# Telemonitoring in Cardiology

JUAN C. CHACHQUES[1], CARLOS BILICH[2], MARCELO FIGUEROA[3]

*Address for reprints:*
Dr. Juan Carlos Chachques
Cardiovascular Surgery Department
Hospital Pompidou
20 rue Leblanc, 75015 Paris, France
Phone: 0033613144398.
Fax: 0033140728608
e-mail: j.chachques@brs.aphp.fr

## SUMMARY

Telemonitoring (home monitoring) builds bridges between clinicians and patients with communication technology. Telemonitoring in cardiology is currently applied in the following situations: follow-up of patients with heart failure (by measuring heart rate, pulse oximetry, intracardiac pressures and pulmonary impedance for diagnosis of pulmonary edema), assessment of pacemaker and implantable cardioverter defibrillator function, monitoring of patients with pulmonary hypertension who are receiving long-term treatment with new drugs, follow-up of patients with sleep apnea, prevention of sudden infant death syndrome, and monitoring of patients with heart valve prosthesis. Trans-telephonic or Internet Monitoring are simple approaches which do not need any extraordinary devices at home. Our team is currently investigating the use of RADAR technology for telemonitoring in cardiology. Home monitoring has the potential for widespread implementation as it can be easily applied to large patient populations and integrated into the current medical care systems. The final objective is to improve the outcomes of current treatments and to reduce the costs of health care.

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**Key words >** Heart Failure, Congestive - Defibrillators - Pacemaker, Artificial - Hypertension, Pulmonary - Heart Valve Prosthesis - Sleep Apnea Syndromes - Sudden Infant Death - Monitoring - Cost-Benefit Analysis

**Abbreviations >**

| | | | |
|---|---|---|---|
| **OSA** | Obstructive sleep apnea | **CHF** | Congestive heart failure |
| **ICD** | Implantable cardioverter defibrillators | **IHM** | Implantable hemodynamic monitors |
| **ECG** | Electrocardiogram | **RADAR** | RAdio Detection And Ranging |
| **TTE** | Transthoracic echocardiogram | **SIDS** | Sudden infant death syndrome |
| **HF** | Heart failure | **UWB** | Ultra wideband |

## BACKGROUND

Congestive heart failure (HF) is a serious public health problem due to its prevalence, high mortality, high morbidity, and the expense of ongoing therapy (Figure 1). Heart failure is associated with a high rate of hospitalization and poor prognosis. (1-4) High cardiac filling pressures and concomitant volume overload are frequently the cause of hospital admission for heart failure. Effective management of heart failure is partly aimed on lowering the filling pressures and improving ventricular performance. (5-9) Telemonitoring (home monitoring) could help to implement and maintain an effective therapy, and detect worsening HF and its causes to prevent symptomatic impairments.

## TELEMONITORING OBJECTIVES

Several strategies are currently used to assess volume and pressure status of cardiopulmonary circuit in clinical practice: clinic visits for assessment of filling pressure by physical examination, multiple types of noninvasive measurements, and repeated cardiac catheterization. These strategies which are not cost-effective and are rather bothersome for patients, might only detect a time-defined pressure and volume status which does not reflect the variations produced by physical activity or everyday stress. To overcome this limitation, the role of "continuous ambulatory" hemodynamic information in the management of heart failure is currently under research. (10, 11)

The use of implantable hemodynamic monitors (IHMs) may assist in the management of patients with severe signs and symptoms of heart failure by providing continuous ambulatory filling pressure status for optimal hemodynamic management. Implantable hemodynamic monitor devices are capable of measuring continuous right ventricular oxygen saturation and detecting the presence of incipient pulmonary hypertension. Pulmonary edema might be detected by continuous measurement of intrathoracic impedance.

[1] European Hospital Georges Pompidou, Paris, France
[2] Departament of Telecomunications, University of Trento, Italy
[3] Instituto Modelo de Cardiología, Córdoba, Argentina

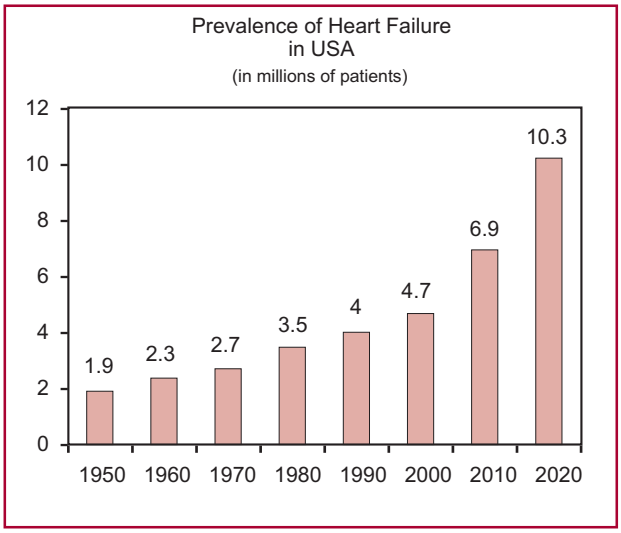


**Fig. 1.** Estimates of mortality from heart failure in USA. (Source: CTSNet, the Cardiothoracic Surgery Network).

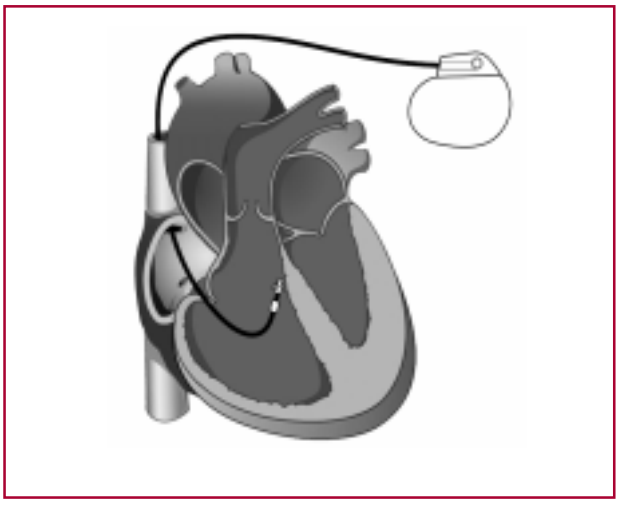

**Fig. 2.** Lead placement for monitoring of temperature, heart rate and intracardiac pressures in patients with heart failure or pulmonary hypertension (example: Chronicle system).

## MATERIAL AND METHODS

Nowadays implantable electronic devices similar in size and shape to cardiac pacemakers are available. Systems are implanted with placement of the sensor lead tip in the right ventricle or in the pulmonary artery to monitor pressures, temperature and heart rate. Current devices (e.g. Chronicle® system) include an implantable monitor, a pressure sensor lead with passive fixation, an external pressure reference (EPR), and data retrieval and viewing components. These implantable hemodynamic monitors (IHM) continuously measure and store the information, which is subsequently inquired and teletransmitted. (12) Systems are implanted using the same technique as a single-chamber pacemaker with preferential placement of the pressure sensor lead tip near the right ventricular (RV) outflow tract, to minimize risk of sensor tissue encapsulation. (Figure 2)

## APPLICATIONS

### Heart failure

Several clinical trials are currently being carried out to determine whether telemonitoring in ambulatory patients with chronic heart failure will reduce the risk of rehospitalizations (for any cause) or death after an "initial hospitalization" for CHF. The hypothesis is that, among patients recently discharged after an admission for CHF, telemonitoring will decrease the rate of rehospitalization or death over the next 6 months.

Preliminary results have reported that the devices are well tolerated without significant adverse events, and the sensors generally function well over time, providing reliable information. (13, 14)

### Pulmonary impedance

CHF is the most frequent cause of admissions in patients older than 65 years old in developed and developing countries. In spite of recent therapeutic advances, most readmissions are due to acute decompensation of chronic CHF. Early detection of volume overload and pulmonary congestion will provide the possibility to optimize CHF treatment in order to avoid clinical decompensations and hospital admissions, and to reduce morbidity, mortality and expenses related. These patients are currently trained to recognize CHF symptoms and signs and to control fluid status. Nevertheless, a great number of CHF decompensations are related to an inadequate adherence to medical treatment and to delayed medical consultation after the onset of clinical worsening. Classic medical measures to assess volume status in the outpatient setting provide limited clinical reliability. For example, the sensitivity of weight gain to detect clinical deterioration in chronic CHF is < 20%. (5, 7)

Intrathoracic impedance seems to be an effective parameter to assess daily changes in fluid status and pulmonary volume. Impedance may be continuously measured by an implanted device and is inversely correlated with changes in left ventricle end-diastolic pressure and in pulmonary capillary wedge pressure. In this way, assessment of fluid loss in patients with volume overload may be regulated. (15-17)

Nowadays, the number of pacemakers for cardiac resynchronization therapy and implantable cardioverter defibrillators implanted to patients with CHF has greatly expanded. It is now possible to add algorithms (InSync Sentry system, Medtronic) which will alert patients in case of clinical worsening and increase in pulmonary fluid accumulation. These devices automatically alert the patient with an audible alarm. (18, 19) Patients may then get in touch with their physicians or self-medicate with diuretics (Figure 3).

### Pulmonary hypertension

In patients with pulmonary hypertension, the desired outcome of pharmacological treatments is the reduc-

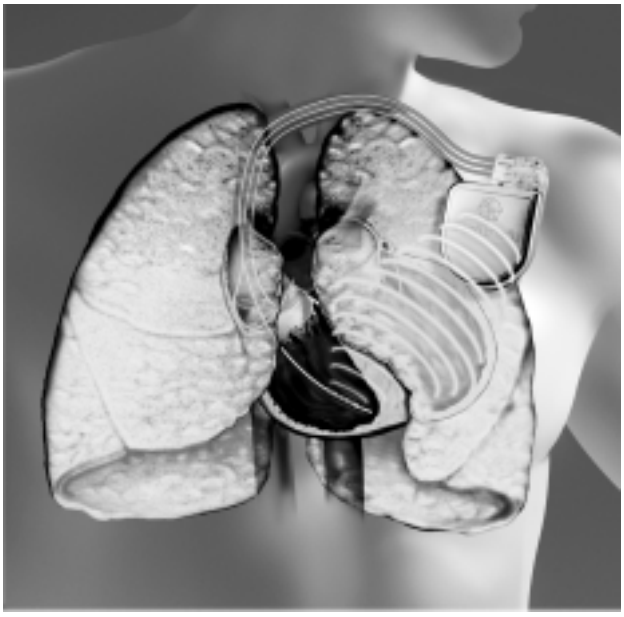

**Fig. 3.** Device for monitoring pulmonary impedance for early diagnosis of edema (example: Sentry Check system).

tion of pulmonary pressure which can be measured by right-heart catheterization or Doppler echocardiography. However, both techniques provide only snapshots of the hemodynamic status. The aim of telemonitoring in these cases is to assess the long-term efficacy of new drug therapies. (20, 21)

Pulmonary artery pressure may be monitored with the Chronicle system or with CardioMEMS® system (Atlanta, USA). This device is incorporated to a stent transcutaneously implanted in the pulmonary artery. A pressure sensor, in contact with the pulmonary artery wall, sends data of the hemodynamic status of the patient. Pressure data are stored and the information should be periodically inquired. (22)

*Study of aneurysm sac exclusion after endovascular repair:* the CardioMEMS device was previously used as a pressure transducer in aortic aneurysms treated with endovascular prostheses. The system uses the EndoSure sensor, size of 30 × 5 × 1.5 mm, which is powered by radiofrequency energy transmitted from an external electronics module and transmits real-time data without batteries. The EndoSure device is intended for measuring intrasac pressure during endovascular aneurysm repair in order to assess the complete exclusion of the aneurysm. Traditionally, this assessment was performed through repetitive aortographies. The APEX (Acute Pressure Measurement to Confirm Aneurysm Sac EXclusion) Trial was designed to evaluate the long-term efficacy of this system. (23)

## TELEMONITORING WITH RADAR SYSTEMS

The aforementioned telemonitoring systems require the presence of a sensor placed through an invasive technique or in contact with the body. For this reason, they cannot be used in severely ill patients. RADAR systems (Radio Detection and Raging) might overcome these limitations, giving the chance to perform a continuous monitoring of a larger population of adults or children during longer periods without reducing patient's mobility or comfort.

The idea of monitoring physiologic functions in humans using radars started in the early seventies, (24) but further development was hindered by the cumbersome and expensive technology of those years. Microwave radiation safety concerns were another deterrent. Recently, telemonitoring with RADAR systems has recovered increasing interest with the coming of Ultra-wideband (UWB), a technology which uses a large portion of the radio spectrum, ranging from 3.1 to 10.6 GHz with very short duration impulses of approximately 200 picoseconds. Ultra-wideband radar has proven to be a very powerful tool for high-resolution images and for transmitting large amounts of digital data. As according to "international regulations" effective isotropic radiated power (EIRP) cannot exceed -41.3 dBm/MHz, pretty lower than levels considered potentially harmful, UWB technology is an excellent candidate for telemonitoring with RADAR systems.

The first paper which described the use of UWB RADAR was published in 1998. (25) There are also several patents describing its biomedical applications. One of the most cited is the one awarded to Thomas McEwan (26), who specifically described the use of UWB for heart rate monitoring, emphasizing that the average emission level used (≈1$\mu$W) is about three orders of magnitude lower than most international standards for continuous human exposure to microwaves, making the device medically harmless. Previously, in 1996 the same author described several applications of UWB technology, (27) such as the possibility to measure heart volumes, respiration movement detection and early diagnosis of sudden infant death syndrome (SIDS) and sleep obstructive apnea (SOA). In general, almost any object of adequate size can be monitored, for example, vocal cords, blood vessels, lungs, chest and fetal growth and development. At present, at the University of California (Davis and Berkeley) several alternative applications in medicine of wireless UEB monitoring, such as breath and speech, are being studied. In addition, the University of Iowa is evaluating RADAR vocal cords monitoring.

## RADAR IN CARDIOLOGY: OUR RESEARCH

We have recently presented at the University of Trento, Italy, an application which combines heart rate telemonitoring and data communications using the same UWB transceiver. (28) Such application is based on the use of a standard UWB communication device commercially available with incorporated state-of-the-

art signal-processing algorithms which decode data communication packages and obtain heart rate readings with a precision greater than 99%. If this device is used with the standard manufacturer's configuration, monitoring may be possible up to a distance of 84 cm, so it may be assumed that greater distances may be obtained with an adequate optimization of the receiver antenna gain. Figure 4 shows the device and both omnidirectional transmission and reception antennas.

The applications of this technology are multiple: pediatric monitoring (to prevent sudden infant death in high-risk populations), cardiovascular rehabilitation programs, and in gym and body building rooms.

## PACEMAKERS AND DEFIBRILLATORS

Recent developed pacemakers and implantable cardioverter defibrillators are equipped with new technologies that monitor the functions of both the heart and the device itself and transfer the information into an Internet record, which is available for the physician, through a system installed at the patient's home.

Four systems for telemonitoring and/or inquiring pacemaker or implantable cardioverter defibrillator are currently under research and development:

- Cardiomessenger & Home Monitoring Service (Biotronik).
- CareLink Programmer & Remote View Software (Medtronic).
- Latitude Patient Management System (Boston Scientific).
- Housecall Plus Remote Patient Monitoring System (St Jude Medical).

In patients with permanent pacemakers, the detection of technical problems of the system based on clinical findings is still a critical issue. (29, 30) Financial charges for use of telemonitoring seem to be significantly less than comparable outpatient visits.

Recent developed implantable cardioverter defibrillators (ICD) (e.g. Lumax® ICD) contain technologies that monitor the functions of both the device itself and the heart. The device automatically transfers all important diagnostic data to the cardiologist over a mobile phone network — once a day, and immediately in case of a critical event. (31-34)

The physician just needs to log in through a secure Internet site to be informed of the patient's current cardiac status. Moreover, the home monitoring technology automatically sends a SMS, email or fax to the physician in case of a serious change in the patient's heart rhythm. A high-definition intracardiac ECG sent over the GPRS network enables the physician to detect arrhythmias in time. As an additional feature, the system also identifies possible technical malfunctions in the device, such as a decreasing signal quality that could impair the precision of future therapies. The physician can clearly distinguish interfering signals from cardiac events on a computer and contact the patient for correction of the technical problem. Another asset of this technology is the considerable improvement of the ICDs' service time as a result of the reduced number of unnecessary electric shocks. (35-38)

**Pediatric pacemakers:** pacemaker control in children through telephone monitoring (TM) arouses great interest. Inherent age-related problems such as potential inability to correlate symptoms with pacemaker performance, places the pediatric patient in a unique category demanding the development of telemonitoring techniques. (39)

## ADULT OBSTRUCTIVE SLEEP APNEA SYNDROME AND SUDDEN INFANT DEATH SYNDROME

Nearly 20% of patients with heart failure present respiratory problems. When stratified by the severity of apnea, investigators report that patients with >15 apnea episodes per hour had a significantly lower survival rate for cardiac death than those with <15 apnea episodes per hour, confirming that sleep apnea is a risk factor for mortality in patients with CHF. These phases of apnea produce decreases in oxygenation of the blood, resulting in more arrhythmias associated with higher mortality. (40)

Sleep apnea is difficult to recognize in daily practice. Heart and pulmonary telemonitoring associated with special alarms are suggested for patients with sleep apnea and in pediatric populations with risk of sudden death. (41)

A home monitoring unit of neonatology has been created for children at risk for sudden infant death syndrome. Breathing, ECG and oxygen saturation are monitored. Audible or luminous alarms detect vital events, such as apnea, for early treatment, and data are memorized. (42)

**Fig. 4.** Use of RADAR (RAdio Detection And Ranging) techniques. Device developed by our team (reference 28) for telemonitoring in cardiology, with two transmission and reception omnidirectional antennas.

## VALVULAR HEART PROSTHESES

Structural damage, endocarditis, thrombosis and pannus are some of the probable complications of mechanical valvular heart prostheses, with an incidence of 6% patient-year. Thromboembolism rate ranges from 0.21% to 2% patient-year. (43, 44)

The ThromboCheck device (Cardiosignal, Hamburg, Germany) analyzes the sound frequency spectra of valve motion. This device, approved by the FDA, allows assessment of the prosthetic valve function of patients at home; it is placed near the chest wall and evaluates the sound frequency phenomena of prosthetic valve motion. If the sound frequency spectra deviates from baseline (sound frequency obtained immediately after surgery), one minute later the signals are returned to the medical center via telephone or the Internet. (45) If prosthesis dysfunction is suspected, fluoroscopy or TTE are performed for early diagnosis of eventual complications and urgent treatment.

Positive predictive value and sensitivity of ThromboCheck in patients with valvular heart prostheses are 97% and 100%, respectively. These devices are recommended to patients with valvular heart prostheses, especially in cases of previous valvular thrombosis, or in patients living in remote locations with difficulties for controlling anticoagulant treatment. (46)

## TELEMONITORING IN CLINICAL CARDIOLOGY

Telemonitoring in clinical cardiology includes assessment of body weight, blood pressure, heart rate, heart rhythm, respiratory rate and oxygen saturation. Subjective data on health status and changes in medication may also be incorporated.

The information can be sent via the Internet or conventional telephone lines to a "Telemedical Center", where it is evaluated. In this way, treatment can be adjusted before the patient deteriorates and hospital admission becomes necessary. In-home communication systems provide education to patients who may actively participate in self-management of their hemodynamic status. (47-51)

Patients may also be monitored by "conventional telephone lines interventions". The DIAL study (Randomized Trial of Telephone Intervention in Chronic Heart Failure), conducted in Argentina, (52) was an open, controlled, prospective, multicenter and randomized trial, which included 1518 outpatients with stable HF. Patients were randomized to centralized telephone intervention plus usual medical care or to usual medical care. The objectives of the telephone intervention were as follows: to improve the adherence to treatment and diet, to provide patients education and to monitor signs and symptoms of decompensation. Telephone interventions reduced hospitalizations due to HF and/or death by 20%, admissions for HF by 30%, and mortality by 5% compared to the control group. Costs in the intervention group were lower, and quality of life and adherence to treatment and diet were greater than in the control group. (52-54)

## CONCLUSIONS AND PERSPECTIVES

Optimal management of patients with CHF should detect emerging symptoms since the onset of hemodynamic imbalance, in order to administer an appropriate therapy to avoid decompensations and subsequent hospital readmissions. Recent studies demonstrated that telemonitoring of hemodynamic data from an IHM was feasible. Patient survey showed that the technology was user-friendly and that the training material provided sufficient information for patients and their families to install and use the transmission equipment at home. (55, 56)

It also suggested that transmission success was independent of patient age or gender. With the monitoring system, physicians and medical institutions can receive all the information about patients while they are at home before symptoms get to a critical point that would require patient hospitalization. Treatment may be modified according to the information received through home monitoring.

Telemonitoring bridges clinicians and patients with communication technology. This technology can be easily applied to large patient populations and integrated into the current medical care systems. The final objective is the improvement of current treatments and the reduction in costs of healthcare. (57, 58)

A multicenter, randomized controlled trial should be organized to determine the effectiveness of a telemonitoring strategy in decreasing hospital readmissions and death in patients with CHF. This intervention is not intended to substitute medical consultations during acute decompensations, and patients should ask for medical advice in case of sudden changes in health status. In these cases, patients are instructed to make direct and immediate contact with their physician or hospital.

Cardiovascular diseases progress at a sustained rate in men, women and young people. (59). Estimates of future mortality are worrisome from the point of view of epidemiology, health care and financial costs. (Figure 1) Prevention and future treatments are real challenges for imagination and scientific creation. (60, 61) E-medicine should improve and form part of this challenge through the new materials and methods offered for telemonitoring of patients (62)

## SUMMARY

La telemonitorización (*home monitoring*) establece un puente entre el clínico y el paciente por medio de nuevas tecnologías de comunicación. Las aplicaciones actuales de las telemonitorizaciones cardiológicas son: seguimiento continuo de pacientes en insuficiencia cardíaca (medición

de frecuencia cardíaca, oximetría, presiones intracardíacas e impedancia pulmonar para diagnosticar edema), monitorización del funcionamiento de marcapasos y desfibriladores, monitorización de tratamientos farmacológicos de la hipertensión pulmonar, seguimiento de pacientes con apnea del sueño, prevención de la muerte súbita infantil y monitorización de pacientes portadores de prótesis valvulares cardíacas. La monitorización telefónica o a través de Internet es simple y no requiere ningún equipo excepcional en los hogares. Nuestro grupo investiga la aplicación de las tecnologías de RADAR en la monitorización cardiológica. La *home monitoring* tiene el potencial para ser aplicada en grandes poblaciones de pacientes y ser integrada en los sistemas actuales de asistencia médica. El objetivo final es mejorar los resultados de los tratamientos actuales y disminuir los gastos de salud.

**Palabras clave >** Insuficiencia cardíaca congestiva - Fibrilación ventricular - Desfibriladores - Marcapasos artificial - Hipertensión pulmonar - Prótesis valvulares cardíacas - Síndromes de la apnea del sueño - Muerte súbita del lactante - Monitorización - Análisis costo-beneficio

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