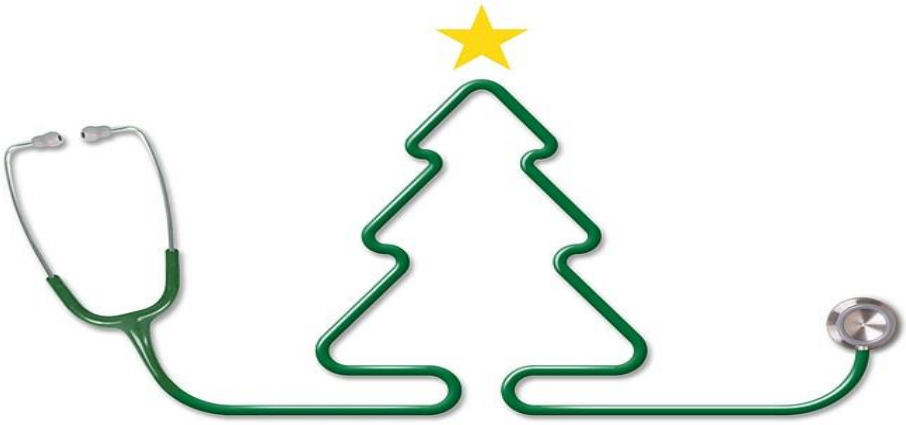


SEASON'S GREETINGS

Multispecialty Outpatient Cardiovascular Association

December Edition

Impella heart pump approved for use in pediatric patients

The US Food and Drug Administration (FDA) has expanded the indications for the Impella 5.5 with SmartAssist and Impella CP with SmartAssist heart pumps (Johnson & Johnson Medtech), granting premarket approval (PMA) for use in specific paediatric patients with symptomatic acute decompensated heart failure (ADHF) and cardiogenic shock.

Johnson & Johnson MedTech has partnered with the Advanced Cardiac Therapies Improving Outcomes Network (ACTION) to provide the real-world data necessary to support on-label use of Impella 5.5 and Impella CP, both left-sided heart pumps, for paediatric patients with symptomatic ADHF and cardiogenic shock.

ACTION is a global healthcare network comprised of patients, families, clinicians, researchers and industry representatives that collaborate with ACTION leadership to improve outcomes for patients.

""This marks a monumental achievement for children with heart failure as, historically, this area of paediatric care has been underfunded and understudied," said Angela Lorts and David Rosenthal, co-founders of ACTION. "We are proud to have worked with Johnson & Johnson MedTech on this crucial approval and look forward to further collaborations that will enhance care for these vulnerable patients."

Impella CP and Impella 5.5 heart pumps unload the heart's left ventricle, allowing the heart to rest while also ensuring delivery of oxygenated blood throughout the body. The PMA amendment expands the usage of left-sided Impella devices to specific paediatric patients weighing ≥52kg for Impella CP and ≥30kg for Impella 5.5.

A dedicated team will develop and refine training and education programs designed specifically for paediatric patients alongside these patients' doctors. In collaboration with ACTION and previously identified hospitals, these tools and resources will be optimised to help improve outcomes and the quality of life for these paediatric patients. This strategic approach will equip the best-in-class heart recovery field team and providers with the skills to best support these patients now and in the future. Impella Heart Pump approved for use in pediatric patients

FastWave Medical closes $19 million financing round to advance IVL portfolio

FastWave Medical announced the close of a US $19 million funding round earlier this year, increasing the total capital invested into the company to over US $40 million.

This investment round was led by Epic Venture Partners with participation from M&L Healthcare Investments and the company's existing investors, and looks to develop FastWave's ongoing regulatory and clinical initiatives of its portfolio of intravascular lithotripsy (IVL) platforms.

Arthur Lee, managing partner of Epic Venture Partners, added: "FastWave is moving quickly and decisively to become best-in-class in the IVL space. We are excited to support the FastWave team, as they continue to take down milestone after milestone in their mission to save lives and offer this groundbreaking technology to all who need it."

Since its formation in 2021, FastWave has been moving in its efforts to tackle the challenges of artery calcification with IVL solutions. As the global population ages, the demand for effective, minimally invasive treatments is escalating.

Steven Kum, chief medical officer of M&L Healthcare Investments, holds similar optimism: "FastWave Medical has all the hallmarks of a company poised for significant growth and impact. Their commitment to evidence-based development aligns perfectly with our investment philosophy, and we're excited to be a part of a new era of IVL innovation that addresses the gaps left by current technologies." FastWave Medical closes $19 million financing round to advance IVL portfolio

Aortic Stenosis, Heart Failure, and Aortic Valve Replacement: Key Points

AS is responsible for the development of HF that is mediated both by AS-associated chronic pressure afterload and subsequent unfavorable cardiac remodeling that includes left ventricular (LV) hypertrophy with impaired coronary microvascular function and eventual myocardial fibrosis.

Evidence of LV impairment caused by AS can be detected using echocardiographic global longitudinal strain imaging for occult myocardial dysfunction, and cardiac magnetic resonance imaging for evidence of focal myocardial fibrosis (using late gadolinium enhancement) or diffuse interstitial myocardial fibrosis (using T1 mapping and myocardial extracellular volume quantitation).

Serum biomarkers including natriuretic peptides (B-type natriuretic peptide [BNP] and N-terminal pro-BNP) and troponin can serve as surrogate markers to help identify patients with asymptomatic AS or moderate AS who might benefit from earlier intervention.

Both patient-related and procedure-related factors can contribute to HF among patients who undergo aortic valve replacement (AVR) for AS.

Guidelines on the management of patients with heart valve disease do not include recommendations specific to the treatment of HF before or after AVR for AS. Published data suggest that treatment with renin-angiotensin-system inhibitor therapy (but not beta-adrenergic antagonist therapy) is associated with decreased all-cause mortality and HF hospitalization.
Aortic Stenosis, Heart Failure, and Aortic Valve Replacement

Association of Palliative Care Consultation in Patients with Heart Failure With Preserved Ejection Fraction With Symptom Burden and Health Care Use

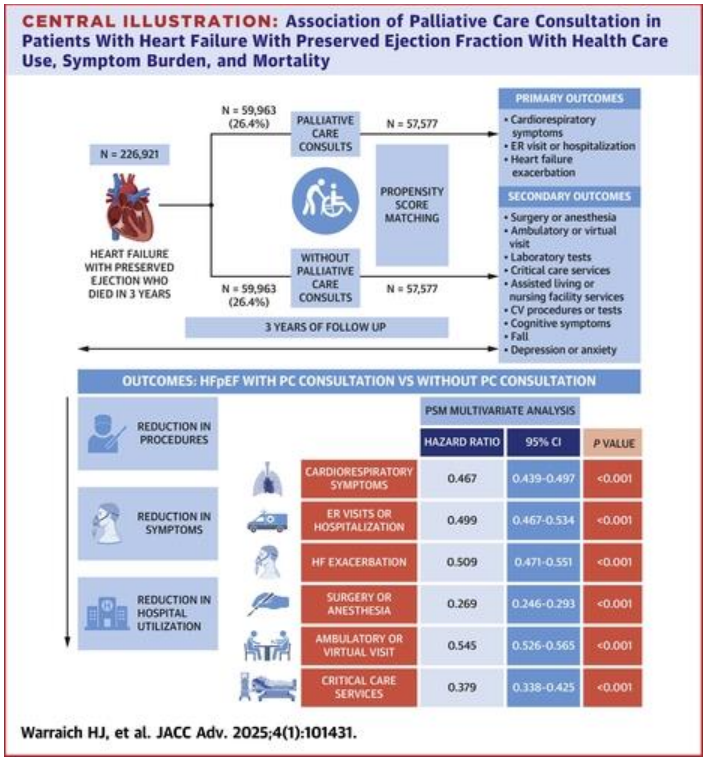
Heart failure with preserved ejection fraction (HFpEF) is rapidly becoming the leading form of heart failure (HF) worldwide. Among elderly populations, HFpEF comprises more than 70% of HF diagnoses, representing a large patient population that has been less well characterized than patients with heart failure with reduced ejection fraction (HFrEF).

Though previously considered on the same spectrum of disease as HFrEF, HFpEF is now recognized as a unique disease process defined as an ejection fraction (EF) ≥50% with evidence of spontaneous or provokable increased left ventricular filling pressures in the 2022 American College of Cardiology/American Heart Association/Heart Failure Society of America guidelines.

Understanding the role and timing of PC for patients with HFpEF is a significant gap in the current literature. To our knowledge, there have been no large-scale studies of PC interventions for patients only with HFpEF assessing symptom burden, broad health care use metrics and mortality. In this paper, we describe a large cohort of deceased patients with HFpEF comparing the clinical outcomes for those who received a PC consult in the last 3 years of life to those who did not. We hypothesized that patients with PC consults would have reduced symptoms and health care utilization than those without.

HFpEF is an increasingly prevalent chronic condition, marked by comorbidities, poor quality of life, and a high rate of mortality from both CV and noncardiovascular causes, lacking a therapy that can significantly alter the natural history of the underlying pathology. Therefore, patients with HFpEF represent an ideal population for PC. While these data reflect that PC is underused in patients with HFpEF, PC consultation is associated with lower potentially unwanted health care use along with a reduction in symptoms. These data could support the use of PC in this population and dedicated clinical trials could further help determine the magnitude of the effect as well as help elucidate the best strategy guiding PC use for this.

Association of Palliative Care Consultation in Patients With Heart Failure With Preserved Ejection Fraction With Symptom Burden and Health Care Use



Warraich HJ, et al. JACC Adv. 2025;4(1):101431.

First patients enrolled in JENA-VAD registry

JenaValve Technology has announced the completion of the first patient procedure for inclusion in the JENA-VAD registry.

The JENA-VAD registry is a prospective, multicentre, single arm clinical registry nested within the ALIGN-AR study evaluating the ability of the JenaValve Trilogy heart valve system device to treat severe symptomatic aortic regurgitation safely and effectively in patients with a continuous flow left ventricular assist device (cfLVAD). The first case was completed at Cedars-Sinai Medical Center in Los Angeles, USA.

Our mission is to address the critical gap for the one third of patients with left ventricular assist devices (LVADs) that develop significant aortic regurgitation (AR) and face significant risk of heart failure," said John Kilcoyne, CEO of JenaValve.

The JenaValve Trilogy heart valve system device is used to treat symptomatic severe AR commercially in the EU under CE mark and is being evaluated in the ALIGN-AR IDE study and ALIGN-AR CAP protocol for patients at high-risk for surgery.

In these situations, patients with LVAD are excluded because of left ventricular fraction (LVEF) <25% and other exclusions. As such, patients with LVAD have been treated under compassionate use consideration in the USA and off-label in the EU. The registry protocol will ensure consistency in performing the procedure, patient management, and documentation of results in this patient population.

First patients enrolled in JENA-VAD registry

Developer of robotic heart valve system closes financing round

Capstan Medical has announced the successful closing of an oversubscribed US$110 million Series C, which will support it bringing its robotic structural heart solution to market.

The round was led by Eclipse, with participation from existing investors Yu Galaxy and Intuitive Ventures, and new investment from Gideon Strategic Partners.

We have pulled together the right people at the right time to make this happen and are energized by the incredible support of our investors." said Maggie Nixon, CEO of Capstan Medical.

Capstan's minimally invasive solution seeks to overcome limitations of current treatment options by bringing together novel heart valve implants and advanced catheter technology, fully enabled through a robotic platform, to treat a broader set of patients, the company says in a press release.

Developer of robotic heart valve system closes financing round

FYI: Upcoming Dates

- January MOCA Meeting: DATE TBD
- Society of Thoracic Surgeons (STS) Annual Meeting: January 25th- 27th
- British Cardiovascular Intervention Society ACI: January 29th- 31st