Recommendations for post-implant monitoring of patients with cardiovascular implantable electronic devices: where do we stand today?

Niraj Varma¹* and Angelo Auricchio²

¹Cleveland Clinic (NV), Cleveland, OH, USA; and ²Clinical Electrophysiology Unit, Fondazione Cardiocentro Ticino, Lugano, Switzerland

Received 25 March 2013; accepted after revision 29 March 2013

The 2008 Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA) consensus document advocated the necessity of monitoring both device function and patient condition post-implantation of a cardiovascular implantable electronic device (CIED). It recommended a regular calendar-based system of follow-up, but lacked supporting data.¹ While generating a huge service commitment, the efficacy of this schedule with regard to patient safety, adherence, incidence of unscheduled encounters, and ability for problem detection were unknown at the time of publication. Furthermore, although follow-up could be accomplished by ‘in person or remote’ methods, the comparative efficacy of these respective techniques in achieving follow-up goals had remained untested until recently. Over the last few years large-scale prospective trials have addressed these questions. These are reviewed by Guedon et al.² and the results have been revealing. Moreover, based on such recent evidence, the 2012 EHRA/HRS consensus document has strongly advocated for the use of remote monitoring in patients with cardiac resynchronization therapy (CRT).³

Firstly, replacement of scheduled in-person evaluation with remote follow-up was tested. The underlying concept was that the bulk of conventional in-person scheduled evaluations do not trigger any changes in patient management, i.e. are ‘non-actionable’, and hence could be supplanted with remote follow-up.⁴ When tested, these theories were confirmed in patient populations implanted with pacemakers, implantable cardioverter defibrillators (ICDs), and CRTs.⁵–⁷ For example, TRUST results confirmed that actionability of 3 monthly (3, 6, 9, and 12 month) scheduled calendar-based checks (whether conventionally or remotely managed) was low (<10%), thus replaceable with remote checks only.⁵ This generated a massive reduction in scheduled follow-up load, with implications for clinic workload and patient convenience. (This may represent one end of the spectrum since most implants in TRUST were for prophylactic indications: actionability may be higher in clinical heart failure patients with CRT devices). Although post-implantation follow-up times were relatively short (15 months in TRUST, 24 months in ECOST⁸), the results have implications for subsequent years to the end of the device service life, when frequency of visits typically increases as a device nears its elective replacement window (which occurs variably and unpredictably) or when lead parameters attract increased vigilance. However, solid demonstration of long-term benefits of remote monitoring, beyond 2–3 years of follow-up, in different patient populations is greatly needed. Of note, the frequency of scheduled follow-up can be flexible, increasing during some periods to monitor response to changes in programming or medical therapies, e.g. for atrial fibrillation. Many of these duties may be accomplished remotely. Thus, the already significant reduction in clinic-based follow-up observed in the trials may underestimate advantages that may be observed in actual practice.

These trials were also the first to measure incidence of unscheduled encounters. This is an important factor, though not directly addressed in the consensus recommendations. Unscheduled evaluations are either patient-driven or physician-driven – in either case signifying a concern – and result in unscheduled office/emergency room visits or even hospitalization. These unplanned encounters further stress an already saturated clinic-based follow-up system by taking more time for the investigation of the root cause and requiring more dedicated personnel to solve the potential issue.⁹ Therefore, the possible and partial conversion of emergent unscheduled encounters into encounters scheduled at short notice improves workflow and patient planning. The trials indicated that the absolute incidence of unscheduled in-person evaluations remained low, even during remote management, i.e. remote care did not generate increased anxiety. In fact, remote management has significant advantages in this situation, e.g. in-patients who receive shock therapy, treatment (or not) may be determined by transmitted data and event electrograms without the need for a hospital visit. When inclusive of all patient encounters (i.e. scheduled and unscheduled), health care utilization was diminished by ~50% with remote management, representing a dramatic reduction in service burden.
Importantly, the extension of face-to-face interaction to yearly was safe. This was a critical endpoint. Studies showed that over a follow-up period of 18–24-month remote management did not result in an increase of the incidence of major adverse events such as death, incidence of stroke, and events requiring cardiac surgical interventions (e.g., device explantations or lead revision), and could possibly be reduced. This may be because although in-person evaluations were reduced, adherence to follow-up was improved. This seemingly paradoxical result resolves the existing concern that remote management may cause patient attrition.

A critical result common to all the reviewed studies was that the deliberate reduction in scheduled face-to-face encounters did not diminish the ability for problem discovery. Rather, the opposite occurred. Remote care promoted early detection of conditions such as arrhythmias or system issues. This ability for near continuous monitoring extends its role beyond simple replacement of scheduled follow-up interrogations, and with these data comes the realization that the scope of remote management is much wider than originally imagined. The ability to reveal diagnostic data (regarding device components or comorbidities) on the same day that they occur is a huge advantage over conventional follow-up when these may remain concealed in-between scheduled office device interrogations for extended periods. Thus, remote management provides the desirable combination of performing intensive device surveillance but reducing device clinic workload. Preliminary data indicate that action taken on early notifications reduced hospital stay for heart failure in one of the first remote monitoring studies to include CRTs and reduced shocks (appropriate and inappropriate) leading to preservation of battery life. Merely being networked may confer a survival advantage. It is important to appreciate that these results cannot be extended to non-implantable remote management methods, or even to all implantable systems. Thus, patient activated (‘inductive’) systems substitute for conventional in-person evaluation but are vulnerable to non-compliance and can generate huge service burdens without providing early detection ability. These are now essentially obsolete.

The accumulating evidence that outcomes are better with remote management compared with standard in-clinic follow-up, and the long distances that some patients have to travel in many parts of North America, have resulted in a large acceptance of remote monitoring in the USA; the widespread use of the technology is particularly high and facilitated by the availability of reimbursement for remote follow-up. In contrast, remote patient management has a highly variable penetration in Europe, due to a number of factors including lack of recommendation in clinical practice guidelines of the European Society of Cardiology, insufficient support of telecommunication technology, but mostly due to the great variation in reimbursement systems among European countries. The latter issue has been addressed by an economic analysis conducted by EHRA and Eucomed, the European Medical Technology Industry Association, resulting in the publication of concrete recommendations for country-level reimbursement of CIED remote monitoring.

**Conclusion**

Recent results from several large prospective trials show safety and efficacy of remote patient management. Automatic home monitoring ensured continuity of follow-up of a large patient volume, avoided unnecessary in-hospital patient evaluation (massively reducing clinic load with associated productivity gains) yet improved adherence to the proposed calendar-based protocol of scheduled follow-up, and maintained near-continuous surveillance to rapidly identify patients requiring attention. The level of evidence to support remote monitoring for this role is very strong – consistent results from large randomized prospective trials in pacemakers, ICDs, CRTs from different manufacturers and conducted in different countries. An important finding was that, when directly compared, the performance of automatic remote monitoring was stronger than conventional methods for achieving goals of follow-up, forcing a re-evaluation of the traditional gold standard of in-person evaluation.

This is a significant landmark and merits incorporation into statements and guidelines from professional organizations to establish automatic remote home monitoring as a new standard of care.

**References**

1. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM et al. HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations: developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. Europace 2008;10:707–25.


