Conclusions: The difference in blood pressure changes in the AA vs. the non-AA subgroup may be due to greater BP reductions in the AA sham control group. This greater than expected drop in BP in the sham control group suggests a post-randomization interaction with an exposure that impacted BP lowering. Further investigation of factors that may impact sham response is warranted.

Methods: Swine underwent bilateral RDN and followed for 7, 30, and 180 days. A representative section of each time point was selected for H&E and immunohistochemical (IHC) analysis. IHC consisted on S100 (Schwann cell), Tyrosine hydroxylase (TH; effector motor renal nerves), calcitonin gene-related peptide (CGRP) and substance P (SP); (CGRP and SP afferent sensory renal nerves).

Results: H&E displayed the typical acute (7 days; nerve necrosis, distal atrophy) and chronic (180 days; nerve fibrosis) nerve injury. At 180 days we could observe evidence of nerve remodeling and tentative regeneration, morphological recovery of S100, and TH staining and to variable degrees of CGRP and SP staining. However, there was evidence of TH and S100 staining spill over and extension of neural bundles within and across the perirenal/perineurium, forming neuromatous bundles and reminiscent of amputation neuromas (neuromatous regeneration). IHC revealed that the nerve displayed early signs of TH and S100 positive fibers within and beyond the fibrous perineurium as early as 7 days following RDN. This perineurial neuromatous regeneration becomes more evident at longer time points. At 180 days, the neuromatous tangents became very prominent with affected nerves completely remodeled into neuromatous proliferative bundles.

Conclusions: It has been previously demonstrated in renal transplant models that sympathetic nerves have the ability to regenerate. Furthermore, there are evident signs of increased nerve count in swine model at longer time points following RDN. However this is the first evidence that this "regenerative nerve attempt" occurs as early as 7 days following RDN therapy and is progressively increasing over time, resulting in the formation of poorly organized tangles of nerve fibers, Schwann cells and connective tissue. This is the first complete histological characterization of neuromatous nerve regrowth following RDN.

TCT-408
Renal Artery Denervation With a New Simultaneous Multielectrode Catheter For Treatment Of Resistant Hypertension: 12-Month Update From The SYMPLECTY Spyrrial First-Man Study

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Background: The SYMPLECTY Spyrrial first-in-man (FIM) study investigated the safety and effectiveness of the Spyrrial™ multielectrode renal denervation catheter to lower blood pressure in patients with resistant hypertension. Methods: The prospective, open label Spyrrial FIM study enrolled 50 subjects with resistant hypertension defined as an office systolic blood pressure of ≥160 mm Hg (≥150 mm Hg for type 2 diabetics) despite adherence to an antihypertensive regimen of ≥3 drug classes (ideally including a diuretic). Subjects with an estimated glomerular filtration rate of <45 ml/min/1.73m2, type 1 diabetes mellitus, renal artery stenosis of >50%, renal artery aneurysm, and prior renal artery intervention were excluded. The protocol specified one denervation treatment per artery via delivery of 4 simultaneous 60 seconds ablations per artery. The safety endpoint is a composite of vascular complications, renal artery reintervention, new onset end stage renal disease, death. Results: The mean age of subjects was 63 years, 64% were men, 46% had type II diabetes mellitus, and 54% had hypertension with a history of myocardial infarction, significant previous event resulting in end-organ damage, hypertensive crisis and new renal artery stenosis. Effectiveness is measured by change in office BP from baseline at 1, 3, 6, and 12 months and annually thereafter.

Results: The mean age of subjects was 63 years, 64% were men, 46% had type II diabetes mellitus, and baseline eGFR was 54.7 ± 18.7 ml/min/1.73m2. Baseline systolic and diastolic blood pressure was 160 ± 22.0 and 101 ± 16.0 mm Hg, respectively, and the mean number of antihypertensive drug classes was 4.5 ± 1.1. The mean number of ablations per artery was 3.25. Three access-site pseudoaneurysms and 1 myocutaneous occurrence during 6 months follow-up. No new renal artery stenosis or hypertensive emergencies occurred, and there was no clinically meaningful change in renal function. The change in office-based blood pressure was -19.9 ± 25.0 ± 7.3 ± 11.5 mm Hg at 6 months, p<0.001.

Conclusions: Renal denervation using the Spyrrial multielectrode catheter is safe and effective in reducing office blood pressure from baseline. 12-month follow-up results will be available for presentation in September.

TCT-409
Preclinical and Early Clinical Experience of a Non-Vascular Treatment for Resistant Hypertension

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Background: The Symplicity HTN-3 recently failed to meet its primary efficacy endpoint in blood pressure reduction. The device used in this study as well as all other denervation systems only ablate peri-arterial nerves. The Verve Medical system directs radiofrequency energy to the renal pelvic space where the preponderance of autonomic nerves originate and are closely accessible. We have previously demonstrated the feasibility of the Verve Medical NephroBlate to ablate these nerves.

Methods: We developed a protocol to treat a small number of patients (n=3, 4 kidney) undergoing elective nephrectomy. After submission to the hospital institutional review board and after patient informed consent we treated three patients with end...