



Telemedical Monitoring Based on Implantable Devices—the Evolution Beyond the CardioMEMS™ Technology

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Abstract

Purpose of the Review We aimed to provide an overview of telemedical monitoring and its impact on outcomes among heart failure (HF) patients.

Recent Findings Most HF readmissions may be prevented if clinical parameters are strictly controlled via telemedical monitoring. Predictive algorithms for patients with cardiovascular implantable electronic devices (e.g., Triage-HF Plus by Medtronic or HeartLogic by Boston Scientific) were developed to identify patients at significantly increased risk of HF events. However, randomized control trial-based data are heterogeneous regarding the advantages of telemedical monitoring in HF patients. The likelihood of adverse clinical outcomes increases when pulmonary artery pressure (PAP) rises, usually days to weeks before clinical manifestations of HF. A wireless monitoring system (CardioMEMS™) detecting changes in PAP was proposed for HF patients. CardioMEMS™ transmits data to the healthcare provider and allows to institute timely intensification of HF therapies. CardioMEMS™-guided pharmacotherapy reduced a risk of HF-related hospitalization (hazard ratio [HR]: 0.72; 95% confidence interval (CI) 0.60–0.85; $p < 0.01$).

Summary Relevant developments and innovations of telemedical care may improve clinical outcomes among HF patients. The use of CardioMEMS™ was found to be safe and cost-effective by reducing the rates of HF hospitalizations.

Keywords Heart failure · Implantable hemodynamic monitor · CardioMEMS technology · Pulmonary artery pressure · Remote monitoring

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Introduction

Heart failure (HF) is one of the most common cardiovascular diseases, with an estimated prevalence of 1–2% of the adults in the developed countries; and rising to > 10% in patients aged > 70 years [1–3]. HF accounts for over 1 million hospitalizations in the US and Europe annually [4]. Given that, an increasing number of patients with HF and a high rate of mortality and morbidity have serious public health and economic consequences.

A range of treatments has been shown to improve the survival and quality of life in HF patients, including pharmacotherapy, cardiovascular implantable electronic devices (CIEDs), implantable left ventricular assist device (LVAD), and heart transplant [5]. Optimal pharmacotherapy consists of beta-blockers, angiotensin-converting enzyme inhibitors, and mineralocorticoid receptor antagonists (if left ventricular ejection fraction [LVEF] $\leq 35\%$) [5]. Recently, new drugs such as the angiotensin receptor neprilysin inhibitor (sacubitril/valsartan) and inhibitors of sodium–glucose

cotransporter 2 (dapagliflozin) have shown better outcomes and survival benefits in HF patients when added to standard pharmacotherapy [6, 7].

Following optimal pharmacotherapy, CIEDs have become the cornerstone of management for patients with brady- or tachyarrhythmias and HF [5, 8–10]. CIEDs include complex stimulation systems—pacemakers (PM), implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy (CRT). It is well-established that rhythm management devices improve the life expectancy and quality of life of HF patients [11].

Despite all the treatment options, the prognosis of HF patients is poor; and patients are still admitted to the hospital with HF worsening or arrhythmia. Acute exacerbations of HF often require prolonged in-hospital treatments and contribute to adverse prognosis [12, 13]. However, the majority of HF readmissions are due to fluid overload, and the process of decompensation may be prevented if clinical parameters are strictly controlled via telemedical monitoring [14, 15]. The likelihood of adverse clinical outcomes increases when pulmonary artery pressure (PAP) rises, usually days to weeks before clinical manifestations of HF [16, 17]. A wireless monitoring system (CardioMEMS™) detecting changes in PAP has been proposed for HF patients. CardioMEMS™ transmits data to the healthcare provider and allows to institute timely intensification of HF therapies [18–20]. In this narrative review, we aimed to provide an overview of telemedical monitoring and its impact on outcomes among HF patients; focusing on the advances of the CardioMEMS™ system.

Search Strategy

A comprehensive literature search was performed, and the relevant studies and systematic reviews were identified. The following search terms were included: *heart failure, telemedical monitoring, remote monitoring, CardioMEMS™ system, cardiac implantable electronic devices, pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy, and pulmonary artery pressure monitoring*. The selected articles and guideline documents were reviewed for inclusion.

Home Monitoring in HF Patients

The “first step” of home monitoring began with daily heart rate and blood pressure measurements performed by patients at home. Poor patient compliance limit the impact on overall care. When combined with structured control, e.g., telephone calls, the effects were better. A meta-analysis of 20 randomized control trials (RCTs) and 12 cohort studies assessed the impact of remote patient monitoring (via regularly scheduled structured

telephone contact between patients and health care providers or electronic transfer of data) on HF patients’ outcomes compared to usual care [21]. Telemedical care was associated with a significantly lower number of deaths (RCTs: relative risk [RR]: 0.83; 95% CI: 0.73–0.95; cohort studies: RR: 0.53; 95% CI: 0.29–0.96) and hospitalizations (RCTs: RR: 0.93; 95% CI: 0.87–0.99; cohort studies: RR: 0.52; 95% CI: 0.28–0.96) [21]. A different meta-analysis compared structured telephone support ($n=5613$ participants) and telemonitoring ($n=2710$ participants) versus standard practice for HF patients to quantify the effects of these interventions [22]. Telemonitoring reduced all-cause mortality (RR: 0.66; 95% CI: 0.54–0.81), while structured telephone had a non-significant positive effect (RR: 0.88, 95% CI: 0.76–1.01) as compared to the usual care. Both telephone support (RR: 0.77, 95% CI: 0.68–0.87) and telemonitoring (RR: 0.79, 95% CI 0.67–0.94) reduced HF-related hospitalizations [22]. However, most studies, when analyzed individually, failed to show significant reductions in hospitalization or mortality.

Remote Monitoring in Patients with CIEDs

Patients with CIEDs have routine in-person appointments every 6–12 months, and unscheduled clinic visits may be required in any case of device malfunction or worsening of health [23]. However, the “conventional” monitoring of the patients with CIEDs is inefficient and outdated [24, 25]. According to expert consensus, telemedical monitoring should be made available for all patients with CIEDs, particularly for those with HF and cardiac arrhythmias [23, 26]. Furthermore, digital healthcare models and telemedical controls involve patients taking an active role in their clinical care. Such a personalized approach is the future of modern medicine and cardiology [27].

A telemedical system transfers the recorded data from the patient’s device to a database; new systems can even transmit the data via the patient’s smartphone. The data are available to the healthcare team on an ongoing basis. Thus, telemonitoring allows assessing the relevant technical parameters of the device (battery status, electrode function, and system compatibility) and provides other key clinical information (stimulation percentage, arrhythmic episodes, or current intracardiac electrogram) [23, 26]. In addition, novel telemetric strategies may provide data on the current clinical status or device alarms, including device-related malfunctions, arrhythmias, heart and respiratory rate statistics, heart sounds, and intrathoracic impedance [28–31].

Individual parameters have a poor predictive value of HF decompensation [32]. However, when combined, allow the implementation of predictive algorithms (e.g., Triage-HF Plus by Medtronic or HeartLogic by Boston Scientific) to identify patients at significantly increased risk of HF events [33, 34]. Given that telemedical monitoring may detect early signs and symptoms of HF decompensation, and the healthcare team

may timely modify the pharmacotherapy and prevent HF hospitalization or incidence of inappropriate ICD shocks. Hence, this could be considered an ongoing “triage” of patients requiring an urgent intervention [29]. A recent EHRA survey [35] showed that the early detection of AF in PM patients, lead failure in ICD patients, and HF-worsening in CRT patients were essential advantages of telemedical monitoring.

However, RCT-based data are heterogeneous regarding the advantages of telemedical monitoring in HF patients (Table 1) [32, 36–45]. In the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial, 1339 patients with ICD were randomized to telemedical care with daily transmissions or conventional care (office visits only) [44]. Telemedical monitoring reduced the number of in-hospital visits and the time to detect arrhythmic events (1 vs. 36 days, respectively, $p < 0.01$) [44]. Further studies confirmed that telemedical monitoring reduced the time from the event onset (arrhythmias, disease progression, and device malfunctions) to a clinical decision (4.6 vs. 22 days; respectively, $p < 0.01$) [43]. However, only two studies showed improved clinical outcomes for HF patients by using telemedical care [36, 40]. Conversely, Böhm et al. reported that fluid status alerts did not improve outcomes (the composite of all-cause death and cardiovascular hospitalization) among ICD patients with advanced HF [45]. Furthermore, the remote monitoring: an evaluation of implantable devices for the management of Heart Failure patients (REM-HF) study showed that telemedical care using weekly downloads and a formalized follow-up did not reduce all-cause mortality and HF-related hospitalizations [39].

CardioMEMS™ Technology

The CardioMEMS™ (CardioMEMS HF System, Abbott, Sylmar, CA) is an implantable wireless sensor placed in the left lower lobe pulmonary artery (through a catheter-delivery system), capable of remotely measuring PAP [18]. It is the only invasive HF remote monitoring sensor with Food and Drug Administration (FDA) approval and European Conformity (CE) mark [19]. Patients take daily home measurements with an external electronics system and transmit the PAP data wirelessly for clinician review [18, 19]. The recent studies showed that the CardioMEMS™ reduced HF hospitalizations and improved quality of life (Table 2) [46–51].

The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA functional class III heart failure patients (CHAMPION) trial was an RCT conducted in 64 centers in the USA [46]. The inclusion criterion was the presence of HF in NYHA class III (irrespective of LVEF), and patients were randomized to PAP-guided therapy ($n = 270$) or standard care ($n = 280$). This trial found that hemodynamic-guided pharmacotherapy

reduced HF hospitalization risk in outpatients (rate of HF-related hospitalizations at 6 months: 0.32 vs. 0.44; HR: 0.72; 95% CI 0.60–0.85, $p < 0.01$) [46]. A sub-analysis of the CHAMPION trial among patients with implanted CRT [52] showed that PAP-guided adjustment of medical therapies decreased the burden of HF symptoms and hospitalizations (beyond the effect of CRT) by 30% compared with standard therapy (0.46 events/patient-year vs. 0.68 events/patient-year; HR: 0.70; 95% CI: 0.51–0.96, $p = 0.03$). Treatment patients had more medication titrations (847 vs. 346 in control, $p < 0.01$), reduction in mean PAP (-413.2 ± 123.5 vs. 60.1 ± 88.0 in control, $p < 0.01$), and improvement in quality of life (Minnesota Living with Heart Failure Questionnaire decreased -13.5 ± 23 vs. -4.9 ± 24.8 in control, $p < 0.01$) [52]. Furthermore, a subanalysis of CHAMPION trial among patients with HF and reduced LVEF showed that patients receiving optimal PAP-guided therapy had lower HF hospitalizations (HR: 0.57; 95% CI: 0.45–0.74, $p < 0.01$) and 57% lower mortality (HR: 0.43; 95% CI: 0.24–0.76, $p < 0.01$) compared with the control group [53].

The CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) provided the first European experience with PAP-guided therapy [49]. It was found that the use of CardioMEMS™ is safe and feasible, with 98.3% of patients remaining free from device- or system-related complications. Physician-directed management based on remotely obtained PAP values were associated with a 62% decrease in HF hospitalizations (at 12 months post- vs. pre-implant, HF hospitalizations: 0.60 vs. 1.55 events/patient-year; HR: 0.38; 95% CI: 0.31–0.48, $p < 0.01$), and marked increase in Kansas City Cardiomyopathy Questionnaire (overall summary score 47.0 ± 24.0 to 60.5 ± 24.3 , $p < 0.01$) [49].

These consistent results support a role for remote PAP monitoring in guiding HF management in outpatients [46–51]. However, in ‘real-life’ practice, this strategy requires commercially available devices and adequate monitoring frequency (gained by patients and healthcare team) with appropriate training to translate the data into appropriate HF treatment modifications. For example, patients should consistently perform their daily PAP measurements early in the morning to improve the CardioMEMS interpretation [54]. It may also indicate actual changes in the patient’s status, rather than “time-of-day-dependent” variations [54]. The patients’ awareness of being monitored is an integral part of this strategy; treatment optimization relies on individual willingness and ability to collaborate [55]. This approach also requires patients’ self-motivation to undergo remote HF management, and timely PAP reassessment must inform caregivers and patients whether their intervention was effective. Notwithstanding these challenges, daily PAP measurements by patients, weekly trend review by healthcare providers, targeted medical interventions, and follow-up of treatment effects are needed. Moreover, each element of

Table 1 Randomized clinical trials comparing telemedical monitoring vs. in-office only follow-up among patients with heart failure and cardiac implantable electronic devices

Reference	Study sample	Follow-up [months]	Device type	Results	Findings
Varma [44] [2010]	1339	12	ICD	Number of total in-hospital device evaluations: 2.1 vs. 3.8 <i>ppy</i> ($p < 0.01$) Adverse event (deaths, stroke and surgical intervention) rate: 10.4% in both groups ($p = 0.01$ for non-inferiority) Time from arrhythmic event to physician evaluation: 1 vs. 36 days ($p < 0.01$)	Telemedical monitoring reduces the number of in-hospital visits; and recudes the time to detection of arrhythmic events
Crossley [43] [2011]	1997	15	ICD/CRT	Time from clinical event (arrhythmias, CV disease progression, and device malfunctions) to clinical decision: 4.6 vs. 22 days ($p < 0.01$)	Telemedical monitoring reduces the time to clinical decisions
van Veldhuisen[32] [2011]	335	14.9	ICD/CRT	Composite of all-cause mortality and HF hospitalizations: 29% vs. 20%; HR 1.52 (95% CI 0.97–2.37)	Telemedical monitoring does not improve outcomes for HF patients
Landolina [41] [2012]	200	16	ICD/CRT	Rate of emergency department or urgent in-office visits for HF, arrhythmias, or ICD-related events: 75 vs. 117 visits ($p < 0.01$)	Telemedical monitoring reduces the number of emergency department/urgent in-hospital visits
Hindricks [36] [2014]	664	12	ICD/CRT	Worsened composite clinical score: 18.9% vs. 27.2%; OR: 0.63 (95% CI 0.43–0.90) Death: 3.0% vs. 8.2%	Telemonitoring improves clinical outcomes for HF patients
Heidbuechel[42] [2015]	303	24	ICD	Total follow-up-related cost for providers: €204 vs. €213 ($p = NS$)	Telemedical monitoring does not reduce the costs for health-care providers
Sardu [37] [2016]	191	12	CRT	HF hospitalization: 15.7% vs. 28.7% HR: 0.6 (95% CI: 0.42–0.79)	Telemedical monitoring may predict HF hospitalization
Böhm [45] [2016]	1002	23	ICD/CRT	Composite of death and CV hospitalization: 45% vs. 48.1%; HR 0.87 (95% CI 0.72–1.04)	Telemedical monitoring does not improve outcomes for HF patients
Morgan [39] [2017]	1650	24–42	ICD/CRT	The primary endpoint (1st event of death from any cause or unplanned hospitalization for cardiovascular reasons): 42.4% vs. 40.8%; HR: 1.01 (95% CI: 0.87–1.18)	Telemedical monitoring does not improve outcomes for HF patients
Boriani [38] [2017]	865	24	CRT	The primary endpoint (composite of death and cardiovascular and device-related hospitalization): 29.7% vs. 28.7%; HR: 1.02 (95% 0.80–1.30) – 41% reduction of in-person visits in telemonitoring group	Telemedical monitoring does not improve outcomes for HF patients Better use of healthcare resources and cost savings
Tajstra [40] [2020]	600	12	ICD/CRT	The primary endpoint (composite of all-cause death and CV hospitalization): 39.5% vs. 48.5% OR 1.24 (95% CI 1.0–1.5)	Telemedical monitoring improves clinical outcomes for HF patients

CI, confidence interval; CRT-D, cardiac resynchronization therapy; CV, cardiovascular; HF, heart failure; HR, hazard ratio; ICD, implantable cardioverter-defibrillator; NS, non-significant; OR, odds ratio; *ppy*, per patient-year

Table 2 Studies among patients with heart failure and implanted CardioMEMS sensor

Reference	Study design	Study sample	Follow-up [months]	Results	Findings
Abraham [46] [2011]	RCT: wireless implantable monitoring system vs. control group	550	15	The rate of heart-failure-related hospitalizations at 6 months: 0.32 vs. 0.44; HR: 0.72 (95% CI 0.60–0.85, $p < 0.01$)	PAP-guided therapy for HF reduces the rates of HF hospitalizations
Jermyn [51] [2017]	Single-centre, prospective	34	15	The difference between rates of hospitalizations 1 year after compared with the 1 year before sensor implantation: HR: 0.16 (95% CI: 0.06–0.35)	PAP-guided therapy for HF reduces the rates of HF hospitalizations
Assaad [48] [2019]	Single-centre, retrospective	27	6–18	The difference between rates of hospitalizations 1 year after compared with the 1 year before sensor implantation: 80.4 and 68.9% reduction in HF and all-cause admissions, respectively	PAP-guided therapy for HF reduces the rates of HF and all-cause hospitalizations
Abraham [50] [2019]	Matched cohort study	2174	12	The rate of HF hospitalization was lower in the treatment cohort at 12 months postimplant HR: 0.76 (95% CI, 0.65–0.89; $p < 0.01$)	PAP-guided therapy for HF reduces the rates of HF hospitalizations
Shavelle [47] [2020]	Multi-centre, prospective	1200	12	The difference between rates of HF hospitalizations 1 year after compared with the 1 year before sensor implantation: 0.54 vs. 1.25 events/patient-years, HR: 0.43 (95% CI: 0.39–0.47)	PAP-guided therapy for HF reduces the rates of HF hospitalizations
Angermann [49] [2020]	Multi-centre, prospective	234	12	The difference between rates of HF hospitalizations 1 year after compared with the 1 year before sensor implantation: 0.60 vs. 1.55 events/patient-year; HR: 0.38, (95% CI: 0.31–0.48, $p < 0.01$) Increase in Kansas City cardiomyopathy questionnaire (overall summary score 47.0 ± 24.0 to 60.5 ± 24.3 ; $p < 0.01$)	PAP-guided therapy for HF reduces the rates of HF hospitalizations and improves the quality of life

RCT, randomized control trial; HR, hazard ratio; CI, confidence interval; PAP, pulmonary artery pressure; HF, heart failure

this PAP-based “package of care” is essential to the final “success” of hemodynamic-guided HF management.

In the USA, from May 28, 2014 (FDA premarket approval) to May 28, 2017, there were approximately 5500 CardioMEMS™ implants [56]. During this interval, 177 adverse events (e.g., pulmonary artery injury/hemoptysis, sensor failure/malfunction/migration, access site-related bleeding/infection, and pulmonary embolism/device thrombosis)—including 22 procedure-related deaths (0.4%) were reported [56]. Hence, candidate selection, operator training, and technological refinement may improve device safety and durability.

Challenges and Future Directions

Telemedical monitoring is not the treatment per se, but it is a tool for better-addressing healthcare requirements, allowing timely medical response to device alerts [40, 57]. The benefits of telemedical monitoring may vary—based on the healthcare reaction to the transmitted data and the level of patient adherence [58]. Therefore, further developments should be focused on improving the feasibility and efficiency of telemonitoring, e.g., artificial intelligence to “triage” patients or integration of extra features to monitor potential comorbidities (blood pressure and sugar levels) [24]. Likewise, artificial intelligence may support diagnostic and treatment decisions, including predicting arrhythmias or other cardiovascular diseases [59, 60].

Further studies may identify the novel functions with a positive impact on clinical outcomes in HF patients (e.g., new sensors capable of measuring left atrial pressures), and evaluation of “real world” data will help define its role in HF management [20, 24, 25, 61, 62]. For example, the Hemodynamic guidance with CardioMEMS in patients with a left Ventricular Assist Device (HEMO-VAD) study was the first prospective pilot study assessing the safety and feasibility of the CardioMEMS™ for optimization of LVAD therapy [63]; and The Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) is ongoing RCT to demonstrate the effectiveness of the CardioMEMS™ in an expanded patient population (HF patients regardless of ejection fraction in NYHA class II–IV) [64]. Furthermore, the CardioMEMS Post-Market Multinational Clinical Study (COAST) will investigate the generalizability of remote PAP-guided management in several national settings (85 sites across Europe and Australia) [65].

However, telemedical monitoring is still underused in clinical practice. Challenges to its implementation are the lack of reimbursement, the adherence to therapeutic protocols by physicians and patients, and the need for significant changes in hospitals’ workflows or data overload [57, 66–68]. Telemedical monitoring is particularly relevant to

prevent hospitalization and reduce the requirement for “face to face” follow-up, for example, to keep social distancing during the current COVID-19 pandemic [69, 70]. Indeed, the advancement of digital health strategy, including smartphones, wearables, and telemedical monitoring, maybe an unexpected outcome of the COVID-19 pandemic [71, 72].

Conclusion

Relevant developments and innovations of telemedical monitoring may improve clinical outcomes among HF patients. The CardioMEMS™ was found to be safe and cost-effective by reducing the rates of heart failure hospitalizations. Telemedical care responds to the unmet need of HF hospitalization and death prevention and should therefore be recommended as part of multidisciplinary management of HF patients.

Declarations

Conflict of Interest DJW: research grants and consultancy fees from Boston Scientific and Medtronic; GYHL: consultant and speaker for BMS/Pfizer, Boehringer Ingelheim, and Daiichi-Sankyo. No fees are received personally.

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