Renal Denervation
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TCT-204
Impact of temperature, energy output and impedance drop during renal denervation on the long-term outcome

Klaus Tiroch1, Armin Sause1, Ina Schmitz1, Jacke Szczynski1, Melchior Seyfarth2
1HELIOS Klinikum, Wuppertal, Germany, 2HelELIOS Klinikum, Wuppertal, Germany

Background: Renal denervation (RDN) through catheter ablation is emerging as a promising therapeutic option for refractory hypertension, but the decrease in blood pressure (BP) is difficult to predict and is usually evident only after months. No acute variable is available to date to predict the BP response.

Methods: This analysis is based on 23 patients with RDN performed at our institution within the last 14 months. Complete information regarding all ablation points was present for 18 patients (194 ablation points). 15 patients had complete 3-months follow-up including 24-hour BP, and for 10 of these patients the complete information regarding the ablation points was present.

Results: 20 patients had a bilateral RDN with 4.5±1.2 ablation points per renal artery. 2 patients only monolateral due to 40% narrowing of the other artery. One patients experienced asystole after initial RDN of the first renal artery requiring CPR and intubation. He received a pacemaker and recovered completely. 79.9% of ablation points required the max. energy output (8W). The BP decreased from 151/77 to 134/72 mmHg (P=0.07 for syst. RR) and the percentage of patients with systolic BP >140mmHg from 57% to 31% (P=0.04) on an average of 3.8±0.9 medications.

Conclusions: RDN can reduce hypertensive peaks. Marked suppression of sympathetic activity can cause bradycardia and hypotension and requires alert supervision during ablation. Impedance drop correlates highly significant with ablation temperature and seems to correlate better with long term reduction of mean BP than ablation temperature, suggesting an impact of impedance drop on outcome.

TCT-205
Histologic analysis of renal nerve injury following catheter-based renal denervation in obese, hypertensive canines

Jeffrey Henegar1, Yongxing Zhang2, Rita DeRama2, Cary Hase2, John Hall1
1University of Mississippi Medical Center, Jackson, MS, 2St. Jude Medical, Inc., Irvine, CA

Background: Catheter-based intravascular renal denervation (RD) using radiofrequency energy has shown promise in the treatment of resistant hypertension. However, to date, no studies have examined the extent of renal nerve injury following RD.

Methods: To examine renal nerve injury following RD, nine obese, hypertensive dogs underwent bilateral RD using the St. Jude Medical EnligHTN™ renal denervation system and eight weeks of hemodynamic monitoring. At the end of the eight-week system, both left and right renal arteries were collected from the aorta to the kidneys. The renal arteries were cut into equal sections, fixed, and embedded in paraffin. Multiple five-micron sections were taken from the bifurcation, main renal artery, and the ostium and stained with hematoyxlin-eosin. Sections were examined for the total number of nerves, number of injured nerves, and the distance measured from nerves to the renal artery lumen.

Results: Renal nerves were found from 0.28 mm to 6.7 mm from the renal artery lumen. Twelve percent of the nerves were between 0.28mm and 1mm from the artery lumen, fifty-seven percent between 1mm and 2.5 mm, seventeen percent between 2.5mm and 3.5mm, and fourteen percent between 3.5mm and 6.7mm. Forty-two percent of nerves exhibited injury due to RD (157 out of 371); however, since samples were examined 8 weeks after RD, some injured nerves may have degenerated and become unobservable. Injury was found at nearly all distances from the artery lumen. In 70%, injury was most prevalent from 0.28mm to 3.5mm. Renal nerve injury was noted further out. The injury further from the luminal surface is presumably the result of Wallerian-type degeneration. The current study showed that RD using the St. Jude Medical EnligHTN™ renal denervation system does cause significant injury to renal nerves.

TCT-206
A Pilot Study on Renal Sympathetic Denervation for Resistant Hypertension in the West of Ireland

Imitza Kalyar1, James Gleeson1, Sajjad Matiullah1, Faisal Sharij2
1Galway University Hospitals, Galway, Galway

Background: Renal Sympathetic Denervation (RSD) is a novel, device-based intervention for the management of resistant essential hypertension (RH). Here we present the data from the initial clinical experience with RSD in the West of Ireland.

Methods: All patients in this pilot study (n=12) had RH, and were on a minimum of 3 medications. The effect of RSD on office blood pressure, 24 hour ambulatory blood pressure, number of anti-hypertensive medications, renal function, weight, serum uric acid concentration, secondary fraction of sodium, and renin-aldosterone levels was investigated. We also assessed the safety of the procedure. Prior to intervention secondary causes of hypertension were excluded, and detailed anatomy of the renal arteries was obtained using either CT or MR angiography. Patients were followed up at 2 weeks, 2 months and 6 months for serum biochemistry, urinalysis and office BP. Ambulatory BP was assessed pre- and 2 months post RSD.

Results: At 2 months the average decrease in office BP was 33/15mmHg (systolic p=0.04, diastolic p=0.03), while the observed reduction in 24 hour ambulatory BP readings was 26/16mmHg (systolic p=0.01, diastolic p=0.01). The range in change of serum creatinine values at 2 months was −10 to +13 μmol/L, and the average change was +1.5 μmol/L (p=0.47). There was a 6.6% reduction in mean uric acid concentration (p=0.371). A trend towards weight loss, with an average reduction in weight of 1.65kg at 2 month follow up was seen (p=0.27). Patients required, on average, 1.3 medications less at follow up. There have been no major complications to date.

Conclusions: RSD was safe, and effective at reducing both systolic and diastolic blood pressure in patients with RH. No acute deterioration in renal function was demonstrated. Findings from this pilot study showed more substantial reductions in ambulatory BP consistent with larger studies.

TCT-207
Beta Radiation For Renal Nerve Denervation: Initial Feasibility And Safety

Ron Waksman1, Israel Barbash2, Rosana Chun1, Pamela Randolph-Jackson2, Richard Bafour2, Rufus Seabron3, David Hellinga2, Addasalam Makaria2, Rana Virmani2
1Georgetown University, Washington, DC, 2Washington Hospital Center, Washington, DC, 3Washington hospital center, Washington, DC, 4Washington Hospital Center, Washington , DC, 5Washington hospital center, Washington, DC, 6Washington hospital center, Washington , DC, 7CVPath, Gaithersburg, MD, 8CVPath Inc, Gaithersburg, United States

Background: Sympathetic renal denervation shows promise in treating resistant hypertension. The percutaneous RF ablation approach is currently undergoing evaluation but has several limitations. Vascular brachytherapy has the potential to damage nerves. The purpose of the present study was to assess safety and feasibility of renal artery brachytherapy for sympathetic renal denervation.

Methods: A total of 10 normotensive domestic swine underwent vascular brachytherapy to left and right renal arteries using the Beta-Cath™ 3.5F system with doses of 25 Gy and 50 Gy at 2 mm from the source center. Each treated group had 8 arteries; 4 untreated arteries served as control. Follow-up obtained at 1 or 2 months included angiogram, intravascular ultrasound, norepinephrine, and renal nerve injury was found in thirty-six percent of the nerves near the bifurcation, forty-one percent in the main renal artery, and fifty-six percent near the ostium.

Results: Overall the vascular brachytherapy procedure was safe and there were no apparent angiographic or ultrasound injuries to the vessel. Histology demonstrated a variable degree of thermal injury more pronounced in the 50 Gy group. The majority of the denervated nerves showed a reduced degree of injury. For the 25 Gy was a dose-related effect on the severity of the nerve injury. There was a varied degree of arteriolar changes in the examined sections; most showed a varied degree of endothelial cell loss of approximately 2% to 20%.
Conclusions: This initial feasibility and safety study of renal nerve denervation mediated by low and intermediate β-radiation dosages indicates that this approach can cause substantial nerve damage while avoiding significant damage to the renal artery.

TCT-209
Catheter-based sympathetic denervation – results of the heidelberg registry

Michael Kirchberger1, Erwin Blessing1, Hugo Katus1, Britta Vogel1, Martin Zeier1
1University of Heidelberg, Heidelberg, Germany

Background: Renal sympathetic denervation is a novel treatment option in patients with treatment resistant hypertension. Registry data allow to evaluate safety and efficacy in a real-world scenario.

Methods: 53 consecutive patients with treatment resistant hypertension underwent renal sympathetic denervation with the Symplicity radiofrequency based catheter. At baseline, mean office blood pressure was 171±22/93±17 mm Hg. The mean number of anti-hypertensive agents was 5.0.

Results: At 6 months follow up, office systolic blood pressure improved to 151±18 mm Hg (minus 20 mm Hg compared to baseline; p<0.0001), the diastolic blood pressure to 86±11 mm Hg (minus 7 mm Hg compared to baseline, p<0.001). The response rate, defined as reduction of office systolic blood pressure of >10 mm Hg was 66%. In 9 Patients (17%), number of dosage of anti-hypertensive agents could be reduced. The mean number of ablation points per kidney was 4.3. There was no correlation between the number of ablation points and blood pressure response (r= 0.25, p=ns).

Conclusions: Renal sympathetic denervation with the Simplicity systems results in a significant reduction of office systolic and diastolic blood pressure reduction in patients with treatment resistant hypertension. Effects on blood pressure were somewhat less profound than reported in the Symplicity trial program, reflecting a real world scenario with more liberal use of the method. Interestingly, there was no correlation between the number of ablation points and blood pressure response.

TCT-210
Decrease of the norepinephrine release from sympathetic nerves during renal denervation

Klaus Tiroch1, Ina Schnitz1, Melchior Seyfarth2, Jacek Szymanski1
1HELIOS Klinikum, Wuppertal, Germany, 2Heidelberg, Germany

Background: Renal denervation (RDN) is a promising new treatment option for pronounced hypertension refractory to medical therapy. Interestingly, only 70-80% of patients have a relevant reduction in blood pressure (BP) three to six months after RDN when assessed by systematic 24h BP measurements. No variables have been identified to date predicting the BP response.

Methods: We assessed the baseline office-based BP to long-term follow-up office-based BP, number of prescribed anti-hypertensive medications, major adverse cardiac and cerebrovascular events (MACCE) and hospital admissions in 8 patients whom had undergone RDN from July 2007 to January 2008.

Results: Our cohort had a mean follow-up of 43 months and we found that office-based BP measurements were reduced by a mean of 30/9 mmHg when compared to baseline and RV (p<0.003 systolic; p<0.09 diastolic). The mean number of prescribed anti-hypertensive medications remained stable throughout the follow-up period (4.88 medications pre-treatment vs 4.1 medications at follow-up; p=NS). Two patients required hospitalisation for late cerebrovascular events. There were no cardiac events reported.

Conclusions: This is the longest reported follow-up of renal sympathetic denervation patients. We have demonstrated a significant and durable decrease in blood pressure. However, there has been no reduction in the number of prescribed anti-hypertensive medications.

Blood Pressure Before and After Renal Sympathetic Denervation