Automatic remote home monitoring of implantable cardioverter defibrillator lead and generator function: a system that tests itself everyday

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The implantation of cardiac electronic devices (CIEDs) has increased exponentially over the last decade in response to widening indications. Assessment of post-implant system performance is an important responsibility but challenging in view of increasing volume, device complexity, and advisory notices. Automatic remote home monitoring (HM) may satisfy these difficult monitoring demands. When tested, HM enhanced the discovery of system issues (even when asymptomatic) and enabled prompt clinical decisions regarding conservative vs. surgical management. This form of remote monitoring may form a device management model in which near-continuous remote surveillance of CIED performance is combined with automatic self-declaration of system problems, enabling prompt medical decisions. The ability to collect detailed device-specific data, with component function assessed daily, sets a precedent for longitudinal evaluation of lead and generator performance. These characteristics have significant ramifications for CIEDs in general and patient safety.

Keywords
- Defibrillators
- Monitoring
- Follow-up
- Remote monitoring

Introduction

The implantation of cardiac electronic devices (CIEDs) has increased exponentially over the last decade in response to widening indications. Compromised CIED system (generator/lead) integrity demands prompt evaluation. Its discovery requires rigorous post-implant monitoring. This is a physician responsibility expressed in several position statements and consensus recommendations and now also often demanded by patients.1-3 The task is daunting in view of increasing volume and complexity of implantable devices, and added burdens imposed by advisory notices. (Fortunately, current era CIEDs are exceptionally reliable, and component failure is infrequent. In relative terms, leads represent the weak link.) Conventionally, patients are seen regularly according to calendar-based schedules [e.g. 3 monthly for implantable cardioverter defibrillators (ICDs)/cardiac resynchronization therapies]. However, this method will miss potentially serious problems occurring between interrogations, which is when they are most likely to occur.

Remote monitoring of patients with implantable devices promises resolution of some of these challenges. This rationale underpinned announcements from professional societies for ‘development and utilization of wireless and remote monitoring technologies’, carrying the expectation of early detection and correction of device malfunction.1-3 However, ‘early’—especially important in an era of multiple advisories—remains undefined. Expectations are for as soon as possible, but the capability of remote monitoring to deliver this function may extend from months to minutes, according to the system selected.4-5 For example, inductive (wand-based) systems depend on patient (and hospital) adherence to scheduled follow-ups (e.g. 3 monthly) which is erratic, and continue to fail to disclose asymptomatic interim problems.6-7 This is not acceptable as an early warning system.

Automatic wireless transmission technologies potentially overcome several of these obstacles. Changes in device (or patient) condition can be notified almost immediately.4 This form of advanced remote monitoring system, pioneered by Biotronik with Home Monitoring™ (HM), effectively provides near-continuous surveillance without patient participation, enabling both detection of asymptomatic events and cataloguing performance history on remote servers. Diagnostic ability may be aided by automatically wirelessly transmitted electrograms (e.g. Figure 1). Daily transmissions generate high-resolution parameter trending and enable assessment of changes
that are significant. For example, with a sudden change in lead impedance of an ICD lead under Class 1 recall, absolute value remained within specifications, but deviation from historical trend triggered event notification (Figure 2). The combination of two or more parameter deviations, as illustrated, may improve specificity of the alert, e.g. linking of non-sustained ventricular tachycardia (VT) events to an impedance deviation improved detection of lead failure. These processes, individualized in each patient, improve the value of alerts received.

This automatic daily surveillance technology which self-declares significant problems as and when they occur, even when the patient is unaware of them, has obvious application to monitoring CIED function. Several short reports support this. For example, failure of an ICD to properly charge its capacitors and deliver appropriate therapy, inappropriate VT detection caused by supraventricular tachycardia (VT) events to an impedance deviation improved detection of lead failure. These processes, individualized in each patient, improve the value of alerts received.

The utility of remote device management illustrated by these earlier reports was confirmed prospectively in the randomized TRUST trial, which tested the hypothesis that HM would be superior to conventional care for surveillance of system integrity and function, and that device initiated event notifications would enable early detection of ICD dysfunction as called for in societies’ statements. Since HM had demonstrated high fidelity transmission with virtually immediate notification ability in pilot studies, TRUST also tested whether early detection could be achieved the ‘same day’ in real-world practice. The results were revealing. Although the number of patients developing problems were equal in both study arms, expected in a large well-randomized trial, the number of detections of ICD system dysfunction were greater with HM. Conventional monitoring grossly under-reported occurrence of ICD dysfunction, and this loss progressively enlarged with time (Figure 3). Notably, 47% of all detected events were asymptomatic—such clinically silent events would have remained undiscovered with conventional care until next in-person evaluation, possibly several months distant to time of occurrence. The capacity for early detection with HM was examined in detail. The majority (51%) of events were detected the same day, even when asymptomatic. Lapses (i.e. discovery >24 h) likely resulted from delays by handling facilities, i.e. although remote monitoring provides a considerable advance over conventional in-person evaluations, early reaction ability nevertheless demands consistent...
The clinical merits of early detection with automatic remote HM for patient and device care are significant. These included prompt decision making and intervention, e.g. surgically for lead failure, or conservatively with reprogramming to prevent potential inappropriate therapies (Figures 1 and 2). Reprogramming changes accounted for the majority of ‘actionable’ interrogations in the TRUST trial. This is important since programming may directly affect mortality. Hence, early notification of a need to optimize programming in any particular patient (which is likely to change during device lifetime) may be beneficial. The non-sustained ventricular arrhythmia notification may be triggered by system issues such as lead electrical noise artefacts caused by fracture or non-physiological electrical signals, and direct intervention to pre-empt shock delivery and reduce patient morbidity. Interruption of repeated charge cycles which occur in a significant minority of ICD patients is important to prevent early battery exhaustion. In the multicentre ECOST trial, clinical reactions enabled by early detection resulted in a large reduction in the number of actually delivered shocks (72%), the number of charged shocks (76%), the rate of inappropriate shocks (52%), and at the same time exerting a favourable impact on battery longevity. These advantages are especially apparent in those in whom conventional follow-up is challenging, e.g. children.

Advisories

Automatic remote monitoring may facilitate management of advisories. These largely encompass disintegration of high-voltage circuitry, battery depletion, and lead failure, which are captured by currently evaluated event triggers. Intensifying surveillance with conventional detection methods, such as increasing the frequency of office visits, e.g. monthly, are impractical, onerous, and inefficient since problem incidence is low and this schedule is likely to miss dangerous interim problems. Patient alert mechanism such as beeps, are insensitive and prone to false-positive evaluations. In contrast, HM generators trigger immediate alerts on deviation from established trends. This reduces burden both for patients to monitor their own devices frequently and for clinics responsible for large populations with a low incidence of typically silent problems. Identification of the small number of affected devices may permit elective replacement of these few and avoid unnecessary large-scale elective replacement. Continuous monitoring may aid balanced management decisions since a similar malfunction may confer different risks in different patients. For example,

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**Figure 2** Implantable cardioverter defibrillator generator with automatic wireless remote monitoring coupled to a Fidelis (MDT 6949) lead. Two event notifications that were transmitted immediately on occurrence of lead fracture, occurring silently during sleep at 4:43 am, 6 weeks after last clinic follow-up on November 14. Left: Two occurrences of detection in VF zone are noted (top) and flagged (red exclamation mark on yellow background). The accompanying wirelessly transmitted electrogram demonstrated irregular sensed events (markers indicate coupling intervals as short as 78 ms) with VF detection (marked). No therapy was delivered indicating spontaneous event termination. Right: The second event report is a separate notification in response to the same event indicating a lead impedance alert. Lead impedance trend had been stable below 600 Ω in prior weeks, but then suddenly increased > 500 Ω triggering an event notification (red dot) although this absolute value was still within specifications. Electrogram definition was modest in first-generation device with wireless intracardiac electrogram transmission (Lumos). Current generation devices transmit electrograms with improved resolution (1/128 s) and longer duration including post-detection sequences (e.g. Figure 1). (Compiled with permission from Varma.) The clinic received these notices and informed the patient who was then reviewed urgently within 24 h and treated with lead extraction and replacement. The case demonstrates the value of remote monitoring with daily automatic surveillance and rapid, automatic (i.e. without patient participation) event notification to the clinic of fault detection which enabled prompt intervention. Without automatic wireless remote monitoring, presentation may have occurred later with inappropriate shocks or catastrophically with failure of pacing or VF sensing.
immediate replacement of a lead under advisory may be unnecessary in patients who are not pacemaker-dependent. Hence, remote management has the potential to diminish morbidity/mortality, and reduce associated hospital admissions with significant implications for cost reduction. This ability may depend on the type of problem. For example, one-third of patients with Fidelis lead failure receive inappropriate shocks within 3 h, the time between the occurrence of event and patient morbidity. This may be too short to permit intervention.\textsuperscript{23} The warning may be advanced by integrating automated safety surveillance systems into remote monitoring databases.\textsuperscript{25} Future technology may incorporate an ability to adjust programming to respond to failures detected during monitoring. Other significant lead problems may occur without deviation of any electrical parameters.\textsuperscript{26}

**Databasing**

Automatic warehousing of performance data retrieved daily from large and complete patient cohorts (without errors associated with manual data entry) permits long-term longitudinal evaluation of system survival. This provides not only a mechanism to rapidly identify individuals who develop out-of-bounds values, but also an opportunity to define standards of performance for device components and function.\textsuperscript{27,28} In comparison, other available techniques have significant limitations. For example, device function has been determined during sporadic conventional in-person follow-up and symptomatic patient presentation, or analysis of voluntary return of products which is vulnerable to reporting bias.\textsuperscript{29} These lead to inconsistent results. For example, 5-year lead malfunction rates varied sharply from 2.5 to 15% in different studies.\textsuperscript{30,31} Even when a single component is being tracked (e.g. the Fidelis lead\textsuperscript{32}) there is variation in incidence of failure among different reports. Definitions of failure themselves are inconsistent. In one study,\textsuperscript{30} problems were discovered during routine face-to-face follow-up and reprogramming changes without surgical intervention were included in the ‘failure’ rate. In contrast, in another study 76% of lead malfunction came to clinical attention because of inappropriate ICD therapies and the
need for surgical revision defined failure. Both reports may underestimate the true incidence of lead failure if malfunctions are asymptomatic, occur intermittently, or result in death (only a minority of devices are interrogated post-mortem). Hence, non-compulsory follow-up methods generate inaccuracies and may undermine the important task of ICD component surveillance and assessment of reliability. In contrast, continuous remote monitoring, as currently described, represents a more comprehensive evaluation mechanism, working independently of symptoms or follow-up schedule, and permitting application of uniform definitions for out-of-range behaviour.

There are limitations. It is important to note that HM does not supplant the first post-implant in-person evaluation, important for assessment of wound healing, determination of chronic thresholds, and setting of final pacing parameters. Problems such as lead perforations or failures requiring revision and symptomatic reactions to implantation (e.g. pacemaker syndrome, diaphragmatic pacing, and pocket infection) cluster in this early post-implant. They occur more frequently with dual-chamber or resynchronization units. However, subsequent to this mandatory initial in-person evaluation, HM surveillance was demonstrated to be superior to regular office checks in the TRUST study. These results described with HM, which has excellent transmission reliability, may not be extrapolated readily to all proprietary technologies. Thus, in the CONNECT trial, which was structured similarly to TRUST but used a different remote wireless technology, a large proportion of attempted transmissions simply failed. When alert transmissions for some conditions were successful, manual reset was required to reactivate this notification ability, i.e. the ability for further notification in the interim was lost until an otherwise unnecessary in-person encounter could be arranged. This design, depending on patient interaction and single transmissions vulnerable to failure, limits its role as an early warning mechanism.

In summary, recent results indicate that HM is a stringent method of post-implant ICD evaluation in which system components are tested, reported, and databased daily. Warehousing of collected data in his fashion will permit characterization of device behaviour, determination of reliability, and definitions of abnormality. Certain points require emphasis. The technology is automatic and maintains high-intensity vigilance without the need for patient interaction, and pre-specified ‘out-of-bounds’ conditions are flagged for attention, enabling same day discovery (irrespective of follow-up schedule). Asymptomatic issues are covered equally well. With regards to the denominator, the very high reliability of implanted systems is to be appreciated since dysfunction is infrequent, but this makes the task of identifying these few especially challenging. However, remote monitoring as described, directs virtually immediate attention to patients developing problems, as and when they occur, thus effective-ly finding the proverbial needle in the haystack, a task beyond conventional means. In practice, this ability may be influenced by engineering differences, transmission frequency, methods of alert notification, and handling by receiving facilities.

In conclusion, automatic continuous remote monitoring represents an early warning system which can provide assurance to both patients and their physicians.

Conflict of interest: N.V.: Modest—Biotronik, Boston Scientific, Medtronic, St Jude Medical. Chair and PI of the TRUST trial; member ALTITUDE Steering Committee.

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