MULTI-ELECTRODE RENAL DENERVATION SYSTEM (EnligHTN™) in the treatment of patients with hypertension and chronic kidney disease (CKD).

METHODS The EnligHTN-II study is a post-market clinical investigation in which patients with uncontrolled hypertension were assigned to one of three groups; Group A, office systolic BP (OSBP) ≥160 mmHg and estimated GFR (eGFR) ≥45 mL/min per 1.73 m2, Group B, OSBP ≥140-159 mmHg and eGFR ≥45 mL/min per 1.73 m2 and Group C, OSBP ≥120-140 mmHg. For all three groups, subjects were required to be on at least 3 anti-hypertensive medications (including 1 diuretic), or to have documented drug intolerance such that they are unable to take 3 anti-hypertensive drugs. Renal denervation was performed using a minimally invasive procedure in ambulatory systolic measurement to define responders.

RESULTS A total of 27 patients with CKD (average age 68.5 (SD 8.2) yrs taking an average of 5.1 (1.53) anti-hypertensive medications) were included in this sub-analysis. At baseline, the mean eGFR (mL/min/1.73m2) was 55.1 (SD, 16 range 43.9). Bilateral renal nerve ablation was performed using a percutaneous femoral approach. Baseline average OSBP was 169 (20.2) mmHg, average ODBP was 85.4 (13.9) mmHg, average ambulatory SBP (ASBP) was 150.2 (18.2) mmHg, and average ambulatory DBP (ADBp) was 82.2 (14.9) mmHg. At present 24 months and 12 month follow-up visits are complete. The average OSBP in OSBP/ODBP was 9.0 (25.8)/8.1 (10.3) mmHg (p<0.0018) and 9.8 (25.6)/8.5 (16.3) mmHg (p<0.0465) at 6 and 12M follow up respectively. The average reduction in ASBP/ADBp was 9.0 (24.1)/6.1 (12.5) mmHg (p<0.0281) and 14.7 (24.5)/8.1 (14.1) mmHg (p<0.01) at both 6 and 12 month follow up respectively. Changes in eGFR, serum creatinine, and urine albumin to creatinine ratio were not statistically different from baseline at either 6 or 12 month follow up respectively. The average reduction in ASBP/ADBP was 39.0 (24.1)/9.6 (12.5) mmHg (p<0.0018). The absolute reduction in mean office systolic blood pressure was 17 mm Hg to 83 mm Hg.

CONCLUSIONS Non-invasive radiofrequency ablation offers a minimally invasive and outcome-related device, and is a promising option for uncontrolled hypertension. Responders were defined as a 5 mmHg reduction in mean office systolic blood pressure.
and contiguous, the opportunity to successfully and consistently ablate renal nerve tissue is enhanced.

**CATEGORIES ENDOVASCULAR:** Hypertension Therapies and Renal Denervation

**KEYWORDS** Renal Denervation

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**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 ≥ 4mm and length > 20mm. 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, EII n=119, EIII n=37). Mean age for the dataset was 62 yr.s with mean of 24 hr systolic ABP of 156 mmHg, or antihypertensive agents (including a diuretic), and renal artery diameter ≥ 4mm and length > 20mm. 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.

**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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**TCT-775**
Rates, Predictors, and Risk Stratification of Mortality after Endovascular and Surgical Revascularization for Octogenarian Patients with Critical Limb Ischemia due to Infrainguinal 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 infrainguinal 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 [1.28-4.80]). 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