Initial Six Month Results of a Novel Inter-atrial Shunt Therapy for Heart Failure with Preserved Ejection Fraction

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Background

Approximately 50% of patients presenting with clinical features of heart failure have a preserved ejection fraction (arbitrarily >45%) = "HFPEF".

The incidence of HFPEF is progressively rising, and will become the predominant form of HF.

Patients with HFPEF and HFREF are similarly affected in relation to symptomatic limitation, hospitalization and survival.

The fundamental pathophysiologic basis for the HFPEF phenotype is impaired diastolic reserve, which manifests itself as elevated resting or as a rapid increase in LVEDP, LAP and pulmonary artery pressures during low level physical activity.

The structural basis of the impaired diastolic reserve remains somewhat controversial, and includes myocardial fibrosis, microvascular endothelial dysfunction, contractile protein abnormalities together with ventriculo-vascular coupling mismatch.

In contrast to HFREF, multiple pharmacological studies in HFPEF have failed to provide clinical benefit (CHARM-preserved, I-PRESERVE, HF-PEF, AIdo-DHF, RELAX-HF, PARAMOUNT, TOPCAT).

Given the failure of pharmacological approaches, the potential for a device based approach has been developed, in part based upon the observation that patients with Lutembacher’s syndrome (ASD + Mitral Stenosis) are less symptomatic than MS without ASD.

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Background (continued)

Methods and Results

KEY PATIENT SELECTION CRITERIA

INCLUSION:
• Age > 40;
• NYHA III-IV for ≥3months, or ≥1 HF admit in 12 months;
• LVEDP or PCWP > 60
• Significant CAD;
• Significant valve disease;
• LVEDP or PCWP > 15 mmHg at rest, or >25 during exercise.

EXCLUSION:
• Significant CAD;
• Significant valve disease;
• RVSP or PAsys > 60 mmHg;
• Pacemaker leads;
• DVT;
• Amyloidosis.

Objective

Approximately 50% of patients presenting with clinical features of heart failure have a preserved ejection fraction (arbitrarily >45%) = “HFPEF.”

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Objectives

To evaluate the safety and clinical efficacy of creating a permanent, small inter-atrial shunt in HFPEF patients to decompress the LA using an inter-atrial shunt device (IASD).

Methods (continued)

Baseline Demographics (n=11)

Parameter Mean ± SD (Range)
Age (yrs) 70 ± 11.9 (55-90)
Age > 75 (%) 45
Female (%) 66
BMI (kg/m²) 39 ± 7.3 (18.7-44.1)
EF (%) 87% ± 9.1 (46-65)
Advanced HF (%) (NYHA Class IV) 80% (10)
Average Rest & Lateral LV end ratio value (n=7) 15 ± 4.73 (7-22.07)
Prior HF Hospitalization (%) 55
NHF index (prior)LAP ± 45 (22-461)
CAD/Prior CABG/SFC (%) 36
Hypertension (%) 91
Diabetes (%) 48
CHF/TIMI (n=6) 9

IASD positioned mid atrial septum using standard trans-septal approach under TEE or ICE imaging

DC Device Inter-atrial Shunt Device (IASD)

IA SD device placement reduces PCWP at follow-up (30-90 d).

Results

Hemodynamics

Baseline Demographic Data (n=11)

Parameter Mean ± SD (Range)
AF (%)
14
EF (L/min/m²)
2.5 ± 0.4 (2.1-3.3)
Systolic ABP (mm Hg)
129 ± 17.4 (115-170)
Resting mean PCWP (mm Hg)
16.2 ± 4.3 (9-20)
Resting mean LAP (mm Hg)
16.2 ± 3.5 (10-20)
Resting gradient mean PCWP: LAP (mm Hg)
7.5 ± 3.0 (3-13)
Resting LAP (mm Hg)
42 ± 13 (27-68)
Resting Mean Pulmonary Greadient (mm Hg)
12.8 ± 4.4 (7-20)
Resting Diastolic Pulmonary gradient (mm Hg)
2.3 ± 2.5 (1.3-4.0)
Peak VO2 (mL/kg/min)
13.7 ± 4.0 (7.3-18.0)

Discussion

This initial study demonstrates that placement of an interatrial shunt device in HFPEF patients is associated with favorable hemodynamic and clinical effects in the early to mid term. Further clinical studies are underway.

Disclosures: Study sponsored by DC Devices.