decreased at 1M after renal denervation procedure. NT-proBNP (126; 87-178 at 1M vs. 353; 178-490 at B, p< 0.01), NE (441; 198-598 at 1M vs. 752; 629-850 at B, p< 0.01) and A (98; 75-128 at 1M vs. 165; 114-269 at B, p< 0.01) all decreased at 1M after renal denervation procedure, while PRA did not change. Percentual decrease of mean arterial pressure was strictly correlated with both percentual decrease in NT-proBNP (r= 0.742, p< 0.05) and NE (r= 0.924, p< 0.01).
Conclusions: Biomarkers of neurohormonal activation and cardiovascular overload such as norepinephrine, aldosterone and B-type natriuretic peptides appear positively affected by renal denervation procedure in resistant hypertensive patients. Interestingly, decrease of such neurohormones strictly reflect decrease in arterial pressure values.

TCT-422

Transluminal Imaging of Renal Nerves using Optical Coherence Tomography

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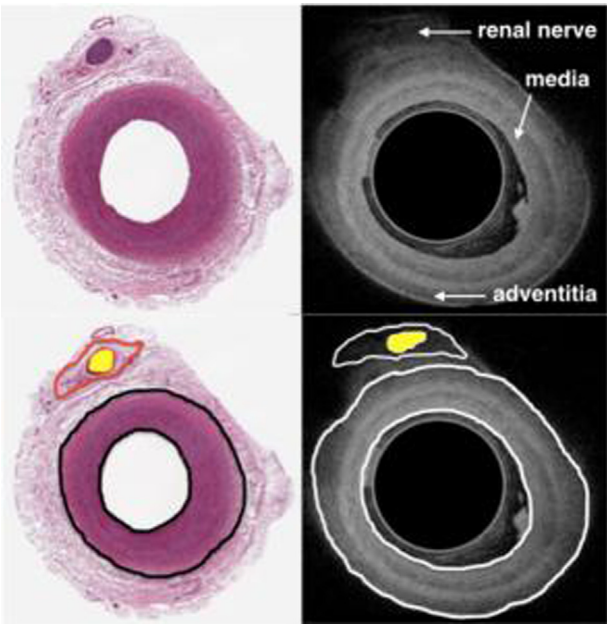
Background: Renal denervation for refractory hypertension has received considerable interest in recent years. Initial clinical data demonstrated a significant reduction in blood pressure following radiofrequency ablation of the renal nerves. However, the recent clinical trial SYMPLICITY HTN-3 failed to meet efficacy endpoints. One theory for insufficient efficacy is incomplete ablation of the renal nerve. In this study we test if the renal nerves, in particular the main renal nerve bundle, could be visualized through the renal arterial wall using optical coherence tomography (OCT) to guide more precise ablative energy.
Methods: Specimens included fresh porcine abdominal aortas with kidneys attached. The Ocelot catheter (Avinger Inc, Redwood City, CA) using a 1300 nm OCT swept source laser was inserted through the aorta and advanced to the renal artery. Following OCT imaging, the tissue was fixed, sectioned (5 µm thick), and stained with hematoxylin and eosin.
Results: Figure 1 displays an OCT image from within the renal artery juxtaposed with the identical histologic arterial section. OCT accurately identifies the location of the renal nerve bundle via the optical properties of the surrounding myelin, which creates delineated borders when compared with neighboring adventitia.
Conclusions: OCT is gaining increased use within cardiovascular imaging and therapy. The clear identification and localization of the renal nerve bundle via OCT may prove useful for targeted ablative therapies, including renal denervation.



TCT-423

The Paradise Renal Denervation System: Initial Clinical Results from the ACHIEVE Study

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Background: While the efficacy of a first generation radio frequency renal denervation device has recently been challenged, new technologies are available designed to optimize procedural success. The Paradise® Renal Denervation System (ReCor Medical, Palo Alto, CA) delivers ultrasound energy to perform targeted circumferential denervation of the renal sympathetic nerves in order to reduce blood pressure (BP) and secondary end-organ damage.
Methods: The ACHIEVE study is a prospective, multi-center, non-randomized, post-market study to evaluate the clinical outcome of renal denervation with the Paradise System in patients with resistant hypertension. Major exclusions include renal artery stenosis and moderate to severe renal insufficiency. Patients were treated with the Paradise system and followed for 12 months. Non-invasive imaging using CR or MRI was performed at 12-months to assess renal artery patency. Safety and efficacy endpoints were evaluated including renal complications, changes in office and ambulatory BP, changes in medication and Quality of Life measures.
Results: Eight sites in Europe are actively recruiting in the ACHIEVE study. Mean age at treatment is 63±11 years (range 38-86 years) and 56% of patients are male. At baseline, mean office systolic BP is 177±20 mmHg (n=67) and mean ambulatory systolic BP is 156±13 mmHg (n=62). Early data demonstrate a significant decrease in systolic office BP at 30 days post treatment (average BP change of -16mmHg, n=47, p< 0.005), sustained at both 3 and 6 months. Patients with baseline office BP ≥160mmHg had larger overall drops in systolic BP versus those whose baseline BP was < 160mmHg (-19±29mmHg; n=29; p< 0.005 versus 2.1±20mmHg, n=8). Average 24-hour ambulatory blood pressure changes are also sustained over follow-up with an average decrease of -7mmHg recorded at both 3 and 6 months post treatment. No procedure related serious adverse events occurred in the initial follow-up. Updated results will be presented at the meeting.
Conclusions: Initial ACHIEVE study results demonstrate that the Paradise System is safe and effective in patients with resistant hypertension. Early data suggests that a reduction in BP occurs within 30 days and is sustained.

TCT-424

Unfavourable Anatomy Of Renal Arteries Should Not Be An Exclusion Criteria For Renal Sympathetic Denervation

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Background: Catheter-based renal sympathetic denervation (RDN) is indicated for treatment-resistant arterial hypertension (systolic pressure ≥160 mmHg on ≥3 antihypertensive drugs). A radiofrequency catheter induces controlled thermal sympathetic nerve destruction in the renal arteries resulting in lowered sympathetic tone and blood pressure (BP). According to the Symplicity trials, patients with anatomical abnormalities of the renal arteries like additional arteries or early bifurcations have not been eligible for this treatment.
Methods: Our study carefully investigated the ambulatory 24 hour blood pressure (ABPM) response to RDN in a cohort of 181 consecutively treated patients with resistant hypertension. A 24h BP monitoring was recorded in every patient 24h before as well as 24h, 3 and 6 months after RDN. According to the renal artery anatomical findings, the following 5 groups have been identified: normal anatomy, additional arteries, early bifurcation (segmental bifurcation < 15mm from the ostium), tortuosity and atherosclerotic plaque. All data were statistically analysed with repeated measures ANOVA and Greenhouse-Geisser correction if indicated.
Results: In treated patients (age 63 ±9.6 years, BMI 31.9 ±5.8 Kg/m2, 48% women, 48% diabetic, 19% coronary artery disease and 5.7 ±1.8 antihypertensive medications) mean averaged systolic 24h BP was significantly reduced in every anatomical group during the first 24 hours. Patients with additional renal arteries or early bifurcations seem to have a more sustained systolic BP reduction at 3 and 6 months compared to tortuous renal arteries, evidence of plaque or normal anatomies. Here a relapse to baseline BP was seen.
Conclusions: Patients with resistant hypertension and unfavourable renal vascular anatomy seem to benefit at least to an equal extent from RDN as patients with normal renal arteries. However, our data suggest, that tortuosity and atherosclerotic plaque may be a negative predictor of BP response, whereas early bifurcations and additional renal arteries appear to be positive predictors.