Results: Twenty patients were enrolled and treated with the Paradise System. The mean baseline systolic was 145 ± 4.6 mm Hg and mean diastolic was 94 ± 2.3 mm Hg. One patient was excluded due to ineligibility. After treatment, mean systolic was 110 ± 4.8 mm Hg and mean diastolic was 70 ± 2.8 mm Hg. Mean difference in systolic was -35 mm Hg and mean difference in diastolic was -24 mm Hg. No significant adverse events were observed.

Conclusions: The EnligHTN renal denervation system is safe and effective for the treatment of drug-resistant hypertension. Further studies are needed to confirm these results in a larger population.

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

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Background: Catheter-based renal artery denervation therapy has become established as a therapeutic option in patients with resistant hypertension. We investigated the safety and performance of the next generation EnligHTN™ Renal Denervation System (St. Jude Medical) in patients with drug-resistant hypertension.

Methods: In the EnligHTN® RDN Rabbit Ablation study, a 24-hour blood pressure (BP) was measured in four rabbits. EnligHTN® RDN was performed with a catheter-like device that was attached to a basket-mounted at the tip of the catheter. The next generation EnligHTN® RDN Ablation Generator utilizes a novel algorithm for the delivery of 1 minute of radiofrequency energy, optimized for simultaneous delivery of therapy across all four ablation catheters with an interactive user 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, and/or 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 six-months as observed in eGFR, serum creatinine, cystatin C, or urine albumin-to-creatinine ratio. 6-months (office and 24 hour ambulatory) BP reductions from baseline were -25.2/7.3 (-8.2/2.0) mmHg, which was statistically significant 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-removeal 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

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Background: Renal denervation is a emerging treatment in patients with resistant arterial hypertension. Neurohumoral activation (renin-angiotensin-aldosterone system) plays an important role in hypertensive patients. B-type natriuretic peptides have been demonstrated as useful biomarkers of both neurohumoral activation and cardiovascular overload.

Aim: To investigate effects of renal denervation on biomarkers of neurohumoral activation (PRA, aldosterone (A)) 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) underwent renal denervation. Norepinephrine (NE), plasma renin activity (PRA), aldosterone (A) and NT-proBNP were collected at baseline (B), 1 day (1D) and 1 month (1M) after the procedure. Patients underwent 24 hours blood pressure monitoring at B, 1D and 1M after the procedure. Any change in antihypertensive medications was made after the procedure.

Results: All procedures were performed without complications. Mean age ± 3.7 years (range 43-75); 5 patients males. Diuretics were used in 6 out of 6 patients. Systolic (138±8 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