One-year data from SYMPLICITY HTN-3 confirm findings from six month analysis

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Longer-term follow-up data from the SYMPLICITY HTN-3 trial confirmed both the safety and absence of clinical benefit of renal denervation, according to the 12 month results presented for the first time at ESC Congress today by Professor George L. Bakris, director of the ASH Comprehensive Hypertension Center, The University of Chicago Medicine in Chicago, Illinois.

Professor Bakris said: "The 12 month results presented today are consistent with the six month findings which were previously reported. We found that renal denervation is safe but resulted in blood pressure reductions similar to a sham procedure."

He added: "Renal denervation has been used in patients with hypertension who do not respond to treatment with medication. A catheter is inserted into the kidney via the femoral artery and a device applies radiofrequency pulses to the renal arteries to damage the nerves and in theory reduce blood pressure. SYMPLICITY HTN-3 was the first trial to compare renal denervation to a sham procedure, in which patients received a surgical intervention with no denervation procedure, to account for any placebo effect."

SYMPLICITY HTN-3 included 535 patients with resistant hypertension (office systolic blood pressure [SBP] >160 mmHg) who were prescribed three or more hypertension medications, including a diuretic, from 88 medical centres in the US. Patients were randomised 2:1 to renal denervation or the sham procedure.

Patients and clinicians assessing blood pressure were blinded to the treatment patients received. They were unblinded following assessment of the six month primary endpoint. At this stage control patients could crossover to the renal denervation group if they met treatment criteria and agreed to the procedure. Of the 171 patients randomised to the sham procedure, 101 crossed over at six months and received renal denervation.

The primary efficacy endpoint was the change in office SBP from baseline to six months in the renal denervation arm (353 patients) compared to the sham control arm (171 patients). The secondary endpoint was the change in 24-hour ambulatory SBP at 6 months. The primary safety endpoint was a composite of major adverse events. As previously reported, the trial met its primary safety endpoint but did not meet its primary or secondary efficacy endpoints.

Safety and efficacy data were reported for three groups in the trial: 12 month outcomes for the original renal denervation group, six month outcomes for the crossover group, and 12 month outcomes for the non-crossover group (control subjects who did not meet inclusion criteria, specifically a SBP >160 mmHg, or did not wish to undergo renal denervation). The non-crossover group had a lower baseline SBP (176.1 mmHg) due to inclusion of subjects with SBP