Renal Denervation

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TCT-204

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

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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 accurate 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 patient experienced asystoly after ostial 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

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Background: Catheter-based intravascular renal denervation (RDN) 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 period, 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 hematoxylin-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 2.5 mm 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. Injury was most prevalent from 0.28mm to 3.5mm. Renal nerve injury near the bifurcation, forty-one percent in the main renal artery, and fifty-six percent near the ostium.

Conclusions: Our data show that renal nerves span a great distance from the renal artery lumen in obese canines. These data also suggest that the RD travels approximately 3.5mm from the artery lumen surface in obese dogs; however, renal nerve injury is 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

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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 our initial experience of renal sympathetic denervation in twenty-six patients (n=26) all with RH.

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, renin-aldosterone levels and renin 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.

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 +15 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

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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 current study showed that RD using the St. Jude Medical EnligHTN™ renal denervation system does cause significant injury to renal nerves.

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 at nearby levels approximately 3.5mm from the artery lumen surface in obese dogs; however, renal nerve injury is 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.

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 examined nerves showed irreversible degree of injury. (Figure) There 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 thermal injury more pronounced in the 50 Gy group. The majority of the nerves near the bifurcation, forty-one percent in the main renal artery, and fifty-six percent near the ostium.