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DEVICES

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Remote monitoring of implantable cardioverter defibrillators: Patient experiences and preferences for follow-up

Ivy Timmermans MSc[1,2] | Mathias Meine MD, PhD[1] | Istvan Szendey MD, PhD[3] | Johannes Aring MD[4] | Javier Romero Roldán MD[5] | Lieselotte van Erven MD, PhD[6] | Philipp Kahlert MD[7] | Edgar Zitron MD, PhD[8] | Philippe Mabo MD, PhD[9] | Johan Denollet PhD[2] | Henneke Versteeg PhD[1]

[1]Department of Cardiology, University Medical Center Utrecht, Utrecht, The Netherlands

[2]CoRPS—Center of Research on Psychology in Somatic Diseases, Department of Medical and Clinical Psychology, Tilburg University, Tilburg, The Netherlands

[3]Department of Cardiology, Kliniken Maria Hilf GmbH, Mönchengladbach, Germany

[4]Department of Cardiology, Klinikum Leverkusen, Leverkusen, Germany

[5]Department of Cardiology, Complejo Hospitalario de Navarra, Pamplona, Spain

[6]Department of Cardiology, Leiden University Medical Center, Leiden, The Netherlands

[7]West German Heart and Vascular Center Essen, Essen University Hospital, Essen, Germany

[8]Department of Cardiology, Universitätsklinikum Heidelberg, Heidelberg, Germany

[9]Department of Cardiology, Centre Hospitalier Universitaire Rennes, Rennes, France

Correspondence
Henneke Versteeg, PhD, Department of Cardiology, University Medical Center Utrecht, Heidelberglaan 100 3584 CX Utrecht, The Netherlands.
Email: H.Versteeg-2@umcutrecht.nl

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Abstract

Background: Patient satisfaction with remote patient monitoring (RPM) of implantable cardioverter defibrillators (ICDs) seems to be high, yet knowledge on long-term patient experiences is limited. The European REMOTE-CIED study explored patients' experiences with RPM, examined patient's preferences for ICD follow-up, and identified determinants of patient's preferences in the first 2 years postimplantation.

Methods: European heart failure patients ($N = 300$; median age = 66 years [interquartile range (IQR) = 59-73], and 22% female) with a first-time ICD received a Boston Scientific LATITUDE RPM system (Marlborough, MA, USA) and had scheduled in-clinic follow-ups once a year. Patients completed questionnaires at 1-2 weeks and also at 3, 6, 12, and 24 months postimplantation and clinical data were obtained from their medical records. Patient evaluation data were analyzed descriptively, and Student's *t*-tests/Man-Whitney U tests or Chi-square tests/Fisher's exact tests were performed to examine determinants of patient preferences.

Results: At 2 years postimplantation, the median patient satisfaction score with the RPM system was 9 out of 10 (IQR = 8-10), despite 53% of the patients experiencing issues (eg, failure to transmit data). Of the 221 patients who reported their follow-up preferences, 43% preferred RPM and 19% preferred in-clinic follow-up. Patients with a preference for RPM were more likely to be higher educated ($P = 0.04$), employed ($P = 0.04$), and equipped with a new LATITUDE model ($P = 0.04$), but less likely to suffer from chronic obstructive pulmonary disease ($P = 0.009$).

Conclusion: In general, patients were highly satisfied with RPM, but a subgroup preferred in-clinic follow-up. Therefore, physicians should include patients' concerns and preferences in the decision-making process, to tailor device follow-up to individual patients' needs and preferences.

KEYWORDS

implantable cardioverter defibrillator, patient experiences, patient preferences, remote patient monitoring

1 | INTRODUCTION

Patients who are at high risk for life-threatening ventricular arrhythmias are preferably treated with an implantable cardioverter defibrillator (ICD). The number of ICD patients has increased due to expanding indications,[1] leading to higher workload and increased healthcare costs.[2] Remote patient monitoring (RPM) systems can send disease- and ICD-related data from the patient's home to the hospital, and are, therefore, a promising alternative to in-clinic follow-up.[3]

Two meta-analyses in ICD patients have shown that RPM is at least comparable to in-clinic follow-up with regard to the clinical outcomes,[4,5] and it might be cost effective.[4] Despite this supporting evidence, and its inclusion in consensus guidelines from the European Society of Cardiology[6] and the Heart Rhythm Society,[7] RPM is not yet a standard practice. The American PREDICT-RM registry indicated that only 62% of the newly implanted RPM-capable devices were enrolled on RPM,[8] probably due to reimbursement issues and hospital policy.[9] In addition, patient participation was suboptimal, as 24% of the enrolled patients did not activate their RPM system at home. Younger age, racial and ethnic minorities, having no health insurance, shorter travel distance to the hospital, and the presence of comorbidities or procedure-related adverse events were associated with a lower likelihood of RPM activation.[8]

Most studies do indicate that ICD patients are generally satisfied with RPM, mostly appreciating the convenience of the fewer hospital visits and the reassurance of being monitored.[10–20] Nevertheless, there seems to be a subgroup (5%-22%) that does not feel comfortable with RPM,[14,18] and reports a strong preference for in-clinic follow-up.[12,15,21] Two studies showed that low satisfaction with RPM was associated with anxiety for technology, less comprehension of RPM,[16] and not being treated with cardiac resynchronization therapy (CRT).[17] However, nearly all studies measured RPM experiences using single-item purpose-designed questions, and do not report study refusals or dropouts due to patient preferences. Moreover, most studies had a 1 year of follow-up, which seems to be too short as patients are still recovering in the first year after implantation, and generally only miss one in-office visit compared to standard in-clinic follow-up.[22]

Better insight into patient experiences with RPM could support its implementation in standard practice, especially since patients' attitudes and perceptions of RPM may influence monitoring quality and outcomes.[23] Therefore, the European REMOTE-CIED study is the first to examine patient evaluations of RPM in the first 2 years after ICD implantation, using Boston Scientific's LATITUDE system (Boston Scientific, Marlborough, MA, USA), including blood pressure cuffs and weighing scale for heart failure monitoring.

2 | METHODS

2.1 | Study design and participants

The study sample consisted of 300 European patients with heart failure and an ICD, participating in the REMOTE-CIED study and randomized to the RPM group. The in-clinic group ($n = 298$) was not included in this study, as these patients did not receive an RPM system and, therefore, could not evaluate it. The REMOTE-CIED study was primarily designed to examine the influence of RPM on patient-reported outcomes.[24] Patients were recruited from 32 general and academic hospitals in France, Germany, the Netherlands, Spain, and Switzerland between April 2013 and January 2016. Inclusion criteria were symptomatic heart failure (ie, left ventricular ejection fraction [LVEF] ≤35% and New York Heart Association [NYHA] functional class II or III) and a first-time Boston Scientific ICD (single- or dual-chamber) or CRT-defibrillator (CRT-D). Patients less than 18 or more than 85 years of age, patients on the waiting list for heart transplantation, patients with a psychiatric history other than affective or anxiety disorders, as well as patients who were unable to complete questionnaires due to cognitive impairment or language problems, were excluded.

Patients randomized into the RPM arm received a Boston Scientific LATITUDE RPM system, including blood pressure cuffs and a weighing scale (ie, model number 6288, 6290, or 6468), during their first in-clinic checkup at 4-8 weeks after implantation. During this visit, they were instructed on how to install and use the system by the hospital staff, and additionally received an instruction manual and installation DVD to use at home. Thereafter, they had a scheduled in-clinic checkup once a year, as most other checkups were performed remotely.[24] The REMOTE-CIED study was conducted in accordance with the Declaration of Helsinki, and the medical ethics committees of all participating centers approved the study protocol. All patients received oral and written information about the study during their hospitalization for ICD implantation and provided written informed consent.

2.2 | Materials

All patients participating in the REMOTE-CIED study completed a set of language-specific questionnaires at 1-2 weeks postimplantation (baseline), and at 3, 6, 12, and 24 months postimplantation.

The patients in the RPM group completed a 28-item purpose-designed questionnaire about the RPM system at 3, 6, 12, and 24 months after implantation (Table 1). Patients were classified as having a preference for RPM or in-clinic follow-up if they reported this preference in the 24-month follow-up questionnaire, or if they switched the study arm (ie, RPM to in-clinic or in-clinic to RPM) on their own request.

Patients' satisfaction with cardiologic care, in general, was measured at 24-month follow-up using a visual analogue scale ranging from 0 to 100, with higher scores indicating higher levels of satisfaction.

Information on **sociodemographic characteristics** was collected using purpose-designed questions in the baseline questionnaire, and it included age, sex, marital status (single vs having a partner), educational level (secondary school or lower vs tertiary school or higher), and employment status (currently employed vs unemployed).

Information on patients' **clinical characteristics** was obtained from their medical records at the baseline, and was recorded into an electronic case report form by local investigators at the participating centers. It included information on type of device (single- or dual-chamber ICD, or CRT-D), indication for ICD (primary vs secondary), NYHA functional class, heart failure etiology (ischemic vs nonischemic), QRS duration, LVEF assessed within 3 months prior to implantation, and

TABLE 1 Outcomes on purpose-designed questionnaire for patient evaluation of RPM using the LATITUDE system[a]

Item	Question	0	1	2	3
1	Are you satisfied with the explanation of the LATITUDE system by the hospital? [b](0 "very unsatisfied" to 3 "very satisfied")	5%	8%	55%	32%
2	The installation DVD helped me with the installation of the LATITUDE system [b](0 "strongly disagree" to 3 "strongly agree")	22%	23%	44%	11%
3	The information in the instruction manual is clear enough [b](0 "strongly disagree" to 3 "strongly agree")	1%	7%	73%	19%
4	How do you experience the ease of use of the LATITUDE system? (0 "very negative" to 3 "very positive")	0%	1%	58%	41%
5	I trust that my personal data are handled correctly by the LATITUDE system (0 "strongly disagree" to 3 "strongly agree")	1%	2%	64%	33%
6	Have you experienced any problems for which you needed to contact the hospital and/or Boston Scientific? (0 "no" or 1 "yes")	47%	53%	-	-
7	If yes, what problems have you faced? (open ended)	–	-	-	-
8	If yes, how satisfied were you with the help you have received? (0 "very unsatisfied" to 3 "very satisfied")	9%	7%	50%	34%
9	Are the problems solved? (0 "no" or 1 "yes")	15%	85%	-	-
10	The LATITUDE system provides me with a feeling of security (0 "strongly disagree" to 3 "strongly agree")	1%	3%	62%	34%
11	Does the LATITUDE system influence your daily functioning? (0 "negative influence"; 1 "no influence"; 2 "positive influence")	2%	69%	29%	-
12	If yes, please explain (open ended)	-	-	-	-
13	Daily weigh moments are a burden to me (0 "strongly disagree" to 3 "strongly agree")	27%	50%	17%	6%
14	I find it bothersome to measure my blood pressure regularly (0 "strongly disagree" to 3 "strongly agree")	32%	57%	7%	4%
15	Because of LATITUDE, I am more aware of my own health status (0 "strongly disagree" to 3 "strongly agree")	4%	9%	73%	14%
16	Because of LATITUDE, I tend to adhere more to given health advice (0 "strongly disagree" to 3 "strongly agree")	1%	30%	62%	7%
17	It is an advantage that I visit the hospital less often because of LATITUDE (0 "strongly disagree" to 3 "strongly agree")	0%	6%	59%	35%
18	Do you experience any disadvantages of the LATITUDE system? (0 "no" or 1 "yes")	95%	5%	-	-
19	If yes, please explain (open ended)	-	-	-	-
20	The LATITUDE device reminds me of my illness and/or ICD/CRT-D (0 "strongly disagree" to 3 "strongly agree")	11%	41%	44%	4%
21	The LATITUDE system improves care for people living with an ICD (0 "strongly disagree" to 3 "strongly agree")	0%	2%	75%	23%
22	Are you satisfied with the number of hospital visits or would you like to visit the hospital more/less often? (0 "less often"; 1 "satisfied"; 2 "more often")	3%	87%	10%	-
23	Do you prefer follow-up at the hospital or through LATITUDE system? (0 "hospital"; 1 "no preference"; 2 "Latitude system")	19%	38%	43%	-
24	Please explain why you have this preference (open ended)	-	-	-	-
25	Do you wish to continue using the LATITUDE system in the future? (0 "no"; 1 "not sure"; 2 "yes")	3%	13%	84%	-
26	Would you recommend LATITUDE to other patients with an ICD? (0 "no" or 1 "yes")	3%	97%	-	-
27	On a scale from 1 to 10, how satisfied are you with LATITUDE? (0 "0-5: unsatisfied"; 1 "6-10: satisfied")	3%	97%	-	-
28	Do you have any additional remarks about the LATITUDE system? (open ended)	-	-	-	-

[a]Questionnaire specifically refers to LATITUDE system, to make sure that patients understand that this questionnaire is about their RPM system ("LATITUDE" is printed on their RPM transmitter); [b]Assessed at 3 months after ICD implantation, all other items are assessed at 24 months postimplantation.
ICD = implantable cardioverter-defibrillator; RPM = remote patient monitoring.

comorbidities (diabetes mellitus, chronic obstructive pulmonary disease [COPD], renal disease, atrial fibrillation, hypertension, and anemia). **Clinical outcome measures** included the number of (un)scheduled cardiac-related in-clinic or telephone consultations (ie, continuous totals), cardiac-related emergency room visits (ie, 0 "no" and ≥1 "yes"), cardiac-related hospital admissions (ie, 0 "no" and ≥1 "yes"), and ICD shocks (ie, 0 "no" and ≥1 "yes") during the follow-up period. These data were collected from patients' medical records, classified and entered into an electronic case report form by the local hospital staff.

Patients' **lifestyle characteristics**, including body mass index, smoking status (ie, no/yes, number of cigarettes per day), alcohol use (ie, no/yes, number of consumptions per week), and attendance to cardiac rehabilitation (ie, are you participating in a cardiac rehabilitation program?), were collected in the baseline questionnaire. Additionally, self-care behavior was measured using the validated 12-item European Heart Failure Self-care Behavior Scale.[25]

Psychological characteristics were collected using questionnaires at the baseline and included information on use of psychotropic medication or treatment for psychological problems; heart failure-specific health status (23-item Kansas City Cardiomyopathy Questionnaire[26]); anxiety and depressive symptoms (7-item Generalized Anxiety Disorder Scale, and the 9-item Patient Health Questionnaire, respectively[27,28]); Type D personality (14-item Type D Scale[29]); heart failure perceptions (9-item brief Illness Perception Questionnaire[30]); ICD acceptance (12-item Florida Patient Acceptance Scale[31,32]); and ICD-related concerns (8-item ICD Patient Concerns Questionnaire[33,34]). Regarding the two last mentioned questionnaires, a forward-backward translation procedure was performed for the German, French, and Spanish version. In all other cases, we used the official and validated language-specific questionnaires. A detailed description of these questionnaires was published before.[35] Previously reported Chronbach's alphas of these questionnaires in the current sample ranged from 0.69 to 0.98, and thereby indicate good levels of internal consistency.[36]

2.3 | Statistical analyses

According to the study protocol, multivariable logistic and linear regression analyses would be performed to examine which factors were independently associated with satisfaction with RPM as a dichotomous outcome (satisfied: ≥6 "yes,"< 6 "no"), and as a continuous outcome (satisfied: 0-10), respectively.[24] Yet, the satisfaction with RPM score was extremely skewed to the right, with only seven patients reporting a satisfaction score of <6 at 2 years after implantation. Therefore, we decided that patient preferences for follow-up would be a meaningful substitute outcome measure. The baseline characteristics and clinical outcomes were reported for the total sample, and for patients with a preference for RPM or in-clinic follow-up. For categorical and continuous variables, we reported frequencies with percentages and means with standard deviation (or medians with interquartile range [IQR] if appropriate), respectively. Student's *t*-tests and Chi-square tests (or Mann-Whitney U tests and Fisher's exact tests if appropriate) were performed to examine which sociodemographic, clinical, and psychological characteristics were associated with preference for follow-up, and to explore associations between patient preferences and clinical outcomes. Other patient evaluation data of the LATITUDE RPM system were analyzed descriptively. All tests were two-tailed, and a P value of <0.05 was used to indicate statistical significance. All analyses were performed using SPSS 22.0 for Windows (IBM Corp., Armonk, NY, USA).

3 | RESULTS

3.1 | Baseline characteristics

In total, 595 patients participated in the REMOTE-CIED study, of which 300 patients were randomized into the RPM group and evaluated the LATITUDE RPM system. Of these 300 patients, 161 were enrolled in the Netherlands, 66 in Germany, 50 in France, 16 in Spain, and seven in Switzerland. The majority of the patients (78%) received a new LATITUDE RPM model (ie, 6288 or 6290). The baseline characteristics of the sample are shown in Table 2.

During the 2-year follow-up, there were 50 crossovers in the total sample (ie, 16 from the RPM to in-clinic group and 34 from the in-clinic to RPM group). Reasons for crossover from RPM to in-clinic included patient request (n = 7), technical issues with the RPM system (n = 5), and noncompliance/RPM not handed out by mistake (n = 4). Reasons for crossover from in-clinic to RPM included patient request (n = 7), long travel distance (ie, >1.5 h, n = 16), and by physicians' choice (n = 11). According to the intention-to-treat principle, patients received questionnaires belonging to their randomization group regardless of crossover. As a result, we do not have evaluations of the RPM system from the 33 patients who switched from the in-clinic to RPM group.

3.2 | Patient evaluations of the RPM system

As patient evaluations of the RPM system were stable over time, we only reported the 2-year follow-up data.

3.2.1 | Installation and usability

Almost all patients were satisfied with the information on the RPM system that they received from their healthcare professional (87%), and reported to understand the information in the instruction manual (91%). For 55% of the patients, the included installation DVD was helpful during installation. However, during the first 2 years after implantation, 53% of the patients experienced issues with the system for which they had to contact their hospital or the Boston Scientific helpdesk. Most issues occurred in the first months, as 34% of the participants already reported issues at 6 months postimplantation (ie, 4-5 months after receiving RPM). Many of these issues concerned problems with installation. For example, patients reported that they did not receive sufficient information or an installation DVD. Some patients also reported to feel insecure about the RPM system, whereupon they contacted the hospital for reassurance (eg, to check if data were transmitted correctly). Over the complete 2-year follow-up,

TABLE 2 Sociodemographic, clinical, and psychological baseline characteristics for the total sample and stratified for follow-up preference[a]

	Total sample (*N* = 300)	RPM preference (*N* = 94)	In-clinic preference (*N* = 43)	*P* value
Sociodemographic characteristics				
Age	66 (59-73)	66 (56-73)	67 (60-74)	0.57
Female	67 (22%)	17 (18%)	10 (23%)	0.48
Having a partner	222 (74%)	71 (76%)	32 (74%)	0.89
High educational level (tertiary)	168 (56%)	59 (63%)	19 (44%)	**0.04**
Employed	60 (20%)	26 (28%)	5 (12%)	**0.04**
Clinical characteristics				
New LATITUDE model[b]	218 (78%)	77 (84%)	27 (68%)	**0.04**
LATITUDE model with GSM module[c]	39 (14%)	16 (17%)	6 (15%)	0.74
Transmission problems during follow-up[d]	103 (53%)	37 (53%)	12 (41%)	0.30
Cardiac resynchronization therapy	114 (38%)	37 (39%)	13 (30%)	0.30
Primary prophylactic ICD indication	258 (86%)	84 (89%)	37 (86%)	0.58
Ischemic heart failure etiology	158 (53%)	50 (53%)	22 (52%)	0.83
QRS duration (ms)	118 (102-157)	118 (104-157)	116 (98-159)	0.61
Ejection fraction	27 (22-31)	26 (20-31)	28 (26-31)	0.15
New York Heart Association class III	98 (33%)	27 (29%)	15 (35%)	0.47
Poor health status[e]	91 (31%)	23 (25%)	13 (30%)	0.52
Diabetes mellitus	90 (30%)	27 (29%)	16 (37%)	0.32
Chronic obstructive pulmonary disease	45 (15%)	7 (7%)	10 (23%)	**0.009**
Renal disease	75 (25%)	24 (26%)	11 (26%)	0.99
History of atrial fibrillation	85 (28%)	25 (27%)	14 (33%)	0.47
Hypertension	171 (57%)	55 (59%)	24 (56%)	0.77
Anemia	29 (10%)	8 (9%)	5 (12%)	0.56
Lifestyle characteristics				
Body mass index > 30	68 (23%)	20 (21%)	10 (23%)	0.80
Smoking	48 (16%)	10 (11%)	9 (21%)	0.11
Use of alcohol	144 (48%)	48 (52%)	20 (47%)	0.54
Self-care behavior[f]	25 (20-33)	24 (18-33)	26 (20-30)	0.95
Cardiac rehabilitation	58 (20%)	17 (19%)	10 (24%)	0.53
Psychological characteristics				
Type D personality[g]	61 (21%)	18 (20%)	7 (17%)	0.67
Anxiety[h]	37 (13%)	7 (8%)	5 (12%)	0.41
Depression[i]	48 (16%)	15 (17%)	5 (12%)	0.46
Illness perceptions[j]	40 (30-47)	40 (29-47)	39 (31-47)	0.82
ICD concerns[k]	8 (3-15)	9 (3-13)	7 (3-19)	0.89
Device acceptance[l]	66 (56-73)	67 (56-75)	65 (54-75)	0.58
Psychotropic medication[m]	48 (16%)	11 (12%)	7 (16%)	0.48

(Continues)

TABLE 2 (Continued)

	Total sample (*N* = 300)	RPM preference (*N* = 94)	In-clinic preference (*N* = 43)	*P* value
Psychological treatment	12 (4%)	4 (4%)	1 (2%)	0.58
Travel distance to hospital (min)	30 (20-45)	30 (20-45)	25 (15-38)	0.10

Results presented as *N* (%) for categorical variables and as median (interquartile range) for continuous variables. Significant results are presented in bold.
[a]Based on 221 patients (79 missing); [b]New LATITUDE model: patient received model number 6288 or 6290, instead of old model number 6468; [c]LATITUDE model with GSM module: patients received model number 6288; [d]Transmission problems during follow-up: yes/no (105 missing); [e]Poor health status: total score Kansas City Cardiomyopathy Questionnaire < 50; [f]Self-care behavior: total score European Heart Failure Self-Care Behavior Scale; [g]Type D personality: score of ≥10 on both negative affectivity and social inhibition subscales of Type D scale; [h]Anxiety: total score of ≥10 on Generalized Anxiety Questionnaire; [i]Depression: total score of ≥10 on Patient Health Questionnaire; [j]Illness perceptions: total score brief Illness Perceptions Questionnaire; [k]ICD concerns: total score on ICD Concerns Scale; [l]Device acceptance: total score on Florida Patient Acceptance Scale; [m]Psychotropic medication: antidepressants, anxiolytics, and/or hypnotics.
ICD = implantable cardioverter-defibrillator; RPM = remote patient monitoring.

most reported issues concerned connection problems resulting in data transmission failure (ie, between LATITUDE system and hospital, or between blood pressure cuffs/weighing scale and LATITUDE system). In total, 85% of all the reported issues were solved, and in 84% of the cases, patients were satisfied with the help they received from their hospital or the Boston Scientific helpdesk to solve their issues. At 2 years postimplantation, 99% of the patients reported that the system was easy to use, 98% reported to have confidence in personal data handling, and 96% reported that the system provided them with a sense of security.

For the majority of the patients (69%), the RPM system did not influence their daily functioning, while 30% of the patients experienced a positive influence (eg, reassurance, better awareness of health, less traveling, and fewer hospital visits), and 1% reported a negative influence on their daily functioning (eg, privacy concerns or concerns about blood pressure results). For 48% of the patients, the RPM system reminded them of their illness and/or ICD, and the majority of patients reported that it improved the awareness of their own health (87%) and their adherence to given health advice (69%).

3.2.2 | Satisfaction

Patients in the RPM group were highly satisfied with the cardiologic care that they received (median = 90/100 [IQR = 80-100]). Of note, their satisfaction levels did not differ from satisfaction levels in the in-clinic group at 24 months after implantation (median = 90/100 [IQR = 80-100]; $P = 0.95$). Patients rated the RPM system with a median score of 9 out of 10 (IQR = 8-10), with patients suffering from renal disease being more satisfied compared to patients without renal disease (median = 90/100 [IQR = 80-100] for both groups; means = 9.02 ± 0.94 vs 8.65 ± 1.25; $P = 0.02$) and patients on psychotropic medicine being less satisfied than patients not using psychotropic medicine (median = 90/100 [IQR = 80-100] for both groups; means = 8.45 ± 1.55 vs 8.80 ± 1.12; $P = .02$). All other sociodemographic, clinical, and psychological characteristics were not significantly associated with satisfaction levels. Nearly all patients (98%) considered RPM to be an improvement of care for ICD patients. Only a small subgroup, varying between 3% and 6% over time, rated their satisfaction with a score of ≤5. Hence, almost all the patients (97%) would recommend the system to other patients, and the majority of them (84%) wished to continue using the RPM system in the future.

Despite positive evaluations, some patients (±5%) reported downsides of the RPM system in an open-ended question during the follow-up period. Missing feedback on transmission success (ie, affirmation that data were correctly received by their hospital) and ICD functioning (eg, using a digital patient portal) were most often mentioned. Additionally, some patients reported trouble sleeping due to the system's lights, and a few patients reported they have a feeling of "being watched."

3.2.3 | Preference for follow-up

At 2 years postimplantation, 79 (26%) patients did not answer the question on their preference for follow-up and were regarded as missing. These patients were more likely to have NYHA class III versus II (46% vs 28%; $P = 0.005$), to smoke (24% vs 13%, $P = 0.03$), and to perform worse self-care behavior (26 [24-34] vs 24 [18-31]; $P = 0.008$). Additionally, they were more likely to have been admitted at least once during follow-up (43% vs 27%; $P = 0.009$), but received fewer hospital consultations (5 [3-9] vs 7 [5-10]; $P = 0.03$) compared with patients who did report a preference ($n = 221$). Of the remaining 221 patients, 94 (43%) preferred RPM, 43 (19%) preferred in-clinic, and 84 (38%) reported to have no preference. Patients who reported to have no preference were comparable to patients with a preference (ie, RPM or in-clinic) on all the baseline characteristics and clinical outcome measures (all Ps > 0.05).

Next, we compared patients with a preference for RPM to patients with a preference for in-clinic follow-up. Results indicated that patients with a preference for RPM were less likely to suffer from COPD (22% vs 46%, $P = 0.009$), and more likely to be higher educated (49% vs 35%, $P = 0.04$), to work (57% vs 39%, $P = 0.04$), and to have received the new LATITUDE model (84% vs 68%, $P = 0.04$), as compared to patients with a preference for in-clinic follow-up (Table 2). There were no associations between patients' preference for follow-up and clinical outcome measures (Table 3). Multivariable analyses were not performed, considering the small sample size of the in-clinic preference group.

TABLE 3 Cardiac-related hospital visits, emergency room visits, hospitalizations, and shocks over the first 24 months postimplantation, for the total sample, and stratified between follow-up preference[a]

	Total sample (*N* = 300)	RPM preference (*N* = 94)	In-clinic preference (*N* = 43)	*P* value
Number of hospital consultations[b]	6 (4-9)	6 (5-10)	7 (4-9)	0.90
≥One emergency room visit	44 (15%)	14 (15%)	4 (9%)	0.37
≥One hospital admission	94 (31%)	26 (28%)	10 (23%)	0.59
≥ICD shocks	27 (9%)	56 (6%)	5 (12%)	0.29

Results presented as *N* (%) for categorical variables and as median (interquartile range) for continuous variables.
[a]Based on 221 patients (79 missing); [b]Including all cardiac-related (un)scheduled in-hospital or telephone consultations.
ICD = implantable cardioverter-defibrillator; RPM = remote patient monitoring.

Looking at country-specific data, the majority of German patients preferred RPM follow-up (64%), 12% of them preferred in-clinic follow-up, and 24% had no preference. Almost half of the French patients preferred RPM (42%), 11% of them preferred in-clinic follow-up, and 47% of them did not have a preference. With regard to Dutch patients, 35% preferred RPM, 23% preferred in-clinic follow-up, and 42% had no preference. Preferences of Spanish and Swiss patients were not analyzed separately due to small sample sizes.

Patient motivations to prefer RPM follow-up included continuous monitoring (eg, immediate action if necessary, compared to hospital follow-up as "snapshot"), reassurance, time savings (eg, less traveling to hospital, no interference with daily activities), cost savings (eg, no costs for public transport or petrol, no parking costs), independence, and ease. On the other hand, motives to prefer in-clinic follow-up included human contact with physicians (eg, to discuss their personal situation and to ask questions), trust in physician (eg, visiting cardiologist is more reassuring than RPM system), short travel distance to hospital, and negative experiences with the RPM system. Patients who had no preference often acknowledged benefits of RPM, while emphasizing that hospital visits could never be fully replaced. Also, at 2 years postimplantation, 10% of the patients would like to go to the hospital more often than once a year.

4 | DISCUSSION

To the best of our knowledge, this was the first study to examine long-term patient experiences with RPM, and to explore which sociodemographic, clinical, and psychological factors are associated with patients' preferences for ICD follow-up. The findings of this study are in line with the findings of the previous studies with smaller sample sizes, shorter follow-up periods, and different RPM systems,[22] and underline that most ICD and CRT-D patients are highly satisfied with RPM. Patients rated the LATITUDE RPM system with a median score of 9 out of 10. They perceived the system to be easy to use, trusted the handling of their personal data, reported that the system provided them with a sense of security, and felt that it improved their health awareness and adherence to physicians' health advices. Nearly all patients perceived RPM as an improvement of care for ICD and CRT-D patients, and would recommend it to other patients.

However, similar to previous studies,[12,14,15,18,21] a subgroup of our sample (16%-19%) did not wish to continue RPM in the future, reported a preference toward in-clinic follow-up (19%), or reported to have no preference (38%). Furthermore, 15% of all the patients who refused study participation were not willing to be randomized to RPM follow-up (15%).[37] Motives to prefer in-clinic follow-up were a need for personal contact with physicians, short travel distance to the hospital, and negative experiences with the RPM system. Patients with a preference for in-clinic follow-up were more likely to be less educated, unemployed, to suffer from COPD, and to be equipped with an older LATITUDE model. Cognitive abilities seem to play an essential role in the use and maintenance of technological products,[38] including RPM systems. Also, patients who are unemployed may find the regular in-clinic visits during office hours less bothersome compared to patients with a job. The American ALTITUDE registry and PREDICT-RM trials indicated that patients with comorbidities were less likely to use RPM.[8] However, in the current study, only COPD was positively associated with a preference for in-clinic follow-up. This could possibly be explained by the fact that these patients, often suffering from dyspnea, value visiting physicians who review both their heart and lungs in order to get better insights in their symptoms. However, the general tendency of patients with comorbidities preferring regular follow-up underlines the importance to investigate the integration of other devices with CIED hardware to allow for monitoring of comorbid conditions and a complete assessment of patient status.[39] We did not observe associations between patient preferences and cardiac-related clinical outcomes (ie, hospital consultations, emergency room visits, hospital admissions, and ICD shocks). Future studies with larger sample sizes and longer follow-up periods with more events are necessary to reexamine this.

Patients who received a newer LATITUDE model (ie, 6288/6290) were more likely to prefer RPM follow-up compared to patients who received an older model (ie, 6468). This is surprising, as the newer models no longer have a touch screen, allowing patients to see, for example, if a transmission was successful. Missing feedback (eg, on transmission success and device functioning) was one of the main issues reported by the patients in our study. This is in line with a study by Petersen et al,[18] where 84% of the patients wanted to receive more information about transmissions, and 21% wished for a faster reply. While direct feedback on transmission success and device functioning might enhance patient-centered care, it will have considerable consequences for the workflow. In this real-world practice study, most participating centers contacted patients to discuss RPM data only if necessary, and therefore handled a "no news is good news" policy.

Nevertheless, it would be valuable to explore options to share data with patients, and it speaks for itself that this must happen in close collaboration with them. Recent research indicates that patients generally hold positive attitudes toward using mobile applications to review their own RPM data and that this may lead to improved self-management and a drop in their cardiovascular risk.[40] Patient-centered continuous technological developments like these may further enhance patient experiences with RPM.

In our study, 38% of the patients did not have a strong preference for either RPM or in-clinic follow-up, and 10% stated that they would like to go to the clinic more than once a year. Most of these patients wanted to benefit from RPM, as well as regular personal contact with their physician. This may be driven by patients' concerns about the depersonalization of healthcare, and about maintaining the relationship with their physician.[41] All the patients who are involved in the study suffered from heart failure, which may lead to additional questions and concerns that patients want to discuss personally. A good physician-patient relationship could enhance patients' adherence,[13] and patients are more likely to use their RPM systems if they discussed the functions, benefits, and limitations of this technology with their physician, especially in an early stage.[41]

In the current study, we observed that patients enrolled in the Netherlands more often preferred in-clinic follow-up (23%) compared to patients from Germany and France (12% and 11%, respectively). This finding is of interest, although a clear explanation is missing. Akar et al[8] showed that patients in rural areas were more likely to receive RPM from their physician, and subsequently observed a distance-dependent increase in the likelihood of RPM activation. This shows that travel distance may influence treatment decisions regarding follow-up. Physicians in rural areas could be more inclined to opt for RPM, as they may perceive greater benefits for patients.[8] Despite travel distances being shorter in the Netherlands compared to Germany and France, our univariate analyses did not indicate an effect of travel time on patient preferences for follow-up. This may be due to relatively low travel times with little variation. However, the impact of travel distance and costs might be interesting for future studies to look into.

Taken all together, although recent clinical ICD guidelines strongly advise routine use of RPM for ICD follow-up and patient satisfaction with RPM is high, it remains important that patients are well-educated about the installation, possibilities, and limitations of the system. Patients' concerns and preferences regarding follow-up should be considered in a shared decision-making process, especially when a patient is less educated, unemployed, or suffers from a comorbid disease. Also, future research is warranted on how RPM can help to actively involve patients in managing their own health. A recent overview of systematic reviews concluded that RPM of heart failure data has no positive effect on patients' disease awareness and self-care.[42] The effect of RPM on patients' self-care behavior in our sample will be discussed in a future article.

Finally, this study has some limitations that have to be acknowledged. Patient preferences for follow-up and experiences with RPM were only assessed in patients who were initially randomized to the RPM group. As a result, we only have limited information on patients who switched from in-clinic to RPM over time. Also, insights in patients who received care as usual are limited. It would have been valuable to gain more knowledge on their attitudes toward RPM and preferences for follow-up as well. The large number of missings on the preference question (26%) may have introduced attrition bias, as these patients may be systematically different from the others.[43] In this particular study they suffered from more severe heart failure symptoms, performed worse self-care behavior, were more likely to be admitted during follow-up, and received fewer hospital consultations. The needs and preferences of this high-risk group deserve extra attention in clinical practice. Furthermore, all participating hospitals performed in-clinic follow-up according to their standard practice. Although these visits generally consist of device interrogation with or without physical examination, they may have differed between centers. On a positive note, these between-center differences reflect real-world practice and enhance the environmental validity of this study. The number of (un)scheduled RPM transmissions may have varied between centers as well. Unfortunately, information on these transmissions was not collected, preventing us from examining the relationship between RPM transmission frequency and patient satisfaction and preferences. Results of the current study cannot automatically be generalized to samples from other (non-European) countries, as there may be important differences in race/ethnicity, comorbidities, healthcare access, and satisfaction with healthcare, as well as to patients with other types of cardiac electronic implantable devices. It would be interesting for future studies to examine this. Finally, this study examined the LATITUDE system from Boston Scientific, and the RPM questionnaire was designed to evaluate this system in particular, which may limit the generalizability of our findings to other RPM systems. However, all previous studies reporting on patient experiences or satisfaction with RPM focus on systems from Medtronic (Minneapolis, MN, USA),[10,12,17–21] Biotronik (Berlin, Germany),[13–16] St. Jude Medical (St. Paul, MN, USA),[11] or Boston Scientific (Marlborough, MA, USA)[8] alone. Despite the evident benefits of including systems from multiple manufacturers, results from the REMOTE-CIED study are in line with these previous studies on different systems and indicate that the majority of patients are much satisfied with RPM, with only a small subgroup preferring regular follow-up.

AUTHOR CONTRIBUTIONS

Study concept and design: Versteeg, Timmermans, Meine, Denollet, Zitron, and Mabo. *Data collection*: Timmermans, Meine, Szendey, Aring, Roldán, van Erven, Kahlert, Zitron, Mabo, Denollet, and Versteeg. *Data analysis and interpretation*: Timmermans and Versteeg. *Drafting of the manuscript*: Timmermans and Versteeg. *Critical revision of the manuscript*: Timmermans, Meine, Szendey, Aring, Roldán, van Erven, Kahlert, Zitron, Mabo, Denollet, and Versteeg. *Approval of the manuscript*: Timmermans, Meine, Szendey, Aring, Roldán, van Erven, Kahlert, Zitron, Mabo, Denollet, and Versteeg. Obtained funding: Meine and Versteeg.

ORCID

Ivy Timmermans MSc https://orcid.org/0000-0003-4965-1683

REFERENCES

1. Wijers SC, van der Kolk BY, Tuinenburg AE, Doevendans PA, Vos MA, Meine M. Implementation of guidelines for implantable cardioverter-defibrillator therapy in clinical practice: Which patients do benefit. *Neth Heart J*. 2013;21:274-283.
2. Wilkoff BL, Auricchio A, Brugada J, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): Description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm*. 2008;5:907-925.
3. Dubner S, Auricchio A, Steinberg JS, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). *Ann Noninvasive Electrocardiol*. 2012;17:36-56.
4. Klersy C, Boriani G, De Silvestri A, et al. Effect of telemonitoring of cardiac implantable electronic devices on healthcare utilization: A meta-analysis of randomized controlled trials in patients with heart failure. *Eur J Heart Fail*. 2016;18:195-204.
5. Parthiban N, Esterman A, Mahajan R, et al. Remote monitoring of implantable cardioverter-defibrillators: A systematic review and meta-analysis of clinical outcomes. *J Am Coll Cardiol*. 2015;65:2591-2600.
6. Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy. *Europace*. 2013;15:1070-1118.
7. Slotwiner D, Varma N, Akar JG, et al. HRS expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart Rhythm*. 2015;12:E69-E100.
8. Akar JG, Bao HK, Jones P, et al. Use of remote monitoring of newly implanted cardioverter-defibrillators: Insights from the patient related determinants of ICD remote monitoring (PREDICT RM) study. *Circulation*. 2013;128:2372-2383.
9. Mairesse GH, Braunschweig F, Klersy K, Cowie MR, Leyva F. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: A survey from the Health Economics Committee of the European Heart Rhythm Association. *Europace*. 2015;17:814-818.
10. Al-Khatib SM, Piccini JP, Knight D, Stewart M, Clapp-Channing N, Sanders GD. Remote monitoring of implantable cardioverter defibrillators versus quarterly device interrogations in clinic: Results from a randomized pilot clinical trial. *J Cardiovasc Electr*. 2010;21:545-550.
11. Joseph GK, Wilkoff BL, Dresing T, Burkhardt J, Khaykin Y. Remote interrogation and monitoring of implantable cardioverter defibrillators. *J Interv Card Electr*. 2004;11:161-166.
12. Marzegalli M, Lunati M, Landolina M, et al. Remote monitoring of CRT-ICD: The multicenter Italian CareLink evaluation—Ease of use, acceptance, and organizational implications. *Pacing Clin Electrophysiol*. 2008;31:1259-1264.
13. Ricci RP, Morichelli L, Quarta L, et al. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. *Europace*. 2010;12:674-679.
14. Watanabe E, Kasai A, Fujii E, Yamashiro K, Brugada P. Reliability of implantable cardioverter defibrillator home monitoring in forecasting the need for regular office visits, and patient perspective—Japanese HOME-ICD study. *Circulation*. 2013;77:2704-2711.
15. Guedon-Moreau L, Lacroix D, Sadoul N, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: Safety and efficacy report of the ECOST trial. *Eur Heart J*. 2013;34:605-614.
16. Laurent G, Amara W, Mansourati J, et al. Role of patient education in the perception and acceptance of home monitoring after recent implantation of cardioverter defibrillators: The EDUCAT study. *Arch Cardiovasc Dis*. 2014;107:508-518.
17. Morichelli L, Porfili A, Quarta L, Sassi A, Ricci RP. Implantable cardioverter defibrillator remote monitoring is well accepted and easy to use during long-term follow-up. *J Interv Card Electr*. 2014;41:203-209.
18. Petersen HH, Larsen MCJ, Nielsen OW, Kensing F, Svendsen JH. Patient satisfaction and suggestions for improvement of remote ICD monitoring. *J Interv Card Electr*. 2012;34:317-324.
19. Raatikainen MJ, Uusimaa P, van Ginneken MM, Janssen JP, Linnaluoto M. Remote monitoring of implantable cardioverter defibrillator patients: A safe, time-saving, and cost-effective means for follow-up. *Europace*. 2008;10:1145-1151.
20. Schoenfeld MH, Compton SJ, Mead RH, et al. Remote monitoring of implantable cardioverter defibrillators: A prospective analysis. *Pacing Clin Electrophysiol*. 2004;27:757-763.
21. Siebermair J, Clauss S, Martens E, et al. Remote monitoring of implantable cardioverter-defibrillators problems and implications using a telemonitoring system. *Herz*. 2015;40:110-118.
22. Timmermans I, Meine M, Zitron E, et al. The patient perspective on remote monitoring of patients with an implantable cardioverter defibrillator: Narrative review and future directions. *Pacing Clin Electrophysiol*. 2017;40:826-833.
23. Anker SD, Agewall S, Borggrefe M, et al. The importance of patient-reported outcomes: A call for their comprehensive integration in cardiovascular clinical trials. *Eur Heart J*. 2014;35:2001-2009.
24. Versteeg H, Pedersen SS, Mastenbroek MH, et al. Patient perspective on remote monitoring of cardiovascular implantable electronic devices: Rationale and design of the REMOTE-CIED study. *Neth Heart J*. 2014;22:423-428.
25. Jaarsma T, Arestedt KF, Martensson J, Dracup K, Stromberg A. The European heart failure self-care behaviour scale revised into a nine-item scale (EHFScB-9): A reliable and valid international instrument. *Eur J Heart Fail*. 2009;11:99-105.
26. Green CP, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City cardiomyopathy questionnaire: A new health status measure for heart failure. *J Am Coll Cardiol*. 2000;35:1245-1255.
27. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9—validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16:606-613.
28. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med*. 2006;166:1092-1097.
29. Denollet J. DS14: Standard assessment of negative affectivity, social inhibition, and type D personality. *Psychosom Med*. 2005;67:89-97.
30. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. *J Psychosom Res*. 2006;60:631-637.
31. Burns JL, Serber ER, Keim S, Sears SF. Measuring patient acceptance of implantable cardiac device therapy: Initial psychometric investigation of the Florida Patient Acceptance Survey. *J Cardiovasc Electrophysiol*. 2005;16:384-390.
32. Versteeg H, Starrenburg A, Denollet J, Palen J, Sears SF, Pedersen SS. Monitoring device acceptance in implantable cardioverter defibrillator patients using the Florida Patient Acceptance Survey. *Pacing Clin Electrophysiol*. 2012;35:283-293.
33. Frizelle DJ, Lewin B, Kaye G, Moniz-Cook ED. Development of a measure of the concerns held by people with implanted cardioverter defibrillators: The ICDC. *Br J Health Psychol*. 2006;11:293-301.
34. Pedersen SS, van Domburg RT, Theuns DAMJ, Jordaens L, Erdman RAM. Concerns about the implantable cardioverter defibrillator: A determinant of anxiety and depressive symptoms independent of experienced shocks. *Am Heart J*. 2005;149:664-669.

35. Versteeg H, Timmermans I, Meine M, Zitron E, Mabo P, Denollet J. Prevalence and risk markers of early psychological distress after ICD implantation in the European REMOTE-CIED study cohort. *Int J Cardiol*. 2017;240:208-213.
36. Timmermans I, Versteeg H, Meine M, Pedersen SS, Denollet J. Illness perceptions in patients with heart failure and an implantable cardioverter defibrillator: Dimensional structure, validity, and correlates of the brief illness perception questionnaire in Dutch, French and German patients. *J Psychosom Res*. 2017;97:1-8.
37. Versteeg H, Timmermans I, Widdershoven J, et al. Effect of remote monitoring on patient-reported outcomes in European heart failure patients with an implantable cardioverter defibrillator: Primary results of the REMOTE-CIED study. submitted manuscript.
38. Czaja SJ, Charness N, Fisk AD, Nair SN, Rogers WA, Sharit J. Factors predicting the use of technology: Findings from the Center for Research and Education on Aging and Technology Enhancement (CREATE). *Psychol Aging*. 2006;21:333-352.
39. Ganeshan R, Enriquez AD, Freeman JV. Remote monitoring of implantable cardiac devices: Current state and future directions. *Curr Opin Cardiol*. 2018;33:20-30.
40. Coorey GM, Neubeck L, Mulley J, Redfern J. Effectiveness, acceptability and usefulness of mobile applications for cardiovascular disease self-management: Systematic review with meta-synthesis of quantitative and qualitative data. *Eur J Prev Cardiol*. 2018;25:505-521.
41. Ottenberg AL, Swetz KM, Mueller LA, Gerhardson S, Mueller PS. "We as human beings get farther and farther apart": The experiences of patients with remote monitoring systems. *Heart Lung*. 2013;42:313-319.
42. Bashi N, Karunanithi M, Fatehi F, Ding H, Walters D. Remote monitoring of patients with heart failure: An overview of systematic reviews. *J Med Internet Res*. 2017;19:E18. https://doi.org/10.2196/jmir.6571
43. Damen NL, Versteeg H, Serruys PW, et al. Cardiac patients who completed a longitudinal psychosocial study had a different clinical and psychosocial baseline profile than patients who dropped out prematurely. *Eur J Prev Cardiol*. 2015;22:196-199.

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