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Remote management in patients with heart failure (from new onsetto advanced): A practical guide

Cédric Kleina,*, Serge Boved a,b, Pascal De Groote a,c, Michel Galinier d,e, Patrick Jourdain f,g, Jacques Mansourati h,i, Atul Pathak j, François Roubille k,l, Rémi Sabatier m, Laurence Guedon-Moreaua, n

a Department of Cardiovascular Medicine, CHU de Lille, 59000 Lille, France

b Heart Rhythm Department, clinique Pasteur, 31076 Toulouse, France

c Inserm U1167, institut Pasteur de Lille, 59000 Lille, France

d Cardiology Department, CHU de Toulouse, 31300 Toulouse, France

e University Paul-Sabatier - Toulouse III, 31062 Toulouse, France

f Covidom Regional Telemedicine Platform, AP-HP, Paris, France

g Cardiology Department, University Hospital Bicêtre, AP-HP, 94270 Le Kremlin-Bicêtre, France

h Department of Cardiology, CHU de Brest, 29200 Brest, France

i University of Bretagne Occidentale, 29238 Brest, France

j Department of Cardiovascular Medicine, Princess Grace Hospital, 98000 Monaco, Monaco

k Cardiology Department, CHU de Montpellier, 34295 Montpellier, France

l Inserm, PhyMedExp, CNRS, université de Montpellier, 34295 Montpellier, France

m Cardiovascular Department, CHU de Caen Normandie, University of Caen-Normandie, 14000 Caen, France

n University of Lille, 59000 Lille, France

Abbreviations

AHF acute heart failure CIED cardiac implantable electronic device GDMT guidelinedirected medical therapy HF heart failure HFrEF heart failure with reduced ejection fraction NYHA New York Heart Association RM remote monitoring

Keywords :

Remote monitoring, Remote, management, Heart failure.

*Tweet: Remote management in patients with heart failure: which strategy for which patient ? Find some answers in this collaborative work.

*Corresponding author.

E-mail address: cedric.klein@chru-lille.fr (C. Klein).

ABSTRACT

Heart failure is a chronic condition that affects millions of people worldwide and is associated with high morbidity and mortality. Remote monitoring, which includes the use of non-invasive connected devices, cardiac implantable electronic devices and haemodynamic monitoring systems, has the potential to improve outcomes for patients with heart failure. Despite the conceptual and clinical advantages, there are still limitations in the widespread use of these technologies. Moreover, a significant proportion of studies evaluating the benefit of remote monitoring in heart failure have focused on the limited area of prevention of rehospitalization after an episode of acute heart failure. A group of experts in the fields of heart failure and digital health worked on this topic in order to provide a practical paper for the use of remote monitoring in clinical practice at the different stages of the heart failure; (3) heart failure in stable period; and (4) advanced heart failure. A careful and critical analysis of the available literature was performed with the aim of providing caregivers with some recommendations on when and how to use remote monitoring in these different situations, specifying which variables are essential, optional or useless.

1. Background

Heart failure (HF) is a complex clinical syndrome consisting of cardinal symptoms (e.g. breathlessness, ankle swelling and fatigue)that may be accompanied by signs (e.g. elevated jugular venous pressure, pulmonary crackles and peripheral oedema) [1].

The prevalence of HF appears to be 1-2% of adults [1]. HF hospitalizations represent 1-2% of all hospital admissions, and HF is the most common diagnosis in hospitalized patients aged > 65 years [2,3].

Despite advances in HF therapy and management, the absolute number of hospital admissions for HF is expected to increase by about 50% over the next 25 years, as the result of a growing and aging population [4]. Approximately half of patients will be admitted at least once within

1 year after diagnosis, 20% will be readmitted within that same year and > 80% will be readmitted within 5 years [2,5,6].

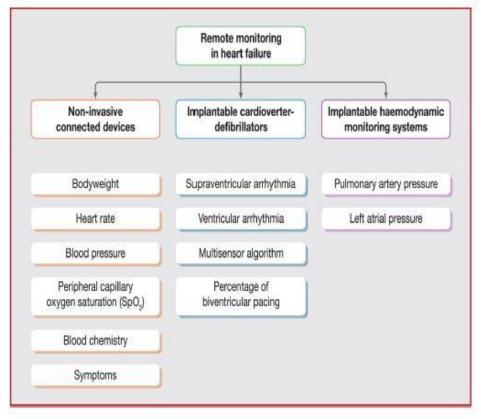


Fig. 1. Remote monitoring technologies: types of devices and corresponding monitorable variables.

Advances in remote monitoring (RM) allow caregivers to better monitor patients with HF, by providing access to pathophysiological data on these patients. RM solutions use everything from simple and non-invasive connected devices (such as scales or blood pressure cuffs) to sophisticated implanted devices, such as implantable cardioverter defibrillators and implantable cardiopulmonary sensors (Fig. 1).

Despite conceptual advantages, the clinical evaluation of RM for HF has shown mixed results [7–13]. Most studies have included patients recently admitted to the hospital for acute HF, and their primary objective was to reduce readmission rates and mortality. Clearly, the potential benefits of RM approaches in HF cannot be restricted to this specific and restrictive condition, but must be evaluated in the broad and comprehensive field of HF syndrome.

The aim of this collaborative work was to provide a comprehensive overview of the current state of knowledge, limitations and evidence gaps for RM in HF, in order to provide clinicians with practical guidance on RM modalities for their patients with HF, from initial diagnosis to advanced HF.2.

2. Methods

To establish this paper, a working group composed of 10 clinical cardiologists and researchers in the fields of HF and digital health was formed. First, a literature review was performed to assess the current evidence for the benefit (and non-benefit) of different RM modalities in patients with HF. Then, three remote working meetings were held to discuss and consider the place of the different RM modalities. In addition, a cardiologist practicing tele titration of drug therapy and a cardiologist specialized in advanced HF were consulted about questions specific to their area of expertise.

To best fit clinical practice and the different possible presentations of a patient, we divided the HF syndrome into its different stages according to the natural history of this disease: (1) discovery of HF; (2) acute decompensation of chronic HF; (3) HF in stable period; and (4) advanced HF (Fig. 1).

For each of these presentations, a discussion was conducted on:(1) the level of current evidence in the scientific literature; (2) the usefulness or uselessness of a remote management strategy; (3) the profile of eligible patients and possible contraindications; (4) the essential variables to be monitored and those that may be useful to monitor; and (5) the technologies that should then be used or that could be useful.

A final report was written by the first and last authors of this paper, and was approved by all the participants in this working group.

In order not to overload the main paper, an annotated review of original studies on RM in HF is provided in the Online material.

3. Clinical presentations

3.1. New-onset HF

Drug therapy is the cornerstone of treatment for HF with reduced ejection fraction (HFrEF), and is associated with: (1)reduced mortality; (2) prevention of recurrent hospitalizations resulting from worsening HF; and (3) improved clinical status, functional capacity and quality of life.

Although optimal pharmacological treatment is carefully defined by clinical practice guidelines [1], in practice, many eligible patients with HFrEF are not treated according to guideline-directed medical therapy (GDMT) [13]. The timing of such GDMT (clinicians should strive to implement optimal GDMT within 3–6 months of the initial diagnosis of HF) may be challenging for some patients when it has been shown that an intensive treatment strategy of rapid up titration of GDMT and close follow-up after an acute heart failure (AHF)

admission reduced the risk of 180-day all-cause death or HF readmission compared with usual care [14].

There are multiple reasons for the delay in initiating and optimizing medical treatment for patients when their HF is discovered. The difficulty of establishing frequent encounters between health-care providers and patients is a real barrier to the realization of the GDMT, whether because of time constraints, limitations in transportation or availability of infrastructure for frequent visits to the practitioner.

The use of resources, such as RM and remote follow-ups, can help patients in whom maintaining sustained face-to-face follow-ups to achieve GDMT proves difficult.

A recently published randomized controlled trial showed that a remote titration intervention facilitated by telemonitoring had the potential to increase the proportion of patients who achieve optimal GDMT doses, to decrease time to dose optimization and to reduce the number of clinic visits, compared with standard care [15]. Moreover, patients and clinicians indicated that the remote titration intervention was easy to use and integrated well into their routines, and also removed practical barriers to titration [16].

The 2021 Update to the 2017 Expert Consensus Decision Path-way for Optimization of Heart Failure Treatment suggests that "options such as virtual care [. . .] may aid in remote optimization of GDMT" [17].

Based on emerging data [15,16,18,19], we suggest that remote optimization of GDMT in patients newly diagnosed with HF could be offered to all patients with reduced ejection fraction(< 40%), except those for whom a significant risk of an adverse event related to titration can be predicted, according to the following criteria: severe (New York Heart Association [NYHA]class IV) HF; current exacerbation of HF; hypotension (systolic blood pressure < 90 mmHg); heart block or heart rate < 50beats/minute; significant renal dysfunction (estimated glomerular filtration rate < 30 mL/min/1.73 m2; with caution if estimated glomerular filtration rate < 45 mL/min/1.73 m2).

This remote optimization of GDMT can be performed via non-invasive connected devices and tele consultation.

The essential variables to monitor for this remote optimization strategy are heart rate, blood pressure, weight, symptoms and blood chemistry (urea, creatinine, potassium). Variables that maybe useful are transcutaneous arterial oxygen saturation, temperature and pulmonary artery pressure.

In the absence of clinical evidence, titration of these therapies is not justified in HF with preserved ejection fraction.

3.2. Acute decompensation of chronic HF

AHF refers to rapid or gradual onset of symptoms and/or signs of HF, and may lead to an unplanned hospital admission, which is a serious adverse event. Indeed, in-hospital mortality for patients with AHF ranges from 4% to 10% [20]. Moreover, the post discharge period is a well-recognized phase during which patients are at high risk of readmission and mortality.

The value of RM could be, on the one hand, to avoid hospitalizations for AHF and, on the other hand, to allow early discharge in case of unavoidable hospitalization.

3.2.1. Prevention of hospitalization for AHF

As a serious adverse event, hospitalization for AHF deserves to be prevented. RM can contribute to the detection of decompensating factors in HF, with the aim of early management to avoid decompensation. RM can also allow early detection of AHF, leading to early initiation of treatment before it becomes serious.

The incidence of hospitalization for AHF is particularly high in patients with previous hospitalization for AHF. The postdischarge1-year mortality can be 25-30%, with death or readmission rates of up to > 45%. This is why most clinical studies in the field of RM of HF have been conducted in the context of the recently (< 12 months) hospitalized patient with HF, with an RM strategy aimed at reducing the risk of rehospitalization and mortality. A descriptive and critical analysis of these trials is provided in the online material.

The first point when considering an RM solution is the necessity of patient adherence. Active transmission of weight, symptoms and other data requires good adherence/education in order to benefit from the RM strategy.

In the OSICAT study [9], which evaluated the benefit of an RM solution combining weight measurement and symptom questionnaires, a significant clinical benefit was found in patients with > 70% compliance with weight measurement, whereas the overall study result was not significant. In the TIM-HF2 study [10], which showed a benefit for RM compared with usual monitor-ing, 97% of patients were compliant > 70% of the time with regard to daily transmissions. In this study, patients with an ongoing depressive syndrome (Patient Health Questionnaire for Depression [PHQ-9D] score < 10) were excluded. Other well-conducted studies have failed to demonstrate a benefit for RM compared with usual follow-up, possibly because of a lack of adherence by patients included in and randomized to the RM group [8,21].

This compliance issue is particularly relevant for non-invasive connected devices, and also for some of the more complex connected devices, such as those that provide pulmonary pressure data, because for all of these devices a daily data transmission must be performed by the patient. Most cardiac implantable electronic devices (CIEDs) perform automatic transmissions, usually during the night, as long as the patient is close to the transmitter.

Finally, it appears that early appropriate specialized interventions are essential to figure out the benefits of telemonitoring inpatients with HF [10,22].

3.2.1.1. Non-invasive connected devices.

We suggest that RM maybe considered for all patients with HF (irrespective of LVEF) recently hospitalized (< 12 months) for AHF, except those with a predicted low adherence to the RM solution (such as patients with depressive syndrome).

The essential variables to monitor are weight and signs/symptoms of congestion. The variables that may be useful are heart rate, blood pressure, transcutaneous arterial oxygen saturation and temperature.

3.2.1.2. CIEDs. We suggest that RM should be consider for all patients with HF and a CIED in order to reduce cardiovascular events.

The essential variables to monitor are: the technical data of the implantable device and its leads, in order to verify the absence of dysfunction; supraventricular rhythm disorders, as the occurrence of atrial fibrillation is a factor that can precipitate a decompensation of HF; ventricular rhythm disorders; in the case of cardiac resynchronization therapy, the percentage of biventricular pacing, as a decrease in this percentage may, on the one hand, favour a decompensation of HF and, on the other hand, may be a sign of insufficient optimization of drug treatment and/or of CIED settings; and multivariable indices. The variable that may be useful is periodic electrogram tracings (to detect clinical events that may not trigger RM alerts).

3.2.1.3. Implantable haemodynamic systems.

In accordance with the CHAMPION and MONITOR-HF trials, we suggest that pulmonary artery pressure-guided management, through a wireless implantable device, can be useful in patients in NYHA class III3 (irrespective of LVEF), in order to improve quality of life and reduce HF hospitalization [23,24]. Whereas the NYHA classification is somewhat elusive, the INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) classification could be useful in the context of advanced HF. In this case, profiles 4 and 5can be considered.

In patients with HFrEF on GDMT, a prespecified subgroup analysis of the CHAMPION trial showed that pulmonary artery pressure-guided HF management reduces morbidity and mortality [23].

3.2.2. Early discharge and initial post discharge period

Given the emphasis on preventing readmissions, current strategies for the management of HF focus on establishing closeout patient follow-up during the high-risk period after hospital discharge, which is known as the vulnerable phase. It is therefore recommended that: (1)

patients hospitalized for AHF be carefully evaluated before discharge to exclude persistent signs of congestion; and (2) an early follow-up visit takes place 1–2 weeks after discharge to assess signs of congestion and drug tolerance, and to start and/or up titrate evidence-based therapy [1].

Diuretics are the cornerstone of standard therapy for AHF. Intra-venous administration (by bolus or continuous infusion) of a loop diuretic is initially preferred because of potentially poor absorption of the oral form in the presence of bowel oedema. The transition to oral diuretic therapy occurs when the patient reaches a near euvolaemic state.

Weight, signs and symptoms, fluid balance, electrolyte levels and renal function are then generally monitored for 2–3 days before considering the patient's discharge.

An RM strategy may be useful to consider for early discharge after transition to oral therapy (24 hours or less after this transition).

We suggest that RM associated with an early discharge strategy may be offered to all patients with HF (irrespective of LVEF),except for those with a predicted high risk of early AHF readmission according to the following criteria: patients with previous AHF hospitalization (< 6 months); patients with persistent signs/symptoms of congestion and/or minimal or no weight loss; patients in NYHA class IV; patients with a high level of co-morbidities (anaemia, renal dysfunction, nutritional or metabolic disorder, lung disease, such as chronic obstructive pulmonary disease, depression, etc.).

The essential variables to monitor for an early discharge strategy are heart rate, blood pressure, weight, signs/symptoms of congestion and blood chemistry (urea, creatinine, potassium). Variables that may be useful are transcutaneous arterial oxygen saturation, temperature and pulmonary artery pressure. These variables could be monitored for 1-2 weeks after discharge, which would avoid the need to plan an in-office visit nearby.

As mentioned in the 2021 European Society of Cardiology guidelines, a supervised exercisebased cardiac rehabilitation programme should be considered in patients with more severe disease, frailty or co-morbidities [1]. Clinical trials and meta-analyses inpatients with HFrEF show that exercise rehabilitation improves exercise capacity and quality of life, and reduces all-cause and HF hospitalizations [25–27].

3.3. Stable HF

Limited data are provided in the setting of patients with chronic HF and no admission for AHF in the previous 12 months. There-fore, RM through invasive or non-invasive connected devices instable patients with chronic HF is not suggested for routine use. However, RM of CIEDs may be useful to identify decompensation factors such as the occurrence of atrial fibrillation or a decrease in the percentage of biventricular pacing.

3.4. Advanced HF

Many patients with HF progress into a phase of advanced HF, characterized by persistent symptoms despite maximal therapy. The prevalence of advanced HF is increasing as a result of the growing number of patients with HF, the ageing of the population and better treatment and survival.

Mechanical circulatory support can improve survival and symptoms of patients with advanced HF. Heart transplantation remains the gold standard for the treatment of advanced HF in the absence of contraindications.

Limited data are available on the value of RM in these specific conditions. However, the conceptual benefit of RM appears relevant in so far as the follow-up of the patients concerned must be nearby and the referred centre where they are followed up may be far from their home.

3.4.1. Mechanical circulatory support

RM can be initiated as soon as mechanical circulatory support is implemented, and is based on alerts and/or scheduled trans-missions. Alerts should be adaptable to individual patients (alerts according to machine parameters, symptoms, international normalized ratio targets, etc.).

RM can be supported by remote visits, with the possibility of sending messages and prescriptions to the patients. Tele-expertise can also support the patient's general practitioner, the nurse in charge of dressings and cardiologists in peripheral centres with less experience in the management of this type of patient, in order to reduce the number of face-to-face visits at the referral centre.

3.4.2. Heart transplantation

3.4.2.1. Patients on the waiting list.

All patients listed for trans-plantation should have RM. The main objectives combine early detection of worsening HF and regular updating of each patient's position on the national transplant priority list.

RM can be coupled with remote visits, especially in case of worsening of the disease (e.g. worsening of biological variables); it can also be used to update the heart score for positioning the patient on the transplant list.

3.4.2.2. Transplanted patients.

All newly transplanted patients are eligible for RM. Formerly transplanted patients may be considered for remedial RM on a case-by-case basis (difficulties in understand-ing treatment/social isolation/the need to be coached because of limited intellectual resources). Formerly transplanted patients who are stable and well educated do not represent a priority for the initiation of RM.

The modalities of the RM may be adjusted according to the post-transplant delay, and can be based on alerts and/or scheduled transmissions at calendar intervals. We suggest a scheduled transmission every 15 days for newly transplanted patients, and then to space out these transmissions for stable patients.

RM can be combined with remote visits if necessary, particularly in order to limit transportation.

4. General aspects

4.1. Therapeutic education

Several studies have demonstrated the benefits of therapeutic education for patients with chronic HF. Individualized one-on-one nurse-led HF education improves patients' knowledge, self-care maintenance, management and confidence [28,29].

A randomized trial that included 201 patients admitted for AHF showed that the combination of specific discharge guidance and a telephone follow-up after 7 and 30 days resulted in greater therapeutic adherence, as well as a decrease in rehospitalization compared with the control group [30].

Another randomized trial showed that the addition of a 1-hournurse educator-delivered teaching session at the time of hospital discharge resulted in improved clinical outcomes, including death and rehospitalization, increased self-care measure adherence and reduced cost of care in patients with systolic HF [31].

In elderly patients with chronic HF, a comprehensive and exclusive theory-based education programme showed a significant benefit in relieving depression symptoms, enhancing self-monitoring and improving the quality of life [32].

On the basis of these data, it seems crucial to systematically integrate therapeutic education into the RM of patients with chronic HF.

4.2. Team of caregivers

Providing a systematic framework model specifying the appropriate structure of the RM team in patients with HF is challenging. There is a wide heterogeneity of situations (small local teams versus large teams centralizing active files of patients; externalized staff versus staff integrated into medical centres; availability of nurses with advanced knowledge of HF, etc.), leading to differing organizations between hospitals. Furthermore, few data are available on the superiority of one organization over another. In any case, it remains essential to structure and organize the department and the team of caregivers to respond to: (1) patients' expectations; (2) the requirements of standards of care; and (3) the satisfaction of customers.

4.3. Duration of RM

The duration of RM is not consensual. The TIM-HF2 and OSICAT studies included patients who had been admitted to hospital for HF within 12 months before randomization [9,10]. We can therefore suggest a duration of 1 year of RM after hospitalization. On the other hand, it is conceivable that RM could be maintained for an indefinite period for patients with advanced HF.

5. Limitations and evidence gaps

RM of HF has been the focus of high-quality research literature, with mixed results in terms of reduction of critical criteria, such as mortality or rehospitalization for HF.

Although some studies, such as TIM-HF2 and IN-TIME, have associated an RM strategy with a reduction in all-cause mortality, the latter is achieved at the cost of a strict and complex monitoring method (daily transmission of body weight, systolic and diastolic blood pressure, heart rate, analysis of heart rhythm, peripheral capillary oxygen saturation and self-rated health status; physician-led medical support and management of patients 24 hours/day, 7days/week) that appears to be difficult to implement in clinical practice at this time.

Nevertheless, it seems important to specify that benefits of RM are also expected in terms of: (1) the quality of life of the patient (reassurance, autonomy, motivation and psychological sup-port, saving time by avoidance of transport); 2) the quality of work life of health professionals (strengthening of collaborative work, reactivity and capacity of early reaction); and (3) the health care system in general (facilitation of access to care, cost-utility and cost-effectiveness performance, improvement of care pathways).

Each patient is unique. The method of monitoring should be a combination of remote and inperson follow-up, with a patient-specific proportion of each. Compliance with RM should be verified by the care team. The patients must be familiar with the care team that follows them remotely. RM brings the patient "closer" to the care team at the time of their need. Some of the proposals made are forward looking, and are not yet based on scientific evidence, which must continue to be obtained(especially to prove the safety of RM) in order to propose guidelines for a combination of face-to-face visits and RM for patients with HF.

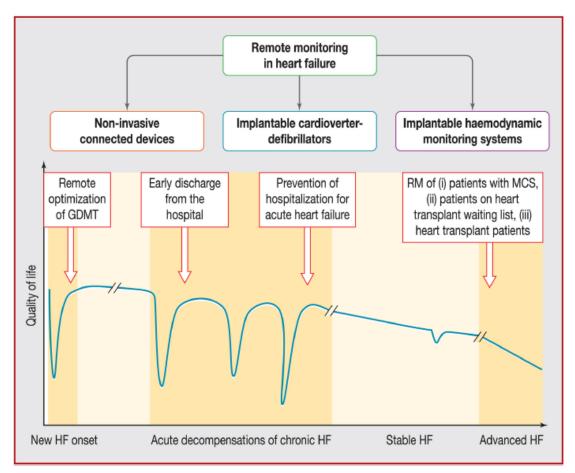
Finally, we did not address the subject of tele-therapeutic edu-cation, which surely has an interesting place in the care of patients with HF. Another subject of interest relates to the ethical aspects of RM, and it is essential not to over empower patients.

6. Conclusions

RM of HF is an interesting and topical subject. The related scientific literature is already vast, but remains difficult to summarize because of the heterogeneity of the HF syndrome.

In this collaborative work, bringing together different experts in HF and telemedicine, we have carried out a literature review and then outlined the potential interests of RM at the different stages of this syndrome, from the initial diagnosis to advanced HF.

The objective of this work is to provide clinicians with some tools and advice to better comprehend the use of RM in HF (Central Illustration).



Central Illustration. Remote monitoring (RM) technologies and the potential value of remote management throughout the natural history of heart failure (HF). GDMT: guideline-directed medical therapy; MCS: mechanical circulatory support.

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Appendix A. Supplementary dataSupplementary data associated with this article can be found, in the online version, at <u>https://doi.org/10.1016/j.acvd.2023.11.013</u>.

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