Europace (2011) **13**, 221–229
doi:10.1093/europace/euq447

Remote monitoring of implantable-cardioverter defibrillators: results from the Reliability of IEGM Online Interpretation (RIONI) study

Christian Perings[1]*, Wolfgang Rudolf Bauer[2], Hans-Jürgen Bondke[3], Christian Mewis[4], Michael James[5], Dirk Böcker[6], Paul Broadhurst[7], Thomas Korte[8], Egon Toft[9,10], Florian Hintringer[11], Jacques Clémenty[12], and Jörg Otto Schwab[13]

[1]Department of Cardiology and Angiology, Marienhospital Herne, University of Bochum, Bochum, Germany; [2]Medical Clinic, University of Würzburg, Würzburg, Germany; [3]Department of Internal Medicine Cardiology and Angiology, Campus Mitte, Charité Universitätsmedizin Berlin, Berlin, Germany; [4]Internal Medicine III—Cardiology, Angiology and Intensive Care Medicine, Saarland University Hospital, Homburg/Saar, Germany; [5]Department of Cardiology, Taunton and Somerset Hospital, Somerset, UK; [6]Department of Cardiology and Angiology, Hospital of the University of Münster, Münster, Germany; [7]Department of Cardiology, Aberdeen Royal Infirmary, Aberdeen, UK; [8]Department of Cardiovascular Medicine, Hannover Medical School, Hannover, Germany; [9]Department of Cardiology, Aalborg Hospital, Arhus University Hospitals and Center for Sensory-Motor Interaction, Aalborg, Denmark; [10]Department of Health Science and Technology, Aalborg University, Aalborg, Denmark; [11]Clinical Department of Cardiology, Medical University Innsbruck Anichstrasse, Innsbruck, Austria; [12]Hôpital Cardiologique du Haut-Lévêque, Université Victor Segalen Bordeaux II, Bordeaux, France; and [13]Department of Medicine/Cardiology, University of Bonn, Bonn, Germany

Received 25 August 2010; accepted after revision 17 November 2010

Aims Intracardiac electrograms (IEGMs) recorded by implantable cardioverter-defibrillators (ICDs) are essential for arrhythmia diagnosis and ICD therapy assessment. Short IEGM snapshots showing 3–10 s before arrhythmia detection were added to the Biotronik Home Monitoring system in 2005 as the first-generation IEGM Online. The RIONI study tested the primary hypothesis that experts' ratings regarding the appropriateness of ICD therapy based on IEGM Online and on standard 30 s IEGM differ in $<10\%$ of arrhythmia events.

Methods and results A total of 619 ICD patients were enrolled and followed for 1 year. According to a predefined procedure, 210 events recorded by the ICDs were selected for evaluation. Three expert board members rated the appropriateness of ICD therapy and classified the underlying arrhythmia using coded IEGM Online and standard IEGM to avoid bias. The average duration of IEGM Online was 4.4 ± 1.5 s. According to standard IEGM, the underlying arrhythmia was ventricular in 135 episodes (64.3%), supraventricular in 53 episodes (25.2%), oversensing in 17 episodes (8.1%), and uncertain in 5 episodes (2.4%). The expert board's rating diverged between determinable IEGM Online tracings and standard IEGM in 4.6% of episodes regarding the appropriateness of ICD therapy (95% CI up to 8.0%) and in 6.6% of episodes regarding arrhythmia classification (95% CI up to 10.5%).

Conclusion By enabling accurate evaluation of the appropriateness of ICD therapy and the underlying arrhythmia, the first-generation IEGM Online provided a clinically effective basis for timely interventions and for optimized patient management schemes, which was comparable with current IEGM recordings.

Keywords Implantable cardioverter-defibrillator • Remote monitoring • Home Monitoring • Intracardiac electrogram • ICD therapy appropriateness • Arrhythmia detection

Introduction

Inappropriate device therapies and technical issues adversely affect the clinical course, treatment satisfaction, and the quality-of-life of patients with implantable cardioverter-defibrillators (ICDs).[1–5] Early diagnosis and treatment of adverse events and their precursors between clinical visits may improve clinical outcomes. Home Monitoring technology (Biotronik SE and Co. KG, Berlin,

* Corresponding author: Prof. Dr. med. Christian Perings, Chefarzt der Medizinischen Klinik I, Klinik für Kardiologie, Elektrophysiologie, Pneumologie und Intensivmedizin, Klinikum Lünen, St.-Marien-Hospital, Altstadtstr.23, 44534-Lünen, Germany. Tel: +49 2306 772351; fax: +49 2306 772335, Email: perings.christian@klinikum-luenen.de

Germany) offers remote monitoring of the device's status and therapies without direct patient contact and involvement. Data are transmitted automatically from the implanted device to a secure website once a day as well as immediately following an arrhythmia.[6–10] Because intracardiac electrogram (IEGM) snapshots are essential for arrhythmia diagnosis and assessment of ICD therapy,[11,12] 'IEGM Online' was added to the Home Monitoring system in 2005. It covered the last 3 s before detection of rapid arrhythmia, or up to 10 s for slower arrhythmia, and the IEGM tracing was compressed to reduce the size of the file for remote transmission.[13–15] Owing to these constraints, the interpretation of episodes and therapeutic decisions based on the first-generation IEGM Online might be expected to vary in some cases from conclusions drawn from standard IEGM recordings.

The Reliability of IEGM Online Interpretation (RIONI) study was a prospective multicentre study designed to investigate whether a remote evaluation of the ICD's therapeutic decisions using the first-generation IEGM Online is safe and reliable, and did not lead to a clinically relevant number of inappropriate remote evaluations by the physician.

Methods

Study design

The study design was described in a previous publication.[14,15] The current report focuses on the evaluation of an expert board consisting of three members identified in the Appendix. The primary hypothesis states that the rating regarding the appropriateness of ICD therapy based on IEGM Online differs from the rating based on standard IEGM recordings in <10% of arrhythmia events.

A statistically sound, pre-specified sample of 210 arrhythmia events was selected among all events detected by the ICDs using a predefined procedure described in a later section. For each episode, both the IEGM Online printout and the standard 30 s IEGM printout derived from the ICD were prepared (*Figure 1*), and evaluated by the expert board. Without knowing the link between the two printouts for the same episode, the board members rated the appropriateness of ICD therapy ('safety') and classified the underlying arrhythmia for each printout ('reliability'). Although a relative margin of 20% is typical for non-inferiority testing, our predefined criteria for clinical acceptability were more stringent, requiring <10% divergence between the two IEGM types for findings on therapy appropriateness and <15% divergence for arrhythmia classification. The difference between the two latter numbers reflects our anticipation that in some instances it may be more difficult to accurately diagnose arrhythmia (for instance, self-terminated ventricular tachycardia vs. supraventricular tachycardia) than to conclude that no shock delivery is appropriate therapy in either case.

The examinations were conducted according to the Good Clinical Practice Guidelines and Declaration of Helsinki. Ethics committee approval was obtained, and all patients provided written informed consent.

Patients

A total of 619 patients were enrolled from May 2005 to June 2007 at 49 clinical centres in six European countries (Appendix). The enrolled patients had indications for the implantation of either an ICD or a cardiac resynchronization therapy-defibrillator (CRT-D), were in stable medical condition, and were willing to attend all follow-ups. The patients were not admitted to the study if they had contraindications for ICD or CRT-D implantation, New York Heart Association (NYHA) functional class IV symptoms, advanced brain disease, life expectancy shorter than 6 months, or age <18 years. Further exclusion criteria were patients' inability to operate the Patient Device needed for Home Monitoring or living in an area without mobile phone coverage (GSM).

Table 1 shows baseline characteristics of the enrolled patients. The study cohort represented a typical ICD population with respect to age, gender, and aetiology. Sixty-five per cent of the patients had heart failure with NYHA class II or III symptoms. The proportion of secondary prevention indications of 58% was higher than seen in contemporary practice in the USA (22%).[16] Approximately every fourth patient had a history of documented supraventricular tachyarrhythmia.

Devices

The majority of patients (63%) received a single-chamber ICD (model LUMOS VR-T, $n = 392$), and the others received either a dual chamber ICD (LUMOS DR-T, $n = 189$) or a CRT-D (KRONOS LV-T, $n = 38$) (Biotronik SE and Co. KG, Berlin, Germany). The programmed duration of the standard IEGM snapshot before ventricular or supraventricular arrhythmia detection was 30 s. The SMART algorithm for arrhythmia discrimination[17] was activated in dual chamber ICDs and CRT-Ds.

Remote monitoring

All implanted devices had Home Monitoring and IEGM Online capability.[9,10,13] Home Monitoring is a remote monitoring system consisting of an implant capable of sending data daily at a prescheduled time, typically in the early morning hours while patients are asleep, including IEGM Online for the most recent arrhythmia episode.[10,13–15] Data are received by a mobile-phone like Patient Device and passed on via the mobile phone network to a service centre. In addition to time-triggered transmissions, data can be sent automatically after an arrhythmia episode if the patient is in the vicinity of the Patient Device. Home Monitoring has recently been approved by the US Food and Drug Administration (FDA) and Conformité Européenne (CE) for extending follow-up intervals due to its ability to reliably detect clinical events. The first-generation IEGM Online employed by the ICD models used in this study covered the last 3 s before detection of rapid arrhythmia, or up to 10 s for slower arrhythmia. The IEGM tracing was graphically condensed using a stylized drawing to reduce the size of the file for remote transmission (*Figure 1B*).[13–15]

Follow-up

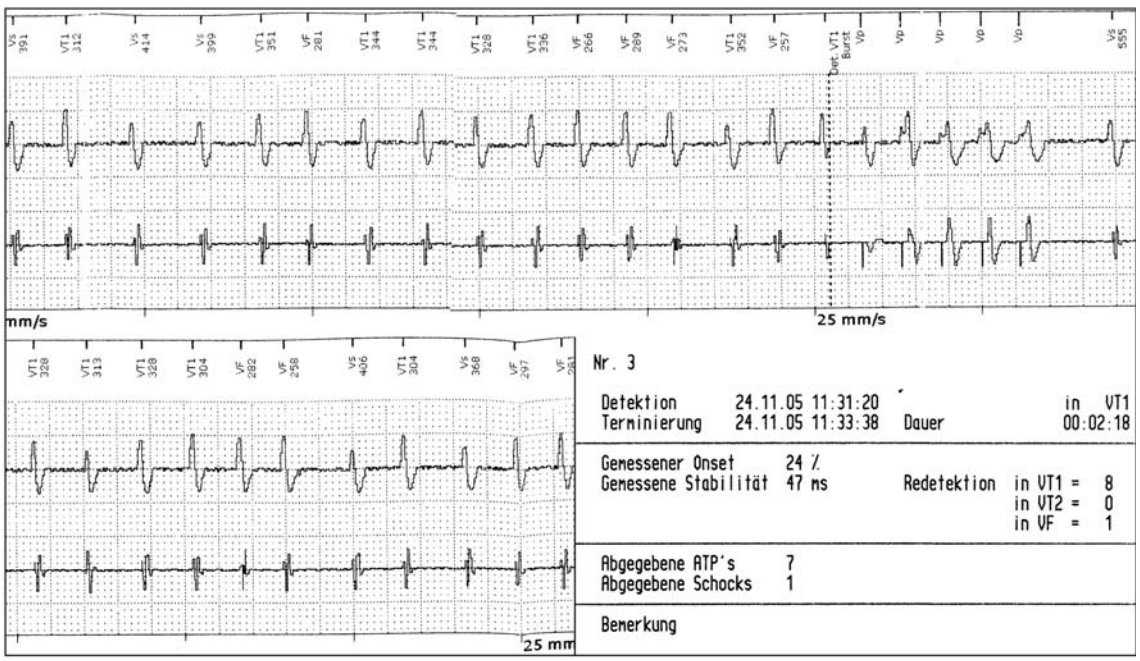
Routine office visits were scheduled every 3 months until 12 months after hospital discharge. Additional follow-up checks were performed based on the investigator's own discretion or on patient demand.

Selection and analysis of intracardiac electrogram printouts

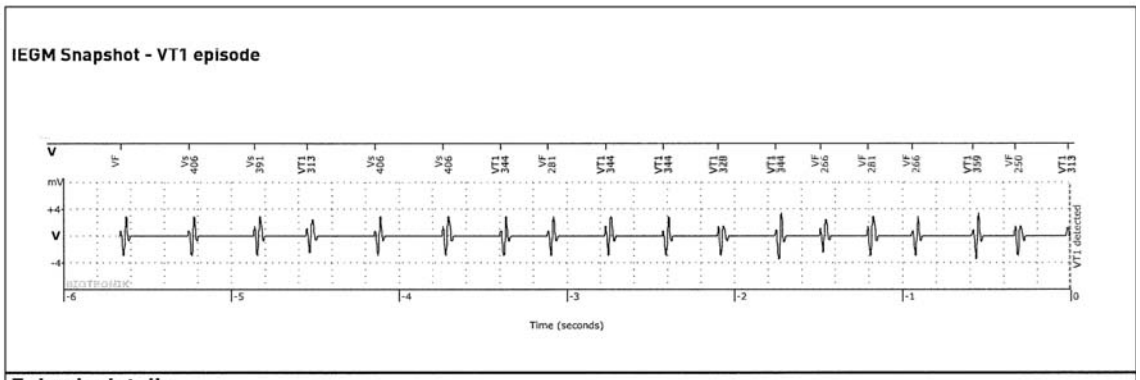
As of the time, the episodes were compiled for evaluation by the expert board, 1382 ICD episodes were available from 166 patients. Of these, 674 episodes were accompanied by IEGM Online and had been properly documented by the attending investigators. According to study protocol, the 210 events that occurred first were selected with a restriction to a maximum of five episodes of the same rhythm type per patient.[14]

The IEGM Online and standard IEGM were printed for these 210 episodes together with all accompanying information except for patient or device identifiers (*Figure 1*). For each printout, three

A



B



Episode details

Episode number	3
Detection	Nov 24, 2005 11:31:20 AM
Termination	Nov 24, 2005 11:33:36 AM
Duration	2 min 16 s
Detection in	VT1
Redetection	VT1: 8, VF: 1
Delivered ATPs	7
Delivered shocks	1 (last shock impedance: 58 ohm)
Remark	

Figure 1 The pivotal segment of the standard IEGM snapshot (10 s of the 30 s available, *A*) and the corresponding full IEGM Online (*B*), both including episode details, for an arrhythmia detected as VT1 by a single-chamber ICD. The expert board concluded that atrial fibrillation was the underlying arrhythmia due to the relatively slow, irregular rhythm with ineffective ATP and shock therapy, evident in either IEGM report. Both IEGM channels in (A) are ventricular, using different electrode configurations. Apart from its shorter duration, IEGM Online has also a lower graphic resolution, resulting in slightly different RR-intervals for IEGM Online vs. standard IEGM (numbers above tracings). ATP, antitachycardia pacing; ICD, implantable cardioverter-defibrillator; IEGM, intracardiac electrogram; SVT, supraventricular tachyarrhythmia; VF, ventricular fibrillation; Vs, sensed ventricular beat outside an arrhythmia zone; VT1, ventricular tachycardia detected in zone 1 (slow); VT2, ventricular tachycardia detected in zone 2 (rapid). Translation of specific German words for episode details in (A): Dauer 'duration'; Gemessener 'measured'; Abgegebene 'delivered'; Bemerkung 'remark'.

expert board members rated the ICD therapy as appropriate, not appropriate, or indeterminable (not possible to decide based on available data), and classified the underlying arrhythmia as ventricular, supraventricular, oversensing, or indeterminable. A consensus between at least two of three members was taken as the board's decision.

Table 1 Baseline population characteristics

Baseline characteristic	*n* = 619
Age (years)	63 ± 12
Female (%)	108 (17)
Primary prevention ICD indication (%)	258 (42)
Secondary prevention ICD indication (%)	361 (58)
Ejection fraction	36% ± 15%
Ejection fraction ≤45%	402 (65)
NYHA functional class (%)	
I	92 (15)
II	289 (47)
III	110 (18)
Underlying disease (%)	
Ischaemic heart disease	406 (66)
Non-ischaemic dilated cardiomyopathy	116 (19)
Diabetes	115 (19)
Chronic kidney disease	114 (18)
History of AFib/or any SVT	142/162 (23/26)
Medication (%)	
Antiarrhythmic	197 (32)
Beta-blocker	516 (83)
ACE-inhibitor or angiotensin-antagonist	482 (78)
Ca-antagonist	62 (10)
Digitalis	89 (14)
Anticoagulant	268 (43)
Diuretics	371 (60)
Platelet agglutination inhibitor	309 (50)

ACE, angiotensin-converting enzyme; AFib, atrial fibrillation; ICD, implantable cardioverter-defibrillator; NYHA , New York Heart Association; SVT, supraventricular tachyarrhythmia; VF, ventricular fibrillation; VT, ventricular tachycardia.

A few of the 210 episodes could not eventually be included in the endpoint analyses because they were classified as indeterminable based on IEGM Online (a situation equivalent to having no IEGM Online) or did not reach 'at least two of three' consensus for either IEGM Online or standard IEGM, leading to discordant expert's opinion on the potential divergence between the two IEGM types. The counts of these cases are provided in Results.

In all determinable IEGM Online episodes with 'at least two of three' consensus, the divergence in findings between the IEGM Online and standard IEGM printouts was expected to be statistically significantly <10% for therapy appropriateness (primary endpoint), and statistically significantly <15% for arrhythmia classification (the main secondary endpoint). These criteria were predefined according to perceived clinical acceptability and are more stringent than a typical relative margin for non-inferiority testing of 20%.

Statistical methods

Continuous variables are reported as mean ± SD. Categorical variables are reported as numbers (percentages). The one-sided 95% confidence interval (CI) of relative frequencies was calculated based on a binomial distribution. In all cases, statistical significance was established as $P < 0.05$. Analysis was performed using the software package IBM SPSS/PASW Statistics 18 (SPSS, Inc., Chicago, IL, USA).

The trial was powered to prove with a statistical power of 80% at the one-sided significance level of 5% that the rating regarding the appropriateness of ICD therapy based on IEGM Online differs from the rating based on standard IEGM recordings in <10% of arrhythmia events. The number of episodes needed for the analysis ($n = 210$) was computed assuming the rate of episodes misclassification of 4%, a conservative drop-out of 20% (indeterminable episodes), and that interim analyses will be performed after 70 and 140 episodes with adjusted level of significance according to the sequential group method of Pocock. The interim analyses were eventually not conducted due to delays in data completion and hence there was no need for adjustment of significance levels. Furthermore, we estimated that 210 episodes would require ~2880 patient months of follow-up. Hence, 240 patients should be followed for 12 months. We did not assume any proportional distribution of single chamber vs. dual chamber devices. The proportion shown in Results reflects routine clinical practice at the participating centres.

During the study, the number of patients was increased to 600 because many detected arrhythmia episodes were not eligible for endpoint analyses due to missing standard IEGM printouts or missing arrhythmia classification by the attending investigators. This cohort expansion was simplified by the fact that study participants received ICD therapy identical to non-investigational routine ICD therapy.

Results

Cumulative follow-up of the 619 enrolled patients was 577 years. The annual mortality rate was 4.9%. None of 28 patient deaths was considered likely or clearly device related. Eighty-nine patients contributed between one and eight episodes (median two) to the 210 episodes evaluated by the expert board. Distribution of the 210 episodes per device type was proportional to the distribution of device types at implantation (*Table 2*), with the majority of episodes (63%) being detected by single-chamber ICDs without atrial IEGM or atrial markers.

The mean (± SD) length of the 210 IEGM Online snapshots was 4.4 ± 1.5 s. Several examples are shown in the figures, including an episode of atrial fibrillation (*Figure 1B*), ventricular fibrillation (*Figure 2A*), ventricular tachycardia (*Figure 2B*), and T-wave oversensing (*Figure 2C*), with case descriptions in the figure legends. Despite their shorter duration and reduced graphic resolution, IEGM Online snapshots along with the available episode details were conclusive in the vast majority of cases.

The proportion of appropriate ICD therapy was 84.8% based on standard IEGM printouts, which may be regarded as a true value. Based on IEGM Online, the proportion of appropriate ICD therapy was 87.1%, i.e. slightly overestimated. On the other hand, the proportion of inappropriate ICD therapy was underestimated for IEGM Online (5.7 vs. 14.3%), mostly because of the more difficult recognition of supraventricular tachyarrhythmia (*Table 3*). Consequently, the number of episodes that were indeterminable or lacked consensus was considerably higher for IEGM Online than in standard IEGM, for both therapy assessment and arrhythmia classification ($P < 0.01$) (*Table 3*).

Primary endpoint

The analysis of the appropriateness of the ICD therapy could not include 15 episodes (7.1%) with indeterminable or 'no consensus'

Table 2 Episodes analysed by the expert board across device types

Device type	Distribution of 619 enrolled patients, *n* (%)	Distribution of 210 episodes analysed, *n* (%)	Distribution of 89 patients with episodes analysed, *n* (%)
Single-chamber ICD	392 (63)	133 (63)	54 (61)
Dual chamber ICD	189 (31)	63 (30)	27 (30)
CRT-D	38 (6)	14 (7)	8 (9)

CRT-D, cardiac resynchronization therapy defibrillator; EB, Expert Board; ICD, implantable cardioverter-defibrillator.

IEGM Online and one episode (0.5%) lacking consensus for standard IEGM (*Table 4*). In the remaining 196 episodes, the expert board's rating based on online vs. standard IEGM printouts diverged in 9 episodes (4.6%). The upper boundary of the 95% CI for this divergence was 8.0% and thus lower than the predetermined 10% threshold for clinical significance.

Secondary endpoint

The expert board's classification of arrhythmia to the three main categories (ventricular, supraventricular, and oversensing) could not include 26 episodes (12.4%) with indeterminable or 'no consensus' IEGM Online and three episodes (1.5%) lacking consensus for standard IEGM (*Table 5*). In the remaining 181 episodes, the expert board's rating based on online vs. standard IEGM printouts diverged in 12 episodes (6.6%). The upper boundary of the 95% CI was 10.5% and hence lower than the predetermined 15% threshold for clinical significance.

It was generally easier to identify in IEGM Online ventricular tachyarrhythmia and oversensing than supraventricular arrhythmia (*Tables 3* and *5*). Without atrial markers in the majority of implanted devices, suspected supraventricular arrhythmia could sometimes be neither confirmed nor ruled out based on a short ventricular IEGM snapshot, often falling into the indeterminable group or being mistaken for ventricular arrhythmia, as opposed to somewhat easier classification based on a longer ventricular IEGM snapshot in standard IEGM. Furthermore, the first-generation IEGM Online did not cover the time after therapy delivery, which impeded verification of a suspected arrhythmia self-termination or acceleration.

Discussion

Reliability of IEGM Online Interpretation

The main finding of the present study is that experienced observers can correctly assess the appropriateness of ICD therapy based on the first-generation IEGM Online in 95.4% of the episodes that they regard as conclusive. Furthermore, the observers can correctly classify the underlying event as ventricular, supraventricular, or oversensing in 93.4% of the episodes in which they feel confident to classify. Intracardiac electrogram Online is therefore clinically useful even though it cannot fully replicate the performance of the standard IEGM retrieved from the ICD memory during a usual device interrogation. On top of the error rate, IEGM Online did not provide sufficient information for the rating of 7.1% of events regarding ICD therapy appropriateness and of 12.4% of events regarding underlying arrhythmia. In these situations, the observer must decide how to proceed without useful IEGM information. One could argue that this situation is no worse than it used to be without IEGM Online, when arrhythmia and therapy counters alone occasionally provided misleading information or implied arrhythmic events that were not genuine.[7–9,18–25] Of greater concern are situations when wrong conclusions can be drawn from IEGM Online. If the observer misinterprets supraventricular tachyarrhythmia as ventricular, or an inappropriate therapy (triggered by supraventricular tachycardia or oversensing) as appropriate, this may preclude timely clinical interventions. The most critical case would be if a ventricular tachyarrhythmia were mistaken by the device as supraventricular and thus elicited no device therapy and remained unrecognized based on interpretation of IEGM Online. However, this situation was not encountered in a single case in our study because all arrhythmias classified by the expert board's members as supraventricular based on the Online-IEGM were indeed classified as supraventricular based on the standard IEGM. Other authors have described several situations in which the first-generation IEGM Online played a key role in the timely detection and management of adverse events and of inappropriate device therapy.[13,26–28]

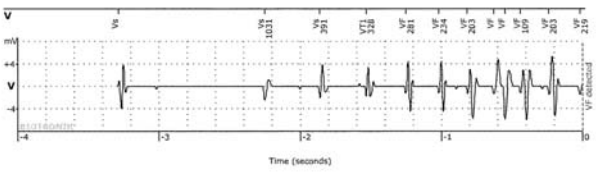
Concise RIONI data evaluation due to new technology

Improved transmission technology paved the way to the second-generation IEGM Online in 2007. It covers 10–20 s before arrhythmia detection and 5–10 s for the verification of therapy success, and contains graphically uncompressed IEGM.[10,29] Therefore, the major limitations of the first-generation IEGM Online investigated in the RIONI study seem to have been overcome and we limited the current report to the core study findings, disregarding a number of additional analyses initially planned as superfluous under current conditions.[14,15]

Impact on remote follow-up

Increasingly, attempts are being made to optimize follow-up schemes of ICD patients using remote monitoring data.[10] In 2008, the international expert consensus endorsed the strategy of remote follow-up after the completion of device therapy optimization and lead maturation phases.[30] Office follow-up visits can now be omitted or drawn forward, depending on the status of the patient and the implanted system as reported by remote data. Now that this individual adjustment of the office follow-up schedule is covered by the instruction for use for the first

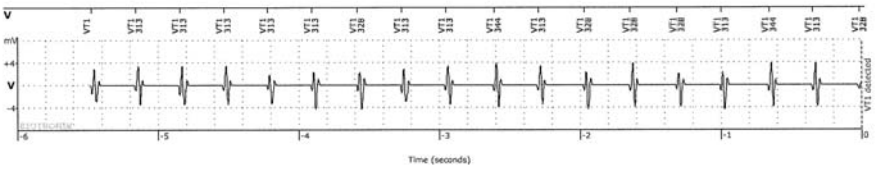
A



Episode details

Episode number	3
Detection	Aug 13, 2006 12:39:43 PM
Termination	Aug 13, 2006 12:39:56 PM
Duration	13 s
Detection in	VF
Redetection	0
Delivered ATPs	0
Delivered shocks	0
Remark	

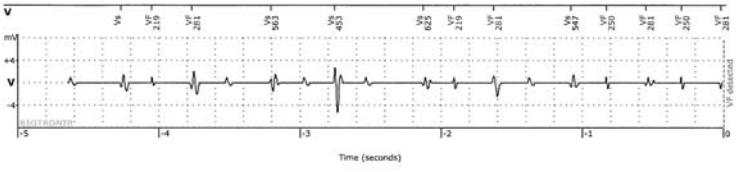
B



Episode details

Episode number	11
Detection	Oct 28, 2005 3:56:19 PM
Termination	Oct 28, 2005 3:56:28 PM
Duration	9 s
Detection in	VT1
Redetection	0
Delivered ATPs	1
Delivered shocks	0
Remark	

C



Episode details

Episode number	19
Detection	Jul 7, 2007 4:58:48 PM
Termination	Jul 7, 2007 4:59:16 PM
Duration	28 s
Detection in	VF
Redetection	VF: 1
Delivered ATPs	0
Delivered shocks	1 (last shock impedance: 48 ohm)
Remark	

Figure 2 Examples of intracardiac electrogram Online for ventricular fibrillation with self-termination (*A*), ventricular tachycardia (*B*), and T-wave oversensing leading to inappropriate shock therapy (*C*). The expert board reached a consensus on these underlying arrhythmia classifications both in intracardiac electrogram Online and in the standard intracardiac electrogram. For example, in (A), the sudden-onset very fast, irregular rhythm was suggestive of ventricular fibrillation. In (B), a stable and relatively slow arrhythmia of short duration was indicative of ventricular tachycardia. In (C), the apparent T-wave artefacts in the tracings associated with the same, repetitive RR-interval values were suggestive of T-wave oversensing, which was incorrectly classified by the implanted device as ventricular fibrillation.

Table 3 Overview of classifications of 210 events by the expert board

Classification by expert board	IEGM type	
	Standard	Online
ICD therapy appropriateness, *n* (%)		
Appropriate ICD therapy	178 (84.8)	183 (87.1)
Inappropriate ICD therapy	30 (14.3)	12 (5.7)
Other[a]	2 (1.0)	15 (7.1)
Event, *n* (%)		
Ventricular	135 (64.3)	139 (66.2)
SVT	53 (25.2)	28 (13.3)
Oversensing	17 (8.1)	17 (8.1)
Other[a]	5 (2.4)	26 (12.4)

ICD, implantable cardioverter-defibrillator; IEGM, intracardiac electrogram; SVT, supraventricular tachyarrhythmia.
[a]ICD therapy or event could not be classified or the consensus of at least two of three expert board members was not obtained.

remote monitoring system, the medical benefit of completed office follow-up examinations will be increased.

Although the impact of remote monitoring on clinical outcomes is still under investigation in large-scale randomized controlled trials,[31,32] it has been demonstrated that clinically relevant events are detected earlier with remote monitoring.[33–35] It has also been shown that the growing workload of outpatient facilities due to the rising number of eligible ICD patients[36] can be reduced by remote monitoring.[37–39] Using a similar technology as in the current study, the TRUST (Lumos-T Reduces Routine Office Device Follow-Up) trial demonstrated a reduced median time to the evaluation of clinically relevant events by Home Monitoring (3 days) compared with conventional care (>30 days), together with a safe reduction in the need for conventional office follow-up visits by 42% compared with standard care.[35,37] The recently presented data from the CONNECT (Clinical Evaluation of Remote Notification To Reduce Time to Clinical Decision) study indicate that remote monitoring reduces time to a clinical decision from 22.0 to 4.6 days (ACC 2010).[40] Another aspect, patient satisfaction, has also been favourably influenced

Table 4 Implantable cardioverter-defibrillator therapy appropriateness for intracardiac electrogram online vs. standard intracardiac electrogram for 210 events

Standard IEGM	IEGM Online			
ICD therapy was . . .	Appropriate	Not appropriate	Indeterminable	No consensus[a]
Appropriate	**173**	0	(5)	(0)
Not appropriate	8	**12**	(7)	(3)
Indeterminable	1	0	(0)	(0)
No consensus[a]	(1)	(0)	(0)	(0)

The values in bold indicate equal rating of IEGM Online vs. standard IEGM (total 185 events); the values in non-bold without brackets indicate a diverging rating of IEGM Online vs. standard IEGM (9 events); the values in brackets were excluded from the analysis. Overall, rating diverged in 9 of 194 eligible episodes (4.6%), with the upper bound of the 95% confidence interval of 8.0%. The predetermined threshold for clinical significance was 10%.
ICD, implantable cardioverter-defibrillator; IEGM, intracardiac electrogram.
[a]Consensus of at least two of three expert board members was not obtained.

Table 5 Arrhythmia classification for intracardiac electrogram online vs. standard intracardiac electrogram for 210 events

Standard IEGM	IEGM Online				
Arrhythmia . . .	Ventricular	SVT	Oversensing	Indeterminable	No consensus[a]
Ventricular	**127**	0	1	(4)	(3)
SVT	9	**28**	0	(13)	(3)
Oversensing	1	0	**14**	(0)	(2)
Indeterminable	1	0	0	(0)	(0)
No consensus[a]	(1)	(0)	(2)	(1)	(0)

The values in bold indicate equal classification for IEGM Online vs. standard IEGM (total 169 episodes); the values in non-bold without brackets indicate diverging classification for IEGM Online vs. standard IEGM (12 events); the values in brackets were excluded from the analysis. Overall, classification diverged in 12 of 181 eligible episodes (6.6%), with the upper bound of the 95% confidence interval of 10.5%. The predetermined threshold for clinical significance was 15%.
IEGM, intracardiac electrogram; SVT, supraventricular tachyarrhythmia.
[a]Consensus of at least two of three expert board members was not obtained.

by the remote monitoring concept,[41,42] whereas impact on patients' quality-of-life will need further investigation.

Our prospective study shows for the first time that the IEGM Online information, even in the limited quality of its first generation, is sufficiently reliable for Home Monitoring of ICD patients. Intracardiac electrogram Online is commonly available for the last arrhythmia event preceding a scheduled, automatic, daily Home Monitoring message. How the completeness and quality of IEGM Online reports and of other remote monitoring data translate into the effectiveness of a given follow-up scheme (i.e. how many follow-ups are needed per patient-year and whether remote monitoring improves clinical outcomes) cannot be estimated from our results and will be elucidated in several trials addressing this topic.[31,32,34,43,44]

Conclusion

The first-generation IEGM Online allows accurate remote classification of the appropriateness of ICD therapy, with <10% difference compared with the conclusions based on the standard IEGM. The classification of underlying events into the three main categories (ventricular, supraventricular, and oversensing) was also possible in the vast majority of cases. The addition of the IEGM Online feature provides the basis for timely and effective interventions, potentially reducing the need for clinic visits if no change in device or drug therapy seems necessary.

Conflict of interest: C.P. has received research grants from Biotronik and Medtronic as well as consulting fees from Biotronik, Medtronic, Boston Scientific, and St Jude Medical. W.R.B. is an adviser for Biotronik with respect to lead development. P.B. is currently conducting research sponsored by Biotronik. F.H. is a member of the speaker's bureau for Biotronik, Medtronic, and Boston Scientific. J.C. has received research grants from Biotronik, Medtronic, St. Jude Medical, and Sorin Group. J.O.S. is currently conducting research sponsored by Biotronik and has received consulting fee from Biotronik.

Acknowledgements

The authors thank Karsten Wallbrück for study design and study management, Bernd Brüsehaber, Ph.D., for study management and data analysis, Jürgen Schrader, Ph.D., for data analysis, and Dejan Danilovic, Ph.D., for assistance in manuscript preparation.

Funding

This work was supported by Biotronik SE and Co. KG (Wörmannkehre 1, D-12359 Berlin, Germany).

Appendix

Expert Board: P. Brugada (Aalst, Belgium), C. Kolb (Munich, Germany), G. Stix (Vienna, Austria).

Steering Committee (alphabetical order): D. Böcker (Münster, Germany), T. Korte (Hannover, Germany), D. Klug (Lille, France), C. Moro (Madrid, Spain), C. Perings (Bochum, Germany, coordinating clinical investigator), E. Toft (Aalborg, Denmark).

RIONI principal investigators (alphabetical order of countries/authors)

Austria: F. Hintringer (Innsbruck); *Belgium*: P. Geelen (Aalst), H. Heidbuchel (Leuven); *Denmark*: E. Toft (Aalborg); *France*: S. Boveda (Toulouse), J. Clémenty (Bordeaux), R. Frank (Paris), J-.S. Hermida (Amiens), S. Kacet (Lille), G. Lascault (St. Denis), A. Leenhardt (Paris), P. Mabo (Rennes), C. Moini (Antony), O. Paziaud (St. Denis), N. Sadoul (Vandoeuvre-Les-Nancy), O. Thomas (Neuilly Sur Seine); *Germany*: D. Andresen (Berlin), W. Bauer (Würzburg), D. Böcker (Münster), H.-J. Bondke (Berlin), W. Duckeck (Bremen), L. Gogoll (Berlin), A. Hartmann (Leipzig), E. Hoffmann (München), G. Hoh (Wittenberg/Lutherstadt), W. Jung (Villingen), T. Korte (Hannover), R. Lange (Hartmannsdorf), T. Lawo (Bochum), B. Lemke (Lüdenscheid), G. Mentz (Wiesbaden), C. Mewis (Homburg/Saar), W. Mißler (Kirchberg), A. Mügge (Bochum), H. Nägele (Reinbek), F. Niroomand (Mülheim/Ruhr), C. Perings (Bochum), J. O. Schwab (Bonn), H. Schwacke (Hamburg), T. Stein (Bassum), A. Tiroke (Kiel), H.-J. Trappe (Bochum), R. Ventura (Hamburg), H. Wieneke (Essen), B. Wille (Berlin), E. Wunderlich (Dresden); *Spain*: C. Moro (Madrid); *UK*: P. Broadhurst (Aberdeen), N. Grubb (Edinburgh), M. James (Taunton/Somerset), V. Paul (Chertsey).

References

1. Daubert JP, Zareba W, Cannom DS, McNitt S, Rosero SZ, Wang P *et al.* Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. *J Am Coll Cardiol* 2008;**51**:1357–65.
2. Poole JE, Johnson GW, Hellkamp AS, Anderson J, Callans DJ, Raitt MH *et al.* Prognostic importance of defibrillator shocks in patients with heart failure. *N Engl J Med* 2008;**359**:1009–17.
3. Tzeis S, Andrikopoulos G, Kolb C, Vardas PE. Tools and strategies for the reduction of inappropriate implantable cardioverter defibrillator shocks. *Europace* 2008;**10**:1256–65.
4. Wilkoff BL, Williamson BD, Stern RS, Moore SL, Lu F, Lee SW *et al.* Strategic programming of detection and therapy parameters in implantable cardioverter-defibrillators reduces shocks in primary prevention patients: results from the PREPARE (Primary Prevention Parameters Evaluation) study. *J Am Coll Cardiol* 2008;**52**:541–50.
5. Hauser RG, Hayes DL, Epstein AE, Cannom DS, Vlay SC, Song SL *et al.* Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators. *Heart Rhythm* 2006;**3**:640–4.
6. Theuns DA, Res JC, Jordaens LJ. Home Monitoring in ICD therapy: future perspectives. *Europace* 2003;**5**:139–42.
7. 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**(Suppl. 1):S2–S12.
8. Nielsen JC, Kottkamp H, Zabel M, Aliot E, Kreutzer U, Bauer A *et al.* Automatic home monitoring of implantable cardioverter defibrillators. *Europace* 2008;**10**:729–35.
9. Jung W, Rillig A, Birkemeyer R, Miljak T, Meyerfeldt U. Advances in remote monitoring of implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy systems. *J Interv Card Electrophysiol* 2008;**23**:73–85.
10. Burri H, Senouf D. Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators. *Europace* 2009;**11**:701–9.
11. Marchlinski FE, Callans DJ, Gottlieb CD, Schwartzman D, Preminger M. Benefits and lessons learned from stored electrogram information in implantable defibrillators. *J Cardiovasc Electrophysiol* 1995;**6**:832–51.
12. Auricchio A, Hartung W, Geller C, Klein H. Clinical relevance of stored electrograms for implantable cardioverter-defibrillator (ICD) troubleshooting and understanding of mechanisms for ventricular tachyarrhythmias. *Am J Cardiol* 1996;**78**:33–41.
13. Ritter O, Bauer WR. Use of "IEGM Online" in ICD patients—early detection of inappropriate classified ventricular tachycardia via Home Monitoring. *Clin Res Cardiol* 2006;**95**:368–72.

14. Perings C, Klein G, Toft E, Moro C, Klug D, Bocker D *et al.* The RIONI study rationale and design: validation of the first stored electrograms transmitted via Home Monitoring in patients with implantable defibrillators. *Europace* 2006;**8**: 288–92.
15. Perings C, Korte T, Trappe HJ. IEGM-online based evaluation of implantable cardioverter defibrillator therapy appropriateness. *Clin Res Cardiol* 2006;**95**(Suppl. 3): iii22–8.
16. Hammill SC, Kremers MS, Kadish AH, Stevenson LW, Heidenreich PA, Lindsay BD *et al.* Review of the ICD Registry's third year, expansion to include lead data and pediatric ICD procedures, and role for measuring performance. *Heart Rhythm* 2009;**6**:1397–401.
17. Sinha AM, Stellbrink C, Schuchert A, Mox B, Jordaens L, Lamaison D *et al.* Clinical experience with a new detection algorithm for differentiation of supraventricular from ventricular tachycardia in a dual-chamber defibrillator. *J Cardiovasc Electrophysiol* 2004;**15**:646–52.
18. Koos R, Sinha AM, Stellbrink C. Home Monitoring in an ICD patient with incessant ventricular tachycardia. *Z Kardiol* 2005;**94**:461–4.
19. Res JC, Theuns DA, Jordaens L. The role of remote monitoring in the reduction of inappropriate implantable cardioverter defibrillator therapies. *Clin Res Cardiol* 2006;**95**(Suppl. 3):iii17–21.
20. Siaplaouras S, Buob A, Neuberger HR, Mewis C. Remote detection of incessant slow VT with an ICD capable of Home Monitoring. *Europace* 2006;**8**:512–4.
21. Ricci RP, Morichelli L, Santini M. Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization. *Europace* 2008;**10**: 164–70.
22. Theuns DA, Rivero-Ayerza M, Knops P, Res JC, Jordaens L. Analysis of 57,148 transmissions by remote monitoring of implantable cardioverter defibrillators. *Pacing Clin Electrophysiol* 2009;**32**(Suppl. 1):S63–5.
23. Hauck M, Bauer A, Voss F, Weretka S, Katus HA, Becker R. "Home monitoring" for early detection of implantable cardioverter-defibrillator failure: a single-center prospective observational study. *Clin Res Cardiol* 2009;**98**:19–24.
24. Zartner P, Handke R, Photiadis J, Brecher AM, Schneider MB. Performance of an autonomous telemonitoring system in children and young adults with congenital heart diseases. *Pacing Clin Electrophysiol* 2008;**31**:1291–9.
25. Marine JE. Remote monitoring for prevention of inappropriate implantable cardioverter defibrillator shocks: is there no place like home? *Europace* 2009;**11**: 409–11.
26. Varma N. Remote monitoring for advisories: automatic early detection of silent lead failure. *Pacing Clin Electrophysiol* 2009;**32**:525–7.
27. Sacher F, Probst V, Bessouet M, Wright M, Maluski A, Abbey S *et al.* Remote implantable cardioverter defibrillator monitoring in a Brugada syndrome population. *Europace* 2009;**11**:489–94.
28. Spencker S, Coban N, Koch L, Schirdewan A, Muller D. Potential role of home monitoring to reduce inappropriate shocks in implantable cardioverter-defibrillator patients due to lead failure. *Europace* 2009;**11**:483–8.
29. Varma N, Johnson MA. Prevalence of cancelled shock therapy and relationship to shock delivery in recipients of implantable cardioverter-defibrillators assessed by remote monitoring. *Pacing Clin Electrophysiol* 2009;**32**(Suppl. 1):S42–6.
30. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM *et al.* HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Europace* 2008;**10**:707–25.
31. Arya A, Block M, Kautzner J, Lewalter T, Mortel H, Sack S *et al.* 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.
32. Ip J, Waldo AL, Lip GY, Rothwell PM, Martin DT, Bersohn MM *et al.* Multicenter randomized study of anticoagulation guided by remote rhythm monitoring in patients with implantable cardioverter-defibrillator and CRT-D devices: rationale, design, and clinical characteristics of the initially enrolled cohort the IMPACT study. *Am Heart J* 2009;**158**:364–70.
33. Ricci RP, Morichelli L, Santini M. Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation. *Europace* 2009;**11**:54–61.
34. Crossley GH, Chen J, Choucair W, Cohen TJ, Gohn DC, Johnson WB *et al.* Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. *J Am Coll Cardiol* 2009;**54**:2012–9.
35. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C. 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.
36. Fye WB. Cardiology workforce: there's already a shortage, and it's getting worse! *J Am Coll Cardiol* 2002;**39**:2077–9.
37. Varma N, Epstein A, Schweikert R, Love C, Shah J, Irimpten A. Evaluation of efficacy and safety of remote monitoring for ICD follow-up: the TRUST trial. (abstract) *Circulation* 2008;**118**:2316.
38. Wetzel UR, Geller JC, Kautzner J, Moertel H, Schumacher B, Taborsky M *et al.* Remote follow-up for ICD-therapy in patients meeting MADIT II criteria—the REFORM trial. (abstract) *Heart Rhythm* 2009;**6**(Suppl. 1):S259.
39. Hindricks G, Bauer WJ, Schwab JO. Was bringt die Telekardiologie für Patient und Arzt? *Dtsch Arztebl* 2008;**105**:A156–9.
40. Crossley G. http://www.themdtv.org/play.php?submission_id=792 (9 July 2010, date last accessed).
41. Al-Khatib SM, Piccini JP, Knight D, Stewart M, Clapp-Channing N, Sanders GD. 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.
42. Ricci RP, Morichelli L, Quarta L, Sassi A, Porfili A, Laudadio MT *et al.* Long-term patient acceptance of and satisfaction with implanted device remote monitoring. *Europace* 2010;**12**:674–9.
43. Crossley G, Boyle A, Vitense H, Sherfesee L, Mead RH. Trial design of the clinical evaluation of remote notification to reduce time to clinical decision: the Clinical evaluation Of remote NotificatioN to rEduCe Time to clinical decision (CONNECT) study. *Am Heart J* 2008;**156**:840–6.
44. Marzegalli M, Landolina M, Lunati M, Perego GB, Pappone A, Guenzati G *et al.* Design of the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study to assess the ability of remote monitoring to treat and triage patients more effectively. *Trials* 2009;**10**:42.