

Remote Monitoring Reduces Healthcare Use and Improves Quality of Care in Heart Failure Patients With Implantable Defibrillators

The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) Study

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Background—Heart failure patients with implantable cardioverter-defibrillators (ICDs) or an ICD for resynchronization therapy often visit the hospital for unscheduled examinations, placing a great burden on healthcare providers. We hypothesized that Internet-based remote interrogation systems could reduce emergency healthcare visits.

Methods and Results—This multicenter randomized trial involving 200 patients compared remote monitoring with standard patient management consisting of scheduled visits and patient response to audible ICD alerts. The primary end point was the rate of emergency department or urgent in-office visits for heart failure, arrhythmias, or ICD-related events. Over 16 months, such visits were 35% less frequent in the remote arm (75 versus 117; incidence density, 0.59 versus 0.93 events per year; $P=0.005$). A 21% difference was observed in the rates of total healthcare visits for heart failure, arrhythmias, or ICD-related events (4.40 versus 5.74 events per year; $P<0.001$). The time from an ICD alert condition to review of the data was reduced from 24.8 days in the standard arm to 1.4 days in the remote arm ($P<0.001$). The patients' clinical status, as measured by the Clinical Composite Score, was similar in the 2 groups, whereas a more favorable change in quality of life (Minnesota Living With Heart Failure Questionnaire) was observed from the baseline to the 16th month in the remote arm ($P=0.026$).

Conclusions—Remote monitoring reduces emergency department/urgent in-office visits and, in general, total healthcare use in patients with ICD or defibrillators for resynchronization therapy. Compared with standard follow-up through in-office visits and audible ICD alerts, remote monitoring results in increased efficiency for healthcare providers and improved quality of care for patients.

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Key Words: cardiac resynchronization therapy ■ defibrillators, implantable ■ heart failure ■ telemedicine

Hospital admissions for heart failure (HF) are an increasingly serious clinical issue and carry a heavy economic burden.¹ Thus, new strategies to keep HF patients out of the hospital are needed. Based on positive outcomes from numerous randomized controlled trials, the current guidelines for the management of chronic HF¹ include the use of implantable cardioverter-defibrillators (ICDs) and defibrillators for resynchronization therapy (CRT-D) as the standard care in selected chronic HF patients.

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The ability of implantable devices to continuously monitor variables such as heart rate,^{2,3} the patient's daily activities,⁴

intrathoracic impedance for the detection of fluid accumulation,⁵ the occurrence of arrhythmias,^{6,7} and the integrity of the system⁸ may provide early warning of changes in cardiac status or of safety issues and allow timely management. When these patients have clinical events such as ICD shocks or device audible alert notifications of possible critical situations, they often visit the emergency department or clinic for an unscheduled examination. These unplanned visits place an even greater burden on healthcare providers.

Several major manufacturers of devices offer technology for remote ICD monitoring⁹⁻¹¹ with the purpose of reducing unnecessary routine and interim visits and allowing physi-

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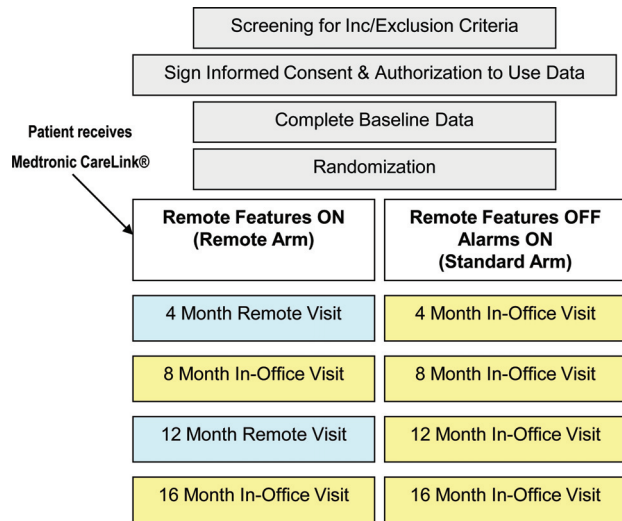


Figure 1. Trial design: enrollment and follow-up schedule.

cians to remotely access patients’ data. Timely remote notification of potentially critical situations, as detected by implantable devices, may also have the effect of shifting healthcare visits from the emergency department to the clinic, thereby reducing costs and the burden on the healthcare system. In addition, remote monitoring with these enhanced features may improve patients’ quality of life by reducing anxiety between follow-up visits.

The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) study was designed to test the hypothesis that remote management can reduce emergency healthcare use (emergency department or urgent in-office visits) in HF patients implanted with wireless-transmission-enabled ICD/CRT-D endowed with specific diagnostic features for HF, thereby increasing efficiency compared with standard management consisting of scheduled in-office visits and patient response to audible ICD alerts.

Methods

Study Design

The EVOLVO study was a prospective, randomized, open, multi-center evaluation of wireless remote monitoring in a population of 200 patients implanted with a Medtronic (Minneapolis, MN) wireless ICD/CRT-D using the Medtronic CareLink Network. The CareLink system performs full interrogation and transmission of ICD data through a standard telephone connection. Wireless communication with the ICD allows transmission at scheduled intervals without patient intervention, as well as alert-based downloads. Specifically, in the case of programmable alert conditions, the system can transmit data and notify the physician via phone or e-mail. Device information can be reviewed on a secure Web site via the Internet.

The detailed study design has been reported elsewhere.¹² In summary, patients were enrolled and randomized to “remote transmission on” (remote arm) or “remote transmission off” (standard arm). Randomization was stratified by center and by time from implantation (≤ 6 and > 6 months). Enrolled patients were followed up for a 16-month period according to the schedule described in Figure 1.

All eligible patients had to fulfill the following conditions: (1) left ventricular systolic dysfunction or left ventricular ejection fraction $\leq 35\%$ documented at the moment of implantation, (2) implantation with a wireless-transmission-enabled Medtronic ICD or CRT-D endowed with thoracic impedance measurement capabilities (OptiVol algorithm), (3) ability and willingness to undergo remote follow-up

Table 1. Demographics, Baseline Clinical Parameters, and Pharmacological Treatment of the Study Population at the Time of Enrollment

Parameter	Remote Arm (n=99)	Standard Arm (n=101)	P
Male sex, n	81	76	0.338
Age, y	66 (60–72)	69 (60–73)	0.142
Underlying heart disease, n			0.071
Ischemic	38	54	
Dilated CMP	53	38	
Valvular	8	9	
Permanent atrial fibrillation, n	8	10	0.839
NYHA class, n			0.797
I	11	13	
II	71	68	
III	17	20	
Primary prevention, n	87	95	0.201
CRT defibrillator, n	94	87	0.060
Time since implantation > 6 mo, n	46	45	0.897
Myocardial infarction, n	37	42	0.642
Previous CABG or angioplasty, n	39	48	0.309
Valve disease, n	52	53	1.000
Previous valve surgery, n	10	13	0.695
Hypertension, n	46	52	0.570
Diabetes mellitus, n	22	26	0.676
Chronic kidney disease, n	21	22	1.000
COPD, n	19	15	0.500
LV ejection fraction, %	31 (25–35)	30 (25–34)	0.386
LVEDV, mL	200 (160–240)	180 (136–226)	0.206
LVESV, mL	137 (99–175)	125 (90–165)	0.086
β -blocker use, n	84	85	1.000
ACE inhibitor use, n	90	90	0.850
Diuretic use, n	91	91	0.839
Class III antiarrhythmic use, n	34	35	1.000
Anticoagulant/antiplatelet use, n	77	85	0.332

CMP indicates cardiomyopathy; NYHA, New York Heart Association; CRT, cardiac resynchronization therapy; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LV, left ventricular; LVEDV, LV end-diastolic volume; LVESV, LV end-systolic volume; and ACE, angiotensin-converting enzyme. Continuous variables are reported as median (25th–75th percentile).

instead of scheduled routine in-office follow-up visits, and (4) ability to attend all required follow-up examinations at the study center.

The Institutional Review boards at the 6 participating Italian centers approved the study. All patients gave written informed consent.

Programming of Diagnostic Features and Management Strategies

In the remote arm, all alerts regarding clinical management (intrathoracic impedance for fluid accumulation monitoring, atrial arrhythmias, ICD shocks delivered) were turned on for wireless notification through CareLink; no audible alerts were used. In the standard arm, patients did not have access to the CareLink network, and the alerts were turned on for audible notification only. All system-integrity alerts were turned on for both wireless and audible notification in the remote arm and for only audible notification in the standard arm.

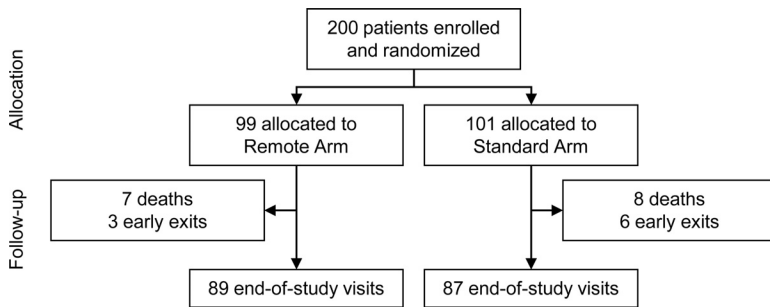


Figure 2. Consolidated Standards of Reporting Trials (CONSORT) diagram of the study.

Clinics checked the CareLink Web site at least once daily for transmissions. Management strategies and data collection were predefined and have previously been described.¹²

Objectives

The primary objective of the study was to determine whether remote monitoring was associated with a different rate of emergency department and urgent in-office visits for HF, arrhythmias, or ICD-related events from patients in the standard arm. The primary end point included all emergency department visits and urgent in-office visits, ie, all visits, when the interval between the decision to see the patient and the visit was <24 hours. The events anticipated to prompt these visits were ICD alerts for system integrity, atrial and ventricular arrhythmias, decrease in intrathoracic impedance signifying possible fluid accumulation, and patient symptoms.

The emergency department/urgent in-office visits representing the primary end point were also subdivided as follows: visits related to episodes of worsening of HF (secondary end point 1) and visits for arrhythmias or ICD-related episodes (secondary end point 2). Additionally, the rate of total healthcare use (any in-office visit, emergency department visit, and hospitalization requiring at least 1 overnight stay) for HF, arrhythmias, or ICD events was compared between groups (secondary end point 3). End points were adjudicated by a blinded End Point Advisory Committee (see the Acknowledgments).

Visits were also scrutinized and classified as necessary or unnecessary for the clinical management of the patient. Specifically, each visit was judged necessary if it resulted from an appropriate and clinically meaningful ICD alert (eg, intrathoracic impedance alert associated with clinically deteriorated HF) and if the clinician was not previously aware of the clinical/ICD condition.

The study also tested whether remote monitoring reduced the time from any alert condition to the ICD data review, modified the patient's clinical status as measured by the Clinical Composite Score,¹³ or modified the patient's quality of life as measured by the Minnesota Living With Heart Failure Questionnaire.

Statistical Analysis

All patients in the analysis cohort were included in this analysis. An intention-to-treat analysis was performed for all objectives. The primary and secondary hypotheses were tested by use of the combined Mantel-Haenszel estimate stratified by center and other potential confounders. All events from the day after randomization to patient exit/death were included. As previously specified, the sample size was intended to provide adequate power for the analysis of the primary objective.¹²

Descriptive statistics are reported as mean±SD for normally distributed continuous variables or medians with 25th to 75th percentiles in the case of skewed distribution. Normality of distribution was tested by means of the nonparametric Kolmogorov-Smirnov test.

Differences between mean data were compared by use of a *t* test for gaussian variables with an *F* test to check the hypothesis of equality of variance. A Mann-Whitney nonparametric test was used to compare nongaussian variables. Differences in proportions were compared by application of χ^2 analysis or the Fisher exact test as appropriate.

A value of $P<0.05$ was considered significant for all tests. All statistical analyses were performed with STATA 9.2 version software (STATA Corp, Houston, TX).

Results

Study Timelines and Population

Two hundred patients were enrolled from May 2008 through July 2009 from 6 centers. The last follow-up visit was held in December 2010. Ninety-nine patients were randomly assigned to the remote arm, and 101 patients were allocated to the standard arm. Demographic data, clinical parameters, and pharmacological treatment were similar between the study arms at the time of enrollment (Table 1).

After enrollment, patients in the remote arm received the home monitor and were instructed on how to use it. All patients were able to correctly set up and initiate the system to send out transmissions.

During the course of the study, 15 patients died (7 in the remote arm and 8 in the standard arm). Moreover, in the standard arm, 2 patients underwent heart transplantation and 1 patient underwent ICD removal for device-related infection. In accordance with the protocol, these subjects were withdrawn from the study, together with 3 patients in the remote arm and 3 in the standard arm who exited the study because of their inability to attend all required follow-up visits (Figure 2). All patients with incomplete follow-up were included in the analysis until study exit or death. For the assessment of the incidence rate of study end points, there were 127 person-years in the remote arm and 126 person-years in the standard arm.

Primary End Point

By the end of the study, a total of 192 emergency department/urgent in-office visits for HF, arrhythmias, or ICD-related events (129 urgent in-office visits and 63 emergency room visits) occurred in the study population (Table 2 and Figure 3). Specifically, 75 events were reported in the remote arm and 117 in the standard arm (0.59 versus 0.93 events per year; incident rate ratio [IRR], 0.65; 95% confidence interval [CI], 0.49–0.88; $P=0.005$; Figure 4). The IRR was adjusted for center, use of CRT, and ischemic origin.

Secondary End Points

Compared with standard management, remote monitoring reduced the risk of emergency department/urgent in-office visits for episodes of worsening of HF (48 versus 92; 0.38 versus 0.73 events per year; IRR, 0.52; 95% CI, 0.37–0.75; $P<0.001$; Figure 4). On the other hand, comparable rates of emergency department/urgent in-office visits for arrhythmias

Table 2. Number (Annualized Rate per Patient-Year) of Healthcare Visits for Heart Failure, Arrhythmias, or Implantable Cardioverter-Defibrillator–Related Events by Arm

	Remote Arm	Standard Arm
Clinical event		
Total healthcare uses	559 (4.40)	726 (5.76)†
Protocol-defined clinic visits	283 (2.23)	451 (3.60)†
Nonurgent in-office visits	144 (1.13)	109 (0.87)
Urgent in-office visits*	50 (0.39)	79 (0.63)†
Emergency room visits*	25 (0.19)	38 (0.30)
Hospitalizations requiring at least 1 overnight stay	57 (0.45)	49 (0.39)
Alert condition		
Total alert conditions	315 (2.50)	256 (2.39)
OptiVol alert	274 (2.17)	231 (2.16)
AT/AF burden at least 6 h	13 (0.10)	17 (0.16)
Ventricular rate at least 100 bpm during AT/AF episodes lasting ≥6 h	8 (0.06)	4 (0.04)
Shock delivered	9 (0.07)	2 (0.02)
Lead impedances out of range	8 (0.06)	0 (0)
VF detection/therapy off	1 (0.01)	2 (0.02)
Low battery	2 (0.02)	0 (0)

AT indicates atrial tachycardia; AF, atrial fibrillation; and VF, ventricular fibrillation.

*Primary end point.

†Significant difference in the rate of events ($P < 0.001$).

or ICD-related episodes (ie, occurrence of atrial or ventricular arrhythmias, ICD therapies, system-integrity alerts) were reported in the remote and standard arms (27 versus 25; 0.21 versus 0.20 events per year; IRR, 1.14; 95% CI, 0.65–1.99; $P = 0.649$; Figure 4).

Overall, there were 1285 healthcare uses (any in-office visit, emergency department visit and hospitalization requir-

ing at least 1 overnight stay) for HF, arrhythmias, or device-related events, and there was a statistical difference in the rates of events between the 2 arms (4.40 events per year in the remote arm versus 5.74 events per year in the standard arm; IRR, 0.79; 95% CI, 0.71–0.89; $P < 0.001$; Figure 4).

There were 76 hospitalizations requiring at least 1 overnight stay for worsening of HF and 30 for arrhythmias or ICD-related episodes. The admission rates were comparable between arms (0.45 versus 0.39 events per year; $P = 0.464$; Table 2).

Device Alerts

Device-stored data were available for a total of 126 person-years in the remote arm and for 107 person-years in the standard arm. By the end of the study, 571 alert conditions had been detected by the ICD. In accordance with the protocol-required device programming, 315 wireless remote notifications were generated in the remote arm (2.50 events per year) and 256 audible notifications in the standard arm (2.40 events per year; IRR, 1.04; 95% CI, 0.89–1.23; $P = 0.602$; Table 2).

After automatic notification via CareLink, the clinicians performed remote data review and telephone follow-up of patients in the remote arm. An extra visit was requested in 84 cases; 72 of these visits (86%) were deemed necessary for the clinical management of the patient (ie, resulting from an appropriate and clinically meaningful ICD alert).

In the standard arm, patients presented to the clinic after 79 acoustic alerts. In the remaining cases, the patients did not recognize the alert or the clinicians did not consider urgent in-office visit necessary once notified of the alert by the patient. In 42 of the 79 postalert in-office visits, the alerts were determined by clinicians to be clinically meaningful (53%; $P < 0.001$ versus the remote arm). Therefore, compared with standard management, remote monitoring increased the rate of appropriate visits for clinically relevant ICD alerts

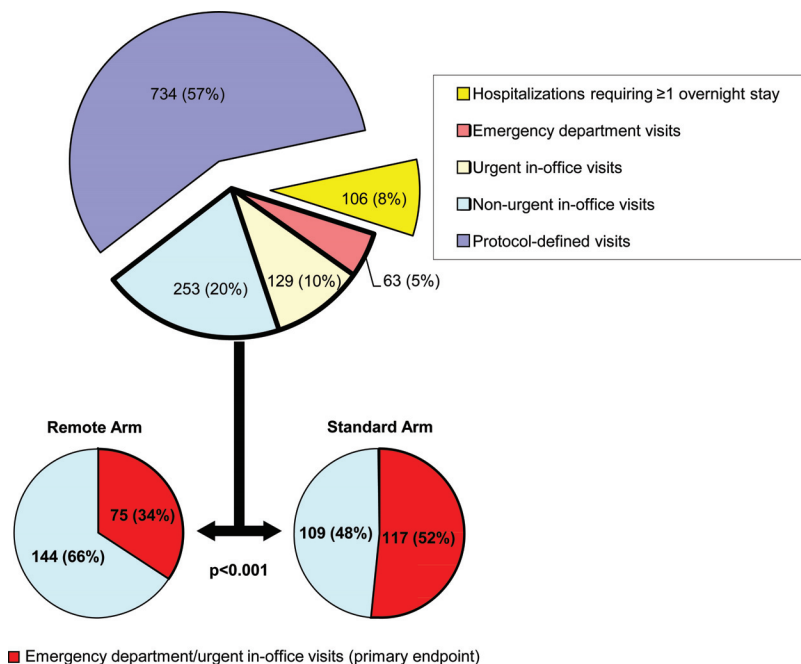


Figure 3. Total healthcare use for heart failure, arrhythmias, or implantable cardioverter-defibrillator–related events and proportion of emergency department/urgent in-office visits (primary end point) by arm.

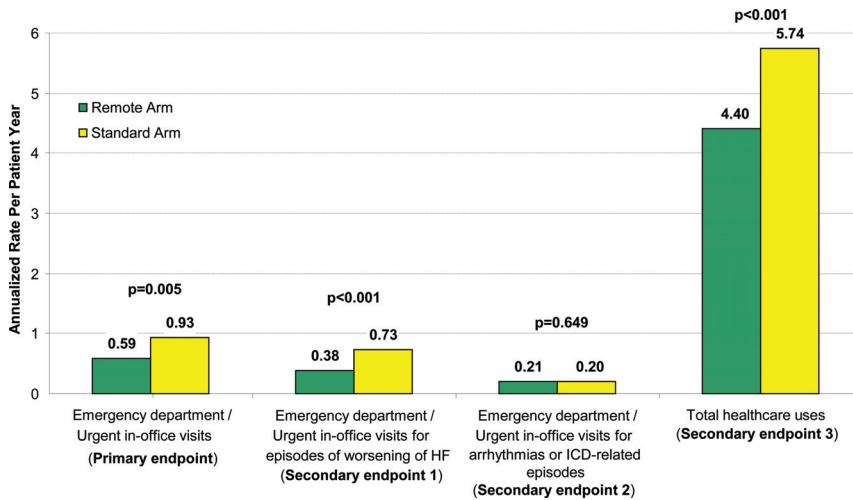


Figure 4. Annualized rate of healthcare use for heart failure (HF), arrhythmias, or implantable cardioverter-defibrillator (ICD)-related events per patient-year by arm.

(0.57 versus 0.33 events per year; IRR, 1.71; 95% CI, 1.15–2.55; $P=0.003$).

In the standard arm, the median time from the alert condition to the ICD data review was 24.8 days (25th–75th percentile, 9.5–48.8). In the remote arm, the median time from the trigger of an automatic alert to review of the information was 1.4 days (25th–75th percentile, 0.8–7.3; $P<0.001$ versus standard arm).

In 57 events that occurred in 36 patients in the remote arm, the time from the alert to the transmission exceeded 3 days (eg, patient not home, monitor accidentally unplugged). In these circumstances, the ICD produces an audible notification of the condition. In 36 of these events, transmission was subsequently carried out successfully; in the remaining 21 cases, the patient presented to the hospital before data transmission.

Quality of Life and Clinical Status

The patient's quality of life was investigated by means of the Minnesota Living With Heart Failure Questionnaire. Baseline values were comparable between the remote (19; 25th–75th percentile, 9–40) and standard (20; 25th–75th percentile, 9–35; $P=0.817$) arms. However, the change in quality of life from the baseline to the 16th month was more favorable in the remote arm (–2; 25th–75th percentile, –17 to 8) than in the standard arm (2; 25th–75th percentile, –7 to 10; $P=0.026$).

The change in clinical status during the study was measured according to the Clinical Composite Score. In the remote arm, 17% of patients were defined as improved, 49% as unchanged, and 34% as worsened from the time of enrollment to the 16-month follow-up visit. Similarly, 20% were improved, 36% were unchanged, and 44% were worsened in the standard arm. No statistical difference existed between the 2 arms.

Discussion

The main finding of the EVOLVO study is that remote management of HF patients implanted with ICD/CRT-D decreases the rate of emergency department/urgent in-office visits and in general reduces total healthcare use. In the presence of symptoms or device alerts, remote monitoring allows early ICD data review while reducing the need for

urgent hospital examinations and increasing the appropriateness of in-office visits.

The feasibility and ease of use of remote monitoring in European clinical practice have previously been demonstrated.¹⁴ Moreover, it has been suggested that, by improving the clinical management of tachyarrhythmias and HF episodes in ICD patients,¹⁵ remote monitoring could lead to a reduction in healthcare use. In particular, it could be effective in decreasing unplanned in-office visits, which are more costly than scheduled visits in terms of time dedicated by specialized personnel because they take $\approx 30\%$ longer.¹⁶ This hypothesis was tested in the present randomized study, which was designed to compare the remote management of HF patients wearing ICD/CRT-D with the standard follow-up by means of in-office visits and audible ICD alerts for clinical management and system integrity.

As expected, the EVOLVO study did not show different rates of hospital admissions requiring at least 1 overnight stay. Indeed, alerting algorithms (eg, OptiVol) were adopted in the management strategy of both study arms, allowing potential prevention of clinical deterioration in all patients. Nonetheless, it cannot be excluded that the observed prompt data review and improved appropriateness of in-office visits in remote arm could result in improved outcome and fewer long-lasting hospitalizations at the long-term follow-up.

In the present study, we compared a standard arm in which patients underwent 4 in-office examinations per year with a remote arm in which 2 of the 4 examinations were replaced by remote interrogations, as previously proposed.^{14,17} Our study design allowed total office evaluations to be reduced, although the proposed reduction in scheduled in-person encounters was less drastic than in other experiences. Indeed, in previous randomized trials,^{18,19} regular 3-month visits were replaced with transmissions, and ICD patients underwent in-office evaluation every 12 or 14 months. This interval was considered excessively long for our population of patients with moderate to severe HF.

The Pacemaker Remote Follow-up Evaluation and Review (PREFER) study showed that remote pacemaker monitoring led to quicker and more frequent detection of clinical events (eg, atrial and ventricular arrhythmias, indicators of system

failure) than standard care.²⁰ Similarly, the Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision (CONNECT) trial¹⁹ demonstrated that, compared with standard in-office follow-up of ICD patients, wireless remote monitoring with automatic notifications significantly reduced the time to a clinical decision in response to events such as atrial arrhythmias, ICD therapies, and system-integrity alerts. In the control group of the CONNECT trial, audible alerts were disabled, whereas in the present study, all alerts were available and turned on for audible notification in the standard arm. This approach was chosen specifically to assess the benefits of physician notification and remote access to data, in addition to the diagnostic and alerting capabilities of ICD, including the OptiVol algorithm, that were available in both study arms.

The audible alert feature currently represents the most common method of ICD event notification^{7,8,21} because it may facilitate the discovery of ICD events.²² Moreover, although ICD implantation per se may worsen quality of life, especially in subjects receiving device shocks, audible alerts were not associated with increased patient anxiety.

In the EVOLVO study, patients in the standard arm were instructed to contact the center in the case of symptoms or alerts. During follow-up, we observed that only some of the ICD alerts were followed by a clinic visit, and the median time for ICD data review was >20 days. Indeed, it has been reported that patients frequently do not hear or respond to the audible alert.^{23,24}

In contrast, in the remote arm, the clinician was automatically notified of the alert condition, and no direct patient interaction was required; this reduced potential patient compliance issues. Data were promptly reviewed, and triage of patients could be performed remotely. Thus, visits were requested only in the case of appropriate and clinically meaningful ICD alerts. This increased the proportion of visits deemed necessary for the clinical management of the patient and allowed emergency department/urgent in-office visits to be requested only when immediate intervention was actually needed.

Among emergency department/urgent in-office visits, remote monitoring significantly reduced those related to episodes of worsening of HF, ie, possible fluid accumulation according to the OptiVol algorithm and patient signs and symptoms of decompensation. Because of the characteristics of the study population and the expected rate of OptiVol alerts, these events accounted for the majority of end points recorded, which is in line with the hypotheses of the sample size estimation.¹²

In the control group of the CONNECT trial, ICDs were not equipped with the OptiVol alert capability. Indeed, in US centers, ICD diagnostics for HF are not managed through automatic alerts; rather, information is reviewed periodically, and physicians may receive reimbursement for remote monthly assessment.²⁵ This approach differs from standard practice in Europe, where audible notification of OptiVol events is available and frequently enabled.²⁶

In the Diagnostic Outcome Trial in Heart Failure (DOT-HF) study, patients were randomly assigned to a control group, in which the ICD diagnostic capabilities were disabled, or to an access group, in which the patients were audibly notified that

impedance had fallen below a threshold.²¹ Unexpectedly, the study recently showed an increased number of hospital admissions in the access arm, and data seemed to suggest that this could be ascribed to the audible alert requiring patient-physician contact for evaluation and possible adjustment of treatment.²⁷

Nonetheless, the use of implantable hemodynamic monitoring systems was previously demonstrated to be associated with a significant reduction in HF hospitalizations when the hemodynamic information in the access group was provided only to clinicians and patients were blinded.^{28,29} Therefore, it could be hypothesized that in the DOT-HF trial, remote monitoring availability could have avoided outpatient visits for the review of diagnostic information, thus reducing healthcare use in the access arm. By directly comparing audible notification with remote access to ICD data, the EVOLVO study demonstrated a reduction in healthcare use and confirmed that hypothesis.

Moreover, CareLink allows access to the full set of ICD data, and previous findings³⁰ have shown that the combined use of all parameters available for remote data review (ie, presence of atrial fibrillation, ventricular rate, patient activity, resting heart rate, heart rate variability, OptiVol data) significantly improved the ability to identify patients at risk of HF events beyond the use of intrathoracic impedance alone, thereby increasing the positive predictive value of the diagnostic system.

Events such as arrhythmias, ICD shocks, and technical problems could be managed remotely via CareLink. However, in the present study, we did not observe different rates of emergency department/urgent in-office visits for these episodes, mainly because of the low number of events reported. Nonetheless, it is predictable that, in the long term, the rate of such events (eg, impending elective replacement indicator) would increase. Moreover, these events prompted some patients to seek urgent attention at the clinic before data were remotely reviewed (eg, after an ICD shock), even though they were trained to contact the center before presenting to the hospital.

Although remote management required less healthcare use than standard strategy, the change in patients' clinical status was similar as measured by the Clinical Composite Score. A larger study is currently ongoing to confirm whether remote monitoring may affect this end point in a similar population of HF patients.³¹ Nonetheless, in our experience, remote monitoring was associated with a more favorable change in quality of life during the study compared with the standard arm.

Limitations

Because the present findings were obtained with state-of-the-art ICD/CRT-D equipped with advanced diagnostic and alerting capabilities, they cannot be fully extended to different technologies. Diagnostic enhancements are continuously being developed to improve the ability to risk stratify patients for subsequent HF events³⁰; almost certainly, this will further increase the effectiveness of remote management. The aim of the EVOLVO study was to assess the benefits of remote notification and access to ICD data. The study design did not allow us to estimate the clinical value of diagnostic features that were available in both study arms.

The present study was not designed and sized to demonstrate a reduction in hospitalizations requiring at least 1 overnight stay, which are a measure of clinical deterioration frequently adopted as end point in HF trials and represent the driving cost of healthcare in these patients.

Other trials are currently ongoing to evaluate whether remote monitoring associated with advanced diagnostic algorithms may reduce long-lasting hospitalizations and deaths compared with the in-office follow-up of ICD with no diagnostic features.^{32,33} Although we demonstrated that remote monitoring reduced inappropriate visits resulting from false alerts, alerting algorithms, which are intended to detect clinical worsening early, may lead to preemptive hospitalizations in patients who are deteriorating but not yet in crisis. Therefore, earlier detection combined with remote management could be more effective in reducing the duration of hospitalization¹⁹ or the risk of death³⁴ than in reducing the number of hospitalizations. Recently, Saxon et al³⁵ analyzed data from >185 000 patients within the Altitude project and reported higher survival in patients on remote monitoring. Although these results are very intriguing, the study was nonrandomized and limited by the lack of information about the patients' clinical characteristics.

Conclusions

The results of the EVOLVO study demonstrate that remote monitoring can reduce emergency department/urgent in-office visits and, in general, total healthcare use in HF patients with modern ICD/CRT-D. Compared with standard follow-up through in-office visits and audible ICD alerts, remote monitoring results in increased efficiency for healthcare providers and improved quality of care for patients.

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Disclosures

Dr Landolina has speakers' bureau appointments and an advisory board relationship with Medtronic and other device companies. Dr Valsecchi is an employee of Medtronic Inc. The other authors report no conflicts.

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CLINICAL PERSPECTIVE

Heart failure patients with implantable defibrillators often visit the hospital for unscheduled examinations, placing a great burden on healthcare providers. Device manufacturers offer a technology for remote defibrillator monitoring with the purpose of allowing physicians to remotely access patients' data and reducing unnecessary routine and interim visits. The Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) study was a multicenter randomized trial designed to assess whether remote management can reduce emergency healthcare use in heart failure patients implanted with defibrillators endowed with specific diagnostic features compared with standard management consisting of scheduled in-office visits and patient response to audible alerts. Over 16 months, the rate of emergency department or urgent in-office visits for heart failure, arrhythmias, or device-related events decreased by 35% and total healthcare visits were 21% less frequent with remote monitoring. Moreover, with remote monitoring system, the time from an alert condition to review of the data was reduced from 24.8 to 1.4 days, and the change in patients' quality of life was more favorable. These findings may have important implications. Indeed, our study confirmed that remote management of heart failure patients implanted with defibrillators allows timely notification of potentially critical situations. Moreover, it has the effect of shifting healthcare visits from the emergency department to the clinic and increasing the appropriateness of in-office visits, thereby reducing costs and the burden on the healthcare system. Thus, compared with the standard follow-up through in-office visits and audible alerts, remote monitoring results in increased efficiency for healthcare providers and improved quality of care for patients.