

# Telecardiology and Remote Monitoring of Implanted Electrical Devices: The Potential for Fresh Clinical Care Perspectives

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Telecardiology may help confront the growing burden of monitoring the reliability of implantable defibrillators/pacemakers. Herein, we suggest that the evolving capabilities of implanted devices to monitor patients' status (heart rhythm, fluid overload, right ventricular pressure, oximetry, etc.) may imply a shift from strictly device-centered follow-up to perspectives centered on the patient (and patient-device interactions). Such approaches could provide improvements in health care delivery and clinical outcomes, especially in the field of heart failure. Major professional, policy, and ethical issues will have to be overcome to enable real-world implementation. This challenge may be relevant for the evolution of our health care systems.

**KEY WORDS:** defibrillator; devices; heart failure; monitoring; pacemaker; telemedicine; telecardiology.  
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## INTRODUCTION

Long-distance transmission of data recorded by implanted electrical devices is fast becoming a technological reality. After initially being adopted for efficient remote follow-up of implanted devices and patient-device interactions, use of this technology could be extended to monitor patients' hemodynamic conditions. Such a shift would enable remote monitoring (telemonitoring) of the clinical condition of heart failure (HF) patients and pave the way to a broad, multidisciplinary approach to disease management offering potential advantages both in terms of clinical outcome and economic savings.

In this article, we will first consider the potential of telemonitoring for follow-up of patients carrying implantable devices in the context of increased usage and widening indications. We will then look at experiences regarding the use of external stand-alone devices to monitor HF patients. This will lead us to consider possible additional benefits of telemonitoring in HF patients who have indications for an implantable cardioverter-defibrillator (ICD) or pacemaker. We

conclude by highlighting some important issues regarding this upcoming challenge.

## TECHNOLOGICAL EVOLUTION OF ELECTRICAL DEVICES: PREMISES FOR TELEMONITORING

The use of implantable electrical devices entails periodic device follow-up to check if the pacemaker system (device/leads) is working properly, and to allow detection of lead failure or pulse generator exhaustion/malfunction. Proposals to develop transtelephonic monitoring systems as a way of reducing cardiac pacemaker follow-up visits were first made in the 1970s.<sup>1</sup> The question of how best to manage the follow-up of patients implanted with a device has become increasingly topical in recent decades, which have also seen vast changes in cardiac device therapy, leading to a greatly expanded population of implanted patients and new technical follow-up requirements.<sup>2-4</sup>

Along with new pacing functions, novel types of devices (not primarily intended for treatment of bradycardia) have been introduced for the treatment of HF and prevention of sudden death.<sup>5,6</sup> These developments, combined with the increased life expectancy of patients carrying pacemakers to treat bradycardia,<sup>7</sup> have enlarged and diversified the population of device recipients. A key factor in the growing device follow-up burden has been the shift in indications for implantable cardioverter defibrillator (ICD) from secondary to primary prevention of sudden death.<sup>2,8</sup> Furthermore, indications to device implantation have been extended to selected groups of HF patients who may benefit from biventricular pacing (cardiac resynchronization therapy; CRT).<sup>6</sup> Currently, over 225,000 pacemakers and 150,000 ICDs appear to be implanted in the USA each year.<sup>9</sup> Most implanted patients have impaired systolic left ventricular function and are therefore at risk of events such as new-onset (or worsening) HF, life-threatening ventricular tachyarrhythmias, atrial fibrillation (AF), and stroke.

The changing profile of the overall device-carrying population (larger, more heterogeneous, and affected by more complex disease) is being met by expanded device capabilities. A single device can deliver multiple therapies, while also monitoring various cardiovascular parameters. Information can be obtained on underlying heart rhythm, burden of supraventricular or ventricular arrhythmias, and (in some devices) fluid overload.<sup>10,11</sup> Such advances are likely to provide the premise for relevant changes in follow-up modalities and objectives, as discussed in the rest of this article.

## TELEMONITORING AND THE POTENTIAL FOR DEVICE FOLLOW-UP

ICD manufacturers have developed a variety of telemonitoring systems. Three separate systems from Medtronic, St. Jude Medical, and Boston Scientific all currently require patients to perform a device questioning procedure to allow data transmittal to the referral center via the internet or phone network.<sup>4</sup> A different approach used by Biotronik (Berlin, Germany) involves automatic transmittal (usually daily, or on appearance of relevant events) from the device to a service center that processes the data and informs physicians via the internet (or in cases of alerts, through additional channels such as fax and mobile phone messages).<sup>12</sup> Current systems for remote ICD follow-up provide information on device status, detected events (including intracardiac electrograms of arrhythmic events), and the therapies delivered.<sup>4,12-15</sup>

Although still in an experimental phase, telemonitoring can provide a similar quality of data retrieval to conventional office visits,<sup>4,13,14</sup> satisfying both clinicians<sup>13</sup> and patients.<sup>13,15</sup> Various clinically relevant points can be identified allowing prompt intervention based on detection of abnormalities in sensing/pacing function, evidence of new AF or of therapy appropriately delivered for a ventricular tachyarrhythmia, and so-called "phantom shocks" (sensations of device-delivered shocks in the absence of detected events).<sup>13,15</sup>

Telemonitoring of ICDs has the potential to improve patients' safety regarding both spontaneous clinical events and device-related events. The device-driven aspect is of particular interest given the problem of device advisories, which seem to have increased in recent years.<sup>16</sup> The availability of "patient alert" features in some current ICDs can facilitate early detection of serious (sometimes life-threatening) device system complications entailing the need for reprogramming or device/lead replacement.<sup>17</sup>

The economic potential of telemonitoring was highlighted in a French survey, which indicated that this approach could help cut overall ICD follow-up costs, thanks to transport savings, particularly for patients living over 100 km from their referring center.<sup>18</sup> When the costs of home monitoring were factored in, the time to onset of cost saving ranged from about 1.5 years (for patients living >150 km from the referring center) to about 4 years.<sup>18</sup> Telemonitoring may cover a wide range of situations (including routine follow-up and nonscheduled follow-up because of new or phantom shocks, suspected electromagnetic interference, or suspected onset of new arrhythmias such as AF), thereby sparing patients the need to travel to the referring center except for reprogramming.

### TELECARDIOLOGY IN THE MANAGEMENT OF HF: EXPERIENCES WITH EXTERNAL DEVICES

There is growing interest in home-based care for HF patients to reduce hospital admissions. Telecardiology could be a key player in this strategy. HF is a common disease, whose prevalence is increasing alongside the aging of the general population. The impact of HF on health care costs is mainly caused by hospitalization (in western countries, HF is the most common cardiovascular cause of hospitalization in the elderly, and repeated admissions are often required).<sup>19</sup> The conven-

tional approach to home monitoring relies on external devices connected to a telecommunication system.<sup>19</sup> Regular (daily or even continuous) transmittal of data regarding heart rate, blood pressure, ECG, weight, body temperature, oxygen saturation, or transthoracic impedance (for control of fluid overload) can provide a basis for disease management decisions. Non-randomized clinical trials on strict telemonitoring of HF patients have identified several predictors of mortality or hospitalization, and indicate that telemonitoring is associated with a reduction in the number of hospitalizations in comparison with regular conventional follow-up.<sup>19,20</sup>

In a randomized controlled study of NYHA III-IV HF patients,<sup>21</sup> telemonitoring of weight and symptoms led to improved survival in the absence of reduced hospitalization (the primary outcome measure). The Trans-European Network Home-Care Management System (TEN-HMS) study randomized patients with left ventricular dysfunction and a recent history of hospitalization because of HF either to home telemonitoring (of weight, blood pressure, and heart rate/rhythm, as recorded by automated external devices), to nurse support by telephone, or to usual care. During an 8-month follow-up, both telemonitoring and telephone support reduced mortality in comparison with usual care. Furthermore, telemonitoring was associated with shorter hospital stays (but not lower hospital admission rates).<sup>22</sup> So far, the benefits of telemonitoring seem to be less impressive than was originally hoped. Despite some cost-effectiveness evaluations,<sup>19,20</sup> the overall economic profile of telemedicine awaits clarification.<sup>23</sup>

Whereas telemonitoring has traditionally made use of external devices, the frequent indications for electrical device (pacemaker, ICD, or CRT) implantation in the field of HF suggest the prospect of closer and more detailed monitoring of patients' conditions.<sup>20</sup> This avenue could become even more attractive if the sensors integrated into implanted devices to monitor hemodynamic conditions are further developed and improved.<sup>11,24,25</sup> Although further technological evolution is probably necessary before we can gain a true picture of the potential of telemonitoring, even now it does seem to hold out the prospect of improvements in the quality of life, health status, and safety in specific groups of patients, while at the same time enhancing economic efficiency.

### MONITORING OF PATIENTS CARRYING IMPLANTED ELECTRICAL DEVICES: A CHANGING SCENARIO

At present, HF appears to be an ideal target for pilot disease management programs based on telemonitoring via implantable electrical devices. Telemonitoring of implanted devices could provide various kinds of useful information (Table 1), suggesting the possibility of an acceptable and efficient strategy to improve patients' outcomes while cutting costs. Clinical management could greatly benefit from timely information on electrophysiological and hemodynamic parameters (ventricular tachyarrhythmia burden, new onset of AF, rhythm pattern during syncope, evolution of hemodynamic state, fluid overload, etc.).

In patients with advanced HF (NYHA class III-IV), intrathoracic impedance monitored by implanted devices has been found to correlate inversely with pulmonary capillary wedge pressure and fluid balance, and can provide early warning

**Table 1. Types of Information that Implanted Devices (Pacemakers, ICDs, Devices for CRT) with Telemonitoring Capabilities could Potentially Provide**

| Information   | Details  |
|---|--|
| Device information  | Battery status and voltage<br>P and R wave amplitudes<br>Capture thresholds<br>Lead impedance<br>Autocapture thresholds<br>Shock impedance   |
| Information on patients' heart rhythm/arrhythmias and on device therapies | Heart rate<br>Heart rate variability<br>Atrial and ventricular electrograms<br>Percentage atrial pacing<br>Percentage ventricular pacing<br>Number of supraventricular tachyarrhythmias (AT, AF)<br>Number of ventricular tachyarrhythmias (VT, VF)<br>Number of non-sustained VTs<br>Number and outcome of delivered therapies (atrial, ventricular)<br>Number of aborted therapies (atrial, ventricular)<br>Electrograms of detected arrhythmias (atrial, ventricular) |
| Information on patients' status and hemodynamic condition                 | Right ventricular dP/dt<br>Right ventricular pressure<br>Right ventricular impedance<br>Venous oxygen saturation<br>Fluid overload<br>Muscular activity<br>Ventilation   |

AF atrial fibrillation, AT atrial tachycardia, CRT cardiac resynchronization therapy, ICD implantable cardioverter-defibrillator, VF ventricular fibrillation, VT ventricular tachycardia.

signs of impending decompensation (about 15 days before onset of symptoms).<sup>11</sup> This example illustrates how a device-assisted approach could be applied in clinical practice. The clinical potential and possible cost-effectiveness benefits (through reductions in hospitalization- and disease-related costs) are under evaluation.<sup>11</sup>

The increasing capabilities of implanted devices to monitor patients' status suggest a shift in post-implant follow-up objectives from a strictly device-centered perspective ("Is the device working properly?") to perspectives centered on the patient-device interactions and on patient status ("Is the device programming appropriate for the patient's status?" "Has something changed in the patient's status?" "What clinical options are most appropriate for this patient?"). Health care could benefit from automatic or periodic data transmission, coupled with alert features (when the device detects significant abnormalities) to warn patients to contact physicians.<sup>4,12,20</sup> Upfront increases in costs (physician/nurse surveillance, phone calls, internet/phone checks, etc.) could eventually be offset by reduced hospitalization costs, thanks to the beneficial effects of timely recognition of changes in patients' status and prompt therapeutic response.

Another innovative technological approach to HF management involves use of stand-alone devices designed exclusively for the telemonitoring of cardiac function by measurement of various indicators.<sup>25</sup> Obviously, such an approach could also be used for patients without pacemaker or ICD indications.

However, the need for an invasive intervention entails risk-benefit considerations (implantation side effects versus possible management benefits) that could make this approach less amenable to study than approaches involving provision of additional telemonitoring capabilities to routinely implanted devices. In any case, experiences garnered in the telemonitoring of pacemakers, ICDs, and CRT devices could be useful for development and application of other implantable monitoring systems.

## TELECARDIOLOGY WITH IMPLANTED ELECTRICAL DEVICES: PERSPECTIVES AND OPEN ISSUES

In HF, acute exacerbation is thought to contribute to disease progression, leading to progressive ventricular dysfunction and dilation.<sup>26</sup> This concept could stimulate early detection of hemodynamic alterations as a marker of HF exacerbation. Telemonitoring of implantable devices could enable timely therapeutic adjustments aimed at preventing severe derangement and disease progression. Such strategies might lead to profound changes in care delivery to HF patients based on coordinated multidisciplinary disease management with the potential to improve outcomes.<sup>27</sup> Patients would be the focus of a network of physicians and other clinicians, including the referral electrophysiologist, HF specialist, family doctor, inter-nists, and other relevant health professionals. Similar scenarios might also be considered for diabetes and other chronic diseases, as and when appropriate technologies become available.<sup>28,29</sup>

For such possibilities to become a reality, several issues must be overcome. Technological compatibility would be an important premise. The different proprietary technologies for telemonitoring could pose a major obstacle to data integration.<sup>4,13,14</sup> Although commercial enterprises find it difficult to agree on shared standards, within the health sector ethical pressures might be decisive. Propagation of the Digital Imaging and Communications in Medicine (DICOM) standard provides a promising example.<sup>30</sup> Another issue regards the choice of approach for a specific telemedicine program.<sup>31</sup> For example, interactive real-time telemedicine has greater overheads than "store-and-forward" approaches (e-mails, pre-recorded images/videos, etc.), but permits interaction and provides more immediate results.<sup>29</sup> However, the store-and-forward approach may be fully sufficient for the purposes of telemonitoring of patients with implantable devices, where data collection has already been performed by the device itself.

Although development of dedicated guidelines<sup>32</sup> could constitute a key step to improve the consistency and efficiency of telemedicine, this topic remains largely unaddressed. Barriers to guideline development include emphasis on technology rather than the principles and targets of telemedicine,<sup>33</sup> coupled with medical organizations' tendency to feel they lack necessary technical expertise.

Telemedicine is particularly vulnerable to ethical and legal conflict, mainly because the law-making process tends to lag behind the high pace of technological evolution, and also because of national/federal differences.<sup>34,35</sup> New sets of medicolegal regulations will be required to define professional responsibilities for decisions guided by transmitted data, especially with regard to suspected equipment malfunction.

Response strategies will be required for out-of-hours calls, including emergencies.<sup>4</sup> Personnel accreditation/certification, jurisdiction, and choice of law in the case of cross-border patient–doctor relationships may be complicated (what to do when doctors certified for given countries are contacted by internet by patients from elsewhere?).

Widespread implementation of telemedicine will entail management of huge amounts of data, with important privacy implications. It will be essential to define responsibilities for data management/access (by hospital personnel, providers, public/private institutions, etc.), and formulate regulations to protect the rights of both patients and health care professionals. Patients' provision of consent to medical treatment could be a particularly delicate ethical issue. Questions regarding protection of intellectual property rights will also have to be addressed. From a societal perspective, implementation of telecardiology using implanted devices will obviously depend on evidence that this option improves efficiency and is cost effective. Moreover, research will presumably be needed to identify subgroups of patients for whom use of specific telemonitoring devices is both feasible and cost-effective.

## CONCLUSIONS

In the context of the rapid ongoing evolution of electronic technology, telemedicine has the potential to enhance and rationalize clinical monitoring of patients implanted with pacemakers, ICDs, and CRT devices. It is likely that this prospect will be encouraged by further technological advances in the development of useful novel sensors. A consequent shift from device-centered to patient-oriented telemonitoring could in turn favor a transition to a broader multidisciplinary approach to "disease management" based on a system of coordinated health care interventions, not only in the field of cardiovascular medicine. However, a series of economic, regulatory, and organizational issues will have to be faced before such an approach can take root in real-world clinical practice, where institutional, cultural, and financial forces interact in complex ways. The ability to overcome these obstacles so as to take full advantage of the potential benefits offered by telemedicine technology may be relevant for the evolution of our financially challenged health care systems.

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