

Home monitoring of implantable cardioverter-defibrillators: interpretation reliability of the second-generation “IEGM Online” system

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Received 30 June 2014; accepted after revision 10 November 2014; online publish-ahead-of-print 7 January 2015

Aims

Intracardiac electrograms (IEGMs) are essential for the assessment of implantable cardioverter-defibrillator (ICD) function. The Biotronik Home Monitoring systems transmit an 'IEGM Online' that is shorter than the full-length programmer IEGM due to technical constraints. The aim of this study was to evaluate the accuracy of the physician's classification of the underlying rhythm based on the second-generation IEGM Online.

Methods and results

In total, 1533 patients treated with single- and dual-chamber ICDs and cardiac resynchronization therapy defibrillators were enrolled at 67 investigational sites and followed for 15 months. The investigators classified the rhythm shown in IEGM Online as ventricular tachycardia, ventricular fibrillation, atrial fibrillation, other supraventricular tachyarrhythmia, oversensing due to lead failure, T-wave oversensing, or other rhythm. At the next in-office follow-up, the investigators classified independently the rhythm seen in the corresponding programmer IEGM. The two rhythm classifications were compared thereafter. Both IEGM Online and programmer IEGM were available in 2099 arrhythmic or oversensing events, of which 146 (7.0%) were classified as other rhythm or artefacts and were excluded as inconclusive or atypical. The remaining 1953 events, affecting 352 patients (23.0%), were classified correctly in 1803 cases (92.3%). The accuracy of rough rhythm classification as ventricular, supraventricular, or oversensing was 97.2%.

Conclusion

The Lumax and IEGM Online HD Evaluation study demonstrates that remote IEGM analysis is reasonably accurate in a remote monitoring system that transmits shorter IEGM than the full-length programmer IEGM for the sake of frequent, fully automatic data transmission.

Keywords

Implantable cardioverter-defibrillator • Intracardiac electrogram • Arrhythmia detection • Telemedicine • Remote monitoring • Home monitoring

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What's new?

- Remote monitoring of implantable defibrillator-cardioverters is gaining wide-spread acceptance in guidelines and clinical practice, and the assessment of intracardiac electrograms from arrhythmias or oversensing episodes is relevant for clinical decision making in remotely monitored patients.
- In a large real-world population of device patients, we show that the accuracy of rhythm evaluation in remote monitoring transmitted electrograms improved significantly with the second-generation IEGM Online.

Introduction

Intracardiac electrograms (IEGMs) recorded upon arrhythmia detection by implantable cardioverter-defibrillators (ICDs) are essential for the assessment of the patient's status and the appropriateness of arrhythmia classification and device therapy, and are thus indispensable for the management of patients with an ICD.¹ The implementation of remote management in these patients^{2–4} requires the transmission of IEGMs by remote monitoring systems.

Automatic, daily Biotronik Home Monitoring[®] technology includes IEGM as part of the transmitted ICD diagnostic data.^{5–7} The first-generation 'IEGM Online', which covered 3–10 s of compressed right ventricular electrogram before arrhythmia detection, was evaluated in the 'Reliability of IEGM Online Interpretation' (RIONI) study. After exclusion of 12.4% of events as inconclusive, the rest was classified correctly in 93.4% and incorrectly in 6.6%.⁸

To improve remote IEGM interpretation, the second-generation 'IEGM Online HD' was introduced. It is multi-channel and uncompressed, has the same sample rate and layout as the programmer IEGM, and covers 10–20 s before arrhythmia detection and additional 5–10 s after episode termination. The reliability of the second-generation IEGM Online has not been investigated. Thus, this study was undertaken to evaluate in a real-world setting the interpretation reliability of a large sample of transmitted IEGMs.

Methods

The 'Lumax and IEGM Online HD Evaluation' (LION) study was a prospective, international, non-randomized investigation aimed at assessing the percentage of correct classification of IEGM Online HD in a real-world setting. Lumax and IEGM Online HD Evaluation was conducted in compliance with Good Clinical Practice guidelines and the Declaration of Helsinki. The study protocol was approved by appropriate national and local ethics committees. Patients gave their written informed consent before enrollment.

Patient selection

Patients with an accepted indication for the implantation of an ICD or cardiac resynchronization therapy defibrillator (CRT-D) were eligible for enrollment up to three months after device implantation. Additional study inclusion criteria were the patient's stable medical status, geographical stability, and ability and willingness to attend all follow-ups. Exclusion criteria were a life expectancy shorter than 6 months, inability to handle

the Home Monitoring system, living in an area lacking the GSM mobile phone coverage, age < 18 years, or participation in another clinical study.

Devices

Patients received an ICD or a CRT-D from the Lumax[®] family (Biotronik SE & Co. KG), capable of transmitting device diagnostic data at a programmed time every day (e.g. 3 a.m.) and upon detection of a relevant arrhythmic or technical event.^{5–13} A mobile phone-like patient device receives these data and relays them automatically over GSM mobile phone links to the Biotronik Home Monitoring Service Center. At this centre, data incoming from all countries are processed automatically and posted on a secure internet site accessible to patients' physicians. Additional event notifications are sent to patients' physicians per email or SMS for pre-specified events such as supraventricular or ventricular tachyarrhythmia.

An IEGM Online HD (HD = 'high definition') is automatically transmitted to the Service Center after device detection of an episode classified as ventricular or supraventricular tachyarrhythmia (SVT). It consists of marker channels, episode details, and uncompressed electrogram recordings from the left ventricular lead (CRT-D), right atrial lead (dual-chamber ICD and CRT-D), and right ventricular lead (all device types) (Figure 1).

Because this remote monitoring system was designed for frequent transmissions, data quantities are carefully controlled to limit the energy consumption of the implanted devices. To this end, the original IEGM length of up to 180 s, stored in the device memory, is shortened in the IEGM Online HD to 10–20 s before arrhythmia detection and 5–10 s after episode termination.

Follow-up

Patient management was left to the attending physician's discretion. All in-office follow-ups, whether regular or additional, had to be documented.

To reflect real-world situation, there was no core lab, but IEGMs were interpreted by clinical investigators. They were asked to classify the rhythm seen in IEGM Online HD within two working days of the corresponding event notification. During in-office follow-up, they independently classified the rhythm seen in the programmer IEGM of all available episodes. The classification of rhythms in ICD IEGMs is mostly based on cycle length and regularity because less morphology information is available than in ECG. The device's own rhythm classification was not used for IEGM classification.

Six episode categories were pre-defined for classification: ventricular tachycardia (VT), ventricular fibrillation (VF), atrial fibrillation (AF), other SVT, oversensing due to lead failure, and T-wave oversensing. Episodes matching none of these were reported as 'other rhythm or artefacts'.

Study objective

Study objective was to investigate if the rhythm classification based on IEGM Online HD was equivalent to the rhythm classification based on the programmer IEGM.

Reliability of IEGM Online Interpretation study

The IEGM Online HD, which was investigated in this study, is the direct successor of the first-generation IEGM Online, which was investigated in the RIONI study. In that study, an expert board classified a sample of 210 IEGM Online strips into the three episode categories ventricular, supraventricular, or oversensing events.⁸ After exclusion of 12.4% of events as inconclusive, the rest was classified correctly in 93.4% and incorrectly in 6.6% (verified against the full-length programmer IEGMs). The results from our study will be compared with the RIONI results.

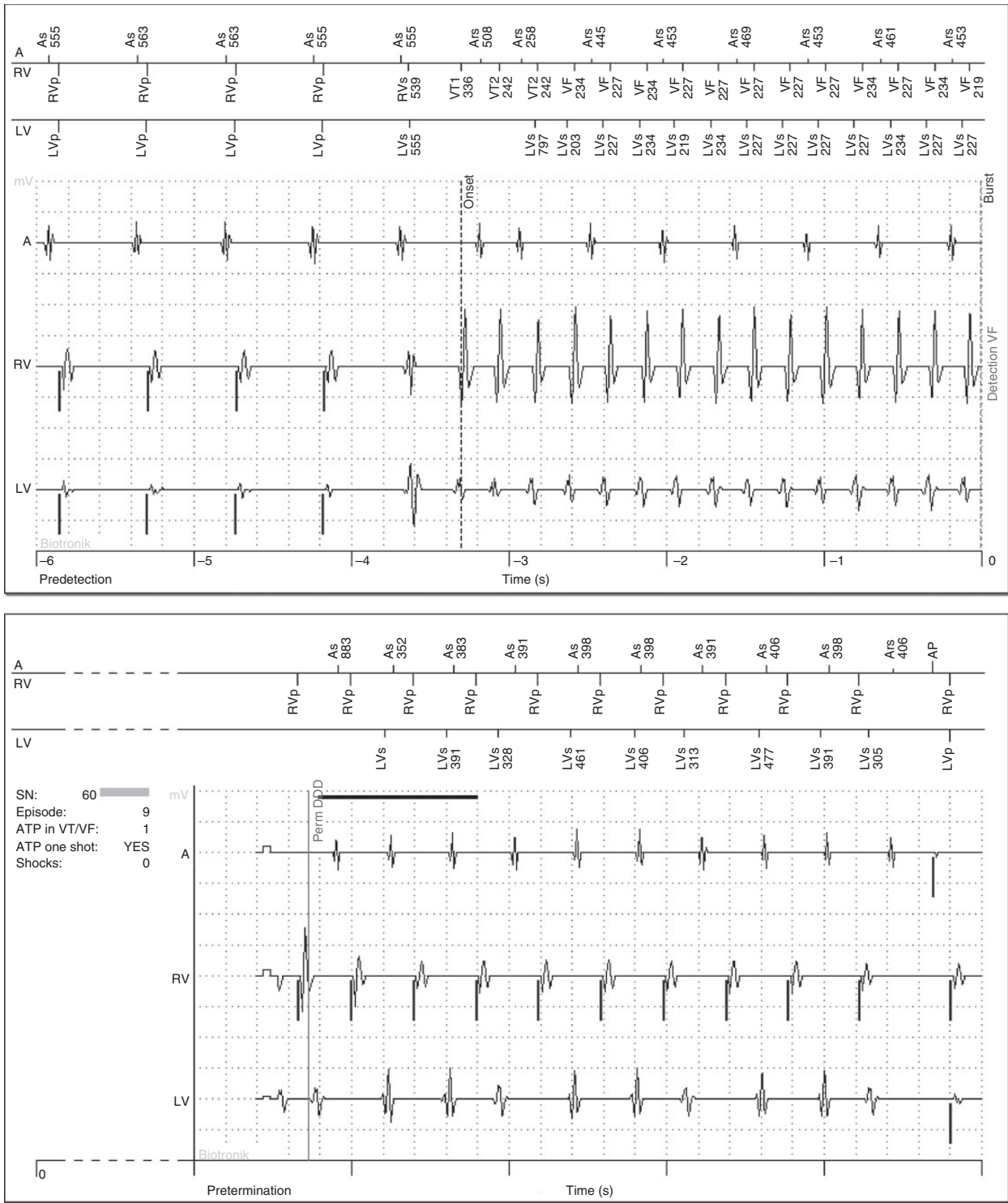


Figure 1 ‘IEGM Online HD’ obtained from a cardiac resynchronization therapy defibrillator device (Lumax HF-T, Biotronik). Upper panel, before episode detection. Lower panel, after episode termination. Both panels are shortened here to obtain acceptable figure size with readable letters and numbers. The numbers in the marker channels indicate P-P and R-R intervals in ms. Right ventricular arrhythmia markers VT1, VT2, and VF indicate fulfilling of the detection zone according to the implant’s programming. A, atrium; Ars, atrial refractory sensed beat; As, atrial sensed beat; ATP, anti-tachycardia pacing; LV, left ventricle; LVp, left ventricular paced beat; LVs, left ventricular sensed beat; RV, right ventricle; RVs, right ventricular sensed beat; RVp, right ventricular paced beat; VF, ventricular fibrillation; VT1, slow ventricular tachycardia; VT2, fast ventricular tachycardia.

Table 1 Baseline patient characteristics (n = 1537)

	N (%), or mean ± SD
Age (years)	64 ± 12
Male	1263 (82)
Ejection fraction ^a (%)	32 ± 12
NYHA functional class	
I	141 (9)
II	507 (33)
III	481 (31)
IV	18 (1)
No heart failure	99 (6)
Not evaluated	287 (19)
Underlying disease	
Ischaemic heart disease	900 (59)
Cardiomyopathy	1006 (66)
Diabetes	452 (30)
Renal insufficiency	353 (23)
History of AFIB	422 (28)
Medication	
Beta-blocker	1344 (88)
ACE-inhibitor or angiotensin-antagonist	1270 (83)
Diuretic	1174 (77)
Class I or III antiarrhythmic drug	335 (22)
Ca-antagonist	133 (9)
Digitalis	305 (20)
Anticoagulant	667 (44)
Platelet aggregation inhibitor	816 (53)
Secondary prevention ICD indication	598 (39)
Implanted device ^b	
Single-chamber ICD	717 (47)
Dual-chamber ICD	361 (24)
CRT-D	452 (30)

ACE, angiotensin-converting enzyme; AFIB, atrial fibrillation; CRT-D, cardiac resynchronization therapy defibrillator; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association; SD, standard deviation.

^aReported in 1236 patients.

^bReported in 1530 patients.

Statistical methods

No study hypothesis was specified. A sample size of 1500 patients followed for 15 months was deemed sufficient for the given study objective. Episodes reported as other rhythm or artefacts based on any IEGM were excluded from the analysis as inconclusive or atypical. Data are shown as absolute values, percentages, means with standard deviation, and median with interquartile range. The χ^2 test was used to compare LION and RIONI study results. *P* value of < 0.05 was considered statistically significant. The analyses were conducted with the IBM SPSS 21 for Windows (IBM Corporation, Armonk) statistical software.

Results

Between March 2007 and February 2012, a total of 1533 patients were enrolled in the LION study at 67 investigational sites in seven European countries (see Supplementary material online, Appendix).

Table 2 Percentage of correct rhythm classifications based on IEGM Online HD

The underlying rhythm (Investigators' judgement)	No. of episodes based on programmer IEGM	No. (%) of correct classifications based on IEGM online HD
Total	1953	1803 (92.3)
Classification into 6 categories		
Ventricular fibrillation	106	68 (64.2)
Ventricular tachycardia	472	443 (93.9)
Atrial fibrillation	816	772 (94.6)
Other supraventricular tachyarrhythmia	426	395 (92.7)
Lead-related oversensing	40	37 (92.5)
T-wave oversensing	93	88 (94.6)
Device types		
Single-chamber ICDs	614	571 (93.0)
Dual-chamber ICDs	705	651 (92.3)
CRT-Ds	628	575 (91.6)
Rhythm groups as used in RIONI ⁸		
Ventricular tachyarrhythmia	578	555 (96.0)
Supraventricular tachyarrhythmia	1242	1219 (98.1)
Oversensing	133	125 (94.0)
Total	1953	1899 (97.2)

CRT-D, cardiac resynchronization therapy defibrillator; HD, high definition; ICD, implantable cardioverter-defibrillator; IEGM, intracardiac electrogram; RIONI, the Reliability of IEGM Online Interpretation study.

Forty-seven percent of patients had a single-chamber ICD, 24% a dual-chamber ICD, and 30% a CRT-D. At baseline, the patients presented with characteristics and medical history of a typical ICD population (Table 1). The proportion of patients with a secondary prevention indication was 39%. Two-thirds of patients had New York Heart Association (NYHA) class II–IV heart failure.

The cumulative follow-up was 1749 years. The median follow-up period was 455 days (interquartile range, 420–482).

Both IEGM Online HD and programmer IEGM were available in 2099 arrhythmic or oversensing episodes, of which 146 (7.0%) were classified as other rhythm or artefacts in any IEGM (59 in both IEGMs, 36 in IEGM Online HD only, and 51 in programmer IEGM only). The final analysis was conducted with the remaining 1953 episodes in 352 patients, each contributing a median of two episodes (interquartile range, 1–5).

In 1803 of the 1953 episodes (92.3%), rhythm classifications by the investigators were identical for IEGM Online HD and programmer IEGM. The proportion of identical classifications did not vary significantly by device type (single-chamber ICD: 93.0%; dual-chamber ICD: 92.3%; CRT-D: 91.6%; all *P* > 0.4) (Table 2).

The most common arrhythmia, AF, accounting for 41.8% of all events, and T-wave oversensing were the most correctly classified events (each 94.6%), followed by VT (93.9%), SVT other than AF

Table 3 Details of rhythm classification by investigators

Programmer IEGM arrhythmia ...	IEGM online HD					
	VF	VT	AF	Other SVT	Lead ^a	T-wave ^a
VF	68	20	17	1	0	0
VT	24	443	2	1	1	1
AF	3	5	772	35	1	0
Other SVT	1	13	17	395	0	0
Lead-related oversensing	2	0	0	1	37	0
T-wave oversensing	0	5	0	0	0	88

The values in bold indicate equal classifications based on IEGM Online HD and Programmer IEGM.

AF, atrial fibrillation; HD, high definition; IEGM, intracardiac electrogram; SVT, supraventricular tachyarrhythmia; VF, ventricular fibrillation; VT, ventricular tachycardia.

^aLead-related or T-wave oversensing.

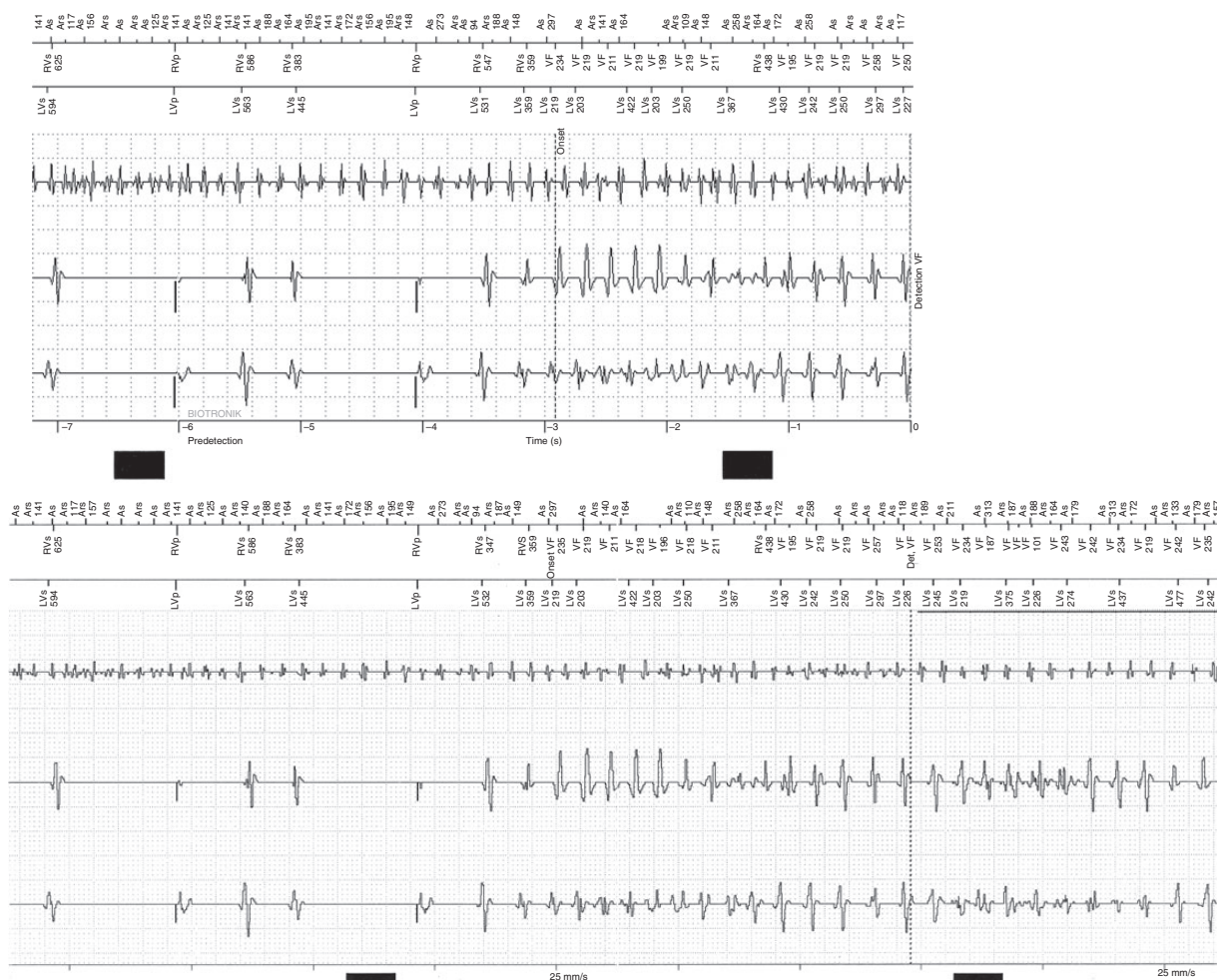


Figure 2 A borderline case between VF and fast polymorphic VT. The investigator opted for VT in the IEGM Online (upper panel) and for VF in the programmer IEGM (lower panel). Both IEGMs show a similar pre-detection arrhythmia appearance. Note that the programmer IEGM continues also during capacitor charging (to save space, only the beginning of charging is shown in the figure), which provides additional information for arrhythmia classification. A, atrium; Ars, atrial refractory sensed beat; As, atrial sensed beat; ATP, antitachycardia pacing; LV, left ventricle; LVp, left ventricular paced beat; LVs, left ventricular sensed beat; RV, right ventricle; RVs, right ventricular sensed beat; RVp, right ventricular paced beat; VF, ventricular fibrillation; VT1, slow ventricular tachycardia; VT2, fast ventricular tachycardia.

(92.7%), and lead-related oversensing (92.5%) (Table 2). Investigators were less successful in identifying VF (64.2%), whereby VF was often mistaken for VT (18.9%, Table 3) that required the same ICD therapy anyway. Other misclassified VF episodes (17.0%) were taken for AF or SVT. Of all 150 misclassifications, 96 (64.0%) were due to confusion either between VF and VT or between AF and other SVT forms. Figure 2 shows an example of misclassification of VF as VT.

For the comparison with the RIONI study,⁸ we calculated the classification accuracy based on the three episode categories used in that study (ventricular, supraventricular, oversensing). The resulting classification accuracy of 97.2% in our study (Table 2) was significantly better than the 93.4% accuracy reported by the RIONI investigators⁸ ($P = 0.004$, χ^2 test). The recognition of supraventricular arrhythmia, including AF, was improved from 75.7% (RIONI) to 98.1% (LION; $P < 0.001$, χ^2 test).

Discussion

In this large-scale study conducted in a real-world setting, the accuracy of rhythm classification based on the IEGM Online HD was 92.3% for the six rhythm categories: VT, VF, AF, other SVT, oversensing due to lead failure, and T-wave oversensing. For basic rhythm classification as ventricular, supraventricular, or oversensing, it was 97.2%.

Owing to its graphic content, IEGMs are relatively large files for remote transmission compared with numerical data. In the remote monitoring system used in this study, the length of transmitted IEGM tracings is limited to reduce the energy consumption of the implanted devices. The first and second generation of IEGM Online were clinically evaluated in the RIONI and LION studies, respectively.

Comparison of Reliability of IEGM Online Interpretation and Lumax and IEGM Online HD Evaluation results

The RIONI study indicated that arrhythmia classification based on the first-generation IEGM Online left some room for improvement, as 6.6% of IEGMs were not classified correctly as ventricular, supraventricular, or oversensing events, after exclusion of 12.4% of IEGMs as inconclusive.⁸ In LION, only 2.8% of classifications into these three basic rhythm categories were incorrect, after excluding 7.0% episodes as inconclusive. The observed improvement with the second-generation IEGM Online was driven by enhanced discrimination between supraventricular and ventricular tachyarrhythmias.

Detailed rhythm classifications, studied only in LION, were correct in 64.7% of cases with VF and in 92.8%–94.6% of cases with VT, AF, other SVT, T-wave oversensing, and lead-related oversensing.

Two methodological differences between LION and the RIONI study are worth mentioning: the number of evaluated events was 10-fold larger in LION (2099 vs. 210), and IEGMs were interpreted by clinical investigators (LION) rather than three members of an expert board (RIONI). These differences imply that LION results may be more generalizable.

Reasons for arrhythmia misclassifications in Lumax and IEGM Online HD Evaluation

Incorrect VF classifications were mostly caused by confusion of VF with polymorphic VT that are difficult to discriminate without

the morphology information from surface ECG. Likewise, AF is in IEGM often similar to atrial flutter, in this study classified as 'other SVT'.

Since the LION study protocol did not require systematic collection of programmer IEGM printouts for a post-hoc analysis of reasons for misclassification, we are not able to systematize and quantify the reasons. However, the fact that all types of misclassifications, except for VT vs. VF, and for AF vs. other SVT, occurred with a similar rate indicates that the quality of the IEGM Online does not have a specific weakness. We also cannot exclude that some misclassifications were by mistake (reflecting a subjective error rate of investigators) rather than due to a deficiency of the IEGM Online.

Intracardiac electrogram in other remote cardioverter-defibrillator monitoring systems

Other remote ICD monitoring technologies transmit uncompressed full-length IEGMs that can probably be interpreted identically to the corresponding programmer IEGMs, although this has not been confirmed by clinical studies. However, these systems do not transmit data on a daily basis and usually require certain degree of patient compliance, so that a problem obviating transmissions may remain unnoticed for a longer period, along with silent arrhythmia during that period.^{2,6,7,14}

Benefit of remote monitoring

The analysis of episode IEGM is an essential element of the follow-up of patients with an ICD. The good accuracy of remote IEGM classification that we are able to report is important and reassuring because remote monitoring of implantable electronic cardiac devices is rapidly becoming the standard of care.^{2–4} It had already led to a new organization of care based on dedicated allied professionals and/or the creation of remote monitoring units.^{4,9} The goals are to improve the quality of care for the patients and increase efficiency for the healthcare providers.^{2–4,9,10,13–17} The medical benefit of remote monitoring has been increasingly substantiated by randomized, controlled clinical trials, such as TRUST,¹⁰ CONNECT,¹⁴ COMPAS,¹⁸ and EVOLVO.¹⁶

Recently, the IN-TIME landmark trial showed a reduced risk for a worsened clinical composite score combining death, hospitalization for heart failure, NYHA class, and patient global self-assessment in remotely monitored heart failure patients with ICDs and CRT-Ds, along with all-cause mortality reduction after one year.¹⁹ While a deeper understanding of the mechanisms of the clinical benefit of remote monitoring is still lacking, it is plausible that the continuous information about the patient's status, especially when worsening, and the appropriate reaction of the physician are the two main contributing mechanisms. To get immediate information about arrhythmias is a major requirement in this process,¹⁹ and IEGM tracings are essential for arrhythmia classification.

Study limitations

The major limitation of the LION study was that usually the same investigators evaluated the IEGM Online HD and the programmer IEGM for the same episode, without being blinded to the link between the IEGMs. Investigators might have also omitted IEGMs

that were difficult to interpret; however, we deem that the large number of patients and investigators contributing episodes and their classifications reduce this potential bias. Furthermore, investigators may have classified the episodes concordant with the device's episodes classification.

In the final analysis, 146 episodes (7.0%) classified as 'other rhythm or artefact' in one or both IEGMs were excluded. In these episodes, only a *post hoc* subjective interpretation of the equivalence of free-text entries describing the rhythm was possible to perform, which would not be scientifically sound for reporting.

Conclusion

The second-generation IEGM Online was evaluated in a large-scale study, based on 2099 arrhythmic and oversensing events affecting 352 of 1533 patients enrolled at 67 investigational sites. The underlying rhythm shown in IEGMs was correctly classified as VF, VT, AF, other SVT, lead-related oversensing, or T-wave oversensing in 92.3% of events. A rough rhythm classification as ventricular, supraventricular, or oversensing was correct in 97.2% of events, as compared with 93.4% for the first-generation IEGM Online in a previous publication.⁸

The LION study demonstrates that remote IEGM analysis is highly accurate in a remote monitoring system that transmits shorter IEGM than the full-length programmer IEGM for the sake of frequent, fully automatic data transmission.

Supplementary material

Supplementary material is available at *Europace* online.

Acknowledgements

The authors would like to thank Sabine Mitzenheim and Herdis Bender, PhD, for study management, Jochen Proff for scientific input, and Dejan Danilovic, PhD, for medical writing assistance.

Conflict of interest: H.N. and E.V. have (also received speaker fees) from Biotronik. H.O. is conducting research sponsored by Biotronik, Medtronic, St. Jude Medical and Sorin, has received consulting fees from Biotronik and Medtronic, and lecture fees from Biotronik, Medtronic and St. Jude Medical. S.R. reports receiving honoraria for lectures from Medtronic, Sorin and travel grants from Biotronik, Boston Scientific, Medtronic and Sorin. J.S. is a full-time employee of Biotronik. G.Z. has received lecture fees from Biotronik and Medtronic. All other authors reported no conflict of interest.

Funding

The study was supported by Biotronik SE & Co. KG, Berlin, Germany. Funding to pay the Open Access publication charges for this article was provided by Biotronik.

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