CORONARY-Coronary

CRT-162

Impella® and Tandem Heart® for Circulatory Support in Refractory Cardiogenic Shock

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Background: Previous studies demonstrate that in patients with cardiogenic shock the Impella® (Abiomed, Danvers, MA) and Tandem Heart® (CardiacAssist, Pittsburg, PA) percutaneous left ventricular hemodynamic support devices improve cardiac index, systemic blood pressure and mixed venous oxygen saturation. These devices are expensive, survival data in this patient population is missing and comparisons between devices are lacking.
Study Objective: Compare clinical and procedural characteristics, outcomes and complications in patients with refractory cardiogenic shock (RCS) treated with the TH and IMP for hemodynamic support.
Methods: Baseline demographics, clinical characteristics, procedural information and hospital outcomes were investigated from January 2008 to June 2013 in patients treated with either IMP or TH at Keck Medical Center of USC and LAC-USC Medical Center.
Results: A total of 83 patients had TH or IMP for circulatory support; 20 patients had device implantation for RCS (12 TH and 8 IMP). Mean age was 54.1±16.4, 80% of patients were male, 45% smokers, 35% diabetic and 20% CRI. Ischemic cardiomyopathy was the etiology of RCS in 55% of patients. Ejection fraction averaged 21±12%. IMP patients were older (66±9 vs. 46±15, p=0.004). The overall mortality was 65% (TH 58.3% vs. IMP 75%, p=0.64). Table outlines in-hospital outcomes.
Conclusions: In this small patient cohort we found no significant difference between IMP and TH for the treatment of RCS. Vascular, neurological and rhythm related complications were similar. Overall mortality remains high in patients with RCS despite TH and IMP support. Prospective trials and comparative studies of TH and IMP in patients with RCS are needed before a recommendation for use is made.

In-hospital outcomes				
Complications	All n (%)	Impella® n (%)	Tandem Heart® n (%)	p value
Arrhythmia	8 (40.0)	3(37.50)	5(41.67)	1.0
Vascular Repair	1(5.0)	0(0)	1(8.33)	1.0
Acute Limb Ischemia	2(10.0)	1(12.50)	1(8.33)	1.0
Hematoma	1(5.0)	0(0)	1(8.33)	1.0
Acute Renal Failure	16(80.0)	7(87.50)	9(75.0)	0.62
GI Bleed	1(5.0)	0(0)	1(8.33)	1.0
Stroke	2(10.0)	1(12.50)	1(8.33)	1.0
Death	13(65.0)	6(75.0)	7(58.33)	0.64

ENDOVASCULAR-Renal Intervention

CRT-217

Long Term Safety and Efficacy of a Multi-electrode Renal Artery Denervation Catheter in Patients with Drug-Resistant Hypertension: Twelve and 18 Month Results of a First-in-Human, Multicenter Study

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Background: Recent estimates indicate that 8-12% of patients with hypertension do not respond adequately to optimal medical therapy. Sympathetic renal artery denervation is emerging as a viable treatment option for patients with drug resistant HTN but long-term results using multi-electrode ablations systems have not been reported.
Methods and Results: The EnligHTN renal denervation system (St Jude Medical) has 4 electrodes attached on a basket mounted at the tip of the catheter and can deliver multiple transmural lesions in a predetermined pattern. The EnligHTN-I first-in-human study was designed to assess the safety and efficacy of this multi-electrode ablation system in patients with drug-resistant hypertension. A total of 46 pts (av. age 60±10yrs, on 4.8±0.6 meds) were enrolled. Of these pts 33% were female, 98% were white, 20% had Coronary Artery Disease, 59% had hyperlipidemia, 33% had type II Diabetes Mellitus, and 30% had history of sleep apnea. On average 7.7±0.8 lesions were created in the right renal artery and 7.4±1.4 in the left. Baseline av. office BP was 176/96 mmHg and average 24 hr ambulatory BP 150/83 mmHg. Average reductions (mmHg) of office BP at 1, 3, 6 and 12 months were -28/10, -27/10, -26/10 and -27/11 mmHg ($p<0.001$) respectively and for 24hr ambulatory BP -10/5, -10/5 and -10/6 mmHg ($p<0.001$) data for 12 month N/A. At 12 months 80% of patients were responders, 75% had office BP <160 systolic and 29% had normalized BP. At 6 months there was a small reduction in the estimated glomerular filtration rate (from 87 to 82 μL/min/1.73m^2) driven by a small increase in serum creatinine from 78 to 83 μmol/L), but both values returned to baseline at 12 months. Cystatin C levels and microalbuminuria improved significantly up to 12 months. There were 3 device/procedure related serious adverse events reported to date: hypertensive renal disease progression, symptomatic hypotension and worsening of pre-existing renal artery stenosis. Eighteen month efficacy and safety data will be available to be presented at the meeting.
Conclusions: We conclude that data demonstrates that the EnligHTN ablation system continues to be safe and effective in the treatment of patients with drug-resistant hypertension.

TECHNOLOGY-Renal Denervation

CRT-609

Renal Denervation Using Standard 5F Radiofrequency Ablation Catheter in Patients with End Stage Renal Disease: A 6 Month Follow-Up

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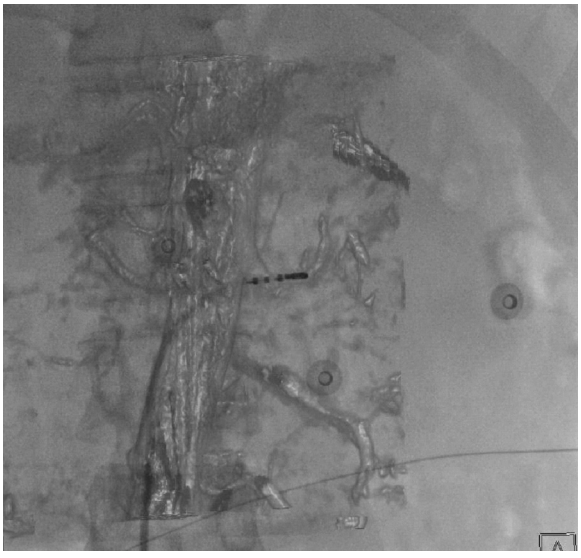
Background: Renal denervation has been proven to be beneficial in treating resistant hypertension in patients with normal renal function. There are a significant number of

end stage renal disease (ESRD) patients who have resistant hypertension despite being on multiple drugs and the benefits of RDN in such patients have not been reported. Renal denervation has been studied using proprietary catheters but the same procedure can be done by conventional catheters. The use of additional mapping and imaging techniques can help in precise localization of the RF lesions.

Methods: We report use of standard 4mm tip 5F RF catheters with conventional RF generators to give RF lesion to renal arteries using rotational angiography and 3D electroanatomical mapping to plan and guide the placement of these lesions in 9 patients with ESRD and uncontrolled hypertension.

Results: There was a significant drop in blood pressure in all the patients 26.8 ± 13.5 mmHg in systolic and 14.8 ± 6.7 mmHg fall in diastolic BP at 1week follow up and 38.0 ± 12.12 mmHg systolic, 19.3 ± 7.21 mmHg fall in diastolic BP at 1 month follow up. The drop in blood pressure was persistent and was 41.8 ± 16.3 mmHg in systolic and 20.4 ± 9.7 mmHg fall in diastolic BP at 6month follow up as compared to baseline. There were no peri-procedural complications.

Conclusions: The use of conventional RF catheters for renal denervation is feasible and effective. Renal denervation in ESRD patients is as effective in controlling hypertension as in patients without renal failure. The use of additional mapping and imaging modalities helps in more precise location of the lesions and may increase the safety of the procedure.



VALVE & STRUCTURAL HEART-Aortic Valve

CRT-713

Usefulness of a Novel Index in Predicting the Permanent Pacemaker Necessity Following Transcatheter Aortic Valve Replacement

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Background: Permanent Pacemaker implantation (PP) following Transcatheter Aortic Valve Replacement (TAVR) is associated with increased morbidity and costs. However, PP predictors have been scarcely investigated.

Methods: We retrospectively analyzed data from a cohort of symptomatic aortic stenosis patients who underwent TAVR and had 2-dimension echocardiogram derived left ventricular outflow tract (LVOT) diameter available. The exclusion criteria were: prior pacemaker and more than 1 valve implanted. We calculated the index as: [valve size (VS)/LVOT]*100. Receiver-operating curve (ROC) was used to determine the binary cut-off value. Variables were selected from univariate analysis and adjusted in the logistic regression model.

Results: The study cohort consisted of 450 consecutive patients. From those, 17% had a prior PPM and 9 received more than 1 valve. ROC analysis demonstrated the best cut-off value of 129 for VS/LVOT index (sensitivity=71%, specificity=67%) to predict PP (C-Statistic=0.74; figure). VS/LVOT index as a function of PP probability is depicted (figure). The adjusted determinants of PP following TAVR were: atrial fibrillation (odds ratio (OR): 4.8 [95% Confidence Interval [CI]: 1.6-11.3; $p<0.01$), left bundle branch block (OR: 2.7 [1.0-7.4]; $p<0.05$) and VS/LVOT of 129 (OR: 3.5 [1.3-9.3]; $p<0.01$).

Conclusions: A simple and non-invasive index of valve size and the left ventricular outflow tract independently predicts the PP requirement following TAVR with good accuracy. Further validation and incorporation in the clinical practice may improve the valve selection size and decrease the PP incidence.