24h Ambulatory Blood Pressure (ABPM) Change After Using The New Symplicity Spyral Renal Sympathetic Denervation Device In Patients With Resistant Hypertension – First Results From The Halle-RDN-Registry

Alexander Plehn1, Wolf Baeremueller1, Alexander Vogl1, Daniel Medenwald1

1Martin Luther University Halle-Wittenberg, Halle, Germany

Background: Despite the widely discussed unfavorable outcome of the SymplicityTM HTN 3 trial, several independent trials and registries have shown a blood pressure (BP) lowering effect in the majority of patients treated with a renal denervation (RDN) device. So far, current available data are almost entirely based on the SymplicityTM Flex System, a second-generation RDN device. Although well established and approved, it revealed several limitations like high time consumption, high rigidity and often a more or less random ablation pattern. The next generation SymplicityTM Spyral device has been designed to overcome many of these shortcomings by using multiple electrodes strung on a helical shaped catheter. However, the question about the effectiveness of the new system still remains.

Methods: Our study carefully investigated the ABPM response to RDN in a cohort of 29 consecutively treated patients with resistant hypertension using the Spyral renal ablation catheter. The baseline values included a mean age of 67 ± 9.8 years, BMI of 31.3 ± 4.4 Kg/m², 48% women, 56% diabetic, 29% coronary artery disease and 5.4 ± 2.1 antihypertensive medications. A 24 h BP monitoring was recorded in every patient 24 h before as well as 24 h and 3 months after RDN. BP readings were then averaged according to daytime (7:00am-22:00pm), nighttime (22:00pm-7:00am) and 24 hours. All data were statistically analyzed using mixed models with repeated measurements.

Results: In treated patients mean averaged systolic 24 h BP was reduced by 14.5±4.6 mm Hg (p<0.005; n=29) during the first 24 hours. A similar effect on diastolic BP was observed: 4.9±2.26 mmHg (p<0.005). First analyses of 17 patients reaching the 3 months follow-up visit revealed a sustained systolic (7.3±2.39 mmHg, p<0.05) as well as diastolic (4.8±1.46 mmHg, p<0.05) ABPM reduction, without further decrease – on the contrary a slight relapse to higher BP was seen.

Conclusions: Using the multi-electrode SymplicityTM Spyral renal ablation device did not only improve steerableity, ablation pattern and procedure time. It also seems to show a significant immediate as well as persisting reduction of systolic and diastolic ABPM.

TCT-420

Safety and Performance of the Next Generation EnligHTN Renal Denervation System in Patients with Drug-resistant Hypertension: 12-Month Results From a First-in-Human Multicenter Study

Stephen G. Worthley1, Mark W. Webster2, Joseph Montazeroz1, Paul Antonis3, Robert J. Whitbourn4

1The University of Adelaide, Adelaide, Australia, 2Auckland City Hospital, Auckland, New Zealand, 3Royal Adelaide Hospital, Adelaide, Australia, 4Monash Heart, Melbourne, Australia, 5Cardiovascular Research Centre, St. Vincent Hospital Melbourne, Melbourne, Australia

Background: Cather-based renal artery denervation therapy has become established as a therapeutic option in patients with resistant hypertension. We further investigated the safety and performance of the next generation EnligHTN™ Renal Denervation System (St. Jude Medical) in patients with drug-resistant hypertension. Methods: Our study carefully investigated the ABPM response to RDN in a cohort of 39 consecutively treated patients with resistant hypertension using the EnligHTN Renal Denervation System, which is attached on a basket mounted at the tip of the catheter. The next generation EnligHTN RF Ablation Generator utilizes a novel algorithm for the delivery of 1 minute of radiofrequency energy, optimized for simultaneous delivery of therapy through all 4 electrodes with an interactive and user-friendly software interface. Renal denervation was performed on 39 patients across 6 centers meeting the following inclusion criteria: 18-80 years of age, a systolic BP ≥160 mmHg, an average daytime systolic ambulatory BP ≥135 mmHg, on three or more antihypertensive agents (including a diuretic). Renal artery CT angiography was repeated at 6 months in all patients.

Results: To date 37/38 patients have completed 6-months of follow-up post procedure. No serious device or procedure related adverse events have been observed as adjudicated by an independent Clinical Events Committee. There were no clinically significant changes in renal function through 6-months as observed in eGFR, serum creatinine, cystatin C, or urine albumin-to-creatinine ratio. 6-month office (24 hour ambulatory) BP reductions from baseline were -25.2/-7.3 /±0.8/-2.0 mmHg, which were statistically significant except for the ambulatory diastolic reduction. Renal artery denervation procedures were performed successfully in all patients, with an average of 4.33 ablation sets and 15.85 ablations performed per patient. The mean total ablation catheter insertion-to-removal time was 22.38 min and mean ablation time was 4.33 min per patient.

Conclusions: Accumulated 12-month results from all sites will be presented. After 6-months follow-up in this first-in-human study, we conclude that data demonstrates the next generation EnligHTN Renal Denervation System continues to be safe, rapid, and effective in the treatment of patients with drug-resistant, uncontrolled hypertension.

TCT-421

Renal denervation in hypertensive patients: effects on neurohormonal activation and cardiac natriuretic peptides

Marco Ciardetti1, Luigi E. Pastormerlo2, Cataldo Palmieri3, Michele Cocceani4, Claudio Cassino5, Michele Emanuelli5, Sergio Berti5

1Fondazione Toscana Gabriele Monasterio, Pisa, Italy, 2Fondazione Gabriele Monasterio, Ospedale di Massa, Pisa, Toscana, 3Fondazione Toscana, Massa, ID, 4Fondazione Toscana Gabriele Monasterio, Pisa, Tuscany, 5Fondazione Toscana G Monasterio, Pisa, Italy, 6Fondazione Toscana CNR, Pisa, Italy, 7Heart Hospital-Massa- Fondazione CNR Reg, Toscan4a, G. Monasterio, Massa, Italy

Background: Renal denervation is a emerging treatment in patients with resistant arterial hypertension. Neurohormonal activation (catecholaminergic and renin angio- tensin aldosterone systems) play an important role in hypertensive patients; B-type cardiac natriuretic peptides have been demonstrated as useful biomarkers of both neurohormonal activation and cardiovascular overload. Aim: To investigate effects of renal denervation on biomarkers of neurohormonal activation and NT-proBNP serum values.

Methods: 6 patients with resistant hypertension (mean value 140/90 mmHg at 24 hours blood pressure monitoring despite use of three or more antihypertensive medications were made after the procedure. Cardiac natriuretic peptides have been demonstrated as useful biomarkers of both neurohormonal activation and cardiovascular overload. Results: All procedures were performed without complications. Mean age 64 ± 17 (range 43-75), 5 patients males. Diuretics were used in 6 out of 6 patients. Systolic (138±6 at 1M vs. 150±8 at 1D and 151±6 mmHg at B, p< 0.01), diastolic (73±10 at 1M vs.79±12 at 1D and 81±12 mmHg at B, p< 0.01) and mean (94±6 at 1M vs. 102±7 at 1D and 105±6 mmHg at B, p< 0.01) arterial pressure values, all