Device Therapy Approaches for Advanced Heart Failure

Written by **Mary Mosley**

Daniel Burkhoff, MD, PhD, Columbia University, New York, New York, USA, discussed the innovations in device therapy for advanced heart failure (HF). Systolic HF is characterized by progressive deterioration in cardiac function with episodic exacerbations that increasingly require unscheduled office and emergency room visits, or hospitalizations. As the disease progresses, some patients require intravenous inotropic support and periods of inotrope dependence.

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) classification is the standard for characterizing patients when they reach the advanced stages of HF. Current ventricular assist devices (VADs) have been designed to provide hemodynamic support for treatment of patients with end-stage HF (INTERMACS 1, 2, 3).

However, a very large number of patients suffer from slightly lesser degrees of compromise (INTERMACS 4, 5, 6) and have very poor quality of life. A number of new approaches are being pursued to address the spectrum of advanced HF. Dr. Burkhoff and colleagues, among others, have been pursuing the hypothesis of implanting ventricular pumps which require a less invasive procedure than that required by current VADs. While this type of VAD would pump less blood than current VADs, this approach offers the potential to interrupt the progression of HF and improve exercise tolerance in a broader population.

HF is now understood to have three unique domains, which also can overlap: acute HF, HF with reduced ejection fraction (HFrEF), and HF with preserved ejection fraction (HFpEF). Each type of HF requires a unique approach for medical and device therapy. A range of approaches is being studied for treating patients with NYHA Stage III to IV HFrEF.

There are three types of acute percutaneous ventricular assist devices (pVAD). The Impella, manufactured by Abiomed, involves a retrograde trans aortic valve pump that is implanted percutaneously via the femoral artery to provide support for blood flow from the left ventricle (LV) to the aorta. The Tandem Heart pVAD is inserted through the femoral vein and advanced across the intraatrial septum into the left atrium. The pump withdraws oxygenated blood from the left atrium and pumps it to one or both femoral arteries via arterial cannulas. Extracorporeal membrane oxygenation (ECMO) devices provide long-term support for HF patients with severely impaired oxygenation. The venoarterial ECMO partially supports cardiac output in addition to oxygenating the blood, while the venovenous ECMO device primarily supports oxygenation.

Dr. Burkhoff noted that as mechanical circulatory support has evolved, there has been a reduction in both size and invasiveness of the devices used. These technological advances to make such devices smaller is important for reducing complications associated with implantation such as bleeding, vascular injury, and infection.

HFpEF is characterized by an abnormality of LV compliance. Most patients with HFpEF have diastolic dysfunction leading to increased pressure within the LV cavity. This higher level of LV pressure impacts the left atrium (LA), which must deliver blood during diastole into a LV that has a higher level of pressure which results in LA dilation. The higher pressure and enlargement of the LA reflects back on the lungs leading to breathlessness.

Devices for HFpEF include an interarterial shunt created by a transcatheter implant to reduce LA pressure. This device is thought to improve exercise capacity and hence QoL in patients with HFpEF.

Acute and chronic HF remain an area in need of continued advancement noted Dr. Burkhoff. Device-based approaches offer potential temporizing measures until cures are developed, using cell or gene therapy for example. Many challenges remain for device development, including identifying appropriate technologies, a challenging regulatory environment with a high bar for approval, and obtaining funding. Furthermore, in order to have widespread acceptance of device therapy, minimally invasive or interventional approaches are mandatory.

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