Is the last before-death alert remote monitoring transmission in patients with heart failure life-threatening?

Maciej Dyrbuś, Mateusz Tajstra, Anna Kurek, Łukasz Pyka, Mariusz Gąsior

3rd Department of Cardiology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland

Editorial

by Masarone

Correspondence to:

Maciej Dyrbuś, MD, 3rd Department of Cardiology, Medical University of Silesia, Silesian Center for Heart Diseases, Curie-Skłodowskiej 9, 41–800 Zabrze, Poland, phone: +48 32 373 38 60, e-mail: mdyrbus@op.pl Copyright by the Author(s), 2022

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ABSTRACT

Background: Remote monitoring (RM) of cardiac implantable electronic devices (CIED) allows for a regular analysis of the occurrence of arrhythmias and functioning of the devices.

Aims: To date, no study investigated the characteristics of the alert-triggered ultimate transmissions before death, which was the aim of the present analysis.

Methods: Patients monitored remotely in our center, whose baseline characteristics were obtained from the COMMIT-HF Registry (NCT02536443) were analyzed and divided according to the occurrence of alert transmissions during the RM. In patients who had an alert transmission, the last transmission was analyzed. All RM data were obtained from the software provided by four RM manufacturers.

Results: Of 1271 patients with CIEDs which transmitted at least one message to the RM center, 198 (15.6%) had no alert transmissions, while 1073 (84.4%) had at least one alert transmission. Respective mortality in patients with and without alerts during RM was 29.7% and 12.6%, respectively. In patients who had ever an alert, the last recorded transmission before death was scheduled in 166 patients and alert-triggered in 152 patients. The most frequent alert-triggered last transmissions were atrial fibrillation/flutter (39.4%) and ventricular tachyarrhythmias (26.8%). The median period from the last alert-triggered transmission to death was 10 days.

Conclusion: This is the first analysis of the ultimate RM transmissions delivered by CIEDs before death. In approximately 85% of RM patients with CIEDs, at least one alert transmission occurred during the RM, and in patients who had ever an alert, almost half of the last transmissions before death were alert-triggered.

Key words: remote monitoring, implantable cardioverter–defibrillators, cardiac resynchronization therapy, heart failure, last transmission

INTRODUCTION

Despite significant improvements in healthcare organization and treatment modalities, the prognosis in patients with heart failure (HF) remains poor [1–3]. Due to the high risk of sudden cardiac death, a certain percentage of patients with HF have indications for implantable cardioverter–defibrillators (ICDs) or for implantable cardioverter–defibrillators (CRT-D) used in cardiac resynchronization therapy [4–6]. Although in specific groups of patients, implantation of ICD or a CRT-D increases survival, the percentage of patients who die with the devices remains considerable [7]. Remote monitoring (RM) of patients with ICDs and CRT-Ds allows one to gather detailed information concerning the functioning of the device on the regular basis, without the necessity of patients to present themselves for in-person examinations [8–12]. Moreover, RM allows to continuously measure various vital parameters of the patient, such as the arrhythmia burden, the percentage of biventricular pacing, and thoracic congestion indicators, which have been proven to predict HF decompensation and worsen the patient's prognosis. In the large meta-analysis of randomized controlled trials, RM was asso-

WHAT'S NEW

To date, this is the first analysis of the last transmissions delivered before death by remotely monitored implantable cardioverter-defibrillators and cardiac resynchronization therapy implantable cardioverter-defibrillators. In approximately 85% of remotely monitored patients with heart failure and cardiac electronic implantable devices, at least one alert-triggered transmission occurred during the median of almost 5 years of remote monitoring. In patients with at least one alert delivered by the devices from the enrollment into remote monitoring, 48% of the last before-death transmissions were alert-triggered, while the remaining 52% were scheduled transmissions. In patients in whom the last transmission was alert-triggered, its most frequent causes were atrial fibrillation or flutter episode, ventricular tachyarrhythmia, or reduction in the percentage of biventricular pacing, and the median time from the last transmission to death was 10 days.

ciated with a significant reduction in the rate of in-person examinations [11]. On the contrary, the data on mortality reduction are inconsistent. In the IN-TIME trial, a significant reduction in mortality of patients monitored remotely was observed; however, it was not demonstrated in the other large trials conducted to date [8, 13, 14].

One of the possible explanations of these discrepancies in the results of the trials evaluating the efficacy of RM could have been related to differences in the organizational scheme of the RM centers, including the frequency and types of transmissions generated by the devices, the contents of the alert-triggered transmissions, and the type and timing of the clinical reactions undertaken [15].

To date, no study investigated the characteristics of ultimate messages obtained from the RM of ICD/CRT. Moreover, data on the percentage of patients having conditions requiring alert transmissions during the RM period are scarce.

Therefore, the present study aimed to examine the type and contents of the ultimate transmissions in the cohort of remotely monitored patients and to summarize the causes of the alert-triggered ultimate transmissions occurring before death.

METHODS

The details of the Contemporary Modalities In Treatment of Heart Failure Registry (COMMIT-HF) registry have already been described [7, 16]. In brief, COMMIT-HF is a single-center, ongoing prospective registry (NCT02536443), with patient-based data collection. Consecutive patients hospitalized with a diagnosis of systolic HF (left ventricular ejection fraction [LVEF] \leq 35%) not caused by an acute coronary syndrome (ACS) at index hospitalization in the tertiary cardiovascular centers are prospectively enrolled in the Registry. The Registry encompasses detailed patient demographic characteristics, prior medical history, and complete data from the index hospitalization, including the type of implantable device and medications administered at discharge. The study protocol was approved by an appropriate institutional review board and ethics committee.

During the duration of the study, RM was assigned to consecutive patients depending on the reimbursement limitations and device availability in our hospital. Each patient, who had an implanted device eligible for RM and who declared willingness to adhere to the schedule of remote transmissions, received a transmitter compatible with the implanted device. The Central Remote Monitoring Office of our center involves two physicians (a cardiology consultant and a resident) and two electrophysiology nurses, who on weekdays analyze data derived from RM online systems and undertake adequate actions if indicated. The RM office provides surveillance of transmissions from all four major devices and RM manufacturers (Merlin. net[™] of St. Jude — now Abbott, CareLink[®] of Medtronic, Latitude[™] of Boston Scientific, and Home Monitoring[®] of Biotronik). Transmitted data are recorded and stored in the RM online software of all four major RM manufacturers. The undertaken clinical reactions, along with their results are archived in the paper and electronic databases. In general, the standard measured preset parameters transmitted remotely to the RM facility vary slightly according to the manufacturer and are described in detail in Supplementary material, Table S1.

The long-term RM data concerning the type of transmissions (scheduled or alert-triggered) and their contents, with particular emphasis on the occurrence of adequate or inadequate antiarrhythmic interventions of the devices, have been obtained from the investigator-initiated single-center RM database. In the database, the clinical course of RM is summarized for each patient on the yearly basis and includes the number, the type of alert-triggered transmissions, and the most clinically relevant programmed parameters.

All transmissions are initially labeled as unscheduled or scheduled by the RM system, however, for the registry, all transmissions were individually assessed by the authors of this study and classified accordingly to their content. In the cases of uncertainties about the contents or significance of the ultimate transmissions, representatives of the respective manufacturers were contacted for their verification.

At the time of the transmission, all therapeutic interventions were performed according to the current clinical situation of each patient based on the contents of the transmission and phone calls to patients or authorized relatives performed, when necessary, by the employees of the RM center. All interventions adhered to the European Society of



Figure 1. The study flowchart is presented on the left. The characteristics of the ultimate alerts are presented on the right Abbreviations: AF, atrial fibrillation; AFL, atrial flutter; BiV, biventricular; CRT-D, cardiac resynchronization therapy, implantable cardioverter-defibrillator; ICD, implantable cardioverter-defibrillator, RM, remote monitoring; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia

Cardiology (ESC) guidelines for Heart Failure, along with the ESC guidelines for Cardiac Pacing and Cardiac Resynchronization Therapy [17, 18]. The possible interventions included a referral for an in-person visit in the general practitioner's (GP) office or the outpatient specialist clinic, referral for an urgent or planned hospitalization, or modification in the patient's pharmacotherapy. In general, if a sustained ventricular tachyarrhythmia occurred, patients were al-ways contacted, and if no reversible cause of arrhythmia had already been identified, most patients were referred for urgent hospitalization. The general scheme of clinical interventions undertaken in response to the alert-triggered transmissions is summarized in Supplementary material, *Figure S1*.

The long-term follow-up data were obtained from the National Health Fund, the only Polish healthcare provider. Based on this source, the causes of in-hospital deaths were available, established according to the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). The list of all causes of death with respective ICD-10 codes in the analyzed population is presented in Supplementary material, *Table S2*.

Statistical analyses

This was an explorative study using the methods of descriptive statistics. The continuous variables were presented as mean (SD) for normal distribution or as median (interquartile range [IQR]) for non-normal distributions. Categorical variables were expressed as the absolute numbers and relative proportion (percentage) of patients with the respective attribute. The normality of distribution was verified using the Shapiro–Wilk test. All analyses were conducted using the Statistica 10 software (StatSoft, Inc., Tulsa, OK, US).

RESULTS

Between January 2009 and December 2017, 1271 patients were enrolled in the RM program after implantation of an ICD or CRT-D in our facility, and their devices transmitted at least one message. Of those, 198 (15.6%) generated no alert-triggered transmissions, while in the remaining 1073 (84.4%), there was at least 1 alert-triggered transmission, as presented in Figure 1A and Supplementary material, *Table S3*. The percentage of patients with any alert-triggered transmission during RM were 68.7%, 73.7%,

 Table 1. Device parameters and manufacturers in patients with last alert-triggered transmission

Device parameters	All (n = 142)
Implantation due to the secondary preven- tion of sudden cardiac death, n (%)	37 (26.1)
ICD, n (%)	71 (50.0)
Single-chamber	34 (23.9)
Dual-chamber	37 (26.1)
CRT-D, n (%)	71 (50.0)
Device manufacturers	All (n = 142)
Biotronik, n (%)	4.9 (5.2)
Boston Scientific, n (%)	10 (7.0)
Medtronic, n (%)	13 (9.2)
St. Jude (Abbott), n (%)	112 (79.6)

 $\label{eq:abstructure} Abbreviations: CRT-D, cardiac resynchronization therapy --- implantable cardioverter-defibrillator; ICD, implantable cardioverter-defibrillator$

and 79.6% in the first, second, and third years of monitoring, respectively. Of the 198 patients with scheduled-only transmissions, 25 (12.6%) died during the RM period, while among 1073 patients with at least one alert, there were 318 (29.7%) deaths. In patients who had ever had an alert, 166 of the last transmissions sent by the devices were scheduled, while 152 were alert-triggered. In 8 patients, the last alert-triggered transmission was followed by the device replacement, 1 had the device explanted due to infective endocarditis, and 1 resigned from RM. Therefore, these patients were excluded from the present analysis, which eventually included 142 patients, in whom the last transmission sent before death was alert-triggered.

Among those individuals, there were 71 patients with ICDs (50.0%) and 71 with CRT-D devices (50.0%). The vast majority of patients received a St. Jude device (79.6%), while the remaining devices were manufactured by Medtronic, Boston Scientific, and Biotronik as described in Table 1. More than a quarter of devices were implanted due to secondary prevention of SCD.

The baseline characteristics of the 142 patients, in whom the last remote transmission was alert-triggered are presented in Table 2. Women constituted approximately 20% of the studied group and the median age at implantation was 64 years. The ischemic cardiomyopathy was the primary indication for implantation of the devices (68.3%). At implantation, 35.9% of patients were in New York Heart Association (NYHA) functional class II and 52.1% in the NYHA class III. The mean left ventricular ejection fraction (LVEF) was 23% and the median left ventricular end-diastolic diameter (LVEDD) was 68 mm. At discharge, 95.1% of patients were prescribed a beta-blocker, 89.4% were administered a loop diuretic, and 74.0% an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB), as described in Table 3.

 Table 2. Baseline demographic and clinical characteristics of patient with last alert-triggered transmission

Demographics	Alert-triggered (n = 142)
Female, n (%)	32 (22.5)
Age at implantation, years, median (IQR)	64 (57–73)
Baseline characteristics	
Indication for implantation	
Ischemic cardiomyopathy, n (%)	97 (68.3)
Non-ischemic cardiomyopathy, n (%)	45 (31.7)
Arterial hypertension, n (%)	71 (50.0)
Atrial fibrillation, n (%)	54 (38.0)
COPD, n (%)	21 (14.8)
Dyslipidemia, n (%)	64 (48.6)
Smoking, n (%)	42 (33.1)
Prior stroke, n (%)	4 (2.8)
Prior MI, n (%)	77 (54.2)
Prior PCI, n (%)	61 (43.0)
Prior CABG, n (%)	26 (18.3)
Anemia, n (%)	39 (27.5)
Hemoglobin at implantation, g/l, mean (SD), (n/N)	140 (17.7) (122/142)
Diabetes, n (%)	62 (43.7)
NYHA class	
ll, n (%)	51 (35.9)
III, n (%)	74 (52.1)
IV, n (%)	13 (9.1)
WBC, $\times 10^{3}/\mu$ l, median (IQR), (n/N)	7.2 (5.8–8.6) (122/142)
PLT, \times 10 ³ /µl, median (IQR), (n/N)	188 (154–224) (122/142)
GFR ≤60 ml/min/1.73 m², n (%)	55 (38.7)
Serum creatinine, µmol/l, median (IQR) (n/N)	102 (84–121) (122/142)
BMI, kg/m², median (IQR), (n/N)	26.8 (23.5–30.8) (84/142)
LVEF, %, mean (SD)	23 (5)
LVEDD, mm, mean (SD), (n/N)	68 (10) (138/142)
LVESD, mm, median (IQR), (n/N)	57 (50–64) (138/142)

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft surgery; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; LVESD, left ventricular end-systolic diameter; MI, myocardial infarction; NYHA, New York Heart Association, PCI, percutaneous coronary intervention, PLT, platelet count, RBC, red blood cell count; WBC, white blood cell count

Table 3. Pharmacotherapy after baseline hospitalization for device implantation

Pharmacotherapy at discharge	All (n = 142)
Oral anticoagulant (any), % (n/N)	38.0 (54/142)
Antiplatelet drugs, % (n/N)	66.2 (94/142)
ACE-I/ARB, % (n/N)	74.0 (105/142)
Beta-blocker, % (n/N)	95.1 (135/242)
Loop diuretics, % (n/N)	89.4 (127/142)
Other diuretics, any, % (n/N)	14.8 (21/142)
Mineralocorticoid receptor antagonist, % (n/N)	83.8 (119/142)
Digitalis, % (n/N)	27.5 (39/142)
Other antiarrhythmic drugs, any, % (n/N)	19.0 (27/142)

Abbreviations: ACE-I, angiotensin convertase enzyme inhibitors; ARB, angiotensin receptor blockers

Table 4. Types of the last alert-triggered transmissions

Cause of alert	All alert-triggered transmissions (n = 142)
AF/AFL episode, n (%)	56 (39.4)
Permanent/persistent AF	33 (58.9)
New-onset AF, n (%) ^a	2 (3.6)
SVT episode, n (%)	5 (3.5)
Lead dysfunction suspicion, n (%)	2 (1.4)
Ventricular tachycardia, n (%)	23 (16.2)
Treated with ATP/HV, n (% of all VTs)	10 (43.5)
Ventricular fibrillation, n (%)	15 (10.6)
Requiring ATP/HV, n (% of all VFs)	14 (93.3)
Ventricular tachyarrhythmias fulfilling criteria of ES, n (% of all VT/VFs)	11 (28.9)
Biventricular pacing percentage reduction, n (%)	15 (10.6)
Others	26 (18.3)
Congestion monitor indications, n (%)	5 (3.5)
Patient triggered ^b	7 (4.9)

^aNew-onset AF, n (%)^a — although the threshold for AF detection was \geq 5 minutes, both episodes lasted \geq 2 hours; ^bPatient triggered — alert with no signs of hardware/software device malfunctions and/or device indications

Abbreviations: AF, atrial fibrillation; AFL, atrial flutter; ATP, antitachycardia pacing; ES, electrical storm; HV, high-voltage therapy; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia

The median (IQR) time from implantation to death in patients with last alert-triggered transmission was 3.24 (2.01-4.36) years. The most prevalent type of the ultimate alert-triggered transmission was an atrial fibrillation/atrial flutter episode, which occurred in 56 (39.4%) of patients, as presented in Table 4 and Figure 1B. Two (3.6%) of those were new onsets of atrial fibrillation and 33 (58.9%) of patients had persistent/permanent AF. There were 38 transmissions triggered by ventricular tachyarrhythmias, of which 23 were ventricular tachycardia (VT) and 15 were ventricular fibrillation (VF) episodes. Approximately 44% of VTs and 93% of VFs were treated with the device and in 11 cases, the transmitted arrhythmias fulfilled the criteria of an electrical storm (ES). In 15 patients (10.6%) a reduction in biventricular pacing occurred, and in 26 (18.3%) other causes of alert transmissions occurred, including the indications of a congestion monitor. There were 7 patient-triggered transmissions, in which no hardware- or software-related issues were detected. In only 12 patients, the cause of the last alert-triggered transmission occurred for the first time, and in the remaining population, it had occurred during monitoring, as described in detail in Supplementary material, Table S4.

The clinical reactions of the RM center were undertaken in 62.6% (n = 89). The median time (IQR) from an alert-triggered transmission to the clinical reaction was 1 (0–2) day. There were 36 telephone consultations, 13 referrals to the GP or specialist clinics for in-patient visits, and 18 referrals for the urgent hospital admission. In 20 patients with alert-triggered last transmission, the clinical reaction, although undertaken, did not let change their condition. The most prevalent cause for such a state was that the patient

Table 5. The clinical reactions to the last alert-triggered transmissions

Clinical reaction	Alert-triggered transmission (n = 142)
Any clinical reaction, n (%)	89 (62.6)
Telephone consultation, n (%)	36 (25.3)
Referral to the GP or outpatient specialist clinic visit, n (%)	13 (9.2)
Referral for hospital admission, n (%)	18 (12.7)
Pharmacotherapy modification, n (%)	2 (1.4)
Reaction not changing patient's condition, n (%)	 20 (14.1) 4 patients who died during/immediately after transmission 12 patients who were already admitted to the hospital 3 patients deemed critically ill in whom no action could bring a benefit 1 patient who did not answer the phone de- spite numerous contact attempts

Abbreviation: GP, general practitioner

had already been taken to the hospital and the transmission signal was generated from the hospital, or the patient died in an immediate period before transmission, as described in detail in Table 5. The median (IQR) time from the last alert-triggered transmission to death was 10 (2–26) days.

Finally, based on the administrative data, patients who died in the hospital were identified. In the analyzed population of 142 patients, in whom the last transmission was alert-triggered, data were available for 134, of whom 78 (58.2%) died in the hospital while the remaining patients died elsewhere. Worth noting is that in the 90 days preceding death, the median (IQR) number of hospital admissions of these patients was 1 (0–2), as was the number of visits in the outpatient clinics. The clinical causes of death in that group are summarized in Supplementary material, *Table S5*.

DISCUSSION

The main findings of our study are: (1) our analysis was the first to specifically examine the ultimate transmissions delivered by the CIEDs in patients with HF who were remotely monitored at the tertiary cardiovascular center; (2) during the RM period, the alert-triggered transmissions occurred in approximately 85% of the whole population of patients; (3) in patients who had had at least 1 alert-triggered transmission, the ultimate transmission was alert-triggered in 48% while the remaining transmissions were scheduled; (4) in patients in whom the last before-death transmission was alert-triggered, the most frequent causes of alerts were atrial fibrillation or flutter, ventricular tachyarrhythmias or a significant reduction in the biventricular pacing percentage; (5) the median (IQR) period from the last alert-triggered transmission to death was 10 (2–26) days. Due to the concomitant presence of multiple risk factors predisposing to the development of patient- or device-related events, the risk of alert-triggered transmissions is higher than in the overall population of patients with implanted CIEDs [19] In the recent analysis by O'Shea et al. [21], the alert-triggered transmissions occurred in 45.7% of patients with ICDs. However, it should be noted that that study analyzed one calendar year, between November 2018 and November 2019. In our analysis, the monitoring period was substantially longer, as in some patients the RM, monitoring continued for more than 8 years. Therefore, the duration of the analysis period could explain a higher percentage of patients with alert-triggered transmissions [20].

In patients who had ever an alert condition, more than 50% of the last transmissions were scheduled — suggesting that at that time there were no indications of worsening of patients' conditions. One of the possible explanations for that high percentage of scheduled last transmissions is that less than half of all deaths in HF are due to sudden cardiac causes [21–23]. Hence, in the case of most patients who do not die due to non-cardiovascular causes or non-sudden cardiac death, even if their clinical condition significantly deteriorates, no arrhythmical abnormalities can be recorded in their last transmissions.

In those, whose ultimate transmission before death was alert-triggered, the most frequent cause of alert was an atrial flutter or a fibrillation episode, which constituted almost 40% of the ultimate alerts. Ventricular tachyarrhythmias constituted more than 25% of alerts, while reduction of biventricular pacing was responsible for more than 10% of all ultimate alerts. The presence of each of those conditions substantially worsens prognosis in HF, and a wide variety of mechanisms has been defined through which their occurrence could lead to a significant, abrupt deterioration of patient's conditions and decompensation of HF, often leading to death.

Although in approximately one-third of cases no clinical reaction has been performed, one has to acknowledge that in some cases the ICDs/CRTs generate alerts that are repeatable and consistent with the patient's history, such as the high AF burden in a patient with permanent AF or a persisting reduction of the biventricular pacing percentage. In our analysis, more than 90% of patients with either AF or reduction of the biventricular pacing percentage, had such alerts during the prior course of RM, and only in 4 subjects, such events occurred for the first time. In the trial by Crossley et al. [24] which randomized 1997 patients to RM or standard care, 62% of automatically triggered alerts were considered clinically meaningful, and therefore, required a reaction. In the IN-TIME trial, out of an average of 4.0 alerts delivered to the RM facilities per patient-year, patients were contacted in a mean of 2.1, thus the rate of reactions to alerts was 53% [15].

Limitations

The present analysis has a few limitations, mostly regarding its retrospective character. First of all, although all data have been transmitted to a single, tertiary center with more than 10-year experience in remote-monitoring of patients with ICDs and CRT-Ds, the use of four different manufacturers and software with different transmission schedules and settings could potentially influence the contents of the final transmission and its interpretation.

Second, the analyzed population, although highly specific, is not numerous and the generalization of data should be performed cautiously because baseline characteristics, adherence to the therapy and other external factors could potentially bias the results. Third, no exact information on the specific cause of death derived from autopsy has been obtained, therefore, no adjudicated classification of deaths has been possible. Moreover, no post-mortem analyses of the implantable devices were performed. If any patients remained in the distance from the transmitters disallowing the generation of the transmission, their data was available only through post-mortem examination of the device. Consequently, those data were not included in the present analysis.

Finally, despite a thorough analysis of data, the study was performed retrospectively and investigated the reallife practice. Hence, although most of the data were scrupulously archived in either a paper or electronic form, results of some clinical reactions, such as phone calls to patients, could be not saved for future examination.

CONCLUSIONS

This is the first analysis of the last-before-death transmissions delivered in the remotely monitored patients with heart failure and an ICD or a CRT-D. The alert-triggered transmissions occurred in approximately 85% of the whole population of patients under remote monitoring. In patients who had had at least 1 alert transmission, the ultimate transmission was alert-triggered in 48% while the remaining transmissions were scheduled. In patients, in whom the last before-death transmission was alert-triggered, the most frequent causes of alerts were atrial fibrillation or flutter, ventricular tachyarrhythmias, or a reduction in the biventricular pacing percentage.

Supplementary material

Supplementary material is available at https://journals. viamedica.pl/kardiologia_polska.

Article information

Conflict of interest: None declared.

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