

Interventional radiology treatment takes blood pressure to new lows -- and results last

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CHICAGO, Ill. (March 28, 2011)—Interventional radiologists have completed the first human randomized controlled trial of therapeutic renal denervation or RDN—a procedure that uses a catheter-based probe inserted into the renal artery that emits high-frequency energy to deactivate the nerves near the kidneys (or in the renal artery) that are linked to high blood pressure. The researchers say these results confirm that RDN may be an effective therapy for reducing—and consistently controlling—resistant hypertension when current medications have failed. The results were presented at the Society of Interventional Radiology's 36th Annual Scientific Meeting in Chicago, Ill.

"Renal denervation, a minimally invasive, effective treatment, appears to be safe in the short term with a low incidence of local complications. Its efficacy to lower blood pressure in patients with resistant high blood pressure will be better evaluated with the results of a subsequent trial," said Marc R. Sapoval, M.D., Ph.D., professor of clinical radiology and chair of the cardiovascular radiology department at Hôpital Européen Georges-Pompidou in Paris, France. "After six months, 39 percent of patients receiving the endovascular denervation treatment had reached the recommended blood pressure level and, overall, 50 percent of patients showed a measurable benefit of the intervention," he added.

"It is estimated that one in every four American adults has high blood pressure. High blood pressure increases the risk of heart and/or kidney disease and stroke because it makes the heart work too hard," Sapoval explained. "The renal sympathetic system, which are the small nerves that carry the signal from the brain to the kidney and back from the kidney to the brain, plays an important role in the regulation of blood pressure levels. The disruption of these nerve fibers has a positive effect on blood pressure levels," he continued.

"Given its impact on the central sympathetic drive, endovascular renal denervation may have applicability in additional disease states such as heart failure, cardio-renal syndrome, hepato-renal syndrome, and in the prevention of progression of chronic kidney disease and hypertension in end-stage renal disease—with the added benefit of helping to raise public awareness on the dramatic burden of this disease," said Sapoval.

This study targeted only patients with resistant essential hypertension, which means that a doctor couldn't find any reason for the condition. Sapoval said the causes of high blood pressure can be wide-ranging, such as a benign tumor in the adrenal gland, stenosis of the renal artery, the taking of certain prescription drugs

or other factors. By randomized assignment, 106 adult patients with uncontrolled hypertension received either oral medication or the renal denervation treatment. Six months after the intervention, systolic pressure (the top number in a blood pressure measurement) fell an average of 32 mmHg (millimeters of mercury, the standard for measuring blood pressure) and diastolic pressure (the smaller number in a blood pressure reading) fell an average of 12 mmHg. This initial cohort has been expanded to a multicenter randomized controlled trial at 24 international sites.

Sapoval conceded that this was a small study, that the work still experimental, and that renal denervation should be performed only by interventional radiologists on screened patients in strictly controlled academic and/or research settings. However, he noted that it shows great promise for those suffering from resistant hypertension. Sapoval remarked that the patients had a short hospital stay for safety reasons, but that the treatment might possibly be performed in an outpatient clinic in the future.

While the treatment's efficacy to lower blood pressure in patients with resistant hypertension will be better evaluated with the results of future trials, the interventional radiologist said that some clinical findings (like hypertension in young patients, hypertension after child bearing, etc.) can also be used by doctors to determine if other specific diagnostic tests are needed to rule out potential causes of the hypertension.

Sapoval stated that the trial was funded by the catheter and specific generator manufacturer and that there is a huge need for more research in independent hands. To that end, there will be an upcoming nationwide U.S. Food and Drug Administration trial involving more than 100 U.S.-based interventional radiology teams. He also stressed that the published results need confirmation by follow-up with the succeeding trial's patients after one and two years. Sapoval hopes that new trials, conducted and funded by public entities, such as the National Institutes of Health in the United States; NICE (the National Institute for Clinical Excellence) in the United Kingdom and the Ministry of Health in France, for example, and similar agencies in other countries, will help researchers to move forward and discern which patients would benefit from this technique, possibly in addition to medication.

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