

	Group A	Group B
Sex	177M vs 44F	168M vs 49F
Age	62,4±11	65,8±11
Mean EF [%]	28,8±6,9	27,4±5,8
Atrial fibrillation [%, p=ns]	16,2	18,8
NYHA III & IV [%, p=ns]	29,8	32,7
Chronic kidney disease stage III-V [%, p=0,02]	32,3	42,4
Diabetes [%, p=0,04]	38,4	47,9

TCT-76

Percutaneous Ventricular Restoration (PVR) therapy using the Parachute® Device in Patients with Ischemic Dilated Heart Failure: PARACHUTE III, European Post Market Trial, Primary Endpoint Results

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Background: Left ventricle (LV) remodeling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients.

Methods: Aims: The primary objective is to continue to assess the long term safety of the CardioKinetix Parachute Implant System in the partitioning of the left ventricle in patients with heart failure due to ischemic heart disease. One hundred patients with NYHA class II-IV HF secondary to AWMI, with akinetic or dyskinetic wall motion abnormality, and LV ejection fraction < 40%, were enrolled in Europe. The primary endpoint was site-reported procedural and device related MACE in real world use of the Parachute Implant through 5 years of clinical follow-up. Secondary endpoints included changes in LVESVi, LVEDVi, 6MWT, and the number of and time to the combined cardiovascular mortality and morbidity that includes all cause death, hospitalization for heart failure, myocardial infarction, and stroke, whichever is earlier, within 6, and 12 months from the date of implantation of the study device.

Results: As of the last data cut in early 2014, a pooled analysis which included 77 of the 100 PARACHUTE III patients, showed significant reductions (p < 0.05) in LVESVi and LVEDVi at 1 year as well as a significant improvement in the 6MWT data. One-year follow-up of the full cohort of 100 patients will be available for the TCT conference in September 2014.

Conclusions: The analysis of the post market data confirms the safety and longer term efficacy of the Parachute device in treating HF.

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Midterm results of a Novel Interatrial Shunt Therapy for Heart Failure and Preserved Ejection Fraction

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Background: Approximately 50% of patients presenting with clinical features of heart failure have a preserved ejection fraction ("HFPEF"). The fundamental pathophysiologic basis for the HFPEF phenotype is impaired diastolic reserve, with elevated resting, or rapid increase in LVEDP, LAP and pulmonary artery pressures during low level physical activity. We report the midterm results of a novel device intended to lower left atrial pressure by creating a small permanent atrial septal shunt. Objective: Evaluation of safety and potential benefits of the intra atrial shunt device (IASDTM) System in patients with symptomatic heart failure with preserved or mildly reduced ejection fraction, despite appropriate medical management

Methods: Eleven patients were enrolled under an approved protocol in a prospective multicenter feasibility study. Key inclusion criteria were: EF > 45%; PCWP at rest ≥ 15 or exercise ≥ 25mm Hg; ≥ 1 hospitalization for heart failure within prior 12 months, or persistent NYHA Class III/IV for at least 3 months.

Results: Mean age, and EF, were 75 Y, and 57 %, respectively. Most patients had multiple comorbidities. The IASD Device was successfully implanted in each patient. Two SAE occurred within 30 days, and both were resolved. At 30-90 days, PCWP was reduced (4 mmHg, P< 0.001) with no change in CVP, and at 6 months clinical symptoms had improved (See Table). One year follow-up data will be presented.

Parameter	Baseline	6 months	P value
NYHA III/IV (%) (n=10)	80/20	20/0	NA
6 MWD (m) (n=9)	342 ± 139	369 ± 92	0.096
NT-Pro-BNP (pmol/L) (n=9)	193 ± 153	262 ± 210*	0.370
MLWHF score (n=10)	54 ± 18	31 ± 17	0.009

Conclusions: This initial data demonstrates that the shunt device can be safely implanted and that midterm clinical improvement can be obtained in patients with heart failure and preserved or mildly reduced ejection fraction.

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Predictors of Survival in Patients Undergoing Trans-Catheter Aortic Valve Closure for Significant Left Ventricular Assist Device Associated Aortic Insufficiency

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Background: Left ventricular assist devices (LVADs) have been shown to increase survival and quality of life in patients with end-stage congestive heart failure. However, severe aortic insufficiency (AI) can develop in up to 50% of patients with LVADs at 12 months resulting in significant morbidity and mortality. Trans-catheter treatment of LVAD associated AI has emerged as a potential alternative to surgical treatment, but long term clinical benefits are yet to be determined.

Methods: We conducted a retrospective analysis of all patients undergoing transcatheter aortic valve closure using an Amplatzer Multi-Fenestrated Septal Occluder "Cribiform" device (AGA Medical, Plymouth, Minnesota) at our institution between September 2011 and September 2013 to assess potential clinical and procedural factors associated with survival. Unpaired student's t-tests were used to compare baseline patient demographics and procedural characteristics, as well as patient outcomes immediately post procedure and at 6 months. A p-value of < 0.05 was considered statistically significant.

Results: A total of 8 patients (75% male, median age 59 years) were included in this analysis. Technical success of the procedure including total cessation of AI without evidence of coronary compromise was accomplished in 100% of patients with a 6 month survival rate of 38% (3/8). Predictors of survival include the absence of significant co-morbidities such as chronic renal insufficiency, smaller occlusion device placement, and the absence of right heart failure (Table 1).

Table 1. Predictors of Survival

	Survivors	Non-Survivors	p-value
Age (years)	62.33 ± 6.51	57.00 ± 15.33	0.30
Male Gender (#, %)	2 (67%)	4 (80%)	0.72
BMI (kg/m2)	30.91 ± 4.12	29.90 ± 8.72	0.43
Etiology, ICM (#, %)	2 (67%)	3 (60%)	0.86
DM (#, %)	0 (0%)	3 (60%)	0.06
GFR (mL/min/BSA)	82.00 ± 30.35	39.60 ± 4.39	0.02
Device Size (mm, %)	18 (33%), 25 (33%), 30 (33%)	30 (80%), 35 (20%)	0.03
PA Systolic Pressure (mmHg)	25.50 ± 6.36	54.60 ± 6.50	< 0.01
PA Mean Pressure (mmHg)	18.00 ± 0.00	38.40 ± 4.16	< 0.01
PA Saturation (%)	68.40 ± 8.20	49.36 ± 6.68	0.01
Δ WBC @ 96hr (K/μL)	0.03 ± 0.81	6.40 ± 2.74	< 0.01
Δ Platelet @ 96hr (K/μL)	-32.00 ± 31.42	-168.50 ± 98.69	0.04
Δ LDH @ 96hr (U/L)	157.67 ± 110.55	2287.75 ± 1223.89	0.02
Δ Total Bilirubin @ 96hr (mg/dL)	-3.10 ± 6.42	11.88 ± 6.32	0.01

Conclusions: Trans-catheter aortic valve closure successfully treats late severe AI in LVAD patients, however, the presence or development of right heart failure portends a worse prognosis. Further studies are needed to investigate the potential right ventricular failure in patients undergoing trans-catheter aortic valve closure.