

openheart Remote monitoring in patients with heart failure with cardiac implantable electronic devices: a systematic review and meta-analysis

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ABSTRACT

Background Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is now the standard of care, but whether the demonstrated benefits of RM translate into improvements in heart failure (HF) management is controversial. This systematic review addresses the role of RM in patients with HF with a CIED.

Methods and results A systematic search of the literature for randomised clinical trials in patients with HF and a CIED assessing efficacy/effectiveness of RM was performed using MEDLINE, PubMed and Embase. Meta-analysis was performed on the effects of RM of CIEDs in patients with HF on mortality and readmissions. Effects on implantable cardiac defibrillator (ICD) therapy, healthcare costs and clinic presentations were also assessed. 607 articles were identified and refined to 10 studies with a total of 6579 patients. Implementation of RM was not uniform with substantial variation in methodology across the studies. There was no reduction in mortality or hospital readmission rates, while ICD therapy findings were inconsistent. There was a reduction in patient-associated healthcare costs and reduction in healthcare presentations.

Conclusion RM for patients with CIEDs and HF was not uniformly performed. As currently implemented, RM does not provide a benefit on overall mortality or the key metric of HF readmission. It does provide a reduction in healthcare costs and healthcare presentations.

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INTRODUCTION

Despite substantial improvements in the treatment of heart failure (HF), contemporary studies show that the 1-year mortality for patients with HF remains at 20%–30% post hospital admission.^{1–3} Cardiac implantable electronic devices (CIEDs) have evolved in their role in the management patients with HF. Implantable cardiac defibrillators (ICDs) provide protection against sudden cardiac death. Cardiac resynchronisation therapy (CRT) reduces mortality and improves quality of life. More recently, remote monitoring

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is the standard of care. While this improves management of these devices, how this contributes to the management of heart failure (HF) is unclear.

WHAT THIS STUDY ADDS

⇒ RM of CIEDs does not improve the management of patients with HF.
⇒ In patients with HF who have a CIED, the utility of RM and its role with respect to HF is poorly defined.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ RM requires further refinement and investigation before it can be recommended routinely for patients with HF and CIED.

(RM) provides the ability to collect regular detailed data about cardiac function and rhythms. These data from CIEDs may include measurement of resting heart rate, patient activity level, heart rate variability, respiratory rate, heart sound intensity and intrathoracic impedance. Thus far, studies using these data to improve patient risk stratification have not shown benefit.⁴

RM for CIEDs is the ‘automated transmission of data based on pre-specified alerts related to device functionality and clinical events’.⁵ The use of RM for patients with a CIED carries a class 1A recommendation⁵; however, major guidelines are unclear on their recommendations for how RM should be used in patients with HF and a CIED.

A previous work published in 2015 focused on the use of RM on the management of ICDs and did not show a mortality benefit. Since that review, several large studies have contributed to our understanding.⁶

In this review, we sought to bring together data from all randomised clinical trials

involving RM with a CIED in patients who have HF and examine the effects of RM on outcomes, including mortality, HF readmission, device therapies, health economics and the use of outpatient clinic visits.

METHODS

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.⁷ The protocol was prospectively registered with the International Prospective Register of Systematic Reviews (registration number CRD42019129270).

Data sources and searches

Databases PubMed, MEDLINE and Embase were searched from January 1990 to February 2019. The search terms used were those associated with CIEDs (Permanent Pacemaker, ICD, CRT) HF and RM (home monitoring). The bibliographies of all relevant studies were searched for by the authors for additional relevant articles. The search was restricted to English language and human subjects. See Search strategy, online supplemental appendix 1.

Study selection

Studies were eligible if (1) they were randomised controlled trials; (2) they included adults (≥ 18 years) with a confirmed diagnosis of HF, including both preserved and reduced systolic functions according to diagnostic methods; (3) subjects had a CIED that was subject to RM; (4) they compared RM of CIEDs to control (CIEDs without RM); and (5) they reported one or more of the following primary outcome measurements: mortality (all-cause and HF-related), hospitalisation (all-cause or HF-related hospitalisation) or the following secondary outcome measurements: device therapies, health economics or reduction in outpatient clinic visits.

Data extraction and risk of bias assessment

Data were extracted using a customised template for this study. Data extracted included the number of patients, age, sex, duration of the study, type of CIED devices, ejection fraction, use of HF medication, QRS measurements, New York Heart Association classification, mortality and HF readmission data. Data pertaining to device therapy and economic assessment were also recorded.

Study risk of bias was assessed using Cochrane standard criteria.⁷ Study selection, data extraction and risk of bias assessment were carried out independently by two authors (MM and MR). Abstracts of the papers identified by title in the initial search were evaluated by two authors (MM and MR) for appropriateness to the study question. Full-text articles of all potentially relevant papers were obtained and evaluated in detail. Articles were assessed independently by two authors against the eligibility criteria. Any disagreements were resolved by consensus, and decisions were independently checked by a third author (AS).

Statistical analysis

Summary statistics from the individual studies were used as patient-level data were not available. Included studies were grouped according to primary outcome data (mortality and HF readmission) and a pooled unadjusted risk of 12-month mortality and 12-month HF readmission was obtained where relevant data were available. Studies were weighted according to their size in the pooled analysis.

We used a fixed effects model to pool results across studies. Estimates of heterogeneity are reported as the I^2 statistic (where I^2 of $>50\%$ was assumed to be a result of significant heterogeneity) and are presented together with the test of statistical significance.

Meta-analysis of the outcomes was conducted using 'Metan' function. All analyses were undertaken using Stata V.15.1.

RESULTS

Summary measures and synthesis of results

A total of 607 articles were identified in the literature search. Three hundred sixty-one duplicates were removed, and subsequently, 246 studies were screened for inclusion. This resulted in removal of 200 studies after abstract review and 46 full-text studies assessed for eligibility. Thirty-five full-text studies were excluded according to the predefined inclusion criteria for study design ($n=18$), previously unidentified duplicate studies ($n=5$), lack of HF outcomes ($n=7$), lack of remote or home monitoring ($n=2$), intervention type ($n=2$) and patient population ($n=1$). Eleven studies were included in the final review. This process is summarised in the Consolidated Standards of Reporting Trials diagram (figure 1; online supplemental file 2).

Risk of bias

The risk of bias was assessed for 11 studies using the Cochrane Collaboration Tool.⁷ One study was deemed to be at high overall risk of bias due to incomplete outcome data, underpowered for the study question and was therefore excluded. Ten studies were included in the final analysis.⁸ All other studies were deemed to have low to moderate risk of bias. The most common reason for moderate overall risk of bias was inability to blind participants and study personnel from RM.

Study characteristics

The characteristics of the included studies are summarised in table 1. Follow-up duration was between 12 months and 34 months. All studies included patients with both ICDs and CRT devices. No study included patients with single-chamber or dual-chamber pacemakers. All studies reported systolic function, and the average ejection fraction for all studies was between 23% and 35%. All studies reported New York Heart Association class and were predominately classes II and III. Cardiovascular medications were reported in nine studies. There was

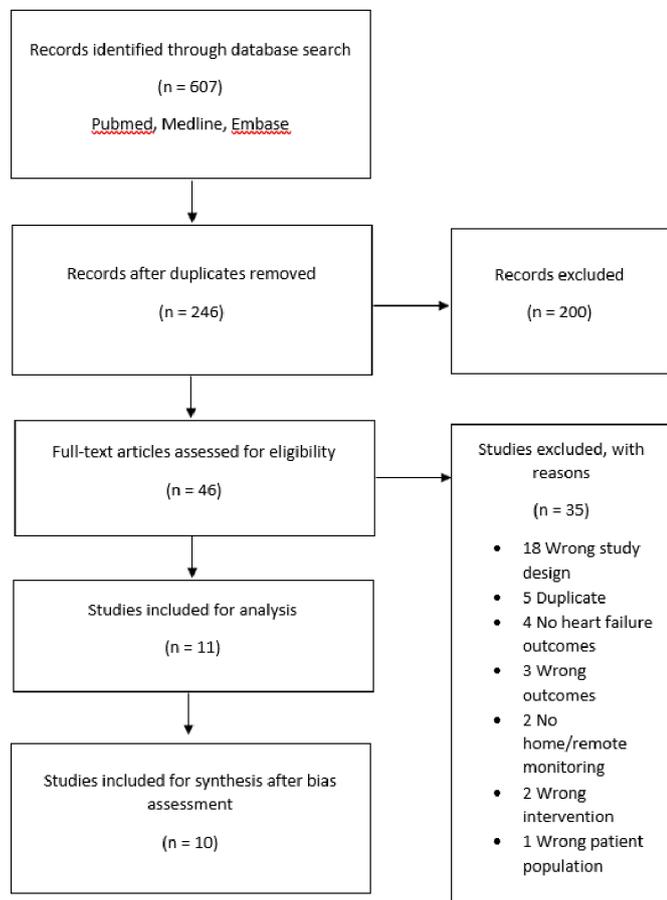


Figure 1 Consolidated Standards of Reporting Trials diagram.

significant variation in standard of care between studies, ranging between 3 monthly and 6 monthly reviews or follow-up at physicians' discretion.

Mortality outcomes were reported in nine studies, and data on 12-month mortality were available for eight studies. Admission for HF (including readmission) was reported at 12 months for seven studies. In total, 6579 patients are represented in these 10 studies with 3045 in the control arms and 3534 in the RM arms.

Primary outcome

Effect of RM on mortality

Nine studies reported mortality.^{9–17} One study was excluded from the pooled analysis as 12-month outcomes were not reported.¹⁷ Eight studies were assessed for 12-month mortality outcomes, representing 6106 total patients with 3295 patients in the active arms and 2811 in the control arms. At 12 months, there was no significant difference in mortality with a total of 218 deaths in the active arms and 213 deaths in the treatment arms. Four studies reported mortality outcomes beyond 24 months,^{9 10 15 17} with the longest mean follow-up period being 34 months, and in these studies, there was also no difference in mortality between the groups. Only one study demonstrated a statistically significant reduction in mortality (3.0% vs 8.2%, p value 0.004).¹²

Pooled outcomes for the unadjusted 12-month mortality of the eight studies were negative with a relative risk of 1.02 (95% CI 0.85 to 1.23, p=0.055, I²=49.2%) (figure 2).

Effect of RM on HF readmissions

Seven studies reported HF admission or readmission outcomes, representing a total of 4767 patients with 2387 patients in the active arms and 2380 in the control arms.^{9–15} While follow-up duration was variable (12–34 months), all seven studies reported HF admission outcomes at 12 months: these were similar in both groups (592 events in the active arms and 551 events in the control arms). Only one study demonstrated reduced risk of presentation for worsening HF in the RM arm,¹³ with the remaining six studies reporting no difference.

Pooled outcome analysis for unadjusted 12-month HF readmission including patients from all seven studies showed no difference between RM and control arms with a relative risk of 1.07 (95% CI 0.97 to 1.20, p=0.658, I²=0.0%) (figure 3).

Secondary outcomes

Effect of RM on ICD therapy

Three studies reported ICD therapy outcomes representing 849 patients in total.^{11 14 17} Two studies^{11 14} documented no difference between the active and control arms. The Effectiveness and Cost of ICDs Follow-up Schedule with Telecardiology (ECOST) study¹⁷ demonstrated a reduction in inappropriate and appropriate shocks in the RM group compared with the standard care group. In the ECOST study, there were a total of 193 shocks in the active arm and 657 in the control arm (p value of 0.02). Of the delivered therapy, 11 patients (28 total shocks) in the active arm, and 22 patients (283 total shocks) in the control arm received inappropriate shocks (p value of 0.03).

Economic analysis

Two studies, representing 1065 patients, reported economic outcomes.^{10 18} An economic analysis of the Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators (EVOLVO) was performed by Zanaboni *et al.*¹⁸ The principal finding was that RM reduced associated healthcare costs for patients but not the healthcare system. This outcome was driven by a reduction in outpatient clinic visits. The Monitoring Resynchronization dEVICES and CARDiac patiENTS (MORE-CARE) study found a statistically significant reduction in healthcare-associated costs for both patients and the healthcare system itself.¹⁰

Reduction in clinic presentation

Four studies, representing 1748 patients, reported data regarding the number of clinical reviews.^{10 11 13 17} One study documented no difference between the active and control arms.¹¹ Three studies^{10 13 17} documented a statistically significant reduction in healthcare interactions in patients on RM compared with standard care which was

Table 1 Summary of studies included in this systematic review and meta-analysis

Paper	n	Age (mean)	Duration (mean)	LVEF (mean %)	NYHA II and III (%)	Intervention	Outcomes reported
Varma <i>et al</i> (USA) ¹⁶	1339	64	12	29	87	RM at 6, 9 and 12 months with office visit at 3 and 15 months versus standard of care	In-hospital evaluations of device, mortality and adverse events
Adamson <i>et al</i> (USA) ⁸	400	55	12	23	100	RM with implantable haemodynamic monitor with weekly assessment versus standard of care	HF hospitalisations, emergency department visits, urgent clinic visits
Guédon-Moreau <i>et al</i> (France) ¹⁷	473	62	24	35	65	RM with review triggered by RM, patient or physician versus standard of care	Mortality, major adverse event including hospitalisation, required intervention, inappropriate ICD therapy, device infection and device failure
Landolina <i>et al</i> (Italy) ¹³	200	68	16	30	88	RM with daily assessment of alerts with 4 monthly office or phone review versus standard of care to reduce unscheduled presentations	Presentation for HF, arrhythmia or device-related events, and healthcare use
Zanaboni <i>et al</i> (Norway) ¹⁸	200	68	16	30	88	RM to reduce unscheduled presentations and economic analysis	Economic analysis of Landolina <i>et al</i> (Italy) ¹³
Hindricks <i>et al</i> (Germany) ¹²	664	65	12	26	100	RM and centralised assessment of multiple parameters with clinical action at investigator's discretion versus standard of care	Mortality, HF admission, worsening functional class and quality of life
Lüthje <i>et al</i> (Germany) ¹⁴	176	66	15	32	86	RM with novel parameters (optivol) and alert management protocol with triggered phone review versus standard of care	Mortality, HF hospitalisation, tachyarrhythmia and device therapy
Böhm <i>et al</i> (Germany) ⁹	1002	66	22.8	27	100	RM clinical alert triggering review, otherwise 6 monthly office/phone review versus standard of care	Mortality, cardiovascular hospitalisation, death from cardiovascular cause and any cause for hospitalisation
Boriani <i>et al</i> (Italy) ¹⁰	865	66	24	27	100*	RM with alternating 4 monthly reviews in office or with monitoring only versus standard of care	Mortality, cardiovascular or device hospitalisation and economic assessment,
Morgan <i>et al</i> (UK) ¹⁵	1650	70	34	30	100	RM with weekly data assessment with predefined active follow-up versus standard of care	Mortality, cardiovascular mortality and cardiovascular hospitalisation
Hansen <i>et al</i> (Germany) ¹¹	210	64	12	28	90	Automated telemetry only with 3 monthly reviews versus telephone or telephone and physical clinic	Quality of life, all-cause mortality, HF hospitalisations, arrhythmias, unscheduled follow ups, appropriate or inappropriate device therapy

HF, heart failure; ICD, implantable cardiac defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RM, remote monitoring.

driven by reduction of protocol defined follow-up and urgent in-office visits.

DISCUSSION

This systematic review and meta-analysis of the effects of remote CIED monitoring were conducted in adults with HF with reduced ejection fraction and demonstrated that remote CIED monitoring did not reduce HF mortality or readmissions.

The overall benefit from RM is not in dispute.⁵ There is robust evidence that healthcare use overall is reduced,^{16 19} and there is more timely diagnosis of device complications and significant arrhythmias.^{17 20} However, there is no consistent evidence that hospital admissions are reduced—an especially important metric in patients with HF where frequent readmissions result in major morbidity. To date, the EVOLVO study is the only RM study that has documented a reduction in HF admissions,

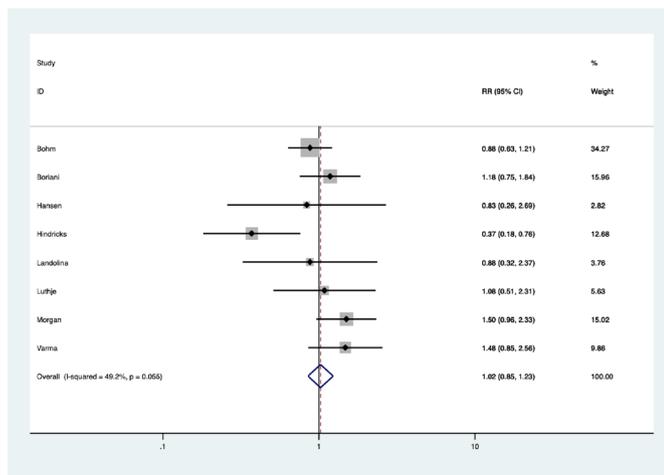


Figure 2 Twelve-month mortality, the value for the I^2 statistic and p value associated with the heterogeneity Q test are shown in parentheses for each overall total.

but this was a pooled outcome driven by a decrease in protocol-defined clinic visits and urgent in-office visits.

The reasons why a more prompt assessment of cardiac arrhythmia, device function and device-derived measures of well-being do not reduce HF readmissions remain unclear. One possible explanation arose in the Telemedical Interventional Management in HF II (TIM-HF2) trial. This trial was not included in this systematic review as not all patients had CIEDs but is important to discuss in this context.²¹ It included 30% of patients who had an ICD and 16% of patients who had CRT and demonstrated both had a small reduction in hospitalisation days for HF and all-cause mortality in patients with HF with RM. This study included clinical and patient measures including weight, blood pressure, heart rhythm, oxygen saturation and self-rated health status. The TIM-HF2 study suggests that a comprehensive implementation of RM, involving a combination of device and other measures, and collaboration between arrhythmia and HF physicians, might

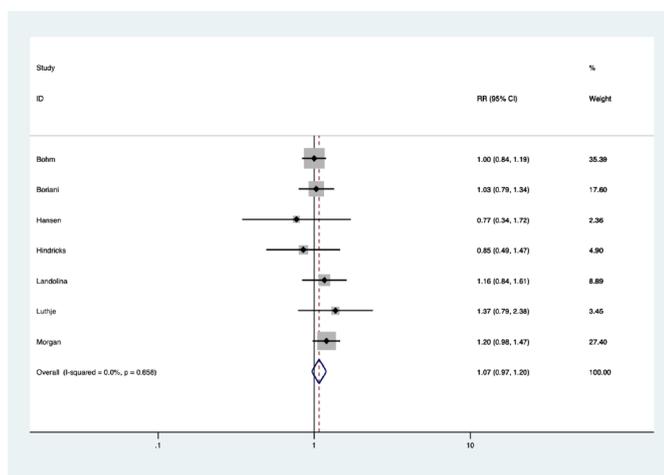


Figure 3 Twelve-month heart failure readmission, the value for the I^2 statistic and the p value associated with the heterogeneity Q test are shown in parentheses for each overall total.

be a more effective strategy in the HF population than a simple device-based approach.

The trials of RM in HF have major limitations. All CIED types were not represented despite their widespread use. No studies included patients with single-chamber or dual-chamber pacemakers, despite evidence that up to 30% of such patients will have systolic HF and have not met the criteria for CRT or ICD therapy.²² No studies included patients with heart failure with preserved ejection fraction (HFpEF) even though up to 10% of the HFpEF population have a CIED.²³ No studies included subcutaneous, leadless or conductive system pacing.

Implementation of RM also varied widely across the trials. For example, the IN-TIME study, the only study to document a decrease in mortality, required daily, implant-based, multiparameter central telemonitoring by trained staff before dissemination to local investigational sites.¹² This form of RM, combined with telehealth, is more comprehensive than the methodology of other studies included in this analysis, some of which instituted RM without centralised training, oversight or with protocol-defined intervention.

A pooled analysis of the individual patient data from three trials (Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST), ECOST and Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME)), using the same home monitoring technology, demonstrated a statistically significant reduction in all-cause mortality and the composite endpoint of all-cause mortality or worsening HF hospitalisation.²⁴ The results are encouraging but have to be interpreted with caution, as this was a post hoc and pooled analysis.

CIEDs and rapid use of RM technology, as is clear from our systematic review, lacks standardisation across CIED types, healthcare systems and supporting clinical services. There is a paucity of research in this area and, as such, our findings remain hypothesis generating. As is currently implemented, RM does not reduce mortality or hospital readmission.

Trial enrolment is often associated with positive outcomes in clinical research, often thought due to increased monitoring compared with standard care. Similarly, we postulate that comprehensive RM when integrated with telehealth programmes, as was employed by the IN-TIME investigators, which includes patient clinical data alongside device data, can improve patient mortality, but larger trials are required to confirm the magnitude, consistency and costs.

CONCLUSION

RM for patients with HF and CIEDs does not confer a demonstrable advantage with respect to HF outcomes. As currently implemented, RM does not provide a benefit with respect to all-cause mortality, HF readmissions or decreased therapy from ICDs. There was a trend towards reduced patient healthcare expenditure driven predominantly by reduced clinic presentations.

Further well-designed, adequately powered, randomised controlled studies are required to determine the effectiveness of RM of CIEDs in patients with HF.

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Contributors All authors played a role in the design, drafting, revision and review of the manuscript and read and approved the manuscript. MM, SB and MR: methodology, data curation, writing—original draft and supervision. AS, MM, AB, SS, MR and SS: conceptualisation, methodology, writing—original draft and supervision. MM, NJ, SS, AB and JL: methodology, writing—original draft, validation editing and supervision. MM, MR, SB and SS: validation and formal analysis. AS is the guarantor for this work.

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