Remote Management of Pacemakers and Implantable Defibrillators – Role and Long-term Viability

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Abstract

Modern pacemakers and implantable defibrillators from all major device companies have wireless capabilities that allow them to automatically communicate data to a transmitter unit installed at the patient's home, which then relays the data to a secure database. The data are available for consultation by the physician, who can thereby remotely follow-up and monitor both the patient and the device. There is solid evidence showing that remote device follow-up can safely reduce the number of clinic visits. The strategy is well accepted by patients (with advantages such as a reduction in travel and waiting time) and physicians. The remote monitoring of parameters tracking heart failure, arrhythmias or technical issues has the potential to improve patient safety and outcomes. Secondary endpoints of randomised trials indicate that remote device monitoring may reduce the duration of hospital stays and the number of adverse events such as strokes and inappropriate shocks. Reimbursement of remote device monitoring became available in the US in 2006 and more recently in a few European countries. However, to make remote device management viable in the long term, the issue of reimbursement still needs to be addressed by the healthcare authorities of many countries.

Keywords

Remote device monitoring, telemedicine, implantable cardioverter defibrillator, pacemaker

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Patients using a pacemaker or implantable cardioverter defibrillator (ICD) require regular follow-up to control the performance and remaining longevity of the device. Traditionally, these device checks have been performed manually during a clinic visit using a dedicated device programmer. In 1971, transtelephonic monitoring was introduced to remotely follow up basic parameters (such as battery status) of pacemakers. Many modern pacemakers and ICDs are able to automatically perform technical checks, such as battery status, lead impedance and sensing and pacing thresholds. With the evolution of communication technologies, remote device management has become available which allows the pacemaker or ICD to transmit such information to the physician. Current guidelines stipulate that the patient should be seen in the clinic at least once a year until battery depletion, with remote management being possible after the initial post-operative follow-up.[1]

When talking about remote device management, a distinction should be made between remote follow-up (which involves scheduled automatic device interrogations), remote monitoring (which involves automatic unscheduled transmission of event – e.g., onset of atrial fibrillation – alerts) and patient-initiated interrogations (which are non-scheduled follow-ups initiated manually by the patient).[2] This article aims to briefly overview the current status of remote device management, which is widely implemented in the US (where it is reimbursed since 2006) and increasingly adopted in Europe.[3]

Existing Systems

Most major device manufacturers offer a remote monitoring system (see *Figure 1*), Biotronik being the pioneer in this field. Sorin is in the process of introducing its system, which should be available in Europe in 2012. The various systems function in a similar manner, although they do have technical differences. Older implantable devices require a telemetry wand for manual interrogation by the patient, which is an obvious drawback. Recent implantable devices have an incorporated antenna that allows wireless automatic data transmission to a unit installed at the patient's home without the need for the patient's intervention (other than the correct installation of the system). The data are sent to a secure database server via a landline phone or the global system for mobile (GSM) communications network. A message is then sent by email, short message service (SMS) or fax (depending on the system and its configuration) to the physician, who may then consult the data via a secured Internet access. None of the existing systems currently allow the remote programming of devices.

Evidence of Safety and Efficacy

A recent study reported that 78 % of scheduled in-clinic ICD checks did not involve reprogramming, medication change or any other intervention – and could therefore have been performed remotely.[4] Remote device follow-up allows the number of clinic visits to be reduced safely, which is attractive both from the patient's perspective (less travel and waiting time) and the healthcare provider's

perspective (quicker and more flexible follow-up). In the TRUST trial[5] (ClinicalTrials.gov identifier NCT00336284), 1,339 patients with a single- or dual-chamber ICD were randomised to either three-monthly clinic visits or remote follow-up (with an in-clinic follow-up visit scheduled just after implantation and at 12 months for all patients). There was a 45 % decrease in the number of clinic visits in the remote follow-up group (2.1 per year versus 3.8 per year, p<0.001), without any increase in adverse events. The COMPAS trial[6] (ClinicalTrials.gov identifier NCT00989326) in patients with dual-chamber pacemakers found that home monitoring allowed delaying scheduled clinic visits for as long as 18 months after implantation, without any significant difference in major adverse events compared with routine follow-up.

Remote monitoring has been shown to dramatically reduce the time to detection of events such as arrhythmias and technical issues.[5–7] The remote monitoring of cardiac arrhythmias, heart failure status (through parameters such as heart rate, daily activity, lung fluid, etc.) and device integrity has the potential to improve patient outcomes. Data analysed as secondary endpoints from several trials are encouraging. In the CONNECT trial[7] (ClinicalTrials.gov identifier NCT00402246), which randomised 1,997 patients implanted with dual-chamber or biventricular ICDs to either remote monitoring or clinic visits, there was an 18 % reduction (p=0.002) in the length of cardiovascular hospitalisations in the remote monitoring group. This led to an estimated cost-saving of US$1,793 (95 % confidence interval US$1,644–1,940) per hospitalisation. In the COMPAS trial,[6] patients on home monitoring had a significantly reduced risk of hospitalisation for atrial arrhythmias or stroke (p<0.05). A subanalysis of the ECOST trial[8] (ClinicalTrials.gov identifier NCT00989417) showed that remote monitoring reduced the incidence of inappropriate shocks from 10.4 % to 5.0 % (p=0.03). In the ALTITUDE registry, among 10,272 matched subjects implanted with an ICD or a cardiac resynchronisation therapy device, patients who were on remote monitoring had an approximately 50 % relative reduction of total mortality compared with those on standard care.[9] These data are encouraging, but need to be confirmed by adequately powered randomised trials, several of which are currently under way.[10,11]

Patient Selection for Remote Management

There are currently no guidelines regarding which patients should be followed up by remote device management. Some centres implant all patients with a device equipped with wireless technology, but the common current practice is to choose patients on a case-by-case basis. Travel distance and patient mobility should be considered. Patients who are professionally active or who spend a considerable amount of time travelling are also good candidates. Also, the sickest patients (e.g., those most likely to present arrhythmias or heart failure or who are pacemaker-dependent) are among those who may benefit the most from remote monitoring. Likewise, devices that are most prone to technical issues (e.g., cardiac resynchronisation therapy devices, leads under recall, batteries nearing elective replacement, etc.) are most likely to generate alerts that are of clinical relevance. It is for those reasons that remote device management has been initiated with implantable defibrillators rather than pacemakers, and that many ongoing clinical studies involve patients with cardiac resynchronisation therapy devices. The role of remote device management in patients with a single-chamber pacemaker who are not pacemaker-dependent remains to be determined. Most device clinics follow these patients up once a year in-clinic (the maximal interval according to the current guidelines[1]). However, it is possible that, one day, selected low-risk patients may be followed up remotely for the entire device lifetime.

Figure 1: Existing Remote Device Management Systems from Different Manufacturers

The Biotronik Home Monitoring® system (top left) has a mobile transmitter that patients can carry on them and uses the global system for mobile (GSM) communications network for daily data transmission. The Boston Scientific Latitude™ Patient Management system (top right) has optional wireless weight scales and blood-pressure cuffs; data is sent via a landline phone. The Medtronic CareLink® (bottom left) and St Jude Medical Merlin.net™ (bottom right) systems send data via a landline phone or the GSM communications network.

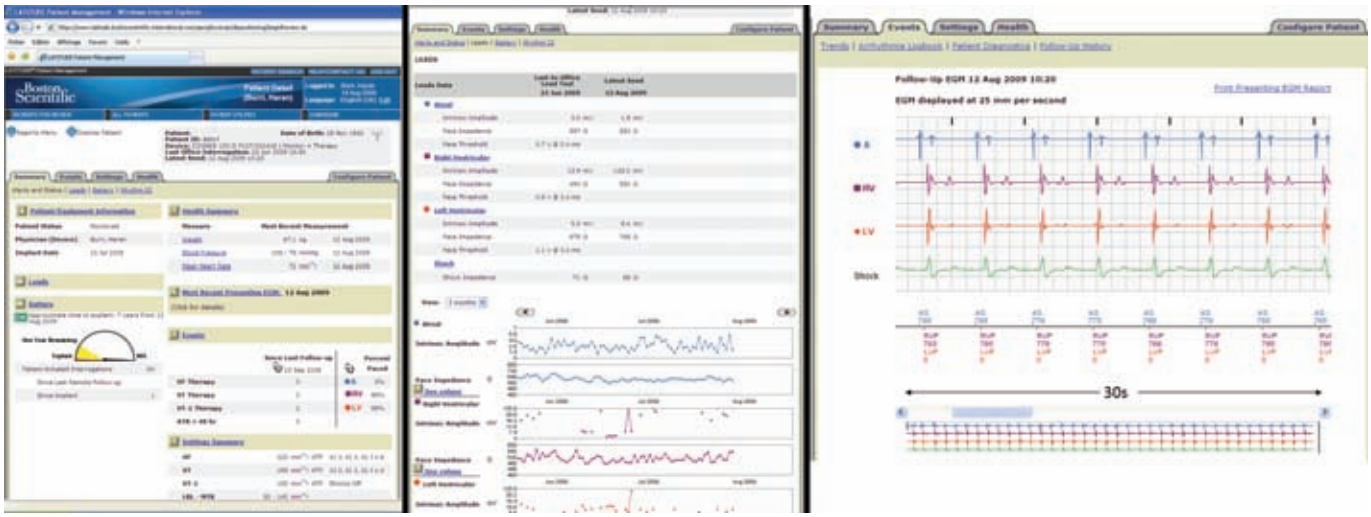
Figure 2: Typical Functioning of a Remote Device Management System

The implanted device communicates wirelessly and automatically with a transmitter installed at the patient's home. Data are transmitted via a landline phone or the global system for mobile communications network to a secure database. The physician is alerted by a short message service, email or fax and can consult the data on a secure webpage. The patient may be contacted by the physician if necessary. Source: Medtronic.

Implications for Workflow

Remote device follow-up has been shown to have a high level of patient satisfaction[12] and has also shown better compliance compared with clinic visits.[5] There is no doubt that remote follow-up can be performed quickly and efficiently by experienced clinic personnel[13] and also that it allows a certain amount of flexibility from an organisational point of view. However, technical troubleshooting, reviewing of alerts and patient contact in response to these alerts may require considerable time and effort. Most centres have a device nurse who periodically logs on to the secure server to perform remote follow-up and deal with the alerts (which may be sent to a dedicated email address). The nurse may triage the alerts (local protocols on how to deal with the different types of alerts are useful in this respect) and thus filter the data that require attention by the physician. In a study of 117 device patients on remote monitoring, a nurse spent

Figure 3: Example of a Remote Device Management System Secure Website (Boston Scientific Latitude™ System)



The panel on the left is a print screen of the overview of the device data and settings. The middle panel gives details of lead measurements and their trends. On the right, a realtime 30 seconds electrogram shows the patient's current rhythm. Source: Boston Scientific.

59 minutes per week screening the messages and a cardiologist spent 12 minutes per week dealing with issues that required attention.[13] It is accepted that remote monitoring is usually only provided during office hours, and patients should be made aware that it does not replace emergency healthcare.[2] Many centres require that patients sign an informed consent form explaining these points.

Economic Aspects

A review of the economic implications of remote device management has been published recently.[14] There is currently a paucity of data on this topic, which means that assumptions have to be made, thus reducing the robustness of economic analyses. Trials are currently under way in Europe which will be useful to make more accurate evaluations of the financial impact of these technologies. The remote follow-up of pacemakers and ICDs has been reimbursed in the US since 2006, in Germany since 2008, and is now also reimbursed in a few other European countries.[2,15] To make remote device management viable in the long term, in addition to the issue of reimbursement, the issue of price premiums to the device companies to cover costs of hardware and servicing also needs to be addressed.

Future Perspectives

There is room for improvement for some systems to avoid recurrent technical issues (mainly related to data transmission) and ease of use (e.g., avoid requiring clinic visits to reset alerts, full online configuration of alert settings, more possibilities of communicating with the patient via the transmitter, etc.). Energy consumption by the system should be minimised to avoid premature battery drain. Daily transmissions by the Biotronik Home Monitoring® system, for instance, only consume the equivalent of a single maximal energy shock over the lifetime of the device, according to the manufacturer. The Medtronic CareLink® system consumes approximately one to two days of device longevity for each transmission,[16] which are therefore usually performed at intervals of several weeks or months. Data transmission by the GSM communications network is usually preferred to landline transmission, and most manufacturers have implemented this in their systems, at least as an option. In order to replace clinic visits, remote management needs to be performed with a device that is able to undertake all routine measurements (e.g., pacing thresholds of all leads, especially of the left ventricular leads) – not all devices currently have this ability.

The direct importation of interrogated data into electronic medical records (EMRs) will be a great asset for staff who perform device follow-up. Even though most systems are Health Level Seven International (HL-7) compatible, few feature software that allows direct importation of data. A common platform that will allow EMRs to import data from all device companies is being developed.

Another aspect is the wealth of data available on remote monitoring databases for conducting clinical research.[9,17] The databases are also likely to prove useful for tracking device performance.

The remote programming of devices, even though technically feasible, has not been implemented so far, mainly for safety reasons. It would nevertheless be useful to be able to adjust device settings remotely in a secure manner.

Conclusions

The remote management of pacemakers and ICDs is preferred to in-clinic follow-up by many patients and physicians. It will be increasingly adopted to deal with the growing number of device patients, and is likely to improve outcomes (although this still needs to be proved by randomised controlled trials). Technological evolution is also likely to further improve the possibilities offered by remote monitoring systems. Finally, the issue of reimbursement needs to be addressed by the healthcare authorities of most European countries, with economic models tailored to local requirements, in order to allow remote device management to be viable in the long term. ■

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