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Implementing Remote Monitoring of Cardiac Implantable Electronic Devices: The Clinical Experience from One Center in Sweden

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ABSTRACT. *Over the past few years, our clinic in Sweden has transitioned to remote monitoring of cardiac implantable electronic devices such that data from the devices can be seamlessly transferred to electronic health records. The process requires a substantial commitment of time and resources and necessitates cooperation with device manufacturers, but streamlines workflow. At our clinic, we had to partner with our information technology (IT) team to ensure successful implementation. Data at our clinic are output as PDF files rather than discrete data. Most patients responded favorably to remote monitoring with appropriate education. A case report illustrates the value of remote alerts in the everyday clinical care of device patients.*

KEYWORDS. *remote monitoring, remote follow-up.*

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Introduction

There are multiple benefits to remote monitoring of implantable cardioverter-defibrillators (ICDs), which offer the advantages of streamlining clinical workflow, saving time, and/or enhancing patient safety. Remote monitoring can allow multiple clinicians, even at geographically separate organizations, to simultaneously review ICD data from a patient. Remote follow-up can be used to develop integrated care models for cardiac patients.¹ The economic benefits of this technology have been demonstrated in that it reduced overall in-clinic visits,^{2,3} can aid clinics in forecasting follow-up visits,⁴ saves time,⁵ and offers greater clinical efficiencies than conventional “face-to-face” follow-up.⁶ Remote monitoring may also reduce the number of both appropriate and inappropriate shocks and spare battery life.⁷ Perhaps most meaningful to clinicians, remote monitoring has

the potential to improve the quality of care in device patients.⁸

Patients, like clinicians, do not always embrace new technologies. In a recent study (n=39,158) of new ICD patients, 76% of patients provided with remote monitoring equipment activated this equipment.⁹ However, not all patients were provided with this equipment, such that just under half of all patients (47%) in that study used remote monitoring. To be fair, remote monitoring adherence can vary widely by institution and likely by the way in which patients are introduced to the technology and equipment. A small focus group explored attitudes among nine device patients and found that those who did not use remote monitoring (50%) were distrustful and less likely to recall having their clinical team explain the equipment to them.¹⁰ In a study of ICD patients who used remote monitoring, 95% reported that they were happy or very happy with it.¹¹ Thus, patient adherence may not be the stumbling block as much as getting patients properly started using remote monitoring.

While remote monitoring is gaining widespread acceptance in the United States,¹² its use is varied around the world. In Australia, about 15%, 40%, and 50% and in Japan 5%, 50%, and 50% of pacemakers, ICDs, and cardiac resynchronization therapy (CRT) devices, respectively, use remote monitoring.¹³ In the United States,

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remote monitoring is increasingly directly integrated into electronic medical records.¹⁴ Statistics on remote monitoring use are not available for all countries, but remote monitoring utilization is clearly increasing in Europe and the United States.

The purpose of this report is to describe our experiences in making the transition to remote monitoring at an outpatient clinic in Sweden.

The transition to remote monitoring

In 2008, our cardiac implantable electrical device (CIED) outpatient clinic at Gavle County Hospital, Sweden, accounted for the follow-up of 1,800, 110, and 20 patients with pacemakers, implantable cardioverter-defibrillators (ICDs), and implantable loop recorders (ILRs), respectively. The corresponding numbers today are 1,800 pacemaker, 260 ICD, and 80 ILR patients. Remote monitoring was considered in the search for new ways of handling the burgeoning workload due to an expanding population of ICD and ILR patients. With the expectations that every other planned ICD and pacemaker in-clinic visit and almost every ILR visit could be replaced by a remote session, we embarked on remote follow-up and monitoring. Although it was not our main goal, it was thought that this transition might bring with it a bonus in the form of higher quality of ICD patient care through early detection of clinical or even subclinical problems, such as atrial fibrillation (AF) or ventricular arrhythmias.

We started with a limited number of ICD patients who agreed to receive a monitoring system and allow the 2G-/3G- and Internet-based transmission of encrypted personal information. Our relatively slow local expansion of ICD remote monitoring allowed for the handling of incoming data in a rather unorganized manner, often performed by a physician between scheduled outpatient device-clinic visits. In the beginning, we set up a fax notification for the most important red alerts. This method was amended later on, as we decided to routinely review the website every weekday. This made more sense for our clinic than the alternative possibilities of SMS messages or emails.

We were soon confronted with our limitations. For example, we lacked the trained personnel to offer 24/7 coverage. Our device-clinic nurses were not certified in the independent handling of ICDs, which limited their participation in the remote clinic. As the remote clinic grew, we set up a weekly schedule for the four arrhythmia device-trained physicians employed at the hospital. To prevent misunderstanding, a patient agreement with the clinic was signed by both parties, stating that follow-up service might be delayed on holidays, and making clear that remote monitoring was not meant to replace emergency care. Most patients signed the agreement: patients who refused did so because they rejected any sort of technical surveillance.

Somewhat unexpectedly, our youngest patients were more reluctant than older patients to participate in remote follow-up. We occasionally overheard comments about the monitor design and size. Some of our patients

used voice-over-internet-protocol (VOIP) connections on their landlines, which sometimes dropped out during sessions, causing time-consuming troubleshooting and patient frustration. Many of our patients had only cell phones and no landlines. For these two reasons, our clinic has almost totally abandoned landline monitor connections during the past years and now only provides 2G/3G- or WiFi router-connected monitors. We have now reviewed nearly 6,000 CIED remote follow-ups and alerts during the 5-year period.

Although the CIED remote care websites offered by various manufacturers are based on the same general principles, they work in quite different ways, which necessitates staff training in each system. To avoid confusion, the planned transmissions from the different systems can be scheduled to occur on different weekdays. However, alerts must be reviewed continuously every day in all systems.

Transitioning to remote following required the investment of a bolus of time for a short period before gains could occur. The staff needs an initial training period for some weeks with manufacturer support. The technical support service of each manufacturer should be available and will likely participate actively in the transition. There may be a need for financial negotiations with the health-care providers, in that the remote service efficiently replaces many in-office visits, and sometimes the reimbursement system is unable to compensate for this in an equitable way. Any additional costs regarding the remote monitors and remote-capable arrhythmia devices must also be taken into financial consideration.

The benefits of a remote clinic

While many patients still need in-office visits to discuss their symptoms, medications, and laboratory findings, at our hospital every second ICD patient visit is now a remote transmission instead. Almost all our ICD patients and the majority of our ILR patients use the remote service. This is not the case for our pacemaker patients; the bulk of pacemakers were implanted before our remote clinic was well established and do not offer remote communication. In contrast to today's ICDs, not every pacemaker model even offers remote monitoring (although many do). Thus, the in-office device clinic is dominated by pacemaker patients, while the remote clinic cares mainly for ICD, CRT, and ILR patients. It is our assumption that pacemaker patients are no less "sick" than ICD and CRT patients and could benefit from remote monitoring. As more and more pacemaker patients can be included in our remote clinic, we will accommodate them. We also follow ILRs remotely and will soon adopt wireless ILR remote monitoring.

In our CIED remote clinic, patient satisfaction has overall been quite good, with a few exceptions regarding phone connection hassles. We discovered that many of our patients expect a written message after each scheduled transmission. Alert actions are discussed with the patient by phone or during an unscheduled in-office visit. For the staff, this has caused a somewhat demanding change

Alert Summary

Fortify® DR, 2233-40 753786

09-02-2012 03:27

The transmission contains the following new alerts: (Note: these alerts were used for possible Alert Notification distribution.)

- Exceeded AT/AF Burden
- Long AT/AF Episode(s)

The transmission contains the following additional alerts: (Some of these alerts may have previously been reported.)

None

Please note: Alert Summary Reports may include information generated by the DirectAlerts® notification feature, selected through the Merlin.net® Patient Care Network DirectAlerts® notification feature settings. The Merlin.net® Patient Care Network DirectAlerts® notification feature information is not included in Implantable Device Summary Reports.

Figure 1: An alert message generated by the remote monitoring system told the clinical team that this patient had a long episode of atrial tachyarrhythmia.

in our clinical workflow, but these challenges were more than outweighed by the ability to shorten a CIED interrogation and the concomitant improvements in patient safety available through remote monitoring.

Our hospital uses electronic health records (EHRs), and it was our initial goal to automatically store data from device programmers as well as remote monitoring directly into the electronic record in a seamless fashion. We preferred that patient data be formatted more or less the same way as they appear on the manufacturer's printouts. In 2011, we worked with two device manufacturers (St. Jude Medical, St Paul, MN, and Medtronic, Inc., St. Paul, MN) to integrate their respective remote monitoring services with our EHR system (Soarian™ Clinicals, Siemens Healthcare, Malvern, PA). The integration was successful and carried out according to the standard Implantable Devices Cardiac Observation (IDCO) profile. It provides automatic and seamless data transfer.

The information technology (IT) department must be involved in the setting up of remote monitoring. It is important to treat these colleagues with respect, but also an awareness that they are not device experts and may need some "education" in terms of the objectives and desired results from remote monitoring. Most remote monitoring systems offer data export, and the IT group may be reluctant to open data ports and firewalls. A joint venture between the manufacturers and the IT department is necessary to resolve justifiable security concerns. One crucial point to avoid malware is that data should be *pulled* from the remote service (and not pushed) into the EHR. No manual export/import operation is needed by the clinician.

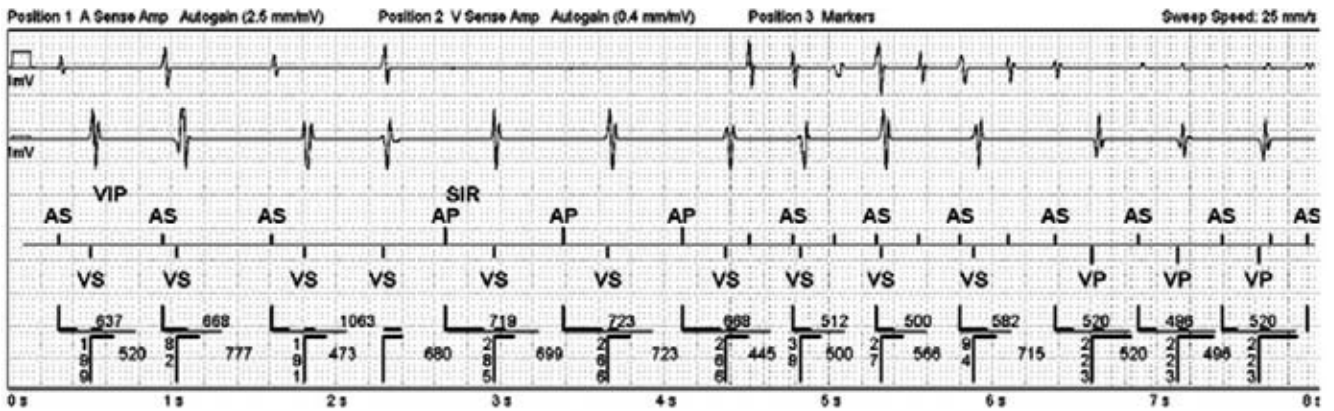
We decided to store patient records as PDF documents of the complete report rather than as discrete data. The advantage of our decision was that PDFs do not require a lot of storage space, but the drawback is that our database is not searchable for research purposes. It

AMS 8 Feb 2012 9:51

Report 1 of 1

Duration 14:35:50 (H:M:S)
 Peak A Rate 640 bpm
 Peak V Rate 121 bpm

Mode DDDR
 Alerts None



(Continued) AMS 8 Feb 2012 9:51

Report 1 of 1

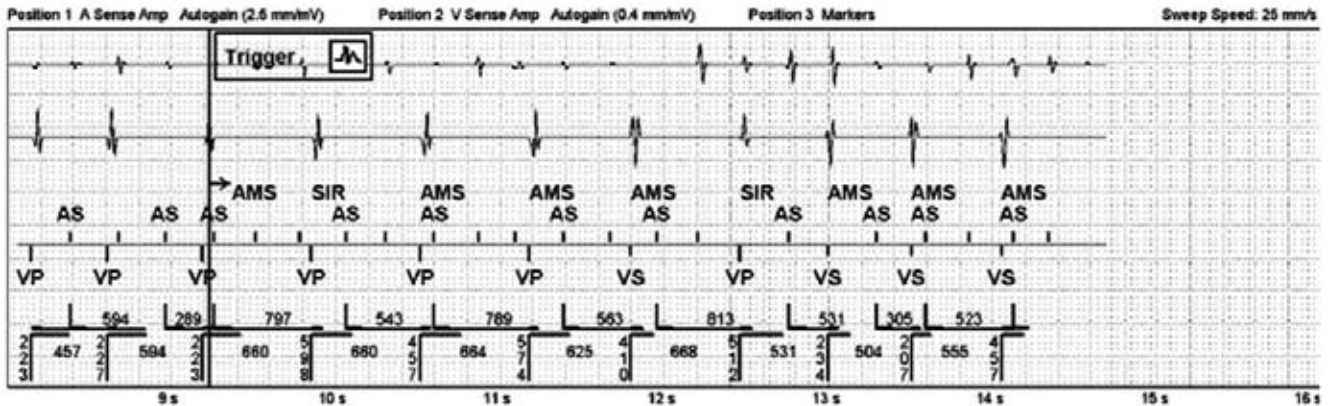


Figure 2: Based on the alert, the relevant electrogram was downloaded, showing atrial fibrillation with a rapid ventricular response. This triggered mode switching, shown in the lower strip.

may be that other clinics would reach the decision to store discrete data rather than PDFs.

With this system, almost no manual documentation is transferred to the EHR, only a summary of the interpretation and any action taken. Collecting or scanning of printouts can be avoided. All patient information is stored in one place and accessible to all authorized clinic staff. The risks of data loss and transfer errors are omitted. The accessibility to device data in the EHR is very important in many cases; for example, if the patient arrives at the emergency room, if the patient is referred for a treadmill test, or if the patient is transferred between hospital wards. Thus, patient safety is increased by both remote monitoring and EHR integration.

Recently, we have set up a wireless network communication feature between several device programmers and the local Intranet for transfer of data to a remote monitoring database (Merlin.net, St Jude Medical). This means that data from in-office programmer follow-ups are likewise automatically transferred into our EHR in the same way as with remote follow-ups. The data can upload in the background without any manual action. If the wireless network connection is temporarily lost, data buffers in the programmer and the upload resumes when the connection is restored. A complete follow-up uploads into our EHR in about 120 s, whether conducted either by a remote monitor or by a programmer. This reduces the documentation workload from in-office visits to the same extent as for remote follow-ups.

Alert Summary

Fortify® DR, 2233-40 753786

02-10-2012 03:53

The transmission contains the following new alerts: (Note: these alerts were used for possible Alert Notification distribution.)

•Successful ATP Therapy Delivered

The transmission contains the following additional alerts: (Some of these alerts may have previously been reported.)

None

Please note: Alert Summary Reports may include information generated by the DirectAlerts® notification feature, selected through the Merlin.net® Patient Care Network DirectAlerts® notification feature settings. The Merlin.net® Patient Care Network DirectAlerts® notification feature information is not included in Implantable Device Summary Reports.

Figure 3: The same patient had an alert message generated months later reporting that the patient had received antitachycardia pacing (ATP) therapy in response to a ventricular tachyarrhythmia. The patient was unaware of the therapy delivery.

Automatic EHR documentation is time-sparing without the compromise of data quality.

Case study

A 78-year-old man with a history of ischemic cardiomyopathy, sinus rhythm, and a left ventricular ejection fraction of 30% received a remote monitoring capable ICD and a remote monitor. An in-office programmer interrogation 10 months later revealed no abnormal observations. The next day, an alert message was received at our clinic, reporting that the patient during the past night suffered from a first episode of AF with a duration of 14 h (Figures 1 and 2). He was contacted by phone and had no clear chest symptoms. Anticoagulant treatment was initiated for stroke prophylaxis. Without the remote monitoring service, this silent episodic AF would not have been revealed until the next in-office visit or with symptoms, which could have been potentially life threatening.

Eight months later, the same patient's remote monitor reported an alert regarding a delivered antitachycardia pacing (ATP) treatment (Figure 3). One important question was if the therapy was appropriate in treating a genuine ventricular tachycardia (VT) or inappropriate and caused by AF with rapid ventricular response. A review of the transmitted intracardiac electrograms showed that the patient experienced VT and the therapy was appropriate (Figure 4). A treadmill test later on revealed exercise provoked ST-segment depressions in the ECG and a coronary angiogram was performed. A *de novo* left descendent coronary artery stenosis could be treated with angioplasty and stenting.

Future directions

The large and growing populations of device patients with AF and heart failure (HF) patients pose special challenges to the health-care system in general and to device clinics in particular. It may be hoped that AF

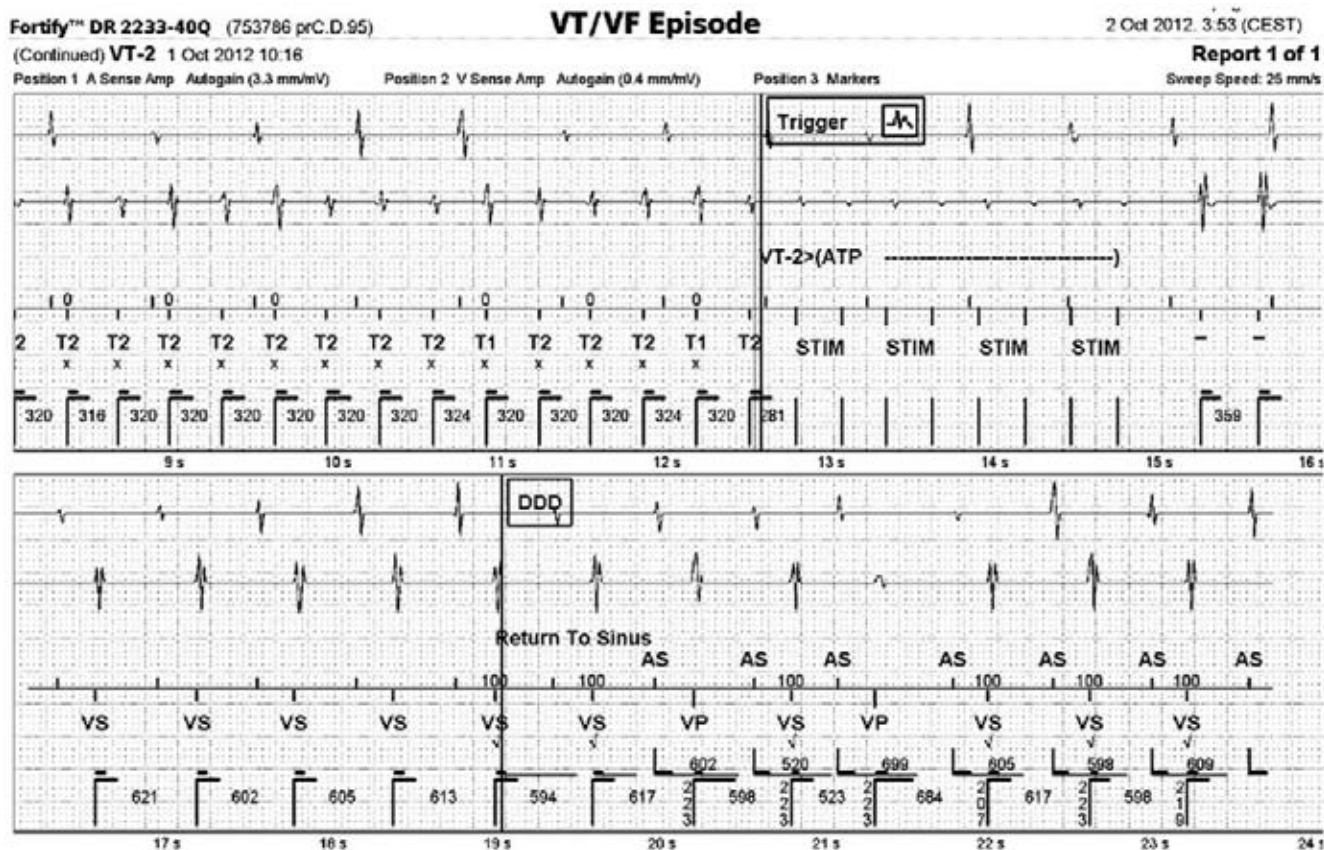


Figure 4: The clinic retrieved the appropriate tracing which clearly showed an episode of ventricular tachyarrhythmia which was successfully treated with antitachycardia pacing.

monitoring will prompt changes in pharmacologic regimens that may prevent intermittent and paroxysmal AF from becoming persistent and permanent and, in some cases, contributing to HF.¹⁵ So-called “actionable parameters” for HF can be used to determine the status of HF patients.¹⁶ Thus, increased emphasis on tools specifically designed to monitor these two conditions may be anticipated and are much needed. Remote monitoring of wireless ILRs may also soon be widely available.

Remote programming could be the logical next step in the remote clinic of the future. From a technical standpoint, remote programming is already possible. Programmability of certain parameters, such as alert settings or transmission intervals, will be less controversial than the ability to adjust pacing, sensing, and VT detection settings. An important option might be remote programming of a patient who is present at a satellite clinic staffed by junior personnel. Some important alerts regarding intracardiac sensing amplitude and pacing threshold values are still absent in some systems.

The growing burdens on the health-care system, including the inversion of the age pyramid, increasing numbers of device patients, cost constraints, and expanding device indications, mean that clinics will have to manage more patients (with more data than ever before) with limited resources. Remote monitoring will likely expand in terms of its use and its functionality as a timely and practical solution. Our experiences found that remote

monitoring requires a commitment of time, resources, and energy to set up, but results in streamlined workflows, improved patient safety, and reduction of paperwork.

Conclusion

Overall, the implementation of a CIED remote monitoring clinic at our hospital has been successful. At our hospital, almost every patient fitted with an ICD or an ILR participates in the remote clinic. After 5 years of remote follow-up for ICDs, only about 20% of all our pacemaker patients are remote monitored. Benefits are recognized in terms of less frequent in-office clinic visits and a higher patient care standard. Several routine checks no longer require in-clinic visits. Furthermore, cardiac arrhythmias, such as paroxysmal AF, can be detected early, sometimes even before the patient has any symptoms. Detection of non-sustained and sustained ventricular arrhythmias can help clinicians reprogram the device to prevent unnecessary shocks and improve patient comfort and quality of life. On the other hand, the complexity of each remote system can be technically challenging and could be simplified. To avoid information overload, technical and clinical alerts must be tailored for each patient and limited to only those useful for that particular patient. The incremental costs of devices that offer advanced remote

monitoring capabilities and the monitor itself can sometimes be constraints, which may require reimbursement negotiations with the health-care provider. Patients must be educated as to the value of remote monitoring and trained to set up the system at home. Before starting a remote monitoring program, a thorough plan is necessary with buy-in from all stakeholders. The interim demands placed on staff must be considered and time carefully scheduled; remote monitoring saves time over the long term but costs an investment of time upfront. Finally, the integration of a remote monitoring system into the local EHR system minimizes the need for manual data storage and saves time while simultaneously reducing errors.

References

- Perings SM, Perings C, Smetak N, et al. Home monitoring technology and integrated follow-up care of ICD patients. *Acta cardiologica* 2013; 68:381–386.
- Perl S, Stiegler P, Rotman B, et al. Socio-economic effects and cost saving potential of remote patient monitoring (SAVE-HM trial). *Int J Cardiol* 2013; 169:402–407.
- 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.
- Watanabe E, Kasai A, Fujii E, Yamashiro K, Brugada P. Reliability of implantable cardioverter defibrillator home monitoring in forecasting the need for regular office visits, and patient perspective. Japanese HOME-ICD study. *Circulation J* 2013; 77:2704–2711.
- Calo L, Gargaro A, De Ruvo E, et al. Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits. A single-center prospective and randomized study. *J Interv Card Electrophysiol* 2013; 37:69–78.
- Guedon-Moreau L, Mabo P, Kacet S: Current clinical evidence for remote patient management. *Europace* 2013; 15(Suppl 1):i6–i10.
- Guedon-Moreau L, Lacroix D, Saoul 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; 34:605–614.
- 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; 125:2985–2992.
- Akar JG, Bao H, Jones P, et al. Use of remote monitoring of newly implanted cardioverter-defibrillators: insights from the patient related determinants of ICD remote monitoring (PREDICT RM) study. *Circulation* 2013; 128:2372–2383.
- Ottenberg AL, Swetz KM, Mueller LA, Gerhardson S, Mueller PS. “We as Human Beings Get Farther and Farther Apart”: the experiences of patients with remote monitoring systems. *Heart Lung* 2013; 42:313–319.
- Petersen HH, Larsen MC, Nielsen OW, Kensing F, Svendsen JH. Patient satisfaction and suggestions for improvement of remote ICD monitoring. *J Interv Card Electrophysiol* 2012; 34: 317–324.
- Slotwiner D, Wilkoff B. Cost efficiency and reimbursement of remote monitoring: a US perspective. *Europace* 2013; 15(Suppl 1):i54–i58.
- Lau CP, Zhang S. Remote monitoring of cardiac implantable devices in the Asia-Pacific. *Europace* 2013;15(Suppl 1): i65–i68.
- Van der Velde ET, Atsma DE, Foeken H, Witteman TA, Hoekstra WH. Remote monitoring of patients with implanted devices: Data exchange and integration. *Eur J Prev Cardiol* 2013; 20(2 Suppl):8–12.
- Santini M. Remote monitoring and the twin epidemics of atrial fibrillation and chronic heart failure. *Europace* 2013; 15(Suppl 1):i47–i48.
- Muller A, Goette A, Perings C, et al. Potential role of telemedical service centers in managing remote monitoring data transmitted daily by cardiac implantable electronic devices: results of the early detection of cardiovascular events in device patients with heart failure (detecT-Pilot) study. *Telemed J e-Health* 2013; 19:460–466.