Journal of Arrhythmia 30 (2014) 421–427

Contents lists available at ScienceDirect

Journal of Arrhythmia

journal homepage: www.elsevier.com/locate/joa

Review

Remote monitoring of cardiovascular implantable electronic devices in Japan

Hideo Okamura *

Division of Cardiology, National Cerebral and Cardiovascular Center, 5-7-1 Fujishirodai, Suita, Osaka 565-8565, Japan

ARTICLE INFO

Article history:
Received 8 January 2014
Received in revised form
17 March 2014
Accepted 17 April 2014
Available online 11 June 2014

Keywords:
Remote monitoring
CIEDs
Japan
Heart failure
Reimbursement

ABSTRACT

The number of patients with chronically implanted cardiovascular implantable electronic devices (CIEDs) keeps growing, and device clinics of major hospitals may soon be unable to fully accommodate the increasing amount of follow-up activities. Consequently, the remote monitoring (RM) technology introduced in Japan in 2010 has been rapidly gaining widespread application in the management of CIEDs.

A modern remote monitor not only acts as an alternative to a device clinic, but also as a security monitor for the device and the patient. A number of papers have confirmed the safety, feasibility, and cost-effectiveness of RM systems. Importantly, remote monitors allow physicians to quickly detect and respond to lead problems, atrial arrhythmias, heart failure, and other adverse events, which may also improve the patients' survival rate. Several reports from Japan have demonstrated that RM systems are well accepted by both the patients and physicians.

However, there remain limitations and problems of the RM technology to be solved, and rules and guidelines for monitor management should be established to fully utilize the advantages of RM systems.

Contents

1. Introduction

The number of implantations of cardiovascular implantable electronic devices (CIEDs), including permanent pacemakers (PPMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) defibrillators (CRT-D) is increasing annually in Japan as well as in Western countries (Fig. 1). The follow-up of the patients with CIEDs must be individualized in accordance with the patient's clinical status and conducted by a physician fully trained in device follow-up. Current guidelines suggest 1 or 2 follow-up evaluations per year for stable patients with PPMs and more than that for patients with defibrillators [1]. As the number of patients with chronically implanted CIEDs grows, the amount of follow-ups also increases, placing an increasing burden on device clinics. Remote monitoring (RM) of CIEDs is expected to provide a solution to this problem.

2. Systems for RM

Modern RM systems adopted in Japan are quite different from the trans-telephonically monitoring system previously used in

* Tel.: +81 6 6833 5012; fax: +81 6 6872 7486.
E-mail address: hokamura@ncvc.go.jp

http://dx.doi.org/10.1016/j.joa.2014.04.012
1880-4276/

Western countries to monitor PPMs. The trans-telephonically monitoring system is mostly aimed at ascertaining battery longevity, appropriate capture, and sensing. On the other hand, the current RM technology makes it possible to transmit and store all the data that the CIED is capable of collecting by using a communicator installed in the patient's house. In this regard, data transmissions can be classified into 2 categories: remote follow-up and remote alarm. Remote follow-up is a scheduled transmission in which routine CIED parameters similar to those obtained during a hospital visit are transferred. Remote alarm stands for the true real-time communication with the device, which automatically transmits critical data related to its functionality or adverse health events and patients' status. That is to say, current RM systems not only act as alternatives to a device clinic, but also as security monitors for the patient and the device itself.

In Japan, the methods of data transmission between the device and the communicator, as well as between the communicator and the Internet, vary among the device manufacturers. Moreover, the transmission frequencies are also different. Table 1 summarizes the characteristics of the 5 systems currently available in Japan: Biotronik's Home Monitoring, Boston Scientific's LATITUDE, Medtronic's CareLink, St. Jude Medical's Merlin.net, and Sorin's SMARTVIEW. Some of them transmit the data automatically as illustrated in the upper panel of Fig. 2, whereas others require the interrogation to be initiated by the patient by placing a special wand in the vicinity of the CIED, as depicted in the lower panel of Fig. 2. The third generation mobile phone network (3G network) has been used to transmit the data to the data server. Wireless transmission of the data between the device and the communicator is performed using a radio frequency range assigned for medical implant communications (402–405 MHz). From the safety standpoint, automatic wireless data transmission from the CIED to the communicator is ideal. Within the wired transmission design, a patient can send the data manually only when he or she senses abnormalities such as palpitation or shock. In this regard, the largest advantage of RM is the possibility to transmit asymptomatic events. The physician can receive such alert messages via e-mail, fax, etc. Once the data have been transmitted to a data server, the physician can also use the Internet to access this information and, if needed, to arrange a hospital visit. However, CIED programming cannot be performed remotely at present.

3. The expected role of RM in overcoming the problems of CIED therapy

Lead dysfunction is a major concern in CIED therapy. Spencker et al. [2] reported that the automatic RM surveillance system enables physicians to detect severe lead problems early and to react quickly. They studied 54 patients who had to undergo resurgery because of malfunctions of the ICD leads. Eleven of these patients had RM systems that interrogated their devices every night. The rates of inappropriate shocks and symptomatic pacemaker inhibition due to oversensing were compared with those in 43 patients without the remote surveillance. RM systems sent alert messages in 91% of all incidents, whereas changes in the pacing impedance were notified only in 18%. Remarkably, 80% of the patients were asymptomatic at the first onset of oversensing. Inappropriate shocks occurred in 27.3% of the patients in the RM group compared to 46.5% in the non-RM group (P=not significant). The mean time between the last ICD interrogation and the event message was 54 days, or about 56 days before the next scheduled visit. Thus, 56 days of reaction time were gained to avoid adverse events. The authors concluded that RM may be

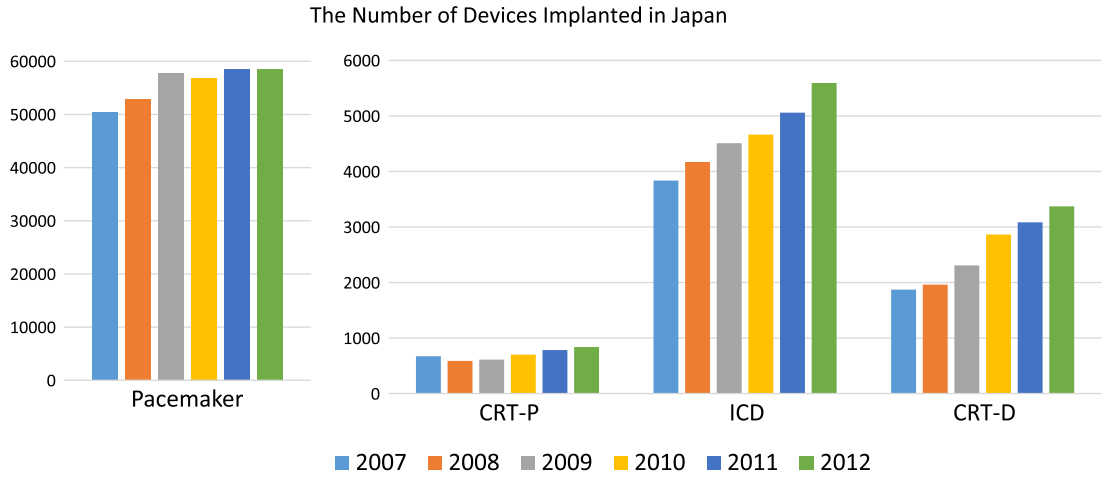

Fig. 1. The number of devices implanted in Japan has been gradually increasing in the recent years. Data were derived from the annual report by JADIA. CRT-P: cardiac resynchronization therapy pacemaker; ICD: implantable cardioverter defibrillator; CRT-D: cardiac resynchronization therapy defibrillator.

Table 1
Summary of characteristics of the five remote monitoring systems currently available in Japan.

	Devices	Device-communicator connection	Communicator-internet connection	Frequency of transmissions
Biotronik (Home Monitoring)	ICD/PPM	Wireless Automatic Transmission (MICS)	3G network (wireless)	Daily and alert events
Boston Scientific (LATITUDE)	ICD/PPM	Wired Manual Transmission	Analog phone line (wired)	Patient-initiated
Medtronic (CareLink)	ICD	Wireless Automatic Transmission (MICS)	3G network (wireless)	Scheduled day and alert events
	PPM	Wired Manual Transmission	Analog phone line (wired)	Patient-initiated
St. Jude Medical (Merlin.net)	ICD/PPM	Wireless Automatic Transmission (MICS)	3G network (wireless)	Scheduled day and alert events
Sorin (SMARTVIEW)	ICD	Wireless Automatic Transmission (MICS)	Analog phone line (wired)	Scheduled day and alert events

ICD: implantable cardioverter defibrillator, MICS: medical implant communications, PPM: permanent pacemaker, 3G network: third generation mobile phone network.

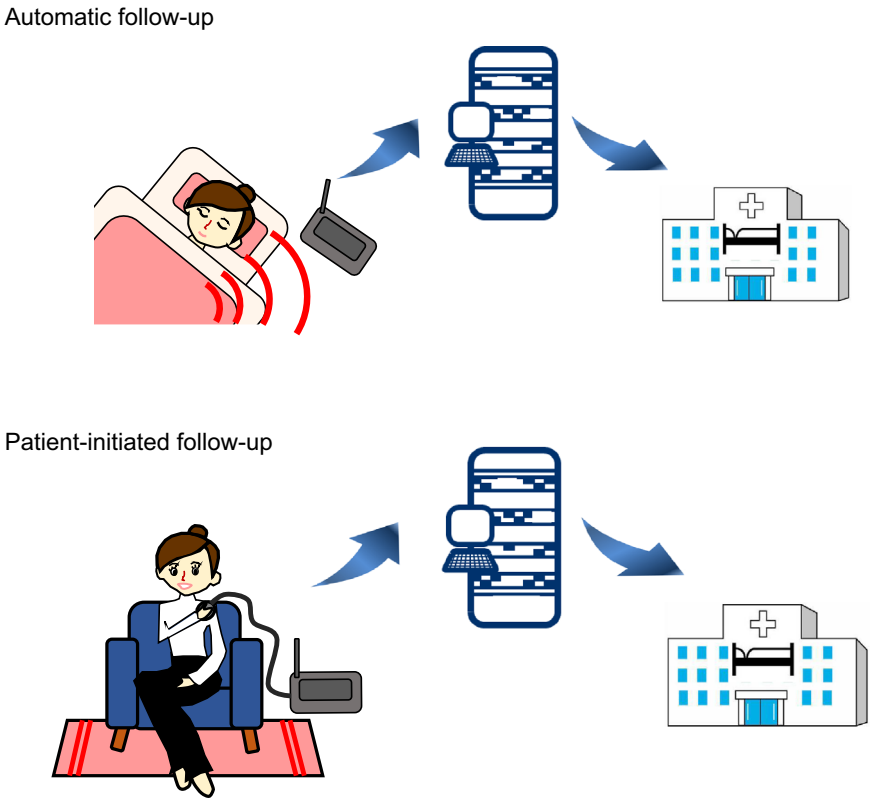

Fig. 2. Illustration of types of data transmission by remote monitoring systems. Upper panel: automatic remote transmission. Lower panel: manual transmission using a wand over the device.

useful for avoiding inappropriate shocks due to lead failure and T-wave oversensing. Similar studies demonstrating the capability of RM to promptly detect lead dysfunction were reported [2–5].

Patients with heart failure are at a high risk of mortality and morbidity. Medical expenses associated with heart failure are increasing, and approaches aimed at early heart failure detection and reduction of the hospitalization rate are yet to be developed. Patients with CIEDs also develop heart failure, and it has been expected that utilization of RM will help effectively manage this problem. One of the applications of the RM technology is monitoring of weight and blood pressure. As shown in Fig. 3, the Boston Scientific's LATITUDE device is capable of such monitoring on a daily basis using a wireless weight scale and a manometer. Intrathoracic impedance monitoring is also available in RM systems from several manufacturers. Yu et al. [6] showed that intrathoracic impedance, measured between the right ventricular lead and the CIED case, inversely correlates with pulmonary capillary wedge pressure and net fluid overload. Some other studies also reported on the usefulness of this parameter [7–9]. In this regard, the CIED made by Medtronic supplies the OptiVol index, which is calculated according to the accumulated difference between the daily and reference impedance. CareLink, the corresponding RM system, can send an alert when this index exceeds a preset value. Although the OptiVol index has limitations in sensitivity and specificity, it can be used as a parameter to detect worsening of heart failure [10]. As an example, Fig. 4 shows a shift in the OptiVol index of a patient with heart failure, which correlates with the shift in the level of blood brain natriuretic peptide and the patient's symptoms. The first of the 3 OptiVol index peaks was associated with an elevation of the brain natriuretic peptide level and a symptom of dyspnea on effort. Additional prescription of a diuretic prevented further worsening of dyspnea on effort, and the OptiVol index decreased. As shown in Fig. 5, St. Jude Medical's Merlin.net and Biotronik's Home Monitoring also monitor intrathoracic impedance. Studies are ongoing to find a more informative index that, in combination with intrathoracic impedance and other parameters, will allow detecting heart failure with better sensitivity and specificity.

4. Acceptance and safety

A number of papers confirmed the safety, feasibility, and cost-effectiveness of the RM technology [11–14]. Lazarus reported that, according to the AWARE trial [14], the broad application of a monitoring system strongly supported its capability to improve the care of cardiac device recipients, enhance their safety, and optimize the allocation of health resources. Specifically, 3,003,763 transmissions from 11,624 recipients of PPMs, ICDs, and CRT-Ds worldwide were analyzed. The vast majority (86%) of events were disease-related. The mean interval between the last follow-up and the occurrence of events notified by the RM system was 26 days, which represents a putative temporal gain of 154 and 64 days in patients usually followed at 6- and 3-month intervals, respectively.

The appropriate follow-up interval for patients with RM systems is an important parameter that directly affects the burden on the device clinic. The REFORM trial described by Hindricks et al. [15] studied 155 ICD recipients with MADIT II indications who were randomly assigned either 3- or 12-month follow-up intervals in the period between 3 and 27 months after implantation. The authors compared the burden of scheduled and unscheduled ICD follow-up visits, quality of life (using the SF-36), and clinical outcomes. Compared with the 3-month follow-up interval, the 12-month interval resulted in only a minor increase in the number of unscheduled follow-ups (0.64 vs. 0.27 per patient-year; $P=0.03$). Furthermore, no significant differences were found in mortality, hospitalization rate, and hospitalization length during the 2-year observation period, although more patients were lost to

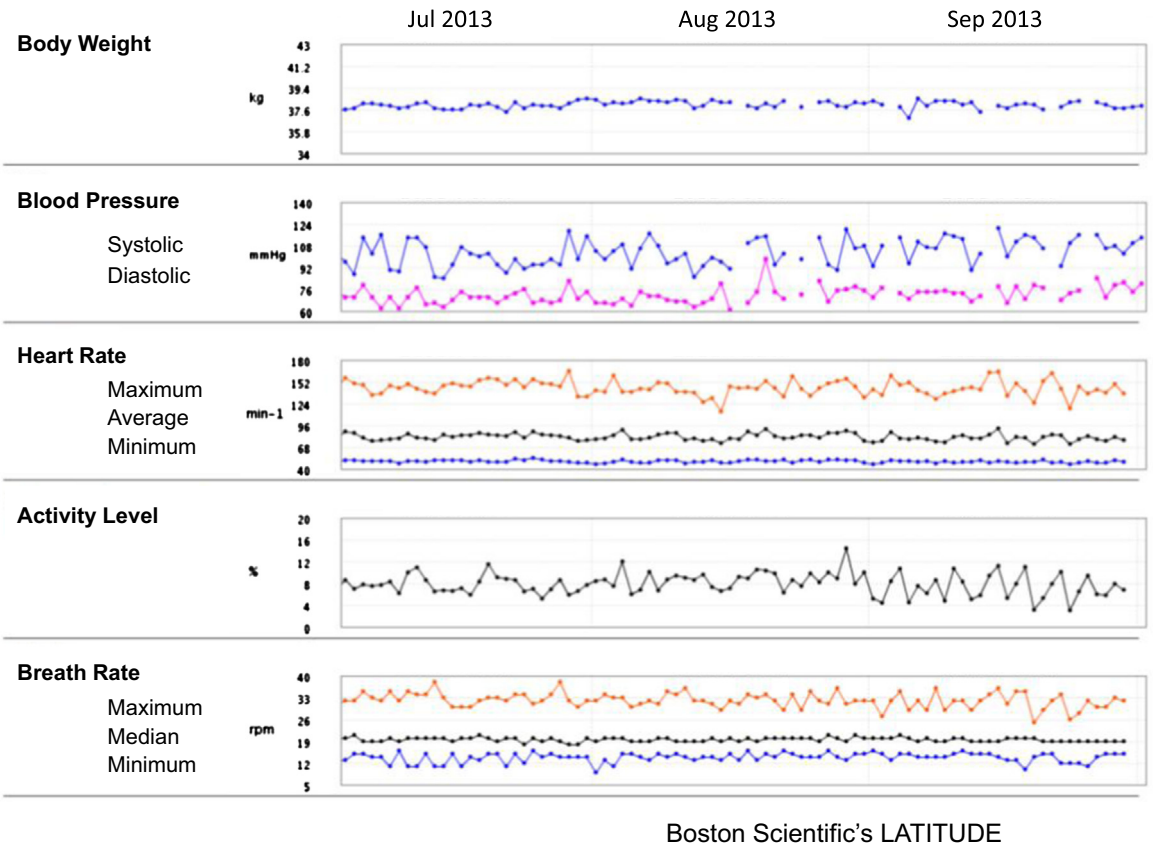

Fig. 3. Trend graph of body weight, blood pressure, and other vital parameters displayed by the Boston Scientific's LATITUDE monitor.

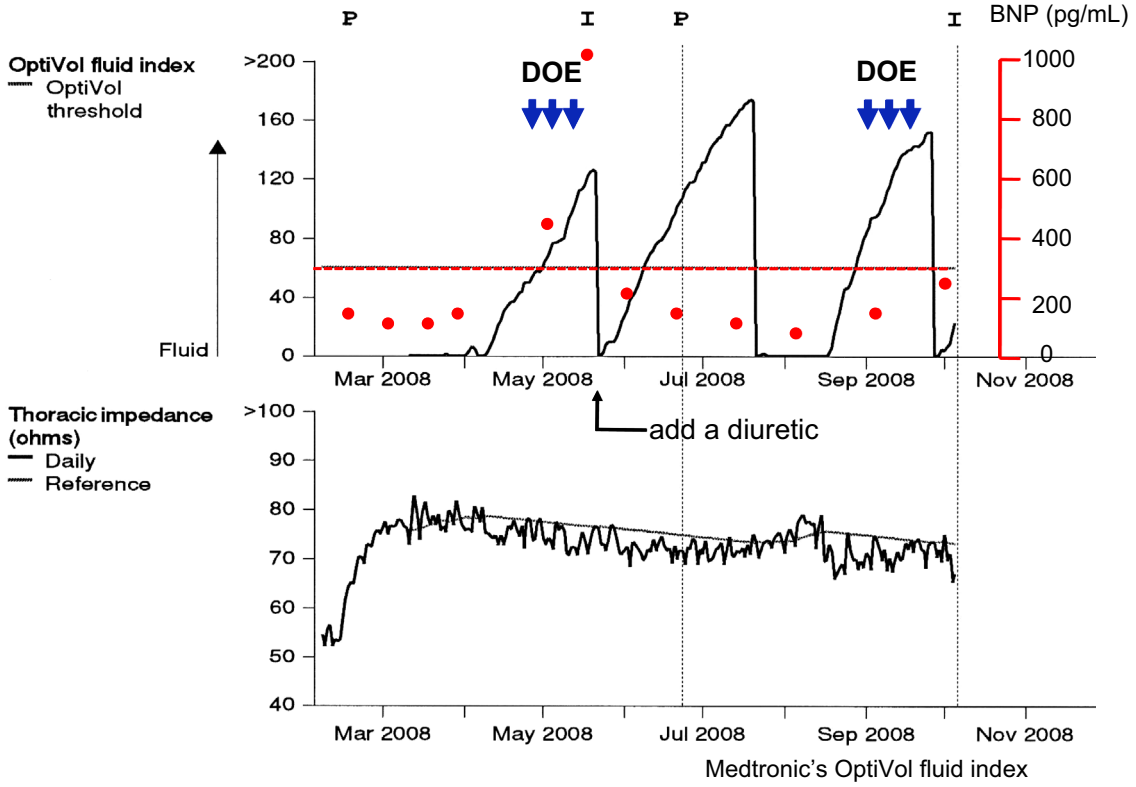

Fig. 4. Time plot of the OpitiVol index (black line) of a patient with heart failure shown along with the levels of blood brain natriuretic peptide (BNP, red dots) and the patient's symptoms. Among the 3 peaks of the OptiVol index, the first was associated with an elevation in the BNP level and the symptom of dyspnea on effort (DOE). Additional prescription of a diuretic prevented further worsening of DOE, and the OptiVol index decreased.

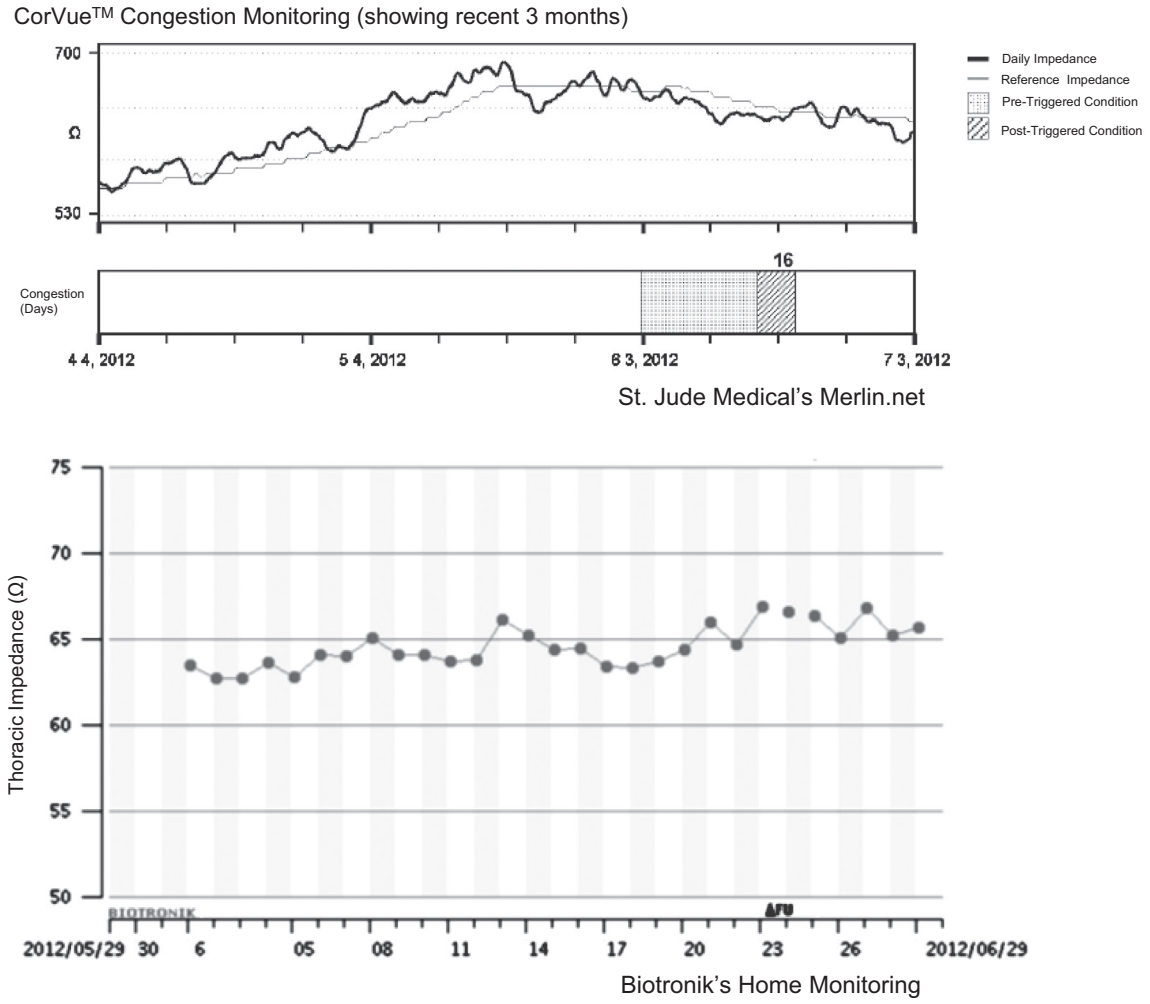

Fig. 5. Trend graph of intrathoracic impedance displayed by the St. Jude Medical's Merlin.net (upper panel) and Biotronik's Home Monitoring (lower panel) systems.

follow-up in the 12-month group (10 vs. 3; $P=0.04$). The SF-36 scores favored the 12-month interval in the "social functioning" and "mental health" domains. Thus, it appears that the extension of the 3-month in-office follow-up interval to 12 months under automatic daily RM reduced the ICD follow-up burden during 27 months after implantation without compromising the patients' safety.

The medical environment in Asian-Pacific countries is widely different from that in Western countries in terms of disease prevalence, CIED implant rates, and other parameters. Moreover, there are remarkable differences in the manner patients are followed-up among the countries in the Asian-Pacific region [16]. In particular, the role of RM may differ in Japan owing to its dense population and developed transportation networks in most cities. RM was tentatively introduced in Japan in 2008, and the reimbursement system was launched in April 2010. Initially, there was a concern that Japanese patients, who prefer face-to-face visits, would not accept the RM system. Accordingly, a feasibility study of CareLink Monitor by Ando et al. [17] enrolled a total of 203 patients who had previously undergone CIED implantation at 5 Japanese centers. A total of 470 transmissions were made. Questionnaires were completed by patients and physicians to evaluate acceptance, ease of use, and satisfaction with the system. More than 87% of the patients felt that the monitor was easy to use, and nearly all of the physicians were satisfied with the system. The majority of the patients felt reassured by having their devices remotely assessed and preferred less frequent hospital visits made possible by the monitor. Thus, the CareLink RM device was well accepted by both the patients and physicians in Japan. As mentioned before, currently all 5 manufacturers have developed their own RM systems for ICDs and CRT-Ds, and most of them support PPMs. The methods of data transmission vary, and the patients' acceptance may differ depending on the system. However, it seems that all systems have been favorably accepted by Japanese patients.

RM has become a standard medical care for patients with CIEDs. However, some limitations and problems are still waiting to be solved. First, RM does not eliminate the necessity of in-hospital follow-up. It would be nearly impossible to detect events other than malfunctioning of the CIED system, arrhythmia, and heart failure. As demonstrated by the Japanese HOME-ICD study [18], it is also inevitable that false-negative events sometimes occur. Nevertheless, according to the results of the previous studies, the interval between face-to-face visits for ICD/CRT-D patients can likely be increased from 3–4 months to 6–12 months in Japan, which will undoubtedly reduce the burden on patients and medical professionals [19]. However, as shown by the REFORM trial [15], stretching the interval to 12 months may increase the number of patients who are lost to follow-up. Hence, an efficient follow-up system will be required to fully utilize the benefits of RM.

5. Emerging clinical evidence for RM

Many larger studies and randomized trials have been recently reported. In particular, the ALTITUDE survival study by Saxon et al. [20] is a large multicenter survey of patients implanted with ICD and CRT devices across the United States. Within this study, outcomes were compared between patients followed in device clinic settings and those who regularly transmitted the data remotely at an average rate of 4 times per month. One- and 5-year survival rates in 185,778 patients after ICD implantation were 92% and 68%, respectively, whereas the corresponding rates for CRT-D device recipients were 88% and 54%. Remarkably, 1- and 5-year survival rates were higher in the 69,556 ICD and CRT-D patients receiving remote follow-up on the network than in the 11,622 patients who received device follow-up in device clinics only (50% reduction; $P<0.0001$).

The TRUST trial reported by Varma et al. [21] was a prospective, randomized, multicenter clinical trial comparing the safety and usefulness of automatic daily RM in ICD recipients with standard in-clinic follow-up. In total, 1339 patients were randomized at a 2:1 ratio to RM or conventional follow-up. Follow-up checks occurred at 3, 6, 9, 12, and 15 months after implantation. At 6, 9, and 12 months, only RM was used as the follow-up for patients randomized to the RM group, but it was followed by office visits if necessary. RM reduced the total number of in-hospital device evaluations by 45% without affecting morbidity. In the RM group, 85.8% of all 6-, 9-, and 12-month follow-ups were performed remotely only. For all arrhythmic events, the median time to evaluation was less than 2 days in the RM group compared with 36 days in the conventional group ($P<0.001$).

The CONNECT trial conducted by Crossley et al. [22] was also a multicenter, prospective, randomized evaluation of wireless RM, which included 1997 patients implanted with ICDs or CRT-Ds. They were randomly assigned to the remote or in-office groups and followed up for 15 months. The median time from a clinical event to the clinical decision per patient was reduced from 22 days in the in-office group to 4.6 days in the remote group ($P<0.001$). Moreover, the health care utilization data revealed a decrease in the mean length of stay per cardiovascular hospitalization from 4.0 days in the in-office group to 3.3 days in the remote group ($P=0.002$).

The Home Guide Registry [23] and the ECOST trials [24] also demonstrated the safety and usefulness of the automatic daily RM technology. In the Home Guide Registry trial, the workflow for RM was based on primary nursing, whereas in-person visits were scheduled once a year. In total, 1650 patients implanted with PPMs, ICDs, or CRT-Ds from 75 Italian sites were enrolled. During the 20 ± 13 months follow-up, 2471 independently adjudicated events were collected in 838 patients (51%), of which 2033 (82%) were detected during RM sessions and 438 (18%) during in-person visits. Sixty were classified as false positive, with generalized estimating sensitivity and positive predictive value of 84.3% and 97.4%, respectively. Overall, 95% of asymptomatic and 73% of actionable events were detected during RM sessions, and the median reaction time was 3 days. The ECOST trial prospectively examined the long-term safety and effectiveness of RM of ICDs. A total of 433 patients were randomly assigned, at a 1:1 ratio, to RM (active) or control groups. During the 24.2 months-long follow-up, 38.5% of patients in the active and 41.5% in the control group experienced one or more major adverse event (MAE) ($P<0.05$ for non-inferiority). The overall number of shocks delivered was significantly lower in the active ($n=193$) than in the control ($n=657$) group ($P<0.05$), whereas the proportion of patients who received inappropriate shocks was 52% lower in the active ($n=11$) than in the control ($n=22$) group ($P<0.05$).

The majority of the existing reports on RM included patients with ICDs, whereas the reports focusing on PPMs are limited. The randomized, multicenter COMPAS trial was conducted in France to evaluate the benefits of automatic daily RM for patients implanted with PPMs [25]. In total, 538 patients were randomly assigned to RM follow-up (active group) vs. standard care (control group). Over a follow-up period of 18.3 months, 17.3% of the patients in the active and 19.1% in the control group experienced at least one MAE ($P<0.01$ for non-inferiority). Hospitalizations for atrial arrhythmias (6 vs. 18) and strokes (2 vs. 8) were fewer ($P<0.05$), and the number of interim ambulatory visits was 56% lower ($P<0.001$) in the active group. Changes in the pacemaker program or drug regimens were made during 62% of visits in the active vs. 29% in the control group ($p<0.001$). The quality of life remained unchanged in both groups.

So far, clinical evidence from Japan supporting the efficacy of the RM technology has been limited. The HOME-ICD study reported by Watanabe et al. [18] evaluated the reliability of daily wireless RM in forecasting the need for regular in-hospital follow-ups (RFUs). Two-hundred fifteen patients implanted with ICDs or CRT-Ds were enrolled, and RFUs were performed at 3, 6, 9, and 12 months after implantation. Immediately before an RFU, the physician forecasted the need for RFU based on RM data (pre-RFU assessment). A completed RFU session was classified as necessary if an action was undertaken (post-RFU assessment). Overall, 663 pairs of pre- and post-RFU assessments were compared. The number of pre-RFU assessments failing to predict the need for RFU was 38 (5.7%), including 2 actions with high clinical relevance (0.3%). Specifically, an additional prescription of warfarin for subclavian vein thrombosis in one case and activation of rate-adaptive pacing in another case were needed. Other actions were of non-critical character, including reprogramming to extend battery longevity, reprogramming to maintain safety margin for pacing. On the other hand, RM correctly forecasted that 498 scheduled RFUs (75.1%) were in fact not necessary. The patient acceptance of RM was also evaluated using a targeted questionnaire. Of 182 interviewed patients, 172 (94.5%) reported feelings of security and comfort. The authors concluded that RM-based forecasts appear to be sufficiently accurate to safely individualize RFU, and that most patients have a positive attitude towards RM. Many trials involving Japanese patients are currently ongoing, and the results are very much awaited.

6. Reimbursement system

The current reimbursement regulations are in need of an update [26,27]. In 2008, the Centers for Medicare and Medicaid Services in the USA approved a revised set of codes developed in collaboration with HRS, the American College of Cardiology, and the American Medical Association that more accurately reflected the services and associated work involved in in-office and remote monitoring of CIEDs. Specifically, the RM codes recognize the critical role of the allied professional by assigning a separate code to cover the work of remote data acquisition, receipt and processing of the transmission, technical review and support, as well as distribution of the results. To prevent overutilization, the codes may be used only once every 90 days [28]. Health systems in Europe are significantly different, which affects their approach to reimbursement of RM and follow-up [29]. In the EHRA survey of 2010, 51 centers reported that reimbursement of remote follow-up was established per episode in 8.9% of cases, but in 82.1% no reimbursement structure was present [30]. A flat fee per patient per month or per year should be adopted for RM as part of integrated care or disease management contracts.

Unfortunately, RM reimbursement is available only once every 4 months in Japan, and it requires face-to-face encounters. Meanwhile, especially in the case of automatic wireless RM systems,

patients are monitored every day, and a substantial amount of effort is required from medical professionals to check the data transmitted by RM devices. The increasing number of the patients followed by RM expands this burden dramatically. Appropriate compensation would be indispensable for establishing a reasonable CIEDs follow-up system at every hospital, so that RM becomes a standard follow-up tool for all patients with CIEDs throughout the country. On the other hand, rules and guidelines for management of RM should be established. If reimbursement for RM without face-to-face encounters and shorter reimbursement intervals are approved, the rules for updating medical records even in the absence of significant events will be indispensable. Additionally, rules covering regular communication with the patients to inform them that RM is working properly may be required to prevent neglecting the RM data. To ease the burden on medical professionals, a new education system also needs to be established to prepare specialists, including nurses, for managing RM systems.

In addition, the patients need to be informed of the purpose and limitations of RM to avoid unnecessary complications. The RM system was not designed to act as an emergency service, and at present, RM data are not checked outside office hours in most hospitals. These data may include critical events such as failure to defibrillate ventricular fibrillation, and the patient may survive provided an immediate response is available to such an alert. However, it is not realistic to manage an RM system in a manner more suitable for a security firm. Therefore, before initiating RM and follow-up, the patient and the family members may be requested to provide written informed consent stating these points.

7. Summary

The RM technology, which was introduced in Japan for the management of CIEDs in 2010, has been spreading rapidly, and it has become a standard medical care for patients with CIEDs. Current RM devices are capable of not only acting as alternatives to a device clinic, but also as security monitors for the device and the patient. A number of papers have confirmed the safety, feasibility, and cost-effectiveness of RM, which allows physicians to promptly detect and react to severe lead problems, atrial arrhythmias, and other adverse events. RM also provides the possibility to detect heart failure at an early stage and reduce heart failure-associated hospitalization by monitoring patient's weight or intrathoracic impedance in combination with other parameters, which may improve the patients' survival rate as well. Several studies have demonstrated that RM is well accepted by the patients and physicians in Japan. However, some limitations and problems of the RM technology remain to be addressed, and rules and guidelines for RM management should be established to fully utilize the potential of this technology.

Conflict of interest

HO receives speaker honoraria from Biotronik Japan, Boston Scientific Japan, Medtronic Japan, and St. Jude Medical Japan.

References

[1] Epstein AE, DiMarco JP, Ellenbogen KA, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation 2013;127:e283–352.

[2] Spencker S, Coban N, Koch L, et al. A potential role of home monitoring to reduce inappropriate shocks in implantable cardioverter–defibrillator patients due to lead failure. Europace 2009;11:483–8.

[3] Guédon-Moreau L, Chevalier P, Marquié C, et al. Contributions of remote monitoring to the follow-up of implantable cardioverter–defibrillator leads under advisory. Eur Heart J 2010;31:2246–52.

[4] Varma N, Michalski J, Epstein AE, et al. Automatic remote monitoring of ICD lead and generator performance: the TRUST trial. Circ Arrhythm Electrophysiol 2010;3:428–36.

[5] Varma N, Pavri BB, Stambler B, et al. Same-day discovery of implantable cardioverter defibrillator dysfunction in the TRUST remote monitoring trial: influence of contrasting messaging systems. Europace 2013;15:697–703.

[6] Yu CM, Wang L, Chau E, et al. Intrathoracic impedance monitoring in patients with heart failure: correlation with fluid status and feasibility of early warning preceding hospitalization. Circulation 2005;112:841–8.

[7] Catanzariti D, Lunati M, Ladolina M, et al. Monitoring intrathoracic impedance with an implantable defibrillator reduces hospitalizations in patients with heart failure. PACE 2009;32:363–70.

[8] Whellan DJ, Ousdigian KT, Al-Khatib SM, et al. Combined heart failure device diagnostics identify patients at higher risk of subsequent heart failure hospitalizations: results from PARTNERS HF (program to access and review trending information and evaluate correlation to symptoms in patients with heart failure) study. J Am Coll Cardiol 2010;55:1803–10.

[9] Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. Circulation 2012;125:2985–92.

[10] Conraads VM, Tavazzi L, Santini M, et al. Sensitivity and positive predictive value of implantable intrathoracic impedance monitoring as a predictor of heart failure hospitalizations: the SENSE-HF trial. Eur Heart J 2011;32:2266–73.

[11] Raatikainen MJ, Uusimaa P, van Ginneken MM, et al. Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and cost-effective means for follow-up. Europace 2008;10:1145–51.

[12] Ricci RP, Morichelli L, Santini M. Home monitoring remote control of pacemaker and ICD patients in clinical practice. Impact on medical management and health care resource utilization. Europace 2008;10:164–70.

[13] Crossley GH, Chen J, Choucair W, et al. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. J Am Coll Cardiol 2009;54:2012–9.

[14] Lazarus A. Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy systems: analysis of a worldwide database. Pacing Clin Electrophysiol 2007;30:S2–12.

[15] Hindricks G, Elsner C, Piorkowski C, et al. Quarterly vs. yearly clinical follow-up of remotely monitored recipients of prophylactic implantable cardioverter–defibrillators: results of the REFORM trial. Eur Heart J 2014;35:98–105.

[16] Lau CP, Zhang S. Remote monitoring of cardiac implantable devices in the Asia-Pacific. Europace 2013;15:i65–8.

[17] Ando K, Koyama J, Abe Y, et al. Feasibility evaluation of a remote monitoring system for implantable cardiac devices in Japan: a prospective analysis. Int Heart J 2011;52:39–43.

[18] Watanabe E, Kasai A, Fujii E, et al. Reliability of implantable cardioverter defibrillator home monitoring in forecasting the need for regular office visits, and patient perspective: Japanese HOME-ICD study. Circ J 2013;77:2704–11.

[19] Kamakura S. Necessity of face-to-face encounters with recipients of cardiovascular implantable electronic devices with remote monitoring. Circ J 2013;77:2691–3.

[20] Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. Circulation 2010;122:2359–67.

[21] Varma N, Epstein A, Irimpen A, et al. The lumos-T safely reduces routine efficacy and safety of automatic remote monitoring for implantablecardioverter–defibrillator follow-up. The Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial. Circulation 2010;122:325–32.

[22] Crossley G, Boyle A, Vitense H, et al. 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.

[23] Ricci RP, Morichelli L, D'Onofrio A, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the Home Guide Registry. Europace 2013;15:970–7.

[24] Guedon-Moreau L, Lacroix D, Sadoul N, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur Heart J 2013;34:605–14.

[25] Mabo P, Victor F, Bazin P, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). Eur Heart J 2012;33:1105–11.

[26] Dubner S, Auricchio A, Steinberg JS, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Europace 2012;14:278–93.

[27] Varma N. Remote monitoring of ICDs and CRTs. J Arrhythm 2013;29:144–52.

[28] Slotwiner D, Wilkoff B. Cost efficiency and reimbursement of remote monitoring: a US perspective. Europace 2013;15:i54–8.

[29] Chronaki CE, Vardas P. Remote monitoring costs, benefits, and reimbursement: a European perspective. Europace 2013;15:i59–64.

[30] Halimi F, Cantu F. on behalf of EHRA SIC. Remote monitoring for active cardiovascular implantable electronic devices: a European survey. Europace 2010;12:1778–80.