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Remote monitoring of severe heart failure

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Patients with advanced heart failure, due to the instability of their clinical conditions, need close surveillance to avoid dangerous exacerbations or sudden events. Digital technology can be of great help in this contest, thanks to remote monitoring, made possible with the use of wearable or implantable instruments. The latter are currently generally inserted inside defibrillators or resynchronization systems, or inserted inside the pulmonary circulation for monitoring pulmonary pressure. Parameters such as thoracic impedance, physical activity, heart rate variability, atrial and ventricular arrhythmias, blood pressure, and O_2 saturation can be controlled remotely. The data relating to the actual benefit in terms of avoidable events (death and hospitalizations) are not definitive, but certainly from an organizational point of view, the benefit is evident, both on the part of the patient and of the organization of care. The latter, provided in the form of televisits, requires a re-modulation of the system, making use of trained personnel, a well-structured network, and digital technologies (platforms, electronic health records) that are not yet perfectly developed. The evolution of the solutions offered by artificial intelligence guarantees a rapid and progressive refinement of telemedicine in this sector.

Few chronic conditions, such as heart failure (HF), require such profound sensitivity and culture for correct treatment. The latter implies great clinical preparation, the ability to work in a multidisciplinary team, management in an integrated network of services, and the right balance between traditional assistance in presence (‘onlife’) and remotely using the most sophisticated digital technologies (‘online’). When the natural history is approaching its end, close monitoring is necessary in order to adapt the therapeutic measures to the patient’s rapidly changing conditions: this may be possible, on the one hand, by bringing the times of in-person checks closer together, but also by using of remote control tools leaving the patient at his home.

There is no doubt that digital technology is changing the world we live in. Tools for detection, screening, diagnosis, and monitoring have improved patient care, but one of the biggest changes is the ability of individuals to use technology to better manage their health and lifestyle. The patients have, in general, become increasingly involved in the objective of maintaining and improving their clinical status. The doctor–patient relationship is gradually abandoning the traditional hierarchical and institutional character in favour of one of collaboration and shared decision-making processes. Patients can obtain health information and guidance from a wide range of sources including websites, computerized medical records, online patient communities on social media, self-monitoring devices, and health applications using smart devices (mobile health or m-Health).

The benefits are potentially enormous but require close interaction with the healthcare providers, as well as flexibility, transparency, trust, and well-defined reimbursement systems.

Definition of advanced heart failure

Advanced HF is characterized by the persistence of symptoms despite optimized and maximal therapy.[1,2] The share of patients with advanced HF is growing, due

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Table 1 Definition of advanced heart failure

(1) Severe and persistent symptoms of HF [advanced NYHA (New York Heart Association) class III or IV].
(2) Severe cardiac dysfunction defined by at least one of the following conditions:
- Left ventricular ejection fraction ≤ 30%;
- Isolated right ventricular failure (e.g. arrhythmogenic dysplasia);
- Severe inoperable valve disease;
- Severe inoperable congenital anomalies; and
- Persistently elevated or significantly increasing B-type natriuretic peptide [BNP or NT-proBNP (N-terminal pro-brain natriuretic peptide)] values and severe diastolic dysfunction or structural abnormalities (according to the definitions of HF with preserved systolic function or HF with preserved ejection fraction).

(3) Episodes of pulmonary or systemic congestion requiring high doses of intravenous diuretics or low-flow episodes requiring the use of inotropes or vasoactive drugs, or malignant arrhythmias requiring more than one visit or hospitalization during the past 12 months.
(4) Severely reduced exercise tolerance with inability to perform as assessed by 6 min walk test (<300 m) or peak exercise oxygen consumption (PVO2) < 12 mL/kg/min or <50% of predicted value judged to be of cardiac origin.

to the improvement of therapies, the aging of the population, and the growing number of patients with HF. One-year mortality in this condition is high and ranges between 25% and 75%.[3,4] The criteria for defining HF as advanced are those listed in *Table 1*.[1]

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In addition to the criteria reported in the table, extra-cardiac problems related to HF may be present, such as cachexia, hepatic or renal dysfunction, and type II pulmonary hypertension.

The context of care

Correct prognostic stratification is very important to identify the right time to direct the patient towards the right device.

The clinical scenarios can be different and can range from the patient who has regained his stability after hospitalization for an exacerbation, and therefore to be shared with the local facilities (community hospital, territorial cardiologist, general practitioner) up to the extremely unstable patient to be followed closely by the HF clinic. In general, patients with advanced HF should be followed in the reference hospital centre to adopt the most appropriate strategies with cardiac intensive care unit, catheterization laboratory, electrophysiology, and cardiac surgery with integrated medical-surgical programme for the treatment. Alongside this, the patient must always be able to count on the territorial network with which the treatment project is shared.

There must be no fragmentation of care, with a defined position regarding the possible path towards ventricular assistance/cardiac transplant systems and end-of-life path.

The nursing clinic and that of the community nurse are acquiring a role of great importance, also for the purposes of our theme of remote control and the use of digital technologies.

How to follow up

From the above, the great importance of follow-up can be seen: regardless of the method of controlling the evolution of the clinical state (both in person and with telemonitoring), the data collected must find a prompt management response to the changing condition of the patient. It is taken for granted that the patient has received all the instructions for self-monitoring (weight, blood pressure, heart rate, oxygen saturation), and this can be done with simple digital instruments also with the possibility of data transmission. These simple systems are now joined by more sophisticated and implantable ones, capable of measuring the degree of congestion and the level of pulmonary pressure. Telemonitoring is currently considered class IIb by the European Society of Cardiology guidelines to reduce the risk of recurrent hospitalization and death due to HF[5]; pulmonary pressure monitoring can be used in patients with symptomatic HF to improve clinical outcomes.[6] Through telemonitoring, patients can remotely provide the information necessary to optimize therapy. Data such as symptoms, weight, heart rate, and blood pressure can be collected repeatedly, stored in an electronic health record, and used to guide patients (directly or through a healthcare professional), adjust therapy, or seek further advice.[7]

In this way, the quality of therapies is guaranteed, rapid access to care is facilitated when necessary, patient travel costs are reduced, and the frequency of clinical visits is reduced to the essentials. Telemonitoring systems have undergone an important boost during the recent

COVID-19 pandemic, which has allowed some of their potential advantages to be highlighted.[8]

Telemonitoring can be provided as a local, regional, or national service. The different systems can be focused on patient management or to provide emergency support. In the first case, the organization requires standard working hours, in the second, it is necessary to provide a 24 h service. The comparative effectiveness and cost-effectiveness of each strategy are uncertain, although systems focused on continuous optimization of care appear to be more successful.[9] In any case, the practice of telemonitoring is an effective method to provide patient education and motivation and promote attention, but it should be adapted to synergize with the existing organization.

A systematic review conducted in 2017 identified 39 relevant studies on telemonitoring, largely based on the assessment of symptoms, weight, heart rate, rhythm, and blood pressure and verified that telemonitoring is associated with a reduction in all-cause mortality of 20% and hospitalization for HF of 37%.[10]

Remote control instrument technology

Remote monitoring generally involves the transmission of patient data to doctors, with a subsequent doctor-patient relationship by telephone or via the Internet, interaction based on predefined warning thresholds and rarely an office visit.

Monitoring systems can be:

- Wearable or implantable;
- Wearable systems; and
- Wearable devices use a variety of sensors, such as accelerometers, barometers, electrocardiogram, and photoplethysmographs.

Table 2 shows the parameters that can be controlled using wearable tools.

Table 2 Wearable tools and measurable parameters

Accelerometer, barometer	Activity (pedometer, step counter, exercise, calories burned
Photo-plethysmographic	Heart rate (HR), rhythm, HR variability, blood pressure, oxygen saturation, cardiac output, systolic volume, sleep and its stages
Electrocardiogram	Single or multiple leads, continuous or as-needed monitoring, arrhythmias, interval measurement, electrolyte alterations
Oscillometer	Blood pressure and heart rate
Biochemical sensors	Invasive: blood sugar and electrolytes
	Non-invasive: sweat, saliva, hydration status

This instrumentation can be easily acquired on the market, but, in the context of the management of the patient with HF, it must be agreed and shared with the reference healthcare centre. Phenomena of 'digital hypochondria' linked to the use of wearable instruments outside of a healthcare setting are now commonly observed. In patients with advanced HF, however, a wealth of experience has been gained on implantable devices.

Implantable systems

The first automatic remote control units associated with implantable electronic instruments used a mobile phone that transmitted the acquired data daily to a service centre that in turn transferred the information for clinical evaluation.[11] In the last two decades, there has been a technological evolution of the systems, which has moved from intermittent transmission activated by the patient to automatic transmission that allows continuous monitoring. Automatic remote control has changed the paradigm, as it allows continuous surveillance of outpatients with the possibility of activating alarms even in apparently asymptomatic subjects.

The thoracic impedance evaluation parameter is now integrated into the implanted defibrillators produced by all companies, with proprietary algorithms (Fluid Status Monitoring feature or Optivol™—Medtronic, CorVue™—Abbott devices, BIO-Link™-Biotronik).

Monitoring the single parameter of intrathoracic impedance was found to have limited value in the prediction and prevention of HF-related events (hospitalization and death) with only modest sensitivity and worse specificity. The systems have therefore evolved by adding the measurement of other physiological parameters to the assessment of intrathoracic impedance, thus reducing the number of false positive alerts. Parameters such as atrial/ventricular arrhythmias, patient activity level, heart rate variability, nocturnal heart rate, and therapy delivered by the defibrillator can increase the sensitivity and/or specificity of monitoring patients with advanced HF (*Table 3*).

Another implantable system is represented by the device for controlling pulmonary pressure 'wireless system for HF monitoring or cardioMEMS',[12] which has proved useful in optimizing therapy and managing hospitalizations. Several meta-analyses on the effectiveness of remote monitoring with implantable devices concluded that overall, there was no significant impact on the all-cause mortality or hospitalizations for HF, while remote monitoring of pulmonary pressure can reduce the risk of hospitalizations for HF,[13, 14] a figure largely based on the results of the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes Study in NYHA Class III Heart Failure Patients (CHAMPION) study[6] Such evidence was recently partially supported by the results of the larger Haemodynamic-Guided management of Heart Failure (GUIDE-HF) study, which found a significant benefit on the incidence of mortality for all causes or events of HF.[15]

However, all data must be able to be collected on a digital platform and on the individual patient's electronic file.

The telemedicine visit

The COVID-19 pandemic has allowed the development of web-mediated virtual visit technology, so as to also develop funding and legal regulations around the topic.

Table 3 Available multisensor algorithms

Boston Scientific	Medtronic
Heartlogic algorithm	Triage-HF algorithm
Heart sounds (first and third heart sounds and the relationship between the two)	Optivol™ (intrathoracic impedance)
Thoracic impedance	Physical activity
Respiratory frequency	Nocturnal ventricular rate
Relationship between respiratory rate and tidal volume	Atrial fibrillation/atrial tachycardia load
Nocturnal heart rate	Ventricular rate during atrial fibrillation
Physical activity	% pacing in patients with cardiac resynchronization therapy
	Ventricular tachycardia/ ventricular fibrillation treated
	Shock

The Ministry of Health has promulgated the national indications for telemedicine services[16] in which it is established that 'outpatient services that do not require a complete objective examination and in the presence of at least one of the following conditions can be provided via televisit:

The patient needs the service as part of a diagnostic therapeutic care path;

The patient is included in a follow-up process for a known pathology;

The patient suffering from a known pathology requires control, monitoring, confirmation, adjustment or change of the ongoing therapy;

The patient requires a medical history evaluation to prescribe diagnostic or staging tests for a known or suspected pathology;

The patient needs the doctor to verify the tests carried out, which can be followed by the prescription of any further investigations or therapy'.

The ministerial indications also include reporting and remuneration methods.

Conclusions

It is clear, from what has been discussed so far, that the patient must be included in a network that includes the hospital for the treatment of patients with advanced HF, the local hospital, the general practitioner, with sharing of a project of comprehensive treatment of comorbidities. Since this is an advanced decompensation, the frequency of periodic in-person visits cannot be established *a priori*, but dictated by the clinical needs of the moment. Telephone references must be provided for the patient, and there must be no fragmentation of care (therapeutic choices, devices, and etc.). Therefore, incorporating remote control systems into standard clinical practice is challenging and requires models and infrastructure. It is necessary to provide an integrated working group, including healthcare professionals (physician, nurses, and technicians) with well-defined complementary roles and responsibilities, with dedicated time, space, and equipment.

More specifically, their duties include patient training and education, website data entry, remote data review, data screening, recognition and management of critical conditions, contact with patients, monitoring patient compliance, and the benefits of therapy.

Doctors are responsible for informed consent, supervision of the entire process, and clinical management of the patient. Ancillary staff can assist healthcare personnel in scheduling appointments, monitoring patient connectivity, reporting results, billing, and updating electronic files. The working group must interact with the emergency room, general practitioners, service providers, and referring hospitals.

The transition towards the integration of traditional assistance with digital technology is underway and will undergo an inevitable acceleration in the coming years, with the help of the solutions offered by the application of artificial intelligence and with the generational change of healthcare personnel and patients.

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