Phase IIIの結果から、従来の治療が無効な高血圧の治療に圧反射活性化が有望であることが示された

新たなデバイスにより従来の治療の無効な高血圧患者の血圧を低下させることができる

New device lowers blood pressure in patients who are unresponsive to conventional therapy

頸部圧反射を刺激する新たなデバイスは重度のコントロール不良な高血圧患者が目標血圧を達成し維持させるのに役立つとの研究結果が第60回American College of Cardiologyで発表された。Rheos®システムを、3剤以上の降圧剤を内服して血圧が>160/80mmHgである難治性高血圧患者265人に埋め込んだ。患者らは2つのグループに無作為に割り付けられた。グループAのデバイスはスタディ全期間の12ヵ月間圧反射刺激療法を行った。グループBの患者はスタディ前半ではコントロール群となり、6ヵ月後からデバイスが治療を開始するようにプログラムされた。両群ともに収縮期血圧（SBP）の有意な低下を示した。グループAにおいては6ヵ月後に41%の患者において、12ヵ月後には54%の患者においてSBPが目標まで低下した。グループBにおいては驚くべき多大なプラセボ効果が認められた。コントロール期間中に21%が目標SBPを達成し、治療6ヵ月後には46%が目標範囲内であった。12ヵ月後のSBP低下は6ヵ月後に認められた血圧低下の50%以上であり、効果が持続していることが示唆された。拡張期血圧も両群において同様の期間に低下した。

Full Text

A novel device that works with the body's natural mechanisms helps patients with severe and uncontrolled hypertension achieve and maintain target blood pressure levels, according to research presented at the American College of Cardiology's 60th Annual Scientific Session.

The Rheos® System device is implanted just below the collarbone, like a pacemaker, and delivers four to six volts of electricity to the carotid arteries. The pulses mimic a spike in blood pressure that activates a process called carotid baroreflex. This approach, known as baroflex activation therapy, tricks the brain into harnessing a network of sensors throughout the body that cause blood pressure to drop.

"People with resistant hypertension are a growing group, and they're in desperate need of additional treatments," said John D. Bisognano, M.D., Ph.D., professor of medicine in the Cardiology Division of the University of Rochester, Rochester, N.Y. "The drugs available now are good for most people with hypertension, but people with resistant sky-high blood pressure need more, and it is important that we develop treatments for this growing set of people."

In this multicenter, Phase III study, the device was implanted in 265 patients with resistant hypertension of >160/80 mmHg who were taking at least three blood pressure drugs, including a diuretic. All patients were then randomly assigned to two groups in a 2-to-1 ratio. The number of medications was similar in the two groups but could not be controlled in the study because most patients had blood pressure far above their goals; thus, physicians often changed their medications. Group A's devices delivered baroflex activation therapy for the study's full 12-month duration. Group B patients served as the control group for the first half of the study, and at six months their devices were programmed to begin treatment. The target for systolic blood pressure (SBP), the top number, was <140, and patients were seen monthly. If the patients had not reached the target SBP, the device was adjusted on an individual basis to assert more voltage and further reduce blood pressure.

Both groups showed significant reductions in SBP. In Group A, SBP decreased to target levels for 41 percent of patients after six months and 54 percent after 12 months. Group B showed a surprisingly large placebo effect, even though patients and clinicians were blinded to treatment until after the 12-month visit. Twenty-one percent achieved target SBP during the control phase, and 46 percent were in the target range after six months of treatment. Reductions in SBP at 12 months were at least 50 percent of those seen at six months, demonstrating a sustained response.

Diastolic blood pressure also fell in both groups at both time periods. Although the trial did not meet all primary endpoints, the data showed that the therapy significantly reduced blood pressure in patients with resistant hypertension. At 12 months, there was an 88 percent responder rate - a 35 mmHg blood pressure drop and a decrease in left ventricular mass. Future trials need to incorporate measures to improve variability in blood pressure in subjects.

"This system is safe, and its effect is as good as two or three drugs for people who are already taking five or six drugs and still can't control their hypertension," Bisognano said. "It's a good additional option for these patients."

The study was sponsored by CVRx, Inc., which developed the RheosR System. Bisognano is a consultant for CVRx, Inc. and has received consulting fees and research support from the company.

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