Remote Monitoring in Heart Failure: Revolutionizing Patient Management and Outcomes

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Abstract

Heart failure (HF) is a global health issue, contributing significantly to morbidity and mortality, particularly in North America. The management of HF is complex, requiring diligent monitoring to prevent decompensation and clinical progression. While there have been improvements in treating HF, it still leads to significant negative health outcomes and heavily contributes to the use of healthcare services. Outpatient management for HF lacks consistent application of proven therapies and the early identification and management of worsening conditions. Remote monitoring (RM) offers a solution to these challenges and there has been growing attention from HF healthcare providers and medical systems. This review explores the evolution and role of RM in the ambulatory care of HF patients, particularly emphasizing the impact of RM on clinical outcomes amid the COVID-19 pandemic.

Keywords

Heart failure, remote monitoring, telemonitoring technologies

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Heart failure (HF) remains a growing health concern worldwide, with the number of affected individuals reaching at least 26 million. It is one of the primary contributors to illness and death on a global scale and affects more than 7.5 million people in North America alone.[1–3] Patients with HF require close monitoring with frequent clinic visits to titrate medications appropriately and avoid worsening congestion and decompensation.

Emergence of Remote Monitoring

Even before the COVID-19 pandemic, remote monitoring (RM) was crucial for both urban and rural populations.[4] However, testing and in-office visits decreased during the pandemic and this placed patients with HF at increased cardiovascular risk.[5] Various RM methods have been explored in the context of HF, ranging from uncomplicated strategies, such as organized phone check-ins or daily weight tracking, to more intricate methods, such as continual pressure monitoring using intravascular devices.[6,7] Wearable devices have become part of the RM landscape for HF, partly due to the restrictions placed on providers during the pandemic.

The swift advance of wireless networks and real-time machine-learning algorithms has set the groundwork for creating advanced HF RM systems. These systems monitor symptoms, vital signs, and weight changes to reduce the rate of HF hospitalizations. Various types of RM exist, ranging from traditional telemonitoring with daily weights and vital signs to more advanced capabilities. Several trials have explored combinations of these traditional methods, with some revealing no discernible benefits, and others showing mortality benefits specifically with round-the-clock medical emergency phone access.[8–11]

Implantable devices are based on the concept that increased intracardiac pressures precede clinical HF decompensation requiring hospitalizations, sometimes even weeks before decompensation occurs.[12] Ensuring adequate reimbursement is key to the successful implementation of RM. There has been significant expansion of 'hospitals at home' in the US since the Centers for Medicare and Medicaid Services (CMS) Acute Hospital Care at Home Waiver in 2020, which approved comparable reimbursement for acute on chronic heart failure management at home as well as in hospital. Similar policies for the management of chronic heart failure are key to incentivizing providers in using RM.[13] Telehealth payment models established by CMS and private insurance companies have been extended beyond the COVID-19 pandemic, but securing permanent reimbursement for remote management of heart failure is key to the broad adoption of RM – in the US at least.[14]

Due to the focused scope of this review on the evidence for each emerging and established technology, we will not delve into the "response element" in remote monitoring data, which refers to the actions or

Table 1: Invasive Heart Failure Monitoring Devices

Device	Clinical Trials	Number of Patients Enrolled	Inclusion/Exclusion Criteria	Primary Endpoints/ Major Findings	FDA Approval Status
CardioMEMS	CHAMPION,[18] post-approval studies[19]	550 (CHAMPION) 1,200 (post-approval)	Chronic HF NYHA class III, optimal medical therapy	Reduction in HF hospitalizations, trend for lower mortality	Approved
Endotronix Cordella	PROACTIVE-HF[20]	Ongoing	NYHA class III symptoms	Composite of mortality, HF hospitalizations, ED/clinic visits	Not approved
Vectorious V-LAP	VECTOR-HF (NCT03775161)	Ongoing	NYHA class III/IV, prior acute HF hospitalization	Safe, correlation with invasive pulmonary capillary wedge pressure	Not approved
FIRE1 System	Single-arm studies[28]	Ongoing	HF patients	Safety and performance in inferior vena cava volume monitoring	Not approved

interventions initiated based on the data collected from remote monitoring technologies, including clinical decisions, adjustments to treatment plans, patient education or other follow-up measures informed by the monitoring system's insights.

Clinical Application of Remote Monitoring in Heart Failure

HF remains an ongoing global health challenge, posing significant complexities for healthcare systems worldwide due to its widespread prevalence.[15] While the conventional approach to HF management relies on periodic in-office clinic visits as outlined above, this potentially results in delayed intervention and limited monitoring capabilities. The advent of RM technologies has presented a promising solution by facilitating continuous data collection and analysis, thereby enabling proactive care strategies.[16] In addition, these technologies can help improve the outcomes for HF patients especially those with limited resources. HF patients, especially those with limited resources, often face barriers, such as reduced access to healthcare facilities, financial constraints and geographic challenges, which make regular in-office visits difficult. Remote monitoring technologies can address these disparities by providing continuous, real-time data on a patient's condition without requiring frequent travel or significant costs associated with traditional care. This accessibility promotes earlier detection of clinical deterioration, timely interventions, and improved disease management, ultimately enhancing outcomes for underserved populations.

This review aims to delve into the role of RM in ambulatory HF care. RM is designed to address existing shortcomings in HF management. It enables healthcare providers to supervise and guide patients beyond the confines of standard medical appointments using synchronous and asynchronous care. This method offers the potential to improve HF treatment by ensuring more comprehensive and prompt provision of treatments that follow established medical guidelines, as well as improving surveillance for signs of clinical deterioration.

Invasive Monitoring Options

Invasive monitoring options are summarized in *Table 1.*

Pulmonary Artery Pressure Monitoring

Pulmonary artery pressure monitoring was the earliest approach. These sensors are able to report pulmonary artery systolic pressure, pulmonary artery diastolic pressure, and mean pulmonary artery pressure.[17] One of the earliest pulmonary artery monitoring devices was the Chronicle (Medtronic), which was tested in clinical trials in the early 2000s. This was a right ventricular pressure sensor that provided only an estimate of pulmonary artery diastolic pressure. However, in a multicenter randomized clinical trial, the device did not reduce HF hospitalizations and did not receive Food and Drug Administration (FDA) approval due to being underpowered at 274 patients.[18]

The next iteration of pulmonary artery pressure monitoring was the CardioMEMS device (Abbott). CHAMPION – a randomized multicenter single blinded trial in 2011 enrolled 550 patients with chronic HF with New York Heart Association (NYHA) class III symptoms on optimal medical therapy to receive an implantable pulmonary artery pressure monitor.[12] Patients were then randomized to either have daily hemodynamic data transmitted to their provider for 6 months versus the control group where hemodynamic data was not transmitted. The primary outcome of HF hospitalizations was significantly reduced in the intervention group (HR 0.72; 95% CI [0.59–0.88]; p=0.002), and there was a trend for lower mortality (HR 0.68; 95% CI [0.45–1.02]; p=0.06). This was the first randomized control trial that showed benefit with implantable hemodynamic monitoring devices, leading to FDA approval of the device. In a post approval study including 1,200 patients across 104 centers, the rate of HF hospitalizations and all-cause hospitalizations were significantly lower 1 year after CardioMEMS implantation compared with the year before implantation (HR 0.43; 95% CI [0.39–0.47]; p<0.001).[19] To date, this system is the most widely used implantable RM device and it is the only FDA-approved invasive pressure monitor with several studies supporting its benefit when used for its approved indication: patients with New York Heart Association (NYHA) class II–III HF symptoms, including both reduced ejection fraction and preserved ejection fraction, and an HF hospitalization in the past 12 months.

Another pulmonary artery pressure monitoring device, the Endotronix Cordella system, combines pulmonary artery pressure monitor data with vital signs (including body weight, blood pressure, heart rate, and blood oxygen saturations) and patient symptoms. The PROACTIVE-HF trial is currently under way, which is a single-arm study to investigate the benefits of a combined system in patients with NYHA class III symptoms in terms of remote titration of guideline-directed medical therapy (GDMT) and congestion management. The primary endpoint encompasses a composite of mortality, HF hospitalizations, and visits to the emergency department or clinic for the administration of IV diuretics.[20]

Left Atrial Pressure Monitoring

Several other implantable RM devices are under development for pressure monitoring in various cardiac chambers. Vectorious' V-LAP system features an implantable left atrial septum pressure sensor that wirelessly connects to a cloud-based transponder worn on the shoulder. This system is being investigated in the ongoing VECTOR-HF trials (NCT03775161), which target patients with NYHA class III or ambulatory class IV HF who experienced at least one prior hospital admission for acute HF within the last 12 months. A subset of VECTOR-HF 1 and in all VECTOR-HF 2 trials, implementation of a physician-directed, patient self-

Table 2: Noninvasive Heart Failure Monitoring Devices

Device	Clinical Trials	Number of Patients Enrolled	Inclusion/Exclusion Criteria	Primary Endpoints/ Major Findings	FDA Approval Status
Edema Guard Monitor	IMPEDANCE-HF[29]	256	Chronic HF patients	Reduction in HF hospitalizations and all-cause mortality	Not approved
ReDS (Sensible medical)	Single-center study, various trials[31–33]	Various	Post-discharge HF patients	Correlation with wedge pressure, reduction in HF hospitalizations	Not approved
ZOLL HF Management System	Ongoing investigation (NCT03476187)	Ongoing	Ambulatory HF patients	Monitoring pulmonary fluid levels, heart rate, respiratory rate	Not approved
µCor	Multicenter study[34]	522	HF patients post-discharge	38% reduction in HF hospital readmission, improved quality of life	Not approved

management paradigm similar to those used in the HOMEOSTASIS and LAPTOP-HF trials is being investigated.[21,22] Initial trial findings suggest the V-LAP monitoring system is safe, offers promising correlations with invasive pulmonary capillary wedge pressure.[23] Early assessments of the V-LAP system's performance during the COVID-19 pandemic have indicated its ability to provide pertinent data for managing HF patients.[23–25] However, the system's delivery via transseptal puncture may carry risks of more complex device placement and potential procedural complications, and may limit transseptal access for other devices.

Inferior Vena Cava Pressure Monitoring

Outside of intracardiac pressure monitoring, there is growing interest in quantifying changes in the size and shape of the inferior vena cava (IVC) in volume status assessment.[26] However, although monitoring IVC dimensions may track central filling pressures in HF patients, discrepancies between right- and left-sided hemodynamics require further evaluation in clinical trials.[27,28] The FIRE1 System is a device that is placed in the IVC between the renal and hepatic veins via a transcatheter delivery system. Transmitting data wirelessly through a wearable belt, it focuses on cross-sectional area and respiratory variation in IVC dimensions.[28]

Non-Invasive Monitoring Options

Non-invasive monitoring options are summarized in *Table 2*.

Thoracic Impedance Monitoring

Increasing congestion can be monitored via a non-invasive approach by measuring thoracic impedance, which involves evaluating lung fluid content through radiofrequency or electromagnetic signals. Devices using this approach include the Edema Guard Monitor (CardioSet Medical), Remote Dielectric Sensing (ReDS; Sensible Medical Innovations), and the ZOLL HF Management System (HFMS).

The Edema Guard Monitor monitors lung impedance via electrodes placed on the chest and back. This was evaluated in the IMPEDANCE-HF study, which enrolled 256 chronic HF patients who underwent monthly lung impedance assessments during clinic visits.[29] The primary efficacy outcome of a reduction in HF hospitalizations was significant during the first year (p<0.0001; number needed to treat [NNT] 1.4) and the entire follow-up period (p<0.001; NNT 1.9). There was also a reduction in all-cause mortality (HR 0.52; 95% CI [0.35–0.78]; p=0.002) and HF-related deaths (HR 0.30; 95% CI [0.15–0.58]; p<0.001).[30]

The ZOLL HFMS employs patch-based radiofrequency technology placed in the left anterior axilla to monitor for pulmonary edema and decompensation, which is validated in numerous studies indicating comparable sensitivity and specificity compared to thoracic computed tomography.[31] Along with monitoring changes in pulmonary fluid levels, the device tracks heart rate, respiratory rate, activity, posture, and electrocardiogram parameters. Using a patient-specific algorithm, baseline patterns are set and providers are alerted of deviations from baseline. This device is currently undergoing investigation in ambulatory HF patients (NCT03476187).

ReDS uses non-invasive, low-power electromagnetic signals to measure lung fluid content by assessing dielectric properties of pulmonary tissue. It incorporates two sensors embedded in a wearable vest or shoulder clip. In a prospective, single-center study with HF patients, ReDS assessment of lung fluid volume exhibited a reasonable correlation with wedge pressure (r 0.492; p<0.001), and demonstrated a high sensitivity (91%) and specificity (77%) in detecting pulmonary capillary wedge pressure >18 mmHg.[31,32] Additionally, prospective studies involving post-discharge monitoring for acute HF showed a significant reduction in HF hospitalizations with daily ReDS assessments.[33]

The BMAD study on the ZOLL Heart Failure Monitoring System (HFMS) was presented at the American College of Cardiology meeting. This study demonstrated the effectiveness of a wearable HFMS in reducing rehospitalization rates for patients recently discharged after a heart failure (HF) event. Conducted at 93 sites with 522 participants, the study compared standard care (BMAD-HF) to an intervention strategy (BMAD-TX), where HFMS data guided patient management. Over a 90-day period, the intervention group experienced a 38% reduction in HF-related rehospitalizations compared to the control group (HR: 0.62; p=0.03). These findings highlight the potential of remote monitoring technology to improve HF outcomes by enabling earlier intervention and reducing the burden of hospitalizations.[34]

The µCor device, which uses radiofrequency signals to assess thoracic fluid index and alert clinicians, demonstrated a 38% lower likelihood of HF-related hospital readmission within 90 days. The study involved 522 HF patients fitted with µCor monitors; half served as a control group, while the other half had their data transmitted to clinicians. The primary endpoint showed a significant 38% relative RR in hospital readmissions for the intervention group, along with a 7% absolute RR at 90 days. Quality-of-life improvements, measured by the Kansas City Cardiomyopathy Questionnaire-12, were significantly higher in the intervention group, showing a 12-point increase compared to the control group. Although the study acknowledges its concurrent control design and non-randomized nature, the results highlight the potential benefits of µCor device monitoring in managing HF complications.[35]

Cardiac Implantable Electronic Devices

The capabilities of cardiac implantable electronic devices (CIED), particularly the measurement of intrathoracic impedance and the use of

Table 3: Cardiac Implantable Electronic and Artificial Intelligence and Machine Learning Devices

Device	Clinical Trials	Number of Patients Enrolled	Inclusion/ Exclusion Criteria	Primary Endpoints/Major Findings	FDA Approval Status
OptiVol	DOT-HF[36] SENSE-HF[37]	345 (DOT-HF) Various (SENSE-HF)	HF patients	High rate of false alerts, limited predictive value for HF hospitalizations	Not approved
HeartLogic (Boston Scientific)	MultiSENSE,[39,40] MANAGE-HF[44]	400 (MultiSENSE) Ongoing (MANAGE-HF)	HF patients	70% sensitivity in predicting HF events, advance warning of 34 days	Not approved
Cordio HearO	Ongoing validation studies[50]	Various	HF patients	High accuracy in predicting HF events, reduction in hospitalizations	Not approved
Acorai Heart Monitor	Feasibility study[44]	400	HF patients	Accuracies similar to other invasive devices	Not approved
Cardiosense (CardioTag)	Various trials[46]	Various	HF patients	Non-invasive estimation of mean pulmonary artery pressure, diastolic and systolic pulmonary artery pressure	Not approved

complex algorithms, have been evaluated for their use in remote patient monitoring for HF (*Table 3*). In the DOT-HF trial, the effectiveness of intrathoracic impedance monitoring through the OptiVol fluid monitoring algorithm was assessed.[36] In this study, 345 HF patients with new CIEDs were split into two groups, with one receiving OptiVol alerts and the other not, for approximately 15 months. It was observed that those in the alert group experienced more hospitalizations and doctor's visits. The OptiVol system showed a 62% sensitivity for detecting HF hospitalizations, but a high rate of false alerts was noted — of 144 alerts, 114 did not correspond with cardiac decompensation signs.

The SENSE-HF trial further corroborated these results, indicating that intrathoracic impedance monitoring alone had limited effectiveness in predicting HF hospitalizations, with a positive predictive value of 38.1% and a sensitivity of 42%.[37]

Multiparameter Sensors

Despite the technology's potential, reliance on intrathoracic impedance monitoring alone showed low accuracy in detecting clinical decompensation in HF, leading to an increased number of hospital and outpatient visits. However, when intrathoracic impedance was used in tandem with other clinical indicators, the predictive accuracy improved significantly.

The MultiSENSE trial explored this by using the HeartLogic algorithm from Boston Scientific, which integrates several indicators such as intrathoracic impedance, respiratory rate, heart rate, heart sound, and activity level to form a composite HeartLogic index.[38,39] This index is updated daily and is designed to trigger alerts when significant deviations from the baseline are detected. In a study of 400 HF patients monitored over an average of nearly a year, the algorithm successfully identified potential HF events with a 70% sensitivity and provided a median advance warning of 34 days, while keeping unexplained alerts to a minimum.[40,41]

While combination algorithms such as HeartLogic have shown promise in predicting HF risk, the impact of these tools on long-term HF outcomes is still being studied.[42] The MANAGE-HF trial is designed to explore the effectiveness of remote patient monitoring using the HeartLogic algorithm, with a focus on overall mortality and HF-related hospitalizations as its primary endpoints.[43]

Another device is the Acorai heart monitor, which offers a scalable solution for non-invasive intracardiac pressure monitoring, aimed at optimizing HF management. Supported by a feasibility study involving 400 patients, the device has demonstrated accuracy comparable to invasive standards.[44] The Cardiosense system features a non-invasive cardiac monitoring solution that uses the CardioTag wearable device. This system comprises patented hardware technology and a proprietary machine learning algorithm designed to estimate mean pulmonary artery pressure, diastolic pulmonary artery pressure, and systolic pulmonary artery pressure non-invasively.[45,46]

The Role of Artificial Intelligence and Machine Learning

Current technological advancements enable the collection and transmission of a diverse range of physiological data with the use of RM devices. The effectiveness of establishing clinical RM programs hinges on how these data are integrated into clinical care and managed by providers. Challenges in automated data processing for RM systems involve accurately identifying which signal or combination of signals accurately signify HF decompensation and require intervention.

Addressing these challenges may be well-suited for machine learning or artificial intelligence (AI) learning-based systems. RM devices continually provide various data streams related to homeostasis and decompensation such as impedance, activity level of the patient, and vital sign changes including heart rate and respiratory rate. Machine-learning techniques, such as supervised anomaly detection and association rule learning, are adept at tackling such issues. While data from current wearable devices alone might have limited value for clinical decision-making by RM system teams, the advancement of AI-driven data processing using AI techniques could potentially establish a set of pertinent non-invasive indicators of HF decompensation. These machine-learning concepts are currently in development.[9,47] For instance, the LINK-HF study used VitalPatch (VitalConnect) to assess the accuracy of non-invasive RM in predicting HF hospitalization through AI analytics.[48,49] By establishing a personalized baseline model of dynamic vital sign patterns post-discharge for HF exacerbation, the system monitored deviations between learned behavior and actual vital sign behavior, reported as a multivariate change index. This approach demonstrated high sensitivity (76.0–87.5%) and specificity (85%) in detecting the risk of hospitalization due to HF worsening, with a median lead time of 6.5–8.5 days before hospitalization.

Another AI-based system geared to treating HF hospitalizations is the mobile app Cordio HearO in predicting worsening HF. Participants recorded daily sentences in their native language, contributing to a training phase with 263 patients and a subsequent validation phase with 153 participants. In the training phase, the app accurately predicted 76% of HF events on average 24 days before hospitalization, generating three unnecessary alerts per patient per year. The validation phase showed 71% accuracy in detecting events about 3 weeks in advance, with a similar

alert frequency. Researchers suggest technology effectively predicts worsening HF episodes with a low unnecessary notification rate, showcasing its potential to reduce hospitalization and enhance patient outcomes. Ongoing US-based research aims to further validate the technology's efficacy.[50]

The Crucial Role of Remote Monitoring in Heart Failure Management During the COVID-19 Pandemic

The COVID-19 pandemic necessitated a rapid shift from in-person visits to telehealth, significantly affecting the management of HF patients. RM devices became essential during this period, allowing healthcare providers to monitor patients' health status remotely. This reduced the need for frequent hospital visits and minimized patient exposure to coronavirus, which was crucial for HF patients who were vulnerable to severe COVID-19 complications. RM devices played a vital role in enhancing the continuity of care by continuously tracking critical health parameters, such as pulmonary artery pressure, heart rate, and thoracic impedance. These real-time data points helped clinicians make informed decisions regarding medication adjustments and other therapeutic interventions, preventing HF exacerbations and reducing hospital readmissions. The ability to maintain high-quality care without in-person visits was particularly beneficial while there were lockdowns and social distancing mandates. The pandemic accelerated the adoption of telehealth and RM technologies, pushing healthcare providers to integrate RM data with telehealth consultations for a comprehensive approach to patient management. This integration ensured that patients received holistic care, combining the convenience of remote consultations with the accuracy of RM data. As healthcare systems adapted to these new practice patterns, the infrastructure for RM expanded, setting a precedent for future healthcare delivery models. Regulatory bodies recognized the importance of RM during the pandemic, providing incentives and easing restrictions to facilitate the adoption of these technologies. In the US, the Centers for Medicare and Medicaid Services expanded coverage for telehealth services, including RM, encouraging healthcare providers to adopt these tools. Additionally, penalties for HF readmissions under the Hospital Readmissions Reduction Program further incentivized the use of RM to prevent hospitalizations and manage HF more effectively.

Future Directions in Remote Monitoring for Heart Failure

With the advent of multiple technological platforms for RM in HF, selecting the best platform involves considering data fidelity, user-friendliness, and growth potential. The CardioMEMS device by Abbott stands out for yielding the highest fidelity data, significantly reducing HF hospitalizations through continuous, accurate pulmonary artery pressure monitoring. For user-friendliness, particularly appealing to advanced heart failure cardiologists and general, community-based cardiologists, non-invasive options such as the ZOLL HFMS and the µCor device are noteworthy. These platforms provide real-time data on thoracic fluid levels, heart rate, and respiratory rate without requiring complex procedures, making them accessible and practical for a broad range of healthcare settings.

Wearable and non-invasive RM technologies show the greatest upswing potential due to their scalability, ease of use, and integration with AI and machine learning, which can significantly enhance HF management on a larger scale. Beyond AI and machine learning, the next frontier in HF remote monitoring includes non-invasive intracardiac pressure monitoring systems and predictive apps such as Cordio HearO. The Acorai heart monitor offers the potential to provide continuous, real-time intracardiac pressure data with accuracies comparable to invasive methods, without the need for surgical implantation. This innovation could revolutionize HF management by enabling precise, proactive interventions, improving patient outcomes, and reducing hospital readmissions.

Conclusion

RM is gaining traction in the management of HF, driven by its potential to enhance clinical outcomes. The increasing burden of HF and economic benefits of RM are likely to boost its integration into standard HF care, especially in light of the practice changes brought about by the COVID-19 pandemic.

Evidence to date points to a higher effectiveness of RM strategies that use invasive sensors for data collection over those that rely on non-invasive sensors. However, RM methods using non-invasive sensors are still of significant interest due to their broader applicability, reduced risks, and costs compared to invasive methods. In summary, RM is a promising approach for monitoring physiological parameters to preemptively identify negative changes before HF patients experience clinical decompensation. While invasive RM devices, such as those measuring pulmonary artery pressure, have been shown to decrease hospital readmissions for certain subsets of patients, the effectiveness of non-invasive RPM technologies is not as clear. Data analytics and machine learning may enhance the identification of non-invasive markers of deterioration and help to clarify the role of wearable RM technologies.

The deployment of these technologies signifies a shift towards a more manageable approach to advanced HF care, one that minimizes the need for frequent in-person consultations. This is expected to lead to better outcomes for the HF patient population, particularly benefiting those in rural areas and those with limited access to healthcare resources, including transportation. ❑

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