

Telemonitoring for the Management of Patients with Heart Failure

Ferdinando Iellamo,^{1,2} Barbara Sposato¹ and Maurizio Volterrani¹

1. Department of Medical Sciences, Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS) San Raffaele Pisana, Rome, Italy;

2. Department of Clinical Science and Translational Medicine, University Tor Vergata, Rome, Italy

Abstract

Advances in technology now make it possible to manage heart failure (HF) from a remote to a telemonitoring approach using either noninvasive solutions or implantable devices. Nowadays, it is possible to monitor at-home parameters that can be recorded, stored and remotely transmitted to physicians, allowing them to make decisions for therapeutic modification, hospitalization or access to the emergency room. Standalone systems are available that are equipped with self-intelligence and are able to acquire and elaborate data that can inform the remote physician of impending decompensation before it results in additional complications. The development of miniature implantable devices, which could measure haemodynamic variables and transmit them to a monitor outside the body, offers the possibility for the physician to obtain more frequent evaluations of HF patients and the opportunity to take these data into account in management decisions. At present, several telemonitoring devices are available, but the only Food and Drug Administration-approved system is the cardio-microelectromechanical system, which is an implantable pulmonary arterial pressure (PAP) monitoring device that allows a direct monitoring of the PAP via a sensor implanted in the pulmonary artery. This information is then uploaded to a web-based interface from which healthcare providers can track the results and manage patients. At present, the challenge point for telemedicine management of HF is to find the more relevant biological parameter to monitor the clinical status.

Disclosure: The authors have no conflicts of interest to declare.

Received: 16 December 2019 **Accepted:** 23 January 2020 **Citation:** *Cardiac Failure Review* 2020;6:e07. **DOI:** <https://doi.org/10.15420/cfr.2019.20>

Correspondence: Maurizio Volterrani, IRCCS San Raffaele Pisana, Via della Pisana 235, 00163 Rome, Italy. E: maurizio.volterrani@sanraffaele.it

Open Access: This work is open access under the CC-BY-NC 4.0 License which allows users to copy, redistribute and make derivative works for non-commercial purposes, provided the original work is cited correctly.

The contemporary treatment planning of heart failure (HF) is based on guideline-directed medical therapy recommendations. The management of HF patients at home has become more driven by symptoms and nurse evaluation, as well as by simple monitoring techniques, such as daily weight measurements, to adjust diuretic therapy.

Noninvasive Monitoring

Nowadays, technological developments have made it possible to monitor at home more precise parameters that can be recorded, stored and remotely transmitted to the physician, facilitating more appropriate management decisions.

In the past, a simple observation of patient clinical variables, collected using bulky devices that did not always work properly, was subsequently sent to the specialist physician. The next stage involved the collection and storage of data in a cloud system that the physician could consult remotely at any time, thereby enabling modification of the ongoing therapy. Each of these systems was linked to its own platform and there was no communication between them. Monitoring devices were secured and impossible to customise to meet specific user needs. In addition, these devices functioned only in selected environments, with a very limited range of action.

Today's standalone systems are intelligent and are able to acquire and elaborate on data in order to inform the patient (who has been previously instructed in the use of the system), and inform the

physician, who can decide on either therapeutic modification, hospitalisation or presentation to the emergency room.

At the beginning of the telemedicine approach, acute MI was the main target, with the objective of reducing time to admission to the intensive care unit or haemodynamic room and, ultimately, mortality. This approach was focused on pre-hospital ECG transmission, with or without teleconsultation.

Since then, telemedicine research has been directed towards other cardiovascular diseases, particularly HF.

Telemedicine can allow for remote monitoring and management of HF patients, making it possible to assess medication adherence and to detect early signs of decompensation before it results in additional complications and hospital readmission.¹

As outlined by Bosson in a recent editorial, transmission of data from the patient's home and the ability of the physician to evaluate the patient remotely can expand the possibilities for home-based care.¹

The 2016 European Society of Cardiology (ESC) HF guidelines indicated the need to include patients with HF in education programmes, as well as in multidisciplinary programmes, which include adequate training on compliance and self-care, given the involvement of patients in self-monitoring and therapeutic control (such as with regard to diuretic control; class II, evidence level B).²

Consistent with this statement, a meta-analysis showed how simple phone support associated with a telemonitoring system significantly reduced hospitalisations and mortality for all causes.³

Implantable Monitoring Solutions

The development of miniature implantable devices that could measure haemodynamic variables and transmit them to a monitor outside the body offered, for the first time, the possibility for the physician to obtain more frequent evaluation of HF patients, and the opportunity to take these data into account in management decisions.

The 2016 ESC guidelines recommended the use of pulmonary arterial pressure (PAP) monitoring in symptomatic patients with previous HF hospitalisation in order to reduce the risk of recurrent HF hospitalisation (with a class IIb recommendation), utilising a microelectromechanical system (MEMS): the CardioMEMS HF System.²

Multiparameter monitoring based on implanted ICDs with this capacity (the Implant-based Multiparameter Telemonitoring of Patients with Heart Failure [IN-TIME] approach [NCT00538356]), was also advised in symptomatic patients with HF with reduced ejection fraction (left ventricular ejection fraction $\leq 35\%$) in order to improve clinical outcomes.⁴

To date, the data collected have indeed indicated that this kind of approach is not suitable for all patients with HF, highlighting greater benefits in those at high risk.

Using this telemedicine approach, the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial demonstrated a significant reduction in HF-related hospitalisations at 6 months and during the entire follow-up.⁵ The treatment group had a 39% reduction in HF-related hospitalisation compared with the control group. Also, medication was observed to change more often in patients followed using a telemedicine approach, resulting in a 49% decrease in HF hospitalisations compared with the control group.⁶

At present, several telemonitoring devices capable of assessing different haemodynamic variables are available.

The IN-TIME trial studied HF patients with a recent dual-chamber ICD or CRT-D implantation randomly assigned to either automatic, daily, implant-based, multiparameter telemonitoring in addition to standard care, or to standard care without telemonitoring.⁴ The primary outcome (death; or HF hospitalisation; or change in either New York Heart Association class or patient global self-assessment) was significantly improved in the treatment group. A possible explanation for these results is that blood volume expansion and incipient pulmonary oedema may start many days before the appearance of classical decompensation symptoms or weight changes, and hence monitoring physiologic signals via implanted devices may provide earlier warning of impending decompensation episodes, facilitating diuretic or haemodynamically acting drug intervention.⁷

An alternative approach involves the implantable impedance monitors, which can detect fluid volumes in the thorax and lungs. However, several studies failed to show significant or meaningful

benefits over standard care on primary outcomes, such as death and/or HF-related hospitalisation during the follow-up period.⁸⁻¹⁰

Other approaches that have been tested include implantable left atrial or ventricular pressure monitoring,^{11,12} but these studies had to be prematurely stopped for various safety problems and still need to be adequately verified.

Currently, many devices are under investigation for the monitoring of HF, but the only Food and Drug Administration-approved remote monitoring system for patients with HF is the CardioMEMS HF system (Abbott). This is an implantable PAP monitoring device that allows direct monitoring of PAP via a sensor implanted in the pulmonary artery. The sensor monitors changes in PAP and communicates via wireless to an external analyser. This information is then uploaded to a web-based interface from which healthcare providers can track the results and manage patients.

Such a novel diagnostic/therapeutic tool should be incorporated into existing HF management strategies. Patients should be monitored using individualised PAP thresholds to trigger medication follow-up by specifically trained nurses in a multidisciplinary HF management team for all patients with advanced HF.

A European prospective, observational study is ongoing to evaluate the safety and feasibility of the CardioMEMS HF system, which could shed new light on the possibility of using haemodynamically guided HF management to improve clinical outcomes (including quality of life) in people with HF.¹³

Perspectives

Telemedicine should also be considered for out-of-hospital rehabilitation programmes in patients with HF.

Some studies appear promising in this context. In a recent study, a home-based integrated project of tele-surveillance and remote monitoring of exercise training in patients with chronic HF and pulmonary comorbidity (chronic obstructive pulmonary disease), has been proven effective in increasing functional capacity and quality of life while reducing hospitalisations and mortality.¹⁴ Similarly, Frederix et al. showed that a telemedical care programme reduced hospital readmissions in a long-term study in patients with chronic HF.¹⁵

Despite the progress made, there are still many obstacles preventing the use of telematic systems in assistance and monitoring, the first of which is the patient opinion that it is not as reliable as face-to-face assessment.

From the point of view of healthcare professionals, there is a need for adequate training and education courses on how to use these systems and how to share duties and tasks.

Therefore, today it seems even more necessary to identify the more relevant of the biological parameters involved in the monitoring of clinical profile, indicating in which specific healthcare subset the intervention should be implemented.

There are no certainties as to what the best system or strategy is, but remote monitoring associated with precise nursing management and scheduled visits are the elements of a successful programme. ■

- Bosson N. Telemedicine to improve outcomes for patients with acute myocardial infarction. *Heart* 2019;105:1454–5. <https://doi.org/10.1136/heartjnl-2019-315278>; PMID: 31296594.
- Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur Heart J* 2016;37:2129–200. <https://doi.org/10.1093/eurheartj/ehw128>; PMID: 27206819.
- Inglis SC, Clark RA, Dierckx R, et al. Structured telephone support or non invasive telemonitoring for patients with heart failure. *Cochrane Database Syst Rev* 2015;(10):CD007228. <https://doi.org/10.1002/14651858.CD007228.pub3>; PMID: 26517969.
- Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet* 2014;384:583–90. [https://doi.org/10.1016/S0140-6736\(14\)61176-4](https://doi.org/10.1016/S0140-6736(14)61176-4); PMID: 25131977.
- Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. *Lancet* 2016;387:453–61. [https://doi.org/10.1016/S0140-6736\(15\)00723-0](https://doi.org/10.1016/S0140-6736(15)00723-0); PMID: 26560249.
- Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary artery pressure-guided heart failure management reduces 30-day readmissions. *Circ Heart Fail* 2016;9:e002600. <https://doi.org/10.1161/CIRCHEARTFAILURE.115.002600>; PMID: 27220593.
- Adamson PB. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. *Curr Heart Fail Rep* 2009;6:287–92. <https://doi.org/10.1007/s11897-009-0039-z>; PMID: 19948098.
- Abraham WT, Compton S, Haas G, et al. Intrathoracic impedance vs daily weight monitoring for predicting worsening heart failure 100 events: results of the Fluid Accumulation Status Trial (FAST). *Congest Heart Fail* 2011;17:51–5. <https://doi.org/10.1111/j.1751-7133.2011.00220.x>; PMID: 21449992.
- Conraads VM, Tavazzi L, Santini M, et al. Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: the SENSE-HF trial. *Eur Heart J* 2011;32:2266–73. <https://doi.org/10.1093/eurheartj/ehr050>; PMID: 21362703.
- Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation* 2012;125:2985–92. <https://doi.org/10.1161/CIRCULATIONAHA.111.088971>; PMID: 22626743.
- Maurer MS, Adamson PB, Costanzo MR, et al. Rationale and design of the Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study (LAPTOP-HF). *J Card Fail* 2015;21:479–88. <https://doi.org/10.1016/j.cardfail.2015.04.012>; PMID: 25921522.
- Adamson PB, Gold MR, Bennett T, et al. Continuous hemodynamic monitoring in patients with mild to moderate heart failure: results of the reducing decompensation events utilizing intracardiac pressures in patients with chronic heart failure (REDUCEhf) trial. *Congest Heart Fail* 2011;17:248–54. <https://doi.org/10.1111/j.1751-7133.2011.00247.x>; PMID: 21906250.
- Angermann CE, Assmus B, Anker SD, et al. Safety and feasibility of pulmonary artery pressure-guided heart failure therapy: rationale and design of the prospective CardioMEMS Monitoring Study for Heart Failure (MEMS-HF). *Clin Res Cardiol* 2018;107:991–1002. <https://doi.org/10.1007/s00392-018-1281-8>; PMID: 29777373.
- Bernocchi P, Vitacca M, La Rovere MT, et al. Home-based telerehabilitation in older patients with chronic obstructive pulmonary disease and heart failure: a randomised controlled trial. *Age Ageing* 2018;47:82–8. <https://doi.org/10.1093/ageing/afx146>; PMID: 28985325.
- Frederix I, Vanderlinden L, Verboven AS, et al. Long-term impact of a six-month telemedical care programme on mortality, heart failure readmissions and healthcare costs in patients with chronic heart failure. *J Telemed Telecare* 2019;25:286–93. <https://doi.org/10.1177/1357633X18774632>; PMID: 29742959.