Rev Port Cardiol. 2013;32(12):965–966

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org

EDITORIAL COMMENT

Follow-up of implantable cardioverter-defibrillators: Face-to-face or remote?☆

Seguimento de cardioversores desfibrilhadores implantáveis: na consulta ou à distância?

Diogo Cavaco

Serviço de Cardiologia do Hospital de Santa Cruz, Carnaxide, Portugal e Centro do Ritmo Cardíaco do Hospital da Luz, Lisboa, Portugal

Available online 14 January 2014

The last ten years have seen a considerable increase in the number of patients receiving cardiac implantable electronic devices (CIEDs). According to the Portuguese Association of Arrhythmology, Pacing and Electrophysiology registry, 1084 new devices were implanted in 2011 in Portugal.[1]

This growth has led to a rise in the number of patients being followed and hence in the number of consultations and increases in the workload of physicians, sonographers, and other staff, since implantation of the device is not the end of treatment, but merely one step in a longer process aimed at treating the condition that prompted implantation.

In Portugal, most patients with such devices are followed in specialized consultations two or three times a year, or more if required. In face-to-face consultations the patient's symptoms and clinical status are assessed (for example, whether there have been periods of decompensated heart failure, or changes in therapy), and the device is interrogated. The latter process assesses various technical aspects of the function and integrity of the system such as lead impedance, pacing thresholds, sensing, and battery status, as well as data stored in the device's memory on episodes of ventricular arrhythmias or atrial fibrillation, anti-tachycardia pacing or shock therapies, and parameters related to treatment of heart failure such as R–R variability and thoracic impedance that indicate the degree of pulmonary congestion. The device's programming and/or medical therapy can then be adjusted according to this assessment.

One of the problems with face-to-face follow-up is that it is not continuous, but occurs at fixed times. This means that a problem that arises with a device the day after a consultation may not be detected until the next consultation, which could be six months later.

Integrated remote monitoring systems for CIEDs, including implantable cardioverter-defibrillators, cardiac resynchronization devices and pacemakers, have recently become available. Data stored in the device's memory are transmitted daily, without direct intervention by the patient, to a central location via a fixed or mobile telephone line. The data are then analyzed and if there is any deviation from pre-established values, the attending physician is alerted by SMS, email or telephone. Even when no alert has been generated by the system, the physician can consult the patient's data by accessing the relevant website.

It is clear that the ability to monitor devices in a continuous fashion has advantages for patients, by reducing the need to travel to the hospital for consultations (which is especially important for the elderly, those with

☆ Please cite this article as: Cavaco D, Seguimento de cardioversores desfibrilhadores implantáveis: na consulta ou à distância? Rev Port Cardiol. 2013;32:965–966.

E-mail address: acavaco@hospitaldaluz.pt

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mobility problems, and those who live far from the center where their device was implanted) and by enabling early detection of problems that require intervention, such as new-onset atrial fibrillation requiring anticoagulant therapy, or device malfunction (for example a sudden increase in lead impedance suggesting fracture). There are also advantages for health care services, with fewer face-to-face consultations, although some reorganization is required to manage remote monitoring and alerts generated by the system.

The first clinical trials showed the advantages of this technology. The TRUST trial,[2] of the BIOTRONIK Home Monitoring system, enrolled around 1400 patients with implantable cardioverter-defibrillators randomized to one conventional follow-up consultation plus three remote assessments in the first year, apart from assessments prompted by alerts, versus four conventional assessments. The study showed that remote monitoring was associated with reduced use of hospital resources and a significantly shorter time from onset of arrhythmias (atrial fibrillation, ventricular tachyarrhythmias or ventricular fibrillation) to physician evaluation (one day compared with 36 days). The CONNECT trial[3] using the Medtronic CareLink system also showed that the time from a clinical alert (defined as occurrence of shock, antitachycardia pacing, atrial arrhythmia, low battery or need for battery replacement, among others) to clinical intervention was significantly lower in patients with remote monitoring.

Although there is some evidence on the usefulness of remote monitoring systems, there are no clinical data on their use in Portugal nor information on their impact on resource management in the National Health Service.

The PORTuguese Research on Telemonitoring with CareLink (PORTLink) trial,[4] to be performed in Portuguese centers, the protocol of which is published in this issue of the *Journal*, is thus important. Medical journals with a high impact factor only publish clinical trials if the study protocol has previously been published. This is considered one of the rules of good practice for clinical trials, since it ensures that any deviation from the initial design in terms of the conduct of the trial and analysis of the data can be verified.

The PORTLink trial sets out to compare conventional follow-up with face-to-face consultations and remote monitoring with fewer consultations. The participants will be divided into four groups: those with a newly implanted device (two groups, one conventional and the other remote) and those who have had a device for some time with conventional follow-up (two groups, one maintaining conventional follow-up and the other changing to remote monitoring). The objective of the trial is to assess the efficiency of remote monitoring of patients with CIEDs in terms of safety, efficacy, patient and physician satisfaction and costs) compared to conventional face-to-face follow-up.

Randomization has begun and we look forward to the results and conclusions of the trial.

Conflicts of interest

The author has no conflicts of interest to declare.

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