Remote monitoring in implantable defibrillator therapy

D.A.M.J. Theuns, L.J. Jordaens

The major device manufacturers have introduced systems for remote patient monitoring. These remote monitoring systems promise more efficient patient management, especially in today's clinical setting with the growing number of defibrillator implantations. The aim of this article is to present the role of remote patient monitoring in implantable cardioverter-defibrillator follow-up, its potential benefits and its barriers to widespread diffusion. (*Neth Heart J* 2008;16:53-6.)

Keywords: remote monitoring, implantable cardioverter-defibrillator, arrhythmias, heart failure

The rate of implantable cardioverter-defibrillator (ICD) implantation has increased, as the ICD has become part of the standard therapy in patients who are at risk for life-threatening ventricular arrhythmias.^{1,2} The majority of ICD recipients are followed routinely at intervals ranging from three to six months. In addition, a substantial number of patients require additional non-scheduled visits due to arrhythmic events or system-related complications. With the growing number of implantations, the demand for ICD follow-up is pushing clinics to their maximum capacity. The added cardiac resynchronisation therapy (CRT) feature in some devices implies that we are even dealing with more complexity, rendering follow-up a multidisciplinary task. The challenge is to be able to avoid routine ICD follow-up visits, such as the system integrity check and/or the confirmation that no

arrhythmic events or CRT-related issues have occurred. A possibility to meet this challenge is the use of remote monitoring.³ This new technology will cause an imminent change in the clinical practice of cardiac rhythm management. The aim of this article is to present the role of remote patient monitoring in ICD follow-up, its potential benefits and its barriers to widespread diffusion.

Follow-up after ICD implantation

Routine technical follow-up visits are usually scheduled at three-monthly intervals due to safety concerns. These three-monthly intervals were initially intended for manual capacitor reformation. With the feature of automatic capacitor reformation it becomes theoretically possible to increase the follow-up interval. The disadvantage of long intervals is the lack of information on system integrity and the clinical status of the patient. The clustering of system-related complications in the early postoperative period makes a close follow-up schedule mandatory in the first three months after implantation.⁴⁻⁶ However, more than half of all complications may occur at any time during long-term follow-up. Therefore, any extension of the follow-up interval carries a small but definite risk of delayed detection of late system-related complications.

From a clinical point of view, a disadvantage of long intervals can be a delay in the physician's or patient's awareness of changes in the clinical status. As a result, prevention of disease progression and the inherent optimisation of therapy can face a setback, for example in patients who are at high risk of developing heart failure. In spite of a regular follow-up scheme, unscheduled visits will occur to investigate symptoms that may or may not relate to their cardiac disease or device.

Another point of ICD follow-up is the level of ICD follow-up, which can range from routine to complex follow-up. During a routine follow-up visit, the system integrity is checked, the confirmation that no arrhythmic events have occurred and that no medical intervention is required. In contrast, the complex follow-up requires active support by the electrophysiologist, i.e. the patient who experiences multiple

D.A.M.J. Theuns

L.J. Jordaens

Department of Cardiology, Erasmus Medical Centre, Rotterdam, the Netherlands

Correspondence to D.A.M.J. Theuns

Department of Electrophysiology, Bd416, Erasmus Medical Centre, PO Box 2040

3000 CA Rotterdam, the Netherlands

E-mail: d.theuns@erasmusmc.nl

ICD therapy. Given the exponential increase in device implantations and follow-up visits, a possibility to reduce routine follow-up visits is the use of remote monitoring.

History of remote monitoring

Transtelephonic monitoring (TTM) allows diagnostic data to be transmitted via a telephone line to a service centre, which then transfers the data to the physician. In the early 1970s, the concept of TTM was introduced to monitor the longevity of pacemakers.⁷ In the late 1970s and 1980s, the usefulness of TTM as a diagnostic tool expanded to other problems, including sensing, capture, lead malfunction, and arrhythmias.^{8,9} The clinical utility of TTM was confirmed in the 1990s.¹⁰ Transtelephonic ICD interrogation was first reported in the early 1990s by Camm et al.¹¹ Transmitted data included programmed VT/VF detection criteria and therapies, battery status, charge time, episode counter and therapy logs for ventricular arrhythmias. In this study, complete concordance was observed between data obtained by TTM and data obtained during standard follow-up. Transtelephonic monitoring was a useful addition to patient management. However, TTM relies on the active cooperation of the patient, who had to place a special device over his/her pacemaker. This arrangement cannot be expected to work properly for the majority of patients. Therefore, TTM has gained little acceptance in Europe, where distances were less important than in the USA and Canada.

Remote monitoring systems

The remote monitoring systems now available range from techniques requiring the patient's active involvement to systems which deploy wireless data transmission without the patient's active assistance (table 1). Wireless data transmission may enable patient mobility either to a communicator unit hooked up to a mobile phone net or to a fixed telephone network. The data are transmitted either via a service provider or directly to the manufacturer's password secured Internet server. In contrast to TTM, remote monitoring provides an extensive set of diagnostic data, which is stored in the device. Remote device interrogation allows the physician to view and analyse device data. Transmission

includes all data within the device memory, including device parameters, diagnostics, stored arrhythmic events with intracardiac electrograms and a real-time electrogram with the presenting rhythm. In addition, the physicians can specify events which they want to be informed about by fax, email, or SMS. These events are related to the system integrity and arrhythmias.

Remote monitoring and system integrity

For appropriate device therapy, the integrity of the implanted system is essential. Unfortunately, a significant proportion of ICD recipients experience system-related complications. The majority of these complications are lead-related and usually occur within three months after implantation.^{6,12-15} Causes of ICD lead failure are an insulation defect or conductor disruption, which can both affect the high-voltage or the pace-sense circuit of the system. Potential complications of ICD lead failure include oversensing of noise, undersensing of ventricular arrhythmias, inappropriate therapy, and lethal proarrhythmia. However, even during long-term follow-up, system-related complications are encountered.^{12,14,16} For example, the annual failure rate of defibrillation leads will increase progressively with time after implantation and will reach 20% in 10-year-old leads.¹⁶ Early detection of these complications is desirable to ensure the patient's safety. Alert features producing an acoustic warning signal have been implemented in ICDs for detection of system-related complications. Acoustic patient-alert features are a useful additional tool facilitating early detection of system-related complications or battery depletion. However, these acoustic features do not substitute regular ICD follow-up, because of low sensitivity to detect lead failures.^{17,18} Prevailing delayed lead-related complications such as lead fracture and insulation defect are directly related to the lead impedance. As the lead impedance is part of the predefined alerts in remote monitoring, these complications can be detected earlier with remote monitoring than with regular routine follow-up visits.¹⁹⁻²²

Remote monitoring and clinical data

The current generation of ICDs has the capability to track several physiologically diagnostic parameters, such as heart rate, heart rate variability, atrial and

Table 1. Current remote monitoring systems.

		Communicator unit hooked to mobile network	
		No	Yes
Patient actively involved in device interrogation?	No	Boston Scientific Latitude	Biotronik Home Monitoring
	Yes	Medtronic Carelink* St Jude Medical* Housecall Plus*	

* These manufacturers will soon have wireless telemetry transmitting data to the communicator unit.

ventricular tachyarrhythmia recurrence and duration, and patient activity. Studies with remote monitoring demonstrated accurate and comprehensive diagnosis of arrhythmic events.^{19,20,23,24} Varma et al.²³ showed the possibility to detect the onset of atrial fibrillation with daily monitoring data, which can initiate anti-coagulation therapy and/or guide cardioversion. The Home ICD trial demonstrated that remote monitoring resulted in an immediate detection of arrhythmic events, which facilitated an optimised and individualised cardiac rhythm management.²²

The standard of care in heart failure includes cardiac resynchronisation therapy (CRT), which is now considered a Class I indication in patients with drug refractory heart failure.²⁵ It is known that 30% of CRT patients do not respond to this therapy. An indication of progression of heart failure can be reflected by physiological parameters including heart rate, heart rate variability, and recurrent arrhythmias.^{26,27} Analysis of remote monitoring data demonstrated loss of CRT delivery and an increased mean resting heart rate.²⁸ Remote monitoring is of importance in heart failure patients to detect problems early, thereby preventing acute disease progression and expensive hospitalisation. A recent study showed that close monitoring of weight and blood pressure in heart failure patients reduced hospitalisations and mortality.²⁹ The Latitude patient management system (Boston Scientific, St. Paul, MN, USA) can be paired to external devices, such as a weight scale and blood pressure cuff. Recently, intrathoracic impedance monitoring has become available in some devices as an index of congestion and thoracic fluid accumulation secondary to decompensated heart failure.³⁰ Remote monitoring may play an increasingly important role in the future.

Issues of remote monitoring

Remote monitoring is feasible, may facilitate ICD follow-up, and leads to early detection of system-related complications and changes in the patient's clinical status. Despite these beneficial effects, several questions regarding remote monitoring remain. There are issues related to quality assurance as well as medico-legal aspects. Who is qualified to access data obtained from remote monitoring? Should access be allowed to the electrophysiologist only, cardiologists or other physicians, the technician or a specialised nurse, i.e. heart failure nurse? Who is responsible, particularly when there is a delay in observing events, which may lead to adverse outcome? Scheduled clinic visits may prevent this situation, as the physician knows that device interrogation is being performed. Transmitted data should be accessed in a regular timely fashion and responded to if events are observed.

Another issue concerns symptoms or problems reported by the patient but not mirrored by indicators in transmitted data. A possibility to manage this issue is the use of short interviews either by telephone or remote management system.

A problem is reimbursement for the 'virtual' outpatient clinic. Medicare in the United States has recently approved reimbursement for the analysis of remote data if a full interrogation occurred. The available remote monitoring systems are not uniform, so how does a specific code describe the specific employed monitoring system?

Conclusion

Not only the number of ICD implantations is increasing, the patient population is becoming more heterogeneous as well, requiring a differentiated approach to patient management. Some patients have the device as an innocent bystander and need only routine follow-up, while others require a more intensive follow-up. Especially patients with advanced heart failure need comprehensive treatment in addition to device-based therapy. The goal of comprehensive disease management is to monitor closely the clinical status to detect problems early, thereby preventing acute disease progression and expensive hospitalisation. What we see now is the change from cardiac rhythm management by device therapy into cardiac disease management. ■

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