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Transmission and loss of ECG snapshots: Remote monitoring in implantable cardiac monitors

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ABSTRACT

Introduction: Remote monitoring including transmission of electrocardiogram (ECG) strips has been implemented in implantable cardiac monitors (ICM). We appraise whether the physician can rely on remote monitoring to be informed of all possibly significant arrhythmias.
Methods: We analyzed remote monitoring transmissions of patients in the ongoing BIO|GUARD-MI study, in which Biotronik devices are used. Once per day, the devices automatically transmit messages with up to six ECG snapshots to the Home Monitoring Service Center. If more than one type of arrhythmia is recorded during a day, at least one ECG of each arrhythmia type is transmitted.
Results: 212 study patients were registered at the service center. The mean age of the patients was 70 ± 8 years, and 74% were male. Patients were followed for an average of 13 months. The median time from device implantation until the first message receipt in the service center was 2 days. The median patient-individual transmission success was 98.0% (IQR 93.6–99.8) and remained stable in the second and third year. The most frequent arrhythmias were atrial fibrillation, bradycardia and high ventricular rate. 17.3% of the messages with ECG snapshots contained more than one arrhythmia type.
Discussion: Our analysis confirms that the physician can rely on Home Monitoring to be informed of all possibly significant arrhythmias during long-term follow-up. We have found hints that the transmission of only one episode per day may lead to the loss of clinically relevant information if patients with ICMs are followed by remote monitoring only.

Introduction

Implantable cardiac monitors (ICMs) are used to detect cardiac rhythm disturbances that are too rare to be captured by conventional 24- or 48-hour Holter electrocardiogram (ECG) [1]. The role of ICMs is established for the clarification of unexplained symptoms [2,3] and ICMs have been shown to be effective in identifying atrial fibrillation (AF) in patients with stroke of unclear origin [4]. Beyond these indications, ICMs are discussed for new fields such as guiding medical therapy for AF and risk stratification in structural heart disease [1,5,6]. Remote monitoring including transmission of ECG strips has relieved the

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problem of the limited storage capacity of the devices (≈1 h of ECG) and allows patient surveillance without regular in-hospital visits [1].

However, a strategy of remote follow-up depends on reliable and complete remote monitoring transmission from ICMs is over longer periods of monitoring. Furthermore, the number of transmitted ECG strips per day is limited by technological constraints, and evidence on relevant rhythm disturbances may therefore be supplanted by less relevant episodes, such as nightly bradycardia, recurrent AF episodes in patients with known AF, or inappropriate detections. In some persons, the truly relevant arrhythmias may be rare in comparison to the episodes of known arrhythmias or incorrect detections, potentially leading to the loss of relevant events which were detected by the ICM but not transmitted by remote monitoring.

The novel ICM model BioMonitor III and its predecessor BioMonitor 2 use the established Home Monitoring system (Biotronik SE & Co. KG; Berlin, Germany) [7–9]. They transmit a daily message that may contain up to six ECG snapshots. In the present subanalysis of the BIO|GUARD-MI study, we evaluate the remote monitoring transmission success rate during long-term follow-up and the availability of ECG strips. The goal of the subanalysis is to appraise to which extent the physician can rely on remote monitoring to be informed of all possibly significant arrhythmias.

Material and methods

BIO|GUARD-MI study design

The completed Cardiac Arrhythmias and Risk Stratification After Myocardial Infarction (CARISMA) study has shown that patients who present with arrhythmias after myocardial infarction (MI) have an increased risk of major adverse cardiac events [5]. However, the study was not able to show that intervention after arrhythmias would improve the outcome. The ongoing BIO|GUARD-MI study is designed to answer this question. It investigates whether the incidence of major adverse cardiac events in patients after MI can be decreased by early detection of cardiac arrhythmias using an ICM, and by the subsequent treatment of the underlying medical cause. A publication of the study rationale and design is under review. Briefly, patients older than 18 years are included in BIO|GUARD-MI after acute or chronic MI if they have a left ventricular ejection fraction >35%, no other cardiovascular implantable electronic device, no permanent anticoagulation treatment for atrial fibrillation (AF) and a CHA_2DS_2-VASc-Score ≥4 (men) or ≥5 (women). The CHA_2DS_2-VASc-Score has been developed the quantify the stroke risk in AF patients but has also been shown valuable as a general cardiovascular risk score. All enrolled patients have given written informed consent before enrollment, which comprises the scientific analysis of remote monitoring data. Appropriate national and local ethics committees approved the study protocol which is performed in compliance with good clinical practice guidelines and the Declaration of Helsinki (ClinicalTrials.gov Identifier: NCT02341534).

Patients are randomized in a 1:1 matrix to standard post-MI treatment with or without ICM insertion. An estimated 1500 patients will be enrolled and followed until 372 primary endpoints have occurred. After randomization, patients are not scheduled to return to the implanting hospital but may be invited for further check-up if an arrhythmia is detected. The retrieval of the information from ICMs is thus completely dependent on a functioning remote monitoring transmission.

Features of the implantable cardiac monitor

The BioMonitor 2 or successor Biotronik ICM devices are used in the study [7,8]. After its subcutaneous insertion, the ICM continuously monitors the heart rhythm to detect and store episodes of AF (based on rhythm irregularity), bradycardia and high ventricular rate (HVR; both based on heart rate and minimum duration), asystole (based on pause length) and sudden rate drop (SRD; based on the heart rate drop in percent). The device automatically records a subcutaneous ECG (sECG) triggered by programmed criteria. Further, sECGs can be stored at predefined regular intervals (scheduled periodic recording) or after manual trigger by the patient.

The ICM automatically transmits a message once per day, typically in the early morning hours [9]. The message can contain up to six uncompressed full-length sECG snapshots. An example sECG is shown in Fig. 1. The most recent recordings are preferentially sent. If more than one type of arrhythmia is recorded during a day, episodes will be transmitted according to the following ranking: patient-triggered recording, asystole, HVR, bradycardia, SRD, AF. This approach ensures that at least one episode of each trigger type is transmitted. The global Home Monitoring Service Center (HMSC) receives the transmitted data using Biotronik Home Monitoring® (HM) technology [9]. The physician can assess the message content on a secure website.

Present analysis

We retrieved from the HMSC all HM transmissions of all patients enrolled in the BIO|GUARD-MI study by Jan 30, 2019. To confine the analysis to spontaneous arrhythmias, we excluded patient-triggered and periodic sECG snapshots. Days with a message are defined as days on which a message is received in the HMSC until 9:00 A.M. next day. This decision was made under the assumption that a clinic typically checks new HM messages at the beginning of a working day. Gross overall transmission rate was calculated as the number of days with a HM message divided by the number of patient-days between the first and the last transmission. We also calculated the transmission rate for all patients individually.

Metric data are reported as mean ± standard deviation (SD) or as median and interquartile range (IQR). Categorical data are shown as absolute and relative frequencies. The analysis was conducted with the R 3.3 statistical software (R Development Core Team, Vienna, Austria).

Results

Patients

On 30 Jan 2019, 212 patients had been registered at the HMSC as participants of the BIO|GUARD MI study. All patients received a BioMonitor 2 ICM device. The mean age of the patients was 70 ± 8 years, and 74% were male. The CHA_2DS_2-VASc-Score was mostly 4 (44%), 5 (37%), or 6 (16%). The prevalence of hypertension was 95%, diabetes 58%, renal disease 10%, and congestive heart failure 39%. In patients with heart failure, the New York Heart Association symptom class was I (45%), II (51%), or III (5%).

Home Monitoring transmission

The median time from device insertion until the first HM message was received in the HMSC was 2 days (IQR 2–4.5; mean ± SD, 5.2 ± 10.1). Thereafter, the total observation period until the last message in each patient was 87,252 patient-days (on average, 13 months per patient). During this period, HM messages were received on 80,404 days, yielding a gross overall transmission rate of 92.2%. The patient-individual transmission success was 93.4 ± 12.1% (median 98.0, IQR 93.6–99.8), with a negligible decline over 3 years of follow-up (Table 1).

ECG transmission and content

The percentage of HM messages with sECG strips was 27.6% (22,158 out of 80,404 messages, excluding patient-triggered and periodic sECG). The 22,158 HM messages contained a total of 78,541 sECG strips (3.5 ± 2.2 per message). As many as 8391 messages (37.9% of messages with

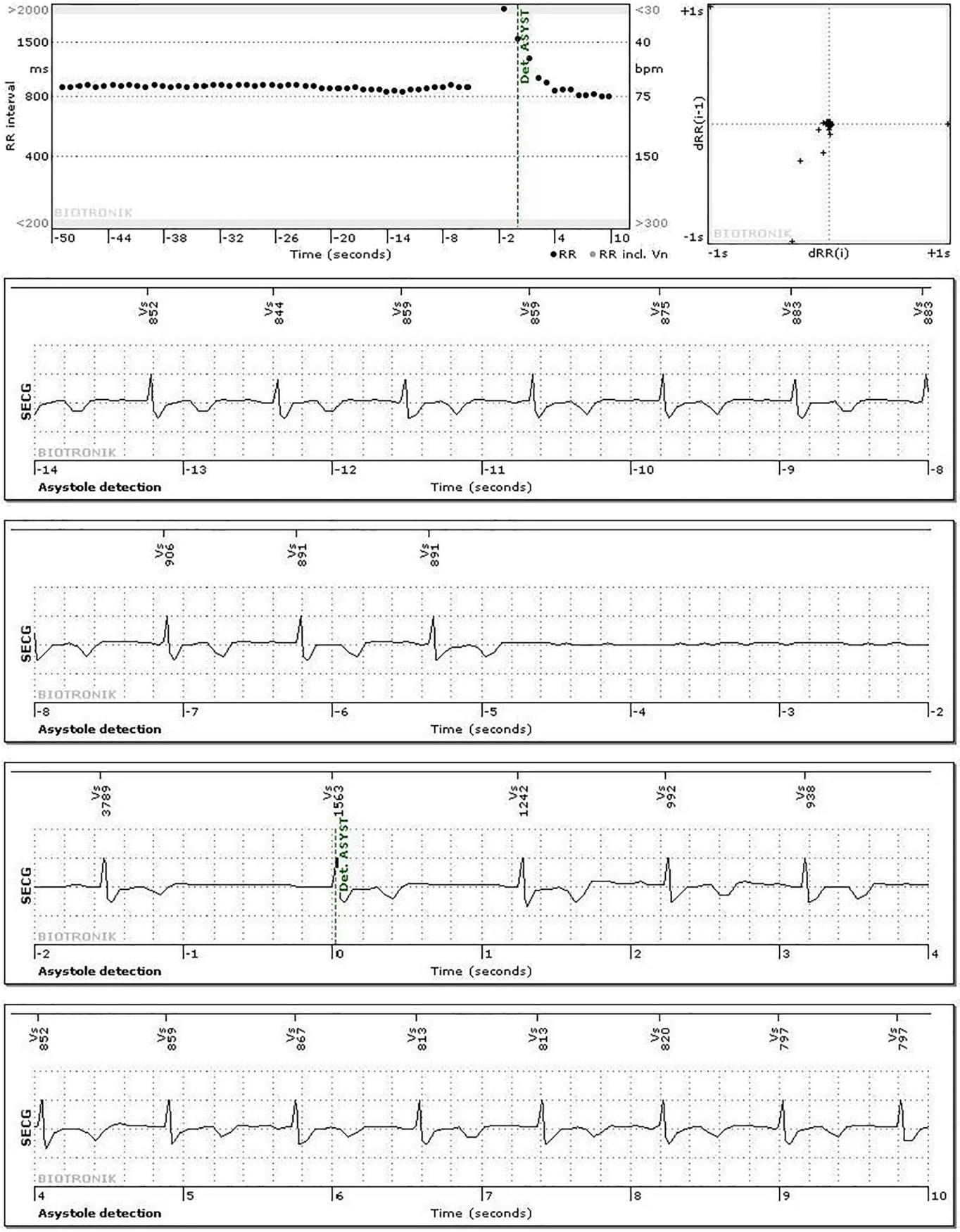

Fig. 1. Example sECG strip. The signal from 50 to 14 s before the asystole was detected is cut for clarity. The patient was diagnosed as a third degree AV block and received a pacemaker.

Table 1
Stability of patient-individual HM transmission success rates over time.

Time period	Patient-individual transmission success rate		
	Mean ± SD	Median (IQR)	N=
During the 1st year of FU (%)	94.2 ± 10.8	98.4 (94.0–100)	212
During the 2nd year of FU (%)	90.3 ± 18.3	97.7 (89.6–100)	113
During the 3rd year of FU (%)	93.8 ± 11.7	97.1 (93.5–100)	37
Total (%)	93.4 ± 12.1	98.0 (93.6–99.8)	212

FU, follow-up; HM, Home Monitoring; IQR, interquartile range; SD, standard deviation.

sECG, 10.4% of all days with messages) contained the maximum number of six sECG strips (Fig. 2).

The prevalence of different trigger criteria in the transmitted sECG strips is shown in Fig. 3. The most frequent trigger criteria were AF (56.8%), bradycardia (29.3%), and HVR (9.1%).

The proportion of patients with at least one sECG attached to a HM message was 90.1% (191/212). Conversely, no automatically detected arrhythmia sECG was obtained from 21 patients (9.9%).

Messages with more than one type of suspected arrhythmia

Of the messages with any spontaneously detected sECG, 82.7% reported on only one arrhythmia type. The remaining messages (17.3%) contained two (15.0%), three (1.8%), or four (0.4%) arrhythmia types.

On the patient level, 117 patients (55.2% of all 212 patients, or 61.3% of the 191 patients with any spontaneously detected sECG) had at least one HM message with more than one type of arrhythmia.

Discussion

Our analysis of the ICM data transmitted by remote monitoring in post-MI patients, comprising >200 patients and 230 patient-years of follow-up, confirms that the physician can rely on remote monitoring to be informed of all possible significant arrhythmias.

The median individual success of daily transmission of HM messages was 98.0%. In practical terms, this means that one half of the patients had a message lost less than once in seven weeks. This figure is comparable to figures from patients with implantable cardioverter/defibrillators with the same remote monitoring system, indicating that it is independent of the device type [10]. The transmission success is stable in the second and third year after implantation (97.7% and 97.1%, respectively), although this result has to be taken with care because only few patients were followed for longer than two years. In any way, the long-term results we can report compare favorably with

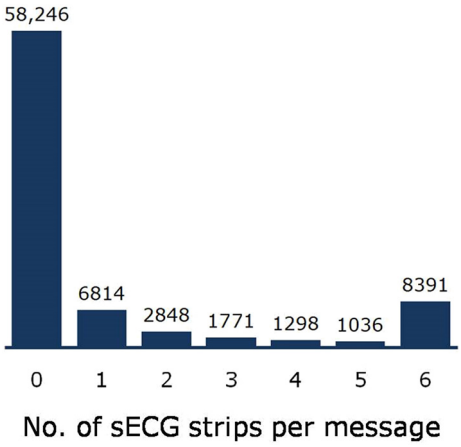

Fig. 2. The number of sECG strips per Home Monitoring message. sECG, subcutaneous ECG.

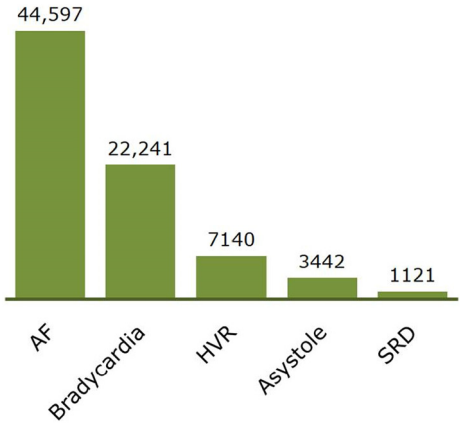

Fig. 3. The number of sECG strips for different arrhythmia types suspected by the ICM. Of note, the SRD criterion is programmed OFF in the standard setting that was used in most patients. AF, atrial fibrillation; HVR, high ventricular rate; ICM, implantable cardiac monitor; sECG, subcutaneous ECG; SRD, sudden rate drop.

results published for the Medtronic LINQ during the first month after implantation [11].

Beyond the overall transmission success, a second requirement for reliable identification of relevant arrhythmias is that they are not supplanted by irrelevant events, e.g., nightly bradycardia, repeating AF episodes, or inappropriate detections. In theory, the truly relevant arrhythmias may be less frequent than known arrhythmias or incorrect detections. Devices that transmit only one event per day may, thus, be at a significant risk of failing to transmit relevant events. While we cannot make any statements on the relevance of the episodes detected in our data set, we found that 17% of the messages with at least one ECG contained evidence of more than one arrhythmia type. In such cases, the ICM normally cannot decide which of the different arrhythmias is clinically most relevant and of the highest priority to be documented by ECG transmission. We estimate that an ICM capable of transmitting only one ECG per day would in about one half of the messages with multiple arrhythmias fail to transmit the most relevant episode.

Overall, our results show that the ICM and the remote monitoring technology used in our study are suited for reliable long-term monitoring, without regular patient visits to the hospital. Even in the third year after study enrollment, we did not find a meaningful decrease of the transmission success. Remote monitoring not only simplifies patient management but also avoids the risk of memory overflow in the devices. The ability to transmit at least one example of all available event types per day ensures that at least single examples of all relevant arrhythmia types will be reliably reported.

It should be kept in mind that we enrolled patients without known arrhythmias. One might assume that patient compliance with remote monitoring would have been even better if they had a primary arrhythmia indication. These patients may better understand the purpose of the ICM than those in whom an arrhythmia is “merely” considered a risk factor that may, or may not, lead to therapeutic intervention. Under these considerations, the transmission result is all the more reassuring.

Our analysis is limited by a few issues. First, we did not adjudicate the arrhythmias as true or false detections because this would have been beyond the scope of this article. Second, our population of MI survivors is not the typical guideline-recommended ICM population. The rate of detections will be different in patients after stroke or with unclear syncopal events, not only because of a different true arrhythmia incidence but also because of the possibility to program the devices according to the specific indication. These constraints prevent a more accurate estimation of a “loss rate” of relevant arrhythmias in devices transmitting only one ECG per day. However, we believe that our general conclusions also apply to typical ICM patients.

Conclusion

Our results show a high success rate of remote monitoring transmission during long-term monitoring with the tested devices. We have found hints that the transmission of only one episode per day may lead to the loss of clinically relevant information if patients with ICMs are followed by remote monitoring only.

Declaration of Competing Interest

CJ, PS, SB and PEBT have received honoraria and non-financial support from Biotronik in the context of this study. SB has further received non-financial support from Medtronic. JB reports grants from Abbott, Biotronik and Medtronic. MK and JS are employees of Biotronik. All other authors report no possible conflicts.

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