Using technology to improve reconnection to remote monitoring in cardiac implantable electronic device patients

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BACKGROUND Remote monitoring (RM) of cardiac implantable electronic device (CIED) patients is now considered standard of care. However, a fundamental requirement of RM is continuous connectivity between the patient's implanted device and the CIED manufacturer's central server. This study examined the rate of RM disconnections in CIED recipients and the impact of short message service (SMS) to facilitate reconnections.

METHODS Using a platform that collects RM data from CIED manufacturers, we retrospectively examined the disconnection and reconnection events in 6085 patients from 20 medical centers. Each medical center reported their usual practice regarding RM disconnections, which consisted of either an automatic SMS from the platform to patients who were disconnected for 2 weeks or the standard of care (SC) of a phone call to patients.

RESULTS During a 1-year period, 43% of patients had at least 1 disconnection. Half of these patients experienced multiple disconnections. The use of SMS reduced the time to reconnection by 43% in comparison to SC. The median time to reconnect a disconnected patient was 11.0 [3.2, 29.0] days for SC vs 6.3 [1.3, 22.0] days for SMS ($P < .0001$). Furthermore, there was a high rate of reconnections within the first 48 hours of the SMS message, which was nearly double that in the SC arm.

CONCLUSION This study demonstrates the feasibility of an automatic system to deliver an SMS to patients with a disconnected CIED to facilitate early reconnection to RM.

KEYWORDS Remote monitoring; Cardiac implantable electronic devices; Remote monitoring disconnection; Telemedicine; eHealth

(Cardiovascular Digital Health Journal 2024;5:1–7)

Introduction

Cardiac implantable electronic devices (CIED) such as pacemakers and defibrillators continuously monitor their own functions; data are transmitted wirelessly to the CIED's manufacturer automatically when activated by the patient, in response to a user-defined alert condition, and at times prescheduled by the physician (eg, monthly or quarterly).

Remote monitoring (RM) was developed to support the long-term follow-up of patients, particularly those presenting with subclinical arrhythmias,[1] and to limit the number of ambulatory visits in CIED recipients.[2] It was particularly useful during the COVID-19 pandemic.[3] The increasing number of alerts transmitted as the population of CIED recipients undergoing RM increases, represents a growing burden for the caregivers and healthcare staff.[4]

It has been reported that, compared with standard care, RM improves compliance with follow-ups.[5] However, in nearly 20% of patients, a disconnection occurs between the CIED and manufacturer's central web server.[6,7] This is an important limitation of RM, which has not been well studied systematically.[7,8] It has been reported that the identification of patients with device connectivity issues alone can use up to 5 minutes per patient per year and patient calls regarding troubleshooting device connectivity up to 10 minutes per patient per year.[9] We hypothesized that the use of short message service (SMS) would facilitate reconnection in these patients. Therefore, this study examined the rate of RM disconnections in CIED recipients and the performance of various methods of reconnecting and maintaining contact with disconnected patients.

Methods

The Implicity™ platform (Implicity, Paris, France) collects RM data from CIED manufacturers, converts these data to

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2666-6936/

https://doi.org/10.1016/j.cvdhj.2023.11.020

Table 1 Definition of disconnection based on manufacturer

Manufacturer	Transmission modes	Manufacturer message	Threshold
Abbott	• Scheduled • Alert-triggered • Patient triggered	No alert checks x days No communication x days	Configurable by the medical center – can be 1–14 days Was set to 14 days by all centers
Boston Scientific	• Scheduled • Alert-triggered • Patient triggered (S-ICD are only patient-triggered)	Implanted device not found Communicator not connecting	14 days
Medtronic	• Scheduled • Alert-triggered • Patient-triggered	Disconnected monitor Missed transmission	Configurable by the medical center – can be 7 or 14 days Was set to 14 by all centers Depends on scheduled transmissions

S-ICD = subcutaneous implantable cardioverter-defibrillator.

a uniform format, and stores them in a secure center where they can be accessed, viewed, and completed by healthcare providers at any time. The Implicity platform embeds a "disconnected patient algorithm" (DPA), a feature dedicated to identifying these patients. This retrospective study enrolled patients according to the self-reported practice of each medical center. The enrolling centers were queried ahead of the patients' enrollment and, for each CIED manufacturer, whether the patients were called 2–4 weeks after a disconnection.

Since this was a retrospective analysis of prospectively collected clinical data in real-life practice, this study was exempt from reviews and approvals by the institutional review boards of the participating institutions; the postprocessing is conducted in accordance with the European "General Data Protection Regulation" (UE 2016/679). All patients had granted their written approval to contribute the data at the time of RM activation. All data were de-identified to ensure the protection of personal health data, according to the European regulation and French reference methodology (MR-004).

Connection

The connection status of each patient was obtained by accessing the information displayed on the manufacturers' websites for Abbott, Boston Scientific, and Medtronic (despite Biotronik and Microport's being technically capable of providing connectivity information, their devices were not supported by the DPA at the time of the study). The reporting of the connection status on the manufacturer websites varied among device models. It typically consisted of regular, automated device signals which, when missing, signified a disconnection. Depending on the device manufacturer and model the settings could be programmed to be warned of disconnections lasting 1, 7, or 14 days, or if the patient was disconnected at the time of a scheduled remote follow-up. All centers used the 14 days option. Table 1 summarizes how each manufacturer defines a disconnected patient and whether this is or is not a programmable feature. The patients were considered as reconnected as soon as the device was noted on the manufacturer's website as reconnected. No patient withdrew from the program.

Interventions

The identification of a disconnection triggered an SMS or standard of care (SC). The entire DPA is shown in Figure 1. The type of intervention, or absence thereof, was chosen by each participating medical center, based on the personnel available. If the only number for the patient on file was a landline number, the patient only received SC. If, on the other hand, a mobile phone number was available, the system automatically sent an SMS within 24 hours of notification by the manufacturer of disconnection. Patients were informed they may be contacted by the medical team by any means (such as SMS or phone call) and were given the opportunity to opt out of SMS. All triggered interventions were recorded.

Short messages

At 10:00 AM Central Europe Time on the day following notification of disconnection, the patient received an SMS to inform them that their device was no longer sending data and urging them to report the reason for their disconnection or seek further help from the CIED manufacturer's customer care center, by accessing a login page as shown in Figure 2. An interactive version of what a patient experienced can be accessed at https://www.figma.com/proto/dP77tgNUk0DP7RXAMXHLeD/Mobile%2Fpatient?type=design&node-id=10174-32703&t=3nXrW02O8i98qNwc-0&scaling=scale-down&page-id=10174%3A31569&starting-point-node-id=10174%3A32703&show-proto-sidebar=1.

Standard of care

The SC procedure reported by the medical centers consisted of calling the patients 2 weeks or more after they were reported as disconnected (ie, 4 weeks or more of disconnection for patients without scheduled remote follow-up), to guide them through the reconnection procedure. This task was assumed by the enrolling medical institution or by the device manufacturer. It is worth noting that the medical centers did not commit to a maximum number of days before calling a patient, nor did they systematically document their interactions.

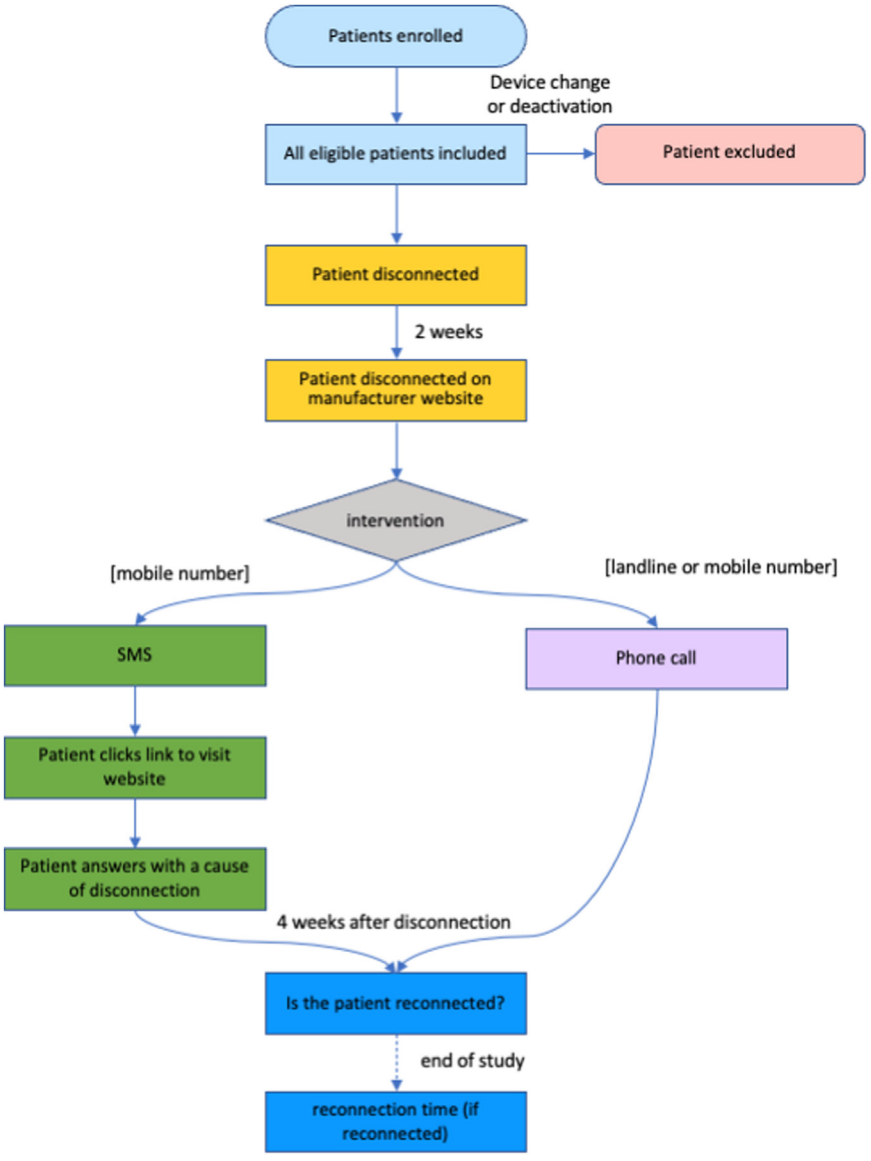

Figure 1 Flow of patients between enrollment in the study and reconnection of remote monitoring. SMS = short message service.

Inclusion/exclusion criteria

The enrolling medical centers all joined the study from November 2021 to October 2022, at which time all their eligible patients entered the study simultaneously. Patients were not included if the system could not determine their connectivity status (Biotronik, Microport), if their devices could not send automatic transmissions (inductive devices), if their devices are expected to send transmissions on a daily basis (ie, an implantable cardiac monitor), if they were younger than 18 years of age, if they could not be contacted by telephone, or if their demographic information was missing. Patients who got a generator change during the study were excluded.

Patient interventions were not considered in the outcomes assessment if the disconnection was due to a terminal event, such as death, device explantation, or cessation of RM. Patients were not excluded after a first reconnection, which allowed for multiple disconnection-reconnection cycles to be tracked for the same patient. Only the first intervention was considered in the outcome assessment.

Data analysis

The detailed SMS interactions with the patients and the reconnection date were recorded. Patient phone calls to the CIED manufacturer's Customer Care lines or to the clinics were not recorded. The main endpoints of the study were (1) time between the disconnection and the reconnection and (2) connection status 4 weeks after a disconnection.

The Gaussian data are expressed as means ± standard deviations or numbers and percentages of observations. Non-Gaussian variables are expressed as median [Q1;Q3] (interquartile range). Proportions were compared with the χ^2 test. Continuous Gaussian variables were compared using a parametric Student *t* test or a Fisher test, depending on the

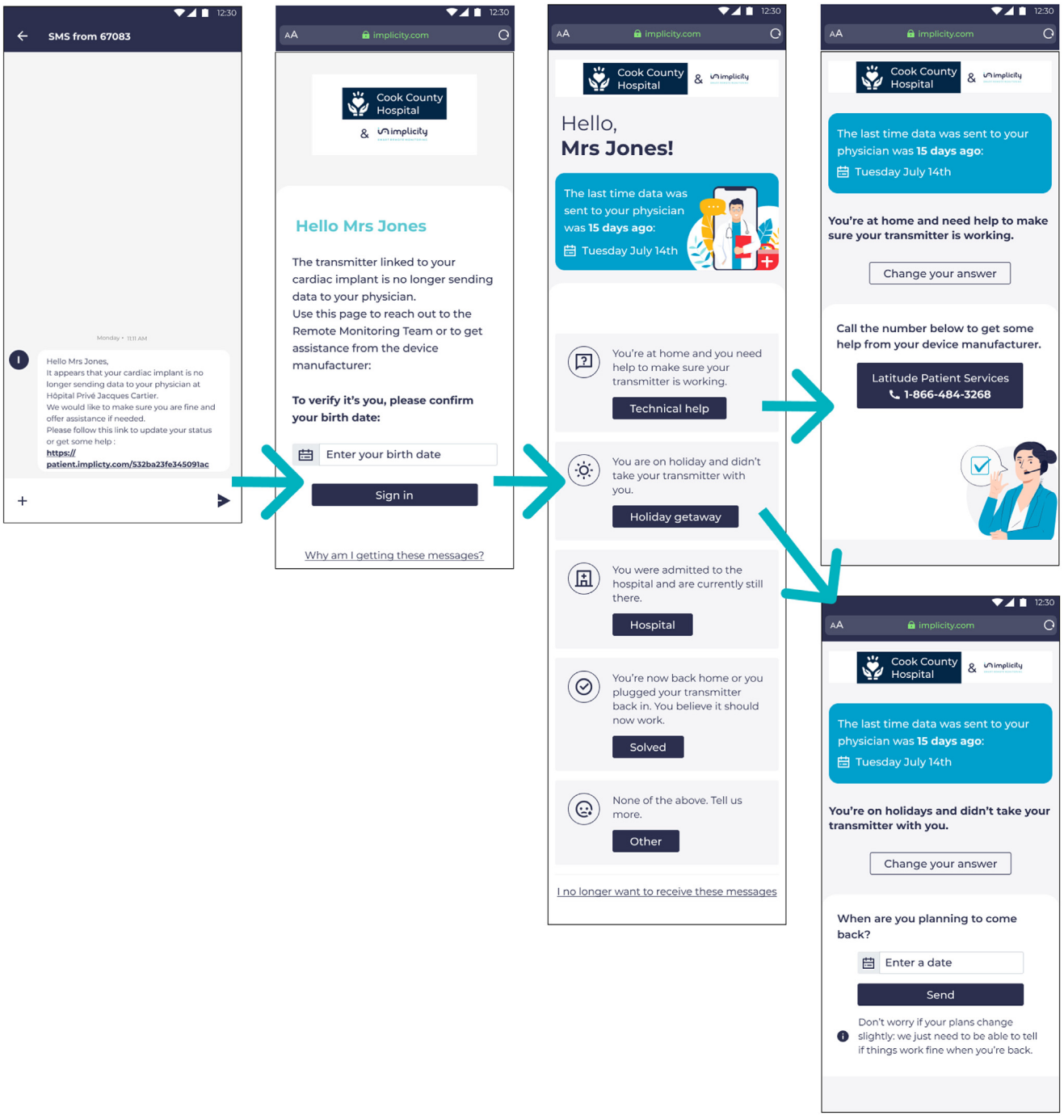

Figure 2 Short message service (SMS) query automatically sent to the patient upon disconnection of remote monitoring.

conditions. For non-Gaussian variables, the medians are compared using a Mood test. A multivariable Cox regression model with sex, age group, device type, center size, and care (SMS or SC) as covariates was used to estimate the hazard ratios, and interquartiles [Q1;Q3] were computed for hazard ratio. A multivariable logistic regression model was used to determine the parameters associated with the occurrence of disconnections; the covariates were center size, age group, care (SMS or SC), sex, and device type. Pearson correlation was used to compute R^2 determination coefficient. All analyses were performed with the XLSTAT version 2023 (Addinsoft, Paris, France).

Results

At the beginning of the study, 8204 patients were enrolled in RM at 20 medical centers. We excluded 1622 patients for the following reasons: 983 died during the study period, 138 had care transferred to another center, 95 had their CIED explanted, and in 406 we could not determine why RM ceased.

Table 2 Characteristics of disconnected and non-disconnected patients

	Non-disconnected n = 3469	Disconnected n = 2616	*P*
Age, years	70.8 ± 13.0	68.0 ± 14.1	<.0001
Sex, male	2476 (71%)	1919 (74%)	NS
Age, tertiles (years)			<.0001
<65.8	1032 (30%)	996 (38%)	
64.8–76.5	1170 (34%)	858 (33%)	
>76.5	1267 (37%)	762 (29%)	
Device type			<.0001
ICD	1248 (36%)	1118 (43%)	
CRT-D	1080 (31%)	831(32%)	
PM	981 (28%)	532 (20%)	
CRT-P	160 (5%)	135 (5%)	
Patients, n			<.0001
<597	1025 (30%)	890 (34%)	
597–1004	1397 (40%)	768 (29%)	
>1004	1047 (30%)	958 (37%)	

CRT = cardiac resynchronization therapy; CRT-D = CRT defibrillator; CRT-P = CRT pacemaker; ICD = implantable cardioverter-defibrillator; PM = pacemaker.

Table 3 Characteristics of short message service vs standard care patients

	SMS n = 4117	Standard care n = 1968	*P*
Age, years	66.9 ± 13.9	75.2 ± 10.8	<.0001
Sex, male	3005 (73%)	1390 (71%)	<.0001
Age, tertiles (years)			<.0001
<65.8	1703 (41%)	325 (17%)	
64.8–76.5	1352 (33%)	676 (34%)	
>76.5	1062 (26%)	967 (49%)	
Device type			<.0001
ICD	1714 (42%)	652 (33%)	
CRT-D	1298 (32%)	613 (31%)	
PM	908 (22%)	605 (31%)	
CRT-P	197 (5%)	98 (5%)	
Patients, n			<.0001
<597	1215 (30%)	700 (36%)	
597–1004	1405 (34%)	760 (39%)	
>1004	1497 (36%)	508 (26%)	

CRT = cardiac resynchronization therapy; CRT-D = CRT defibrillator; CRT-P = CRT pacemaker; ICD = implantable cardioverter-defibrillator; PM = pacemaker; SMS = short message service.

Another 497 patients were excluded because they underwent a CIED generator replacement. The remaining 6085 patients represent the study cohort.

The mean age of the population was 69.6 ± 13.6 years and 4395 (72%) patients were male (Table 2). The types of CIED undergoing RM included an implantable cardioverter-defibrillator (ICD) in 2366 (39%) patients, a cardiac resynchronization therapy (CRT)-defibrillator in 1911 (31%) patients, a pacemaker (PM) in 1513 (25%) patients, and a CRT-pacemaker in 295 (5%) patients. Overall, 1915 (31%) patients were followed at a center with <597 patients on RM, 2165 (36%) patients were followed at a center with 597–1004 patients on RM, and 2005 (33%) patients were followed a center with >1004 patients on RM.

Among the study participants, 3469 (57%) patients remained free from any device disconnection from RM, while 2616 (43%) patients experienced a total of 5778 disconnections. Patients who experienced a disconnection were younger, more likely to have received an ICD, and less likely to have received a PM. In addition, a similar rate of disconnections was observed at the low- and high-volume RM centers (Table 2). Patients in the SMS arm were significantly more likely to have zero disconnections as compared to patients in the SC arm (2242 [65%] vs 1227 [35%], $P < .0001$).

A single disconnection occurred in 1302 patients (50%), while more than 1 disconnection was recorded in the remaining 1314 patients (50%). Among the study cohort, 4117 (68%) patients expected to receive an SMS in case of disconnection, whereas the other 1968 (32%) patients were monitored using SC (Table 3). Patients in the SMS arm were younger, more likely to have received an ICD, and less likely to have received a PM; however, there was no relationship between size of the RM center and SMS use. The most common patient-identified reasons for disconnection are outlined in Table 4; importantly, nearly three-quarters of patients did not indicate a precise reason for disconnection. However, even these patients had a shorter median reconnection time than patients in the SC arm (7.0 [1.3, 23.6] vs 11.0 [3.2, 29.0], $P < .0001$).

Once a patient was considered disconnected (Table 1), those in the SMS were significantly more likely to reconnect within the first 48 hours than in the SC arm (379 [28%] vs 187 [15%] patients, $P < .0004$, Figure 3). The median time to reconnect a disconnected patient was 11.0 [3.2, 29.0] days for SC vs 6.3 [1.3, 22.0] days for SMS ($P < .0001$). Overall, the likelihood of a patient's never reconnecting was significantly greater in the SC arm (138 [11%] vs 83 [7%] patients, $P < .0001$, Figure 3).

Discussion

The 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic states that in patients with CIEDs, RM is recommended

Table 4 Answers and reconnection time for short message service patients

	Patients[†] n = 1366	Never reconnected[†] n = 93	Median [IQR] reconnection time	*P*
SMS: answer	358 (26%)	15 (16%)	5.0 [1.2;14.0]	<.0001
Vacation	158 (12%)	1 (1%)	7.0 [3.0;14.0]	<.001
Technical issue	77 (6%)	6 (6%)	1.6 [1.0;6.8]	<.0001
Solved	67 (5%)	1 (1%)	1.2 [1.0;13.3]	<.001
Other	33 (2%)	3 (3%)	7.5 [2.3:24.2]	NS
Hospitalization	23 (2%)	4 (4%)	5.0 [2.5;21.5]	NS
SMS: no answer	1008 (74%)	78 (84%)	7.0 [1.3;23.6]	<.0001

P: median reconnection time *P* values with standard of care.
[†]Percentage (%) as the ratio between the number of patients in the category and the total number of SMS patients.

as the standard of care.[10] In addition, the document states that in patients with CIEDs on RM with a device capable of continuous connectivity, connectivity should be maintained. Both carry a class I level of recommendation. Furthermore, the expert consensus statement recommends development of "established processes for overcoming challenges with connectivity [to] increase efficiency, thereby reducing response time necessary to address patients' concerns as well as minimizing time patients remain disconnected."

The principal findings of this study are that in a cohort of more than 6000 patients with a PM or ICD (with and without CRT), at least 1 disconnection from RM was observed in 43% of patients. It should be noted that a patient was only considered disconnected when at least 14 days had elapsed without connectivity. It stands to reason that even more patients would have been disconnected for shorter periods of time. Multiple disconnections were observed in 50% of patients with disconnections. We attempted to capture the reasons for CIED disconnections from RM. Unfortunately, three-quarters of patients did not offer a reason for the disconnections; in those that did, being away on holiday was the most offered reason.

The most novel finding in our study is that use of SMS was superior to SC in reestablishing connectivity with RM. In fact, once a patient was identified as being disconnected, a single SMS led to device reconnectivity within 48 hours in 30% of patients, which was double the rate in the SC arm. Despite this, it remains of concern that a significant number of patients took many more days to reconnect (about a third required 3–14 days and another third >14 days) and that some never reconnected to RM.

A recent study showed a 90.9% daily connectivity rate in patients with a Medtronic CIED transmitting to the CareLink server.[11] The authors estimated that it would take clinic staff 9–55 minutes to resolve 1 connectivity failure in a CIED patient. This obviously imposes a significant burden on most device clinics. There are 3 approaches to mitigate this problem. The first is to define an optimal strategy for patient education to ensure that patients understand the importance of continuous connectivity and help ensure that connectivity is maintained daily. The second is to improve technology (eg, Bluetooth-enabled devices with data transmission using a patient's own smartphone[12]) to increase the likelihood of daily connectivity. The third, as shown in this study, is to use technology such as SMS to facilitate reconnections, thus also saving staff time. The ideal system could determine even 1 day of disconnection and help the patient reestablish connectivity immediately.

Conclusion

This study demonstrates the feasibility of an automatic system to deliver an SMS to patients with a disconnected CIED to facilitate early reconnection to RM.

Acknowledgments

We thank Anne Vinas and her team for their help in the data collection, and Marika Gentils for providing the data. Rodolphe Ruffy, MD, reviewed our manuscript for style and language.

Funding Sources

Because this study is a retrospective analysis of prospectively collected clinical data in real-life practice, it is not funded.

Disclosures

Julien Durand and Jean-Luc Bonnet are employed by Implicity. Arnaud Rosier is CEO and major shareholder of Implicity. Suneet Mittal is consultant for Implicity; however, he has not received any compensation for involvement in this project. Arnaud Lazarus is a minor shareholder of Implicity. Other authors have no conflict to declare.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

All patients had granted their written approval to contribute the data at the time of RM activation. All data were de-identified to ensure the protection of personal health data, according to the European regulation and French reference methodology (MR-004).

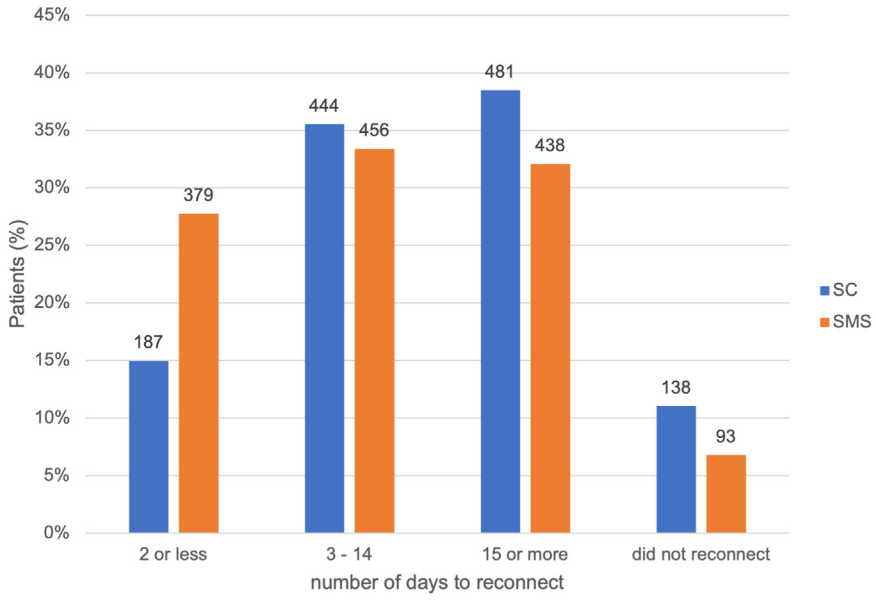

Figure 3 Distribution of reconnections over the time by intervention. SC = standard of care; SMS = short message service.

Ethics Statement

Since this was a retrospective analysis of prospectively collected clinical data in real-life practice, this study was exempt from reviews and approvals by the institutional review boards of the participating institutions; the postprocessing is conducted in accordance with the European "General Data Protection Regulation" (UE 2016/679).

Disclaimer

Given his role as Section Editor, Suneet Mittal had no involvement in the peer review of this article and has no access to information regarding its peer review.

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