TCT-61
Optimized External Focused Ultrasound for Renal Sympathetic Denervation – Wave II trial
Petru Neuzil1, Robert J. Whitbourn2, Zdenek Starék3, Murray D. Esler4, Todd Brinton5, Michael Gertner5
1Nemocnice na Homolce, Prague, Czech Republic, 2Cardiovascular Research Centre, St. Vincent Hospital Melbourne, Melbourne, Australia, 3St. Anne’s University Hospital, Brno, Czech Republic, 4Baker IDI Heart and Diabetes Institute, Melbourne, Australia, 5Stanford University, Stanford, California, 6Kona Medical, Inc, Bellevue, WA

Background: We previously reported the results of the WAVE I trial for Renal Sympathetic Denervation in twenty-four patients with refractory hypertension using the Kona Surround Sound System. Six month results demonstrated a 27mmHg reduction in systolic blood pressure in the study. This technology utilizes external focused ultrasound navigated by a targeting catheter in the renal artery. The WAVE I protocol involved making 18 focused lesions over 12.6 minutes on each side. This study (WAVE II) is evaluating the safety and efficacy of an optimized treatment protocol in which 14 focused lesions produced over 2.8 minutes on each side were utilized to create sympathetic denervation.

Methods: Thirty-three patients (8 men and 25 women; median age: 60 years), with resistant arterial hypertension underwent bilateral externally focused ultrasound utilizing a 2F intravascular catheter for targeting and tracking. Patients were on a minimum of three antihypertensive medications. All treatments were performed in patients under deep analgesic-sedation. The procedure was performed using the 2.8 min protocol for each side and targeting was directed to just proximal to the bifurcation of the renal artery.

Results: During and after the procedure no serious complications were observed. Unlike the WAVE I trial, only one of 33 patients complained of back pain following the index procedure and this resolved within 4 days. To date, eight patients reached the 6-week follow up time point and Systolic BP decreased by 18 mmHg and diastolic BP was unchanged.

Conclusions: The optimized externally focused ultrasound protocol was efficient and well tolerated. There were no serious adverse events reported and 6 weeks results for eight patients were tracking similarly as patients treated in the WAVE I study which ultimately resulted in a 27 mmHg reduction in systolic BP. Since externally focused ultrasound cannot be performed safely, quickly, and effectively, the development of a fully non-invasive system should offer even greater benefits for patient care.

TCT-62
Preliminary Result of the Rapid Renal Sympathetic Denervation for Resistant Hypertension Using the Maya Medical OneShot™ Ablation System (RAPID) Study
Stefan Verheye1, 2Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 3Antwerp, Belgium

Background: Resistant hypertension remains a major health concern despite the availability of effective pharmaceutical agents. Catheter-based renal sympathetic denervation has emerged as a therapeutic option for patients with resistant hypertension. Recent clinical reports show that ablation of the renal sympathetic nerves using radiofrequency (RF) energy is safe and effective. The OneShot™ Renal Denervation System (Coviden, Campbell, CA) is a balloon-based RF system using a mounted spiral electrode with a unique feature of irrigation of the vessel wall—during treatment. The non-compliant balloon is inflated under low pressure (1 atm) in the renal artery, and the electrode delivers RF energy with a single 2-minute treatment.

Methods: RAPID is a prospective, multicenter, single-arm study that enrolled 50 patients at 11 clinical sites in Europe and North America. Patients were enrolled for resistant hypertension based on having an office systolic blood pressure (SBP) ≥160 mmHg despite treatment with a regimen three or more antihypertensive medications including a diuretic. The follow-up period is at 1, 3, 6, 12, 24 and 36 months. The primary safety endpoints include acute procedural safety, death or heart failure, or need for balloon angioplasty and/or stenting.

Results: Five patients were enrolled with a median age of 63.0 years (58.0% male). Patients were on a mean of 4.9 antihypertensive drugs at baseline. The mean baseline office systolic and diastolic blood pressure measurements were 181.6 ± 20.8 and 95.5 ± 15.5 mmHg, respectively. Results at 1 month showed a significant reduction, -17.1 ± 7.0 mmHg (p<0.0001 and p=0.0008), in both systolic and diastolic blood pressure measurements. An update of the ongoing study endpoint results will be presented at TCT.

Conclusions: Preliminary results of the RAPID study demonstrate safe delivery of RF energy for renal sympathetic denervation.