Methods: The REDUCE-HTN trial is a prospective, multicenter, single-arm study. Patients were required to have office-based systolic blood pressure (BP) ≥160 mmHg despite compliance with ≥3 antihypertensive medications at maximally tolerated doses. The primary efficacy endpoints were the 6-month reductions in office-based systolic and diastolic BPs, and reductions in systolic and diastolic BP as measured by 24-hour ambulatory monitoring. Acute safety (ie, freedom from renal artery dissection or perforation requiring stenting or surgery, renal artery infarction or embolus, cerebrovascular accident, myocardial infarction, or sudden cardiac death at the time of the procedure) and long-term safety, including renal artery patency and renal function, were assessed.
Results: Mean baseline office BP was 182.4±18.4/100.1±14.0 mmHg among enrolled patients (N=146; age 58.5±10.5 years, 61% men, 27.4% with type 2 diabetes). No patients experienced any of the prespecified acute safety events. Among 139 patients with 6 month data, mean office BP was reduced to 157.7±23.8/89.4±15.7 mmHg; a reduction of 24.6±22.3/10.3±12.9 mmHg ($p<0.0001$). Mean baseline ambulatory BP was 153.0±15.1/87.5±13.2 mmHg (n=103); at 6 months it was reduced by 8.5±14.6/5.9±9.2 mmHg (n=67; $p<0.0001$). Renal artery patency by duplex ultrasound at 6 months was 99.1%. Mean estimated glomerular filtration rate (eGFR) changed -0.9±16.5 at 6 months, and 11% of patients (15/136) had a reduction in eGFR >25%. Six-month results for the full cohort of enrolled patients are expected to be available at the time of presentation.
Conclusions: Primary endpoint results from the REDUCE-HTN trial demonstrate that the Vessix System is an efficacious method for treating resistant hypertension. No acute safety endpoint events were observed and 6-month patency and renal function results are favorable.

CRT-608*

Pooled 3-Year Symplicity Htn-1 and Symplicity Htn-2 Results and Diabetes Subgroup Analysis

Richard Katholi,[1] Murray Esler,[2] Henry Krum,[3] Krishna Rocha-Singh,[1] Markus Schlaich,[2] Michael Böhm,[4] Felix Mahfoud[4]
[1]*Prairie Education and Research Cooperative, Springfield, IL;* [2]*Baker IDI Heart and Diabetes Institute, Melbourne, Australia;* [3]*Monash University, Melbourne, Australia;* [4]*Universitätsklinium des Saarlandes, Homburg, Germany*

Background: Treatment resistant hypertension (rHTN) is defined as uncontrolled blood pressure despite use of ≥3 antihypertensive drugs including a diuretic. The sympathetic nervous system plays an important role in the pathogenesis of hypertension. The Symplicity™ renal denervation system uses a percutaneous approach to deliver low-power radiofrequency energy to interrupt the efferent sympathetic and afferent renal nerves. Up to 3 year follow-up of pooled patient level data are available to evaluate renal denervation (RDN) efficacy and safety, including patients with type II diabetes mellitus (DM).
Methods: The Symplicity HTN-1 and Symplicity HTN-2 prospective, multicenter trials enrolled rHTN subjects with a systolic BP (SBP) ≥160 mm Hg; (≥150 mm Hg for DM subjects). Subjects remained on their antihypertensive drugs for 6 months after which changes were allowed as clinically indicated. A subset of subjects in Symplicity HTN-1were consented to 3 years; all subjects randomized to immediate RDN on Symplicity HTN-2 were followed to 3 years post-RDN. Change from baseline BP was measured at each follow-up and all safety events were evaluated.
Results: Baseline characteristics of 128 subjects followed through 3 years include mean age, 58 years; 34% DM, 38% female, and body mass index of 32 kg/m^2. Mean baseline SBP was 175.7 ± 14.1 mm Hg and was reduced by 24.6 ± 22.7 mm Hg at 6 months ($p<0.01$). This BP reduction was sustained at 3 years with a mean drop of 32.2 ± 19.7 mm Hg ($p<0.01$). DM and non-DM subjects had similar baseline SBP and experienced a similar and significant reduction in SBP at 3 years (-30.0 mm Hg vs -33.3 mm Hg, respectively, $p<0.001$ compared with baseline, $p=0.37$ between DM and non-DM subjects). Procedure-related adverse events included 2 dissections (1 before radiofrequency energy was delivered), and 1 access site hematoma. Serious adverse events included 6 deaths, 4 renal failure cases (all resolved), and 1 stenosis requiring stenting.
Conclusions: The data indicates that treatment of rHTN with the Symplicity catheter provides safe and sustained reductions in SBP through 3 years. The reduction in SBP was similar in both DM and non DM subjects.

**Indicates iMPACT Trial Accepted for Oral Presentation*

CRT-610

Bipolar Multi-Electrode Balloon Catheter Radiofrequency Renal Denervation with the Vessix System: Preclinical Safety Evaluation

Gregory J. Wilson,[1] Dawn Winsor-Hines,[2] Davis Liza,[2] Radhika Tunstall,[2] Barbara Huibregtse,[2] Jeannette Bankes[2]
[1]*The Research Institute, Division of Physiology and Experimental Medicine, The Hospital for Sick Children, Toronto, ON, Canada;* [2]*Boston Scientific Corporation, Natick, MA*

Background: A bipolar multi-electrode balloon catheter radiofrequency (RF) renal denervation system offers advantages of short procedure time and low power to minimize risk of non-target tissue thermal injury. We report a preclinical safety study of a 7 French (F) system in a domestic swine model.
Methods: The 7F device was used to treat the renal arteries of 20 pigs, with overlapping treatments in the proximal 12 mm to mimic clinical balloon overlap. Each histopathology cohort (30 & 90 day follow-up) had 4 RF-treated and 3 sham-treated (no RF energy delivered) pigs and response of artery and surrounding nerves to bilateral treatment was examined (28 arteries). Scanning electron microscopy was used to examine the renal artery flow surface for endothelialization, with unilateral whole artery treatment with proximal overlap: RF on one side and sham on the other (3 pigs/cohort; 12 arteries). Treatment duration was 30 seconds. Animals received 2 to 3 treatments per artery depending on artery length. Histology on all 40 kidneys and assessment for non-target injury was undertaken in all 20 pigs.
Results: Renal artery injury was transmural and segmental, with variable percentages of the circumference (<10% to >90%, typically 30-50%) demonstrating overlying nerve injury and associated segmental neointimal hyperplasia. No increase in thermal injury was observed in overlapped vs single-treatment segments. At 30 days, "islands" of necrotic media remained, but at 90 days healing was essentially complete with mature replacement fibrosis. Inflammatory activity was mild at 30 days and minimal by 90 days. Maximum lumen stenosis (all sections, both time points) was 17.7%, hemodynamically trivial, and typically <10%. Endothelialization was focally incomplete at 30 days, but completely confluent at 90 days. Sham-treated arteries showed only mild focal mechanical injury, which was also seen with thermal treatment. Kidney histology demonstrated no injury, and there was no injury to renal veins, ureters, adrenal glands, psoas muscles, peritoneum or intestines.
Conclusion: Safety of the Boston Scientific Vessix renal denervation system in 7F configuration was demonstrated for both single and overlap treatment.

Technology

CRT-611

Poor Outcome in Patients Requiring Intra-Aortic Balloon Pump Reinsertion in Cardiogenic Shock

Edward Howard, Jill Steiner, Rebecca Torguson, Julio Panza, Howard Cooper
MedStar Washington Hospital Center, Washington, DC

Background: Intra-aortic balloon pumping (IABP) is the most frequently utilized form of temporary mechanical support in cardiogenic shock. Withdrawal of IABP support occasionally precipitates hemodynamic compromise or collapse such that IABP reinsertion is considered or performed. The outcome of patients undergoing IABP reinsertion has not been formally studied.
Methods: Using the MedStar Washington Hospital Center Cardiac Care Unit (CCU) database, we identified a population of patients presenting with cardiogenic shock who required IABP reinsertion after failed wean. As a control we identified a matched population of patients who had received only a single IABP for cardiogenic shock. The primary outcome investigated was in-hospital mortality. Secondary outcomes included the utilization of other temporary or permanent methods of cardiac support, transplant, and discharge to hospice and a composite thereof.