stage kidney disease on the affected diseased kidney. One patient was pre-transplant and had both kidneys treated. One week after cystoscopy aided transurethral treatment with the NephroBlate™ device, the previously planned nephrectomy was performed. Following this we treated 4 resistant hypertensive patients.

Results: Nephrectomy Patients – Procedure time was between 9 to 15 min., and no adverse effects were recorded. The histopathological results of the treated kidney in all cases showed a significant destruction of the peri-pelvic nerves from the renal pelvic space to the serosa (1.75mm). We then proceeded with our clinical studies on resistant hypertensive patients. Resistant Hypertensive Patients – Four patients were treated utilizing a standard urologic procedure with OR times of 16-25 mm. Within 30 seconds of treatment of the first kidney, a blood pressure response was noted (reduction of mean systolic blood pressure 44mmHg, reduction of mean diastolic blood pressure 13mmHg). Following the procedure, none of the patients had significant pain or bleeding.

Conclusions: At six month follow-up, the patients continue to be normotensive with no need for antihypertensive medications. A safer and more effective approach to renal denervation and delivering the safety and feasibility of a novel approach to this treatment for renal denervation. Focused ultrasound energy was delivered to the proximal renal arteries and surrounding tissue using non-invasive Doppler-based imaging and continuous tracking with automatic correction for kidney motion throughout treatment. All patients received conscious sedation during treatment and tolerated treatment well.

Results: Fourteen patients completed at least the 6-Week Follow-up Visit, and three subjects completed the 24-Week Follow-up Visit. No serious device related events have been reported during treatment or during the initial three week follow-up period. Small amount of transient back pain was reported, clinically insignificant back pain immediately following treatment with complete resolution within 24 hours in a majority of patients. One patient developed post-procedural transient hypokalemia, probably unrelated to renal denervation, which resolved with potassium replacement. Of the 14 patients who have completed the 6-Week Follow-up visits, 11 (78.6%) achieved a systolic blood pressure (SBP) decrease of at least 10 mmHg, with an average SBP decrease of 23 mmHg and an average diastolic blood pressure decrease of 9 mmHg.

Conclusions: Initial results of this fully non-invasive renal denervation system demonstrate it was well tolerated and safely delivered. This study provides clinical image guidance for targeting and continuous tracking with automatic motion correction enabled patients to benefit from renal denervation therapy without the invasive risks associated with catheter based renal denervation.

TCT-413

Intra-luminal ultrasound renal denervation effectively reduces sympathetic nerve activity; a translational comparison of preclinical and clinical data

Anul Pathak1, Lynn Bailey1, James Staley1, Kenichi Sakakura2, Leslie Coleman1, Elena Ludich1, Michael Jones1, Renu Virmani3,4,5
1Cardiovascular and Metabolic Pole, Ramgam Hospital, Toulouse, Toulouse, France,2CSBET, Inc., Lexington, MA, 3CVPath, Institute, Gaithersburg, MD, 4ReCor Medical, Menlo Park, CA, 5CVPath Institute Inc., N/A, 6CVPath Institute Inc., Gaithersburg, United States

Background: The Paradise® Renal Denervation System (ReCor Medical, Palo Alto, CA) is designed to deliver ultrasound (US) energy to perform circumferential denervation of the renal sympathetic nerves. As current renal denervation systems do not allow for immediate biofeedback to the user regarding effective denervation, it is critical to generate mechanism of action data. We demonstrate in a preclinical model and in humans that US denervation decreases sympathetic nerve activity post procedure, which should translate into potential clinical benefit in humans.

Methods: Bilateral ultrasound renal denervation was performed in 8 normotensive pigs. Pigs received 1, 2, or 3 bilateral US emissions. At 7 days, kidney norepinephrine (NEP) levels were measured by HPLC/MS to assess sympathetic nerve activity, and renal nerve injury was assessed histologically. MSNA data was collected at baseline and one month post procedure in 5 patients enrolled in the REALISE trial in France.

Results: 2 or 3 bilateral US emissions. Office BP was recorded at 1 month and correlations between BP and MSNA reduction performed.

Results: Kidney NEPI levels were significantly reduced in all animals and correlated with the degree of nerve damage. 2 or 3 bilateral ultrasound emissions resulted in 89% or 97% NEPI reduction, respectively. A reduction in NEPI ≥99% correlated with ablation of 76% of nerves along the length of the renal artery. In humans, a reduction in MSNA was observed in all 5 patients (mean 17%) 1 month following US denervation. The decrease in MSNA correlated with a decrease in BP ≥10mmHg in 4 of 5 patients suggesting that US is effective in reducing sympathetic nerve activity, which should translate into clinical benefit to a subset of patients.

Conclusions: Translational data is critical towards understanding the mechanism of action associated with renal denervation devices. Ultrasound renal denervation effectively and consistently reduced sympathetic activity acutely in a preclinical model and in a small subset of patients providing evidence that the technology is performing as intended in vivo.

TCT-414

Obesity Is Associated With A Less Pronounced Treatment Response After Renal Denervation

Dane Ild1, Stefan C. Bertog2, Ann-Kathrin Ziegler1, Marius Hornung1, Ilona Hofmann1, Laura Vaskelyte1, Sameer Gafoor1, Horst Sievert1
1CardioVascular Center Frankfurt, Frankfurt, Germany

Background: Catheter-based renal denervation (RDN) causes significant blood pressure (BP) reductions in patients with resistant hypertension. The purpose of this study was to identify predictors of BP response.

Methods: This is a single-center, non-randomized, uncontrolled retrospective analysis of hypertensive patients. One hundred one consecutive patients with resistant hypertension who underwent RDN with the Symplicity™ catheter were included. Uni- and multivariate logistic regression analyses were performed to detect baseline predictors of significant BP response 6 months after RDN (age, gender, of hypertension, weight, body mass index, previous unconventional antihypertensive treatment, diabetes, number of ablations).

Results: The patients included in this study were 61 males and 40 females, with a mean age of 59.2 years [52.8 ± 11.0 years]. The number of previous antihypertensive medications, procedural number of ablation, and the primary endpoint was the change in office BP at 6-month follow-up compared to baseline and between groups.

Results: The patients included in this study were 61 males and 40 females, with a mean age of 59.2 years [52.8 ± 11.0 years]. The number of previous antihypertensive medications, procedural number of ablation, and the primary endpoint was the change in office BP at 6-month follow-up compared to baseline and between groups.

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Results: The patients included in this study were 61 males and 40 females, with a mean age of 59.2 years [52.8 ± 11.0 years]. The number of previous antihypertensive medications, procedural number of ablation, and the primary endpoint was the change in office BP at 6-month follow-up compared to baseline and between groups.
Upon univariate analyses, baseline office systolic BP (p<0.0001) and BMI (p=0.014) were identified as significant predictors of a BP response after 6 months. Obese patients with a BMI ≥ 30.0 had a significantly lower BP response after 6 months (-8.9 ± 18.8 mmHg) compared to normal-weight patients with a BMI ≤ 29.9 (-20.1 ± 24.9 mmHg; p=0.013). Importantly, stepwise backward regression model revealed baseline office systolic BP (standardized β=-0.46; r=-0.47; p< 0.0001) and BMI (standardized β=0.11; r=0.95; p=0.019) as significant variables for BP response after 6 months. The other variables remained insignificant.

Conclusions: Hypertension severity and BMI are important predictors of BP response to RDN. BP reduction after RDN is, in fact, more pronounced in patients with lower BMIs. These findings may help in patient selection.

TCT-415
CATHETER-BASED RENAL SYMPATHETIC DENERVATION FOR RESISTANT HYPERTENSION: A META-ANALYSIS OF RANDOMIZED TRIALS

Daniel Garcia1, Mohammad M. Ansari2, Rhanderson N. Cardoso1, Eduardo de Marchena3
1University of Miami, Miami, FL, 2University of Miami - Jackson Memorial Hospital, Miami, FL, 3University of Miami Miller School of Medicine, Miami, FL

Background: Percutaneous renal artery denervation has been shown to decrease blood pressure among patients with resistant arterial hypertension. We present in this review a meta-analysis of all randomized controlled trials evaluating effectiveness and complications of catheter-based RDN for blood pressure control in patients with resistant hypertension.

Methods: Pub Med, Chocrane and Scopus were systematically searched up to May 2014. Primary outcomes were 6 months reduction of of resistant hypertension. Studies that had a minimum follow up period of 6 months were included. Meta-analysis of the weighted mean difference of pre and post renal denervation blood pressures was performed using random effects model.

Results: A total of 18 studies met our inclusion and exclusion criteria and were included in the final analysis. Office blood pressures were reported in 16 studies, while ambulatory blood pressures were reported in 7 studies. At 6 months, post renal denervation, the office systolic blood pressure decreased by 25.2 mm Hg (95% CI, 24.7 – 25.7 mm Hg). Office diastolic blood pressure was lowered by 9.6 mm Hg (95% CI, 8.1 – 11 mm Hg). The ambulatory systolic and diastolic blood pressures also decreased by 12 mm Hg (95% CI, 4.4 – 19.7 mm Hg) and 6.5 mm Hg (95% CI, 3.3 – 9.5 mm Hg), respectively. At 1 year after renal denervation, the office systolic blood pressure was lowered by 24.6 mm Hg (95% CI, 21.9 – 27.4 mm Hg). The office diastolic blood pressure was decreased by 10.7 mm Hg (95% CI, 8.4 – 12.9 mm Hg) at 1 year follow up.

Conclusions: Renal denervation effectively lowers both systolic and diastolic blood pressures in subjects with resistant hypertension. The blood pressure lowering effect appeared to be sustained at 1 year after renal denervation.

TCT-416
Renal Denervation for the Management of Resistant Hypertension: A Meta-Analyses

Aran K. Kamnathareddy1, Nivedita P. Adabala1, Avanuja R. Buddam2, Venkata Sandeep Koripalli1, Pramod Janga3, Manjari Devidi4, Sunil Dacha4, Madhu Reddy1, Dhanunjaya Lakitikreddy1
1The University of Kansas Hospital, Kansas City, KS, 2The University of Kansas Hospital, Kansas City, KS, 3Th University of Kansas Hospital, Kansas City, KS, 4Emory University Hospital, Atlanta, GA

Background: Renal denervation interrupts the sympathetic pathways to the kidneys and therefore may decrease blood pressure. This technique is increasingly being evaluated for the management of resistant hypertension.

Methods: All the available electronic databases were queried for studies on renal denervation for resistant hypertension. Studies that had a minimum follow up period of 6 months were included. Meta-analysis of the weighted mean difference of pre and post renal denervation blood pressures was performed using random effects model.

Results: A total of 18 studies met our inclusion and exclusion criteria and were included in the final analysis. Office blood pressures were reported in 16 studies, while ambulatory blood pressures were reported in 7 studies. At 6 months, post renal denervation, the office systolic blood pressure decreased by 25.2 mm Hg (95% CI, 24.7 – 25.7 mm Hg). Office diastolic blood pressure was lowered by 9.6 mm Hg (95% CI, 8.1 – 11 mm Hg). The ambulatory systolic and diastolic blood pressures also decreased by 12 mm Hg (95% CI, 4.4 – 19.7 mm Hg) and 6.5 mm Hg (95% CI, 3.3 – 9.5 mm Hg), respectively. At 1 year after renal denervation, the office systolic blood pressure was lowered by 24.6 mm Hg (95% CI, 21.9 – 27.4 mm Hg). The office diastolic blood pressure was decreased by 10.7 mm Hg (95% CI, 8.4 – 12.9 mm Hg) at 1 year follow up.

Conclusions: Renal denervation effectively lowers both systolic and diastolic blood pressures in subjects with resistant hypertension. The blood pressure lowering effect appeared to be sustained at 1 year after renal denervation.

TCT-417
REALISE Trial: Renal Denervation by Ultrasound Transcatheter Emission: Six Month Results

Gilles Montalescot1, Philippe Cluzel1, Xavier Gireoud1, Aat Pathak1
1Pitié-Salpêtrière University Hospital, Paris, France, 2Hopital Pitié-Salpêtrière, Paris, France, 3Cardiovascular and Metabolic Pole, Rangueil Hospital, Toulouse, France

Background: The Paradise® Renal Denervation System (ReCor Medical, Palo Alto, CA) delivers ultrasound (US) energy to perform circumferential denervation of the renal sympathetic nerves. The REALISE trial is a French post-market study in moderate resistant hypertensive (RH) patients with active hypertension medication management. Six-month safety and effectiveness data will be presented, as will MSNA data collected in a subset of patients to evaluate the ability of US denervation to down-regulate sympathetic activity.

Methods: The REALISE trial is a prospective, single-arm, open-label study. The study enrolled patients with office BP >140/90, confirmed by ambulatory measures, and on a minimum of 3 medications. Patients were treated with up to 3 US emissions bilaterally. All patients underwent CT scan or MRI at baseline and follow-up to assess the renal arteries. Office and ambulatory BP measures and changes in medications were recorded at regular intervals. MSNA was obtained in five patients at baseline and post procedure.

Conclusions: Resistant hypertension treated with catheter-based RDN respond better to blood pressure reduction and with sustained control without carrying significant kidney and therapy-associated complications. It is yet to be determined if some RDN catheters are capable to provide more concise results and therefore lead to better procedural outcomes. Therefore more randomized clinical data are warranted.