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Comprehensive Review

Hemodynamic Monitoring Devices in the Management of Outpatient Heart Failure

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ABSTRACT

The prevalence of heart failure continues to increase throughout the world. This rise in diagnoses corresponds with high rates of hospitalization, patient and caregiver fatigue, and ever-increasing economic costs. While numerous investigations have been undertaken in the past looking into remote monitoring or telemedicine strategies, they were unable to show an improvement in clinical outcomes with use. Invasive hemodynamic monitoring in the ambulatory setting has been an area of focus for the last several decades as a possible proactive strategy aiding in the evaluation and management of the heart failure population. Several large, randomized trials have not only shown the safety of a pulmonary artery pressure sensor in the heart failure population but have also confirmed the efficacy of pulmonary artery pressure-guided heart failure management in reducing rates of heart failure hospitalizations. Additional novel implantable devices are in various stages of development and clinical investigation and aim to further help aid in the management of this complex patient population. Future strategies are emerging and include the increased development of wearable devices as well as novel technologies to assess hemodynamics and volume status.

Introduction

Heart failure (HF) is a global pandemic with an estimated prevalence of over 64 million people and is expected to continue to increase with the aging population, increasing incidence of risk factors (ie, obesity, diabetes, and hypertension) and improving survival.[1,2] Despite this improvement in overall mortality, patients with HF continue to have substantial morbidity with persistent symptoms and frequent hospitalizations.

It has been increasingly clear that earlier detection of worsening HF can have a significant impact on not only preventing patient symptoms but also the financial burden frequent hospitalizations bring. The cost of HF on the health care system is projected to cost $70 billion by 2030 in North America alone.[3] These challenges have sparked interest into the development and application of remote hemodynamic monitoring devices.

Historically, remote monitoring strategies have had a variable impact on outcomes in HF when relying on patient-reported data. However, with the development of implantable devices with real-time data, there have been significant improvements with objective and measurable outcomes, primarily with reduction in HF hospitalizations (HFH).[4-6] As medicine enters the age of personal medicine and digital health, implantable hemodynamic monitoring (IHM) devices appear to have a key role. This review will discuss current devices for hemodynamic and volume assessment and the evidence supporting their use, along with insights into historical and future perspectives of this technological space. Implantable devices that are currently in clinical practice or clinical studies are briefly summarized in Table 1.[7-12]

Historical perspective

The field of ambulatory IHM began with the recognition that elevated intracardiac and pulmonary artery (PA) pressures (PAPs) most frequently account for worsening HF symptoms requiring hospitalization and/or intravenous therapies. This led to the development of the first IHM device, the Chronicle Implantable Hemodynamic Monitor (Medtronic) for HF monitoring, in the mid-1990s. The device measured continuous right ventricular pressures and estimated PA diastolic pressure (ePAD) to guide-HF management. While it failed to achieve its

Abbreviations: ePAD, estimated pulmonary artery diastolic pressure; FDA, Food and Drug Administration; HF, heart failure; HFH, heart failure hospitalization; IHM, implantable hemodynamic monitoring; IVC, inferior vena cava; LAP, left atrial pressure; NYHA, New York Heart Association; PA, pulmonary artery; PAP, pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; RHC, right heart catheterization.

Keywords: heart failure; hemodynamic monitor devices; hemodynamics.

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Table 1. Summary of the location of device placement, indications/contraindications, evidence, and how readings are obtained with the implantable hemodynamic devices.

Device	Implant location	Indications	Potential contraindications	Evidence	Readings
CardioMEMS (Abbott)	Pulmonary artery	*FDA approved for:* • NYHA class II-III HF plus • HFH in last 12 mo • And/or elevated BNP/NT-proBNP	• Unable to DAPT • Recurrent pulmonary emboli • Morbidly obese • Right-sided mechanical valve(s)	• CHAMPION[7] • GUIDE-HF[5] • MONITOR-HF[8]	Patient-directed readings via an external interrogation device (pillow)
Cordella (Endotronix, Inc)	Right pulmonary artery	*Under investigation for:* • NYHA class III HF plus • HFH in last 12 mo	• Unable to take anticoagulation/ antiplatelets • Inability to place in right pulmonary artery • Recurrent pulmonary emboli • Right-sided mechanical valve(s)	• SIRONA (feasibility)[9] • SIRONA II[10] • PROACTIVE-HF[11] (results pending)	Patient-directed readings via an external interrogation device (handheld monitor)
V-LAP (Vectorious Medical Technologies)	Interatrial septum	*Under investigation for:* • NYHA class III HF plus • HFH in last 12 mo	• History of intracardiac thrombus • Atrial septal defect • Prior PFO/ASD closure device	• VECTOR-HF[12] (safety and feasibility)	Patient-directed readings via an external interrogation device
FIRE1 (Foundry Innovation and Research 1 Ltd)	Inferior vena cava	*Under investigation for:* • HF diagnosis with hospitalization in 12 mo or urgent HF visit with • Elevated BNP/NT-proBNP • And on ≥40 mg furosemide equivalents	• IVC filter • Abnormal venous anatomy • Severe right-sided valvular disease	• FUTURE-HF (safety and feasibility)	Patient-directed readings via an external interrogation device (belt)

ASD, atrial septal defect; BNP, brain natriuretic peptide; CHAMPION, CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in the New York Heart Association (NYHA) Class III HF Patients; DAPT, dual antiplatelet therapy; FDA, Food and Drug Administration; FUTURE-HF, First-in-Human Clinical Investigation of the FIRE1 System in HF Patients; GUIDE-HF, hemodynamic-GUIDEed management of HF; HF, heart failure; HFH, heart failure hospitalization; IVC, inferior vena cava; MONITOR-HF, remote hemodynamic monitoring of PAPs in patients with chronic HF; NT-proBNP, N-terminal brain natriuretic peptide; NYHA, New York Heart Association; PFO, patent foramen ovale; PROACTIVE-HF, prospective, open-label, single-arm, multicenter clinical trial to evaluate the safety and effectiveness of the Cordella PA Sensor System in NYHA Class III HF Patients compared to a Performance Goal; SIRONA trial, prospective, multicenter, open-label, single-arm feasibility trial to assess device safety and efficacy of the Cordella HF System in 10 NYHA Class III HF patients who will receive the Cordella sensor implant.

primary end point, a reduction in worsening HF events, in a pivotal trial called Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure, it showed that small increases in pressure (ePAD) that occur over an extended period of time is the pressure-based hemodynamic factor most closely associated with the transition to acute decompensated HF.[13,14] Of note, the increases in ePAD were not detectable, and hospitalizations were not predicted by changes in daily weight measurements (ie, weight gain). Taken together, these observations supported the superiority of monitoring intracardiac or PAPs rather than weight changes in the management of HF and ushered in the era of IHM.[13,14]

Implantable hemodynamic monitors

CardioMEMS HF system

Currently, the only Food and Drug Administration (FDA) approved (initial approval 2014, indication expanded 2022) wireless hemodynamic monitoring device is the CardioMEMS HF system (Abbott). This device consists of a coil and pressure-sensitive capacitor that has no leads or batteries (Figure 1). It utilizes 2 nitinol loops to help anchor the device within the appropriately sized PA branch. An electrical circuit is formed by the coil and capacitor and resonates at a specific frequency. When pressure within the pulmonary circulation changes, the resonant frequency is shifted and can be measured by the external interrogation device (pillow) that converts it to a pressure waveform.[15] This device is implanted via right heart catheterization (RHC) utilizing a 12F catheter sheath, with FDA approval for internal jugular or femoral venous access and a specialized delivery system.[16]

The first study showing the clinical utility of this device was the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in the New York Heart Association [NYHA] Class III HF Patients) trial.[7] This study randomized 550 HF patients, regardless of ejection fraction, to 2 groups, 1 in which daily measurement of PAP was used to guide management compared to standard care alone. This study showed a reduction in the primary end point rate of HF-related hospitalizations within 6 months postdevice implant, with a rate of 0.44 (n = 270) in the control group compared to 0.32 (n = 120) in the treatment group (hazard ratio [HR], 0.72; 95% CI, 0.60-0.85; $P = .0002$). Over the entire follow-up period, this trial showed a 37% reduction in HF-related hospitalizations in the treatment group compared with the control group, along with a strong safety profile (98.6% freedom from device- or system-related complications).[7] A reduction in HF-related hospitalizations was also noted in a prespecified subgroup analysis of HF with preserved ejection fraction patients (left ventricular ejection fraction ≥40%), with a 46% lower rate in the treatment group compared to the control group, establishing the CardioMEMS HF system as the first effective approach to reducing HFH in HF with preserved ejection fraction.[17]

Following results from this trial, the CardioMEMS HF system received FDA approval for clinical use in 2014 in HF patients with NYHA class III symptoms and a least 1 HFH within the preceding 12 months. Following approval, a Postapproval Study was undertaken and confirmed clinical benefit with use of the CardioMEMS HF system to guide clinical management. In this study, rates of HFH as well as all-cause hospitalizations were reduced in the year following implant compared to the year before implantation. These results were consistent across a variety of subgroups, again including ejection fraction.[18]

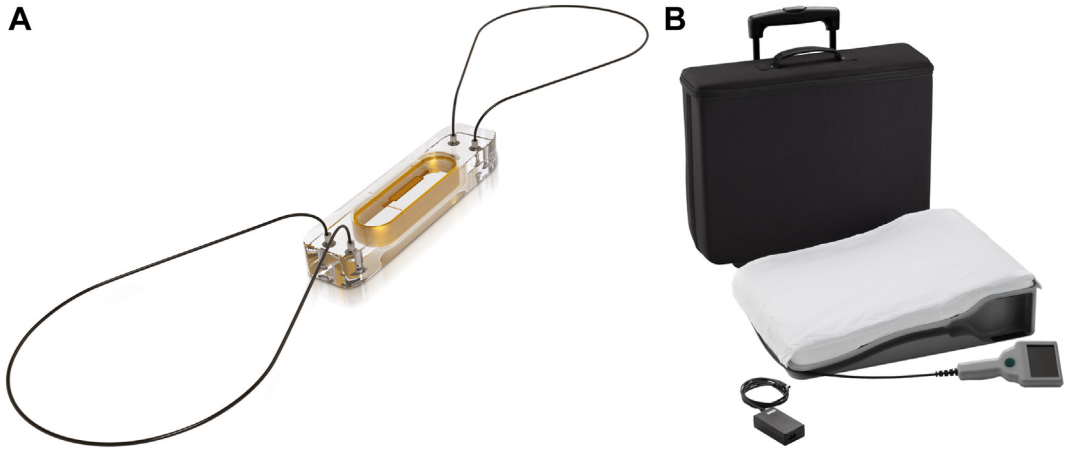


Figure 1.
(**A**) The CardioMEMS pulmonary artery pressure sensor (Abbott). (**B**) The home electronic external unit (pillow) powers and interrogates the sensor and then relays the pressure data to a secure website for clinical review.

The findings from these as well as additional studies lead investigators to hypothesize that the benefits of hemodynamic-guided management might extend to additional HF populations.

The GUIDE-HF (hemodynamic-GUIDEed management of HF) trial was undertaken to assess whether hemodynamic-guided management utilizing the CardioMEMS HF system could result in improved outcomes (reduction in HFH or mortality) in a broader HF population (NYHA class II-IV, including patients with elevated natriuretic peptides without recent HFH).[5] This study again randomized patients (1000 subjects) to hemodynamic-guided HF management compared to standard of care. While this trial did not show a lower composite end point rate of mortality and total HF events in the treatment group compared to the control group, the enrollment and follow-up of this trial were impacted by the COVID-19 pandemic. Thus, a pre-COVID-19 impact analysis was performed and indicated a reduction in the primary end point in the treatment group compared to standard of care (HR, 0.81; 95% CI, 0.66-1.00; $P = .049$). This was primarily driven by a reduction in HFH, with 124 hospitalizations in the treatment group compared to 176 hospitalizations in the control group (HR, 0.72; 95% CI, 0.57-0.92; $P = .0072$).[5] These results led the FDA to expand the clinical indication for use in 2022 to NYHA class II-III HF patients with at least 1 HFH within the previous 12 months and/or elevated natriuretic peptide.

Recently, the MONITOR-HF (remote hemodynamic monitoring of PAPs in patients with chronic HF) trial was completed in the Netherlands and helped further solidify findings from previous trials. This was a prospective, multicenter, open-label, randomized clinical trial assessing the utility of the CardioMEMS device in NYHA class III patients with HFH within the past 12 months or urgent HF visit on mean change in Kansas City Cardiomyopathy Questionnaire (primary outcome) and total number of HFH and urgent visits (secondary outcome).[8] This study, published in June 2023, showed significant improvement in the Kansas City Cardiomyopathy Questionnaire from baseline to 12 months in the CardioMEMS group compared to standard of care (+7.05; 95% CI, 2.77-11.33; $P = .0014$ vs –0.08; 95% CI, −3.76 to 3.60; $P = .97$) along with a significant reduction in HFH in the CardioMEMS group compared to standard of care (rate of total HFH reduced 44%, HR, 0.56; 95% CI, 0.38-0.84; $P = .0053$).[8] An unpublished meta-analysis data from CHAMPION, GUIDE-HF, and LAPTOP-HF (Left Atrial Pressure Monitoring to Optimize HF Therapy) has not only continued to confirm the findings of reduction in HFH (36% reduction at 12 months, HR, 0.64; 95% CI, 0.55, 0.76) but also showed a 25% reduction in mortality with use of hemodynamic monitoring compared to standard of care (HR, 0.75; 95% CI, 0.57, 0.99).[19]

At this time, the cost of the CardioMEMS device is approximately $18,000, and reimbursement for implantation can vary from year to year and depend on the insurance company providing the company for the patient and the diagnosis-related group code utilized for implantation.[20] Several studies have assessed the cost-effectiveness of the CardioMEMS device based on its initial clinical indication in NYHA class II HF patients with HFH within the previous 12 months. These studies have shown a cost ranging from $13,979 per quality-adjusted life-year (QALY) gained in an initial CHAMPION trial looking at 6-month outcomes up to $71,462 QALY gained in a more recent analysis looking at 17-month follow-up data from the CHAMPION trial.[7,21]

Cordella PAP sensor system

The Cordella PAP Sensor (Endotronix, Inc) is another device implanted within the pulmonary arterial circulation via RHC and aims to have an impact on reduction of clinical events in the HF population. The PA pressure sensor remains investigational at this time. The Cordella device is similar in design to the CardioMEMS device, with a central sensor attached to 2 nitinol anchors (Figure 2A).[9] The delivery system has a torque catheter with a handle that allows for adjustment of the orientation of the sensor as well as a stability sheath that enables direct contrast injection without removal of the delivery system. The sensor is placed exclusively within the right PA, given the inferior and posterior orientation of the interlobar artery.[22] Readings are obtained from the anterior chest utilizing a handheld patient reader and can be performed in seated or supine positions (Figure 2B). The PA pressure sensor is combined with the patient management platform to complete the comprehensive Cordella HF system, which allows for measurement, recording, and transmission of blood pressure, heart rate, weight, and oxygen saturation, along with PA pressures to help guide clinical management of this complex patient population.[11,10]

The first-in-human implants were performed as part of the SIRONA trial (prospective, multicenter, open-label, single-arm feasibility trial to assess device safety and efficacy of the Cordella HF System in 10 NYHA Class III HF patients who will receive the Cordella sensor implant) and involved implantation in 15 HF patients with NYHA class III symptoms. This trial showed no device system-related complications and met its primary efficacy end point in mean PA pressure with a cohort difference of only 2.7 mm Hg when comparing the Cordella sensor to the Swan–Ganz catheter on RHC.[9] Following this, 70 patients were implanted with the sensor as part of the SIRONA II trial, which also showed excellent device safety profile and equivalence in PA pressures when compared to those derived from the Swan–Ganz catheter via RHC at 90 days.[10] Currently, the PROACTIVE-HF trial (prospective, open-label, single-arm, multicenter

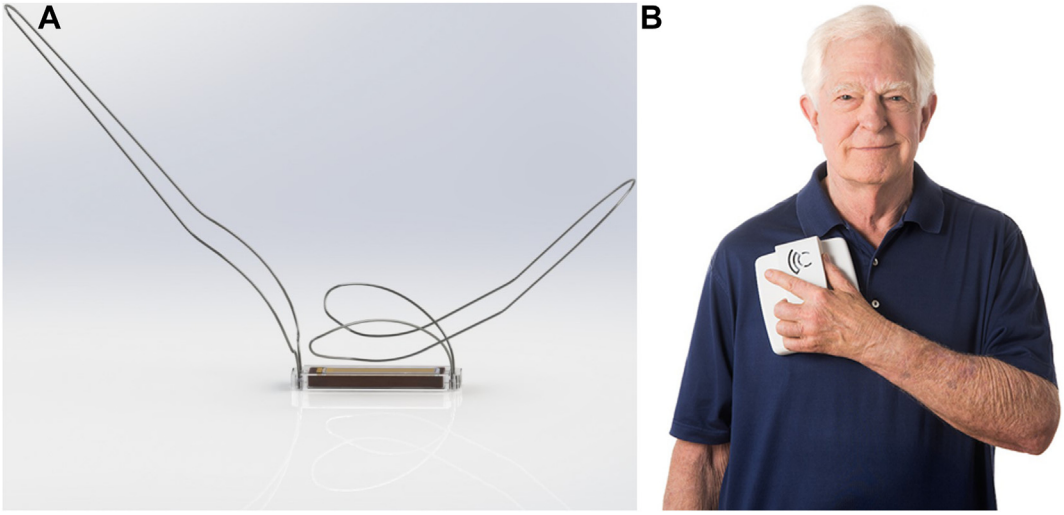


Figure 2.
(**A**) The Cordella pulmonary artery pressure sensor (Endotronix, Inc). (**B**) The handheld patient reader powers the device, allows sensor interrogation, and facilitates readings in seated or supine positions.

clinical trial to evaluate the safety and effectiveness of the Cordella PA Sensor System in NYHA Class III HF Patients compared to a Performance Goal) is being undertaken to assess whether the clinical benefits previously identified with PA pressure-guided HF management extends to the Cordella PA sensor system. This trial is investigating whether utilizing goal PA pressures to target pharmacological interventions will lead to a reduction in mortality and HFH in patients with NYHA class III symptoms or elevated natriuretic peptide. This study was initially designed and approved in 2018 as a randomized, controlled, single-blinded trial, with the first implant in 2020. However, with increasing data supporting the benefit of PA pressure-guided HF management, this trial was adjusted to a single-arm in 2021 with prespecified safety and efficacy end points. Results from this trial are not available at this time.[11] The cost of this device as well as assessment of cost-effectiveness are not available for this or the remainder of the implantable devices as they are not currently commercially available.

Vectorious left atrial pressure monitor system

The vectorious left atrial pressure (V-LAP; Vectorious Medical Technologies) is a wireless remote monitoring system that allows for direct left atrial pressure (LAP) measurement. This sensor is a leadless, batteryless, fully digital intracardiac pressure sensor and allows for bidirectional communication with the external unit (Figure 3). The sensing elements and electronics are located within a sealed tube and surrounded by distal and proximal nitinol-braided disc anchors. The device is implanted via transseptal access with the discs located on the left and right sides of the interatrial septum and the implant body traversing the septum. The external unit provides power to the device and collects data utilizing radiofrequency communication.[23,24] Implantation of the device is achieved via a 12F catheter transfemoral transseptal delivery system. Angiographic and echocardiographic guidance are utilized to guide adequate implantation, and pulmonary capillary wedge pressures (PCWP) obtained from simultaneous RHC are used to correlate simultaneous mean LAP from the V-LAP device.

The V-LAP device showed an excellent safety profile and strong correlation between LAP measurements from the device to PCWP on invasive RHC in animal models.[23] This led to the creation of the VECTOR-HF (V-LAP Left Atrium Monitoring System for Patients with Chronic SysTOlic and Diastolic Congestive HF) trial to assess the safety, performance, and usability of the V-LAP system in HF patients.[12] This study was a single-arm, open-label, first-in-human clinical trial that enrolled 30 patients with NYHA class II HF symptoms to receive the V-LAP system. This study showed an excellent safety profile with the device with no acute major adverse cardiac or neurological events and a 97% freedom from major events at 3 months. This study showed good correlation between simultaneous LAP and PCWP measurements (correlation coefficient 0.79, $P < .0001$) at 3 months with a significant improvement in 6-minute walk distance and improvement in NYHA functional class.[12]

Direct LAP monitoring may have certain advantages over PA pressure monitoring in certain HF populations. Studies have shown a mismatch in left- and right-sided filling pressures in patients with chronic or advanced HF, with some of this discrepancy being related to the frequency of secondary pulmonary hypertension in these populations.[25,26] Direct assessment of LAP may also help better assess for development or progression of other clinical events in these patients

Figure 3.
The V-LAP wireless remote monitoring system is a fully digital intracardiac pressure sensor placed within the interatrial septum via transseptal access (Vectorious Medical Technologies).

Figure 4.
The FIRE1 device is placed within the inferior vena cava (IVC) and measures the IVC area and changes over time (Foundry Innovation and Research 1 Ltd).

with HF, including diastolic dysfunction, presence/frequency of atrial arrhythmias, and hemodynamic implications related to said arrhythmias, and severity and progression of left-sided valvular dysfunction, including secondary mitral regurgitation.[23]

Ongoing studies of the V-LAP system are evaluating a physician-directed, patient self-management approach using LAP-guided HF management, similar to that used in the HOMEOSTASIS and LAPTOP trials.[27]

FIRE1 system

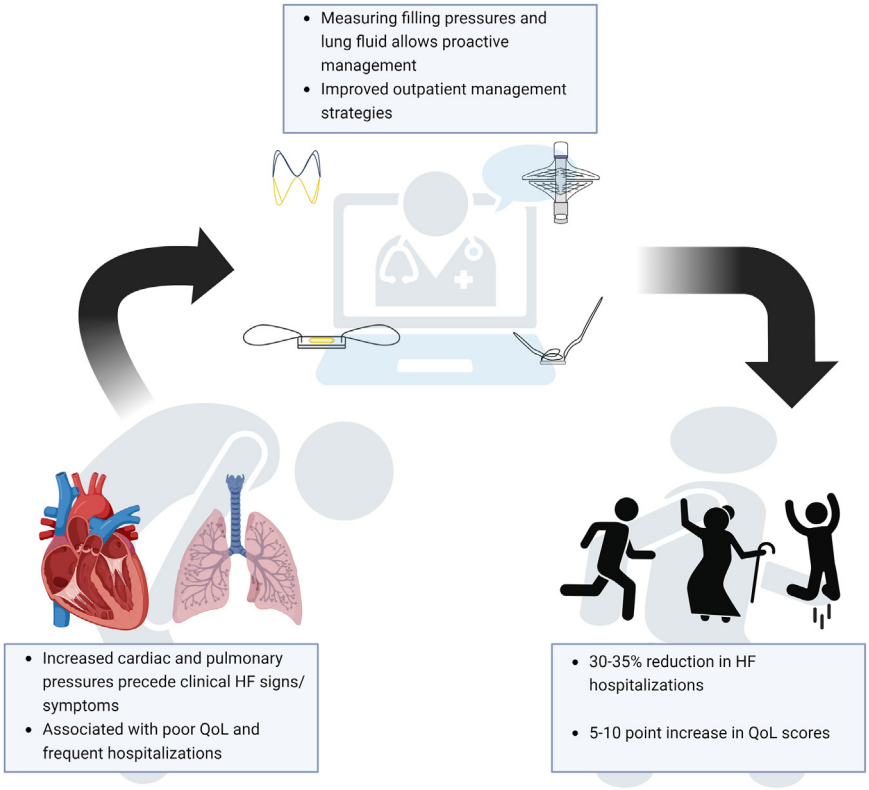
The FIRE1 device (Foundry Innovation and Research 1 Ltd) is an inferior vena cava (IVC) sensor that has been developed to measure the IVC area and its change over time. The sensor comprises a coil of wire and capacitor, which form an electromagnetic resonator (Figure 4). The cross-sectional area of the IVC is measured via the device utilizing radiofrequency energy. The detection system consists of a belt that energizes the implanted sensor and measures the resonant frequency of the sensor, which is dependent on the area of the sensor. The FIRE1 device is implanted within the IVC via a 16F catheter sheath utilizing a device-specific delivery system.[28] Initial animal studies showed successful implantation without complication. In-vitro validation studies showed that changes in IVC area were more sensitive than changes in cardiac and pulmonary pressures during volume infusion ($P < .001$), vasodilation with nitroglycerin ($P < .001$), and cardiac dysfunction mediated by rapid right ventricular pacing ($P \leq .02$). Additional animal studies confirmed device safety with 100% procedural success. This study also showed a more significant change in IVC area with smaller amounts of volume instillation than right atrial pressure, which required a larger volume load to consistently significant changes in pressure.[29] The first-in-human implantation of this device occurred in February 2023 in the United Kingdom as part of the FUTURE-HF (First-in-Human Clinical Investigation of the FIRE1 System in HF Patients) trial, hoping to replicate safety and efficacy in a cohort of HF patients.

Noninvasive hemodynamics

There are many noninvasive approaches to hemodynamic assessment under development, with a few that are approved and available for clinical use. A comprehensive review of noninvasive HF monitoring technologies is beyond the scope of this review. Two examples, both clinically available, are discussed below.

Remote dielectric sensing

Remote Dielectric Sensing (ReDS) (Sensible Medical Innovations Ltd) measures the dielectric properties of tissues utilizing low-power



Central Illustration.
Monitoring invasive hemodynamics allows proactive management strategies and has been associated with improvement in clinical and patient-centered outcomes. HF, heart failure; QoL, quality of life.

electromagnetic signals. These signals are emitted through the right midthorax via a wearable vest and are then received after passing through tissues by the same vest. The signals that are received after passing through tissues reflect the dielectric properties of those tissues and are primarily impacted by the fluid content of those tissues.[30,31] This study was initially studied in 50 patients with stage C HF following HFH. The device was utilized for 90 days postdischarge, and outcomes were compared to the pre and postutilization periods. The readmission rate dropped during the ReDS-guided management period (0.04 events/patient/3 months) compared to the pre-ReDS and post-ReDS periods (0.30 and 0.19 events/patient/3 months), respectively.[30] This technology has been studied in other populations as well, including in evaluating readiness for discharge in patients hospitalized with acute HF, but currently its volume of use clinically in the management of HF patients remains limited.[32]

MicroCor

The MicroCor (Zoll Medical Corporation) device is an adhesive patch-based device that utilizes low-power electromagnetic pulses to assess tissue fluid content. This device also contains 2 electrodes, which allows it to obtain electrocardiographic and heart rate data along with respiratory rate, activity, and posture to form the Zoll HF Management System. The company notes the use of proprietary algorithms that assess patient-specific trends that may allow for early detection of an HF decompensation episode. The company then notifies the physician of these changes to be utilized on a patient-by-patient basis and in appropriate clinical context to determine if changes to the medical plan are needed. This technology has recently been studied in the Benefit of Microcore in Acute Decompensated Heart Failure trial in which patients recently discharged following HF admission were enrolled to utilize this device for 90 days. The trial consisted of 2 arms: (1) a nonrandomized control arm with a MicroCor device without radar-directed therapy and (2) an intervention arm with a MicroCor device utilizing radar-directed therapy. This study was presented as a late-breaking clinical trial at the American College of Cardiology's 2023 Annual Scientific Session and showed a 38% reduction in 90-day hospital readmissions within the intervention arm compared to control ($P = .03$). However, fully published trial results are not available at the time of publication of this review.[33]

Conclusion

While current evidence suggests clinical benefits from IHM, appropriate patient selection, and education regarding these devices are crucial to help facilitate improved clinical outcomes (Central Illustration). Since these devices rely on patients obtaining readings at home, an ability for patient and/or caregiver(s) to adhere to regular readings and adjustment of medical therapy, as well as the ability to communicate with the health care team regularly, are important. Further, device-related indications and contraindications are listed in Table 1.

Worsening HF symptoms, frequently requiring hospitalization and/or intravenous therapies, are due to small increases in intracardiac and PAPs and lung fluid content that occur over an extended period of time. Ambulatory measurement of these parameters is superior to the use of surrogate markers of hemodynamic and pulmonary congestion for the reduction of HF events, including recurrent HFH. The CardioMEMS HF system currently serves as the paradigm for IHM-guided HF management. Next-generation IHM systems and approaches are under investigation and promising for the future of HF management. Likewise, nonimplantable devices that may estimate pulmonary pressures or lung fluid content are emerging as additional and perhaps complementary approaches to guide-HF therapy.

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Declaration of competing interest

Scott Lundgren is on the speaker's bureau for Abbott. William Abraham reports consulting fees from Vectorious Medical Technologies and Sensible Medical. Robert Garvin reported no financial interests.

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Ethics statement and patient consent

The research reported has adhered to the relevant ethical guidelines.

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