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Heart failure remote monitoring: novel approaches and management strategies

Monitoramento remoto da insuficiência cardíaca: novas abordagens e estratégias de gerenciamento Monitorización a distancia de la insuficiencia cardíaca: nuevos enfoques y estrategias de gestión

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ARTICLE INFORMATION

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Main topic: Heart failure remote monitoring Main practical implications:

This article presents the state of the art in heart failure monitoring techniques. The evidence and discussions presented may help decision makers and health managers to update their institutions and formulate monitoring strategies based on the main current technologies.

Originality/value:

The article is original in the sense that it raises a specific discussion with systematized and organized state-of-the-art literature in order to present results that can help mainly developing countries and institutions specialized in cardiac care.

ABSTRACT

Background. Globally, heart failure is a leading health problem, with an estimated 64 million cases worldwide, including 6.7 million in the U.S., according to estimates. The U.S. economic burden is expected to see a steep rise by the year 2030. Heart failure is a cause of 8.5% of heart disease-related deaths and a central cardiovascular killer. Emergency hospitalization rates and readmission rates are high. **Methods**: A systematic methodology was followed to generate authentic and reliable data on remote monitoring in the setting of heart failure patients. The inclusion criteria comprise articles describing remote monitoring interventions published in peer-reviewed journals and carried out in human subjects in English. Critical analysis applies quality assessment tools to assess methodological soundness, possible bias, and relevance to the research objective. **Results**: This review discusses wearable devices, e.g., Zoll HFMS ReDS, and Audicor, each effectively monitoring cardiac parameters and reducing H.F. hospitalizations. Implantable cardiac monitors such as LUX-Dx and CardioMEMS H.F. RM has potential to give real-time data for timely intervention and tailored therapies. The integration of machine learning algorithms in devices, for example VitalPatch and the SimpleSense has led to increased use of these devices to make precise and efficient health care predictions, leading to improved patient outcomes. **Conclusion**: From all the research, remote monitoring devices and strategies are recommendable for patients with various cardiac complications. It can improve heart function, however, R.M. has not been seen to reduce the overall mortality rate among heart patients.

Keywords: Heart Failure, Remote, Monitoring.

RESUMO

Contexto: Globalmente, a insuficiência cardíaca é um importante problema de saúde, com cerca de 64 milhões de casos em todo o mundo, incluindo 6.7 milhões nos EUA, segundo estimativas, Espera-se que o fardo económico dos EUA registe um aumento acentuado até ao ano 2030. A insuficiência cardíaca é a causa de 8,5% das mortes relacionadas com doenças cardíacas e uma causa central de morte cardiovascular. As taxas de hospitalização de emergência e as taxas de readmissão são altas. Métodos: Uma metodologia sistemática foi seguida para gerar dados autênticos e confiáveis sobre monitoramento remoto no cenário de pacientes com insuficiência cardíaca. Os critérios de inclusão compreendem artigos que descrevem intervenções de monitoramento remoto publicados em periódicos revisados por pares e realizados em seres humanos em inglês. A análise crítica aplica ferramentas de avaliação da qualidade para avaliar a solidez metodológica, possíveis vieses e relevância para o objetivo da pesquisa. Resultados: Esta revisão discute dispositivos vestíveis, por exemplo, Zoll HFMS ReDS e Audicor, cada um monitorando efetivamente os parâmetros cardíacos e reduzindo as hospitalizações por IC. Monitores cardíacos implantáveis, como LUX-Dx e CardioMEMS HF RM, têm potencial para fornecer dados em tempo real para intervenção oportuna e terapias personalizadas. A integração de algoritmos de aprendizado de máquina em dispositivos, por exemplo, VitalPatch e SimpleSense, levou ao aumento do uso desses dispositivos para fazer previsões precisas e eficientes de cuidados de saúde, levando a melhores resultados para os pacientes. Conclusão: De todas as pesquisas, dispositivos e estratégias de monitoramento remoto são recomendáveis para pacientes com diversas complicações cardíacas. Pode melhorar a função cardíaca, no entanto, R.M. não foi observado que reduza a taxa de mortalidade geral entre pacientes cardíacos..

Palavras-chave: Insuficiência Cardíaca Remota, Monitoramento.

RESUMEN

Antecedentes: A nivel mundial, la insuficiencia cardíaca es un problema de salud importante, con aproximadamente 64 millones de casos en todo el mundo, incluidos 6,7 millones en los EE. UU., según estimaciones. Se espera que la carga económica de Estados Unidos experimente un fuerte aumento para el año 2030. La insuficiencia cardíaca es la causa del 8,5% de las muertes relacionadas con enfermedades cardíacas y una causa de muerte cardiovascular central. Las tasas de hospitalización de emergencia y las tasas de reingreso son altas. Métodos: Se siguió una metodología sistemática para generar datos auténticos y confiables sobre monitorización remota en el entorno de pacientes con insuficiencia cardíaca. Los criterios de inclusión comprenden artículos que describen intervenciones de monitoreo remoto publicados en revistas revisadas por pares y realizadas en seres humanos en inglés. El análisis crítico aplica herramientas de evaluación de la calidad para evaluar la solidez metodológica, el posible sesgo y la relevancia para el objetivo de la investigación. Resultados: Esta revisión analiza los dispositivos portátiles, por ejemplo, Zoll HFMS ReDS y Audicor, cada uno de los cuales monitorea de manera efectiva los parámetros cardíacos y reduce las hospitalizaciones por insuficiencia cardíaca. Los monitores cardíacos implantables, como LUX-Dx y CardioMEMS H.F. RM, tienen el potencial de brindar datos en tiempo real para una intervención oportuna y terapias personalizadas. La integración de algoritmos de aprendizaje automático en dispositivos, por ejemplo VitalPatch y SimpleSense, ha llevado a un mayor uso de estos dispositivos para realizar predicciones de atención médica precisas y eficientes, lo que lleva a mejores resultados para los pacientes. Conclusión: De todas las investigaciones, los dispositivos y estrategias de monitorización remota son recomendables para pacientes con diversas complicaciones cardíacas. Puede mejorar la función cardíaca, sin embargo, R.M. No se ha visto que reduzca la tasa de mortalidad general entre los pacientes cardíacos..

Palabras clave: Insuficiencia Cardíaca, Remota, Monitorización.

INTRODUCTION

Heart failure is a significant health problem, with 64 million cases globally, which makes about 6.7 million cases in the U.S. alone. The economic influence of the U.S. expands and is forecasted to increase from USD 30.7 billion in 2012 to USD 69.8 billion by 2030 (Vucetic, 2023). The proportion of heart disease deaths related to heart failure is 8.5 %, and this may be the causative factor in about 36% of all the fatalities caused by cardiovascular disease, indicating its high mortality impact. Of all the heart failure statistics, the emergency hospitalization rates, and readmission percentage are considered the most important, at 4.9 and 1.1 per U.S. adults, respectively, in 2017 (Heart Failure Society of America, n.d.). Life expectancy for heart failure patients is grossly different and is around five years for 50% of the patients on average. Nevertheless, for those with controlled conditions and the concomitant medical treatment that is opted for, coupled with having a healthy lifestyle, it can contribute to the better performance of their health status. Thus, those with advanced heart failure and other co-morbidities like diabetes and kidney dysfunction are at higher risk and have only a 10 to 20% chance of surviving a year (Heart Failure Society of America, n.d.). Heart failure is when the heart muscle cannot pump the blood as well as it should, causing the fluids to be collected in the lungs. The factors include arteries getting very narrow and high blood pressure, eating foods with fat, cholesterol, and sodium, lack of physical activity, and excessive alcohol intake. Treatment, along with lifestyle changes like weight loss, proper medication intake, regular exercise, and controlling salt intake while managing stress, helps alleviate the symptoms and improves the quality of life (Mayo Clinic, 2023). H.F. is considered a very life-threatening situation in which actions such as heart transplants or mechanical heart pumps can be used. Symptoms of H.F. include difficulty in breathing, fatigue, swelling of the hands and feet, fast heartbeat, and declining ability to do physical activities. Early medical attention is of primary concern if symptoms like chest pain, fainting, or sudden weight gain are raised, as they may point to worsening H.F. and other severe conditions. Diagnosing H.F. and styling treatment is impossible without a medical examination (Mayo Clinic, 2023).

Heart failure is of various forms, and each of them is associated with different heart dysfunctions. Left-sided heart failure is a condition that involves both systolic failure (where the left ventricle becomes unable to pump blood effectively, thus reducing the circulatory flow) and diastolic failure (where the left ventricle becomes stiff, causing inadequate relaxation between each heartbeat). Moreover, heart failure with mid-range ejection fraction (HFmrEF) brings a new scenario that overlaps systolic and diastolic cardiac failure (American Heart Association, 2023). The result of left heart failure is right heart failure, as right-sided failure follows left-sided. Therefore, the right ventricle has a pumping weakness, developing congestion and swelling of the body's veins. Congestive heart failure (CHF), which may also be written as heart failure, represents a severe condition probably needing urgent medical care as blood flow is poor, leading to congestion and swollen legs and ankles (American Heart Association, 2023). Heart failure can, at times, compound the development of pulmonary edema and kidney impairment, worsening the fluid build-up and swelling in the body. Thus, the knowledge of these differences is paramount for targeted therapy and administration of medical care. Cardiac remote monitoring is highly significant because it allows patient teams can access high-quality data points more precisely compared to in-person monitoring, and clinicians can increase physiologic datasets, so they become able to identify trends more critically and provide high-quality care (American Heart Association, 2023).

METHODOLOGY

The search strategy for this systematic review includes multiple database searches across electronic resources such as PubMed, Scopus, and Web of Science. The search terms will include string for "heart failure", "remote monitoring", and "intervention". Filters will be applied to include studies done on human and published in peer-review journals. The linguistic will be English. Grey literature won't be taken into consideration. The search strategy is targeted to unravel the studies that fulfil the inclusion criteria that has been highlighted in section 2.1. The search process will be well commented, including the duration of the range and the extra filters used, to guarantee the transparency and the reproducibility of the review process.

Main Keywords: Heart failure, Remote monitoring, Wearable devices, Implantable cardiac monitors, pacemakers

Secondary keywords: Intervention, Management, Patient outcomes, Adherence, Self-care, Chronic disease management, Cardiovascular disease, Real-time data, Timely intervention, Quality of life

Designed Boolean Operators:

- (Heart Failure) AND (Remote Monitoring)
- (Wearable Devices OR Implantable Cardiac Monitors) AND Heart Failure
- (Intervention OR Management) AND (Patient Outcomes OR Quality of Life) AND Heart Failure

- (Adherence OR Self-care) AND Chronic Disease Management AND (Cardiovascular Disease OR Heart Failure)
- (Real-time Data OR Timely Intervention) AND (Pacemakers OR Remote Monitoring) AND Heart Failure
- ("Intervention" OR "Management Strategies" AND "Heart Failure" AND "Wearable Devices" AND "Patient Adherence")
- ("Heart Failure" AND "Remote Monitoring" AND ("Timely Intervention" OR "Real-time Data") AND "Pacemakers")
- ("Chronic Disease Management" AND "Cardiovascular Disease" AND ("Self-care" OR "Adherence") AND "Remote Monitoring")
- ("Wearable Devices" OR "Implantable Cardiac Monitors" AND "Heart Failure" AND "Patient Outcomes")

Inclusion Criteria:

Study Design: Peer-reviewed investigations addressed at the effectiveness, usability and patients' outcomes related to the application of remote monitoring technologies on heart failure patients. It involves RCTs (randomized controlled trials), cohort studies, case-control studies, as well as cross-sectional studies.

Interventions: Studies that determine the use of wearable devices, implantable cardiac monitors, pacemakers, or any other remote monitoring technology that is used to treat/manage heart failure. The scope is also to undertake the studies evaluating the role that AI and machine learning play in patient tracking as well as outcome prediction.

Comparators: Reviews of interventions that only compare remote monitoring with usual care, other methods of remote monitoring, or no intervention.

Language: Topic selection was done in English to establish feasibility of in-depth analysis and interpretation by the investigator team.

Exclusion Criteria:

Comments, letters, editorials, abstracts of conference papers, and reviews (systematic or narrative) that do not include the original research data.

Screening and Selection

Our first search produced 1,060 references ranging from different studies that could be relevant according to selection criteria we have defined in advance with keyword-based query.

Removal of Duplicates:

Duplicates were taken out first, giving the search 372 studies.

Application of Inclusion Criteria:

The subsequent screenings were done by the exclusion criteria which considered factors like the publication date (past 10 years), language (English), and applicability to human subjects with associated remote monitoring in heart failure context.

Screening of Abstracts:

We used abstract of each study carefully as the criteria to assess relevance and alignment with the review's objectives. Particularly, the use and effect of remote monitoring technology is the major concern in heart failure management. We screened 419 studies.

Full-Text Review:

After excluding studies, 65 studies were reviewed full texts whereby they underwent a thorough examination to ensure they adequately addressed all the research objectives and agreed to all inclusion criteria. Making use of this thorough assessment, another list of studies was withdrawn due to various reasons, such as the lack of any appropriate outcome data, or being devoted to the non-targeted interventions, and none of them were engaged in the remote monitoring and heart failure context.

Final Selection:

After the papers had been reviewed in their entirety, 26 of them were chosen to be included in the systematic review. Besides, four studies were included into the review due to their value as they address the issue and add to the field. In total, we have 30 studies reviewed.

Figure 1. Review stream





Note: own elaboration (2024)

RESULTS AND DISCUSSION

Introduction to Remote Monitoring of Heart Failure

Heart failure (H.F.) poses a significant burden all around the globe and is characterized by high morbidity, mortality, and increased healthcare costs by expensive medicines and admissions rates. Cardiac management has been revolutionized by the advent of Remote Monitoring (R.M.) and telehealth technologies to solve these issues. R.M. provides a patient-centered healthcare model, facilitating timely intervention and personalized therapy. Its use has become more frequent during the ongoing coronavirus pandemic. R.M. has become critical in managing cardiac implantable electronic devices (CIEDs), improving healthcare accessibility and outcomes for H.F. patients (Abbott, n.d.).

A Journey to Remote Monitoring Among Heart Failure Patients

RPM devices have dramatically transformed the current healthcare practice by allowing patients with chronic conditions to remotely share their vitals with their health providers (Strategic Market Research, 2023). The RPM sector, worth 1.45 billion USD in 2021, is predicted to increase to 4.07 billion USD by 2030, and it is expected to grow at 8.74% CAGR (Strategic Market Research, 2023). In the late 1950s, when the first implantable pacemaker was introduced, cardiac remote patient monitoring was already there (Rocket, 2023). In the early seventies, trans telephonic data monitoring was invented to support traditional office visits. The subsequent breakthroughs, such as magic wands, radiofrequency platforms, and cellular data wireless, provided healthcare providers with access to patient data from a distance due to embedded monitoring tools. In the 21st century, the adoption of implantable electronic devices and remote monitoring platforms has been an important

milestone (Rocket, 2023). These platforms enabled physicians to have the critical patient data that they required at their fingertips to make accurate diagnoses and treat arrhythmias more efficiently. The application of remote monitoring for CIED patients extended widely, and professional societies acknowledged it as the practice of care (Rocket, 2023). The future of cardiac remote monitoring will shortly reach its peak point. As the number of chronic diseases keeps growing, today's technologies give clinicians the ability to track blood pressure, pulse rate, body temperature, and other vital health parameters in real-time, which positively impacts the patient's outcomes and the clinic workflow (Rocket, 2023). The latest approaches of remote monitoring systems like The Vector Patient Care Platform[™] are demonstrated as HIPAA-compliant, secure data exchange kind with a range of capabilities used for effective patient care management. The future will bring tremendous technological progress, and remote cardiac monitoring will be an integrated component of healthcare delivery, providing patients and healthcare providers with more convenience, accessibility, and customizable care (Rocket, 2023).

Devices for Remote Monitoring

The integration of R.M. into heart failure management is broad, involving several devices, each bringing along its unique contribution to the monitoring and the therapeutic H.F. patient's strategies (Imberti et al., 2021).

Pacemakers with Implantable Technology

Pacemakers are reprogrammable artificial electrical pulse generators used temporarily and permanently, built to deliver impulses with specific time, voltage, and frequency characteristics to control the heart's rhythms. Their development and contributions date back over 200 years, with notable milestones, including the experiments of Luigi Galvani in the 1700s and the term "artificial cardiac pacemaker" by Dr. Hyman in 1932 (Puette, 2022). Today's pacemakers, as part of a wider group of cardiac implantable electronic devices (CIEDs), which include implantable cardioverter-defibrillators (ICDs), have significantly evolved since 1980's first "implantable ICD." Such devices are crucial to patients suffering from cardiac conditions such as symptomatic bradycardia or heart block and are programmed after insertion into the heart to control its rhythm harmoniously (Puette, 2022).

The pacemaker implantation guidelines are provided by the American College of Cardiology, American Heart Association, and Heart Rhythm Society (Gregoratos et al., 1998). Typical consequences are pneumothorax, infection, and device failure, which can happen sometimes. Pacemaker insertion, in many cases, results in good short-term outcomes, but the long-term success rates also vary depending on several factors, such as the health status of the patient. Teamwork across the professions is central to the care of patients with pacemakers. Therefore, emphasis is placed on follow-up and device management, which are important for optimizing the patients' outcomes and minimizing complications. The dynamic nature of the evolving technology and guidelines used to guide this critical medical intervention underscores the need to constantly update the knowledge base and interdisciplinary collaboration in managing patients requiring pacemaker support (Gregoratos et al., 1998).

Emergence of Transtelephonic Monitoring

TransTeleMonitor (TTM) is a 30-day loop recording device intended to capture and record the irregular heartbeats that occur for a few seconds and disappear. Resembling the size of a pager, TTM is strapped around a waist and connected to two stickers on the chest, which is a constant measure of the heart rate. TTM is used primarily for children. If a child or guardian experiences a symptom of an abnormal heart condition, the person presses a symptom button on the device, saving data on heart activity. Then, these recordings are broadcast to a monitoring company through a landline telephone and evaluated by the child's healthcare professional (Nationwide Children's Hospital, n.d.). Through the 30-day monitoring period, the child must wear the monitor as instructed by their physician. The device was designed and engineered to be unobtrusive and painless, with the ability to hold up to three event recordings at a time. Thus, videos should be uploaded to the surveillance company in real-time for accurate and timely data analysis. Even though the risk is minimal, this may include deployment problems. Fast contacting of the monitoring company should be done in case of problems. Once the monitoring period is concluded, the TTM unit is sent back to the company by the user using the provided Priority Mail envelope, and results are posted on the doctor's website within two weeks. This system thoroughly monitors the child's heart rhythm, thus detecting any abnormalities or arrhythmias (Nationwide Children's Hospital, n.d.).

Implantable Cardioverter Defibrillators (ICDs)

An Implantable Cardioverter-Defibrillator (ICD) is a tiny device placed in the chest to detect and interrupt cardiac arrhythmias. It constantly monitors the heart and delivers an electric shock when required, thus restoring a normal rhythm. ICDs are usually prescribed as therapy for patients with dangerously fast heart rates (ventricular tachycardia or ventricular fibrillation), those at high risk of very irregular and possibly fatal heart rhythms due to a weak heart muscle, or those who have survived cardiac arrest (Mayo Clinic, 2023). There are two main types of ICDs: older generation ICDs, which are located in the chest and have electrodes attached to the heart, and subcutaneous ICDs (S- ICD), which are placed under the skin at the side of the chest and do not touch the heart (Mayo Clinic, 2023).

Before getting an implantable cardioverter-defibrillator (ICD), specific tests are performed to determine heart health status, including electrocardiogram (ECG), echocardiogram, and Holter monitoring. The ICD is surgically implanted under the skin just below the collarbone and connected to the leads that are introduced into a blood vessel close to the collarbone and guided to the heart. The device is programmed and tested at this time depending on how an individual's rhythm. Risk factors are swelling and pain in the area where the implant is placed and limiting certain activities for some time to let the implant heal correctly. It enables the doctor to examine the device every six months to evaluate its performance and battery life (Mayo Clinic, 2023). ICDs may have some dangers, which include infections, bleeding, blood vessel damage, and device movement, though these complications are rare. Therefore, certain conditions and equipment, such as cellphones, metal detectors, and medical equipment like MRI machines, that may interfere with the function of the ICDs need to be considered (Mayo Clinic, 2023). In the case of terminal illness, the discussions with the physicians may include whether or not to disconnect the ICD to prevent non-useful shocks and pain. Either drive restriction, heart condition, and history, or ICD shocks (Fadheel, et al., 2022).

Cardiac Resynchronization Therapy (CRT) Devices

Cardiac resynchronization therapy (CRT) is implanting a biventricular pacemaker, which synchronizes the heart chambers, boosting efficiency. This device sends electrical signals to both ventricles and can only make synchronized contractions and blood pumping possible (Johns Hopkins Medicine, 2023). CRT is primarily for heart failure patients with a disorganized contraction of ventricles or a left bundle branch block. It attenuates heart failure symptoms and diminishes the risks of associated complications. Risks associated with CRT include infection, bleeding, pneumothorax, cardiac tamponade, device failure, and fragment migration (Johns Hopkins Medicine, 2023). The procedure takes a few hours. It consists of introducing insulated cables into a vein near the collarbone through X-ray images and attaching them to the heart and an implantable generator. There are two types of CRT devices: CRT-P uses a pacemaker leading to the right atria and ventricles. CRT-D involves an ICD, an added implantable cardioverter-defibrillator (ICD) for sudden cardiac death risk. During hospitalization, the device gets tested before discharge, an overnight stay. Most patients resume normal activities within days, but driving and heavy lifting may be temporarily restricted (Chia & Foo, 2016).

Implantable Loop Recorders (ILRs)

An implantable loop recorder (ILR) is a small device placed under the skin on the left side of the chest to monitor heart electrical activity. Heart failure patients are experiencing symptoms like dizziness, blackouts, or palpitations, whose cause could not be diagnosed with routine tests. ILRs are designed to monitor heart rhythm, automatically recording abnormal activity or requiring manual activation via a handheld device or mobile app (Johns Hopkins Medicine, 2019). The procedure of ILR takes 10-15 minutes. All steps, like local anesthesia, a small incision, and insertion of the ILR under the skin, either traditionally or via injection, are completed quickly. It has rare risk factors like bleeding, bruising, and infection. Device movement, usually non-disruptive, is possible. Recovery involves limited upper body movement and keeping the incision dry for about a week (British Heart Foundation, n.d.). Symptoms prompt ILR activation, facilitating diagnosis. Removal, performed similarly to insertion, occurs after diagnosis or when the device's battery depletes, usually after three years. Regular activities and exercising are permitted with an ILR, and travel is feasible, typically without interference at airport security. Patients receive a device identification card for travel and may need to present it if airport metal detectors are triggered (British Heart Foundation, n.d.).

CardioMEMS[™] HF System

CardioMEMS[™] Heart Failure System, the leading-edge remote monitoring technology, is designed to help clinicians care for heart failure patients. It was clinically proven as a safe intervention to slow the progression of HFrEF, reduce mortality rates, and improve the quality of life for HFpEF and HFrEF patients (Abbott, n.d.).

Through continuous P.A. pressure monitoring, the CardioMEMS HF System is a delicate early warning system for worsening heart failure. As this is a proactive approach, frequently, no visit to the physician is required as quick changes can be implemented (Abbott, n.d.). While traditional markers such as patient weight or blood pressure imply decompensation occurs at a later stage, P.A. pressure changes can be found early, so they can be detected when the window of opportunity for interventions is still available. This system's presymptomatic data allows doctors to develop individualized and optimized medical therapy for each patient, translating into optimal health outcomes. Provided an opportunity to establish personalized patient thresholds, clinicians can monitor the heart failure condition promptly and act on the real-time data. In general, the CardioMEMS HF System is a significant step forward in heart failure management, which helps both doctors and patients to ensure safe and reliable care that is proactive (Vyas et al., 2023).

A.I. in cardiology

Introducing Artificial Intelligence (A.I.) in cardiology is an essential milestone in medical science and patient care. A.I.

is used to classify the risk occurrence, early detection, and treatment of myocardial infarction and other complex and severe heart conditions. This is part of a large-scale program aimed at entirely using AI for enhancing health outcomes and involving the most significant research resources and contributions of the clinic in cardiology (Ledziński & Grześk, 2023). A.I. applications in the medical field include programming computers to examine and analyze data much faster and more accurately than humans, which transfers to better performances. A.I. applications in cardiology range from the identification of heart disease to the quick intervention of stroke and the progression of diagnostic radiology. A particular aspect worth highlighting is building an AI-assisted screening instrument for left ventricular dysfunction – a frequently asymptomatic condition that gives a 93% accuracy rating. This marks an immense leap from past diagnostic techniques, such as mammograms, which show an 85% accuracy rate. Additionally, A.I. technology is integrated into devices such as the Apple Watch to detect heart pump weaknesses, disclosing the possibility of wearable technology engagement in health monitoring. A.I. systems have neural networks in the core, which enable computers to learn from large datasets and use them for decision-making, diagnosis, and treatment improvement (Mayo Clinic, 2024).

Functions based Monitoring devices categorization:

Vital Signs Monitoring Devices

These devices are crucial in measuring vital signs like heart rate, blood pressure, oxygen saturation, and body temperature (Johns Hopkins Medicine, 2022). These devices could be, for instance, home blood pressure monitors, pulse oximeters, or remote ECG devices. They make a difference in telehealth locations by offering immediate data about a person's health status regardless of the distance, and some lives may be saved in critical situations (Mph, 2023).

Wearable Devices

The day-to-life biometrics like the number of steps, heart rate, and sleeping patterns are monitored using wristbands, watches, or patches. They allow continuous health monitoring in the daily environment and can support those with healthy lifestyles for a wide range of people beyond a limited number of people with chronic conditions (Alugubelli et al., 2022).

Implantable Devices

Implanted in the body, these devices observe the targeted health conditions. Examples could be implantable cardiac, and glucose monitors that track heart activity and blood glucose levels continuously. They develop treatment options to improve the management of the relevant disease, as well as reduce hospital visits by patients that have chronic diseases (Zhang & Hoshino, 2014).

Mobile Apps & Smartphone-Connected Devices

Some Applications are integrated with smartphones and track multiple health parameters like Nutrition, physical activity, and sleep. They are also sold in innovative scale models nowadays. The devices play the role of never-ending health companions, which are accessible by the patients to monitor their health seemingly, offering lifestyle tracking and health education for self-management (Holzmann & Holzapfel, 2019).

Implantable Pulmonary Artery Pressure Monitoring Devices

CardioMEMS System

CHAMPION Trial (2007–2010): The protocol-defining study in this framework involved 550 patients with New York Heart Association (NYHA) class III HF who were distributed across 64 U.S. sites. Each day, the CardioMEMS device, which is FDA-approved, measures PAP and sends the data to a secured Internet portal for physician interventions. The data was acquired by using a portable EEG unit and a pillow designed for data collection, data that was then applied to the prespecified guidelines for H.F. management according to the readings. An important finding was a decline in heart failure hospitalizations over six months, but the effectiveness of intervention did not influence all-cause mortality (Kobe et al., 2023).

Postapproval Study (2014–2017): Many patients (n=1,200) from NYHA class III HF and with a history of HFH within the previous year were enrolled from 104 sites. This study was conducted in the U.S. It simulated daily PAP monitoring and compliance with the proposed treatment and management guidelines, translating to a remarkable decrease in HFH by the end of 12 months of surveillance (Kobe et al., 2023).

GUIDE-HF (2018–2022): This study was conducted by extending the patient population to include patients classified as NYHA class II-IV with either HFH within the last year or with a high level of biomarkers. The study consisted of 118 sites in the U.S. and Canada. Daily PAP measurements recognized which interventions should be personalized to reproduce the dual outcome of the CHAMPION trial that reduced HFH, E.D. visits for UHF, and all-cause mortality within 12 months (Kobe et al., 2023).

MEMS-HF (2016–2020): Several European centers were involved in a study including 234 subjects with at least NYHA

class III HF within 31 trial sites. The data from Daily PAP were monitored and reviewed every week. Triggering of system alerts resulted in an early review. The study showed reduced HFFH after 12 months and freedom from device- or system-related complications and sensor failure (Kobe et al., 2023).

MONITOR-HF (2019–2022): The purpose of the Dutch investigation was to ensure whether measuring pulmonary arterial pressure (PAP) in 348 class III patients with heart failure with preserved ejection fraction (HFpEF) daily is superior to the existing guidelines, which are mainly aimed at intravascular volume or resistance. Findings showed that quality of life was enhanced as measured by the Kansas City Cardiomyopathy Questionnaire, the number of HFH was reduced, and there were no sensor or system-related complications or sensor failures over 12 months (Kobe et al., 2023).

Cordella Endotronix System

SIRONA Trials (2017–2021). The studies were conducted to evaluate the safety and efficacy of the Cordella system in monitoring PAP for NYHA class III HF patients in Europe. Integrating a handheld reader and tablets for data collection and transmission to a cloud-based platform, SIRONA I, the trial with 15 patients for 90 days was done and proved safety and effectiveness were related to the treatment. The SIRONA II system developed this evaluation, which examined 81 patients and assessed the accuracy of PAP measurements with right heart catheterization as the golden standard, with no complications or sensor failures reported (Kobe et al., 2023).

PROACTIVE-HF (2020–2023): An ongoing trial with 456 enrolled patients across the U.S. and Europe, this study aims to quantify the Cordella PA Sensor System reliability and utilization in controlling NYHA class III HF. It also consists of tight control of PAP together, other signs and symptoms and S.C., and scheduled reviews of data and necessities of the patient taken at least every four days. The trial aims to contribute to guideline-based management by measuring the 7-day mean PAP value and other related data (Kobe et al., 2023).

Left Atrial Implantable Pressure Monitoring

VECTOR-HF Trial: V-LAP, Vectorious Medical Technologies' latest device, sits at the forefront as a sub-septum implant. This offers the advantage of a direct pressure measurement in the left atrium, sending the data wirelessly to the cloud in a secure database. Hence, they can perform continuous remote monitoring as real-time data transmission is possible. The preliminary study results show the V-LAP system to be safe and that patients with heart failure could see an improvement in their NYHA functional class status together with a consistency of data with the traditional wedge pressure means. The anticipated development will deliver more accurate and timely insights regarding cardiac function, which can improve patient management (Kobe et al., 2023).

Implantable inferior Vena Cava Monitoring

FIRE1 System: The FIRE1 device proposes an entirely new principle to observe the inferior vena cava, including the ones related to the respiratory motion of the cross-section. It is placed right between the renal and hepatic veins and wirelessly communicates data to a wearable belt using a hassle-free monitoring technology. Initial verifications in animal models demonstrated good safety, with no severe complications, and the ability to detect changes in the IVC area as correlated with volume status changes. The advantage of this FIRE1 system is that it can respond swiftly to status changes in volume, positioning it as a vital tool in managing heart failure upon a firm foundation laid for the ongoing FUTURE-HF trial. The current clinical trial aims to explore the feasibility and safety of the FIRE1 implant intended for patients with stable heart failure. Besides, this can contribute to the existing heart failure management strategies (Kobe et al., 2023).

Insertable cardiac monitors (ICMs)

LUX-Dx TRENDS Study: Boston Scientific's LUX-Dx ICM represents a significant revolution in subcutaneous heart rhythm monitoring since this technology provides a leadless and minimally invasive treatment choice for patients. The prospective multicenter clinical trial study aims to determine the device's ability to collect and analyze heart rhythm data accurately; the findings are then compared using their data against reference clinical data and heart failure decompensation. The very tech has the potential to take the level of accuracy in diagnosing and managing heart failure through the provision of real-time, continuous cardiac monitoring to new heights (Kobe et al., 2023).

ALLEVIATE-HF Trial: Another experimental work of Medtronic Reveal LINQ ICM trial is a diagnostic approach, using a diagnostic-based risk stratification algorithm within the clinical management of patients with NYHA class II and III HF. This prospective, randomized, controlled trial study is for ascertaining the safety and efficacy of innovation of diagnosing power to upgrade treatment schemes (Kobe et al., 2023). Using the heart rhythm data, considered the most detailed data, the study intends to ensure better patient care pathways that will lead to a possible decrease in heart failure exacerbation and hospitalizations. CIED monitoring is a milestone in managing heart failure, where novel technologies are used to monitor compliance and H.F. acute decompensation events. CIEDs mean collecting diverse data on cardiac function as they provide essential clues into a patient's volume status and indicate the appearance of H.F. exacerbation. The paragraph below

summarizes the findings of the keystone RCTs from CIEDs, stating the specific ICD capabilities, methodologies, and treatment effects (Kobe et al., 2023).

CIED Remote Monitoring Implementation

The latest test trials of cardiac implantable electronic devices (CIEDs) demonstrate their new and advancing capabilities beyond defibrillation and resynchronization therapy. Today, these devices collect valuable cardiac data in realtime to determine when H.F. worsening is occurring. The work similar to FAST suggests a superiority of intra-thoracic impedance monitoring overweight, considering the early detection of H.F. OptiLink HF and PARTNERS-HF trials address the problem of fluid overload detection algorithms. In contrast, the latter example comparison study between CIED RM and standard care provides no statistically significant outcome difference. MULTISENSE and SELENE HF create alert algorithms achieving sound sensitivities for recognizing H.F. exacerbations. Analysis of the TRUST, ECOST, and IN-TIME pooled data in the CIED-based RM Biotronik RM indicates reduced mortality risk and H.F. admissions. Studies clearly show sensitivity accuracy, e.g., FAST, that highlights how intrathoracic impedance monitoring is better in early H.F. detection by impedance level monitoring than weight change detection. Part of the focus of Studies OptiLink HF and PARTNERS-HF is to investigate how fluid overload detection algorithms work, and on Study REM-HF, there is a comparison of CIED remote monitoring mode (R.M.) and the standard care mode, proving both equal results, but still underlining the importance of sensitivity in detecting H.F. exacerbations in a timely fashion. Furthermore, MULTISENSE and SELENE HF trials created sensitive alerts, which are essential because they prompt immediate intervention to improve patient outcomes (Kobe et al., 2023).

FAST and OptiLINK HF Trials:

FAST: The comparative analysis demonstrated better sensitivity and a lower rate of misdiagnosed events with intrathoracic impedance cardiac monitoring via Medtronic OptiFlow compared to weight monitoring in 156 NYHA class III–IV heart failure patients.

OptiLINK HF: This fluid-automated leak detection technology was tested in a trial done on 1,002 patients with NYHA class II–III and swmontage. Notwithstanding the system being advanced and to clinicians, it did not lead to a substantial difference in the outcome (Kobe et al., 2023).

PARTNERS-HF and REM-HF Studies:

PARTNERS-HF: A national 93-site observational study across 694 patients that showed the benefit of CIED-based diagnostic algorithms forecasting H.F. admissions. Monthly device diagnostics reviews are a significant factor in the predictability of H.F. inpatient hospitalization.

REM-HF: A randomized trial comparing weekly CIED remote monitoring (R.M.) to standard care, utilized in 1,650 patients, showed no significant difference in outcomes between the two groups. However, patients on R.M. had a formalized clinical management system (Kobe et al., 2023).

MULTISENSE and SELENE HF

MULTISENSE: I voted to develop the HeartLogic alert algorithm in a study population of 900 patients, having a 70% sensitivity in detecting H.F. exacerbation with a median lead time of 34 days.

SELENE HF: Targeted at validating the predictive algorithm of the Seattle HF Model among 918 patients, the results show 65.5% sensitivity for detecting heart failure hospitalizations with the median time alert to hospitalization of about 42 days (Kobe et al., 2023).

Pooled Analysis of TRUST, ECOST, and IN-TIME

Indoor positioning systems promote effective and efficient operations within the hospital context by enabling realtime monitoring of patients and medical devices.

Observational studies were the data source for 15 randomized controlled trials, including 2,405 patients. They showed a statistically meaningful decline in all-cause mortality and the combined outcome of mortality and heart failure hospitalization with daily remote monitoring (Kobe et al., 2023).

Wearable Devices

Zoll HFMS

Zoll HFMS is a wearable technology revolution because its patch-based sensor utilizes radiofrequency to collect physiologic data, including thoracic fluid levels, heart rate, respiratory rate, activity, posture, and heart rhythm. The BMADHF study revealed that µCor reduced the rate of first H.F. hospitalization to 90 days. This was evidenced by a significant absolute risk difference and an improvement in QOL as measured by the Kansas City Cardiomyopathy Questionnaire (Kobe et al.,

2023).

ReDS-Remote Dielectric Sensing

ReDS (Sensible Medical) is a non-invasive vest that uses a low-power electromagnetic radar beam to assess lung fluid volume, facilitating volume management after discharge. The SMILE-HF trial demonstrated that home ReDS evaluation significantly cut readmission rates, thus proving the effectiveness of this method in post-discharge H.F. management.

Auditor

Auditor (Inovise Medical) measures cardiac acoustic biomarkers using automated acoustic cardiography. In a recent trial, the device's efficacy in managing heart failure patients was demonstrated, with rehospitalization and total mortality reduced remarkably over a year, giving a glimpse of the power of noninvasive cardiac monitoring in improving patient outcomes (Fudim et al., 2022).

BodiGuide Edema Monitor

BodiGuide Edema Monitor uses the sensors on the ankle. These measure the intercellular fluid retention that indicates the imminent H.F. decompensation. An open pilot trial has demonstrated the feasibility of its use for monitoring and identifying ankle circumference patterns that can be used to detect heart failure exacerbation as early as possible.

CardioTag (Cardiosense Inc.) and Acorai Heart Monitor

These models use a combination of seismocardiogram, electrocardiogram, and photoplethysmogram signals combined with machine learning algorithms to estimate pulmonary capillary wedge pressure. These machines have proved their high quality in estimating the hemodynamic parameters, offering noninvasive alternative cardiac monitoring methods.

VitalPatch

VitalConnect (VitalPatch) is the sensor worn on the chest that tracks the ECG, skin temperature, and activity. The LINK-HF study exhibited its efficacy in H.F. hospitalization prediction via high sensitivity and specificity, which provides a worthy tool for early intervention in H.F. management.

SimpleSense

SimpleSense (Nanowear) consists of sensory underwear to establish an algorithm to forecast the development of H.F. The NanoSENSE study is an observational study that aims to validate the multiparameter algorithm as a possible strategy for using wearables to anticipate an H.F. event (Nanowear, n.d.).

Sentinel System

Sentinel System (Analog Devices) analyzes H.F. data by merging several clinical measurements and alerts the clinical care team if defined thresholds are reached. A clinical trial will assess this device's effectiveness in reducing hospital admissions and signal the continuing efforts to improve and validate wearable H.F. monitoring technologies (Nanowear, n.d.).

Bodyport Cardiac Scale

The Bodyport Cardiac Scale is a platform that measures noninvasive hemodynamic biomarkers, and its ability to anticipate heart failure (H.F.) events was tested in the SCALE-HF 1 study. This device stands out as a new method of H.F. monitoring, which can be used as a less complicated yet efficient way of early exacerbation detection (Nanowear, n.d.).

The use of remote monitoring technologies in heart failure management is a significant advancement in healthcare delivery. It allows for timely intervention, personalized therapy, and continuous surveillance. This review examines the various devices and systems used in remote monitoring, highlighting their contributions to improving patient outcomes and increasing access to care. The article covers various topics related to implantable medical devices, including pacemakers, implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, implantable loop recorders (ILRs), and the CardioMEMS[™] HF system, and also discusses recent advances in artificial intelligence (A.I.) for risk assessment and early detection. The article categorizes monitoring devices based on their function, including vital signs monitoring devices, wearable devices, implantable devices, and mobile apps. Insights from clinical trials and studies evaluating the efficacy and safety of remote monitoring devices are synthesized to underscore the promising results in reducing heart failure hospitalizations and improving quality of life. Remote monitoring is emerging as a transformative approach to cardiac care, poised to revolutionize healthcare delivery by empowering patients and improving clinical decision-making through data-driven interventions.

Categorization of monitoring devices based on their functions, including vital signs monitoring devices, wearable devices, implantable devices, and mobile apps connected to smartphones. Each category plays a distinct role in remote monitoring, offering convenience, accessibility, and personalized care to patients with chronic conditions like heart failure.

Clinical trials and studies evaluating the efficacy and safety of remote monitoring devices have shown promising results in reducing heart failure hospitalizations, improving quality of life, and enhancing patient outcomes. It is important to note that these evaluations are objective and based on factual evidence. The field of remote monitoring for the management of heart failure continues to evolve, with devices ranging from implantable pulmonary artery pressure monitors to wearable sensors such as Zoll HFMS and VitalPatch. In summary, remote monitoring is paving the way for more effective strategies in the management of heart failure and other cardiac conditions.

This technology enables patients to receive real-time data and healthcare providers to provide proactive and personalized care - a paradigm shift in healthcare delivery. Remote monitoring will play an increasingly important role in optimizing outcomes for heart failure patients worldwide as technology advances and clinical evidence accumulates.

CONCLUSIONS

H.F. is prevalent, and due to H.F.'s economic burden, especially in modern times, creative solutions to the challenge are needed. Tools for advanced monitoring, such as smartwatches (e.g., Zoll HFMS, ReDS), implants (e.g., LUX-Dx, CardioMEMS HF System), and algorithms (e.g., VitalPatch, SimpleSense) are proven to be efficient in general remote monitoring, exacerbation detection, as well as personalized intervention. Monitoring devices that can function by themselves can be divided into vital signs monitors, wearable devices, implantable devices, and smartphone-connected devices. Vital signs monitors read critical health measures such as heart rate and blood pressure in telehealth routes. Wearable devices target specific health conditions for continuous monitoring and good disease management. Mobile phone-synchronized devices work hand-in-hand with health-tracking apps for a holistic health monitoring process and ease of self-management education. These technologies aim to decrease H.F. hospital admissions, improve patient outcomes, and support resource allocation in healthcare institutions. Future research should concentrate on the tools' fine-tuning, cost-effectiveness appraisal, and implementation of them into the healthcare system to achieve a desirable H.F. management level.

Main limitations of the study and future research

This review discussed effectively the role of remote monitoring (RM) devices in managing heart failure (HF) patients, but some limitations were detected and would be highlighted for future research. Firstly, the review predominantly focuses on the effectiveness of RM interventions without sufficiently addressing the barriers to their widespread adoption, such as cost implications, patient acceptance, and healthcare infrastructure requirements. Moreover, the studies included in the review primarily report short-term outcomes, lacking long-term follow-up data, which is crucial for assessing the sustainability of RM interventions in improving patient outcomes. Future research should also explore the potential of integrating RM with complete care models and discussing advanced technologies like artificial intelligence for personalized intervention strategies, aiming to discuss with more detail the complex challenges associated with HF management and ultimately improve patient care and outcomes.

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B. data research and statistical analysis:	20%	20%	20%	20%	20%
C. elaboration of figures and tables:	20%	20%	20%	20%	20%
D. drafting, reviewing and writing of the text:	20%	20%	20%	20%	20%
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