RESEARCH ARTICLE

Automatic Remote Monitoring of Implantable Cardiac Devices in Heart Failure: the TRUST Trial

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ABSTRACT. Cardiac implantable electronic devices are increasing in prevalence. Post-implant follow-up is important for monitoring both device function and patient condition. However, practice is inconsistent. For example, implantable cardiac device follow-up schedules vary, e.g. from 3-monthly to yearly according to facility and physician preference and availability of resources. Importantly, no surveillance occurs between follow-up visits. In contrast, implantable devices with automatic remote monitoring capability provide a means for performing constant surveillance, with the ability to identify salient problems rapidly. Recent trials demonstrated that remote home monitoring reduced clinic burden and permitted early detection of patient and/or system problems, i.e. enabling efficient monitoring and an opportunity to enhance patient safety. This has significant implications for management of patients receiving all forms of cardiac implantable electronic devices.

KEYWORDS. cardiac implantable electronic devices, early detection, follow-up, ICD, recall management, remote monitoring.

Introduction

The implantation of cardiac electronic devices has increased exponentially over the last decade in response to widening indications.1 Subsequent monitoring is an integral part of both device and patient but remains unguided by any prospectively derived data. Consensus suggests that patients with implantable cardiac devices (ICDs) should report for routine face-to-face clinic checks every 3–6 months. This generates a huge clinical burden.2 Symptomatic events (e.g. shock therapy) prompt additional encounters including unscheduled office/emergency room (ER) visits or even hospitalization. The volume of unscheduled encounters periodically increases, for example, when a device reaches elective replacement indicator or in response to product advisories. A major limitation of this conventional follow-up method based on patient presentation is that there is no monitoring at other times, i.e. the majority of the time. Hence, important diagnostic data such as system problems and onset of atrial fibrillation (AF), particularly if asymptomatic, may remain concealed for extended periods. Remote monitoring may be a mechanism for performing intensive device surveillance and reporting important information rapidly, without over-burdening device clinics.

Remote monitoring

Available technologies have different operating philosophies. Wand-based systems require patient-driven downloads relayed via telephone connections to following facilities.3,4 This time-consuming process may be cumbersome to use, challenges compliance, and remains vulnerable to overlooking asymptomatic events. This technology may fail to reduce cardiac-related resource utilization.5 In contrast, an automatic transmission mechanism fully independent of patient or physician interaction has considerable advantages. It implements the use of automatic (wireless or landline-based) data transmissions, which may be reviewed securely via the internet (Figure 1). This form of technology was pioneered by Biotronik (Berlin, Germany; home monitoring: HM, FDA approved 2002). Reliability, data fidelity, and early notification ability of this communication system were excellent.6 System operation is not energy costly. Remote monitoring with instantaneous event transmission, without any patient or nurse involvement, has the ability to maintain surveillance and rapidly bring to attention
significant data, enabling clinically appropriate intervention. This capability has been tested in recent trials.

The TRUST (The Lumos-T Safely Reduces Routine Office Device Follow-Up) trial has been the only published prospective multicenter clinical study to assess follow-up, both conventionally and with remote monitoring using HM.7,8 Patients (1,516) enrolled at 105 US sites were randomized to conventional care (HM off) or to remote monitoring (HM on) groups (Figure 2). The results demonstrated that:

- HM reduced healthcare utilization by approximately 50% as measured by the total of scheduled and unscheduled (ER visits, patient- or physician-initiated checks) hospital evaluations. This is because the bulk of scheduled encounters involve collection of routine measurements only (e.g. battery status, lead impedance, and sensing function) requiring no clinical intervention (reprogramming, alteration of antiarrhythmic medications), and may be performed by online data review.

**Figure 1:** Home monitoring technology.

**Top:** Transmission steps. A very low-power radiofrequency transmitter circuitry is integrated within the pulse generator, wirelessly transmitting stored data on a daily basis to a mobile communicator (typically placed bedside at night). The data are relayed wirelessly or via landline (automatically seeking the first path available) to a service center. The wireless transmission ability is especially useful as almost 20% (and increasing) of US households are currently estimated to have no landline facility. The service center receives incoming data and generates a customized summary (Cardioreport) available to the physician online via secure internet access. Thus, daily patient monitoring occurs with trend analysis information of typical follow-up data, e.g. battery status, lead impedance, and sensing function. Service center processing and data upload on the home monitoring (HM) webpage is automatic, bypassing potential delays (and errors) associated with manual processing. Critical event data may be transmitted immediately and flagged for attention on the HM webpage (see also Figure 2). Automatic alerts occur for silent but potentially dangerous events and include transmission of intracardiac electrograms (EGM-Online snapshots) similar to those available during office device interrogations. This provides the ability for early detection enabling prompt clinical intervention if necessary (compiled with permission from7).

**Bottom Left:** A feasibility study demonstrated that >90% of transmissions were received in <5 min with 100% preservation of data integrity (compiled with permission from6).

**Bottom Right:** Event notifications are programmable according to need, and reprogramming may be performed online without the need for patient attendance. For example, if atrial fibrillation becomes permanent, then this feature may be disabled, preventing unnecessary daily notifications. Although an event notification may be potentially triggered every day, in practice such messages occurred infrequently.32,33
Importantly, the reduction in face-to-face visits was accomplished safely, as there were no differences between the two study arms for death, incidence of strokes, and events requiring surgical interventions (e.g. device explants or lead revision).

HM permitted earlier detection and physician evaluation (median, 3 days) of cardiac and/or device problems (despite fewer face-to-face encounters) compared to 1 month with conventional care.

HM secured greater follow-up adherence to 3-monthly calendar-based checks. This is presumably because patient data may be monitored remotely anytime and from anywhere, as opposed to the conventional arm, which relies on patients to present themselves physically at their physician's office.

These results indicate that remote monitoring may be adopted as an instrument for device management performing intensive surveillance, substituting for in-office follow-up but also fulfilling the important role of a mechanism for early detection. Management of unscheduled checks may be also facilitated. For example, with patient inquiries, shock data and online electrogram are available and may be used to determine best management confidently. An appropriate shock may require reassurance only without the need for a hospital visit. In contrast, a series of inappropriate shocks may be rapidly evaluated online and the patient would be asked to come in to the hospital promptly. The capacity for early detection is exceptionally valuable for detection of silent events. Potentially dangerous asymptomatic events that typically remain concealed in diagnostic memory and manifest only at formal interrogation may be revealed within hours by automatic HM and direct clinical intervention\(^6,9,10\) (\textit{Figures 3 and 4}).

The TRUST management protocol received FDA approval in May 2009 and has been adopted by several large volume centers. (The follow-up scheme described

\begin{figure}
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\includegraphics[width=\textwidth]{TRUSTStudyDesign.png}
\caption{The TRUST Trial.}
\end{figure}

\textbf{Top}: After randomization, all implantable cardiac device (ICD) patients had scheduled follow-ups at 3, 6, 9, 12 and 15 months post implant, and unscheduled (interim) evaluations as needed. Patients in conventional care were evaluated in-hospital only. Home monitoring (HM) patients had HM checks followed by office visits at 3 and 15 months. At 6, 9, and 12 months and for interim visits, data were remotely retrieved and evaluated. Between these periodic checks, automatic event notifications were evaluated online, and patients were brought in for office visits if deemed necessary by the investigator.

\textbf{Bottom Left}: HM reduced cardiac-resource utilization, i.e. scheduled and unscheduled clinic and hospital visits (including responses to HM event notifications), were reduced by 45% in 1 year.

\textbf{Bottom Right}: Time to physician evaluation of arrhythmias was <48 h in HM, including silent events (compiled from\(^8\)).
is for device management and not intended to replace consultations with internists, cardiologists, or heart failure [HF] specialists, which may otherwise occur.) Reimbursement guidelines were instituted in January 2009 in the USA by the Centers for Medicare and Medicaid Services. Three-monthly checks performed remotely are reimbursed. Between these, additional remote interrogations performed within the 90-day “global period” are only reimbursed if the evaluation prompted an in-office evaluation and device reprogramming.

Emerging applications

Lead and device performance

Assessment of post-implant system performance is an important responsibility, but challenging in view of increasing volume, device complexity, and advisory notices. Management of components under advisory notices poses several daunting challenges. Intensive monitoring by increasing office visits (e.g. monthly) is impractical, onerous, and inefficient (as problem
incidence is very low), and is likely to fail to detect potentially catastrophic problems occurring between interrogations. Remote monitoring systems relying on patient-driven communication may be similarly limited in ability to detect asymptomatic failure.

In contrast, HM technology, which provides constant surveillance of system integrity with automatic alerts, eliminates the burden of patients having to monitor their own devices frequently and coordinate with clinic services. TRUST demonstrated that conventional monitoring methods under-reported device-related problems. HM, in contrast, enhanced discovery of system issues (even when asymptomatic) and enabled prompt clinical decisions regarding conservative versus surgical management. Performance problems were often asymptomatic. Figure 3 illustrates the benefit of HM in the management of recalled components.

Thus, the call for intensive and comprehensive monitoring of implantable devices may be met by remote monitoring technology. The ability to collect detailed device-specific data, with component function assessed daily and automatic archiving, sets a precedent for longitudinal evaluation of lead and generator performance.

**Monitoring disease progression**

Recipients of ICD therapy commonly have HF, which is a dynamic condition. Hospitalizations for acute decompensated heart failure (ADHF) have more than doubled in the last 20 years, and continue to increase. Rehospitalization is an independent predictor of 1-year mortality, especially in elderly patients, with significant fiscal repercussions for health-care services.

The development of ADHF is complex, involving several processes (e.g. hemodynamic, neurohumoral, electrophysiological, and vascular abnormalities) that converge to manifest with fluid congestion. After hospitalization, management is directed to identification and correction of precipitating factors and comorbidities, and management of fluid overload, arrhythmias, and any conduction system problems. Therapeutic strategies aimed at interrupting this train of events are potentially valuable. This may be possible as, in most cases, pathophysiologic processes progress over days to weeks prior to clinical presentation with a fluid-overloaded state. However, the initial inciting event(s) are varied and their early detection challenging as they...
are generally asymptomatic. Implantable devices that collect, quantify, and trend important data may permit identification of upstream factors, triggering HF deterioration, and facilitate diagnosis and direct appropriate treatment. Figure 4 illustrates how the interplay of asymptomatic events (AF and lack of biventricular pacing in this case) contributed to HF decompensation, and also the length of time taken from inciting events to clinical presentation.

As HF precipitants act to produce fluid congestion, which ultimately is the basis of clinical presentation with dyspnea or peripheral edema, attention has centered on identifying fluid excess itself. Intrathoracic impedance (illustrated in Figure 4) correlated inversely with pulmonary capillary wedge pressures21 and began to change approximately 2 weeks before hospitalization for ADHF. Early action taken in response to such data tended to reduce HF hospitalizations.20 Further developments include miniature fully implantable devices for pulmonary artery pressure monitoring,21 direct left atrial pressure monitoring,22 and impedance vectors employing a left ventricular lead only.22 To be effective, these sensors need to have a high predictive value for ADHF requiring hospitalization, and also enable implementation of a treatment algorithm that may prevent hospitalization. Application of stand-alone technology for long-term management of a large number of patients with HF in whom conventional devices are not currently indicated requires prospective evaluation.

All pre-emptive strategies designed to prevent ADHF hinge on early evaluation of deviation of studied parameter(s) from baseline values. Problem detection by an implanted device without concomitant physician notification is ineffective for enabling early therapeutic intervention. Intensive patient surveillance with increased frequency of physician–patient face-to-face encounters is generally not feasible, and in any case no monitoring takes place between hospital visits, i.e. most of the time. In this regard, the results of TRUST are important. TRUST demonstrated that remote monitoring may be adopted as an instrument for efficient management of a large patient volume with implanted devices, performing intensive surveillance and reducing unnecessary routine evaluation, while acting as an early detection mechanism to enable earlier evaluations of patients when necessary. These characteristics are suited to managing HF patients. The ability to generate individually based parameter trends and self-declare out-of-range asymptomatic events is critical to allow timely intervention. For instance, as illustrated in Figure 4, notification of AF, loss of cardiac resynchronization therapy (CRT), and deviation of fluid sensor index all occurred asymptotically well in advance of ADHF presentation. All would have flagged immediate event notifications if the implanted device had been equipped with an automatic remote monitoring mechanism and had enabled early pre-emptive therapy. Alternatively, following physicians may have reviewed and quantified trended data in these higher-risk patients and identified important deviations of single or combined trends.10 Thus, remote monitoring may be the instrument to provide sentinel notification of conditions leading to decompensation and thus prompt rapid pre-emptive therapy to prevent hospitalizations. This is being assessed in prospective studies.24

**Arrhythmias**

AF in HF patients may be associated with increased morbidity and mortality.25,26 This is likely to be multifactorial, involving increased risk of stroke and of HF (Figure 4). Rapid ventricular conduction may diminish the intended beneficial effect of CRT (reduced when pacing is diminished to <92%,27) and also lead to inappropriate therapy. AF facilitates ventricular arrhythmias, and prompt termination of atrial tachyarrhythmia was found to significantly delay the time to the next episode of ventricular tachycardia (VT)/ventricular fibrillation (VF).28 Early treatment of AF may be beneficial but is difficult because most AF is clinically silent. However, early detection of AF by HM was demonstrated in the TRUST trial (Figure 2). Automatic databasing permits evaluation of AF burden and frequency of episodes (Figure 5), which may have a bearing on risks posed by this arrhythmia. Non-sustained VT may indicate future sustained therapy, which may result in shock delivery.9 This is important because emerging data indicate that shock delivery may have deleterious long-term consequences.29,30 Minimizing inappropriate therapy by early identification of atrial arrhythmias and non-sustained ventricular arrhythmias, and maximizing appropriate therapy by evaluating efficacy of drugs and other treatments are important potential benefits of remote monitoring.6,9

**Future**

Remote monitoring provides the mechanism for accessing and delivering prioritized data collected by increasingly sophisticated implantable units. Access to internet-based information systems provides a framework for multidisciplinary communication and collaboration, such as electrophysiologists monitoring device function (e.g. arrhythmias, paced burden) and HF experts assessing diagnostic information regarding HF. Information sharing and multidisciplinary effort aided patient care when applied to a CRT optimization clinic.31 This practice may be facilitated by remote monitoring interfacing with electronic medical records, thus placing all relevant data in a single central database accessible by all treating physicians.

In summary, automatic remote HM fulfills the aims of post-implant device management. TRUST presents a device management model in which near continuous remote surveillance maintains continuity of follow-up and combines with automatic self-declaration of problems, identifying the exceptional group of patients requiring in-clinic attention. Thus, unnecessary in-office follow-up is avoided, and necessary face-to-face encounters facilitated. This reduces clinic load for the physician but permits earlier attention to actionable events. Patient
safety and convenience are improved. Automatic data archiving provides a resource for monitoring system performance and disease progression. In congestive HF patients, there is high value to a mechanism providing early identification of problems that could, if managed expeditiously, prevent patient morbidity and hospitalization. The characteristics of remote HM demonstrated in the TRUST trial have significant ramifications for cardiac implantable electronic devices in general and patient care.

References


