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EDITORIAL COMMENT

Telemonitoring in heart failure: The rise of the insidables

Telemonitoração na insuficiência cardíaca: A ascenção dos *insidables*

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Patients discharged from the hospital after an acute decompensated heart failure (HF) event are at high risk for hospital readmissions and mortality in the subsequent months/years.[1,2]

Remote monitoring (RM) and mobile health technologies have been used as strategies to help HF patients remain free from rehospitalization. These strategies are of particular relevance in environments where the patients have difficulties in accessing healthcare facilities, such as those living in remote areas (islands, locations requiring long journeys to in person consultations with their health care providers (HCPs)), or in the context of restrictions of different kinds on patients' visits to hospitals/clinics, for example, during the current COVID-19 pandemic.

In fact, the COVID-19 pandemic has led to the implementation of multiple telemonitoring programs for chronic conditions in general and for HF patients in particular.[3–5]

Remote monitoring is a useful complement to usual HF care because it allows for early detection of worsened disease while the patient remains outside of the hospital, thus giving HCPs the chance to intervene before another acute decompensation and, at least theoretically, to prevent hospital readmissions. Despite these conceptual benefits, RM for HF has shown mixed results in clinical trials.

Some good state-of-the-art reviews on this subject can be found in the literature,[6–9] including in previous issues of this Journal.[10,11]

Remote monitoring tools often incorporate symptom monitoring and physiologic measures, such as patient weight, blood pressure, and heart rate, which have been shown to be associated with worsening HF.

Multiparameter monitoring with automatic transmission is useful for HF management. Improved adherence to RM and an optimal algorithm for transmitted alerts and their management are warranted in the follow-up of HF patients.

One of the most relevant discussions surrounding the telemonitoring of HF patients is for how long it should be continued to obtain relevant and positive outcomes.[12] Also, where the RM program requires non-invasive evaluation of physiological parameters, this usually means the patients must have good adherence to the recommendations to use several wearables or other connected devices. The failure, by the patients, to take these measurements at the designated time intervals can compromise the entire program and the respective individual and global long-term results.

These difficulties led to the concept of using implantable devices with sensors that could monitor one or more parameters and be connected to communication systems, that can

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send the data collect from the sensors remotely, without the direct intervention of the patients, to the healthcare providers responsible for the telemonitoring of the HF patients. This long-lasting monitoring with implantable devices would solve the patient adherence issues, in a way very similar to what is already usual practice with the monitoring of arrhythmias, in patients carrying pacemakers and other implantable electronic devices.

This was made feasible by technological advances in devices, sensors and communication systems. Constant advances in the miniaturization of the device batteries and sensors made them successively evolve from buildable to movable to carriable to wearable to insidable.

In the past, different approaches were tested, with different implantable devices designed to monitor different hemodynamic and/or rhythmic parameters. From early detection of arrhythmias with cardiac implantable electronic devices (e.g., implantable cardioverter defibrillators (ICDs)),[13] to measuring intrathoracic impedance by adding OptiVol™ technology to either cardiac resynchronization (CRTs) or ICDs (studied in the Medtronic Impedance Diagnostics in Heart Failure Patients (MID-HeFT) Study[14]), to different implantable hemodynamic monitors (IHM) with more or less success.

Different IHM have been designed to assess multiple or single parameters such as:

Multiparameter monitoring

The Chronicle™ (Medtronic Inc., Minneapolis, Minnesota) is an example of an IHM that can continuously monitor and store heart rate, body temperature, patient activity, right ventricular systolic and diastolic pressure, maximal positive and negative rate of change in right ventricular pressure (dP/dt), right ventricular pre-ejection and systolic time intervals, and estimated pulmonary arterial diastolic pressure (ePAD).[15,16]

The COMPASS-HF (Chronicle™ Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) study was a prospective, multicenter, randomized, single-blind, parallel-controlled trial of 274 New York Heart Association functional class III or IV HF patients who were randomized to a Chronicle™ device (n=134) or control (n=140) group. All patients received optimal medical therapy, but the hemodynamic information from the monitor was used to guide patient management only in the Chronicle group.[17]

Direct left atrial pressure monitoring

Assessed in the prospective, multicenter, nonrandomized, open-label feasibility clinical trial called Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS I), which was designed to assess the preliminary safety, reliability, and functionality of the permanently implantable LAP monitoring system (HeartPOD™, Savacor, Inc, a subsidiary of St Jude Medical, Inc, Minneapolis, Minn) in ambulatory patients with HF.[18]

Pulmonary artery pressure monitoring

The PAP monitoring system (CardioMEMS Inc, Atlanta, GA) consists of an implantable HF sensor, a delivery catheter, an electronic monitoring unit that contains a barometer to account for ambient atmospheric pressure changes, and a secure Internet database that stores patient hemodynamic data and makes it available to the clinician. The intermediate-term safety, accuracy, and feasibility of this system were assessed in a prospective, nonrandomized, single-arm trial l conducted at five sites that enrolled 17 patients between December 2006 and August 2007. The results of this trial were published by Abraham et al.[19] and an update on the CardioMEMS™ PAP sensor experience was published by Ayyaduray et al.[20]

The CardioMEMS™ Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial tested the hypothesis that the management of HF using PAP monitoring would reduce the rate of HF-related hospitalizations. CHAMPION was a prospective, multicenter (n=64), single-blind, clinical trial undertaken in the USA. The authors of this trial concluded that it was a positive trial, ''definitively showing a significant and large reduction in hospitalization for patients with NYHA class III HF who were managed with a wireless implantable hemodynamic monitoring system. The addition of information about pulmonary artery pressure to clinical signs and symptoms allows for improved HF management.''[21]

The positive results obtained with the CardioMEMS™ IHM device were recognized in 2014 by the US Food and Drug Administration, by approving the device for clinical use in HF patients with preserved and reduced ejection fraction.

Although still very prudently — some might say conservatively) — the 2021 European Society of Cardiology Heart Failure Guidelines kept a class IIb recommendation for ''Monitoring of pulmonary artery pressure using a wireless hemodynamic monitoring system may be considered in symptomatic patients with HF in order to improve clinical outcomes''.[22]

In this issue of the Portuguese Journal of Cardiology, Ferreira et al.[23] present the initial experience of the Santa Marta Hospital in Lisbon, Portugal with the implantable CardioMems™ device. Although their experience is still very limited and the follow-up of the study population was relatively short, as the authors themselves acknowledged, the results of this study corroborate other investigators' experience regarding the feasibility and safety of the procedure, with relevant impact on the RM of HF patients, particularly in the particular setting of the COVID-19 pandemic.

A very comprehensive review of the different devices and sensors used in the RM of patients with HF was published recently by Radhoe and Veenis.[24]

We can anticipate that, in a near future, we shall witness the rise of increasingly sophisticated, implantable devices with sensors that will be able to more accurately monitor these (and other) haemodynamic and rhythmic variables, with the possibility of sending the data through more reliable and fast communication networks, such as 5 G (or even 6 G in a not so distant future), to be incorporated into RM follow-up programs, which most certainly result in measurable benefits to our HF patients and their healthcare systems.

Conflicts of interest

The author has no conflicts of interest to declare.

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