TCT-493
Renal Sympathetic Denervation In Patients With Resistant Hypertension - Inducing An Immediate And Persisting 24h Ambulatory Blood Pressure (ABPM) Reduction – Results From The Halle-RDN-Registry
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Background: Catheter-based renal sympathetic denervation (RDN) has shown to significantly reduce blood pressure (BP) in patients with resistant hypertension. So far, current available data are almost entirely derived from office-based blood pressure measurements (OBPM) with only few data basing on more reliable 24h ambulatory blood pressure monitoring (ABPM).

Methods: Our study carefully investigated the ABPM response to RDN in a cohort of 181 consecutively treated patients with resistant hypertension. Baseline values included a mean age of 63 ±9.6 years, BMI of 31.9 ±8.5 kg/m2, 48% women, 48% diabetic, 19% coronary artery disease and 5.7 ±1.8 antihypertensive medications. A 24h BP monitoring was recorded in every patient 24h before as well as 24h, 3, 6 and 12 months after RDN. BP readings were then averaged according to daytime (7:00am-22:00pm), nighttime (22:00pm-7:00am) and 24 hours intervals. All data were statistically analyzed using mixed models with repeated measurements.

Results: In treated patients averaged systolic 24h BP was reduced by 10.3 ±4.1 mmHg (p < 0.001; n 181) during the first 24 hours. Systolic blood pressure reduction appeared to be much higher at daytime (13.1 ±1.4 mm Hg; p < 0.001) compared to nighttime (5.3 ±1.40 mm Hg; p = 0.0016) which most likely reflects the physiologically higher sympathetic activity at daytime. A concomitant effect on diastolic BP was observed: 6.8 ±7.6 mm Hg (p < 0.001). Systolic BP reduction sustained at 3 (5.6 ±1.48 mm Hg, p < 0.005, n 147), 6 (4.87 ±1.5 mm Hg, p = 0.0014, n 136) and 12 months (7.9 ±1.82 mm Hg, p < 0.001, n 101) without further decrease – on the contrary a slight relapse to higher BP was seen.

Conclusions: In patients with resistant hypertension, RDN leads to an immediate and persisting reduction of systolic and diastolic ABPM. Compared to OBPM data, ABPM effects are expectedly less pronounced. A gradual drop in BP up to 6 months followed by a slight rebound of BP reduction was observed after the initial drop and the 3, 6 and 12 months follow-ups. RDN may seem to provide an acute as well as chronic therapeutic option to hypertensive Patients at risk.

TCT-494
Renal sympathetic denervation reduces blood pressure in patients with less distinct resistant hypertension
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Background: Hypertension is highly prevalent and a major risk factor for coronary artery disease, myocardial infarction, and stroke. Approximately 5-10% of patients with high blood pressure are resistant to drug treatment. In these patients, renal denervation (RDN) offers an invasive approach to target the renal sympathetic nerves and to hereby reduce blood pressure. To date, the efficacy of RD has been shown in patients with high blood pressure and are resistant to drug treatment. In these patients, renal denervation (RDN) offers an invasive approach to target the renal sympathetic nerves and to hereby reduce blood pressure. To date, the efficacy of RD has been shown in patients with resistant hypertension and a systolic blood pressure (SBP) ≥ 160mmHg (≥ 150mmHg for diabetes type 2 patients), despite treatment with at least 3 antihypertensive drugs (including a diuretic). We therefore investigated the effect of RDN on blood pressure in patients with less distinct resistant hypertension.

Methods: Eligible patients were older than 18 years and had resistant hypertension with an SBP of ≥ 135mmHg in the presence of at least 3 antihypertensive drugs (including a diuretic). We investigated 20 patients and performed RDN using the Simplicity catheter (Ardian, Palo Alto, California). Up to 8 ablations at 8 watt for 2 minutes were performed in both renal arteries. Blood pressure was measures at baseline, at 3-month follow-up, and at 6-month follow-up.

Results: The mean age in the study population was 65 ± 8.2 years. On average, patients were taking 5.1 different antihypertensive drugs. The mean SBP was 148±13mmHg (± 10mmHg) at baseline. RD significantly reduced SBP (-14.2mmHg at 3-month follow-up, p = 0.016, and -22mmHg at 6-month follow-up, p = 0.0014). Diastolic blood pressure (75 ±8mmHg at baseline) did not change significantly.

Conclusions: In patients with resistant hypertension and a SBP ≥ 135mmHg despite treatment with at least 3 antihypertensive drugs, we demonstrate that RD is feasible and significantly reduces SBP. To achieve blood pressure treatment goals, RD should therefore be taken into therapeutic considerations also in these patients. Further studies are needed to investigate possible prognostic benefits.

TCT-495
Novel Use of Micro-Infusion Catheter for Site-Specific Delivery of Local Anesthetic Agent for Pain Control in Renal Sympathetic Denervation – First-in-Man Experience
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Background: Current strategy for pain control in renal denervation includes intra-venous administration of medications, which is often not fully effective and is associated with potential side effects.

Methods: The Bullfrog Micro-Infusion Catheter (Mercator MedSystems, CA, USA) consists of a percutaneous miconeedle which is contained within a semi-rigid polymer actuator. It can be introduced to the target renal artery over a 0.014” guide wire prior to the denervation ablation on each side. A self-balancing balloon inflates to provide a force opposite the needle tip for proper seating of the needle, through which anesthetic agent can be delivered to the adventitia and perivascular tissue. A 1:1 mixture of 1% Lidocaine and intravenous contrast was used for localized injection. Adequacy of agent delivery was determined by the presence of circumferential contrast distribution around the renal artery on fluoroscopy.

Results: Site-specific delivery of anesthetic agent was performed in 4 patients undergoing renal denervation (3 radiofrequency-based and 1 ultrasound-based). Low dose lidocaine was given for 1 patient at the start of the procedure. No intravenous lidocaine or morphine was necessary for the remaining patients. No denervation-specific pain was reported. Final renal angiography showed no significant spasm or dissection. All patients were discharged on the following day.

Conclusion: Site-specific delivery of anesthetic agent may be a feasible strategy to achieve optimal pain control in patients undergoing renal denervation for treatment-resistant hypertension.

TCT-496
Impact of Criteria Stringency on Eligibility for Renal Denervation in Hypertensive Outpatients
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Background: Renal denervation (RDN) has been shown to be safe and effective in reducing blood pressure in select patients with resistant hypertension. Upcoming trials aim to examine its use for more moderate manifestations of resistant hypertension. We sought to determine the impact of broadening the eligibility criteria used in prior RDN studies on the number of patients who could be eligible for RDN, and to compare the clinical characteristics of RDN eligible versus non-eligible hypertensive patients in a fixed population of hypertensive outpatients.

Methods: We applied methodologic criteria from the SYMPLECTHY HTN-3 study to consecutive hypertensive outpatients presenting to an academic cardiology clinic to identify patients eligible for RDN. Inclusion criteria were as follows: age ≥ 18 and <80 years old, systolic BP > 140, and ≥ 2 anti-hypertensive medications at maximal doses of which one was a diuretic, and creatinine clearance > 45. We then examined the impact on eligibility for RDN of including patients with systolic BP >140 and creatinine clearance <30. Patients with renal arterial stenosis, or noncompliance were excluded. Demographic and clinical characteristics of patients were compared between those who did and did not meet criteria for RDN.

Results: We identified 1756 hypertensive outpatients; they were predominantly male (54.9%) and white (53.2%), had a mean age of 66.6 ±12.6 years, and a BMI of 30.1 ±10.8 kg/m2. Only 22 of these patients (1.3%) would be eligible for RDN under SYMPLECTHY HTN-3 criteria. Among these patients, 16 (72.2%) were female and 20 (90.9%) were black, with a mean age of 68.9 ±10.4 and BMI of 33.2 ±6.8. Expanding eligibility for RDN to include patients with SBP >140 and CrCl<30 lead to a near three-fold increase in eligible patients (53 patients or 3.0%).

Conclusions: Patients meeting criteria for RDN based on existing published studies represent an exceedingly small proportion of the total hypertensive population. Broadening inclusion criteria, while still only relevant to only a small proportion of the total hypertensive population, but a 375% increase over what prior studies would predict.

TCT-497
Arterial Media Preservation Associated with The Paradise Ultrasound Renal Denervation System: A Next generation Approach for Treating Resistant Hypertension
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Background: The SYMPLECTHY HTN-3 study is the first large randomized controlled trial to demonstrate the Efficacy and safety of renal denervation (RDN) in patients with resistant hypertension. The SYMPLECTHY HTN-3 study showed that 30 patients with resistant hypertension treated with RDN showed a significant 14±12mmHg decrease in systolic blood pressure (SBP) after 6 months of follow-up compared to a decrease of 7±0mmHg in the control group. However, the impact of using the Paradise Ultrasound RDN system has not been fully elucidated. The Paradise ultrasound RDN system provides a disruptive force opposite the needle tip for optimal seating of the needle and precise delivery of the RDN energy to target renal arteries. In this poster, we will present the outcomes of the PARADISE registry, the largest real-world registry to date, which examined the outcomes of patients treated with the Paradise RDN System.