and contiguous, the opportunity to successfully and consistently ablate renal nerve tissue is enhanced.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

KEYWORDS Renal Denervation

TCT-774
Safety and Performance of the EnligHTN™ Renal Denervation System in Patients with Drug-resistant Hypertension: Pooled analyses from the EnligHTN I, II and III trials

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BACKGROUND Catheter-based renal artery denervation therapy is under evaluation as a therapeutic option in patients with resistant hypertension. Despite promising data from initial studies, the lack of a clear treatment effect from the SYMPLICITY HTN 3 trial raised concerns around the efficacy of renal denervation. Subsequent sub-analysis has suggested significant treatment effects if patients receive more and circumferential lesions, suggesting that multi-electrode renal denervation systems may reduce the risk of an inadequate renal denervation procedure. In order to gain insights from a large patient dataset, we investigated the safety and performance of the EnligHTN™ Renal Denervation System (St. Jude Medical) in patients with drug-resistant hypertension using pooled data from all trials performed to date. This is the first report of pooled data from the EnligHTN I, II and III trials.

METHODS The EnligHTN renal artery ablation catheter has 4 electrodes attached on a basket mounted at the tip of the catheter. We analysed data from the EnligHTN I, III and III trials which met the following criteria: 18-80 years of age, an office systolic BP ≥ 160 mmHg, on three or more antihypertensive agents (including a diuretic), and renal artery diameter ≥ 4 mm and length ≥ 20 mm. All trials used the same renal artery ablation catheter, but in the EnligHTN I and early phase of the EnligHTN II trials, sequential delivery of radiofrequency energy was performed, whereas with the later phase of the EnligHTN II trial and the EnligHTN III trial the next generation simultaneous delivery of radiofrequency was performed.

RESULTS To date 202 patients met this criteria from these 3 studies, with 6 month follow-up data available (EI n=46, EI n=119, EI n=37). Mean age for the dataset was 62 yrs with mean office systolic BP at baseline of 179mmHg and at 6 months of 158mmHg. Therefore a 6 month reduction in office systolic BP of 21mmHg was noted (p<0.05). Mean 24 hr systolic ABP at baseline was 156mmHg and at 6 months was 148mmHg. This 8mmHg drop was statistically significant (p<0.0001). With regards BP reduction within this dataset, baseline systolic office and 24 hour ambulatory BP values at baseline were predictors of the level of BP reduction. Enrollment within the first in human trials (EI) lead larger observed reductions in BP. Complete safety analysis including renal function and adverse events will be included in the presentation.

CONCLUSIONS Pooled data from the complete EnligHTN clinical trial dataset meeting traditional study definitions of resistant hypertension confirm the efficacy and safety of the EnligHTN multi-electrode system for renal artery denervation. Future randomised controlled trials in the patient population with next generation multi-electrode renal denervation systems are warranted.

CATEGORIES ENDOVASCULAR: Hypertension Therapies and Renal Denervation

KEYWORDS Hypertension, Renal Denervation

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Rates, Predictors, and Risk Stratification of Mortality after Endovascular and Surgical Revascularization for Octogenarian Patients with Critical Limb Ischemia due to Infragingual Artery Disease

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BACKGROUND Clinical outcomes after surgical and endovascular revascularization in elderly patients with critical limb ischemia (CLI) remain undefined. This study explored the rate and predictors of mortality after revascularization in octogenarian patients with CLI.

METHODS From 2007 to 2011, 175 consecutive CLI patients (175 first treated limbs) over 80 years old (age, 85±4 years; 52% male; 57% non-ambulatory status; 53% diabetics; 25% on hemodialysis and 77% with tissue loss) who underwent revascularization for infragingual lesions (endovascular therapy: 136, bypass surgery: 39) were retrospectively enrolled. Overall survival rate after revascularization was evaluated by Kaplan-Meier analysis. Predictors for 2-year mortality after revascularization were determined using a Cox hazards model.

RESULTS Median follow-up duration was 17 [range 0-55] months. Overall survival rate was 80% at 1 year, and 69% at 2 years, with infection being the most common cause of death. Predictors of mortality after revascularization were non-ambulatory status (hazard ratio [95% confidence interval], 3.02 [1.61-5.67]), body mass index <18.5 (1.86 [1.06-3.28]), and albumin <3 g/dL (2.48 [1.28-4.8]). Patients with more predictors had a higher incidence of death after revascularization. (Figure)

CONCLUSIONS Non-ambulatory status, emaciation, and low albumin level were independently associated with mortality after revascularization in octogenarian patients with CLI. Risk stratification by these factors might inform revascularization strategy decision.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

KEYWORDS Critical limb ischemia, Octogenarians, Risk prediction