

# Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes

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## Abstract

**Purpose** The aim of the present study is to evaluate if remote monitoring with the CareLink Network may improve clinical management of tachyarrhythmias and heart failure episodes in patients treated with biventricular defibrillators (CRT-D).

**Methods** Patients implanted with CRT-D for more than 6 months received the CareLink monitor and were trained to perform device interrogation. At-home transmissions were scheduled at 2 weeks, 1 and 2 months after training, with a final in-office visit after 3 months.

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**Results** Sixty-seven patients performed 264 data transmissions. Twenty-three unscheduled data transmissions were requested by the centers after patient contact. Ventricular tachyarrhythmias were reported in nine patients during 16 data reviews. Thirteen data reviews (81%) were performed remotely via CareLink transmissions (nine scheduled and four unscheduled), in seven patients. Of these events, in two cases (15%) in-hospital visits were requested, while in 11 (85%) no action was needed and no additional in-clinic visits were scheduled. During the study period, in 20/28 (71%) intra-thoracic impedance alerts, the patients remotely transmitted their device data. After remote data review, in ten cases drug therapy was adjusted by phone and in four cases no action was needed and the patient reassured. In six episodes an in-hospital extra visit was scheduled. On the whole, in 14 cases (70%), the patient could be managed remotely avoiding a visit to the hospital. **Conclusions** Our study showed that remote follow-up is an efficient method to manage tachyarrhythmias and heart failure episodes in CRT-D patients. Early reaction to clinical events may improve overall patient care.

**Keywords** Defibrillator · Cardiac resynchronization therapy · Home monitoring · Remote control · Heart failure · Tachyarrhythmias

## 1 Introduction

Implantable cardioverter defibrillator (ICD) therapy for the prevention of sudden cardiac death [1–4], and cardiac resynchronization therapy (CRT), with or without ICD

capabilities [5, 6], for the treatment of heart failure have been shown to be effective in improving overall survival, and are now included in current guidelines [7, 8]. This has led to a rise in device implantation rate and to a growing demand for device follow-up. In response, several systems are being introduced in Europe capable of remote device monitoring. [9–11].

For heart failure patients, remote monitoring provides an alternative option to frequent in person visits and, by the data stored in the implanted device memory, makes physicians early aware of issues related to device function or patient clinical status. The CareLink Network (Medtronic, Inc, Minneapolis, MN, USA) has been operational in the United States since 2001 and to it has been adopted by several clinics to allow remote device check in defibrillator patients.

The aim of the present study is to evaluate if remote monitoring with the CareLink Network may improve clinical management of tachyarrhythmias and acute heart failure episodes in patients treated with CRT-D devices.

## 2 Methods

### 2.1 The system

The CareLink system includes a patient monitor plugged into a standard analog telephone connection, and a lightweight wand to communicate with the implanted device. Interrogation of the device and transmission of the data occur when the patient places the wand over the implanted device. The patient's information is sent to a secure Network server via the telephone connection. It is not possible to remotely reprogram the implanted device.

The clinical staff can review device information, on a secure Web site via the Internet. Available data are equivalent to that which can be retrieved at an in-office visit: presenting rhythm, automatic device diagnostic data and stored episode electrograms.

### 2.2 Study design

Patients implanted with a CRT-D device according to current guidelines were eligible for the study. At the enrollment the CRT-D (InSync Sentry model 7298, Medtronic Inc., Minneapolis, MN, USA) had to be implanted from more than 6 months. These devices, in addition to standard features, are capable of continuously assessing several diagnostic variables such as patient activity, mean heart rate, heart rate variability and intra-thoracic impedance (as a measure of fluid overload). For this latter variable, an audible alarm may be enabled to alert the patient when a programmable threshold is crossed.

The patients had to be able to use the monitor and had to sign the informed consent approved by the Ethical Committees.

At the enrollment, a baseline visit was performed and the patients received the CareLink monitor and were instructed on how to use the system to perform home interrogation and transmission.

Patients completed a test transmission approximately 2 weeks after the baseline clinic visit and training session. Subsequent data transmissions were performed 1 and 2 months after the baseline visit. A final in-clinic visit was scheduled approximately 3 months after the baseline visit.

The clinic staff was asked to review the implanted device data that had been remotely transmitted from the patients to the Web site.

The patients were instructed to contact the center either if they had received an ICD discharge or if they had heard an audible alert or in case of symptoms. Under these circumstances, the responsible physician had to assess the patient file, to contact him by phone and he could request additional device transmissions, unscheduled visits or emergency room admissions.

In this report continuous data are expressed using means and standard deviation, and categorical data in percentages.

## 3 Results

Sixty-seven patients implanted with a CRT-D device have been enrolled. In Table 1 demographics and clinical parameters at implant have been summarized. The median time since the implant was 11 months [range 6–20].

**Table 1** Demographics and baseline clinical parameters at device implantation

Patients	N=67
Male gender, <i>n</i> (%)	58 (87)
Age, years	64±9
Ischemic etiology, <i>n</i> (%)	24 (36)
Primary prevention, <i>n</i> (%)	56 (84)
NYHA class	2.5±0.5
QRS duration, ms	152±32
LV ejection fraction, %	26±6
LV end-diastolic volume, ml	242±115
LV end-systolic volume, ml	170±89
LV end-diastolic diameter, mm	69±8
LV end-systolic diameter, ml	58±11
Mitral regurgitation, grade	2.2±1.0
Chronic atrial fibrillation, <i>n</i> (%)	5 (7)
Hypertension, <i>n</i> (%)	29 (43)
Chronic obstructive pulmonary disease, <i>n</i> (%)	5 (7)
Diabetes, <i>n</i> (%)	8 (12)

**Table 2** Programming of device features at enrollment with regard to ventricular tachyarrhythmia detection and intra-thoracic impedance monitoring

Device parameters	
VF therapy ON, <i>n</i> (%)	67 (100)
Detection cutoff for VF, ms	312±16
NID for VF: 12/16, <i>n</i> (%)	67 (100)
VT therapy ON, <i>n</i> (%)	30 (45)
VT therapy: CV, <i>n</i> (%)	3 (5)
VT therapy: ATP, <i>n</i> (%)	27 (40)
Detection cutoff for VT, ms	396±22
NID for VT: 16, <i>n</i> (%)	47 (70)
NID for VT: 20, <i>n</i> (%)	5 (8)
NID for VT: 24, <i>n</i> (%)	15 (22)
Intra-thoracic impedance monitoring ON, <i>n</i> (%)	67 (100)
Alert threshold: 60 ohm×day (nominal value), <i>n</i> (%)	58 (87)
Alert threshold: from 70 to 120 ohm×day, <i>n</i> (%)	4 (6)
Alert threshold: from 130 to 180 ohm×day, <i>n</i> (%)	5 (7)

VF ventricular fibrillation, VT ventricular tachycardia, NID number of intervals to detect, CV cardioversion, ATP antitachycardia pacing

In Table 2 the programming of device features at enrollment is reported, with regard to ventricular tachyarrhythmia detection and therapy, and intra-thoracic impedance monitoring.

### 3.1 Clinical events

Clinical events documented in the study included death, hospitalization for cardiac reasons, emergency room admis-

sion, and cardiac symptoms leading to medical intervention. During the follow-up, 32 clinical events were reported in 29 patients.

One patient died because of refractory heart failure. Six patients had to be hospitalized because of acute heart failure; furthermore four emergency room admissions and five in-hospital visits were reported.

Two patients underwent five hospitalizations because of tachyarrhythmias and three additional in-hospital visits were reported during follow-up.

### 3.2 Data transmissions and reviews

During the evaluation, the clinics performed 32 sessions of remote data review. The minimum set of data analyzed by the investigators during the review sessions included the intra-cardiac electrograms collected at the time of the interrogation, the overall summary of the device status and the arrhythmic and alert episode counters, the lead parameters and clinical diagnostic long-term data trends. In 19 of the 32 review sessions, 1 or more technical or clinical trigger events came up (Table 3).

On the whole, the 67 patients performed 264 transmissions, 23 of which were unscheduled. In all unplanned remote sessions, data transmissions were requested by the clinical staff following symptoms or events.

Reasons for these unplanned transmissions were as follows: the audible alert was triggered signifying possible intra-thoracic fluid accumulation (*n*=11), a shock was delivered by the device (*n*=3), patients reported symptoms

**Table 3** Device and patient related observations recorded during follow-up with scheduled and unscheduled data reviews

Events/patients	Description	Management/outcome
<i>Device management</i>		
6 observations in 6 patients	Pacing parameters to be modified Activation of rate response Optimization of A-V delays	The reprogramming was judged as non-urgent and deferred to the upcoming in-hospital visit.
<i>Arrhythmic episodes</i>		
16 interrogations with episodes detected in 9 patients	Ventricular tachycardia and fibrillation detected by the ICD	After remote data review (13 events) In-hospital visits were required (2 events) No actions needed (11 events) ER admissions without data transmission (3 events) for Arrhythmic storms (2 events in 1 patient) Ventricular fibrillation with multiple shocks (1 event)
1 episode in 1 patient	Symptomatic atrial fibrillation	An in-hospital visit was required after data review
<i>Device alerts</i>		
28 alerts in 23 patients	Decrease in intra-thoracic impedance	After remote data review (20 episodes) In-hospital visits were required (6 episodes) Telephone assessment with drug therapy adjustment (10 episodes) No actions needed (4 episodes) In-hospital visits without data transmission (8 episodes): ER admissions (5 episodes) Outpatients' visits (3 episode)

In Fig. 1, an episode of fast ventricular tachycardia appropriately detected and interrupted by shock delivery is reported. After a phone contact to verify the appropriateness of drug therapy and the general status, the patient was reassured and no further action was planned.

In one patient, an episode of paroxysmal 2:1 atrial flutter was detected and remotely reviewed, as shown in the Fig. 2. After data remote reviewing, the patient was called back to the hospital for an extra visit. Antiarrhythmic drug therapy was modified.

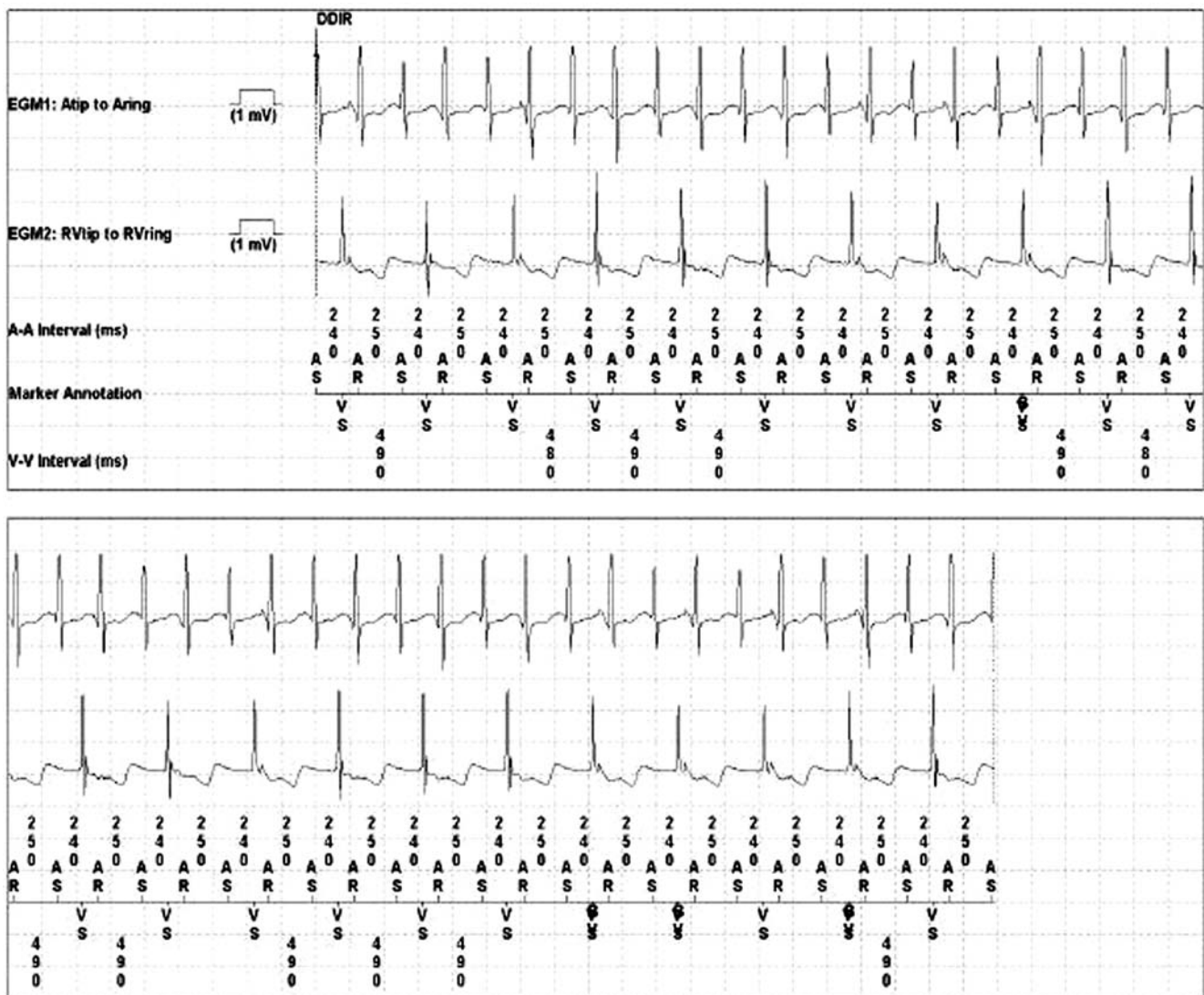
### 3.5 Heart failure alerts

During the study, 22 episodes of worsening heart failure with signs of impending pulmonary congestion occurred in 19 patients (28%). Of these, 20 were associated with a decrease in intra-thoracic impedance based on the diagnostic data in the device and communicated via audible alert. On the whole 28 alerts for possible fluid accumulation were triggered, of which eight were judged to be false positive. Device alerts were defined as false positive in the absence of an episode of heart failure decompensation diagnosed within 2 weeks after initial alert. According to these data, the sensitivity of OptiVol Alert was 91% and the positive predictive value was 71%.

The top trace shows EGM1: AIP to Aving (1 mV) and EGM2: RVtip to Riving (1 mV). Below the EGMs is a timeline with marker annotations (A, R, S, V, T, F, P) and V-V intervals (ms). A burst of FVT Rx 1 is indicated. The bottom trace shows a zoomed-in view of the FVT Rx 1 Burst, with a 34.9 J energy delivery indicated.

investigator to verify the appropriateness of the device programming in terms of tachycardia detection and therapy. After a phone contact to verify the adequacy of the drug therapy and to reassure the patient, no further visits were scheduled





**Fig. 2** The patient (male, 70 years, dilated cardiomyopathy, NYHA Class II, ejection fraction 35%, QRS width 160 ms) called the center for worsening of symptoms and palpitations. An extra data transmission was

requested and the 10 s atrial and ventricular electrogram captured at interrogation showed the occurrence of an ongoing episode of paroxysmal 2:1 atrial flutter. An extra in-hospital visit was performed

Among the 28 intra-thoracic impedance alerts, in 20 the patients remotely transmitted their device data, which allowed the access to more information in order to evaluate their clinical condition. In ten cases drug therapy was adjusted by phone, in four cases no action was needed and the patient reassured, while in six episodes an in-hospital extra visit was scheduled. On the whole, in 14 cases, the patient could be managed remotely avoiding a visit to the hospital.

In eight cases, the patients went directly to the hospital without transmitting their device data to the clinic either to the Emergency Department (five cases) or to the outpatient clinic (three cases).

In Fig. 3(a) case report of a patient remotely managed after an intra-thoracic impedance alert is reported. The fluid index alert was associated with reduced daily activity and

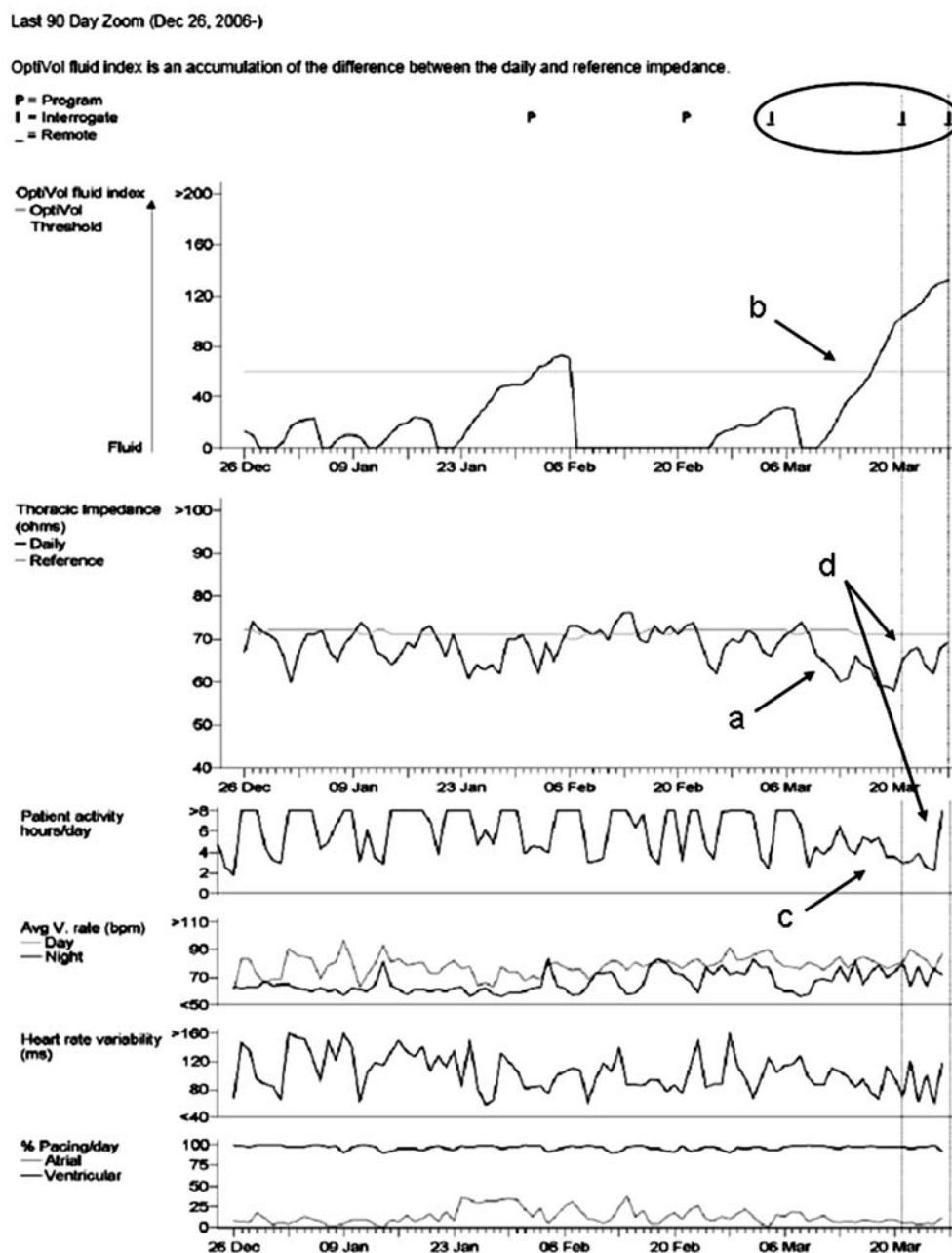
increased mean heart rate. Diuretic dosage was adapted by phone and the benefits of modified therapy could be evaluated after 1 week by a new remote transmission.

#### 4 Discussion

The present study demonstrates that in patients implanted with a CRT-D device atrial and ventricular tachyarrhythmias and heart failure episodes may be effectively managed by the CareLink Network system for remote follow-up.

The CareLink performs full interrogation and transmission of device data. The intra-cardiac electrograms collected at the time of the interrogation, the overall summary of the device status and the counters of arrhythmic and alert episodes, the trends of lead parameters and the long-term

**Fig. 3** The patient (male, 65 years, dilated cardiomyopathy, NYHA Class II, ejection fraction 23%, QRS width 160 ms) heard the alert and contacted the center. An extra transmission was requested and a decrease of intra-thoracic impedance (*a*) with increase of the “Fluid Index” above the alert threshold (*b*) was verified via remote data review, together with a reduction of the patient daily activity (*c*). At the telephone follow-up, the patient reported the worsening of heart failure symptoms. The increase of diuretics dosage was prescribed and an extra data transmission was scheduled after 1 week. This subsequent assessment demonstrated an ongoing increase of impedance and daily activity (*d*) that was accompanied by the remission of patient symptoms



trends of clinical diagnostics may be reviewed remotely. Available information is not different from that retrieved at an in-office visit. The main advantage is represented by the possibility of early reaction to patient symptoms and device alerts without waiting for the patient coming to the hospital either for scheduled or unscheduled follow-ups.

Lazarus [10] showed a high number of device and clinical observations recorded in the subgroup of his CRT-D patients. Similarly, we noticed many events during scheduled and extra transmissions. In particular, the overwhelming majority of episodes and alerts were disease-related: ventricular arrhythmias, atrial fibrillation, and heart failure related events.

A major objective for device follow-up is to ensure proper sensing, classification, and therapy of any tachycardia episodes. The electrograms stored in the ICD memory represent the most useful tool to evaluate appropriate detection and treatment of atrial and ventricular arrhythmias [12, 13]. With remote monitoring systems the electrograms can be retrieved remotely [9, 14, 15].

In our experience, the majority of cases of ventricular arrhythmia episodes were managed remotely without scheduling additional visits, confirming that a large proportion of post-shock interrogations do not require any device reprogramming, as we previously observed [16].

In one patient we recorded the occurrence of an episode of symptomatic paroxysmal atrial flutter that triggered an extra transmission and the prompt adjustment of the therapy.

Early detection of atrial tachyarrhythmias may facilitate the timely introduction of protective interventions against thromboembolic events, limit inappropriate therapy delivery in ICD recipients, and anticipate adverse hemodynamic effects, notably loss of resynchronization, in patients treated with CRT. Thus, remote monitoring with automatic early detection may become an important tool in order to allow prompt and early reaction [17, 18].

The CareLink device tested in this study did not permit to automatically detect atrial fibrillation episodes and perform transmission without patient cooperation. However, the incoming new system version will be able to perform automatic detection and transmission of asymptomatic episodes.

A previous study showed that intra-thoracic impedance, measured by an implanted device, correlates inversely with the pulmonary capillary wedge pressure and the net fluid loss in heart failure patients hospitalized for fluid overload [19].

A recent observational study followed 373 patients implanted with an ICD presenting such diagnostic capability and reported that in clinical practice the algorithm was able to detect clinical heart failure decompensation with both sensitivity and positive predictive value of 60% [20].

For the first time we studied the follow-up of a group of heart failure patients implanted with a device capable of intra-thoracic impedance measurement and alert for possible fluid accumulation, managed with a device for remote monitoring. Regardless of the short follow-up period, we recorded many episodes of heart failure decompensation and signs of impending pulmonary congestion. Many of them were correctly identified by the algorithm (sensitivity 91%, positive predictive value 71%).

The better results obtained in our series with respect to previous experiences with this algorithm [20], may be ascribed to the fact that we enrolled patients implanted from more than 6 months. Indeed, in some cases the patients had experienced a preceding event and the device alert threshold was adjusted in response to that, in order to optimize the detection.

The accuracy of an algorithm for the detection of clinical decompensation assumes even higher importance in the perspective of remote management of heart failure patients: if the patient is seen less often, the detection and subsequent therapy might be significantly delayed in the absence of adequate alert systems.

In addition to the performance of the detection algorithm, it should be emphasized the high percentage of episodes that were successfully managed without requiring additional in-hospital visits, by means of remote data review and assessment of symptom status and therapy compliance by phone.

Moreover, patients might not respond or hear the audible impedance alert, as recently reported [21]. Thus, automated telemetric transmission of alerts to the physician may shorten the delay between alert and therapy initiation, further improving the clinical outcome.

Although we tested remote follow-up only in stable CRT patients, we can hypothesize that it may be very useful also in the initial time of CRT. Indeed, monitoring of heart failure parameters could early identify responders to CRT and could allow prompt titration of drug therapy. Definitely, this could result in more frequent patient transmissions and heavier workload for remote data review, but this aspect will be better addressed with the new system version that allows automatic wireless transmissions.

The lack of remote programming capabilities, common to all currently available follow-up systems, could represent a potential limitation. However, in our population we did not report any need to reprogram the device or to schedule extra visits for this purpose. This confirms our preliminary data showing that reprogramming of device parameters are significantly less frequent 6 months after implant, allowing an efficient use of remote follow-up systems [16].

Finally, as regard to technical issues [22], during the study we did not record device-related observations. Nonetheless, it is predictable that in the long-term an increasing rate of such events (i.e. impending elective replacement indicator) will be transmitted.

Battery depletion is currently identified by standard device surveillance and by shortening of follow-up intervals when the ICD approaches end-of-life [23]. This acceleration of the rate of ambulatory visits could be obviated by remote monitoring.

#### 4.1 Limitations

The main limitation of present study is the lack of a control group of patients managed by traditional methods. Although our findings suggest that remote monitoring may improve the clinical management of CRT-D patients, randomized controlled trials are warranted to evaluate the clinical impact of remote monitoring when compared with standard method.

## 5 Conclusions

Our study demonstrates that remote monitoring may improve clinical management of tachyarrhythmias and heart failure in patients implanted with CRT-D devices and that it may lead to a reduction of health care utilizations, if included in a disease management program.

Early detection and review of device and clinical events, allowed by the diagnostic features of current ICDs and by

remote follow-up systems, suggest the potential impact of this technology on overall patient care. Controlled studies are needed to demonstrate if such a new approach to patient care may improve overall clinical outcome.

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**Conflict of Interest Disclosure** Serena Gilardi and Sergio Valsecchi are employees of Medtronic, Inc. No other conflicts exist.

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