Medtronic Renal Denervation Device Offers Significant Drops in Blood Pressure After Treatment

Medtronic

Longest-term data from the first randomized, controlled trial of renal denervation presented at the 25th Annual Transcatheter Cardiovascular Therapeutics (TCT) Symposium

Medtronic, Inc. presented three-year data from SYMPLICITY HTN-2, the first and longest-running randomized, controlled clinical trial of renal denervation, which continue to demonstrate results consistent with data reported previously at six, 12 and 24-months of follow-up. The data were presented for the first time during an oral abstract session on Tuesday, October 29, 2013 at the 25th Annual Transcatheter Cardiovascular Therapeutics (TCT) Symposium taking place this week in San Francisco. The Symplicity renal denervation system is available for investigational use only in the United States.

“As the first and longest-term experience in a randomized, controlled setting, these data mark a significant milestone for the renal denervation clinical community, as well as the single-electrode Symplicity system,” said Robert J. Whitbourn, M.B.B.S., M.D., associate professor and director of the Cardiovascular Research Centre at St Vincent’s Hospital in Melbourne. “These results continue to demonstrate the impact renal denervation can have on patients with uncontrolled hypertension, and these data are an important contribution to the growing body of evidence supporting renal denervation with the Symplicity system as a therapy option for this underserved population.”

The data show an average blood pressure reduction of -33/-14 mm Hg [$p<0.01$] from baseline and an overall response rate (systolic blood pressure drop of greater than or equal to 10 mm Hg) of 85 percent for patients initially randomized to treatment with the Symplicity system and available for 36-month evaluation ($n=40$). Despite a mean systolic blood pressure of 183.5 ± 19.5 mm Hg pre-denervation, 50 percent of these patients achieved the goal of systolic blood pressure of <140 mm Hg. The safety profile of renal denervation with the Symplicity system was also maintained at three years, with no newly reported device or procedure related serious adverse events. None of the patients treated with the Symplicity system followed through three years required renal artery stenting.

In this trial, patients were required to have severe, uncontrolled hypertension with a systolic blood pressure greater than or equal to 160 mm Hg despite the use of three or more antihypertensive medications, including a diuretic. All patients were maintained on their usual antihypertensive medications and were randomly allocated in a one-to-one ratio to undergo renal denervation or no additional treatment (control group). At baseline, the randomized treatment and control

patients had similar high blood pressures: 178/97 mm Hg and 178/98 mm Hg, respectively, despite both receiving an average daily regimen of five antihypertensive medications. Patients in the control arm of the study were offered renal denervation following assessment of the trial's primary endpoint at six months following randomization. This crossover treatment group experienced significant and sustained blood pressure reductions at 30 months after renal denervation with an average blood pressure reduction of –33/-13 mm Hg [p<0.01] from baseline (n=30).

The complete data were presented by Robert J. Whitbourn, M.B.B.S., M.D., during an oral abstract session titled Renal Denervation and Endovascular Intervention at 1:00 p.m. in Moscone West, 3rd Floor, Room 3022.

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http://www.mdtmag.com/news/2013/10/medtronic-renal-denervation-device-offers-significant-drops-blood-pressure-after-treatment