腎除神経療法による高血圧治療（Abstract＃21826）

Symplicity HTN-2：ラジオ波を用いた腎神経焼灼は難治性高血圧患者の血圧低下に役立つ

Symplicity HTN-2: Blasting kidney nerves with radio waves helps lower blood pressure for those with stubborn hypertension

腎近傍の神経を沈静化する非薬物治療は、平均5種類の薬剤を内服しても血圧がコントロールできない患者の血圧を安全かつ有意に低下させたとのレイトブレイキング臨床試験の結果が2010年AHAで発表されLancetに掲載された。Symplicity HTN-2トライアルは降圧療法を目的とした血管内選択的腎交感神経除神経術に関する国際多施設前向き無作為化コントロールトライアルであり、カテーテル治療と薬物療法の併用群52人と薬物療法のみを受けたコントロール54人を比較した。スタディ開始時に二群の平均血圧はほぼ同等であった（治療群178/98mmHg対コントロール群178/97mmHg）。参加者の平均年齢は58歳であり、35%が女性で97%が白人であった。6ヵ月後の治療群の収縮期血圧は平均33.4mmHg低下し、拡張期血圧は平均12.5mmHg低下した。一方、コントロール群の平均収縮期血圧はやや（0.9mmHg）上昇し、平均拡張期血圧はやや（0.3mmHg）低下した。血圧が140/90mmHg未満に低下したのは腎除神経術で治療された患者では39%であり、それに比べコントロール群では6%であった。

Full Text

A non-drug treatment that silences nerves near the kidneys safely and significantly reduced blood pressure in patients unable to control their hypertension despite taking an average of five medications, according to late breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2010.

This is the first human randomized controlled trial of therapeutic renal denervation (RDN), a procedure using a catheter-based probe inserted into the renal artery emitting high-frequency energy to deactivate nerves near both kidneys that are linked to high blood pressure. This approach is considered minimally invasive since the kidney nerves are nearby and the energy can be delivered via this catheter-based approach.

The trial, Symplicity HTN-2: International, Multicenter, Prospective, Randomized, Controlled Trial of Endovascular Selective Renal Sympathetic Denervation for the Treatment of Hypertension, compared 52 participants who were randomly assigned to catheter treatment plus medication to 54 controls who received medication alone.

"The procedure safely and successfully silences the nerves for six months, and perhaps permanently," said Murray Esler, M.D., principal investigator of the trial and associate director of the Baker IDI Heart and Diabetes Institute in Melbourne, Australia.

"This procedure provides a revolutionary, non-drug method for controlling high blood pressure in patients who are unresponsive to multiple antihypertensive drugs," he said. "Resistant hypertension is common, occurring in perhaps 15 percent to 20 percent of patients. This procedure is likely to have very wide application."

At the start of the study, the two groups had nearly identical average blood pressures: 178/98 mm Hg for the treatment group versus 178/97 mm Hg for controls. Participants were average age 58, 35 percent were female and 97 percent were Caucasian.

Data at six months showed the treatment group's systolic pressure fell an average 33.4 mm Hg while diastolic pressure dropped an average 12.5 mmHg. In contrast, controls' average systolic pressure rose slightly (0.9 mmHg) and their average diastolic pressure fell slightly (0.3 mm Hg).

"In a small minority of patients in the study, some high blood pressure medication could be stopped or reduced," Esler said.

In addition, of the 48 RDN patients for whom the researchers had complete data when the news release was written, 93.8 percent had at least a 5 mm Hg reduction in systolic blood pressure and 87.5 percent had at least a 10 mm Hg drop in systolic blood pressure, Esler said.

In approximately 39 percent of those who received RDN, compared to six percent of the control group, blood pressure was reduced to less than 140/90 mm Hg. Pressure below 140/90 mm Hg is considered controlled to target despite being higher than the120/80 mmHg considered ideal for adults.

"Target blood pressure is usually unattainable with drug therapy in patients with severely resistant hypertension," Esler said.

The study found no serious device or procedure-related events, no cardiovascular complications and no kidney-related complications.

Esler said the results are significant from a public health standpoint because of high blood pressure's well-documented link to the development of myocardial infarction and stroke, and because hyperactivity of the renal nerves is seen in chronic kidney disease, heart failure and high blood pressure. Future studies will evaluate the effects of the new treatment on those conditions.

While the study population was not ethnically diverse, Esler said he expected the findings to extend across all groups.

Co-authors include members of the Symplicity HTN-2 study group. Author disclosures are on the abstract.

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