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Review Article

Remote Patient Management in Heart Failure: An Overview

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Abstract:

Evidence on the beneficial effects of remote monitoring of heart failure patients is multiplying. Mainstay of remote monitoring are multimodality telemonitoring systems, cardiac implantable devices, and wearables. Newer concepts include ambient sensor system derived digital biomarker monitoring. However, there is still a lack of consistent findings in randomized clinical trials, in particular in view of the wide range of available technologies. Therefore, implementing remote patient management in routine clinical practice is not yet unrestrictedly recommended by the current heart failure guidelines. This review is a synopsis of current knowledge and evidence of different remote patient management technologies and their use in heart failure patients.

Key words: remote patient monitoring; heart failure; telemonitoring; digital health

Abbreviations

HF: heart failure

CHF: chronic heart failure

RPM: remote patient management

QOL: quality of life

ESC: European society of cardiology

AHA: American heart association

HTM: home telemonitoring

CV: cardiovascular

NYHA: New York Heart Association

ECG: electrocardiogram

RR: relative risk

CIED: cardiac implantable electronic device

RV: right ventricular

NT-proBNP: N-terminal pro B-type natriuretic peptide

CRT: cardiac resynchronization therapy

ICD: implantable cardioverter-defibrillator

AMG: alert management guide

IHM: implantable hemodynamic monitor

PAP: pulmonary artery pressure

ASS: ambient sensor system

Introduction

Heart failure (HF) is a severe clinical and public health issue, which represents a considerable burden for health systems and related financial resources. A stagnating high mortality and frequent hospitalizations in an ageing population will most likely lead to further challenges for our healthcare systems.[1] Decompensation of chronic heart failure (CHF) has a significant impact on the resources of caregivers, especially in hospital settings. Therefore, the major goals of HF management are continuous optimization of care and early recognition of decompensation onset to prevent hospitalization and concomitant increased morbidity.

In patients with chronic disease, where regular follow-ups are beneficial, telemedicine seems to be a favorable way of patient management due to

the possibility of detecting health deterioration in the early stages. In terms of CHF, worsening of HF symptoms or ultimately HF decompensation could be intercepted by regular telemedical follow-up visits with the possibility of making early adjustments to the therapy and through that, potentially preventing hospital admissions.[2] Non-hemodynamic monitoring includes interventions ranging from telephone calls only and weight monitoring up to complex multi-variable telemonitoring strategies, making it difficult to proof which component drives the effect.[3]

The use of telemedicine with home monitoring of HF patients has been studied under various circumstances. Several controlled studies and meta-analyses investigating remote patient management (RPM) in patients recently hospitalized for HF have shown beneficial effects on mortality, re-hospitalizations and quality of life (QOL).[4–7] Other RPM studies have evaluated technologies embedded in implantable cardiac devices or hemodynamic monitors.[8,9]

HF guidelines of the European Society of Cardiology (ESC) and American Heart Association (AHA) are inconclusive regarding telemonitoring of HF patients. While according to the ESC guidelines non-invasive home telemonitoring (HTM) to reduce the risk of recurrent cardiovascular (CV) hospitalizations, HF hospitalizations and CV death is a class IIb indication, AHA guidelines do not support the use of non-invasive HTM or remote monitoring of physiological parameters to reduce HF hospitalizations.[10,11] The inconclusiveness of the ESC and AHA guidelines on telemonitoring of HF patients may be attributed to a combination of insufficient large-scale randomized controlled trials providing definitive evidence and the rapid pace of technological advancements outstripping the frequency of guideline updates. Current efforts in ongoing studies and anticipated updates to the guidelines may soon address these gaps and provide clearer recommendations for clinical practice. In contrary to current guidelines telemedical surveillance of HF patients is covered by health insurance in Germany.

This article is a synopsis of current knowledge and evidence about RPM approaches in HF patients.

Telemonitoring Systems

Earlier approaches to telemonitoring HF patients were based on structured telephone support by asking patients about HF symptoms, compliance with lifestyle measures, drug treatment or possible weight gain. In a systematic review conducted by Inglis et al. 25 studies using structured telephone support for HF patients with a total of 9332 participants were evaluated.[12] This review found that structured telephone support reduced all-cause mortality and HF-related hospitalizations. Nine of 11 studies reported significant improvements in health-related QOL. Improvements of prescribing, patient knowledge and self-care, and New York Heart Association (NYHA) functional class were observed. In the studies which evaluated participant acceptance of the intervention, the acceptance rate has been reported as being in the range of 76% to 97%.

However, the nowadays commonly used approaches to telemonitoring in HF patients include self-measurements of blood pressure, heart rate, single lead electrocardiogram (ECG), oxygen saturation and body weight. In the more recent TIM-HF2 trial, Koehler et al. investigated the efficacy of an RPM intervention on mortality and morbidity in a well-defined HF population.[5] A total of 1571 HF patients were randomly assigned to RPM or usual care (according to the 2016 ESC guidelines for the diagnosis and treatment of acute and chronic HF). The RPM intervention consisted of a daily transmission of vital parameters and a self-rated health status to the telemedical center. Key elements were a definition of patient's risk category using the baseline and follow-up visit biomarker data in combination with the daily transmitted data, patient education and co-operation between the telemedical center and the patient's GP and cardiologist to guide patients care according to the measured data. Key findings were: 1) a significant reduction of days lost due to unplanned cardiovascular hospital admissions and all-cause death (weighted average days lost per year in RPM group 17.8 vs. 24.2 in usual care group; 2) a significant reduction of all-cause death rate (7.86 per 100 person-years of follow-up in the RPM group vs. 11.34 per 100 person-years of follow-up in the usual care group). Cardiovascular mortality and outcomes measuring QOL were not statistically different between the two groups. Compliance of at least 70% of daily data transfer to the telemedical center was 97% in the interventional arm.

In a meta-analysis performed by Umeh et al., 38 RCT's on telemonitoring of HF patients and a total of 14'993 patients were analyzed.[13] According to this study telemonitoring was associated with reduced all-cause and cardiovascular mortality (relative risk (RR) 0.83 and 0.66). Telemonitoring also decreased the all-cause hospitalization (RR 0.87) but did not decrease heart failure related hospitalization (RR 0.88). The findings showed that prolonged RPM intervention (12 months or longer) was associated with both reduced all-cause and HF hospitalization. Shorter intervention (6 months or less) did not show a beneficial effect. A summary of recent (2018 and newer) meta-analyses on telemonitoring in HF patients is provided in Table 1. Findings suggest that telemonitoring of HF patients has the potential to reduce all-cause and cardiovascular mortality significantly. Regarding all-cause and HF-related rehospitalizations the results are more heterogeneous. Conclusions on improvement of QOL are challenging to draw, as different health questionnaires have been used in the trials, which makes a comparison challenging. Telemonitoring of HF patients has several limitations. Complex telemonitoring systems are labour-intensive and, therefore, probably not feasible in every healthcare system.[14] As biometrical data should be transferred daily in most telemonitoring systems, these interventions carry a significant risk of non-compliance.

Meta-Analysis	**All-cause mortality**	**Cardiovascular mortality**	**All-cause hospitalization**	**HF-related hospitalization**	**Quality of life**
Umeh et al., 2022[13]	Significant reduction, *RR = 0.83, 95% CI: 0.75-0.92, p = 0.001*	Significant reduction, *RR = 0.66, 95% CI: 0.54-0.81, p < 0.001*	Significant reduction, *RR = 0.87, 95% CI: 0.80-0.94, p = 0.002*	No significant reduction	No data provided
Rebolledo del Toro et al., 2023[15]	No significant reduction	No significant reduction	No significant reduction	Significant reduction, *RR 0.77 [0.67; 0.89], I^2 7%*	Significant improvement (KCCQ, SF-36)
Scholte et al., 2023[14]	Significant reduction,	No data provided	No data provided	Significant reduction,	No data provided

	OR: 0.84, 95% confidence interval CI: 0.77–0.93, I^2: 24%			*OR: 0.81, 95% CI 0.74–0.88, I^2: 22%*	
Drews et al., 2021[16]	No significant reduction	No data provided	No significant reduction	No data provided	No data provided
Pekmezaris et al., 2018[17]	Significant reduction (at 180 days follow-up), *OR: 0.6*	Significant reduction, *OR: 0.39 (only 2 studies)*	No significant reduction	No significant reduction	No data provided
Yun et al., 2018[18]	Significant reduction, *RR=0.81, 95% CI: 0.7-0.94, I^2=16%*	Significant reduction, *RR = 0.68, 95% CI: 0.5-0.91, I^2=8%*	No significant reduction	No significant reduction	No significant improvement
Zhu et al., 2019[19]	Significant reduction, *OR 0.75, 95% CI 0.62–0.90, p =0.003*	Significant reduction, *OR 0.54, 95% CI 0.34–0.86, p = 0.009 (for STS)*	Significant reduction, *OR 0.82, 95% CI 0.73–0.91, p = 0.0004*	Significant reduction, *OR 0.83, 95% CI 0.72–0.95, p =0.007*	Inconclusive

KCCQ: Kansas City Cardiomyopathy Questionnaire
SF-36: Short form-36
STS: structured telephone support
RR: relative risk
OR: odds ratio

Table 1: Overview of recent meta-analyses on HF telemonitoring

Cardiac Implantable Electronic Devices

Remote monitoring of patients with cardiac implantable electronic devices (CIED) is nowadays standard in many centers for rhythm monitoring, control of device function and therefore for safety reasons.[20] Intrathoracic impedance can be measured directly between the right ventricular (RV) lead and the device's generator. Decreased intrathoracic impedance is associated with increased ventricular volumes and pressures and overall fluid retention.[21,22] An inverse relation between intrathoracic impedance, pulmonary capillary wedge pressure (PCWP) and N-terminal pro B-type natriuretic peptide (NT-proBNP) has been described.[23,24] Newer technologies unite multiple parameters measured by CIEDs to evaluate the worsening of HF or congestion state. An overview of different technologies is presented in Table 2.

In the Mid-HEFT trial, investigating the OptiVol™ technology (Medtronic, Ireland), changes in intrathoracic impedance preceded the onset of HF symptoms by an average of 15 days.[22] The investigators of the PARTNERS-HF trial were able to identify patients at high risk for HF hospitalization using a combined HF device diagnostic algorithm consisting of long atrial fibrillation episodes, rapid ventricular rate during atrial fibrillation, high fluid index, low patient activity, abnormal autonomics, or notable device therapy (low cardiac resynchronization therapy (CRT) pacing or implantable cardioverter-defibrillator (ICD) shocks).[25]

The REM-HF trial was a prospective RCT investigating outcomes in a HF population by comparing an active device-guided RPM pathway with usual care in 9 centers in England.[26] 1650 patients were randomly assigned to either RPM pathway with active weekly review of remote monitoring data or usual care with an average follow-up of 2.8 years. The primary endpoint was the first event of death from any cause or unplanned hospitalization for cardiovascular reasons. Secondary endpoints included all-cause death, cardiovascular death, unplanned cardiovascular hospitalization, and unplanned hospitalization. The incidence of the primary endpoint did not differ significantly between the groups (42.4 % vs. 40.8%, p=0.87) and there were also no significant differences between the two groups concerning any of the secondary endpoints.

Multiple cardiac sensors for management of heart failure (MANAGE-HF) was a multisite phase I trial for the evaluation of the integration and safety of the HeartLogic™ (Boston Scientific, USA) multisensor algorithm in patients with HF with reduced ejection fraction (HFrEF).[27] The phase I trial was a prospective observational study with a total of 144 patients (initially 200 patients were enrolled). The study aimed to actively manage HeartLogic alerts with an alert management guide (AMG) and to evaluate integration and safety of the intervention. After a baseline period of data collection HeartLogic alerts were activated, and care providers received automated notice when an initial alert occurred and were encouraged to follow an AMG. Providers received re-alerts until the HeartLogic index recovered below the nominal alert recovery threshold. Analyses of the study endpoint included an evaluation of HeartLogic performance, change in medical treatment, plasma natriuretic peptide concentrations and HF hospitalization rate, and adverse events. The investigators of MANAGE-HF stated, that the HeartLogic multisensor algorithm with an AMG was safely integrated into clinical practice and associated with lower natriuretic peptide levels. Despite a significant variability in site responses to alerts, most responses targeted decongestion. Phase II will evaluate the efficacy of augmented HF treatment in remotely monitored patients with HeartLogic alerts turned on compared to patients who have remote monitoring with HeartLogic alerts turned off.

A systematic review and meta-analysis on this topic performed by McGee et al. included a total of 10 RCT's with 6579 patients.[28] The pooled analysis showed no benefit in 12-month mortality for RPM with CIED's. There was no difference in HF hospitalization rates between RPM and control arms. Yet the meta-analysis showed that RPM with CIED's reduced health care costs and overall healthcare presentations.

Technology / manufacturer	Features	Benefits	
MEDTRONIC OPTIVOL 2.0™	Thoracic impedance	Fluid monitoring Risk stratification for hospital admissions and mortality[22,29,30]	
BIOTRONIK HEARTINSIGHT™	Mean heart rate Mean heart rate at rest Premature ventricular contractions Atrial burden Heart rate variability Patient activity Thoracic impedance Baseline risk stratifier	66% alert sensitivity, predicting 2 out of 3 HF hospitalizations, 0.7 false alerts per patient year[31]	
BOSTON SCIENTIFIC HEARTLOGIC™	S1 and S3 heart sounds Thoracic impedance Respiratory rate and RSBI Resting heart rate Patient activity	Identification of patients during periods of significantly increased risk of HF events[32]	
ABBOTT CORVUE™	Thoracic impedance	Congestion monitoring[33]	

RSBI: rapid shallow breathing index

Table 1: Available CIED-based monitoring technologies

Hemodynamic monitoring

Continuous monitoring of hemodynamic parameters may be a more direct measure of HF decompensation than other indirect parameters, which deteriorate later in the development of worsening HF. Different technologies of implantable hemodynamic monitors (IHM) have been evaluated including RV outflow tract, left atrial pressure and pulmonary artery pressure measurement.[9,34–37]

A technology that established itself is the CardioMEMS HF-System™ (Abbott, USA), which allows wireless monitoring of pulmonary artery pressure (PAP) through a microelectromechanical sensor implanted by transcatheter technique. The CHAMPION trial conducted by Abraham et al. was a prospective, parallel, single-blinded, multicenter study that enrolled participants with NYHA Class III HF symptoms and a previous admission to hospital.[38] A total of 550 patients were provided with PAP IHM and randomly assigned to either the treatment group, in which daily uploaded PAP were used to guide medical therapy, or to the control group, where daily uploaded pressures were unavailable to the investigators. The study showed that rates of hospital admissions for HF were reduced by 33% in the treatment group (hazard ratio [HR] 0.67 [95% CI 0.55–0.80]; p<0.0001) compared with the control group. After completion of the randomized access period 177 patients of the former control group transitioned to the open access period and PAP information became available to guide therapy during open access (mean 13 months). Rates of hospital admissions for HF in the former control group were reduced by 48% (HR 0·52 [95% CI 0·40–0·69]; p<0·0001) compared with rates of hospital admissions in the control group during randomized access.

The GUIDE-HF trial conducted by Lindenfeld et al. investigated outcomes of PAP IHM guided therapy in a broader cohort of patients with NYHA functional class II - IV symptoms.[39] 1000 patients were randomly assigned to either IHM guided therapy or control group. In the overall analysis there were no significant differences in either urgent HF hospital visits or mortality between the two groups. However, about 30% of the follow-up time occurred during the COVID-19 pandemic. The prespecified COVID-19 sensitivity analysis suggested an effect of COVID-19 on the primary endpoint (all-cause mortality and total HF events). In the pre-COVID-19 impact analysis a significant reduction in primary endpoint events (HR 0.81, 95% CI 0.66-1.00; p=0.049) and HF hospitalizations (HR 0.72, 95% CI 0.57-0.92; p=0.0072) has been found in the treatment group compared to the control group.

According to the available evidence the monitoring of PAP using a wireless hemodynamic monitoring system may be considered in symptomatic patients with HF to improve clinical outcomes and is therefore regarded as a class IIb indication in the European guidelines for the treatment of HF.[10]

Wearables

Recently, early detection of impending HF hospitalization through continuous wearable monitoring analytics has been described. The LINK-HF study examined the performance of a personalized analytical platform using a wearable multisensory patch (ECG monitoring, thoracic impedance, accelerometry and temperature sensor) placed on the chest that recorded physiological data to predict rehospitalization after HF admission.[40] 100 patients were enrolled and monitored for up to 3 months. During follow-up there were 24 worsening HF events. The platform detected precursors of hospitalization for HF with 76% - 88% sensitivity and 85% specificity.

Another technology evaluated in a clinical trial is the μCor™ (Zoll Medical, USA) which detects heart rate and ECG, respiration rate, activity, and posture through a tri-axial accelerometer. Additionally, lung fluid measure is estimated by using low-power electromagnetic pulses in the radiofrequency wavelength range between 0.5-2.5 GHz. The BMAD-Tx trial is a multicenter, multinational, prospective concurrent control clinical trial consisting of one control arm (n=257) and one interventional arm (n=265), where data collected by the wearable guided HF management. (NCT04096040) The primary endpoint was the comparison of HF hospitalization by time to first event between the two arms. Results, that have been presented at the annual scientific session of the American College of Cardiology, showed a relative risk reduction of 38% for HF hospitalization at 90 days of follow-up (HR 0.62; p=0.03) for the interventional arm.[41]

Other technologies using seismocardiography or edema quantification using textile-based sensors showed promising results in assessing clinical status of HF patients.[42,43] However, wearables are challenging to use in some patient populations, making compliance a problem. This can be particularly challenging for older adults or individuals with limited digital

literacy or cognitive impairment, as devices need to be recharged daily and for example smart watches have rather small screens and complex user interfaces.[44]

Ambient Sensor Systems

Ambient sensor systems (ASS) using passive infrared motion sensors are increasingly used to monitor seniors in their apartments not only for safety but more recently also for monitoring physiological factors such as physical activity and detection of health problems such as frailty, cognitive impairment, depression, social isolation, sleep, pulmonary emboli, heart rhythm disturbances and Covid-19 related health deteriorations.[45–50] Digital biomarkers extracted by ASS signals are a promising tool for early detection of health deterioration in the setting of remote patient management. A first case report about the potential of ambient sensor signal derived digital biomarkers for early signs of HF decompensation has shown promising results.[51] A combination of digital biomarkers for decreased physical activity, increasing number of toilet visits at night, increasing toss and turns in bed and increasing average night-time respiration and heart rate have been found to precede HF decompensation over several months. Contact-free ambient sensors have the advantage, that they can be unrestrictedly used even in a patient population with moderately to severe cognitive impairment as they bypass user-dependent sources of error.[52]

A prospective interventional cohort study with 24 consecutive HF patients hospitalized for HF decompensation evaluates the sensitivity and specificity of ASS-derived digital biomarkers to detect HF decompensation.[53] Enrolment started earlier this year and results are expected by the end of 2025. An example of composition of the ASS that is used in this study is provided in Image 1.

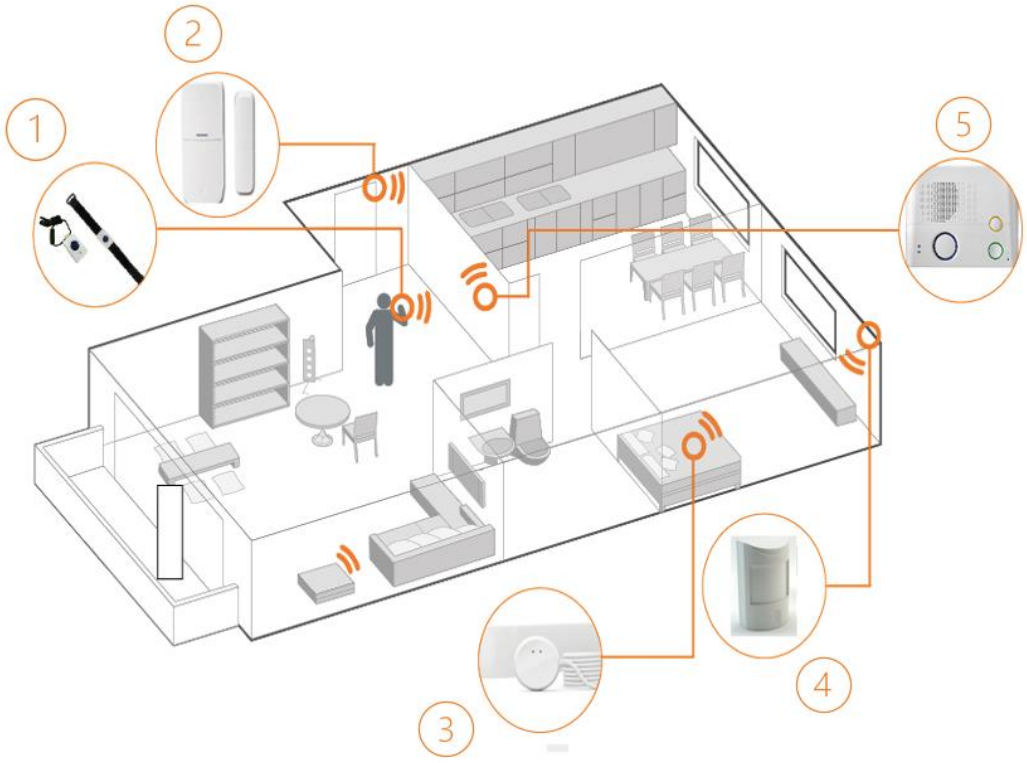

Image 1: Graphical representation of the ambient sensor system: (1) alarm button, (2) door sensor, (3) Emfit QS bed sensor, (4) passive infrared motion sensor in each room (including bathroom), and (5) interphone.

Despite these benefits, there are also some limitations to using ASS in telemonitoring of CHF patients. One of the main challenges is ensuring that patients are comfortable using these sensors in their home. Patients may feel uncomfortable with constantly monitoring their daily activities and may be concerned about privacy issues. However, a recent analysis of the acceptance of an ambient sensor system has shown that the opinions of older adults, family caregivers and nurses were positively related to in-home sensors.[54] Another limitation of using ambient sensors in HTM is the potential for technical issues or data breaches. Additionally, the accuracy of the data collected by the sensors may be affected by environmental factors or other sources of interference for example multi-person households.

Conclusion

Demographic challenges with a continuously growing ageing population pose tremendous pressure on our health care system to provide adequate care at reasonable cost. In this regard, the potential of advanced digital technologies for RPM of HF patients is enormous. The development and advance of technologies has been further accelerated by the COVID-19 pandemic.[55] However, the wide range of available technologies and a lack of consistent evidence still pose challenges to implementing such technologies in routine clinical practice of HF management. Therefore, new models of holistic care including RPM with recent digital technology and eventually supported by artificial intelligence may help managing HF synergistically across health systems and caregivers and with that to reduce the burden of disease.

Conflicts of interest

None declared.

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