TCT-10

Efficacy of renal denervation is positively impacted by longitudinal treatments

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Background: Catheter-based percutaneous renal denervation (RDN) has shown durable reductions of blood pressure in patients with uncontrolled hypertension. The importance of applying circumferential denervations inside the renal arteries is known to contribute to efficacy; however, the significance of denervations along the entire renal artery length is yet to be appreciated.
Methods: We used the V2 System™ (Vessix Vascular Inc., Laguna Hills, CA) for the renal denervation procedures. The V2 System consists of a proprietary bipolar RF generator and an over-the-wire low pressure balloon catheter with an array of radiofrequency (RF) electrodes mounted on the exterior in an offset helical pattern. Each temperature controlled dose (68°C) of bipolar energy is delivered for 30 seconds. A total of 15 juvenile Yorkshire swine were treated bilaterally (n=3 in each group, see table). Efficacy was evaluated at 14 days post treatment using an HPLC-MS/MS method to measure kidney tissue norepinephrine (NEPI). In addition, histopathologic methods were used to assess the percentage of affected nerves.
Results: A single V2 treatment per artery with 95% circumferential coverage and 60% length coverage (21 mm) was applied resulting in 40% of nerves being affected and a NEPI reduction of 46% when compared to control group endogenous level. Increasing the circumferential coverage by 35% did not change efficacy. However, increasing coverage length by 40% significantly increased NEPI reduction to 78% and significantly increased the percentage of affected nerves to 58% ($p<0.05$) and was comparable to surgical denervation.

Treatment	Description	Circumferential coverage (%)	Average length coverage (%)	Average NEPI (ng/g)	NEPI reduction (% vs. control)	Percentage of affected nerves
Single V^2 treatment	One treatment per artery (each electrode = 4 mm long and 2.5 mm wide)	95%	60%	322±331	−46%	40%±11
V^2 treatments of full artery length	Up to 2 treatments in order to treat the entire length of the artery (proximal treatment could be partial, with only a few RF electrodes activated)	95%	100%	132±191	−78%	58%±17
Single V^2 treatment using balloon with horizontal RF electrodes	Electrodes were positioned in an horizontal pattern in order to increase circumferential coverage (each electrode is 2.5 mm long and 4 mm wide)	130%	60%	356±321	−41%	37%±14
Surgical denervation	Adventitia was separated along the entire length of the artery and renal nerves removed	100%	100%	154±285	−75%	NA
Untreated Sham control	Interventional procedure, without renal denervation treatment.	0%	0%	601±61	0%	0%

Conclusions: Longitudinal denervations of the renal artery, in addition to circumferential denervations during RDN procedures, results in greater efficacy. The Vessix V2 Renal Denervation System may offer advantages since it allows for both longitudinal and circumferential denervations with short treatment duration.

TCT-11

Renal Sympathetic Denervation - Inducing An Instantaneous And Persisting 24h Ambulatory Blood Pressure Drop In Patients With Resistant Hypertension – Results From The Halle-RDN-Registry

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Background: Catheter-based renal sympathetic denervation (RDN) has proved 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 relying on 24h ambulatory blood pressure monitoring (ABPM). However, ABPM is commonly regarded as a much more reliable method and therefore a better approach to evaluate the effects of RDN.
Methods: Our study carefully investigated the early and subsequent blood pressure response to RDN in a cohort of 120 consecutive patients with resistant hypertension (systolic BP ≥150 mm Hg on ≥3 antihypertensive drugs). Baseline values included a mean age of 64.5±9 years, 48% women, 45% diabetic, 18% coronary artery disease and 5.7 ±1.5 antihypertensive medications. A 24h Holter BP monitoring was recorded in every patient 24h before as well as 24h, 3 and 6 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 analysed with repeated measures ANOVA and Greenhouse-Geisser correction if indicated.
Results: In treated patients mean averaged systolic 24h BP was reduced by 9.68±1.59 mmHg ($p<0.001$; n 120) during the first 24 hours. Systolic blood pressure reduction appeared to be much higher at daytime (12.1±1.63 mm HG; $p<0.001$) compared to nighttime (4.4±1.79 mm Hg; $p=0.016$) which might indicate the role of sympathetic activity at daytime. A concordant effect on diastolic BP was observed: 5.9±0.88 mmHg ($p<0.001$). Systolic BP reduction sustained at 3 (6.3±1.84 mm Hg, $p<0.005$, n 74) and 6 months (6.7±3.0 mm Hg, $p=0,201$, n 38) without further decrease.
Conclusions: In patients with resistant hypertension, catheter-based RDN results in an immediate and persisting reduction of systolic and diastolic ABPM. Compared to office-based data ABPM effects are expectedly less pronounced. Our analysis did not confirm the so far described gradual drop in BP up to 6 months. On the contrary a slight non-significant compensation of BP reduction was observed after the initial drop between day one and the 3 as well as 6 months follow-ups.

TCT-12

Long-term Follow-up of Catheter-based Renal Denervation For Resistant Hypertension Confirms Durable Blood Pressure Reduction

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Background: Renal denervation (RDN) using low power radiofrequency energy has been shown to substantially reduce blood pressure (BP) in patients with treatment-resistant hypertension. Documentation of duration of antihypertensive effects and the potential for late development of adverse events is important for determining proper positioning of this therapy.
Methods: Symplicity HTN-1 is an open-label cohort study which enrolled 153 patients with systolic BP ≥160 mm Hg while taking ≥3 antihypertensive drugs at optimal dosages, including a diuretic. Patients were followed semi-annually to 3 years post-RDN. Changes in office-based BP, changes in distribution of BP measurements, renal function, electrolytes, and medication usage were monitored through 3 years follow-up. Systolic BP (SBP) reductions of 10 mmHg or more were determined at 1 month and the rates of delayed response thereafter were calculated.
Results: 114 patients have been followed through 2 years post-RDN and 34 patients for 3 years. Mean age at baseline was 57±11 years; 39% of patients were female; 31% had type 2 diabetes mellitus; eGFR was 83±20 mL/min and BP was 175/98±17/15 mmHg. Mean SBP change post-RDN was −32.7 ± 18.4 mmHg at 2 years and −33.1 ± 13.3 mmHg at 3 years. A SBP drop ≥10 mmHg occurred in 69% of patients at 1 month, and of the patients with <10 mmHg drop in SBP at 1 month 64%, 82%, and 100% responded with a reduction in SBP >10 mmHg at 1, 2, and 3 years, respectively. There was one progression of a pre-existing renal artery stenosis and 3 deaths 2.0% unrelated to the device or therapy.
Conclusions: RDN results in a significant and durable reduction of SBP in patients with treatment-resistant hypertension. Patients with minimal initial reduction in BP may have significant reductions later which are not explained by medication changes. Safety and efficacy data on a larger cohort of patients with 2 and 3 year follow-up will be presented.

TCT-13

Renal resistive indices, urinary albumin excretion and renal function in patients with resistant hypertension after catheter-based renal sympathetic denervation

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Background: Increased renal resistive index (RRI) and urinary albumin excretion (UAE) are markers of hypertensive end-organ damage. Increased sympathetic activity is a main contributor to the pathophysiology. Catheter-based renal sympathetic denervation (RD) offers a new interventional approach to reduce renal sympathetic activity and blood pressure in resistant hypertension. The influence of RD on renal hemodynamics, renal function, and UAE in patients with resistant hypertension has not been studied.
Methods: One hundred consecutive patients with resistant hypertension were included in the study. 88 underwent interventional RD and 12 served as controls. Systolic, diastolic