



## OUR POINT OF VIEW

# Remote monitoring for follow-up of patients with implantable cardiac devices<sup>☆</sup>

Mário Oliveira\*, Pedro Silva Cunha, Nogueira da Silva

*Serviço de Cardiologia, Hospital de Santa Marta, Centro Hospitalar Lisboa Central, Lisboa, Portugal*

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### PALAVRAS-CHAVE

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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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\* Corresponding author.

E-mail address: [m.martinsoliveira@gmail.com](mailto:m.martinsoliveira@gmail.com) (M. Oliveira).

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cardioversores-desfibrilhadores e sistemas de ressincronização 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.<sup>1-5</sup> Between 1990 and 2002 the number of ICDs implanted in the US grew 10-fold,<sup>6</sup> 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.<sup>7,8</sup> 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.<sup>9-11</sup> 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.<sup>12,13</sup> 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.<sup>14</sup> 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.<sup>9</sup> ICD leads are the most common cause of complications, with an incidence ranging between 2% and 15% at five years.<sup>15</sup> 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.<sup>16-18</sup>

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.<sup>10</sup> The CONNECT study, which included 1997 patients in 136 American centers with a

15-month follow-up, showed that the mean number of visits for patients with remote monitoring was 3.92, compared to 6.27 for those with conventional monitoring, and that the median time between an event and a clinical decision was significantly shorter in the remote monitoring group (4.6 vs. 22 days). Hospital stays were 18% shorter in the remote monitoring group, leading to a saving of \$1659 per hospitalization.<sup>19</sup>

These advantages mean that remote monitoring is likely to play an increasingly important role in ensuring the safety and quality of medical care.

The different cardiac implantable devices currently available are listed in Table 1. The device can be interrogated manually using a wand linked to the monitor in the patient's home (usually by the patient's bedside), or automatically using wireless systems, in which data are sent regularly without the patient's involvement at intervals set by the hospital team. All systems allow data to be sent when clinical circumstances dictate, as agreed between the patient and the team. The data are transmitted to a central (internet-based) data repository, access to which is limited, each center only having access to data on its own patients through a password-protected web page. Fixed telephone lines at standard call cost are used in the CareLink™, Latitude™, Smartview™, and Merlin™ systems, and the GSM cell network for the HomeMonitoring™ system (Table 1). Members of the hospital team can use the password to access the data via the internet, email, SMS or fax in order to analyze the dynamic parameters of various devices, including detection of arrhythmia episodes recorded on intracavitary electrograms, therapies delivered by the device, the percentage of different pacing modes and tachyarrhythmias treated. The parameters can be configured individually to define alert levels according to the potential clinical impact of the alterations detected.

In patients with heart failure, thoracic impedance could be monitored to detect accumulation of fluid in the lungs. This function, combined with other variables including weight, level of physical activity, heart rate and heart rate variability, and the occurrence of atrial and/or ventricular arrhythmias (even if self-limited), could help to predict cardiac decompensation and to schedule (or even, with prompt pharmacological treatment, to prevent) hospitalization for decompensated heart failure.

Although it is not currently possible to program devices using remote monitoring tools it is technically feasible, and will undoubtedly be the subject of much debate, particularly with regard to the legal and safety aspects.

## Cost-benefit ratio of remote monitoring

According to EUCOMED, the number of ICDs and CRT-Ds implanted in Europe rose by 6% per year between 2003 and 2007.<sup>20</sup> Around a million cardiac devices were implanted in 2007 in the USA alone, requiring at least four million annual visits.<sup>9</sup> The result is an enormous growth in the population being monitored, particularly in centers performing a large number of procedures. The implementation of a monitoring system that reduces costs while maintaining safety using current levels of human and logistical resources is thus an increasingly urgent priority.

Remote monitoring has the potential to reduce hospital visits and admissions, particularly those arising from device malfunction, arrhythmias or heart failure, and can significantly reduce costs and increase patient satisfaction. It has been demonstrated that the transmitted data on device parameters and the quality of the electrograms are sufficient for a detailed analysis of the function of ICDs and CRT-Ds and of arrhythmic events.<sup>21</sup> In our experience with 55 patients using a remote monitoring system (BIOTRONIK Home Monitoring®), there were 30% fewer hospital visits in the first year of follow-up, despite 14 unscheduled visits.<sup>22</sup> In those with CRT-Ds, who would be expected to require closer monitoring due to the complexity of the clinical situation and of the device, it was also observed that the device parameters required reprogramming less often during the first six months of follow-up in patients under remote monitoring, since a significant proportion of interrogations following arrhythmia therapies did not necessitate in-person visits or reprogramming.<sup>23</sup> Routine assessments can thus be performed remotely, with more clinically or technically complex situations being dealt with in hospital visits.

Despite its potential to reduce the number of visits, remote monitoring cannot replace direct contact with the physician, which is important to many patients. The consensus document of the Heart Rhythm Society and the European Heart Rhythm Association on the monitoring of cardiovascular implantable electronic devices recommends that any patient with an implantable cardiac device be assessed in person at least once a year and that remote monitoring should take place every 3–6 months. Remote monitoring can provide an early warning of events, particularly of device malfunction and arrhythmias; the time saved can be over 150 days in patients with the standard six-month follow-up and 64 days in the case of three-month follow-up.<sup>24</sup> This can reduce the number of inappropriate shocks due to lead malfunction<sup>25</sup> and enable early detection and clinical management of atrial fibrillation.<sup>17</sup> A recent study of 5279 ICD shocks showed good inter-observer agreement in interpreting remotely transmitted electrograms assessed by a team that included electrophysiologists from four centers.<sup>26</sup>

In-person hospital visits usually entail traveling, which represents additional costs for patients and for the health system, added to which the patient often needs to be accompanied, further increasing costs due to transportation, time spent waiting and loss of productivity.

Apart from its effects on costs, remote monitoring can improve access to health care by overcoming problems with distance and geographical isolation, as well as improving levels of satisfaction of both patients and hospital teams. An analysis of quality of life using the SF-36 questionnaire showed that 93–97% of patients were satisfied with the convenience and feasibility of remote monitoring.<sup>27</sup> Other studies of patients with ICDs or CRT-Ds have found high levels of satisfaction among both patients and physicians.<sup>11,28</sup>

Another factor is the time taken by specialized personnel to interrogate the device and analyze the data with remote monitoring compared to conventional in-person visits, the latter requiring 4–5 times longer.<sup>11,27</sup> A meta-analysis assessing hospitalizations and costs in a heart failure

**Table 1** Remote monitoring systems for implantable cardiac devices.

- Home Monitoring™ (BIOTRONIK, Berlin, Germany)
- CareLink Network™ (Medtronic Inc., MN, USA)
- Latitude Patient Management system™ (Boston Scientific, St. Paul, USA)
- Merlin.net™ (St. Jude Medical, Sylmar, USA) - Smartview™ (Sorin CRM SAS, Clamart, France)

population in Germany concluded that the hospital costs of follow-up were 60% lower with remote monitoring,<sup>29</sup> thus reducing the overall cost of monitoring patients with cardiac devices and thereby improving cost-benefit ratios. However, its economic benefits may not be the same everywhere, since there are significant differences between countries – even within Europe – in policies governing reimbursement of certain remote consultations, sickness benefits, and reimbursements of indirect costs such as the expenses of those accompanying patients, transport (type and distance from the hospital), and time taken off work, all of which are significant factors in the total cost. The costs of maintaining the data repository and of communications, technical support and the monitor vary according to the services provided by the supplier of the device.

Another issue in which the situation varies in different countries is that of reimbursement of expenses for remote follow-up. In the USA, Medicare and Medicaid extended reimbursement to remote monitoring in all states in 2006, although with differences in the assigned value. There is now legislation covering payment of these services in Portugal, Germany and the UK, but there are differences from payment of in-person visits, and the Portuguese system was changed in 2009 with regard to the value and billing of remote consultations.<sup>30</sup> However, most European countries have yet to specify what services will be reimbursed, as there is a lack of legislation in this area and different degrees of complexity are associated with conventional pacemakers, ICDs and CRT-Ds.

## Legal aspects and data protection

A recent review of publications on remote monitoring of cardiac devices revealed that 38% of the studies included legal and technical issues among the disadvantages of remote follow-up.<sup>31</sup>

Standardization and consensus are essential concerning the requirement and ability of the follow-up team to respond to alerts, to deal with information arriving outside the hospital's normal working hours, to manage the human resources required and to allocate responsibility. There is also the question of whether to inform all patients of the option of remote monitoring. These and other issues must be discussed thoroughly from a multidisciplinary perspective, and further studies are needed focusing on the aspects most relevant to clinical practice.

When remote monitoring of a cardiac device is proposed, the patient must be told clearly how it works, its potential benefits and limitations, and that it cannot replace the emergency department since the data transmitted are

not analyzed immediately. The patient and the attending physician should sign an informed consent form that covers the above issues, authorizes the transmission, recording, analysis and use of data for clinical and research purposes, and ensures respect for privacy and confidentiality on the part of the hospital and the companies providing the service.

The implementation of a remote monitoring program will require a reorganization of the duties of the electro-physiology team, who will require access to the servers hosting the data repository and will need to manage the large quantity of data transmitted. Decisions will need to be taken regarding the management of alerts, telephone contact with patients and type of information provided, requests for unscheduled visits, measures to increase monitoring if necessary, and reprogramming and maintenance of equipment.

The question of data protection is also of considerable importance, which requires the involvement of data protection commissions who will need to approve any submission to ensure that all the components of the system respect legal requirements and confidentiality. The servers that contain patient data are potentially vulnerable to hackers; although there have been no reports of such attacks to date, powerful security software must be installed and constant vigilance is required to ensure that the system is able to resist possible intrusions.

## Conclusions

As the population of patients with implantable cardiac devices increases, the benefits of remote monitoring, as demonstrated in various multicenter studies – increased satisfaction, reduced costs, optimization of resources and improved safety – mean that this type of follow-up, already widely used, will be increasingly applied in clinical practice. As the technology is relatively new, certain complex issues remain to be resolved, particularly regarding resource management, overall costs, reimbursements, legal aspects and data protection. However, the ability to provide effective monitoring of these devices, while ensuring high levels of satisfaction among patients and physicians alike, represents a significant improvement in performance in this area.

## Conflicts of interest

M. Oliveira is an advisor and speaker for Medtronic, Sorin and Boston Scientific.

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