



# Remote monitoring and telemedicine in heart failure: implementation and benefits

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Accepted: 9 March 2021 / Published online: 7 May 2021

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## Abstract

**Purpose of review** Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is recommended as part of the individualized multidisciplinary follow-up of heart failure (HF) patients. Aim of this article is to critically review recent findings on RM, highlighting potential benefits and barriers to its implementation.

**Recent findings** Device-based RM is useful in the early detection of CIEDs technical issues and cardiac arrhythmias. Moreover, RM allows the continuous monitoring of several patients' clinical parameters associated with impending HF decompensation, but there is still uncertainty regarding its effectiveness in reducing mortality and hospitalizations.

**Summary** Implementation of RM strategies, together with a proactive physicians' attitude towards clinical actions in response to RM data reception, will make RM a more valuable tool, potentially leading to better outcomes.

**Keywords** Remote monitoring · Telemedicine · Heart failure · pacemaker · Implantable cardioverter defibrillator · Cardiac resynchronization device

## Introduction

Heart failure (HF) is a highly prevalent cardiovascular (CV) disease affecting approximately 1–2% of the adult population in developed countries [1–3]. Due to a high rate of morbidity and mortality, it imposes a remarkable economic burden on healthcare systems. A growing number of cardiac implantable electronic devices (CIEDs) are used to treat bradyarrhythmias and

tachyarrhythmias in HF patients and in a subset of appropriately selected patients to correct electrical and mechanical dyssynchrony through biventricular pacing [4, 5•, 6–8]. Many modern CIEDs harbor remote monitoring (RM) systems which can gather, store, and transmit to hospitals/clinicians data regarding the status of the device itself and a multitude of clinical parameters while the patient is at home [9]. These include early recognition of device-related malfunctions, detection of arrhythmias, heart and respiratory rate statistics and, in some cases, heart sounds, intrathoracic impedance, and early sign and symptoms of HF [10, 11], potentially leading to a timely clinical action. Thus, RM has joined in-person evaluation in the follow-up of HF patients. Nevertheless, despite the undoubted potential benefits, robust data showing an improvement of outcomes in patients followed-up with RM as compared with in-office only evaluations are scant.

Aim of this article is to critically review recent data on RM of CIEDs in HF patients, highlighting potential benefits and barriers to its implementation. The evaluation of the effects of other types of RM, namely, structured telephone support, telemedicine, and remote monitoring with implanted monitoring-only devices, is outside the object of this review.

This article is part of the Topical Collection on *Myocardial Disease*

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## Detection of CIEDs-related complications

Device-based RM has a well-established role beside in-person office visits in the early detection of CIEDs technical issues [12–16]. Moreover, it is useful to reduce the incidence of inappropriate ICD shocks. The number of system-related complications per year (including lead complications and generator malfunctions) is not negligible [17–20] and their prompt identification can improve patients' management. In the TRUST trial, 1339 ICD patients were randomized in a 2:1 fashion to RM with daily transmissions or to conventional care with office visits only. During the 15th month follow-up, RM detected generator and lead problems earlier than conventional care (median of 1 vs. 5 days respectively;  $p = 0.05$ ) [13]. RM proved also safe and useful in reducing total in-hospital device evaluations [11] and demonstrated robust transmission reliability (91%) without reducing battery longevity [21]. Recently, Watanabe et al. [22•] studied 1274 consecutive patients implanted with a PM randomized to RM only or in-office follow-up (2 visits per year). After 24 months, RM only follow-up did not increase the occurrence of death, stroke, or cardiovascular events requiring surgery (10.9% vs. 11.8%, respectively,  $p < 0.01$  for noninferiority) suggesting that RM is safe and able to reduce resource consumption. Device and lead advisories represent a major concern for the physician and for the patient as well. Despite rare [23], device malfunctions can be life-threatening and, on the other hand, replacement of the generator/leads before an overt malfunction may expose the patient to unnecessary risks [24, 25] as well as an organizational burden and costs for hospitals and the health care system [26]. Guédon-Moreau et al. [14] reported a 7.5% lead dysfunction rate in 40 recipients of a high-voltage lead prone to fracture, remotely followed for  $22 \pm 4$  months. In a retrospective cohort of patients with ICD lead fractures, RM sent alert messages in 91% of all lead-related ICD complications [27]. In this setting, RM offers a double benefit: (1) provides an immediate detection of abnormal device behavior through a continuous surveillance of several parameters such as lead impedance and sensing and (2) avoids too early device replacements.

## Detection and management of cardiac arrhythmias

CIEDs can record, analyze, and store different types of atrial and ventricular arrhythmias through one or more intracavitary catheters. The continuous monitoring of atrial activity can identify arrhythmic episodes characterized by high atrial rate (AHREs) in asymptomatic patients with no history of clinical atrial fibrillation (AF). These episodes, common in patients necessitating CIEDs, include different forms of atrial tachyarrhythmias such as atrial tachycardias, atrial flutter and AF

[28]. AHREs are associated with a considerable risk of adverse clinical events including death [29], hospitalizations [30, 31], stroke/systemic thromboembolism [32–34], occurrence of heart failure [35], and progression to clinical AF [36]. In 2012, 2580 patients with no history of AF were enrolled in the prospective ASSERT [32] trial and were followed for a mean of 2.5 years. AHREs were associated with a 2.5-fold (95% CI 1.28–4.89) higher risk of stroke or systemic embolism at the multivariate analysis. These findings were later confirmed in large observational studies [37–39] and meta-analysis [40]. It also emerged that the higher the burden of AHREs, the higher the risk of future thromboembolic events [41]. RM proved successful in the early identification of AHREs and may reduce the time to potentially meaningful clinical decision such as the institution of an oral anticoagulant therapy, which offers huge and well-established benefits in patients with clinical AF and, presumably, also in selected patients with AHREs [11, 41–46]. Ricci et al. [47] conducted a Monte Carlo simulation showing that in patients with AHREs daily RM may reduce the stroke risk with respect to standard in-person visits scheduled every 6 to 12 months, but ad hoc studies are needed to demonstrate the possible clinical benefits of RM in this setting. In a subanalysis of the ASSERT trial [31], AHREs progression to episodes lasting more than 24 h or to clinical AF was independently associated with HF hospitalization (HR 4.58; 95% CI 1.6–12.8). Therefore, a timely identification of AHREs and of their progression to a higher AF burden or to clinical AF has the potential to improve the outcome of HF patients [36, 48]. Finally, ICDs have a well-recognized life-saving role [49–52], but inappropriate ICD shocks are fearful and common events associated with increased mortality [53]. In the THORN registry [54] (a large RM database of 1882 ICD patients), a 9% prevalence of inappropriate ventricular arrhythmia detection and a 3% prevalence of inappropriate shocks over  $13.7 \pm 3.4$  months of follow-up was reported. In a substudy of the ECOST trial [55], during 27 months follow-up, 5% of patients in the RM group received 1 or more inappropriate shocks versus 10.4% in the control group, suggesting that RM can be effective in the prevention of inappropriate ICD shocks.

## Heart failure: a major public health threat

The prevalence of chronic HF (1–2% of the adult population in developed countries) is expected to increase with ageing population [1–3]. Over the last decades, new treatments improved patients outcomes, but morbidity, mortality, and hospitalization rates remain still high [56]. Acute exacerbations of HF often require prolonged in-hospital treatments and also contribute to disease progression and adverse prognosis. Thirty days all-cause readmission rate reaches up to 20% [57] and 10-year mortality approaches 99% [58]. Hospitalizations are

at the center of the high cost of HF care accounting for approximately 70% of the global costs [59]. Therefore, huge efforts should address this unmet need. The vast majority of HF readmissions are due to fluid overload [60] and the process of decompensation starts weeks before the acute event through subtle hemodynamic changes which can be detected by some RM systems [61]. A persistent increase in filling pressures in response to small augmentation in intravascular volume is the first measurable event that can be observed. Shortly after, autonomic adaptation through sympathetic activation and vagal withdrawal intervene to increase cardiac output. Heart rate variability is a physiologic parameter that can be measured by CIEDs and directly relates to the autonomic control of the heart: the lower the heart rate variability, the higher the sympathetic tone. One study found that heart rate variability was lower in unstable patients at risk for hospitalization and changes could have been seen 16 to 20 days before symptoms of worsening heart failure with a 70% sensitivity [62]. The next pathophysiologic step is progression to pulmonary circulation congestion, which can be detected by changes in intrathoracic impedance about 2 weeks before hospitalization [63]. Weight changes (>2 pounds in 24–36 h) occur approximately 7 days before hospitalization but, although specific (97%), this is not a sensitive (9%) nor an early marker [64]. Several studies failed to demonstrate that weight gain alone is valuable for HF management [65, 66]. Finally, symptoms develop in the last phase of this process, just before the hospitalization [61].

## Remote monitoring of heart failure patients

RM aims to respond to the unmet need of HF hospitalizations and deaths prevention and it is recommended as part of a multidisciplinary approach to the management of HF patients [5, 67] (Fig. 1). Among the multiple parameters that can be continuously or frequently assessed, many commercially available CIEDs allow also the measurement of intrathoracic impedance, which is inversely correlated with pulmonary capillary wedge pressure and fluid balance. A decrease in intrathoracic impedance precedes and predicts patient symptoms and hospital admissions [63, 68–71]. In 2011, van Veldhuisen et al. [72] randomized 335 chronic HF patients implanted with an ICD/CRTD featuring a monitoring tool capable of tracking changes in intrathoracic impedance in two groups. In the access arm physicians received RM information in case of preset threshold crossings, while in the control arm they did not. During  $14.9 \pm 5.4$  months of follow-up, 29% of patients in the access arm and 20% of patients in the control arm reached the composite endpoint of all-cause mortality and HF hospitalizations (HR 1.52; 95% CI 0.97–2.37), showing that the use of the monitoring tool was not beneficial. Additional algorithms incorporating multiple HF related indexes such as

thoracic impedance, heart sounds (S1, S3), respiratory rate and relative tidal volume, activity response and heart rate have been developed to overcome the limited efficacy of single parameters [73]. In the study by Boehmer et al. [10], the device-based diagnostic algorithm combining these indexes showed 70% sensitivity in predicting impending HF decompensation. The reported 34 days median time between the alert and the HF events is potentially valuable to establish an early therapy and the 1.47 per patient-year unexplained alert rate is acceptable. Clinical usefulness of this algorithm will be clarified in upcoming clinical trials (MANAGE-HF, NCT03237858 and PREEMPT-HF, NCT 03579641) targeted to assess if decision making based on the information provided by these algorithms may result in significant changes in hospitalization burden and cardiovascular mortality as compared to standard clinical judgment. More recently, in a cohort of 918 ICD/CRTD patients, D'Onofrio et al. combined the Seattle Heart Failure Score with the temporal trends of specific individual device-based variables to test an index capable of predicting the first HF hospitalization post-implant. Preliminary data show a 73.3% sensitivity, with low false alert rate [74]. Similarly, in 2010, the TRUST randomized controlled trial (RCT) showed that RM was safe and allowed an early detection of actionable events (defined as an event that prompted initiation/up-titration of antiarrhythmic medications or significant ICD reprogramming/system revision) compared with standard care [11], but this advantage failed to translate into a clinical benefit in most of the following RCTs (Table 1). In the MORE-CARE prospective, multicenter, randomized controlled trial, 865 CRTD patients were randomized to RM checks alternating with in-office follow-up or in-office follow-up only. No significant difference was found in the primary endpoint (a composite of death and cardiovascular and device-related hospitalization) between the 2 groups (HR 1.02; 95% CI 0.80–1.30). However, the authors found a significant 38% reduction in the use of healthcare resources (i.e., 2-year rates of CV hospitalizations, CV emergency department admissions, CV in-office follow-up) in favor of the RM group, mainly as a result of a decrease in in-office visits [84]. A total of 1650 HF patients implanted with a CIED (ICD, CRTD or CRTP) were randomly assigned to active RM or to usual care in the REM-HF randomized controlled trial. RM consisted of weekly transmissions in the active arm and also transmissions every 6 months in the usual care arm, but in the latter group, they were not used to manage HF in any form. After a median of 2.8 years follow-up, no significant differences were observed between the 2 arms in the composite endpoint of all-cause death or CV hospitalizations (HR 1.01; 95% CI 0.87–1.18) or in its individual components. The authors concluded that RM strategy provided no benefit over usual care for patients with HF [85]. A considerable proportion of patient (38% at 24 months) transmitted data for <75% of the weeks. Beside this gap in achieving a comprehensive monitoring,

**Table 1** Randomized clinical trials (RCTs) comparing remote monitoring (RM) versus in-office only follow-up

Study	RM system	Sample size (n)	Average follow-up <sup>a</sup> (months)	Device type	Primary endpoint	Results
PREFER, 2009 [75]	CLN	897 (14% HF)	12	PM	<ul style="list-style-type: none"> <li>• Mean time to first diagnosis of clinically actionable events</li> </ul>	<ul style="list-style-type: none"> <li>• 5.7 (RM) vs. 7.7 (CG) months (<math>p &lt; 0.01</math>)</li> </ul>
Al-Khatib et al., 2010 [12]	CLN	151	12	ICD, CRTD	<ul style="list-style-type: none"> <li>• Composite of CV hospitalization, emergency room visit for cardiac cause and unscheduled visit to the electrophysiology clinic for a device-related issue</li> </ul>	<ul style="list-style-type: none"> <li>• 32% (RM) vs. 34% (CG) (<math>p = 0.8</math>)</li> </ul>
ECOST substudy, 2010 <sup>b</sup> [14]	HM	40	22	ICD	<ul style="list-style-type: none"> <li>• Monitoring of device status and leads function in recipients of high-voltage ICD leads under advisory</li> </ul>	<ul style="list-style-type: none"> <li>• 3/18 (RM) vs. 0/18 (CG) lead fracture detection</li> </ul>
TRUST, 2010 <sup>b</sup> [11, 13]	HM	1339	12	ICD	<ul style="list-style-type: none"> <li>• Number of total in-hospital device evaluations</li> <li>• Adverse event (deaths, stroke, surgical intervention) rate</li> <li>• Time from arrhythmic event to physician evaluation</li> <li>• Detection of device-related complications</li> </ul>	<ul style="list-style-type: none"> <li>• 2.1 (RM) vs. 3.8 ppy (<math>p &lt; 0.01</math>)</li> <li>• 10.4% in both groups (<math>p = 0.01</math> for noninferiority)</li> <li>• 1 (RM) vs. 36 (CG) days (<math>p &lt; 0.01</math>)</li> <li>• 4.4% (RM) vs. 1.4% (CG) (<math>p &lt; 0.01</math>)</li> <li>• 4.6 (RM) vs. 22 (CG) days (<math>p &lt; 0.01</math>)</li> <li>• 3.3 (RM) vs. 4 (CG) days (<math>p &lt; 0.01</math>)</li> </ul>
CONNECT, 2011 [42]	HM	1997	15	ICD, CRTD	<ul style="list-style-type: none"> <li>• Time from clinical event (arrhythmias, CV disease progression and device issues) to clinical decision</li> </ul>	<ul style="list-style-type: none"> <li>• 29% (RM) vs. 20% (CG) (<math>p = 0.06</math>), HR 1.52 (95% CI 0.97-2.37)</li> </ul>
DOT-HF, 2011 [72]	OV (CLN)	335	14.9	ICD, CRTD	<ul style="list-style-type: none"> <li>• Mean length of CV hospitalization</li> <li>• Composite of all-cause mortality and HF hospitalizations</li> </ul>	<ul style="list-style-type: none"> <li>• 17.3% (RM) vs. 19.1% (CG) (<math>P &lt; 0.01</math> for noninferiority)</li> </ul>
COMPAS, 2012 <sup>b</sup> [43]	HM	538	18.3	PM	<ul style="list-style-type: none"> <li>• Composite of all-cause death and hospitalizations for device-related or CV adverse events</li> </ul>	<ul style="list-style-type: none"> <li>• 30.1% (RM) vs. 28.5% (CG) (<math>p = NS</math>)</li> </ul>
EVATEL, 2012 [76]	NA	1501	12	ICD	<ul style="list-style-type: none"> <li>• Composite of death, CV hospitalization, and ineffective or inappropriate device therapy</li> </ul>	<ul style="list-style-type: none"> <li>• 75 vs. 117 visits, 35% reduction (<math>p &lt; 0.01</math>)</li> </ul>
EVOLVO, 2012 [77]	CLN	200	16	ICD, CRTD	<ul style="list-style-type: none"> <li>• Rate of emergency department or urgent in-office visits for HF, arrhythmias, or ICD-related events</li> </ul>	<ul style="list-style-type: none"> <li>• 38.5% (RM) vs. 41.5% (CG) (<math>p &lt; 0.05</math> for noninferiority), HR 0.91 (95% CI 0.68-1.23)</li> </ul>
ECOST, 2013 <sup>b</sup> [78]	HM	433	24.2	ICD	<ul style="list-style-type: none"> <li>• Proportion of patients with <math>\geq 1</math> MAE (deaths and CV/procedure/device-related MAE)</li> </ul>	<ul style="list-style-type: none"> <li>• 0.68 (RM) vs. 2.13 (CG) (<math>p = NS</math>)</li> </ul>
SAVE-HM, 2013 [79]	HM	115 PM	17.1	PM, ICD	<ul style="list-style-type: none"> <li>• Number of outpatient follow-ups</li> </ul>	<ul style="list-style-type: none"> <li>• 57.8% reduction in RM group</li> </ul>
IN-TIME, 2014 <sup>b</sup> [80]	HM	36 ICD	26.3	ICD	<ul style="list-style-type: none"> <li>• Number of adverse events</li> </ul>	<ul style="list-style-type: none"> <li>• No difference between groups</li> </ul>
EuroEco, 2015 <sup>b</sup> [81]	HM	664	12	ICD, CRTD	<ul style="list-style-type: none"> <li>• Worsened composite score of all-cause death, hospital admission for HF, change in NYHA class and in patient global self-assessment</li> </ul>	<ul style="list-style-type: none"> <li>• 18.9% (RM) vs. 27.2% (CG) (<math>p = 0.01</math>), OR 0.63 (95% CI 0.43-0.9)</li> </ul>
IMPACT, 2015 <sup>b</sup> [44]	HM	303	24	ICD	<ul style="list-style-type: none"> <li>• Total follow-up-related cost for providers</li> </ul>	<ul style="list-style-type: none"> <li>• 204€ (RM) vs. 213€ (CG) (<math>p = NS</math>)</li> </ul>
LIMIT-CHF, 2015 [82]	HM	2718	24	ICD, CRTD	<ul style="list-style-type: none"> <li>• Composite of stroke, systemic embolism and major bleeding</li> </ul>	<ul style="list-style-type: none"> <li>• 2.4 (RM) vs. 2.3 (CG) p100-pp, HR 1.06 (95% CI 0.75-1.51)</li> </ul>
OptiLink HF, 2016 [83]	CLN, MER	80	12	ICD, CRTD	<ul style="list-style-type: none"> <li>• Number of hospital readmission per patient</li> </ul>	<ul style="list-style-type: none"> <li>• 0.3 (RM) vs. 0.2 (CG) (<math>p = 0.95</math>)</li> </ul>
MORE-CARE, 2017 [84]	CLN	1002	23	ICD, CRTD	<ul style="list-style-type: none"> <li>• Composite of death and CV hospitalization</li> </ul>	<ul style="list-style-type: none"> <li>• 45% (RM) vs. 48.1% (CG), HR 0.87 (95% CI 0.72-1.04)</li> </ul>
REM-HF, 2017 [85]	CLN, LAT, MER	865	24	CRTD	<ul style="list-style-type: none"> <li>• Composite of death, CV hospitalization and device related hospitalization</li> </ul>	<ul style="list-style-type: none"> <li>• 29.7 (RM) vs. 28.7 (CG), HR: 1.02 (95% CI 0.80-1.30)</li> </ul>
REMOTE-CIED, 2019 [86]	LAT	1650	33.6	ICD, CRTD/P	<ul style="list-style-type: none"> <li>• Composite of death and CV hospitalization</li> </ul>	<ul style="list-style-type: none"> <li>• 42.4 (RM) vs. 40.8 (CG), HR 1.01 (95% CI 0.87-1.18)</li> </ul>
		595	24	ICD	<ul style="list-style-type: none"> <li>• Effects of RM on health status</li> <li>• Effects of RM ICD acceptance</li> </ul>	<ul style="list-style-type: none"> <li>• No effect on KCCQ total score</li> <li>• No effect on FPAS total score</li> </ul>

**Table 1** (continued)

Study	RM system	Sample size (n)	Average follow-up <sup>a</sup> (months)	Device type	Primary endpoint	Results
At-Home, 2020 <sup>b</sup> [22-]	HM	1274 (25% HF)	24	PM	• Composite of death, stroke, or cardiovascular events requiring surgery	• 10.9% (RM) vs. 11.8% (CG) ( $p < 0.01$ for noninferiority)

Table 1 shows pivotal RCTs comparing RM vs. in-office only follow-up in heart failure patients implanted with CIEDs in terms of mortality, hospitalizations, and other potential RM benefits

CI confidence interval, CLN CareLink Network (Medtronic Inc.; Minneapolis and Tempe, USA); CG control group, CRT-D cardiac resynchronization therapy defibrillator, CRT-P cardiac resynchronization therapy pacing (no defibrillator), CV cardiovascular, FPAS Florida Patient Acceptance Survey, HF heart failure, HM Home Monitoring (Biotronik SE & Co. KG; Berlin, Germany), HR hazard ratio, ICD implantable cardioverter-defibrillator, KCCQ Kansas City Cardiomyopathy Questionnaire, LAT Latitude Patient Management System (Boston Scientific; St Paul, USA), MAE major adverse event, MER Merlin.net (St. Jude Medical; Sylmar, USA), NA not available, NYHA New York Heart Association class, NS nonsignificant, OR odds ratio, OV OptiVol (pulmonary congestion) algorithm, PM pacemaker, ppy per patient-year, RM remote monitoring, RR relative risk

<sup>a</sup> Mean or median, whatever provided in the original publication.

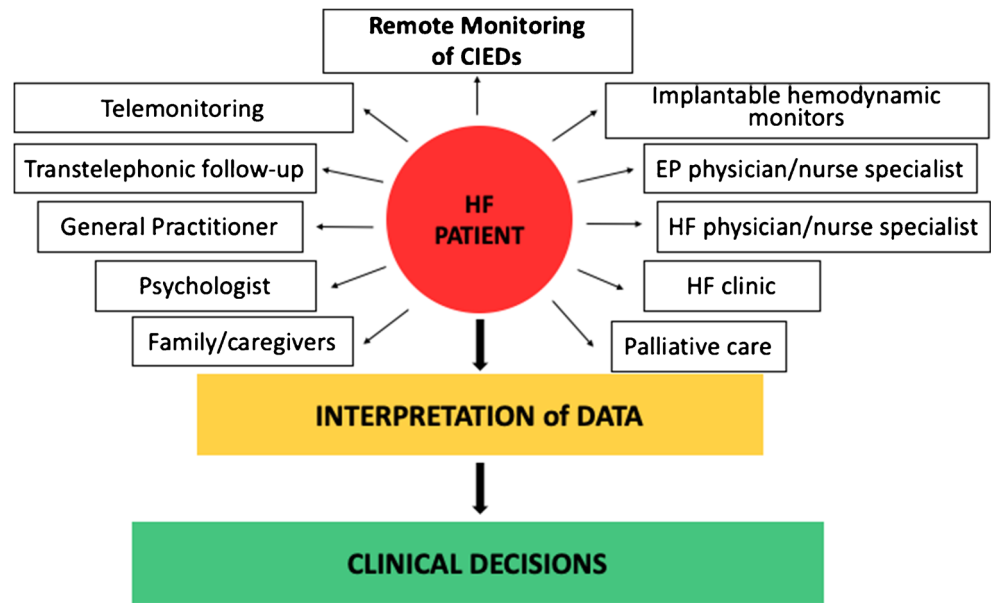
<sup>b</sup> Daily RM transmissions.

centers were overloaded by unfiltered data (a total of 79325 downloads with 10-15 transmission/day per site) rarely leading to a significant clinical action. Less than 1.2% of the transmissions lead to an advise to medical attention and less than 0.3% lead to a medication change. These data highlight the need for collecting the right data and that the benefit on outcomes depend on prompt reactions to a critical interpretation of data and not by informations themselves.

Parthiban et al. [87] meta-analyzed data extracted from 9 RCTs comparing RM versus conventional in-office follow-up. All-cause mortality and hospitalizations data were available for 7 RCTs, including 4932 and 5372 patients, respectively. No significant difference between RM and conventional care groups was observed for neither outcome (odds ratio (OR) 0.83; 95% CI 0.58-1.17 and OR 0.83; 95% CI 0.63-1.10, respectively). The meta-analysis by Klersy et al. [88••] included 11 RCTs for a total of 5702 patients followed for 12-36 months. Consistently with the previous meta-analysis, rates of cardiac hospitalizations (RR 0.96; 95% CI 0.82-1.12) and the composite of emergency room, unplanned hospital visits or hospitalizations (RR 0.99; 95% CI 0.68-1.43) were similar between the RM and the conventional care groups (Table 2). A recent meta-analysis showed no differences in all-cause mortality and HF-related hospitalizations in patients with RM compared with standard care [89]. However, this meta-analysis included also invasive hemodynamic monitoring systems and not only CIEDs-based RM. Finally, Versteeg et al. [86] tried to evaluate the effects of RM on patient-reported outcomes in a cohort of 595 HF patients in the first 2 years after ICD implant. The authors found no difference in terms of patients' health status (assessed by the Kansas City Cardiomyopathy Questionnaire) and ICD acceptance (assessed by Florida Patient Acceptance Survey) between the group of patients randomized to RM and the group randomized to in-office visits only.

IN-TIME is the only RCT up to now that showed a significant mortality benefit of automatic, daily, multiparameter telemonitoring as compared with usual care alone (3% of patients in the RM arm vs. 8.2% in the control arm,  $p = 0.004$ ) in HF patients implanted with ICD or CRTD, albeit hospitalizations for worsening HF did not differ between the two groups. Mean follow-up duration was ≈1 year and mortality was not the primary end point. A considerable deployment of resources has to be acknowledged in this trial. In the RM group (333 patients), the investigators contacted patients on the basis of telemonitored data, starting a standardized telephone interview to establish whether the patient's overall condition or symptoms had worsened or not, whether the patient was regularly taking prescribed drugs, whether there was a sudden increase in body weight or whether and additional clinic follow-up or a visit to the family doctor was scheduled. On the other hand, in the control group (331 patients), telemonitoring data were not accessible until study completion [80]. Large-scale nonrandomized studies point in a

**Fig. 1. Remote monitoring as part the multidisciplinary approach to the treatment of heart failure patients.** *CIEDs* cardiac implantable electronic devices, *EP* electrophysiology, *HF* heart failure



similar direction, showing a survival advantage for patients undergoing RM as compared with those receiving in-person only follow-up [90–92]. However, given the nonrandomized design of these studies, several biases may have affected the results and their generalizability, thus requiring caution in data interpretation.

In recent years, the possibility that daily RM transmissions may increase data processing capacity leading to higher sensitivity and specificity as compared with weekly transmissions has been investigated. Hindricks et al. [93] performed a pooled patient-level meta-analysis of 3 RCTs (TRUST, ECOST, IN-TIME) using the Home Monitoring system that is based on daily verification of transmissions. The authors reported a 1.9% ( $p = 0.037$ ) reduction in the absolute risk of all-cause death at 1 year in the RM group and a 5.6% ( $p =$

0.007) reduction in the composite endpoint of all-cause mortality or hospitalization for worsening HF. The latter analysis was conducted including only 2 trials (ECOST, IN-TIME). Daily transmission of data is an alternative approach as compared to RM systems transmitting preset alerts activated at specific predefined thresholds. In the absence of direct comparisons between these 2 approaches, the superiority of daily RM remains speculative and should be tested towards clinical outcomes at long-term in dedicated randomized trials.

Altogether, these data indicate that RM of CIEDs represents a valuable tool in the early diagnosis of HF decompensation, but its effectiveness in reducing mortality and hospitalizations is still uncertain. They anyway suggest that implementation of RM can be a worth doing strategy, especially in consideration of the impact

**Table 2** Meta-analysis of randomized clinical trials on remote monitoring of cardiac implantable electronic devices from various device manufacturers: effects on mortality, hospitalizations, and visits

Meta-analysis	RM system	Sample size (n)	Average follow-up <sup>a</sup> (Months)	No of studies included	Primary endpoint	Results
Parthiban et al. (2015) [87]	HM, CLN	4932	14.4	7	<ul style="list-style-type: none"> <li>• All-cause mortality (RM vs. CG)</li> <li>• Hospitalizations (RM vs. CG)</li> </ul>	<ul style="list-style-type: none"> <li>• OR 0.83 (95% CI 0.58-1.17)</li> <li>• OR 0.83 (95% CI 0.63-1.10)</li> </ul>
		5372	NA	7		
Klersy et al., (2016) [88••]	HM, CLN	5702	12-36	11	<ul style="list-style-type: none"> <li>• Reduction in total number of visits (RM vs. CG)</li> <li>• Cardiac hospitalizations (RM vs. CG)</li> <li>• Composite of emergency room, unplanned hospital visits, or hospitalizations (RM vs. CG)</li> </ul>	<ul style="list-style-type: none"> <li>• RR 0.56 (95% CI 0.43-0.73)</li> <li>• RR 0.96 (95% CI 0.82-1.12)</li> <li>• RR 0.99 (95% CI 0.68-1.43)</li> </ul>

CI confidence interval, CLN CareLink Network (Medtronic Inc.; Minneapolis and Tempe, USA), CG control group, HM Home Monitoring (Biotronik SE & Co. KG; Berlin, Germany), No number, NA not available, OR odds ratio, RM, remote monitoring, RR, relative risk

<sup>a</sup> Mean or median, whatever provided in the original publication

of COVID-19 pandemic [94, 95] with need for more accurate analysis in the next future.

### Progresses and pitfalls in everyday implementation of remote monitoring

The use of RM has markedly increased in recent years, as shown by the comparison of two Italian surveys conducted in 2012 and 2017 [96]. The global COVID-19 pandemic is further boosting the RM implementation in order to keep social-distancing to the utmost [95]. However, RM is still largely underused in clinical practice [92]. Barriers to its implementation are mainly the lack of reimbursement, need for significant changes in hospitals' workflows, data overload, and increased workload for health-care providers [97–101]. The growing bunch of clinical evidence on the safety and usefulness of RM, combined with the overcoming of the reimbursement issue, will probably lead to a wider overall adoption of this valuable tool, which will obviously will markedly benefit from active involvement of general practitioners, caregivers, and empowered patients [102].

### Conclusions

RM is recommended for the early detection of CIEDs technical issues and early diagnosis and management of cardiac arrhythmias [5, 67]. In recent years, multiparameter RM has gained relevance in the individualized management of HF patients implanted with a CIED. Despite good sensitivity in predicting worsening HF, the role of RM in improving patients' outcome is still matter of debate. Factors that may lead to a more profitable use of RM include a better selection of parameters to monitor and patients to candidate to RM and a more proactive attitude towards disease management of HF, with an appropriate organization of care strictly linking hospital care to home care. A paradigm shift from remote patient monitoring to remote patient management is warranted, translating data into prompt clinical actions.

### Compliance with ethical standards

**Conflict of interest** Dr. Boriani has received small speaker's fees from Medtronic, Boston, Biotronik, Boehringer, and Bayer outside of the submitted work. The other authors report no conflict of interest.

**Consent for publication** This article does not contain any studies with human or animal subjects performed by any of the authors.

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