stage kidney disease on the affected diseased kidney. One patient was pre-renal transplant and had both kidneys treated. One week after cystoscopy aided transurethral treatment with the Nephirole™ 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 urorologic 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).

Followingle 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 adverse effects. MSNA response was immediate and occurred while the patients were under general anesthesia. In this small series of humans treated with limited follow-up, we see a promising nonvascular alternative for renal denervation for treatment for resistant.

TCT-410

**Evaluation of the Acute and Long Term Renal Artery Re-Innervation Attempt Response Following Radiofrequency Catheter-Based Renal Nerve Ablation in a Swine Model: A Immunohistochemical Characterization**

Serge D. Rousselle', Randy Harr', Javier A. Garza', Joan Wicks', Armando Tellez', 'Alizee Pathology, LLC, Thurmont, MD

**Background:** Catheter-based renal denervation (RDN) has demonstrated efficacy in controlling blood pressure in clinical trials. The long-term effect in blood pressure and nerve “regrowth” has been questioned. We aimed to study and characterize the renal nerve response following RDN acutely and long-term.

**Methods:** Swine underwent bilateral RDN and they were followed for 7, 30, 90 and 180 days. At each time point renal arteries were harvested for further histological analysis. A representative section of each time point was selected for regular H&E staining and immunohistochemical (IHC) analysis. The IHC evaluation of the renal arteries consisted on S100 (Schwann cell), Tyrosine hydroxylase (TH; efferent motor fibers and con- nective tissue. This is the first complete histological characterization of neuromatous nerve regrowth following RDN.

TCT-411

**Abstract Withdrawn**

TCT-412

**Non-invasive Renal Denervation Using Externally Delivered Focused Ultrasound: Early Experience Using Doppler based Imaging Tracking and Targeting for Treatment**


1Cardiovascular and Metabolic Pole, Ramspol Hospital, Toulouse, Toulouse, France
2Cardiovascular and Metabolic Pole, Ramspol Hospital, Toulouse, Toulouse, France
3CVPath, Institute, Gaithersburg, MD, 4ReCor Medical, Menlo Park, CA, 5CVPath, Institute, Gaithersburg, MD

**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 noradrenaline (NE) 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:** Patients received 2 or 3 unilateral US emissions. Office BP was recorded at 1 month and correlations between BP and MSNA reduction performed.

**Conclusions:** 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 was correlated with a decrease in BP ≥10mmHg in 4 of 5 patients suggesting that US is effective in reducing sympathetic nerve activity, which may translate into clinical benefit in a subset of patients.

TCT-413

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


1CVPath, Institute, Gaithersburg, MD, 2ReCor Medical, Menlo Park, CA, 3CVPath, Institute, Gaithersburg, Maryland, 4CVPath Institute Inc., N/A, 5CVPath Institute, Inc., Gaithersburg, United States

**Background:** Targeting for Treatment

Targeting for Treatment

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, office and ambulatory BP, MSNA, body mass index, body fat mass, diabetes, history of angina, medication, number of ablations). Primary endpoint was the change in average 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 58.2 ± 11.9 years and BMI of 30 ± 11.4 kg/m². A total of 56 (71%) patients received combination therapy with at least 3 medications, with antihypertensive medications. The most common medications used were angiotensin converting enzyme inhibitors (ACEIs) (n=19, 25%), beta blockers (n=16, 21%), calcium channel blockers (n=14, 18%), diuretics (n=12, 16%), angiotensin receptor blockers (n=9, 12%), and others (n=2, 3%). The mean baseline systolic and diastolic pressures were 182 ± 15 mmHg and 109 ± 10 mmHg, respectively. Mean office and ambulatory BP at baseline were 166.0±16.0/90.2±16.0 mmHg and 122.5±15.0/75.0±16.0 mmHg, respectively.

**Conclusions:** The results of this study suggest that the use of RDN in patients with resistant hypertension is associated with significant BP reductions. The most important predictors of BP response were age, gender, and number of medications.