

Remote monitoring of cardiac implantable electronic devices in Europe: results of the European Heart Rhythm Association survey

Antonio Hernández-Madrid^{1*}, Thorsten Lewalter², Alessandro Proclemer³, Laurent Pison⁴, Gregory Y.H. Lip⁵, and Carina Blomstrom-Lundqvist⁶, conducted by the Scientific Initiatives Committee, European Heart Rhythm Association

¹Cardiology Department, Ramón y Cajal Hospital, Carretera Colmenar Viejo, km 9, 100, 28034 Madrid, Spain; ²Isar Heart Center, Munich, Germany; ³Department of Cardiothoracic Science, University Hospital S. Maria della Misericordia, Udine, Italy; ⁴Department of Cardiology, Maastricht University Medical Center, Maastricht, The Netherlands; ⁵University of Birmingham Centre for Cardiovascular Science, City Hospital, Birmingham B18 7QH, UK; and ⁶Department of Cardiology, Institution of Medical Science, Uppsala University, SE 751 85 Uppsala, Sweden

Received 29 November 2013; accepted after revision 29 November 2013

The aim of this European Heart Rhythm Association survey was to provide an insight into the current use of remote monitoring for cardiac implantable electronic devices in Europe. The following topics were explored: use of remote monitoring, infrastructure and organization, patient selection and benefits. Centres using remote monitoring reported performing face-to-face visits less frequently. In many centres (56.9%), a nurse reviews all the data and forwards them to the responsible physician. The majority of the centres (91.4%) stated that remote monitoring is best used in patients with implantable cardioverter-defibrillators and those live far from the hospital (76.6% top benefit). Supraventricular and ventricular arrhythmias were reported to be the major events detected earlier by remote monitoring. Remote monitoring will have a significant impact on device management.

Keywords

Remote monitoring • Pacemaker • Defibrillator • Cardiac implantable electronic devices • EHRA survey • EP wire

Introduction

The approach to follow-up of cardiac implantable electronic devices (CIEDs), such as pacemakers and implantable cardioverter-defibrillators (ICDs) has evolved over the last decade after the introduction of remote monitoring (RM).^{1–3} Remote monitoring of CIEDs is an alternative to the traditional outpatient visits which provides an access to complete information on device performance, including the patient's history of arrhythmias and battery and lead parameters. The main objectives of RM are to avoid multiple face-to-face visits to the hospital, to enable continuous follow-up and early detection of problems, thus improving safety and quality of life, and generally to provide better processing of information.⁴ However, RM has yet been partially implemented in Europe. The purpose of this survey was to assess the experience and practices in RM of CIEDs at centres—participants of the European Heart Rhythm Association (EHRA) electrophysiological (EP) research network.

Methods

Characteristics of the participating centres

Responses were received from 54 centres belonging to the EHRA EP research network spanning the wide European geographical area. The majority of responding centres performed a high volume of invasive procedures. In the last calendar year, a total of 53.7% of the centres performed 200 or more catheter ablation procedures, and 24.1% performed 100–199 procedures. The number of implantations performed (including new implants and replacements) was more than 400 at 46.3% of the centres. Almost 50% of the centres implanted more than 100 ICDs per year, and 68.5% implanted more than 200 pacemakers per year.

The majority (83.3%) of the centres were university hospitals, 11.1% were private hospitals, and the rest were other hospital types. Cardiac surgery was available at 96.3% of the surveyed hospitals. This point may indicate that teaching, tertiary, and high-volume centres are more interested in RM.

* Corresponding author. Tel: +34 913369006; fax: +34 913368183, E-mail: antoniomadrid@gmail.com

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2013. For permissions please email: journals.permissions@oup.com.

Results

Use of remote monitoring

A total of 23.5% of the centres have reported that they are not actively using RM. Most of the centres that have incorporated RM into clinical practice do not use RM routinely for pacemakers [RM is used rarely or never used (>80%)]. Most of the centres, however, employ RM in patients with ICDs. Many centres not using RM have routine device check-up visits every 6 months or even more frequently (52%). However, centres using RM report less frequent face-to-face visits: they conduct almost half as many 6-month visits as other centres (23.2 vs. 51.1%) and 25.6% of face-to-face visits are at intervals of >12 months (Figure 1). Just over half the centres actively use alert systems, and 17.6% of all the centres only perform Internet check-ups at predefined intervals.

Infrastructure and organization of remote monitoring

Two-thirds of the centres (64.3%) have no specific unit for RM. The RM workflow varies, but in many centres (56.9%), a nurse reviews all the data and forwards them to the responsible physician. However, in 25% of the centres, there is no specific workflow designed for RM. In half the centres, information obtained by RM is available only for physicians in charge of arrhythmia service (51.1%), while in 17.1%, this information is available for the implanting physician and heart failure specialists (Figure 2). Information obtained by RM is incorporated into the clinical patient file (most often an electronic clinical history) in only 6.4% of the cases. The structure of the management of device follow-up is different between ICDs and pacemakers; in 37% of the sites, ICD follow-up is managed by RM for more than 50% of patients, in addition to events that prompt hospital visits.

Patient selection

Most of the centres in Europe have agreed that a RM system is best suitable for follow-up of patients with ICDs with or without cardiac resynchronization therapy (CRT-D). Remote monitoring

was regarded to be of high or medium benefit for management of CRT-D devices by 98% and for management of ICDs by 94.1% of the centres. This is in contrast to the follow-up routine used for pacemakers where most of the centres (86.2%) found RM to be of only medium/small benefit or no benefit at all. The system is regarded to be of a greater benefit in patients with biventricular pacemakers (43.1% of the centres reported RM to be of high benefit), although not as beneficial as in patients with ICD/CRT-Ds.

The majority of the centres (91.4%) have stated that RM is useful for patients who live far from the hospital (76.6% identified it as highly beneficial and 14.9% as of medium benefit), followed by patients treated with CRT, children, the elderly, and patients with heart failure. For patients with ischaemic heart disease and patients with a history of atrial fibrillation, 55% of the centres believe that RM use has less benefit irrespective of the type of CIEDs.

Benefits for the patients, physicians, and health system

When asked how many patients appreciate the introduction of RM for follow-up, most of the centres replied that RM was well accepted by patients, but many patients preferred outpatient follow-up at the hospital or a combination of both hospital and RM follow-up. However, 39.7% of the patients were reported to prefer RM as their main follow-up management, because it help avoiding the unnecessary visits to the hospital.

Some events are detected earlier by RM than by regular follow-up and the patient alert system. Supraventricular and ventricular arrhythmias are the major events that have been detected earlier by RM, followed by generator and lead problems and worsening heart failure. Suboptimal device programming is the least frequent event reported. When asked about their mean delay time between detection of an abnormality by RM systems and the physician's response, 48.9% of the European centres reported a delay of about 24–72 h, whereas 29.8% claimed to respond within 24 h. No centres admitted to 1-month delay.

Another question focused on the percentage of RM alerts that led to decision-making and interventions. The majority of cases (36%) did not require any action, followed by altering antiarrhythmic drug therapy (17%) or reprogramming of the device (18%). Advisory

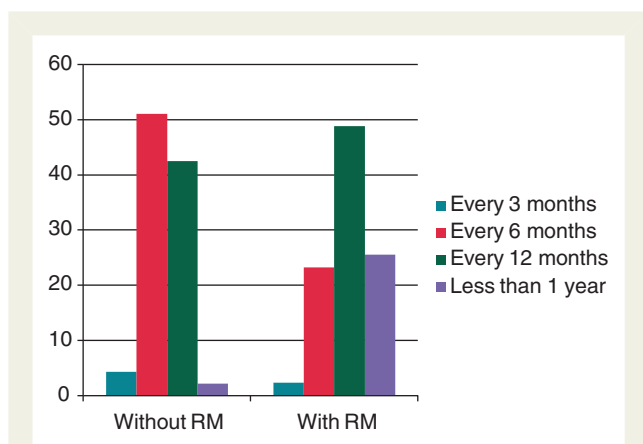


Figure 1 Distribution of frequency of face-to-face visits at each hospital depending on the use of RM. The percentages of centres are shown. RM, remote monitoring.

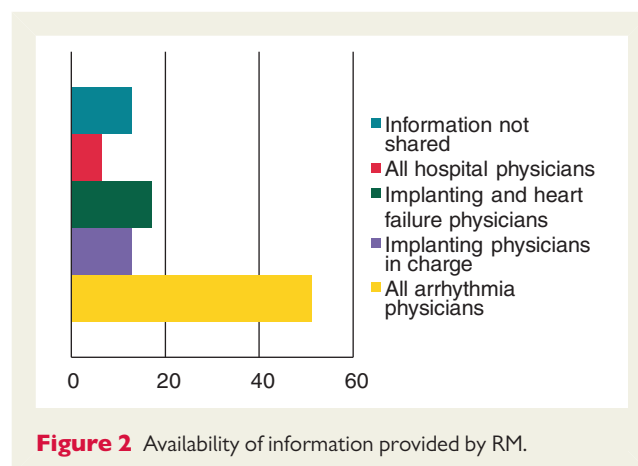


Figure 2 Availability of information provided by RM.

notification management also accounted for a good percentage (10%) of RM decision-making activities.

Many centres believe that the main benefit of RM is an effective and early detection of major clinical events (97.8%) and that it improves the patient's quality of life (91.1%). In addition, many centres (86.7%) feel that RM may reduce costs (e.g. hospitalization, transport) or improve patient outcome.

Most of the centres (73.2%) believe that RM follow-up of ICDs is cost-effective, whereas RM of pacemakers is not (83.3%). Remote monitoring costs are included within the overall budget for cardiology/arrhythmia treatment in 53.5% of the centres. However, nine (20.9%) respondents reported specific reimbursement codes for RM at their institution, and 4.5% reported the availability of funding specifically designated for RM.

Four (8.9% of the surveyed centres) recognized the potential legal problems related to RM (i.e. patient data protection, lawsuits, medical liability concerns for underdiagnosis/failure to anticipate problems). One centre reported lawsuit issues and another stated that there was a problem having the server located outside Europe, while other reported that some patients felt they were not adequately protected. At present, RM systems cannot be used for remote programming. The majority (65.1%) of the centres would like to have the possibility of remote device programming in the future. However, 30.2% of physicians think that remote programming would be potentially dangerous and would not support such development.

Discussion

Remote monitoring systems have arisen as a safe, effective method of CIED follow-up in addition to outpatient visits. The EHRA expert consensus recommends different schedules for follow-up depending on device type.¹ The usefulness of RM has been demonstrated in several clinical trials.^{5,6} Although the progress is slow, RM has been steadily implemented in Europe, and 76.5% of the surveyed centres reported an active use of RM systems. Different studies have suggested scheduling remote visits at intervals ranging from 3 to 6 months for ICDs and 3 to 12 months for pacemakers.^{2,5,7} The immediate consequence of RM availability is that the frequency with which devices are checked at the hospital (face-to-face visits) clearly differs between centres with RM and centres without RM. However, the use of the alert systems is low, only slightly more than half the centres actively use RM alerts via email, fax, or SMS.

Infrastructure and organization of remote monitoring

Two-thirds of the centres in Europe do not have a specific unit for RM as many run their RM programs as part of their traditional CIED follow-up clinics, although there is a transition from outpatient visits to more frequent RM utilization.

The organization of a hospital RM workflow contributes largely to the amount of advantage that can be taken of the technique. The workflow for RM in Europe is based primarily on nursing with easy communication with the responsible physician for medical decisions. Many centres, however, conduct only sporadic reviews or have no specific protocol, suggesting that some events may be undetected, and the opportunity to adjust therapy may not be undertaken.

Existing evidence points to the key role played by the nurse in this arrangement, in comparison with the physician-based schemes, and the results of this survey further confirm this.

The large amount of data that RM provides is not yet adequately transmitted to all parts of the healthcare system. The information is put into the patient's medical records in only 6.4% of cases. Thus, there is a need to make this information available to all physicians (e.g. emergency physicians, heart failure specialists, general cardiologists, etc.), and probably the only way to do that is to transfer information in a digital format to electronic medical records that can be accessed by the relevant hospital staff.

Patient selection

Most of the centres agreed that RM provides the most benefit and is most suitable for follow-up of ICD or CRT-D devices.⁸ Many physicians believe that the majority of patients with pacemakers, with good longevity and performance, will not need any specific treatment or device follow-up for a long time, and therefore, RM is of no or little use in such patients. However, it is important to take into account other aspects which are not uncommon in patients with pacemakers and may be associated with a higher likelihood of reprogramming (e.g. heart failure, a history of mainly undiagnosed atrial fibrillation and subsequent risk of thromboembolic events, diagnosis of ventricular arrhythmias and management of advisory notifications). These are just some of the aspects that advocate the use of RM in the pacemaker population.⁹

Remote monitoring systems could benefit different type of patients. For example, patients with complex problems that need a tight follow-up schedule are potential candidates for RM. Patients who benefit the most from this technology are those who find clinical visits to be a disruption to their daily life (children and elderly patients), patients (often elderly) who are alone and need to call on multiple family and social resources to get to the clinic, and patients who live far from the hospital. In addition, stable patients that are unlikely to require changes in programming or to have any device-related events could be monitored remotely.

Benefits of remote monitoring

Although patients generally like the fact that RM means fewer in-office visits, many feel more comfortable and safe when face-to-face visits are scheduled; for them, remote follow-up becomes a useful complement in device management. In this survey, however, 39.7% of patients, a significant share, preferred RM as their main follow-up system.

Remote monitoring is highly effective at detecting clinical events. The clinical merits of early detection of important events with RM are significant. Reported response time is about 24–72 h at 48.9% of the centres which is encouraging in view of the fact that some events may take place out-of-work hours, when specialized healthcare professionals may not be available. Events may require decision-making and intervention, which could include changing in antiarrhythmic drug therapy or reprogramming to prevent inappropriate therapies if atrial or ventricular arrhythmias (the most common findings), were detected¹⁰ or even surgery for lead failure. Cardiovascular events, such as worsening of heart failure also occur relatively frequently, and these patients may benefit from the use of RM, as has recently been demonstrated in the IN-TIME (INfluence of home monitoring on The Clinical Management of heart failure) trial presented at

the European Society of Cardiology (ESC) Congress in 2013.¹¹ The IN-TIME is the first implant-based RM randomized controlled trial demonstrating significant benefits of implant-based home monitoring for patients with advanced heart failure. At 12 months, significantly fewer patients in the home monitoring group had reached the composite primary endpoint of mortality, overnight hospitalization for worsening heart failure, and New York Heart Association class global self-assessment. Moreover, fewer patients in the home monitoring arm died of any cause over the study period.

Lead and generator dysfunction are less common findings. In most cases, RM is used to monitor normal functioning of devices and no medical advice or intervention is necessary.

Remote monitoring improves the quality of life in patients with CIEDs, especially patients who have mobility difficulties and patients with complex cardiomyopathies, where RM may improve outcomes. Furthermore, since RM substitutes office visits, cost are reduced without compromising the patient safety. The ability to perform an early diagnosis of arrhythmias, thoracic impedance disturbances, or a low percentage of stimulation in CRT recipients could reduce hospitalization in patients with severe heart disease.

The use of RM will reduce healthcare resource consumption. Overall costs are reduced by decreasing outpatient clinic workload and by reducing patient visits and the cost of patient transport (some patients have to travel long distances). However, before any centre can run a successful RM programme, it must face a learning curve, it needs to train nurses and allied professionals, and it must define a specific protocol. The costs of RM are charged directly to the overall cost of cardiology/arrhythmia treatment at most centres in Europe (53.5%). However, nine responding centres (20.9%) reported specific reimbursement codes for RM, and 4.5% reported the availability of specific funding designated for RM programmes.

Remote monitoring will eventually be widely used in all over the world, but a delay in physician acceptance and implementation has been observed. Probably, the lack of a designated workflow, reimbursement, and allied staff make progress slow. There are also concerns related to data privacy and fear of legal problems. Some legal problems were reported in the survey. A clear, concise informed consent form should be given to patients to avoid this type of problem.

Conclusions

Remote monitoring of CIEDs is safe and cost-effective. It is well accepted by most patients and enables early detection of important clinical problems. Centres using RM perform face-to-face visits less frequently. Supraventricular and ventricular arrhythmias are the major events that are detected earlier by RM, with a reaction time

of <72 h. Remote monitoring will have a significant impact on CIED management (both ICDs and pacemakers), and most centres would like to be able to programme devices remotely in the future. It is likely that RM will replace most in-person follow-up of patients with CIEDs.

Acknowledgements

The production of this EP wire document is under the responsibility of the Scientific Initiative Committee of the European Heart Rhythm Association: Carina Blomström-Lundqvist (chairman), Maria Grazia Bongiorni (co-chair), Jian Chen, Nikolaos Dargès, Heidi Estner, Antonio Hernández-Madrid, Melece Hocini, Torben Bjerregaard Larsen, Laurent Pison, Tatjana Potpara, Alessandro Proclemer, Elena Sciraffia, Derick Todd.

The authors acknowledge the EHRA Research Network centres participating in this EP Wire. A list of the Research Network can be found on the EHRA website.

Conflict of interest: none declared.

References

- Dubner S, Auricchio A, Steinberg JS, Vardas P, Stone P, Brugada J et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). *Europace* 2012;**14**:278–93.
- Varma N, Epstein A, Irimpen A, Schweikert R, Shah J, Love CJ, investigators, T. Efficacy and safety of automatic remote monitoring for ICD follow-up: the TRUST trial. *Circulation* 2010;**122**:325–32.
- Osca J, Sancho-Tello MJ, Navarro J, Cano O, Raso R, Castro JE et al. Fiabilidad técnica y seguridad clínica de un sistema de monitorización remota de dispositivos cardiaco-sintárrítmicos. *Rev Esp Cardiol* 2009;**62**:886–95.
- Ricci R, Morichelli L, D'Onofrio A, Caló L, Vaccari D, Zanotto G et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry. *Europace* 2013;**15**:970–7.
- Mabo P, Victor F, Bazin P, Ahres S, Babuty D, Da Costa A et al. A randomized trial of long-term remote monitoring of pacemaker recipients (The COMPASS trial). *Eur Heart J* 2012;**33**:1105–11.
- Sack S, Wende CM, Nagèle H, Katz A, Bauer W, Barr C et al. Potential value of automated daily screening of cardiac resynchronization therapy defibrillator diagnostics for prediction of major cardiovascular events: results from Home-CARE (Home monitoring in cardiac resynchronization therapy) study. *Eur J Heart Fail* 2011;**13**:1019–21.
- Burri H. Remote follow-up and continuous remote monitoring, distinguished. *Europace* 2013;**15**:114–6.
- Whellan DJ, Ousdigian KT, Al-Khatib S, Pu W, Sarkar S, Porter C et al. for the PARTNERS Study Investigators. Combined heart failure device diagnostics identify patients at higher risk of subsequent heart failure hospitalizations. *JACC* 2010;**55**:1803–10.
- Santini M. Remote monitoring and the twin epidemics of atrial fibrillation and heart failure. *Europace* 2013;**15**:147–8.
- Crossley G, Boyle A, Vitense H, Chang Y, Mead RH. The clinical evaluation of remote notification to reduce time to clinical decision (CONNECT) trial: the value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol* 2011;**57**:1181–9.
- Arya A, Block M, Kautzner J, Lewalter T, Mörtel H, Sack S et al. IN-TIME Investigators. Influence of home monitoring on the clinical status of heart failure patients: design and rationale of the IN-TIME study. *Eur J Heart Fail* 2008;**10**:1143–8.