トライアルの結果が腎除神経術の論議を再開させる (LBT Session, Abstract 3052)

SPYRAL HTN-OFF MED：腎除神経術は降圧薬を内服していない高血圧患者の血圧を低下させる

SPYRAL HTN-OFF MED: Renal denervation lowers blood pressure in hypertensive patients not taking medication

腎除神経術は降圧薬を内服していない高血圧患者の血圧を低下させる、とのSPYRAL HTN-OFF MED試験の結果が2017 ESC Congress で発表され、*Lancet* に掲載された。施術3か月後、診察室における収縮期および拡張期血圧は、腎除神経術群においてそれぞれ10.0 mmHg（p<0.001）および5.3 mmHg（p=0.008）低下したのに対し、シャム群ではそれぞれ2.3 mmHg（p=NS）および0.3 mmHg（p=NS）の低下であった。24時間自由行動下血圧測定では、収縮期血圧および拡張期血圧は腎除神経群でそれぞれ5.5 mmHg（p=0.04）および4.8 mmHg（p<0.01）低下したのに対し、シャム群ではそれぞれ0.5 mmHg（p=NS）および0.4 mmHg（p=NS）の低下であった。

Full Text

Renal denervation lowers blood pressure in hypertensive patients not taking medication, according to late-breaking results from the SPYRAL HTN-OFF MED study presented in a Hot Line LBCT Session at the 2017 ESC Congress and published in the *Lancet*.

Renal denervation is a minimally invasive catheter-based procedure that delivers energy to the nerves in the kidneys that help regulate blood pressure. It was developed to treat resistant hypertension.

"The sham-controlled SYMPLICITY HTN-3 trial failed to show a significant blood pressure lowering effect of renal denervation," said co-principal investigator Prof. Michael Boehm, chairman, Department of Internal Medicine, University of Saarland in Homburg/Saar, Germany. "We applied lessons from this trial to the SPYRAL HTN-OFF MED study regarding how the procedure was performed, the patient population, and the influence of medications."

SPYRAL HTN-OFF MED is an international, multicenter, prospective, randomized, sham-controlled study designed to test the safety and blood pressure lowering efficacy of treatment with the multi-electrode Symplicity Spyral renal denervation system. The study included patients with uncontrolled hypertension who were drug naïve or stopped taking antihypertensive medications at least four weeks prior to randomization.

Uncontrolled hypertension was defined as an office systolic blood pressure between 150 and 180 mmHg and diastolic blood pressure more than 90 mmHg, and a 24-hour mean systolic blood pressure between 140 and 170 mmHg.

Patients were randomized to renal denervation in the main renal arteries and branches, or a sham procedure. Blood pressure was measured at baseline and three months, and compared within each treatment group.

Researchers presented three-month results of the first 80 patients, of whom 38 received renal denervation and 42 had a sham procedure. Compared to baseline, at three months after the procedure office-based systolic and diastolic blood pressure had declined by 10.0 mmHg (p<0.001) and 5.3 mmHg (p=0.008) in the renal denervation arm, respectively, compared to a decline of 2.3 mmHg (p=NS) and 0.3 mmHg (p=NS) in the sham arm, respectively.

For 24-hour ambulatory blood pressure, compared to baseline the systolic and diastolic blood pressure of patients undergoing renal denervation decreased by 5.5 mmHg (p=0.04) and 4.8 mmHg (p<0.001), respectively, while in the sham control arm they decreased by 0.5mHg (p=NS) and 0.4 mmHg (p=NS), respectively.

The decreases in systolic and diastolic office and 24-hour blood pressure were confirmed by direct comparisons between the renal denervation and sham groups.
There were no major safety events in either arm, even with the revised procedural approach which increased the total number of ablations and included denervation in the branch arteries.

"All blood pressure measurements within the renal denervation arm showed statistically significant reductions from baseline, while none of the measurements in the sham arm were significantly reduced from baseline," said Prof Boehm. "This is particularly important as even small reductions correlate to significant reductions in death, stroke, and overall cardiovascular risk."

He concluded: "The effectiveness of renal denervation in this study may have been due to the new procedural approach, which aimed to achieve complete denervation, and the fact that patients were not taking antihypertensive medications which may have confounded the results of previous studies."

The study was sponsored by Medtronic. Prof. Boehm receives honoraria for lectures and scientific advice from Abbott, Astra-Zeneca, Boehringer-Ingelheim, Medtronic, Servier and Vifor.

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