MedicalXpress

Renal denervation patient registry finds low rate of adverse events

March 31 2014

Patients with uncontrolled high blood pressure treated with renal denervation had low rates of adverse events and significant lowering of blood pressure at six months, according to a registry-based study presented at the American College of Cardiology's 63rd Annual Scientific Session.

The Global SYMPLICITY Registry is the first and largest dataset of patients with uncontrolled hypertension treated with renal denervation. The open-label, multicenter study was established to examine the safety and effectiveness of the procedure. Outcomes presented were for the first 1,000 consecutively enrolled patients at six months. There were five adverse events attributed to the procedure, including four vascular access site complications (0.34 percent) and one renal artery dissection that was treated. There were also nine hospitalizations for hypertensive emergency (1.0 percent), eight for atrial fibrillation (0.9 percent), eight strokes (0.9 percent), six hospitalizations for new onset heart failure (0.7 percent), five heart attacks (0.6 percent), four deaths (0.4 percent) and two cases of new onset end stage kidney disease (0.2 percent) that were considered unrelated to the procedure.

In addition, office systolic blood pressure showed a significant drop at six months of 11.9 mmHg for all patients and of 19.8 mmHg for patients with baseline office pressures greater than or equal to 160. Ambulatory systolic blood pressure – measured by a portable machine that patients wore for 24 hours – dropped significantly for all patients at six months, with a drop of 7.9 mmHg for all patients with blood pressure readings of

140 or higher – and the largest reductions, 9.2 mmHg, for the subset of patients with ambulatory systolic blood pressure of 160 or higher.

"This study shows that renal denervation may be an alternative treatment for uncontrolled hypertension," said Michael Böhm, M.D., Ph.D., University of Saarland in Homburg, Germany, and lead investigator of the study. "Our study provides a significant contribution to the discussion about renal denervation when considering the procedure for high risk patients who are suffering from uncontrolled hypertension and have exhausted all other options."

Hypertension increases the risk for heart attack and stroke for more than 77 million Americans and up to one billion adults worldwide. During the Symplicity renal denervation procedure, a catheter is threaded through arteries to deliver radiofrequency energy that inactivates kidney nerves, interrupting electrical signals to and from the kidney, an organ that performs a major role in regulating blood pressure. Although renal denervation is in clinical use for uncontrolled hypertension in more than 80 countries, it is still an experimental approach in the United States.

Enrollment in the registry began in February 2012 and includes patients from 111 international sites. The registry is currently following 2,000 patients with an enrollment goal of 5,000.

Of the 1,000 patients included in this analysis, 60 percent were male and the average age was 61; 49 percent had cardiac disease, 41 percent diabetes, 30 percent chronic kidney disease and 17 percent sleep apnea. At baseline, patients were taking an average of 4.4 blood pressure medications and had an office blood pressure of 164/89. The study collected information on patients' procedures, office and ambulatory blood pressure readings, kidney function, vascular complications and other safety events.

In January 2014, Medtronic announced that it was halting its U.S. pivotal trial on renal denervation because the study had failed to reach its primary efficacy endpoint, though it did meet its primary safety endpoint. Results from this trial will also be presented at ACC.14.

Limitations of the Global Registry study include its open label design and lack of comparison group. Böhm recommends additional research to demonstrate the efficacy of renal denervation and to identify the patient populations who might benefit most from the procedure.

Provided by American College of Cardiology

Citation: Renal denervation patient registry finds low rate of adverse events (2014, March 31) retrieved 2 February 2024 from https://medicalxpress.com/news/2014-03-renal-denervation-patient-registry-adverse.html

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