

run in period, baseline blood pressure, type and quality of sedation, and power levels.

RESULTS The office blood pressure (obp) drop in the sham and treatment groups respectively for all patients at 3 months was 20.4 (sd 22.3) and 16.3 (sd 17.5). The ambulatory blood pressure (ABPM) for all patients in the sham and treatment group respectively at 6 months was 8.2 (n=25, sd 16.3) and 7.2 (n=27, sd 12.8). In the subgroup with pulse pressure <65, obp in the sham and treatment groups at 3 mos were 12.7 (n=9, sd 20.1) and 31.7 (n=8, sd 31.7) respectively and ambulatory BP in the sham and treatment groups was 8 (n=5 sd 16.6) and 19 (n=7 sd 19.4) respectively. In the subgroup of patients who were stable in the run in or who had a pulse pressure <65, obp drop was 15.6 (n=22 sd 13.5) and 19 (n=25 sd 21.7) in the sham and treatment groups respectively. ABPM drop at 6 mos was 2.8 (n=15 sd 11.6) and 9.8 (n=18 sd 15.6) in the sham and treatment groups respectively.

CONCLUSION These data are intriguing and hypothesis generating. Specific subgroups may have a greater propensity toward being sham responders. Perhaps patients with the most unstable and volatile blood pressures are also most likely to have a sham response. These data show that patients with stable run in and with lower pulse pressure have a smaller sham effect. Subgroup selection for future studies may be more about minimizing sham effect than maximizing the absolute treatment effect. Treatment optimization could be called sham effect minimization strategies.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

TCT-205

Effect of renal denervation on cardiac function in post-infarction swine models induced by balloon occlusion

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BACKGROUND The study sought to assess whether catheter-based renal denervation (RDN) could prevent cardiac function deterioration early after myocardial infarction (MI).

METHODS Anterior MI was induced in 28 male Chinese mini-swines by transient balloon occlusion of left anterior descending coronary artery. Then the swines were randomly assigned to receive bilateral catheter-based RDN (RDN group, n=14) or sham-denervation (sham group, n=14). Both two groups were studied up to 8 weeks. All of the RDN procedures were performed by experienced operators strictly adhered to recommendations provided by the catheter manufacturer. Before and after the modeling and 8 weeks after the intervention, the cardiac function would be determined by measuring left ventricular ejection fraction (LVEF) with 2-D echocardiography and Cardiac Output (CO) with Swan-ganz catheter. Data from two group were compared using repeated measures ANOVA (rmANOVA).

RESULTS Modeling process is optimal and the baseline characters were well adjusted as covariable using rmANOVA. Significant time x group interaction effects were detected with respect to LV end diastolic volume (EDV) and LVEF. EDV and LVEF increased more in RDN group than sham group after AMI (32.55±8.90 to 52.69±9.73 ml vs. 31.05±14.56 to 38.5±12.33 ml, P=0.015 for interaction; 53.06±11.11 to 60.47±9.30 % vs. 57.29±11.42 to 51.71±12.24 %, P=0.016 for interaction). Meanwhile heart rate tended to be lower and CO tended to be higher in RDN group but they both failed to show a significant benefit (122±21 to 101±33 bpm vs. 118±28 to 114±36 bpm, P=0.346 for interaction; 2.00±0.55 to 2.59±0.41 L/min*m2 vs. 1.98±0.50 to 2.19±0.72 L/min*m2, P=0.336 for interaction). There were no significant changes in left ventricle geometric patterns and diastolic function as well as the blood pressure.

CONCLUSION Renal denervation shows significant improvements on cardiac function in acute myocardial infarction swine models induced by balloon occlusion, mainly due to the increase of EDV which suggests beneficial effects on ventricular remodeling.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

TCT-206

Atrial Fibrillation Reduction by Renal Sympathetic Denervation (AFFORD study), one-year outcome

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BACKGROUND Hypertension is most common cardiovascular condition responsible for the development and maintenance of atrial fibrillation (AF). While renal denervation (RDN) has been studied to help controlling drug-resistant hypertension its potential value in improving signs and symptoms of AF is currently unknown. The aim of the present pilot study is to assess whether RDN will decrease AF burden and symptoms in patients with symptomatic AF at one-year follow-up as measured using an implantable cardiac monitor (ICM) and the Atrial Fibrillation Effect on Quality-of-life [AFEQT] questionnaire.

METHODS Between July 2014 and February 2016 a total of 20 patients with symptomatic paroxysmal or persistent AF (EHRA ≥ II) and primary hypertension with a mean office systolic blood pressure (BP) of >140mmHg were enrolled, after enrollment and 3 months before RDN, an ICM was implanted to monitor AF burden prior to the RDN procedure and during the follow-up period. RDN was performed using a dedicated multi-electrode unipolar denervation catheter with the intention to achieve 8 successful ablations per artery. Patients were subsequently followed-up at 1, 3, 6, and 12 months for AF burden, BP control and quality of life using the AFEQT questionnaire.

RESULTS A total of 11 females and 9 males were included, mean age was 64 ± 7yr. At baseline, 75% of the patients presented in EHRA class II and 25% in EHRA class III. Most patients were on rhythm control (19/20) and 4 patients had a history of pulmonary vein isolation. Office BP decreased from 153 ± 17/88 ± 10mmHg at baseline to 147 ± 17/80 ± 10mmHg at 6 months, while ambulatory BP changed from 131 ± 16/78 ± 9mmHg at baseline to 121 ± 9/72 ± 6mmHg at 6 months (p<0.01). Mean heart rate on 24h holter monitoring remained unchanged. AF minutes/day (median [IQR]) was 1.26 minutes [0-10.6] at baseline versus 0.67 minutes [0- 31.6] at 6 months (p=0.98), the number of AF episodes remained unchanged. At 6 months 75% of the patients were in EHRA class I (p<0.001) and QOL improved significantly. One-year results will be presented at the meeting.

CONCLUSION Preliminary results of this single center pilot study suggest that RDN was able to significantly improve symptoms of AF at 6 months. While AF burden measured using an ILR was lower than expected, a numerical change was found in AF burden following RDN.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

TCT-207

Endovascular renal sympathetic denervation to improve heart failure with reduced ejection fraction, preliminary results IMPROVE-HF-I study

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BACKGROUND Chronic heart failure (CHF) has been characterized by sympathetic overactivity. Despite improvements in medical and device therapy, patients remain symptomatic and the prognosis remains poor. The aim of the present study is to assess the safety and efficacy of decreasing sympathetic activity by renal sympathetic denervation (RDN) in patients with symptomatic heart failure with reduced ejection fraction (HFrEF).

METHODS A total of 70 patients with an left ventricular ejection fraction (LVEF) ≤ 35% and NYHA class ≥ II will be randomized (1:1) to treatment with RDN or optimal medical therapy (OMT) alone. Patients will be followed for 5 years and will assessed at 1, 3 and 6 months, and yearly up to 3 years, with change in heart to mediastinum ratio at 6 months assessed by 123 meta-iodobenzylguanidine (123I-mIBG) as the primary endpoint. Secondary endpoints include; echocardiographic