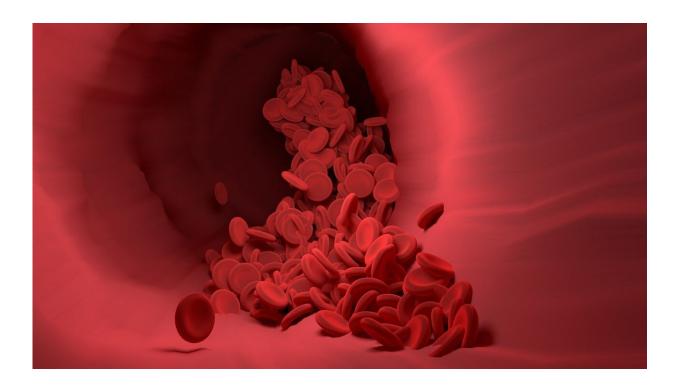


Zapping nerves with ultrasound lowers drugresistant blood pressure

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Brief pulses of ultrasound delivered to nerves near the kidney produced a clinically meaningful drop in blood pressure in people whose hypertension did not respond to a triple cocktail of medications, reports a new study led by researchers at Columbia University Vagelos College of Physicians and Surgeons and NewYork-Presbyterian.



In a clinical trial of the procedure, called renal denervation, daytime blood pressure after two months had dropped 8 points compared to a 3-point drop in patients who were treated with a sham procedure. Nighttime blood pressure decreased by an average of 8.3 points in the treatment group versus 1.8 points in the sham group.

"For patients with drug-resistant hypertension, a drop in blood pressure of 8 points—if maintained over longer-term follow-up—is almost certainly going to help reduce the risk of heart attack, stroke, and other adverse cardiac events," says Ajay Kirtane, MD, professor of medicine at Columbia University Vagelos College of Physicians and Surgeons, an interventional cardiologist at NewYork-Presbyterian/Columbia University Irving Medical Center, and co-principal investigator of the trial.

"These results suggest that renal denervation has potential to become an important add-on to <u>medication therapy</u>—including for those who have difficulty managing several medications to control their hypertension."

Data from the trial, called RADIANCE-HTN TRIO, were presented May 16 at the American College of Cardiology conference and simultaneously published in *The Lancet*.

The treatment is still experimental, has not been approved for use by the FDA, and is only available through clinical trials. The trial will follow patients for five years to determine if the drop in blood pressure is maintained over time.

Need for Additional Blood Pressure-Lowering Therapies

About two-thirds of people who take medications to lower blood



pressure are able to control their condition. But in others, the drugs do not work or people do not take them as directed.

"There are a variety of effective medications for lowering blood pressure, but many people need to take several drugs to control their hypertension, which can have side effects. In addition, many people simply don't want to take additional medications and are poorly adherent to them," says Kirtane. "It's clear that we need additional therapeutic approaches to help patients get their blood pressure under control."

Why Renal Denervation?

The kidney plays a role in blood pressure by controlling how much water is in the bloodstream (more water = more pressure) and acting as a central signaling center for other systems that regulate blood pressure. Renal denervation, a minimally invasive procedure, uses ultrasound energy to disrupt signals from overactive nerves in the renal arteries. The therapy is delivered via a catheter that is threaded through an artery in the leg.

Targeting these nerves is not a new idea in hypertension treatment; several existing medications reduce renal nerve activity to reduce blood pressure.

"But unlike medications, which are only effective when you take them, renal denervation is a therapy that's always 'on,'" Kirtane says.

Initial studies of renal denervation had several flaws—including the lack of an adequate control group, variable measurement of participants' blood pressure, and frequent changes in background medications—that made the results challenging to interpret.



How the Study Worked

In this study, the researchers tested the effectiveness and safety of a device that delivers two to three short blasts of ultrasound to nerve fibers that travel close to the renal artery.

The study included adults with moderate to severe hypertension despite taking three or more antihypertensive drugs. All of the patients were switched to the same medication regimen for their hypertension. (To help with patient adherence, participants took a single pill that combined three commonly used antihypertensive drugs.)

"In our study, 80% of patients continued to take their medication as directed, and while that's a good adherence rate, it still means that one in five patients weren't adherent to the <u>medication</u> regimen," Kirtane adds.

Of 136 patients whose <u>blood</u> pressure remained high after four weeks on the new regimen, 69 were treated with renal <u>denervation</u> and 67 had the sham procedure.

Previous studies in patients with less severe hypertension who were not taking any antihypertensive medications showed that <u>renal denervation</u> was more effective than a sham procedure in lowering <u>blood pressure</u>.

"Additional studies will be needed to determine if this therapy may be effective for other groups, including older patients with hypertension and those with chronic kidney disease," says Kirtane.

More information: Michel Azizi et al, Ultrasound renal denervation for hypertension resistant to a triple medication pill (RADIANCE-HTN TRIO): a randomised, multicentre, single-blind, sham-controlled trial, *The Lancet* (2021). DOI: 10.1016/S0140-6736(21)00788-1



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