



OUR POINT OF VIEW

Remote monitoring for follow-up of patients with implantable cardiac devices[☆]

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Abstract With a widening of indications for cardiac devices, especially in view of the clinical benefits of implantable cardioverter-defibrillators and cardiac resynchronization therapy, the number of patients with such devices is growing steadily. However, the resources required, and the need for long-term regular interrogation in dedicated clinics, represent a significant burden for already overstretched electrophysiology teams and hospital services. Remote telemonitoring is increasingly used for such follow-up, as it is a safe and effective alternative to conventional follow-up programs in outpatient clinics. This technology has been shown to be technically reliable, enabling early identification of device malfunction, arrhythmic events and heart failure decompensation, while reducing the risk of under-reporting, the number of outpatient clinic visits and hospitalizations due to cardiac events, and healthcare costs. Further studies are needed to determine how best to implement this new technology in a cost-effective manner, and what new legislation governing the use of remote monitoring in clinical practice may be required. In this article, we describe current systems, review the technical and clinical evidence in the literature regarding remote monitoring of implantable cardiac devices, and expand on outstanding questions.

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Monitorização à distância no seguimento de portadores de dispositivos cardíacos implantados

Resumo O aumento significativo registado nas implantações de dispositivos cardíacos, sobretudo como consequência dos benefícios demonstrados com a utilização de

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cardioversores-desfibrilhadores e sistemas de ressíncronização cardíaca na redução da mortalidade, trouxe para a prática clínica hospitalar o problema da gestão de recursos para responder ao crescimento exponencial do número de doentes em consultas regulares de seguimento especializado. A era das tecnologias da comunicação permitiu desenvolver sistemas de monitorização à distância, que são hoje uma realidade em franca expansão na Europa e Estados Unidos, com diversas vantagens e níveis de eficácia e segurança bem documentados. A sua utilização tem permitido obter um elevado grau de satisfação para o doente e médico, reduzindo o número de visitas hospitalares e os custos inerentes ao seguimento desta população. Os resultados dos diferentes estudos têm mostrado elevada capacidade na deteção mais precoce de problemas clínicos, arrítmicos ou de descompensação da insuficiência cardíaca, e de anomalias no funcionamento do dispositivo implantado. Apesar da experiência favorável com o recurso a esta metodologia de *follow-up*, são necessários estudos para avaliar o seu impacto clínico a longo-prazo, em comparação com as consultas convencionais, bem como a introdução e adaptação da legislação referente a este tipo de evolução tecnológica aplicada à saúde. No presente artigo, revimos os aspectos técnicos e a evidência recente da relevância clínica da monitorização à distância em portadores de dispositivos cardíacos implantados.

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Introduction

The clinical benefits demonstrated by multicenter studies of implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy devices with defibrillator capability (CRT-D) in selected patients have led to a significant and progressive increase in the number of implantations of these devices.¹⁻⁵ Between 1990 and 2002 the number of ICDs implanted in the US grew 10-fold,⁶ while a similar increase was seen in the last decade in Portugal, reaching 98 devices per million population in 2009, approaching the European average of 150 per million.^{7,8} However, this growth has led to difficulties in providing the specialized follow-up required for patients with these devices, many of whom have significant comorbidities. Considerable human and logistical resources are needed to provide appropriate care, particularly for regular interrogation of the technical parameters of different devices, detection and resolution of problems, identification and treatment of arrhythmias via the ICD, ensuring biventricular stimulation to optimize cardiac resynchronization, and specialized clinical care. These services can only be provided by hospital teams that are trained and able to perform tasks that are ever more complex and challenging.

In the last ten years, telemedicine systems for remote monitoring of these devices have become a reality and are increasingly used in clinical practice, enabling changes in the specialized follow-up of this population, with well-documented benefits and levels of safety.⁹⁻¹¹ Monitoring of these patients has conventionally involved the participation of a team of health professionals, with hospital visits of varying frequency depending on local conditions, different centers and teams having different capacities and levels of experience. In most cases visits are scheduled at intervals of 3–6 months.^{12,13} The inevitable consequence of the growth in numbers of patients with implanted devices

is an enormous increase in the number of follow-up visits, overloading health institutions and their staff, which in this highly specialized area of cardiology are relatively few in number.¹⁴ Wider use of remote monitoring is therefore a hotly debated subject, on issues ranging from clinical and technological aspects (particularly concerning the long-term performance of the devices) to implementation, management and organization, legal questions, data protection, and funding.

Advantages of remote monitoring systems

One of the main functions of systems for monitoring cardiac implantable devices is to detect malfunctions as early as possible.⁹ ICD leads are the most common cause of complications, with an incidence ranging between 2% and 15% at five years.¹⁵ Recalls, although uncommon, are an important factor in decisions concerning the frequency of consultations and clinical management.

Electronic malfunctions in these devices are unpredictable, and inappropriate detections, failure to apply therapies when required and problems of lead and/or generator malfunction may only occur between scheduled hospital visits. Remote monitoring systems, by contrast, provide regular assessment of the function of the various components of implanted devices, as well as detection and characterization of arrhythmias, therapies applied, and even identification of factors that could indicate risk of hospitalization for decompensated heart failure.¹⁶⁻¹⁸

It has been suggested that remote monitoring can substantially reduce the number of hospital visits, freeing up hospital staff to attend other patients and to perform other tasks. In the TRUST study, of over 1300 patients, remote monitoring reduced the number of hospital visits by over 40% while maintaining similar levels of safety to the group with conventional follow-up.¹⁰ The CONNECT study, which included 1997 patients in 136 American centers with a

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