CONCLUSIONS Our study showed that the transcatheter closure of large post tricuspid shunts in pediatric patients with severe PAH was safe, feasible and efficacious alternative to conventional surgery.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease
KEYWORDS Congenital heart disease, Device closure, Pediatric cardiology

TCT-30
PREMIUM Trial: Double blind study of percutaneous closure of patent foramen ovale with the AMPLATZER® PFO Occluder as a treatment for migraine with or without aura

Jonathan Tobis,1 Andrew Charles,2 Stephen D. Silverstein,3 Sherman Sorensen,4 Bijj Maini,5 Philip A. Horwitz,7 John c Gorley6 David Geffen School of Medicine, UCLA, Los Angeles, California; 4David Geffen School of Medicine at UCLA, Los Angeles, California; 5Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, Pennsylvania; 6Great Basin Cardiovascular, Murray, Utah; 7PinnacleHealth Cardiovascular Institute, Wormleysburg, Pennsylvania; 8University of Iowa Carver College of Medicine, Iowa City, Iowa; 9University of Kentucky College of Medicine, Lexington, Kentucky

BACKGROUND Population studies have identified a correlation between migraine and patent foramen ovale (PFO), and observational studies have reported that PFO closure results in improvement in migraine frequency compared with a sham procedure, or in those with aura occurring during the majority of headache days (3.4 vs 2.0 days, p=0.05) in the device group. A subset analysis revealed that individuals with aura occurring during the majority of their attacks may respond more favorably to PFO closure. Specifically, the study demonstrated that a small but significant percentage of migraine with aura patients may experience complete remission of migraine.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease
KEYWORDS Clinical Trial, Migraine, Patent foramen ovale

TCT-31
Title: Immediate and One Year U.S. IDE Trial Results of the New GORE® CARDFORM Septal Occluder for transcatheter closure of secundum atrial septal defects

Joseph Paolillo,1 D. Scott Lim,2 Phillip Moore,3 Tom Forbes4 1Sanger Heart & Vascular Institute, Charlotte, NC; 2University of Virginia Health Systems, Charlottesville, VA; 3University of California San Francisco, San Francisco, CA; 4Children’s Hospital of Michigan, Detroit, United States

BACKGROUND The GORE® CARDFORM Septal Occluder (studied as GORE® Septal Occluder) was recently FDA approved for the transcatheter treatment of ostium secundum atrial septal defects. It is a low profile double disc device composed of a nitinol 5-wire frame, and covered with expanded polytetrafluoroethylene. We present the first data including both Pivotal and early Continued Access trial subjects with one year follow-up.

METHODS Patients were enrolled from 17 Pivotal and Continued Access U.S. sites in a prospective single arm trial. Follow-up was immediately post-procedure, and at scheduled intervals through one year. Endpoints included successful device placement, immediate and late closure success, and serious adverse events, including serious device-related events requiring reintervention.

RESULTS Between October, 2012 and January, 2014, 125 patients were enrolled with a median age of 7.4 years (range 2.4-78.6). Devices treated had a static diameter of 10.1-13.2mm (maximum 17mm), and stop flow stretched diameter of 12.2±3.2mm (range 5.7-17.5). Deficient retroaortic rim (< 5.0 mm) was present in 36.3%, multiple fenestrations in 18.4%, and atrial septal aneurysm in 10.4%. A CARDFORM Septal Occluder was successfully implanted in 92% of patients (115/125), with a serious adverse event rate of 0.8% at one year. Immediate closure success (0-2 mm residual shunt) was 98.3% and a 2.1-4 mm residual defect was present in 1.7%. Clinical closure success, defined as normalization of right heart size, was 100%. There were no cases of post-procedural embolization or reintervention.

CONCLUSIONS The GORE® CARDFORM Septal Occluder provides a new option for percutaneous closure of small and medium sized secundum atrial septal defects, with high implant success, occlusion rate, and safety profile.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease
KEYWORDS Atrial septal defect, Congenital heart disease, Occluder
CATEGORIES STRUCTURAL: Heart Failure
KEYWORDS Left ventricular remodeling

TCT-33
Left Atrial Decompression with the V-Wave Shunt Device for the Treatment of Heart Failure: Preliminary Safety and Efficacy Results

Maria Del Trigo,1 Sebastien Bergeron,1 Mathieu Bernier,1 Ignacio J. Amat-Santos,2 Francisco Campelo-Parada,3 Omar Abdul-Jawad Altisent,1 Philippe Pibarot,4 Neal Eglez,2 Frank Litvack,1 Rotem Katzenellenbogen,2 Lior Rosen,2 Erez Rozenfeld,3 William Abraham,3 Josep Rodes-Cabau3

1Quebec Heart and Lung Institute, Quebec, Canada; 2Hospital Clinico Universitario de Valladolid, Valladolid, Spain, Valladolid, Valladolid; 3V-Wave Ltd, Or-Akiva, Israel; 4V-Wave Ltd, Or Akiva, Israel; 5The Ohio State University, Columbus, United States

BACKGROUND Elevated left atrial (LA) filling pressures leading to pulmonary congestion is the common final pathway in decompensated heart failure (HF). The V-wave unidirectional shunt is a novel percutaneously-implemented device intended to regulate LA pressures by creating a low volume, left-to-right atrial shunt. The objectives of this study were to evaluate the feasibility and preliminary efficacy of the V-Wave shunt for treating systolic HF.

METHODS Patients were enrolled if they had chronic cardiomyopathy regardless of etiology with NYHA class III/IV symptoms, LVEF >15% and ≤40% and PCWP >15 mmHg. All implants were performed following femoral transeptal catheterization, under general anesthesia and TEE guidance. Patients were followed clinically and with serial echo and RHC.

RESULTS Ten patients (90% male; 62±17 years, mean LVEF 27±7%) underwent successful shunt implantation without complications (average procedure time 59±25 minutes without contrast injection). One patient with prior history of severe ventricular arrhythmias died after 2 months due to ‘ventricular tachycardia storm.’ At 1-month, all shunts were patent on TEE without evidence of thrombus or device migration. Functional and hemodynamic results at 3 month follow-up (first 8 patients) are shown in the Table.

CONCLUSIONS This study demonstrates initial safety and early beneficial clinical and hemodynamic outcomes for the V-Wave unidirectional shunt in patients with HF and reduced LVEF. Complete results and 1-year follow-up will be presented at the meeting. Extensive evaluation of this novel therapeutic approach in patients with symptomatic heart failure is warranted.

CATEGORIES STRUCTURAL: Heart Failure
KEYWORDS Device, Heart failure, Interventional cardiology

TCT-34
Completeness of defect closure determined the resolution of hemolytic anemia in patients undergoing transcatheter paravalvular leak closure

Grzegorz A. Smolka,1 Piotr Pysz,2 Michal Kozłowski,3 Tomasz Rolderer,1 Wojciech Zasada,2 Łukasz Partyka,2 Bartłomiej Dudek,1 Andrzej J. Ochala,1 Michal Tendera,1 Wojciech Wojakowski1

1Medical University of Silesia, Katowice, Poland; 2Krakow Cardiovascular Research Institute, Krakow, Poland; 3Jagiellonian University Medical College, Krakow, Poland

BACKGROUND Paravalvular leak (PVL) after surgical valve replacement is associated with heart failure and hemolytic anemia. Transcatheter PVL closure (TPVLC) is effective in reduction of HF symptoms, however there are no prospective studies on effects on hemolysis.

METHODS Prospective registry enrolled 75 adult patients after surgical valve prosthesis implantation with single PVL in aortic (n=32) or mitral (n=43) location treated with TPVLC using AVPII, AVP III and PLD devices. Criteria for closure were: significant hemolytic anemia and HF symptoms despite OMT and related to presence of PVL. Hemolysis was present in 46 (61.3%) pts with baseline HGB <110g/L in 25(33.3%) and transfusions in 8 (10.7%) pts. HF symptoms and laboratory data (hemoglobin, RBC, LDH) were assessed before, in-hospital (3-5 d post procedure) and after 1 and 6 months. Regurgitant area in color Doppler TEE was recorded using same settings in each observation and residual flow location was assessed (through and/or beside of occluder). Effects of TPVLC were quantitated depending on reduction of regurgitation area respectively as class 1: <50%, 2: 50-75%, 3: 75-90%, 4: 90-99% and 5: complete closure.

RESULTS Comparison of patients with classes 1-3 (group 1) and classes 4-5 (group 2) with regard to baseline and follow-up hemolysis is shown in table. TPVLC led to a significant decrease in LDH activity (LDH baseline vs LDH 6 months: 708.2±500.9 vs 433.0±189.0 IU/l) and the follow-up values were significantly lower in patients with complete closure (class 5) of the defect versus incomplete (classes 1-4) (367.08±83.59 vs. 474.65±185.02 IU/l, p<0.05). Regurgitant area and residual flow through occluder were independent variables predictive of the decrease in LDH (OR 9.69; 95%CI 1.85-109.88 and OR 5.36, 95%CI 1.85-15.87, p<0.05). The table shows the results of RBC levels and resolution of hemolysis in 6 months follow-up.

CONCLUSIONS Only in patients with >90% reduction of regurgitation area and no flow through occluder TPVLC leads to recovery of Hb and RBC levels and resolution of hemolysis in 6 months follow-up.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease
KEYWORDS Occluder, Paravalvular leaks