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Management of cardiac implantable electronic device follow-up in COVID-19 pandemic: Lessons learned during Italian lockdown

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Abstract

Introduction: Remote monitoring (RM) has significantly transformed the standard of care for patients with cardiac electronic implantable devices. It provides easy access to valuable information, such as arrhythmic events, acute decompensation manifestations and device-related issues, without the need of in-person visits.

Methods: Starting March 1st, 332 patients were introduced to an RM program during the Italian lockdown to limit the risk of in-hospital exposure to severe acute respiratory syndrome-coronavirus-2. Patients were categorized into two groups based on the modality of RM delivery (home [n = 229] vs. office [n = 103] delivered). The study aimed at assessing the efficacy of the new follow-up protocol, assessed as mean RM activation time (AT), and the need for technical support. In addition, patients' acceptance and anxiety status were quantified via the Home Monitoring Acceptance and Satisfaction Questionnaire and the Generalized Anxiety Disorder 7-item scale.

Results: AT time was less than 48 h in 93% of patients and 7% of them required further technical support. Despite a higher number of trans-telephonic technical support in the home-delivered RM group, mean AT was similar between groups (1.33 ± 0.83 days in home-delivered vs 1.28 ± 0.81 days in office-delivered patients; p = .60). A total of 28 (2.5%) urgent/emergent in-person examinations were required. A high degree of patient satisfaction was reached in both groups whereas anxiety status was higher in the office-delivered group.

Abbreviations: AF, atrial fibrillation; CESC, Cardiac Electrophysiology and Stimulation Center; CIED, cardiac implantable electronic device; COVID-19, coronavirus disease-2019; CRT, cardiac resynchronization therapy; GAD-7, Generalized Anxiety Disorder 7-item; HF, heart failure; HoMASQ, Home Monitoring Acceptance and Satisfaction Questionary; ICD, implantable cardioverter defibrillator; ICU, intensive care unit; ILR, implantable loop recorder; IPE, in-person evaluation; PMK, pacemaker; RM, remote monitoring; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2; SVT, supraventricular tachycardia; S-ICD, subcutaneous implantable cardioverter defibrillator; VT, ventricular tachycardia.

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Conclusions: The adoption of RM resulted in high patient satisfaction, regardless of the modality of modem delivery; nonetheless, in-office modem delivery was associated with a higher prevalence of anxiety symptoms.

KEYWORDS
cardiac implantable electronic device, CIED, COVID-19, GAD-7, remote monitoring

1 | INTRODUCTION

Over the last decade, remote monitoring (RM) systems have significantly transformed the standard of care for patients with cardiac implantable electronic devices (CIEDs). RM provides access to the same information as in-person evaluation (IPE) via data transmission from a CIED to a dedicated platform easily accessible by medical staff. Mounting evidence has confirmed its usefulness for early detection of atrial and ventricular arrhythmias, as well as monitoring of system performance (e.g., lead failure and battery depletion[1–4]). Additional benefits were also demonstrated among heart failure (HF) patients in terms of preventing unfavorable cardiovascular events and reducing hospital readmissions.[5–9] The outbreak of the novel severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) forced a prompt reorganization of healthcare service delivery, mostly for nonurgent or nonemergent patients, including in-office follow-up appointments for patients with a CIED.

In line with the recently issued Heart Rhythm Society indications,[10] our Cardiac Electrophysiology and Stimulation Center (CESC) revised the preexisting workflow for CIED patients. The cornerstone of the novel management protocol was the improvement of RM coverage to prevent any potential risk of exposure for patients and healthcare providers, without jeopardizing the quality of care. The purpose of the present study was to report the efficacy and patient satisfaction with the new CIED management protocol adopted during the coronavirus disease-2019 (COVID-19)-related Italian lockdown.

2 | MATERIALS AND METHODS

2.1 | Baseline population and study period

This single-center study was prospectively conducted at the Department of Cardiovascular and Respiratory Diseases, Umberto I Hospital, Sapienza University of Rome, Rome, Italy. Our study cohort included 3762 non-COVID-19 CIED patients who had been routinely followed by our CESC.

Baseline, clinical and device characteristics, and follow-up data were prospectively collected in an Institutional Review Board approved database. Patients were asked to sign an informed consent for data collection and study participation.

2.2 | CESC during COVID-19 Italian lockdown

Among 3762 patients with a CIED, 425 (11.4%) patients had a single chamber implantable cardioverter-defibrillator (ICD), 528 (14.0%) a dual-chamber ICD, 95 (2.5%) a subcutaneous ICD, 283 (7.7%) a cardiac resynchronization therapy (CRT) device, 231 (6.1%) a single-chamber pacemaker (PMK), 1472 (39.1%) a dual-chamber PMK, and 728 (19.3%) an implantable loop recorder (ILR). Of them, 662 (17.6%) patients were already in RM before the COVID-19 outbreak.

A description of the CESC workflow is depicted in Figure 1.

Patients with an IPE scheduled between March and April 2020 were categorized into two groups: patients with a RM system before the lockdown (*Group wRM*) and without a RM system (*Group w/oRM)*.

Group wRM: Scheduled IPEs for these patients were canceled upon exclusion of any patient- and device-related issues assessed via a trans-telephonic contact and a device transmission performed within a week from the scheduled IPE appointment. For those reporting symptoms of HF or whose latest transmission documented a problem with system performance were followed up over the phone or, if necessary, scheduled for an IPE.

Group w/oRM: Patients without an RM system before the lockdown were further classified upon assessment of device features and compatibility for RM, individual clinical risk, and patient's agreement.

Patients implanted with a CIED without RM capabilities or not willing to receive an RM system were classified by reviewing the available medical charts and over a trans-telephonic screening contact. Two groups were identified:

- "Low-Risk" group:
  a) CIED with a battery longevity ≥12 months estimated during an IPE performed within the 6 months before study initiation
  b) No device alerts detected during the last IPE performed within the 6 months before study initiation
  c) No history of complex arrhythmias
  d) No referred symptoms of acute decompensation and syncope.
- "High-Risk" group:
  a) CIED with battery longevity of less than 12 months estimated during an IPE performed within the 6 months before study initiation
  b) Abnormal lead impedance, threshold, or sensing
  c) Recent history (<3 months) of acute HF requiring hospitalization

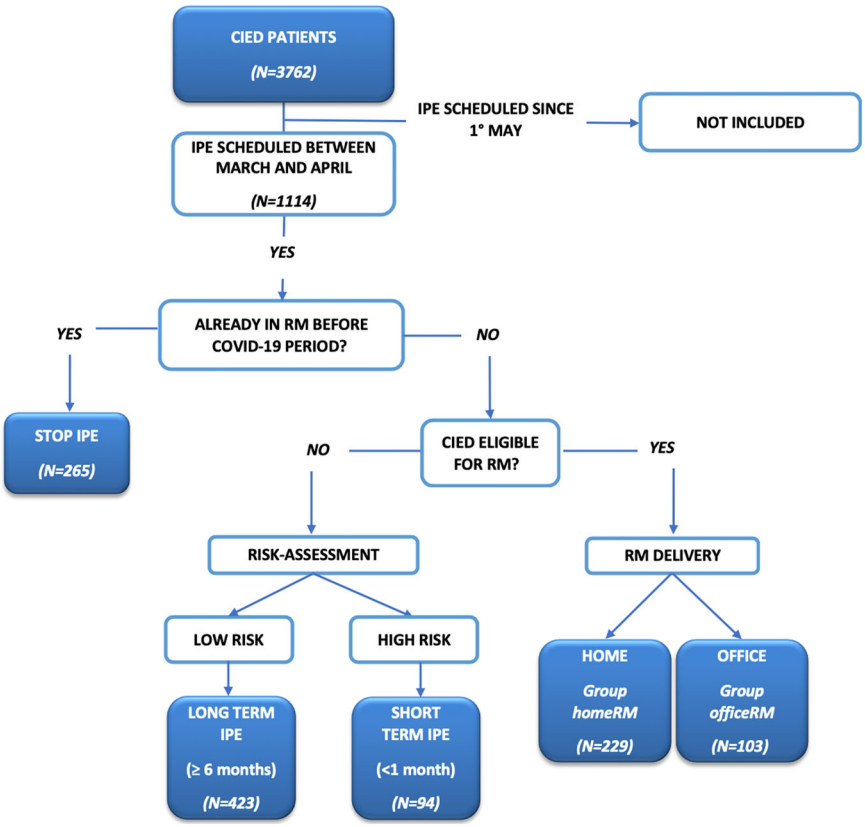

FIGURE 1 CIED management protocol adopted during COVID-19 Italian lockdown. CIED, cardiac implantable electronic device; COVID-19, coronavirus disease-2019; Group homeRM, RM home delivered; Group officeRM, RM in office delivered; IPE, in-person evaluation; RM, remote monitoring

d) Appropriate and inappropriate ICD therapy detected in the last IPE
e) New onset of acute decompensation symptoms or referred syncope.

For "Low-Risk" patients the IPE was directly postponed within 6–9 months (long-term IPE) from the original in-hospital visit. Yet, a direct phone line with a team of specialized nurses was provided and patients were asked to report any new symptoms, emergency room visits, or hospital admissions.

The remaining patients deemed being at "High-Risk" were scheduled for an IPE to be performed the same day or within 1 month from their original in-hospital examination.

Patients implanted with a CIED with RM capabilities and willing to receive the system were further categorized into two groups on the basis of the modality the RM system was assigned.

Home-delivered RM (*Group homeRM*): The device manufacturer agreed to provide the modem through a home delivery service. Once the modem was delivered, a specialized nurse contacted the patient to train and educate him/her on the use of the modem and offer technical support when needed. A manual transmission within 24 h was requested to verify the correct activation of the modem and only once the patient successfully completed the transmission, the IPE scheduled for March or April was canceled.

Office delivered RM (*Group officeRM*): A short-term IPE (the same day or within a month from the original in-hospital visit) was scheduled. A dedicated questionnaire to screen for COVID-19 symptoms and rule out any at-risk exposure was administered to all patients before IPE was performed. In a suspected case of COVID-19 infection, a serological test was requested. A specific pathway was created for IPEs to guarantee patients' and workers' safety. IPEs were performed in two different office rooms; one caregiver per patient was allowed to enter the room and only if properly wearing personal protective equipment. A maximum of eight patients per room were scheduled every day and, between one visit and the next, a period of approximately 45 min was respected to sanitize the room. A single specialized nurse delivered the RM system and performed patient training and education. Every 2 weeks, or in case an at-risk exposure was suspected, a COVID-19 test, either viral or serological, was performed for all nurses and physicians. After discharge, the patient was asked to perform a manual transmission from home.

Each nurse reported to a referring physician responsible for informed consent submission and clinical management. Yet, a direct phone line with a team of specialized nurses was provided and patients were asked to report any technical issues with the system, as well as new symptoms, emergency room visits, or hospital admissions. Compliance to drug therapy was monitored by phone contacts conducted either periodically (monthly or bimonthly based on patient's risk profile and medical history) or in case of event recurrences. Pharmacological therapy titration and clinical event management were discussed among the clinical staff and, when necessary, an IPE or a hospital admission was programmed according to the clinical status of the patient. All patients admitted to the

emergency room underwent a serological test for COVID-19. If the serological test was negative, the patient was hospitalized in a "COVID-19-Free" Cardiology Unit. Otherwise, patients who tested positive were admitted to a dedicated Department.

2.3 | Patient satisfaction and anxiety status

To evaluate the patients' acceptance and satisfaction with the RM program, two nurses administered (within a month since the first transmission) the Home Monitoring Acceptance and Satisfaction Questionnaire (HoMASQ) to all new patients who received the RM system.[11] HoMASQ includes 12 items aimed at investigating five different aspects: 1—relationship with their healthcare provider, 2—ease of use of home monitoring technology, 3—related psychological aspects, 4—implications on general health and 5—overall satisfaction. Each item is rated on a 5-point scale (from 0 [*strongly unfavorable*] to 4 [*strongly favorable*]); each answer was considered favorable with a score ≥2.

Furthermore, the Generalized Anxiety Disorder 7-item (GAD-7) scale was administered by the same nurses to all new patients in RM. GAD-7 was administered to assess the level of safety or anxiety associated with RM and the psychological discomfort related to the home-delivery and office-delivery services. The questionnaire consists of seven items: 1—feeling nervous, anxious, or on edge; 2—being able to stop or control worrying; 3—worrying too much about different things; 4—trouble relaxing; 5—being restless; 6—becoming easily annoyed or irritable; 7—feeling afraid as if something awful might happen.[12] Response options are "not at all" (scores as 0), "several days" (scores as 1), "more than half the days" (scores as 2), and "nearly every day" (scores as 3). The total score ranges from 0 to 21, with scores of 5, 10, and 15 representing the cut-off points for mild, moderate, and severe anxiety, respectively.

2.4 | Study endpoints

The aim of the study was to evaluate the efficacy and patient satisfaction with the new CESC protocol adopted during COVID-19 lockdown.

The primary endpoints were: (1) "RM Activation Time (AT)" in *Group homeRM* versus *Group officeRM*, defined as the time to first independent manual transmission since modem was received; (2) Need for technical support in *Group homeRM* versus *Group officeRM*, defined as the number of phone calls or IPEs the patient required due to technical problems activating the RM system.

The secondary endpoints were: (1) Number and type of clinically relevant RM transmissions in the overall RM population, including CIED alerts (battery depletion time, abnormal threshold, sensing, and impedance measurements), arrhythmic events (atrial fibrillation [AF], supraventricular tachycardia [SVT], ventricular tachycardia [VT], and bradycardia), ICD therapies, HF-related alerts. (2) Number of emergent/urgent IPEs and hospitalizations; (3) patient's acceptance and anxiety status with the new workflow.

2.5 | Statistical analysis

Continuous data were described as mean ± *SD*, while the median (interquartile range) was used for abnormal data. Categorical data were described with a number (percentage). All tests were two-sided, and a *p* value of less than .05 was considered statistically significant. The statistical analysis was performed using SPSS version 25.0 for Windows (IBM Software, Inc).

3 | RESULTS

3.1 | Demographic characteristics

The study population included 3762 CIED patients systematically followed-up at our Institution, 662 (17.6%) of whom were in RM before the COVID-19 outbreak. Among the 3762 patients, 1114 had an IPE scheduled between March and April 2020 and were included in the study cohort. Baseline characteristics are summarized in Table 1.

3.2 | Subgroup characterization, RM coverage and distribution, and study endpoint

Among 1114 CIED patients, 265 (23.8%) were already in RM (*Group wRM*). RM eligibility was checked for the remaining 849 (76.2%) patients not in RM (*Group w/oRM*). A total of 517 (60.9%) patients were ineligible for RM owing to connectivity or device-compatibility issues. Therefore, individual risk assessment was performed: a long-term IPE was scheduled for 423 (81.8%) "Low-Risk" patients, whereas 94 (18.2%) patients were deemed being at "High-Risk" and scheduled for a short-term IPE.

The remaining 332 patients implanted with a CIED with RM capabilities (Table 2) were further categorized into two groups on the basis of the modality the new RM system was assigned. In 229 (69.0%) patients, the modem was directly delivered home (*Group homeRM*) whereas in 103 (31.0%), the modem was assigned during an in-office visit (*Group officeRM*). Among 332 new RM patients, 116 (34.9%) patients were enrolled into the CareLink Network (Medtronic, Inc), 96 (28.9%) into the Merlin.net System (Abbott), 66 (19.9%) into the LATITUDE monitoring system (Boston Scientific Corp), and 54 (16.3%) into the Home Monitoring remote control system (Biotronik GmbH). Starting March 1st, 229 RM devices were shipped to each patient's home address (*Group homeRM*). Mean delivery time was 2.8 ± 1.1 days and by March 15th all *homeRM* patients had received the modem.

In *Group officeRM* ($n = 103$), an in-office visit was scheduled within an average of 4.2 ± 1.4 days from the date of the original IPE. None of the patients, family members, or healthcare workers being affected by the virus during the 2-month study period. By March 27th all *Group officeRM* patients had received the device for RM.

The time invested by each nurse for patient training and education on the use of the modem was 20.2 ± 3.6 min/patient;

TABLE 1 Baseline characteristics of study population (*N* = 1114)

Demographics	All patients (*n* = 1114)	Group wRM (*n* = 265)	Group w/oRM (*n* = 849)	*p* Value
Age, year	64.5 ± 18.4	63.3 ± 17.9	64.2 ± 18.3	.74
Male, *n* (%)	638 (57.3)	149 (56.2)	489 (57.6)	.69
CIED				
ICD, *n* (%)	429 (38.5)	100 (37.7)	329 (38.8)	.76
Single chamber, n (%)	228 (20.5)	57 (21.5)	171 (20.1)	.37
Dual chamber, n (%)	177 (15.8)	34 (12.8)	143 (16.8)	.09
S-ICD, n (%)	24 (2.2)	9 (3.4)	15 (1.8)	.22
PM, *n* (%)	425 (38.1)	102 (38.5)	323 (38.0)	.89
Single chamber, n (%)	61 (5.5)	18 (6.8)	43 (5.1)	.28
Dual chamber, n (%)	364 (32.6)	84 (31.7)	280 (33.0)	.28
ILR, *n* (%)	171 (15.4)	35 (13.2)	136 (16.0)	.27
CRT, *n* (%)	89 (8.0)	19 (7.2)	70 (8.2)	.57
Heart disease				
No, *n* (%)	101 (9.1)	25 (9.4)	76 (8.9)	.81
Ischaemic HD, *n* (%)	451 (40.5)	95 (35.8)	356 (41.9)	.08
Valvular HD, *n* (%)	116 (10.4)	24 (9.1)	92 (10.8)	.41
Channelopathies, *n* (%)	12 (1.1)	2 (0.8)	10 (1.2)	1
Congenital HD, *n* (%)	7 (0.6)	1 (0.4)	6 (0.7)	1
Others, *n* (%)	22 (2)	5 (1.9)	17 (2.0)	.92
NYHA				
I, *n* (%)	278 (25.0)	63 (23.8)	215 (25.3)	.61
II, *n* (%)	473 (42.5)	117 (44.2)	356 (41.9)	.52
III, *n* (%)	330 (29.6)	78 (29.4)	252 (29.7)	.92
IV, *n* (%)	33 (2.9)	7 (2.6)	26 (3.1)	.73
LVEF [range]	46 ± 12 [20–60]	44 ± 11 [20–60]	45 ± 12 [20–60]	.81
Comorbidities				
Diabetes mellitus, *n* (%)	413 (37.1)	101 (38.1)	312 (36.7)	.69
Chronic obstructive pulmonary disease, *n* (%)	187 (16.8)	40 (15.1)	147 (17.3)	.40
Hypertension, *n* (%)	601 (53.9)	146 (55.1)	455 (53.6)	.67
Chronic kidney disease, *n* (%)	231 (20.7)	52 (19.6)	179 (21.1)	.61

Abbreviations: CRT, cardiac resynchronization therapy; Group wRM, patients in RM before the lockdown; Group w/oRM, patients without a RM system; HD, Heart disease; ICD, implantable cardioverter defibrillator; ILR, implantable loop recorder; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PMK, pacemaker; S-ICD, subcutaneous implantable cardioverter defibrillator.

longer time was spent when modem was home-delivered (20.6 ± 3.8 vs. 19.2 ± 2.6; $p = .01$). On average, every nurse involved in the program managed the delivery of 12.2 ± 1.2 transmitters daily.

A RM AT within 24 h was observed in 271 (81.6%) patients and was significantly less frequent in patients older than 75 years (73.2% vs. 88.2% in patients <75 years old; $p < .01$) and in those living alone (81.5% vs. 89.4% in patients not living alone; $p < .01$).

No differences were reported between PMK- and ICD-patients, as well as between *Group homeRM* and *Group officeRM*. The mean AT was 1.33 ± 0.83 days in *Group homeRM* and 1.28 ± 0.81 days in *Group officeRM* ($p = .60$). Specifically, a first manual transmission within 24 h was recorded in 186 (81.2%) patients in *Group homeRM* and 87 (84.5%) patients in *Group officeRM* ($p = .47$; Figure 2).

However, a trend toward a higher number of transtelephonic technical support contacts due to problems completing the first transmission was observed in *Group officeRM* (4 [4.2%] patients vs. 21 [9.9%] patients; $p = .09$). Moreover, two patients per group required a new IPE (0.9% vs. 2%; $p = .59$); in one case a modem manufacturing defect was detected (Figure 3).

3.3 | RM transmissions

A comparison of number and type of clinically relevant RM transmissions among newly-enrolled RM patients and those with a previous RM system is depicted in Table 3.

TABLE 2 Baseline characteristics of patients enrolled in RM adopting new CESC protocol (*N* = 332)

Demographics	Newly-enrolled RM (*n* = 332)	Group homeRM (*n* = 229)	Group officer (*n* = 103)	*p* Value
Age, year	64.2 ± 17.4	63.8 ± 17.2	65.5 ± 18.0	.67
Male, *n* (%)	196 (59.0)	135 (58.9)	61 (59.2)	1
CIED				
ICD, *n* (%)	131 (39.5)	90 (39.3)	41 (39.8)	.92
Single chamber, *n* (%)	56 (16.9)	37 (16.2)	19 (18.4)	.60
Dual chamber, *n* (%)	58 (17.5)	40 (17.4)	18 (17.5)	1
S-ICD, *n* (%)	17 (5.1)	13 (5.7)	4 (3.9)	.49
PM, *n* %	129 (38.8)	89 (38.9)	40 (38.8)	1
Single chamber, *n* (%)	20 (6.0)	13 (5.7)	7 (6.8)	.69
Dual chamber, *n* (%)	109 (32.8)	76 (33.2)	33 (32.0)	.84
ILR, *n* (%)	53 (16.0)	37 (16.1)	16 (15.6)	.89
CRT, *n* (%)	19 (5.7)	13 (5.7)	6 (5.8)	1
Heart disease				
No, *n* (%)	33 (9.9)	23 (10.0)	10 (9.7)	.92
Ischaemic HD, *n* (%)	127 (38.3)	89 (38.9)	38 (36.9)	.73
Valvular HD, *n* (%)	36 (10.7)	23 (10.0)	13 (12.6)	.48
Channelopathies, *n* (%)	5 (1.5)	3 (1.3)	2 (2.0)	1
Congenital HD, *n* (%)	2 (0.6)	1 (0.4)	1 (1.0)	1
Others, *n* (%)	7 (2.1)	5 (2.2)	2 (2.0)	1
NYHA				
I, *n* (%)	90 (27.1)	63 (27.5)	27 (26.2)	.81
II, *n* (%)	146 (43.9)	99 (43.2)	47 (45.6)	.68
III, *n* (%)	87 (26.2)	60 (26.2)	27 (26.2)	1
IV, *n* (%)	9 (2.8)	7 (3.1)	2 (2.0)	1
LVEF [range]	45 ± 12 [20–60]	44 ± 12 [20–60]	47 ± 12 [20–60]	.43
Comorbidities				
Diabetes mellitus, *n* (%)	123 (37.0)	87 (38.0)	36 (35.0)	.60
Chronic obstructive pulmonary disease, *n* (%)	54 (16.3)	40 (17.5)	14 (16.5)	.38
Hypertension, *n* (%)	174 (52.4)	123 (53.7)	51 (49.5)	.48
Chronic kidney disease, *n* (%)	67 (20.2)	46 (20.1)	21 (20.4)	1

Abbreviations: CRT, cardiac resynchronization therapy; Group homeRM, RM home delivered; Group officeRM, RM in office delivered; HD, heart disease, ICD, implantable cardioverter defibrillator; ILR, implantable loop recorder; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PMK, pacemaker; S-ICD, subcutaneous implantable cardioverter defibrillator.

The higher incidence of VT alerts documented in patients with a previous RM system (0.7% vs. 0.4%; $p = .01$) can be attributed to a hospitalized patient who was admitted to the intensive care unit (ICU) and subsequently underwent catheter ablation of VT (29 transmissions of VT episodes were documented before hospital admission).

In the same group of newly-enrolled RM patients, 4365 clinically relevant RM transmissions were registered: no significant differences in the number of transmissions were reported between *Group homeRM* and *Group officeRM* (13.4 vs. 13.2 transmissions/patient; $p = .18$; Table 4).

Some critical alerts were recorded. Specifically, a symptomatic sinus pause (average duration: 5.1 ± 1.7 s) was found in 12 patients with ILR: in 8 (66.7%) a PMK was implanted, while in the other 4 (33.3%) beta-blockers and/or amiodarone were discontinued. A total of 10 ILR patients (1%) were diagnosed with sustained episodes of SVT, 3 (30%) of whom referring presyncopal or syncopal symptoms and requiring an electrophysiological study and radiofrequency catheter ablation.

Newly diagnosed AF was reported in 26 (2.6%) patients, 22 (84.6%) of whom were contacted by phone and prescribed with long-term oral anticoagulation according to their CHA_2DS_2VASc score.

Episodes of sustained VT appropriately treated by the ICD were reported in 3 patients (0.3%): in 2 (66.7%) cases amiodarone was added whereas catheter ablation was performed in 1 (33.3%). Increased lead impedance without a threshold or sensing changes was reported in 4 (0.4%) patients.

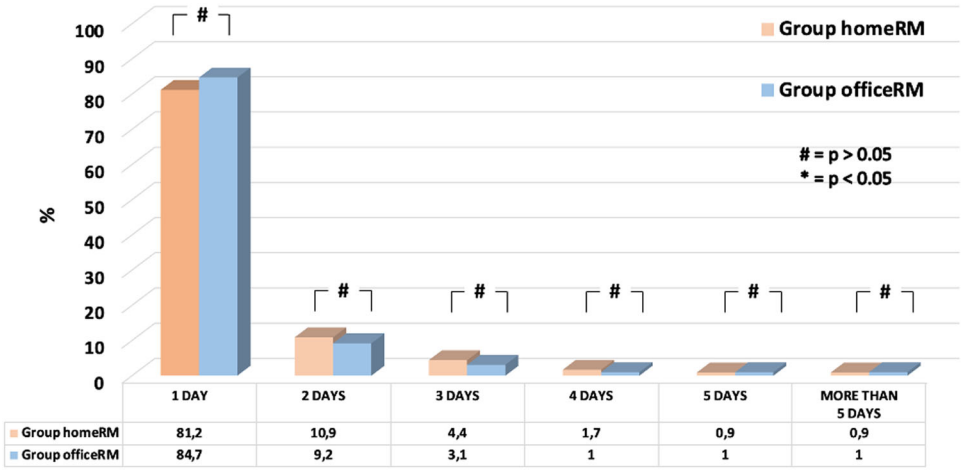

FIGURE 2 RM Activation Time in Group homeRM and Group officeRM. Group homeRM, RM home delivered; Group officeRM, RM in office delivered

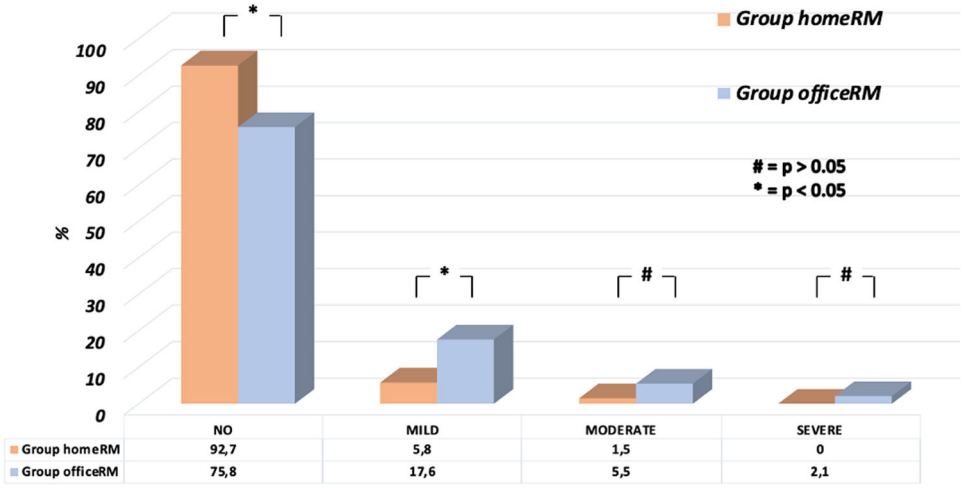

FIGURE 3 GAD-7 results comparing in Group homeRM and Group officeRM. GAD-7, Generalized Anxiety Disorder 7-item; Group homeRM, RM home delivered; Group officeRM, RM in office delivered

TABLE 3 Number and type of clinically relevant RM transmission

	Overall RM population (*n* = 994)	Previous RM (*n* = 662)	Newly-enrolled RM (*n* = 332)	*p* Value
Transmissions, *n*	13 157	8792	4365	
Transmission type				
CIED parameters problems, *n* (%)	26 (0.2)	18 (0.2)	8 (0.2)	.79
AHRE, *n* (%)	10502 (79.8)	7029 (79.9)	3473 (79.6)	.60
SVT, *n* (%)	442 (3.4)	305 (3.5)	137 (3.1)	.32
VT, *n* (%)	79 (0.6)	63 (0.7)	16 (0.4)	**.01**
ICD shock, *n* (%)	7 (0.1)	5 (0.1)	2 (0.1)	1
Bradycardia, *n* (%)	1750 (13.3)	1154 (13.1)	596 (13.6)	.40
Symptoms, *n* (%)	263 (2.0)	156 (1.8)	107 (2.4)	**.009**
Heart failure monitoring, *n* (%)	88 (0.7)	62 (0.7)	26 (0.6)	.47

Abbreviations: AHRE, atrial high rate episode; CIED, cardiovascular implantable electronic devices; ICD, implantable cardioverter defibrillator; RM, remote monitoring; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

TABLE 4 Number and type of clinically relevant transmissions in patients enrolled in RM adopting new CIED protocol

	Group homeRM (*n* = 229)	Group officeRM (*n* = 103)	*p* Value
Transmissions, *n*	3043	1322	
Transmission type			
CIED parameters problems, n (%)	6 (0.2)	2 (0.2)	1
AHRE, n (%)	2357 (79.8)	1017 (79.6)	.70
SVT, *n* (%)	96 (3.4)	41 (3.1)	.92
VT, *n* (%)	11 (0.6)	5 (0.4)	1
ICD shock, *n* (%)	2 (0.1)	0 (0.1)	1
Bradycardia, *n* (%)	423 (13.3)	173 (13.6)	.47
Symptoms, *n* (%)	74 (2.0)	33 (2.4)	.89
Heart failure monitoring, *n* (%)	18 (0.7)	8 (0.6)	1

Abbreviations: AHRE, atrial high rate episode; CIED, cardiovascular implantable electronic devices; ICD, implantable cardioverter defibrillator; RM, remote monitoring, SVT, supraventricular tachycardia; VT, ventricular tachycardia.

Acute HF decompensation was suspected in 25 (2.5%) patients via the OptiVol Alert (Medtronic) or HeartLogic (Boston) indexes; in all of them, a transtelephonic contact was performed and detailed information on clinical status and compliance to drug therapy were collected. Overall, 10 (40%) patients were managed trans-telephonically via loop diuretic titration, 7 (28%) required hospitalization, and 8 (32%) were scheduled for an IPE to optimize the pharmacological therapy.

3.4 | Emergent/urgent IPEs and hospitalizations

Since the adoption of this new protocol, 230 (20.6%) of the 1114 IPEs scheduled for March–April were performed, 33 (3%) of which were urgent/emergent and required hospitalization in 24 (2.1%) cases. Specifically, four "Low-Risk" patients required an IPE and three were admitted to the cardiology department or the ICU due to PMK pocket infection, syncope secondary to high-degree atrioventricular block documented by the ILR requiring PMK implantation and advanced HF unresponsive to diuretic therapy in a CRT patient. Moreover, one "High-Risk" patient with an ICD for primary prevention of sudden cardiac death was admitted to the ICU due to an electric storm. A total of 28 (2.5%) of the 989 patients in RM required an urgent/emergent IPE and 19 (1.7%) were admitted to the hospital. In all 19 (1.7%) hospitalized patients (mean hospitalization time: 7.4 ± 4.6 days) serological test was negative at admission. A 78-year-old man with advanced HF and multiple comorbidities died from multiorgan failure as a consequence of bacterial sepsis.

3.4.1 | Patient satisfaction and anxiety status

The HoMASQ was completed by 287 of the 332 patients (86.4%) within 30 days from the first manual activation (mean 23.4 ± 2.3 days). A trend toward a higher satisfaction and a better relationship with healthcare providers, even if not statistically significant, resulted from the answers of patients in *Group officeRM*. No crucial differences in terms of the patients' preferences were observed regarding the different RM networks. The average and standard deviation of the 5-point scale mean scores of each question and the percentage of favorable answers (score ≥2) are shown in Table 5.

GAD-7 was administered to 297 (89.5%) newly-enrolled RM patients to compare the level of anxiety associated to different RM enrolment protocols. No anxiety status was reported in 260 (87.5%) patients, whereas mild, moderate, or severe levels of anxiety were documented in 28 (9.4%), 8 (2.7%), and 2 (0.7%) of patients, respectively. Of note, a significantly higher number of patients in *Group officeRM* referred a mild level of anxiety at the time of their in-office visit compared to those of *Group homeRM* at the time they contacted the hospital to confirm receipt of the RM device.

4 | DISCUSSION

Herein, we describe our institutional experience on the feasibility and patient satisfaction with a novel CIED follow-up protocol during the COVID-19 Italian lockdown. Our main findings were the following:

- A reorganization of follow-up workflow with transition from IPE to RM was easily achieved in a short period of time in a large population of CIED patients, without jeopardizing the quality of care of our service
- Approximately 93% of the patients newly introduced to RM performed their first manual transmission within 48 h. Despite a trend toward a higher number of trans-telephonic technical support contacts in *Group homeRM*, RM AT was similar among patients who received the modem at home and those whose monitor was delivered during an IPE
- No significant differences in number of transmissions were reported between *Group homeRM and Group officeRM*. A total of 28 (2.5%) urgent/emergent IPE were easily and safely planned in the RM population when a transtelephonic examination was not enough;
- A high degree of patient satisfaction was reached among patients who were newly-enrolled in a RM-based follow-up
- A higher prevalence of anxiety was documented when the transmitter was delivered during an in-office visit.

RM allows for transmission of essential clinical data to virtual platforms accessible to physicians and dedicated healthcare

TABLE 5 HoMASQ results

Item description	Group officer (*n* = 71)		Group homeRM (*n* = 216)	
	Mean ± *SD*	Favourable responses %	Mean ± *SD*	Favourable responses %
Relationship with healthcare provider				
Was the explanation of RM system exhaustive?	3.04 ± 0.82	95%	3.15 ± 0.87	90%
During the contacts have you received clear information?	2.97 ± 0.80	94%	2.75 ± 0.89	89%
Easiness of use of this new technology				
How was it simple to connect and turn on the transmitter?	3.19 ± 0.73	96%	2.87 ± 0.85	91%
How was simple to assure transmissions?	3.27 ± 0.76	95%	2.96 ± 0.86	90%
Psychological aspects related to remote control				
How much did the transmitter affect your daily activity?	3.05 ± 0.88	91%	3.05 ± 0.86	92%
Did you ever feel observed by the transmitter?	3.17 ± 0.86	96%	3.1 ± 0.80	95%
Does the transmitter provide you a sense of security?	2.89 ± 0.82	92%	3.06 ± 0.84	93%
Is the transmitter a bother?	3.28 ± 0.79	93%	3.14 ± 0.85	93%
Implication of RM on general health				
How much important was the information for physician?	3.3 ± 0.75	95%	2.94 ± 0.92	90%
Do you think that HM had positive effects on your health?	3.09 ± 0.81	95%	2.87 ± 0.89	91%
Overall satisfaction of RM				
Are you satisfied of RM organization?	3.08 ± 0.75	95%	2.91 ± 0.84	93%
Do you want to continue to use RM technology?	3.42 ± 0.79	96%	3.29 ± 0.87	91%

Abbreviations: Group homeRM, RM home delivered; Group officeRM, RM in office delivered; HoMASQ, Home Monitoring Acceptance and Satisfaction Questionary.

personnel. To reduce the risk of exposure to SARS-CoV-2, the aim of the described management protocol for patients with a CIED was to expand coverage for RM to include patients scheduled for an IPE during the period of the Italian COVID-19 lockdown. Owing to the wide range of accessible information, RM may contribute to the early detection of a wide range of arrhythmic manifestations, acute decompensation, and device-related issues.[5] As reported in several studies,[8–13] RM not only plays a central role in preventing hospitalizations, improving survival and quality of life in patients with CIEDs, but is also a cost-effective alternative to IPEs.[14]

4.1 | Role of RM during the Italian COVID-19 lockdown

In our experience, RM allowed for an effective and safe delivery of healthcare services. A large number of patients were quickly and safely introduced to an RM-based follow-up, with high patient satisfaction. In addition, the continuous technical assistance offered by our medical staff led to a high degree of patients' compliance to the RM system; about 93% of our patients performed the first manual transmission within 48 h since the modem was received, with no difference observed between the two modalities of modem delivery (*home* vs *office delivery*). All patients successfully completed RM activation, even if a longer RM AT was observed in patients older than 75 years and/or those living alone. These subpopulations are also at higher-risk of COVID-19-related complications and mortality, due to a higher prevalence of comorbidities. Nonetheless, RM allowed for a safe and uninterrupted patient care, avoiding the risk of in-hospital virus exposure.[15]

4.2 | RM transmissions and emergent/urgent IPEs

A recent study[16] has observed a significant reduction in hospital admissions for acute coronary syndromes during the Italian lockdown. In this context, RM represented a valuable tool for continuous clinical assistance and monitoring, thereby avoiding potentially life-threatening consequences.[4,5] In our population, no significant differences in the number of transmissions were reported between *Group homeRM* and *Group officeRM*. Furthermore, an urgent/emergent IPE was planned in 28 (2.5%) patients due to arrhythmic events and 19 (1.7%) were admitted to the hospital.

4.2.1 | Patient satisfaction and anxiety status

From a psychological standpoint, the COVID-19 outbreak and the Italian lockdown had a serious impact on the mental health of the entire population. In this context, we decided to administer

the HoMASQ to evaluate RM acceptance and the GAD-7 questionnaire to assess the level of anxiety associated with the new RM-based follow-up and the modality of delivery of the modem. A high patient satisfaction rate was documented from the HoMASQ; specifically, patients reported an easy understanding of the device activation process, as well as high satisfaction with the use of the transmitter.[11] In addition, despite the ongoing pandemic and national lockdown, patients referred to a sense of security and expressed interest in continuing with RM. Yet, GAD-7 results confirmed that SARS-CoV-2 has increased patients' level of anxiety and psychological pressure, as demonstrated in *Group officeRM* patients who reported a higher rate of anxiety associated with in-office delivery of the RM system.

5 | LIMITATIONS

Several limitations should be considered. First, this is an observational study and carries the inherent limitations of this study design. Second, the study reflects the experience of a single medium-large volume Italian; therefore, generalizations should be considered with caution, as a result of the unique scenario of the Italian lockdown.

6 | CONCLUSION

In our study, a transition to an RM-based follow-up protocol facilitated continuous healthcare coverage in eligible CIED patients scheduled for an IPE during the Italian lockdown.

A comprehensive patient education plan on the technical and clinical features of the system, either in person and/or via transtelephonic contacts, allowed for the rapid activation and adoption of the RM system. The adoption of RM resulted in high patient satisfaction, regardless of the modality of modem delivery; nonetheless, in-office modem delivery was associated with a higher prevalence of anxiety symptoms.

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