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Remote monitoring and heart failure

Nicola Pierucci • 1*, Domenico Laviola • 1, Marco Valerio Mariani 1, Alessio Nardini 2, Francesco Adamo 3, Karim Mahfouz 3, Carlo Colaiaco 3, Fabrizio Ammirati 3, Luca Santini 3, and Carlo Lavalle • 1

¹Department of Clinical Internal Anesthesiologic and Cardiovascular Sciences, Sapienza University of Rome, Rome 00161, Italy; ²General Direction of the Mission Unit for the Implementation of PNRR Interventions, Italian Ministry of Health; and ³Cardiology Unit, Ospedale G.B. Grassi, Ostia, Rome, Italy

KEYWORDS

Heart failure; Remote monitoring; Multi-parametric evaluation; Connectivity Heart failure (HF) represents one of the leading causes of morbidity and mortality worldwide. In recent years, remote monitoring (RM) and telemedicine have emerged as a promising strategy to improve the management of patients with HF, reducing hospitalizations and enhancing the quality of life. Through the integration of technologies such as implantable sensors, home monitoring devices, and mobile applications, it is possible to detect clinical changes early, enabling timely interventions. This article provides an overview of available technologies for RM in HF, analyses the clinical benefits observed in various studies, and addresses the remaining challenges, such as the need for standardization, long-term sustainability, and widespread adoption. Remote monitoring offers significant potential to improve clinical outcomes but requires further research and development to optimize its use in clinical practice.

Introduction

Heart failure (HF) is a chronic 'pandemic' condition characterized by the heart's inability to pump blood effectively, leading to significant morbidity and mortality. The goals of treatment in patients with HF are to improve their clinical status, functional capacity, and quality of life (QoL), prevent hospital admissions, and reduce mortality. Traditionally, HF management has heavily relied on the optimization of medical and device therapy, in-person clinical visits, and hospitalizations. However, in recent years, patient management with HF has shifted towards care models based on prevention and continuous monitoring of clinical conditions, aiming to avoid exacerbations and hospitalizations, which represent a major economic burden on healthcare systems. Remote monitoring (RM), or telemonitoring, is a significant innovation in this regard. This technology

enables physicians to remotely monitor patients' vital signs and clinical data in real time, allowing for rapid intervention in case of deterioration of the patient's condition.⁴

Remote monitoring technologies in heart failure

Remote monitoring technologies can be divided into several categories, depending on the type of device used and the data monitored. Among the most relevant are as follows:

- (1) Pulmonary artery pressure monitoring:
 - CardioMEMSTM: This implantable sensor uses microelectromechanical system technology to monitor and transmit pulmonary artery pressure. The CHAMPION trial⁶ showed that CardioMEMS reduced HF hospitalizations and improved QoL. It was effective regardless of ejection fraction, with

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^{*}Corresponding author. Fax: +0649978022, Email: npierucci@gmail.com

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a 48% reduction in hospitalizations after 6 months. Medicare data confirmed similar outcomes in real-world use.

- (2) Cardiac and vital parameter monitoring:
 - Wearable devices: Devices like portable electrocardiograms (ECGs) and KardiaMobile continuously track heart rate (HR), variability, and ECG, transmitting real-time data to clinicians.
 - Smartwatches/fitness trackers: New models (e.g. Apple Watch) monitor ECG, blood oxygen levels, and other health metrics.
- (3) Fluid and body weight monitoring:
 - Smart scales: These scales detect weight changes related to fluid retention, a sign of worsening HF (e.g. Withings Body Cardio).
 - Thoracic impedance sensors: These sensors estimate lung fluid levels to catch early signs of pulmonary congestion (e.g. Zephyr BioPatch, Zoll HFMS).
- (4) Telemedicine and health monitoring:
 - Telemedicine platforms: Enable regular patientdoctor communication via video and chat, with patients manually inputting vital signs.
 - Health monitoring apps: Patients can track symptoms, medications, and vitals, while some apps use artificial intelligence (AI) for personalized feedback.
- (5) Cardiac and respiratory function monitoring:
 - Implantable monitors: Devices like pacemakers (PMK), implantable cardioverter-defibrillator (ICD), and implantable cardiac monitor (e.g. Reveal LINQIITM) continuously monitor arrhythmias and transmit data to healthcare teams for real-time analysis.
 - Respiratory monitors: Sensors track respiratory rate and air volume to detect HF deterioration (e.g. ResMed AirSense 10).

These technologies enhance HF management by improving condition control, reducing hospitalizations, and improving QoL.

Technological advancements in remote monitoring

monitoring technologies have significantly, integrating various physiological sensors and advanced data analytics to monitor HF patients. Among the most promising studies in this area is certainly the SELENE-HF study, published in 2022 by D'Onofrio et al.⁷ in Europace. This multi-centre study explored a new algorithm to predict hospitalizations in HF patients using implanted cardiac devices, leveraging RM data combined with a risk stratification model based on physiological parameters. The algorithm integrated several parameters, including HR variability, physical activity, thoracic impedance, and arrhythmia burden, along with the 'Seattle Heart Failure Model', a well-known risk stratification model for HF patients. When the data indicated a high risk of disease progression, an alert was generated, allowing physicians to intervene proactively. The results were promising: the algorithm predicted two-thirds of the first post-implant hospitalizations for HF, with an average lead time of 42 days before the event. This early warning allowed clinicians to take preventive measures, potentially reducing hospitalizations. Additionally, the false alarm rate was low, with only 0.7 false positives per patient per year. In conclusion, this study demonstrated that the combined use of RM and risk stratification can be effective in predicting HF worsening, offering clinicians a valuable tool to improve patient management and reduce hospitalizations. The SELENE-HF study led to the synthesis of a predictive algorithm for HF based on daily transmissions from home monitoring (HM).⁷

From these results, predictive algorithms for HF were derived, based on daily transmissions from HM, and were implemented in clinical practice onboard implantable devices (Table 1). The HeartInsight system, for example, exemplifies a modern RM tool designed for ICDs. It tracks seven parameters such as HR, HR variability, patient activity, thoracic impedance, atrial, and ventricular arrhythmic episodes, providing a comprehensive overview of the patient's cardiac status. HeartInsight uses Biotronik's RM system, called HM, which transmits daily data from the patient's implanted device to a central server. The collected data are processed by a predictive algorithm that combines the eight critical parameters into a single score. 8 This score reflects the patient's cardiac health and is tracked over time. When it surpasses a preset threshold, HeartInsight triggers an alert. This alert (Figure 1A) is based on long-term analysis, not short-term fluctuations, and signals an increased risk of HF. The warning arrives an average of 42 days before possible hospitalization, enabling preventive interventions. Importantly, HeartInsight generates only one alert per patient, minimizing notification overload and false positives. Data are organized in a digital dashboard, easily integrated with electronic health records (EHRs), allowing quick consultation and data-driven decisions. This proactive approach helps avoid hospitalizations, optimizing resources and improving patient QoL.8

A recent meta-analysis by Botto et al. 9 examined data from nine clinical trials on patients with ICDs to understand whether the HeartInsight algorithm could hospitalizations due to worsening hospitalization (WHFH) in advance. The main findings are that patients who experienced a WHFH had significantly higher HF scores as early as 12 weeks before hospitalization compared with those who did not experience hospitalizations. The score continued to rise markedly until the hospitalization event. Some parameters, such as 24-h HR, HR variability, and thoracic impedance, were already higher in patients destined for a WHFH compared with the control group, while others, such as nighttime HR and arrhythmias, showed an increase closer to the hospitalization event. The various components of the HF score exhibited different temporal patterns, indicating that not all parameters rise simultaneously, but each contributes differently to the worsening of the cardiac condition. Further real-world data confirmed usefulness of HeartInsight algorithm. 10

In summary, the HeartInsight algorithm appears to be a valuable tool for monitoring and predicting HF exacerbations, enabling timely interventions to prevent hospitalizations. 9

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Author	Year of publication	Article title	Торіс
McDonagh et al.	2021	2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure	ESC guidelines for the diagnosis and treatment o acute and chronic HF
Gheorghiade et al.	2005	Pathophysiologic targets in the early phase of acute Heart Failure syndromes	Pathophysiologic targets in the early phase of acute HF syndromes
Stevenson et al.	2023	Remote monitoring for heart failure management at home	RM for home HF management
Taylor and Ahmed.	2023	Clinical pathways guided by remotely monitoring cardiac device data: the future of device heart failure management?	HF management through remotely monitored cardiac devices
Bezerra Giordan et al.	2022	The use of mobile apps for heart failure self-management: systematic review of experimental and qualitative studies	Systematic review on the use of mobile apps fo HF self-management
Abraham <i>et al</i> .	2014	Benefits of pulmonary artery pressure monitoring in patients with NYHA Class III HF and chronic kidney disease: results from the CHAMPION trial	Benefits of pulmonary artery pressure monitoring in patients with NYHA Class III HF and chronic kidney disease
D'Onofrio et al.	2022	Combining home monitoring temporal trends from implanted defibrillators and baseline patient risk profile to predict heart failure hospitalizations: results from the SELENE HF study	Prediction of HF hospitalizations based on RM and patient risk profile
Cowie et al.	2013	Development and validation of an integrated diagnostic algorithm derived from parameters monitored in implantable devices for identifying patients at risk for heart failure hospitalization in an ambulatory setting	Development of an integrated diagnostic algorithm for identifying patients at risk of H hospitalization through implantable devices
Botto et al.	2024	Predicting worsening heart failure hospitalizations in patients with implantable cardioverter defibrillators: is it all about alerts? A pooled analysis of nine trials	Prediction of WHFhospitalizations in patients with ICD defibrillators
Santini <i>et al</i> .	2024	Optimizing remote heart failure management: first experiences with the HeartInsight score for implanted defibrillators	Optimizing remote HF management through the HeartInsight score for implanted defibrillator
Alvarez et al.	2021	Chronic disease management in heart failure: focus on telemedicine and remote monitoring	Chronic disease management in HF, focusing or telemedicine and RM
Boehmer <i>et al</i> .	2017	A multisensor algorithm predicts heart failure events in patients with implanted devices	Multi-sensor algorithm for predicting HF events in patients with implanted devices
Liu et al.	2024	Unveiling the potential: remote monitoring and telemedicine in shaping the future of heart failure management	RM and telemedicine in shaping the future of H management
Ferrick <i>et al</i> .	2023	2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic	Expert consensus statement on practical management of the remote device clinic

The 'HeartLogic' algorithm by Boston Scientific (Boston Scientific, Boston, MA, USA), is integrated into the resonate series of cardiac resynchronization therapy devices and ICDs. The system operates by collecting data from five sensors that monitor various physiological parameters associated with HF: heart sounds (indicative of cardiac function), thoracic impedance (reflecting pulmonary congestion), respiratory rate, HR, and physical activity level. These data are processed daily to produce an index, the 'HeartLogic Index', which is patient specific and continuously updated (Figure 1B). When this index exceeds a preset threshold (usually 16), the algorithm generates an alert that signals to physicians an increased risk of HF. The RM system

Latitude NXT allows medical staff to remotely track the index's progress and intervene before the patient requires hospitalization. The MultiSENSE study validated the effectiveness of HeartLogic, demonstrating 70% sensitivity in predicting HF episodes with an average lead time of 34 days and a very low false alarm rate (1.47 per patient per year). This system has been shown to significantly reduce hospitalizations, improve patients' QoL, and reduce healthcare costs. 12

Triage HF (Medtronic Inc., Minneapolis, MN, USA; Figure 1C) is an algorithm available in all cardiac implantable electronic devices (CIEDs) manufactured by Medtronic. It integrates multiple parameters [thoracic impedance measured by Optivol $^{\rm TM}$ algorithm, patient

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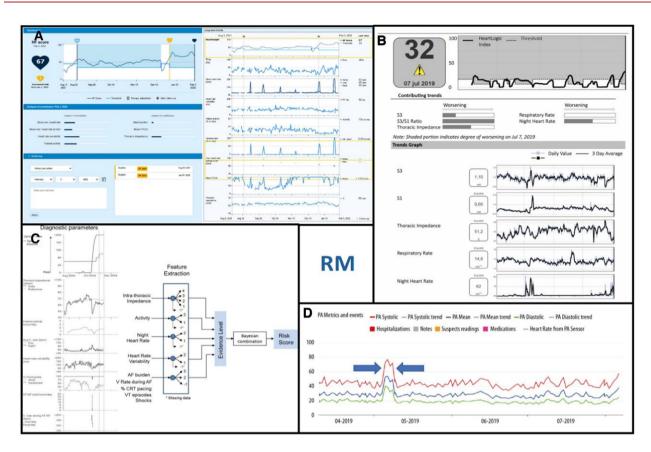


Figure 1 (A) HeartInsight system interface. (B) HeartLogic system interface. (C) Triage heart failure system algorithm. (D) CardioMEMS system interface.

activity, burden of atrial fibrillation, ventricular rate during atrial fibrillation, ventricular pacing rate, nocturnal HR, heart rate variability (HRV), shocks delivered, and treated episodes of ventricular tachycardia (VT)/ventricular fibrillation (VF)]. The main difference with the already mentioned algorithms is that it does not compute a numerical index but a score of risk of hospitalization for acute HF in the next 30 days divided into HIGH, MEDIUM, and LOW. Based on a Bayesian probabilistic model, it uses 30 days of diagnostic data to predict the risk of decompensation in the next 30 days. The risk score starts to be calculated upon receipt of data on Carelink (Medtronic Inc.) after the first 65 days after implantation (34 days for Optivol calibration and 30 days for TriageHF risk stratification).

The efficacy of this algorithm in accurately categorizing patients according to their risk of a HF exacerbation has been substantiated by multiple studies. 8

Benefits of remote monitoring

Remote monitoring in HF management provides key advantages, including early decompensation detection, reduced hospitalizations, better clinical outcomes, and improved QoL. Remote monitoring systems can detect subtle physiological changes before clinical signs emerge, such as a rise in HR or a drop in thoracic impedance indicating fluid build-up. More impactful than individual metrics, RM allows a multi-parametric assessment, integrating different clinical indicators into

a single index. Alerts from RM systems enable early interventions, preventing hospitalizations and reducing episode severity. Studies confirm RM's role in significantly lowering HF-related hospitalizations, improving patient outcomes, and reducing healthcare costs. For example, in a multi-centre study of over 1000 patients, the CardioMEMS system (Figure 1D) cut HF hospitalizations by 33%. Remote monitoring also enhances clinical outcomes through better symptom control, reduced mortality, and fewer complications, largely due to timely interventions and improved treatment adherence. Patients benefit from less frequent hospital visits, reduced stress, and increased confidence, knowing their health is constantly monitored.

Compared with traditional care, RM and telemedicine offer several advantages: better accessibility, more frequent monitoring, active patient engagement, faster response times, improved data collection, and better care coordination. Traditional management is constrained by location and infrequent check-ups, whereas RM offers continuous, real-time monitoring. It also promotes patient involvement via regular updates and mobile apps. Telemedicine enables rapid responses to clinical changes, reducing travel and hospitalizations.

Implementing RM entails initial and operational costs; however, the long-term benefits can outweigh these investments. According to data from AIAC and ANMCO in 2020, RM led to a 66.4% reduction in visit-related expenses for patients and a 70.4% decrease in the monetary value of lost work hours for family members. For the healthcare system, there was a 54% reduction in

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the annual cost per patient, while healthcare providers experienced a 60% decrease in unnecessary outpatient visits, allowing resources to be reallocated to other activities. Additionally, RM reduced the number of outpatient visits by 50% and decreased the duration of individual follow-ups from 26 min in traditional controls to 4-8 min, enhancing QoL, compliance, and patient satisfaction.

Continuous data collection via RM devices offers a more detailed clinical picture, while integrated care platforms enhance co-ordination among healthcare providers. Ultimately, RM and telemedicine improve clinical outcomes through early diagnosis, personalized interventions, and real-time data collection.¹³

Challenges and barriers to implementation

Despite the significant benefits, several challenges hinder the widespread adoption of RM in HF management. Is Implementing RM systems requires sophisticated technology and infrastructure. Ensuring reliable data transmission, maintaining system accuracy, and integrating RM data into existing EHRs are critical challenges. Furthermore, a strict organizational model needs to be set-up, providing for a dedicated staff and clearly establishing roles and competencies. At the outset of the implementation of a RM structure, there is a risk of an increase in workload for centres, as RM has been shown to potentially led to a paradoxical increase the number of accesses to hospitals consequently increasing the workload of the centres themselves.

An integrated and efficient organizational model must be developed. The guidelines¹⁴ recommend adopting an alert-based strategy to reduce the workload of operators and optimize resources. This strategy manages only clinically relevant transmissions and avoids reviewing scheduled transmissions, which diverts time and resources from patients who need them most. The evidence from real-life experiences and published clear: multi-parametric evaluation algorithms are highly effective at stratifying patients according to risk of decompensation. Patients out of an alert status were free from incoming events. To adopt an alert-based strategy effectively and safely, it is essential to ensure constant connectivity of the patients. This requires devoting time and resources to systematically contact disconnected patients to verify the causes of missed transmissions and re-establish the connection as soon as possible. Finally, it is crucial that alarms are correctly and personally programmed and set up and that only the necessary and actionable alerts are activated for each patient.

Additionally, the initial cost of setting up RM systems can be a barrier for many healthcare providers. The large volumes of data generated by RM systems necessitate robust data management strategies. Protecting patient data privacy and ensuring compliance with regulations such as the General Data Protection Regulation (GDPR) is essential. Healthcare providers must implement stringent data security measures to prevent unauthorized access and breaches. The ownership and storage of data generated by RM systems represent critical aspects for the adoption and

acceptance of these technologies. There are significant differences between data managed by academic institutions and data controlled by private industries. typically Academic management emphasizes transparency and shared access for research purposes, while private industries may prioritize data for proprietary use. Legal and ethical considerations require clear policies to ensure that patients and healthcare providers are fully informed about who owns the data. how it is stored, and how it is utilized. Compliance with regulations such as GDPR in Europe and Health Insurance Portability and Accountability Act (HIPAA) in the USA¹² is paramount to protect patient privacy and maintain trust in these systems. Future systems will likely include better patient education tools and apps to enhance self-management and adherence to treatment plans. For RM to be effective, patients must be actively engaged and compliant with the monitoring protocols. Educating patients about the importance of RM, how to use the devices, and what to do in case of alerts is crucial. Non-compliance can lead to missed alerts and delayed interventions, undermining the effectiveness of RM. Remote monitoring requires a multi-disciplinary approach involving cardiologists, HF specialists, nurses, and IT professionals. Co-ordinating care among different healthcare providers and ensuring seamless communication is challenging but necessary for successful RM implementation.

Legal responsibility

Legal responsibility is a pivotal issue in the deployment of RM systems. Manufacturers, healthcare providers, and patients each bear specific responsibilities regarding the use, maintenance, and interpretation of RM data. To mitigate legal risks, it is essential to establish clear contractual agreements outlining responsibilities and liabilities. For instance, device manufacturers must ensure the accuracy and reliability of their systems, while healthcare providers are responsible for appropriate interpretation and timely intervention based on transmitted data. Regulatory frameworks, such as those enforced by GDPR and HIPAA, play a crucial role in defining these responsibilities and safeguarding patient rights.

Future directions

The future of RM in HF is promising, thanks to advancements in technology and data analytics. Key trends include the integration of RM with wearable devices, such as smartwatches and fitness trackers, improving patient engagement and offering real-time health data. Predictive analytics and AI will enhance RM by identifying early signs of HF exacerbation, enabling personalized and preventive care. The COVID-19 pandemic gave a 'Tech-celleration' to the use of telemedicine, highlighting RM's potential to provide continuous monitoring, virtual consultations, and remote care, reducing the need for in-person visits. Personalized medicine, guided by RM, will tailor treatment to individual needs, improving patient outcomes.

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Conclusions

Remote monitoring offers a transformative way to manage HF by enabling early detection, reducing hospitalizations, and improving patient outcomes and QoL. Despite implementation challenges, advances in technology and data analytics will drive its wider adoption. The future of RM in HF lies in integrating predictive analytics, wearables, telemedicine, and personalized care, improving both treatment and patient outcomes. Ongoing innovation will allow healthcare providers to deliver more effective, efficient care, ultimately easing the burden on healthcare systems and enhancing patient lives.

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Data availability

All data discussed are publicly available in the sources cited within the manuscript.

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