Telemonitoring

Remote Monitoring of Patients with Implanted Cardiac Devices – A Review

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Abstract
There has been a rapid growth in the number of patients with cardiovascular implantable electronic devices (CIEDs), due to the consistent good results from large randomised trials and changing worldwide demographics with progressive ageing in all developed countries. Early generations of CIEDs provided only basic operations and stored only rudimentary data, but the evolution of all types of CIEDs (pacemakers, defibrillators, cardiac resynchronisation devices, implantable monitors) has led to their increased complexity and the development of a myriad of specialised features. As an outgrowth of this increased sophistication, once implanted, CIEDs can provide significant amounts of important clinical information, allowing to identify the presence of significant arrhythmias, assess drug efficacy, evaluate heart failure status and continuously monitor device function. With the advent of new methods of remote monitoring, the information recorded by these devices can be accessible in real time and thus lead to more timely clinical decision-making. This article summarises the impact of remote monitoring on clinical practice today and how the use of remote monitoring may evolve to affect the practice of medicine in the future.

Keywords
Cardiovascular implantable electronic devices, remote monitoring, transtelephonic monitoring, heart failure monitoring, pacemaker follow-up, lead recall

Since the first implantable pacemaker was introduced in 1958, electronic devices designed to treat cardiac problems have experienced technological leaps. A rapidly expanding number of patients depend on this technology.¹ Cardiovascular implantable electronic devices (CIEDs) now include implantable cardioverter defibrillators (ICDs), pacemakers (PMs), cardiac resynchronisation therapy (CRT) devices, implantable loop recorders (ILRs) and implantable haemodynamic monitors (IHMs).² The indications for CIED implantation have also broadened, and CIEDs are now important therapeutic options for selected patients with bradycardia, tachycardia or heart failure as well as a diagnostic option for patients with syncope.

Regardless of type, once a device has been implanted, its continued monitoring is necessary for evaluating the effects of therapy and has become part of a complete cardiac evaluation, much like an electrocardiogram, echocardiogram or stress test. Data from the device may alert the physician and/or the patient to important events, such as device malfunction, arrhythmia, changes in haemodynamic status or inadvertent changes in programmed parameters. The goals of CIED monitoring include optimising device function, improving patient quality of life, and identifying and correcting device malfunction in a timely fashion.

This article will focus primarily on the remote monitoring of ICDs, PMs and CRT devices (which can be subdivided into devices with additional defibrillator capabilities [CRT-D] or without defibrillator capabilities [CRT-P]). An extensive discussion of ILRs and IHMs is beyond the scope of this article, but these devices will be briefly described in the last section.

The 2008 collaborative Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA) expert consensus statement on the monitoring of CIEDs serves as a useful reference point for physicians caring for patients with CIEDs.³ Monitoring of a CIED can be done by scheduled or unscheduled clinic visits (in-person monitoring), by data transmission to the physician initiated by the device or the patient (remote monitoring), or using a combination of both modalities. The recommended frequency for both in-person and remote monitoring is based on patient-specific factors – such as left ventricular function or the possible presence of atrial arrhythmias – and device-specific factors – such as device type (e.g., PM or ICD) and possible hardware issues (e.g., the lead under advisory due to higher than expected failure rates). The data collected at follow-up should be tailored to fit the individual clinical scenario, but often include battery voltage and impedance, magnet rate, sensing and pacing thresholds, review of programmed parameters, pacing requirements, device therapies and detected arrhythmias, haemodynamic measurements, and lead parameters and impedances – plus, for defibrillators, charge time and shock impedance.³

The importance of flexibility in frequency and modality of follow-up is reflected in the HRS/EHRA expert consensus statement – the
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Table 1: Details of Five Remote Monitoring Systems

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Medtronic</th>
<th>Boston Scientific</th>
<th>St Jude Medical</th>
<th>Biotronik</th>
<th>Sorin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote monitoring system</td>
<td>Carelink®</td>
<td>Latitude®</td>
<td>Housecall Plus®</td>
<td>Home Monitoring®</td>
<td>SMARTVIEW®</td>
</tr>
<tr>
<td>Data transmission</td>
<td>Analogue and mobile</td>
<td>Analogue</td>
<td>Analogue and mobile</td>
<td>Mobile</td>
<td>Analogue and mobile</td>
</tr>
<tr>
<td>Physician notification</td>
<td>SMS, email</td>
<td>Fax, telephone</td>
<td>Fax, email, SMS</td>
<td>Fax, email, SMS</td>
<td></td>
</tr>
<tr>
<td>Transmitted data and other features</td>
<td>All stored episodes, configurable alerts, real-time EGM, OptVol® fluid status</td>
<td>All stored episodes, configurable alerts, real-time EGM, weight and BP</td>
<td>All stored episodes, configurable alerts, real-time EGM, heart failure monitor, intrathoracic lead impedance</td>
<td>All stored episodes, configurable alerts, real-time EGM, SMARTVIEW® heart failure clinical status</td>
<td></td>
</tr>
</tbody>
</table>

BP = blood pressure; EGM = electrogram; SMS = short message service.

Although there are operational differences between manufacturers, the general flow of information is similar with all systems (see Table 1). Data from the CIED are transmitted via radiofrequency waves to a home receiving station. In the past, the information would have been transmitted via a hand-held ‘wand’ but, with the current generation of CIEDs, it is transmitted using wireless technology. The home receiver has indicators that the patient can use to confirm information transfer. The encrypted information is collected and transmitted from the receiver via an analogue or mobile phone line to an Internet-based server that decodes and stores it. The information is then sent to the physician by fax, short message service (SMS) or email. The physician can also access it by logging into a secure database. Scheduled or unscheduled transmissions are available for review. Almost any parameter obtained from a standard device interrogation can be evaluated, including programmed pacing mode, lead parameters, automatic threshold tests, activity logs, automatic alert events, patient-triggered events, all memorised episodes, configurable alerts, heart failure management parameters and more. Although the collected data are basically the same, collection and management require manufacturer-specific equipment. For safety reasons, although the CIED can be interrogated remotely, programming cannot be done without an in-clinic visit using a special programmer.

**Technical Aspects**

Transtelphonic monitoring (TTM) was the first method for the remote evaluation of CIEDs. Over 40 years ago, Furman et al. described the use of transmitting data from pacemakers via telephone connections using a special device that can record baseline rhythms and rhythms associated with magnet application from pacemakers from any manufacturer. TTM can be used to provide a rudimentary assessment of pacing and sensing function, but has been particularly effective for monitoring battery depletion, with an error rate of <1 %. However, this method of monitoring device function does not replace in-clinic visits that provide more comprehensive information from pacemaker interrogation and also allow direct contact with a healthcare professional.

As communication technology improved, more than a decade ago, devices were developed that allowed the remote transfer, via a telephone connection, of more comprehensive information regarding device function, similar to the information that would be obtained during an in-clinic interrogation of the device. This technology was first applied to ICDs but was later incorporated into most PMs. The next important steps in the evolution of remote monitoring were the application of wireless technology, which meant that no programming head needed to be placed on the implanted device, and the use of the automatic download of information, which essentially eliminated any patient duties for data transfer.

All of the major manufacturers have developed proprietary methods for data transfer from a patient’s device to the healthcare professional. Although there are operational differences between manufacturers, the general flow of information is similar with all systems (see Table 1). Data from the CIED are transmitted via radiofrequency waves to a home receiving station. In the past, the information would have been transmitted via a hand-held ‘wand’ but, with the current generation of CIEDs, it is transmitted using wireless technology. The home receiver has indicators that the patient can use to confirm information transfer. The encrypted information is collected and transmitted from the receiver via an analogue or mobile phone line to an Internet-based server that decodes and stores it. The information is then sent to the physician by fax, short message service (SMS) or email. The physician can also access it by logging into a secure database. Scheduled or unscheduled transmissions are available for review. Almost any parameter obtained from a standard device interrogation can be evaluated, including programmed pacing mode, lead parameters, automatic threshold tests, activity logs, automatic alert events, patient-triggered events, all memorised episodes, configurable alerts, heart failure management parameters and more. Although the collected data are basically the same, collection and management require manufacturer-specific equipment. For safety reasons, although the CIED can be interrogated remotely, programming cannot be done without an in-clinic visit using a special programmer.

**Potential Clinical Value of Remote Monitoring**

**Arrhythmia Identification**

Remote monitoring could improve outcomes by more timely identification of new or worsening medical conditions (such as arrhythmia or heart failure) and the detection of device-related problems. Identification of atrial arrhythmias by CIEDs may provide important prognostic information. In the recently published ASSERT trial (Asymptomatic atrial fibrillation and stroke evaluation in pacemaker patients and the atrial fibrillation reduction atrial pacing trial), 2,580 patients with an ICD or a PM and without a history of atrial fibrillation were followed for 2.5 years. Approximately 10 % of patients had subclinical atrial fibrillation identified by the device and, at follow-up, these patients had a 6-fold increase in the likelihood of developing symptomatic atrial fibrillation and a 2.5-fold increased risk of stroke or thromboembolism. However, it is not known whether placing patients with atrial fibrillation identified solely by an CIED on anticoagulation therapy is beneficial, although many clinicians will use a risk stratification score such as CHADS2 or CHADS2-VASC to estimate the individual risk of stroke and tailor treatment appropriately. Other investigators have reported the use of remote monitoring for evaluating efficacy of antiarrhythmic therapy for atrial fibrillation. Remote monitoring has also been proposed as a method for identifying patients with ventricular arrhythmias. In a prospective cohort study of 200 patients with CRT-P devices, 4 %
unaware of it. This finding led to a comprehensive cardiovascular evaluation.

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Monitoring

Figure 1: Stored Electrogram Obtained via Remote Monitoring

This electrogram from a patient complaining of palpitations confirms the presence of ventricular tachycardia (tan) and delivery of a shock (arrow). The episode occurred at night and the patient was unaware of it. This finding led to a comprehensive cardiovascular evaluation.

despite, developed ventricular tachycardia, often identified only by the evaluation of stored electrogram signals from the CRT-P device. in patients with ICDs, life-threatening arrhythmia electrograms transmitted remotely are helpful in reaching the correct diagnosis and ensuring appropriate and effective therapy (see Figure 1).

Device Function

Recent advisories and recalls have made timely access to device data critical to clinical practice. Several years ago, an ICD lead (Medtronic Sprint Fidelis) was noted to have a higher than expected failure rate (5–20 %), and that lead failure was associated with inappropriate therapy or ineffective delivery of therapy. In response, the manufacturer developed specialised algorithms that, when coupled with remote monitoring, led to more timely identification of lead failures. In an early analysis of data from 40 patients who had an implanted Medtronic Sprint Fidelis lead, remote monitoring triggered events notifications and led to unscheduled visits within one to three days of the event in four patients, three of whom had confirmed lead fractures. Recently, the St Jude Medical Riata ICD lead has been associated with failures due to the extrusion of one of the conductor wires through the external insulation. In one study of 171 of these leads with electrical abnormalities, there was a reported occurrence of inappropriate therapy in 33 % and failure to deliver high voltage therapy in 6 %. In all cases of potential lead malfunction, remote monitoring is an important tool that allows more timely identification of problems and reduces the likelihood of significant clinical consequences. Lead performance can be evaluated by analysing stored data for evidence of noise and over-sensing and by measuring temporal changes in impedance.

Heart Failure

Manufacturers have developed algorithms and specialised monitors (both stand-alone and incorporated into CIEDs used for heart rhythm therapy) to facilitate the management of heart failure (see Figure 2). One commercially available system (OptiVol®, Medtronic) measures intrathoracic lead impedance as an estimate of fluid status, with decreasing impedance correlating with increased pulmonary oedema. Several other sensors that have been evaluated include stand-alone or integrated direct left atrial pressure monitoring (HeartPOD® System or Promote LAP® System, St Jude Medical), an intracardiac right ventricular pressure sensor (Chronicle® IHM, Medtronic) or a pulmonary artery pressure transducer (Champion®, CardioMEMS), with many more in development. The information gathered from the device or algorithm is incorporated to clinical data to assist the physician in managing complex patients. A meta-analysis of randomised controlled and cohort trials of remote monitoring in heart failure patients showed that remote monitoring was associated with a significantly lower number of deaths and hospitalisations. The study population included more than 8,000 patients followed for up to 18 months, with a mean ejection fraction of 35-40 % and New York Heart Association (NYHA) functional class III-IV.

Randomised Studies of Remote Monitoring

Several recently published prospective multicentre trials have established the benefits of remote monitoring (see Table 2). In the PREFER (Pacemaker remote follow-up evaluation and review) study, 897 patients with a clinical indication for a permanent pacemaker (33 % for sinus node dysfunction and 67 % for atrioventricular block) were randomised to either a remote monitoring group (remote interrogation every three months and clinic visit at one year) or a conventional follow-up group (clinic visits at six and 12 months combined with transoral TTM every two months). The primary endpoint of the study was the identification of ‘clinically actionable events’ (defined as events that might be associated with a change in patient management), which included identification of atrial and ventricular arrhythmias, an increase in ventricular pacing and a possible device malfunction. Remote monitoring was associated with earlier identification of a clinically actionable event (5.7 months) compared with conventional follow-up (7.7 months). Importantly, in the conventional follow-up group, TTM only detected three out of 190 events, while, in the remote monitoring group, 446 out of 676 events were identified.

In the Clinical evaluation of remote notification to reduce time to clinical decision (CONNECT) study, 1,997 patients undergoing ICD or CRT-D device implantation were randomised either to follow-up using wireless automatic remote monitoring or to conventional in-clinic follow-up. The interval between a clinical event and a clinical decision was reduced from a median time of 22 days for patients monitored in-clinic to 4.6 days for those in the remote monitoring group (p<0.001). Remote monitoring was not associated with a decrease in healthcare use parameters, such as hospitalisation or accident and emergency department visits, but did increase the number of unscheduled clinic visits.

In the TRUST (Lumos-T safely reduces routine office device follow-up) trial, 1,339 patients undergoing ICD implantation (approximately 75 % for primary prevention) were randomised to standard in-clinic follow-up (every three months) or remote follow-up (initial in-clinic evaluation three months after implant, online evaluations every three months, second planned in-clinic visit 15 months after implant). At one year, remote monitoring was associated with a 45 % reduction in unscheduled in-hospital device evaluations without morbidity being affected. The curves between the two groups began diverging at approximately five months and, importantly, continued to diverge after the initial separation, suggesting that the potential benefits of remote monitoring may be even higher with longer follow-up. Furthermore, median time from onset of clinically significant events to physician evaluation of patients with first episodes of atrial fibrillation, ventricular tachycardia and ventricular fibrillation was lower in remotely monitored patients than in the conventional group (1 day versus 35.5 days). Surprisingly, the promptness of arrhythmia
The patient contacted the pacemaker clinic with increased symptoms. Remote monitoring episode confirmed the redevelopment of atrial fibrillation (horizontal arrows). With the development of atrial fibrillation, the patient starts to develop pulmonary congestion (vertical arrow) associated with a decrease in physical activity (arrowheads). During episodes of atrial fibrillation, the heart rate is approximately 100 beats per minute and the patient has ventricular pacing 25–36% of the time. Possible reasons for clinical decompensation include loss of atrioventricular synchrony, high heart rates and increased ventricular pacing.
Telemetry

Recent studies have evaluated the impact of remote monitoring on hospitalisation rates and mortality. A large randomised study involving 1,501 patients with newly implanted ICDs was presented at the 2011 European Society of Cardiology meeting. The study randomised patients to remote monitoring or clinic visits. At one year after implant, there was no difference in hospitalisation rates between the two groups. However, patients who were remotely monitored had fewer inappropriate ICD therapies (4.7% versus 7.5%, p=0.03).

The second study, the ECOST (Benefits of implantable cardioverter defibrillator follow-up using remote monitoring) trial, enrolled 433 patients, lasting for 27 months and randomised patients to remote monitoring with daily data transmission or conventional clinic visits. Similarly, the ECOST trial found that patients monitored remotely had fewer inappropriate ICD therapies (4.7% versus 7.5%, p=0.03). These studies highlight the potential benefits of remote monitoring on mortality and hospitalisation rates.

Data Registries

Another benefit of remote monitoring has been the development of large databases containing a significant number of device evaluations. For example, the CareLink registry (Medtronic) will examine whether the addition of remote monitoring to patient care, as a secondary outcome measure, will evaluate clinician and patient ease of use and satisfaction, cost-effectiveness and workflow issues associated with remote monitoring.

An analysis of data from the Discovery Link® database (generated from the Medtronic remote monitoring system) evaluated more than 100,000 patients from almost 3,000 institutions and found that lower thresholds (both rate and duration) for diagnosing ventricular arrhythmias and the presence of atrial fibrillation with rapid ventricular rates were associated with an increased likelihood of shocks. A future analysis of the same database will compare remote monitoring of implanted cardiac devices to in-clinic monitoring and, as a secondary outcome measure, will evaluate clinician and patient ease of use and satisfaction, cost-effectiveness and work flow issues associated with remote monitoring.
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Other Questions

A concern arising from the widespread use of remote monitoring is the lack of direct contact and interaction between physician and patient. Although certain clinical decisions cannot be made without a formal clinical evaluation, having prior knowledge of remotely gathered data (or a lack thereof) can facilitate decision-making. At the present time, there is no capability for the remote reprogramming of CIEDs; patients may therefore still require clinic visits. A questionnaire-based study of patients with implanted devices followed via a remote monitoring system as standard clinical practice showed a high level of acceptance and satisfaction of this new technology.10 In another study of Italian patients with different types of CIEDs, 88 % of patients had a positive attitude towards remote monitoring, particularly those with ICDs or CRT-D devices.11

With the accumulation of vast amounts of patient information, data protection and safety becomes even more important. Every manufacturer has incorporated safeguards to protect patient data. However, in 2008, Halperin and colleagues published a report demonstrating that unauthorized access to information on stored data and actual reprogramming is feasible, although difficult, using radio-based ‘attacks’. Currently, data are stored and managed by the device manufacturers with individual password-protected access given to healthcare providers. In a multispecialty setting, data sharing among physicians involved in the patient’s care is limited to information provided to team members by the physician with primary access. Patient privacy laws must be respected without limiting access to data. The responsibility for data protection falls primarily on the manufacturer and data could be acquired in one country and stored in another with differing data protections laws. With the large amount of data transmitted from a growing number of CIEDs, healthcare providers could be held liable for event notifications and interpretation in the future. If this was to happen, would physicians be as willing to follow patients via remote monitoring? Remote monitoring also brings up patients’ rights issues. Should patients have access to their own data? Should they provide specific consent that information from their device can be used to monitor left atrial pressure and fluid status. Beyond this, another manufacturer has developed a special left atrial pressure sensor that can be used to monitor left atrial pressure and fluid status. It is important to remember that careful follow-up once a patient has a device will have frequently have an impact on their outcomes and quality of life as the initial decision on whether or not to implant the device. Remote monitoring allows more timely identification of problems and this benefit has been noted in numerous studies. In the future, we believe that remote monitoring will become the standard method for follow-up of patients with CIEDs.

Conclusions

Remote monitoring has emerged as a welcomed tool. Patient satisfaction and compliance increase, while use and cost of healthcare decrease. A clinic visit before which a remote transmission has been evaluated means the clinician has more time to focus on pertinent and pressing medical issues. It is important to remember that careful follow-up once a patient has a device will have frequently have an impact on their outcomes and quality of life as the initial decision on whether or not to implant the device. Remote monitoring allows more timely identification of problems and this benefit has been noted in numerous studies. In the future, we believe that remote monitoring will become the standard method for follow-up of patients with CIEDs.

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