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.

	African American Denervation (n=90)	African American Sham (n=50)	P value	Non-African American Denervation (n=273)	Non-African American Sham (n=121)	P value
Office BP						
SBP Baseline	180.6 ± 16.4	183.9 ± 19.8	0.294	179.5 ± 16.0	178.6 ± 15.3	0.611
3 month change	-16.0 ± 22.0	-13.7 ± 21.8	0.546	-15.5 ± 24.5	-14.6 ± 22.4	0.710
6 month change	-15.5 ± 25.4	-17.8 ± 29.2	0.641	-15.2 ± 23.5	-8.6 ± 24.8	0.012
DBP Baseline	101.1 ± 17.0	104.4 ± 16.5	0.264	95.0 ± 16.2	96.6 ± 14.9	0.368
3 month change	-8.3 ± 11.9	-4.9 ± 11.6	0.114	-6.9 ± 12.0	-4.5 ± 11.1	0.067
6 month change	-8.2 ± 12.1	-6.8 ± 17.1	0.631	-6.0 ± 11.8	-3.7 ± 11.8	0.086
ABPM						
SBP Baseline	160.4 ± 13.8	162.7 ± 16.2	0.384	158.7 ± 13.0	158.2 ± 14.8	0.729
6 month change	-7.6 ± 16.3	-6.7 ± 18.4	0.782	-6.5 ± 14.8	-4.0 ± 16.8	0.158
DBP Baseline	92.7 ± 14.6	95.3 ± 13.2	0.308	86.6 ± 13.4	89.1 ± 14.6	0.094
6 month change	-4.8 ± 9.9	-3.6 ± 11.6	0.542	-3.89 ± 9.0	-2.9 ± 9.5	0.337

TCT-406

Renal Artery Trauma Induced By Four Different Renal Denervation Systems. A Multi-Modality Intra-Arterial Imaging Study

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Background: Renal denervation is a new treatment for resistant hypertension. As new systems are introduced, the incidence of acute renal artery wall injury with relation to the denervation method is unknown. We aimed to investigate by quantitative angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT), the acute repercussion of renal denervation for treatment of resistant hypertension on the renal arteries treated with 4 different systems.
Methods: Nineteen patients underwent bilateral renal denervation in two centers with 4 different systems: Symplicity™ (n=6), Paradise™ (n=5), Oneshot™ (n=6) and Vessix V2™ (n=2). Analysis included quantitative angiography pre- and post-procedure, morphometric measurements by IVUS pre- and post-procedure, and assessment of vascular trauma (dissection, oedema, or thrombus) by OCT after denervation.
Results: No significant differences between pre- and post-procedure were observed in lumen and vessel dimensions by quantitative angiography or IVUS. By post-denervation OCT, dissection was seen in 12 arteries (37.5%), 11 of which were treated with balloon-based denervation catheters. Thrombus and oedema were detected in 26 (81.2%) and 22 arteries (68.8%), respectively. In arteries with any dissection by OCT the balloon-to-artery ratio was higher (1.24±0.13 versus 1.10±0.11, p=0.01), while 6 out of 7 arteries (86%) treated with balloon catheters with a balloon-to-artery ratio>1.18 had evidence of dissection by OCT. In arteries with lumen contour irregularities or dissection by angiography there was higher incidence of dissection and a trend for higher thrombus (dissection: 66.7% versus 15.8%, p< 0.01; thrombus: 100.0% versus 68.4%, p=0.06).
Conclusions: A varying extent of vascular injury was observed after renal denervation in all systems. Dissections were observed mainly in arteries treated with balloon-based denervation catheters and were associated with a higher balloon-to-artery ratio and vessel wall irregularities on post-procedural angiogram.

TCT-407

Evaluation of the Acute and Long Term Renal Artery Re-Innervation Attempt Response Following Catheter-Based Renal Denervation in a Swine Model: An Immunohistochemical Characterization

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Background: Catheter-based renal denervation (RDN) emerged as a therapeutic option fo r resistant hypertension patients. Nerve "regrowth" has been questioned. We aimed to characterize the renal nerve response following RDN acutely and long term.
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; efferent 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 thickened perineurium, forming neurofibrous tangles highly 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 proliferation becomes more evident at longer time points. At 180 days, these neuromatous tangles 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 SYMPLICITY Spyral First-In-Man Study

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Background: The SYMPLICITY Spyral first-in-man (FIM) study investigated the safety and effectiveness of the Spyral™ multielectrode renal denervation catheter to lower blood pressure in patients with resistant hypertension.
Methods: The prospective, open label Spyral 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, myocardial infarction, significant embolic 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 estimated glomerular filtration rate was 85.1 ± 32.1 mL/min/1.73m2. Baseline systolic and diastolic blood pressure was 181 ± 17 mm Hg and 95 ± 12 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 myocardial infarction occurred 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 Spyral multielectrode catheter is safe and results in significant reduction of 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 afferent 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 kidneys) undergoing elective nephrectomy. After submission to the hospital institutional review board and after patient informed consent we treated three patients with end