Interventional Heart Failure and Hemodynamic Monitoring

Umair Ahmad, MD[a], Scott M. Lilly, MD, PhD[a,b,*]

KEYWORDS

• Heart failure • Hemodynamic monitoring • Implantable devices • Intervention

KEY POINTS

- Device-based therapies for heart failure have several advantages; they may reduce polypharmacy and attenuate the consequences of medical nonadherence.
- Although new, the interventional heart failure discipline is based on previous examples of successful device-based heart failure therapies, including cardiac resynchronization therapy and devices for invasive hemodynamic monitoring.
- The potential spectrum of interventional heart failure devices is broad and may include temporary mechanical left ventricular support devices (eg, intra-aortic balloon pump, extracorporeal membrane oxygenation), and transcatheter-based therapies for valvular heart disease.

INTERVENTIONAL HEART FAILURE

Device-based therapies for heart failure (HF) have several advantages, they may reduce polypharmacy and attenuate the consequences of medical nonadherence.[1] Although new, the interventional HF discipline is based on previous examples of successful device-based HF therapies, including cardiac resynchronization therapy and devices for invasive hemodynamic monitoring (eg, CardioMEMS HF System, St. Jude Medical, St. Paul, MN). The potential spectrum of interventional HF devices is indeed broad, and may include temporary mechanical left ventricular (LV) support devices (eg, intra-aortic balloon pump, Impella, TandemHeart extracorporeal membrane oxygenation) and transcatheter-based therapies for valvular heart disease.[1] However, the focus next is on novel, nonvalvular, and percutaneously implantable devices for the management of HF.

INTERATRIAL SHUNT DEVICES

HF with preserved ejection fraction accounts for approximately 50% of HF admissions. Unfortunately, effective pharmacologic treatment strategies remain elusive.[2] The clinical manifestation of HF with preserved ejection fraction is exertional breathlessness often caused by an abnormal increase left atrial pressure (LAP) leading to increased pulmonary venous pressure. Although diuretic therapy is commonly used to reduce LAP, side effects and diuretic resistance are common, and the effectiveness of diuretics on long-term outcomes is difficult to establish.[3] Mechanical devices intended to reduce LAP have been developed, and operate by creating an interatrial shunt.[3] Three such devices are currently being investigated and early clinical experience has been promising.[4,5]

Disclosure: The authors have nothing to disclose.

[a] Department of Cardiology, Ohio State University Wexner Medical Center, 473 West 12th Avenue, Suite 200, Columbus, OH 43210-1252, USA; [b] Interventional Cardiology, 473 West 12th Avenue, Suite 200, Columbus, OH 43210, USA

* Corresponding author. Interventional Cardiology, 473 West 12th Avenue, Suite 200, Columbus, OH 43210.
E-mail address: Scott.Lilly@osumc.edu

Heart Failure Clin ■ (2018) ■–■
https://doi.org/10.1016/j.hfc.2018.06.007

V-Wave Device

The V-Wave device (V-Wave Ltd, Or Akiva, Israel) is a trileaflet porcine tissue valve housed in a hourglass-shaped nickel titanium frame (Fig. 1).[6] This device is a unidirectional (valve) left-to-right shunt device that is implanted via 14F catheter femoral venous approach under fluoroscopic and echocardiographic guidance. After transseptal puncture ideally through the center of the fossa ovalis, the waist of the hourglass (5-mm diameter) is placed across the fossa, securing the device in place.[4] The device allows blood to flow from the left to right only, and requires a pressure difference of greater than or equal to 5 mm Hg. Following device placement, patients have been provided anticoagulation (warfarin or direct-acting oral anticoagulant) for 3 months in addition to low-dose aspirin indefinitely.[4] The use of this unidirectional left-to-right interatrial shunt device was reported in a patient with New York Heart Association (NYHA) functional class III HF and an LV ejection fraction of less than 35%. Implantation was associated with a pulmonary artery (PA) to systemic (ascending aorta) blood flow ratio (Qp/Qs) of 1.17, improvement in the NYHA functional class, quality of life score, and exercise capacity at 3 months.[4] Following device implantation there was also an observed decrease in LV volumes and pulmonary capillary wedge pressures (PCWP; 23–17 mm Hg at 3 months; $P = .035$).

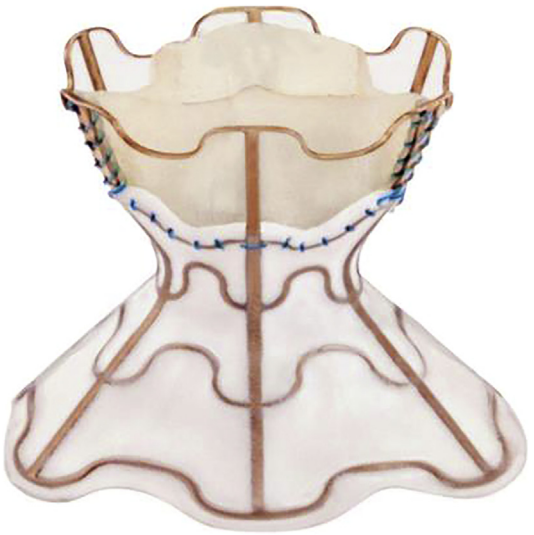

Fig. 1. The V-Wave interatrial shunt device. (*From* Del Trigo M, Bergeron S, Bernier M, et al. Unidirectional left-to-right interatrial shunting for treatment of patients with heart failure with reduced ejection fraction: a safety and proof-of-principle cohort study. Lancet 2016;387:1290–7; with permission.)

These findings are consistent with those reported in a pilot study of 10 patients, and the large animal preclinical studies that preceded human utilization.[6]

InterAtrial Shunt Device System

The InterAtrial Shunt Device (IASD) system (Corvia Medical Inc, Tewkesbury, MA) consists of a nitinol device (outer diameter 19 mm) inserted percutaneously via a 16F catheter venous approach into the interatrial septum to produce a permanent 8-mm atrial septal communication (Fig. 2). Unlike the V-Wave device this does not incorporate a biologic tissue. REDUCE LAP-HF (REDUCe Elevated Left Atrial Pressure in Patients with Heart Failure) was a phase I, open-label nonrandomized trial that evaluated the safety and performance of this device.[5,7] Within this trial 68 patients were enrolled with an average ejection fraction of 57% and mean PCWP at rest of 17 mm Hg. The coprimary end points of the study were reduction of PCWP at rest and exercise along with evidence of left-to-right shunt on echocardiography.[5] IASD placement was successful in 66 of 68 patients (97%). All patients received dual antiplatelet therapy with aspirin and clopidogrel post-procedure. There were no major adverse events and there was no need for cardiac surgical intervention for device-related complications. After 6 months, IASD system implantation demonstrated a reduced rest or exercise mean PCWP in 71% of patients (n = 42).[5] The follow-up to the REDUCE LAP-HF trial subsequently recruited additional patients that were randomized (n = 44) to device placement versus a sham procedure (REDUCE LAP-HF I).[8] Distribution of results was just presented at the American Heart Association Scientific Sessions in 2017 and simultaneously published in *Circulation*.[8–10] Results showed that at 1 month, the interatrial shunt device resulted in a greater reduction in PCWP pressure versus the sham procedure ($P = .028$ accounting for all stages of exercise). In addition, peak PCWP decreased by 3.5 ± 6.4 mm Hg in the interatrial shunt device group versus 0.5 ± 5.0 mm Hg in the sham procedure group ($P = .14$).[8]

A larger scale trial (REDUCE LAP-HF II) has initiated recruitment with the enrollment goal of 380 patients and completion date of July 2024 (NCT03088033).

Atrial Flow Regulator

The Atrial flow regulator (Occlutech International AB, Helsingborg, Sweden), is a self-expandable double-disc wire mesh device constructed from nitinol and braided into two flat discs connected