

Use of remote monitoring in the management of system-related complications in implantable defibrillator patients

D. A. M. J. Theuns · L. Jordaens

Published online: 1 December 2011
© Springer Media / Bohn Stafleu van Loghum 2011

Abstract Remote monitoring of implantable defibrillators (ICDs) is designed to minimise regular follow-up visits and to facilitate early detection of adverse events. With the increased rate of ICD implantations in today's clinical setting and multiple device advisories, which pose management challenges, this approach becomes very attractive. The aim of this article is to present the role of remote monitoring in the detection of system-related complications, its potential benefits and its barriers in the outpatient management of ICD patients.

Keywords Implantable cardioverter-defibrillator · Remote monitoring · Lead failure · Arrhythmias · Complications

Introduction

Randomised clinical trials have demonstrated that primary prevention with implantable cardioverter-defibrillators (ICDs) and cardiac resynchronisation therapy defibrillators (CRTDs) improve survival in patients with heart failure due to ischaemic or nonischaemic cardiomyopathy [1–4]. The implantation rate of ICDs and CRTDs has increased exponentially in response to these trials. Assessment of post-implant system performance and the patient condition is a recognised

responsibility for the physician [5]. Expert consensus advocates scheduled in-clinic checks at 3- to 6-monthly intervals with increased frequency in response to product advisories [5]. The major limitation of conventional follow-up is the lack of information on system performance and the clinical status of the patient between hospital visits. Remote monitoring of devices offers a possibility for continuous surveillance and rapid event identification notification [6, 7]. The aim of this article is to present the role of remote patient monitoring in ICD follow-up, its potential benefits and its barriers in the management of system-related complications.

Monitoring of system integrity

The integrity of the implanted system is essential for appropriate device therapy. Unfortunately, a significant proportion of ICD recipients experience system-related complications. The majority of these complications are lead-related, which may occur at any time during follow-up. The annual failure rate of defibrillation leads will increase progressively over time after implantation and will reach 20% in 10-year-old leads [8]. Causes of ICD lead failure are an insulation defect or conductor disruption, which can both affect the high-voltage or the pace-sense circuit of the system. Potential complications of ICD lead failure include undersensing of ventricular arrhythmias, oversensing of noise, inappropriate therapy, and in the worst case lethal proarrhythmia. Early detection of these complications is desirable to ensure the patient's safety.

Conventional devices have an extensive self-monitoring ability and data are recorded in the device's memory. When asymptomatic events occur, this diagnostic information is only manifest at scheduled follow-up visits. This is a potential

D. A. M. J. Theuns (✉)
Department of Cardiology, Bd416, Erasmus MC,
PO Box 2040, 3000 CA, Rotterdam, the Netherlands
e-mail: d.theuns@erasmusmc.nl

L. Jordaens
Department of Cardiology, Ba581, Erasmus MC,
PO Box 2040, 3000 CA, Rotterdam, the Netherlands

problem with regard to system-related complications, which can be silent and may leave the patient unprotected from life-threatening tachyarrhythmias. Patient-alert features have been implemented in ICDs for detection of system-related complications, for example acoustic alerts. Swerdlow et al. [9] demonstrated that the Medtronic lead integrity alert algorithm triggered an acoustic alert of impending inappropriate shocks at least 3 days in advance in 76% of patients with lead failure. However, although these acoustic alerts are a useful tool facilitating early detection of system-related complications, they are insensitive and prone to false-positive evaluations [10, 11]. Prevailing delayed lead-related complications such as lead fracture and insulation defect are directly related to the lead impedance. As the lead impedance is part of the pre-defined alerts in remote monitoring, this technique has the potential for early detection of lead-related complications (Fig. 1). In Table 1, common alert options regarding system integrity are presented. The device-related alerts are non-programmable, while the lead-related alerts are programmable with respect to lower

Table 1 Remote monitoring alert options regarding system integrity

Device-related
Ventricular detection OFF
Device reset
End of service
Elective replacement indication
Active emergency brady pacing
Backup pacing mode
Lead-related
Pacing lead impedance out-of-range
High-voltage impedance out-of-range
Right ventricular sensing amplitude

and upper limits for normal impedance characteristics of the implanted leads.

Remote monitoring of system integrity

Several observational studies and randomised clinical trials have shown the beneficial effect of remote monitoring on outpatient management of ICD patients [12–19]. Data regarding system-related complications and remote monitoring are presented in Table 2. The Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) Trial demonstrated that remote monitoring is safe and allows early detection of events compared with conventional follow-up [20]. In this trial, system-related complications were infrequent and often asymptomatic; 62 system-related events (53 remote vs. 9 conventional) in 46 patients (40 remote vs. 6 conventional) were observed. Post-hoc analysis of these system-related complications revealed that remote monitoring permitted prompt detection (remote vs. conventional: median 1 vs. 5 days) and facilitated management decisions [18]. Twenty system-related complications required surgical intervention (remote vs. conventional, 15 vs. 5). In a retrospective cohort analysis of patients with an ICD lead failure, remote monitoring resulted in a significant reduction of inappropriate shocks and symptomatic pacing inhibition compared with those without remote monitoring (27% vs. 53%, $P=0.04$) [21].

The diagnosis of lead-related complications may be challenging and cannot be solely based on impedance changes [11]. In case of lead fractures, alerts triggered by out-of-range impedances are one step beyond as the fracture has already occurred. For early detection of lead failure, continuous monitoring of sensing values and especially the detection of episodes caused by electrical oversensing would be more helpful. Spencker et al. [21] found that up to 90% of the patients with lead failure presented with

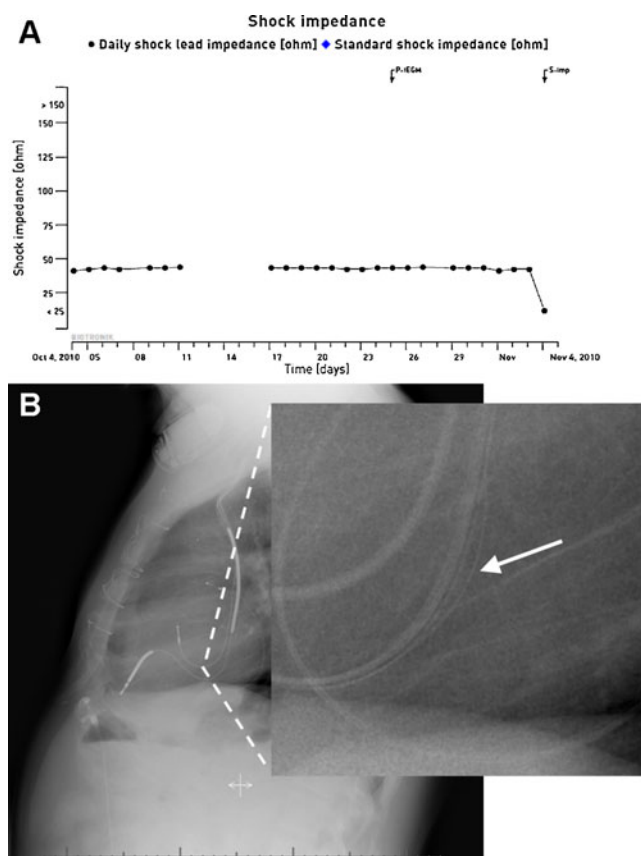


Fig. 1 Panel a Transmitted event notification due to a low shock impedance ($< 25\Omega$). The graph demonstrates a sudden drop in the daily measured shock impedance. Panel b Fluoroscopy, lateral view with zoomed image demonstrating inner coils out of the insulation of the high-voltage lead

Table 2 System-related adverse events and remote monitoring studies

Author	Patients (n)	Follow-up	Events		System-related events	
			Reports	Patients	Reports	Patients
Observational cohort studies						
Nielsen et al. [12]	260	10±5 months	–	41.2%	–	3.1%
Hauck et al. [13]	169	18±9 months	206	48	6	6
Theuns et al. [14]	146	22±16 months	1009	138	50	11
De Ruvo et al. [15]	133	7 months	407	–	7	–
Folino et al. [19]	206	13±9 months	417	–	7	–
Randomised clinical trials						
Al-Khatib et al. [16]	1151	12 months	–	–	–	7%
Guédon-Moreau et al. [17]	1433	22±4 months	–	–	–	4
Varma et al. [18]	1339	14±3 months	2784	908	53	40

episodes of electrical oversensing detected as ventricular tachyarrhythmias.

Remote monitoring and device advisories

Concerns about the reliability of implanted systems rose after recent device and lead advisories from all major manufacturers. These advisories have put remote monitoring in a new perspective. Immediate solutions such as systematic ICD generator replacement are associated with a substantial rate of complications, including death [22]. To prevent serious health consequences associated with system-related complications, regulatory institutions and scientific societies drew guidelines to manage patients with advisory systems. A continuous surveillance of defibrillation systems at risk is the most attractive alternative, which provides an immediate detection of device or lead failure. In addition, continuous monitoring of specific device parameters may avoid unnecessary replacements. From this viewpoint, the Heart Rhythm Society recommended that cardiac rhythm management device manufacturers develop and use remote monitoring technologies for early detection of abnormal device behaviour and to reduce underreporting of device malfunction [23, 24]. The Effectiveness and Cost of ICDs Follow-up Schedule with Telecardiology (ECOST) Trial demonstrated the value of remote monitoring for follow-up of ICD leads under advisory [17]. A total of 40 recipients of a high-voltage lead, prone to fracture, were remotely followed. Of these, four lead dysfunctions were discovered due to remote transmission of noise artefacts, abrupt rise in impedance, or both. In a recent report of ICDs under advisory, lower than expected failure rates were observed in explanted advisory devices; 0% and 0.34% for observed versus 0.72% and 1.83% for expected [25]. The finding

of this report emphasises the need for continuous monitoring of implanted defibrillation systems to avoid unnecessary replacements.

Taken together, remote monitoring may change management decisions because malfunction of devices or leads may confer different risks in different patient groups. For example, elective replacement of a lead under advisory may be unnecessary in patients who are not pacemaker-dependent or who have a primary prevention indication. Remote management of systems under advisory has the potential to reduce morbidity/mortality and associated hospital admissions with implications for cost reduction.

Conclusion

Remote monitoring is feasible, may facilitate ICD follow-up, and lead to early detection of system-related complications. Continuous monitoring of specific device parameters may avoid unnecessary replacements of devices or leads. However, as with every new technology, there are areas of uncertainty. Remote monitoring is associated with a redesigned organisation of the care system, including physicians, allied professionals, and a dedicated remote monitoring service. Another area of uncertainty is related to the question of liability. The now “virtual patient” poses a paradigm shift. Physicians have the responsibility for responding to the new sources of data. How fast must a physician react to the transmitted alerts? Do we need 24 h, 7 days a week coverage or is it legally acceptable not to check event notifications outside the office hours? The development of practice guidelines on the appropriate role of remote monitoring of patients with implanted cardiac devices would help to address many of these issues.

References

- Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. 2002;346:877–83.
- Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med*. 2004;350:2140–50.
- Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. 2005;352:225–37.
- Theuns DA, Smith T, Hunink MG, et al. Effectiveness of prophylactic implantation of cardioverter-defibrillators without cardiac resynchronization therapy in patients with ischaemic or non-ischaemic heart disease: a systematic review and meta-analysis. *Europace*. 2010;12:1564–70.
- Wilkoff BL, Auricchio A, Brugada J, 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.
- Theuns DA, Jordaens LJ. Remote monitoring in implantable defibrillator therapy. *Neth Heart J*. 2008;16:53–6.
- Schoenfeld MH, Reynolds DW. Sophisticated remote implantable cardioverter-defibrillator follow-up: a status report. *Pacing Clin Electrophysiol*. 2005;28:235–40.
- Kleemann T, Becker T, Doenges K, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation*. 2007;115:2474–80.
- Swerdlow CD, Gunderson BD, Ousdigian KT, et al. Downloadable algorithm to reduce inappropriate shocks caused by fractures of implantable cardioverter-defibrillator leads. *Circulation*. 2008;118:2122–9.
- Vollmann D, Erdogan A, Himmrich E, et al. Patient alert to detect ICD lead failure: efficacy, limitations, and implications for future algorithms. *Europace*. 2006;8:371–6.
- Kallinen LM, Hauser RG, Lee KW, et al. Failure of impedance monitoring to prevent adverse clinical events caused by fracture of a recalled high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. 2008;5:775–9.
- Nielsen JC, Kottkamp H, Zabel M, et al. Automatic home monitoring of implantable cardioverter defibrillators. *Europace*. 2008;10:729–35.
- Hauck M, Bauer A, Voss F, et al. “Home monitoring” for early detection of implantable cardioverter-defibrillator failure: a single-center prospective observational study. *Clin Res Cardiol*. 2009;98:19–24.
- Theuns DA, Rivero-Ayerza M, Knops P, et al. Analysis of 57,148 transmissions by remote monitoring of implantable cardioverter defibrillators. *Pacing Clin Electrophysiol*. 2009;32 Suppl 1:S63–5.
- De Ruvo E, Gargaro A, Sciarra L, et al. Early detection of adverse events with daily remote monitoring versus quarterly standard follow-up program in patients with CRT-D. *Pacing Clin Electrophysiol*. 2010;34:208–16.
- Al-Khatib SM, Piccini JP, Knight D, et al. Remote monitoring of implantable cardioverter defibrillators versus quarterly device interrogations in clinic: results from a randomized pilot clinical trial. *J Cardiovasc Electrophysiol*. 2010;21:545–50.
- Guedon-Moreau L, Chevalier P, Marquie 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.
- Varma N, Michalski J, Epstein AE, et al. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial. *Circ Arrhythm Electrophysiol*. 2010;3:428–36.
- Folino AF, Chiusso F, Zanotto G, et al. Management of alert messages in the remote monitoring of implantable cardioverter defibrillators and pacemakers: an Italian single-region study. *Europace*. 2011;13:1281–91.
- Varma N, Epstein AE, Irimpen A, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial. *Circulation*. 2010;122:325–32.
- Spencer S, Coban N, Koch L, et al. Potential role of home monitoring to reduce inappropriate shocks in implantable cardioverter-defibrillator patients due to lead failure. *Europace*. 2009;11:483–8.
- Gould PA, Krahn AD. Complications associated with implantable cardioverter-defibrillator replacement in response to device advisories. *Jama*. 2006;295:1907–11.
- Carlson MD, Wilkoff BL, Maisel WH, et al. Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines Endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and the International Coalition of Pacing and Electrophysiology Organizations (COPE). *Heart Rhythm*. 2006;3:1250–73.
- Maisel WH, Hauser RG, Hammill SC, et al. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines: developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). *Heart Rhythm*. 2009;6:869–85.
- Perrotta L, Pieragnoli P, Ricciardi G, et al. Multicenter experience with implantable defibrillators subject to recall. *Pacing Clin Electrophysiol*. 2011;34:998–1002.