CLINICAL INVESTIGATIONS

Home monitoring after ambulatory implanted primary cardiac implantable electronic devices: The home ambulance pilot study

Mariana S. Parahuleva¹ | Nedim Soydan² | Dimitar Divchev¹ | Ulrich Lüsebrink¹ | Bernhard Schieffer¹ | Ali Erdogan²

¹Internal Medicine/Cardiology and Angiology Department, University Hospital of Giessen and Marburg, Marburg, Germany

²Internist Practice Center, Balserische Stiftung Hospital, Giessen, Germany

Correspondence

Mariana Parahuleva, MD, University Hospital of Giessen and Marburg, Internal Medicine/Cardiology and Angiology, Baldingerstrasse, 35043 Marburg, Germany
Email: mariana.parahuleva@innere.med.uni-giessen.de

Funding information

This study was funded by Biotronik Inc. Funding to pay the Open Access publication charges for this article was provided by Biotronik Inc.

Background: The Home Monitoring (HM) system of cardiac implantable electronic devices (CIEDs) permits early detection of arrhythmias or device system failures. The aim of this pilot study was to examine how the safety and efficacy of the HM system in patients after ambulatory implanted primary CIEDs compare to patients with a standard procedure and hospitalization.

Hypothesis: We hypothesized that HM and their modifications would be a useful extension of the present concepts for ambulatory implanted CIEDs.

Methods: This retrospective analysis evaluates telemetric data obtained from 364 patients in an ambulatory single center over 6 years. Patients were assigned to an active group (n = 217), consisting of those who were discharged early on the day of implantation of the primary CIED, or to a control group (n = 147), consisting of those discharged and followed up with the HM system according to usual medical practices.

Results: The mean duration of hospitalization was 73.2% shorter in the active group than in the control group, corresponding to 20.5 ± 13 fewer hours (95% confidence interval [CI]: 6.3–29.5; $P < 0.01$) spent in the hospital (7.5 ± 1.5 vs 28 ± 4.5 h). This shorter mean hospital stay was attributable to a 78.8% shorter postoperative period in the active group. The proportion of patients with treatment-related adverse events was 11% (n = 23) in the active group and 17% (n = 25) in the control group (95% CI: 5.5–8.3; $P = 0.061$). This 6% absolute risk reduction (95% CI: 3.3–9.1; $P = 0.789$) confirmed the noninferiority of the ambulatory implanted CIED when compared with standard management of these patients.

Conclusions: Early discharge with the HM system after ambulatory CIED implantation was safe and not inferior to the classic medical procedure. Thus, together with lower costs, HM and its modifications would be a useful extension of the present concepts for ambulatory implanted CIEDs.

KEYWORDS

Adverse Events, Ambulatory Device Implantation, Home Monitoring, Telemedicine

1 | INTRODUCTION

Telemedicine is offering new choices for the long-term surveillance of cardiac implantable electronic devices (CIEDs).^{1,2} Remote monitoring (RM) of CIEDs was introduced just over 10 years ago, and its use is

rapidly increasing.³ RM of CIEDs is addressed in a joint European and American expert consensus statement, and is now a class IIa recommendation of the 2013 European Society of Cardiology guidelines on cardiac pacing and cardiac resynchronization therapy (CRT).⁴ The Home Monitoring (HM) system (Biotronik, Berlin, Germany) was implemented

TABLE 1 Characteristics of the patients

Characteristics	Active Group	Control Group	P Value
Age, y, average	67.5	69	NS
Female gender, n (%)	51 (23.5)	35 (23.8)	NS
CIED indications, n (%)			
Ischemic cardiomyopathy	11 (5)	14 (9.4)	NS
Dilated cardiomyopathy	11 (5)	14 (9.5)	NS
Other cardiomyopathies	5 (2.9)	3 (2.5)	NS
Bradycardia-tachycardia	22 (10.1)	14 (9.5)	NS
Bradyarrhythmia	29 (13.4)	12 (8.2)	NS
Sick sinus syndrome	40 (18.4)	29 (19.7)	NS
First- or second-degree AV block	32 (14.7)	18 (12.2)	NS
Third-degree AV block	56 (25.8)	35 (23.8)	NS
Others	9 (4.3)	10 (6.2)	NS
Discharge after first implant, hr	7.5 ± 1.5	28 ± 2.5	<0.01
Postoperative period, hr	5.5 ± 1	26 ± 2	<0.01

Abbreviations: AV, atrioventricular; CIED, cardiac implantable electronic device; NS, not significant.

Data were compared; the *P* values indicate the difference between the active group and the control group.

to follow-up and autonomously generate daily data transmissions from the pacemaker (PM) to a central service center where the data are stored and evaluated with regard to system integrity and arrhythmic events.⁵ Prominent among the potential benefits of HM system are the early detection of arrhythmias and safety issues, including lead fracture, insulation defects, or premature battery depletion.⁶ Recent studies have also explored the role of device-based sensors in the detection of worsening heart failure and risk stratification.^{7,8}

We retrospectively analyzed the data obtained by the HM system with regard to the safety and effectiveness of the HM system when implemented during the relatively high-risk 24 h and first month that follows the ambulatory, primary implantation of the single- and dual-chamber PM, implantable cardioverter-defibrillator (ICD), and CRT-Pacemaker/CRT-Defibrillator (CRT-P/CRT-D), respectively (Tables 1 and 2). the HM system transmissions were reviewed daily by the

cardiologist throughout the study. In-clinic visits were scheduled, and clinical intervention was prepared within 2 working days upon HM notification of adverse events (AE), if necessary. One of the objectives of this pilot study was to determine whether, by continuously monitoring all parameters of device function, the HM system enables a significant shortening of postoperative hospitalization or ambulatory implantation of primary CIEDs, while preserving a safety level equivalent to that associated with standard management, usually consisting of a hospital stay of 24 h or longer. Another objective of the study was confirmation that the proportion of patients who experienced 1 or more technical or clinical AEs (Table 3), as well as the incidence of their treatment modification, was not higher in the group of patients assigned to early discharge from the hospital or ambulatory implanted devices (active group [AG]) than in a control group (CG). The secondary objectives of the trial included (1) an estimation of the putative cost savings associated with ambulatory device implantation in the group assigned to shorter hospitalization, and (2) a measurement of the possible impact of the HM system on quality of life.

2 | METHODS

2.1 | Study population and derivation of study cohort

This pilot study was a retrospective, single-center, parallel, noninferiority case series study of 364 patients. The study protocol was reviewed and approved by the ethics committee of the University of Giessen. The participants provided written informed consent to participate in the study. Between January 2010 and February 2016, 381 devices with the HM system were implanted. A total of 381 first device implant patients were enrolled in the study. Remote monitoring was accomplished with the Biotronik HM system based on daily or event-triggered transmissions immediately after a CIED implant.^{9,10} The HM system was initiated by all patients at the day of discharge, and transmission took place every day including the night after discharge or if an AE-triggered transmission took place.

TABLE 2 Disease manifestations and electrocardiographic indications for device therapy in both study groups

Indications	SR-PM		DR-PM		SR-ICD		DR-ICD		CRT-P		CRT-D	
	AG	CG	AG	CG	AG	CG	AG	CG	AG	CG	AG	CG
Primary implantation of ICD/CRT												
Ischemic cardiomyopathy					2	5	7	7		1	2	1
Dilated cardiomyopathy					4	3	4	5	2	4	1	2
Other cardiomyopathies/ channelopathies					2	1	2	1	1			1
Electrocardiographic indications												
Bradycardia-tachycardia	5	5	17	9								
Bradyarrhythmia	29	12										
Sick sinus syndrome			40	29								
First- or second-degree atrioventricular block			32	18								
Third-degree atrioventricular block			56	35								
Others	7	7	2	3								

Abbreviations: AG, active group; CG, control group; CRT, cardiac resynchronisation therapy; CRT-D, cardiac resynchronisation therapy defibrillator; CRT-P, cardiac resynchronisation therapy pacemaker; DR-ICD, dual-chamber ICD; DR-PM, dual-chamber pacemaker; ICD, implantable cardioverter-defibrillator; SR-ICD, single-chamber ICD; SR-PM, single-chamber pacemaker.

TABLE 3 Listing of all technical and clinical transmitted adverse event messages

Daily Transmitted Event Messages	Active Group		Control Group	
	PM/CRT-P, n = 195	ICD/CRT-D, n = 22	PM/CRT-P, n = 119	ICD/CRT-D, n = 28
Technical information				
RA lead failure detected: RA impedance out of range (<200 Ω or >3000 Ω)	1		2	
RA lead failure detected: P wave safety margin <50%	2		1	
RV lead failure detected: RV impedance out of range (<200 Ω or >3000 Ω)	4		3	1
RV lead failure detected: R wave safety margin <50% ventricular capture threshold >2.5 V	3		2	
Shock impedance out of range		1		2
Autothreshold deactivated	2		3	
Clinical information				
Mode switch counter above limit	10	1	12	1
Mode switch duration longer than limit	1		2	
Duration of episode with fastest ventricular rate	4		3	
CRT pacing below limit	1			1
No transmission in last 36 h	6		5	
Episode details received	7		8	
Periodic IEGM	4		6	
Total	45	2	47	5

Abbreviations: CRT, cardiac resynchronisation therapy; ICD, implantable cardioverter-defibrillator; CRT-D, cardiac resynchronisation therapy defibrillator; CRT-P, cardiac resynchronisation therapy pacemaker; IEGM, intracardiac electrogram; PM, pacemaker; RA, right atrial; RV, right ventricular.

After exclusion because of refusal to participate or not matching the inclusion criteria, the final analysis included 364 patients treated with 306/8 pacemakers (PM/CRT-P), respectively, and 43/7 ICD/CRT-D, respectively (Tables 1 and 2, Figure). The mean age was 65.5 years. Pacemaker patients were older (mean age, 75 ± 7 vs 65 ± 8 years) and more balanced in gender than the ICD patients (48% vs 11% female) (Table 1). Patients who fulfilled the inclusion criteria and indications for permanent pacing described in the guidelines issued by professional societies were assigned to an AG vs a CG.^{3,4} In the absence of an AE, patients were discharged early on the same day as their procedure after a first device implant and were assigned to the AG (n = 217). Early discharge from the hospital was defined as within 7.5 ± 1.5 h. Patients in the CG (n = 147) were managed according to the usual practice and discharged on the basis of their medical status within 28 ± 2.5 h after the first implant, but not on the day of implantation. In patients who had undergone a subclavian puncture, a chest radiograph was obtained, and an electrocardiogram was examined before their discharge from the hospital. Patients in the 2 groups were monitored daily by the HM system. The HM system data were transmitted and analyzed daily directly after discharge throughout the study. In the event of a device malfunction or clinical event, the cardiologist was notified by email and/or fax, allowing the rescheduling of the next ambulatory follow-up visit, if necessary. Additional visits could be scheduled if requested by the patient or a cardiologist. The daily transmitted HM system data were available to the cardiologist during the study, but not to study investigators. All of the HM system transmissions were evaluated for clinical relevance by an investigator blinded to group assignment and analyzed retrospectively. In addition, all study participants were seen by a cardiologist in the ambulatory

department within the first month after CIED implantation for a first follow-up. Further visits were synchronized, with a regular follow-up every 6 months or adapted to the events communicated by the HM system in both groups. The derivation of the study cohorts and general design and characteristic of the study population are shown in Table 1 and the Figure.

All patients included in this trial underwent primary implantation of Biotronik devices, equipped with the HM system, a system capable of automatically transmitting the data stored in implantable devices (Tables 1 and 2). The functionality of the HM system has been previously described.⁵ Briefly, the pulse generator includes radiofrequency circuitry and an antenna, which emits the data daily to the CardioMessenger. This base station automatically reroutes the data over a wireless global system to the Biotronik service center. After an automatic analysis, the data (daily messages) are made available on a secure Internet site to the physician responsible for the patient. In case of clinical or technical anomaly (or both), the device emits additional warning messages, which are immediately delivered via the service center to the physician by email and/or fax. The criteria for inclusion in this pilot study were: (1) age > 18 years, (2) indication for first implant of CIEDs, (3) stable medical status, and (4) the ability to discharge the patient from the hospital within 24 h after first device implant. Patients were excluded if they (1) had a spontaneous ventricular rate < 30 bpm, (2) were in overt heart failure, (3) had a history of cardiac surgery or myocardial infarction within 1 month, (4) were systemically anticoagulated, (5) were unable to understand the HM system, (6) were pregnant or breastfeeding, or (7) they were unwilling to provide written informed consent to participate.

2.2 | Costs analysis

The hospitalization cost was determined by the German national health insurance billing system and by the health insurance system by its diagnosis-related group class, which is weighted by the hospitalization duration and associated comorbidities. A cost analysis compared the individual costs in each study group during the study period. The costs of PM/CRT-P and ICD/CRT-D are invoiced, in addition to the diagnosis-related groups, and are covered by the health insurance system. Their prices, which are set by a German economics committee for health products, appear on the list of products and services.

2.3 | Quality-of-life estimates

The 36-Item Short Form Health Survey was completed 3 months after the index implant procedure by 197 study participants assigned to the AG and 110 patients assigned to the CG.

2.4 | Statistical analyses

The patients were assigned to an AG vs a CG. Comparisons between the 2 study groups were made by Fisher exact test and χ^2 test for nominal, qualitative variables and by a Student parametric test for normal distributions of quantitative, continuous, and discrete variables. Absolute risk reduction and 95% confidence interval (CI) were calculated. We analyzed time to event data with the Kaplan–Meier method and compared them with the log-rank test. A *P* value of 0.05 was considered significant. SPSS version 18.0 (IBM, Armonk, NY) was used for the analyses.

3 | RESULTS

3.1 | Patient selection and implanted devices

The pacemakers, either alone (*n* = 306; single chamber *n* = 65 and dual chamber [DR] *n* = 241) or combined with a cardiac resynchronization device (*n* = 8), were implanted to treat first-, second- or third-degree atrioventricular block (28.1% in the AG and 22.3% in the CG), sick sinus syndrome (18.4% in the AG and 19.7% in the CG), bradycardia-tachycardia (10.1% in the AG and 9.5% in the CG), bradyarrhythmia (13.4% in the AG and 8.2% in the CG) or else (5.1% in the AG and 8.2% in the CG) (Table 1). The ICDs, either alone (*n* = 43 [VR *n* = 17 and DR *n* = 26]) or combined with a cardiac resynchronization device (*n* = 7), were implanted in patients who fulfilled MADIT II (Multicenter Automatic Defibrillator Implantation Trial II) criteria and had other primary prevention indications. The ICD patients presented with ischemic heart disease (53%), nonischemic dilated cardiomyopathy (44%), or other cardiomyopathies and channelopathies (18.6%) (Table 1). Approximately half of the ICD patients were in the New York Heart Association functional class II (36%) or III (15%); none were in class IV. The mean left ventricular ejection fraction in the ICD group was $34\% \pm 3.7\%$.

3.2 | Duration of hospitalization

The mean duration of hospitalization was 73.2% shorter in the AG than in the CG (95% CI: 58%–88%), corresponding to 20.5 ± 13 fewer hours (95% CI: 6.3–29.5; *P* < 0.01) spent in the hospital (7.5 ± 1.5 h vs 28 ± 2.5 h). This shorter mean hospital stay was

FIGURE 1 Study population. Abbreviations: HM, Home Monitoring system.

attributed to a 78.8% shorter postoperative period in the AG (95% CI: 71%-85%) compared with the CG (5.5 ± 1 vs 26 ± 2 h). Thus, 89.6% of patients left the hospital on the day of the implantation procedure, in contrast with 29.3% of patients managed by standard methods who were discharged from the hospital within 24 h.

3.3 | Adverse events and messages

There were 47 (13 technical and 34 clinical) AEs in the AG vs 52 (14 technical and 38 clinical) in the CG during the trial (Tables 3 and 4). There were no patients with multiple AEs. The percentage of warnings prompted by clinical AEs was higher than by technical AEs (Tables 3 and 4). The types and time of incidence of technical and clinical AEs that occurred in the overall population and in each study group, before and after discharge from the index hospitalization, are detailed in Table 4. Reported AEs varied according to the CIED type (Table 3). In PM patients, the most important reported benefit was the early detection of sustained atrial fibrillation (5.6% in the AG and 11.8% in the CG), followed by early detection of lead failure (5.1% in the AG and 6.7% in the CG), or ventricular arrhythmias (2% in the AG and 2.5% in the CG), which were confirmed by in-clinic visits where treatment actions were performed. In ICD patients, the most important reported benefit was the early detection of lead failure (1 patient in the AG and 2 patients in the CG), followed by the early detection of atrial fibrillation (1 patient in the AG and 1 patient in the CG). In contrast, for CRT patients, the most important reported benefit was

the early detection of loss of biventricular capture and worsening heart failure (Table 3).

3.4 | Incidence of treatment modifications

Thirty percent of all event messages were received within 24 to 48 h after ambulatory implanted primary CIEDs and nearly 50% within 2 weeks. Approximately the same applies to AEs, of which 55% were received within the 4 weeks after implantation of primary CIEDs in patients who were managed by the standard procedure. In 55%, in-office follow-up was reduced to less than 1 per year within the first 2 years after ambulatory implanted pacemakers.¹¹ In 23%, in-office follow-up was reduced to less than 1 per year within the first 2 years after ambulatory implanted ICDs.¹¹

A total of 48 (48.5%) of 99 patients underwent treatment modification after the analysis of the telemetric data. Daily reported lead parameters helped to define if and when a system revision was necessary. The Kaplan–Meier estimate of 4 weeks of all-cause AE messages reported that changes in lead parameters in the AG were 5.3% versus 8.2% in the CG (log-rank $P = 0.22$). Observing the daily updated follow-up parameters on mode switch episodes in relation to patient's activity and mean heart rate helped detect worsening arrhythmia (AG, $n = 12$; CG, $n = 15$), which led to adjustment of individual medical therapies or electrophysiological studies with ablation (AG, $n = 8$; CG, $n = 10$) and observing the patients' compliance in taking β -blockers (AG, $n = 7$; CG, $n = 9$). Supraventricular tachycardia episodes were observed in 3 patients (AG, $n = 1$; CG, $n = 2$), which

TABLE 4 Adverse events and treatment actions up to 30 days of follow-up in each study group

	Active Group	Control Group	P Value
Adverse events from implantation			
All adverse events, n (%)	47 (21.7)	52 (35.4)	NS
All technical AEs, n (%)	13 (27.7)	14 (27)	NS
24–48 h, n (%)	7 (53.8)	8 (57.1)	
2 weeks, n (%)	3 (23)	4 (28.6)	
4 weeks, n (%)	3 (23)	2 (14.3)	
All clinical AEs, n (%)	34 (72.3)	38 (73)	NS
24–48 h, n (%)	7 (20.6)	9 (23.7)	
2 weeks, n (%)	7 (20.6)	10 (26.3)	
4 weeks, n (%)	20 (58.8)	19 (50)	
Revision indications			
All treatment actions, n (%)	23 (11)	25 (17)	0.061
All revision of device dysfunction, n (%)	11 (47.8)	10 (40)	NS
RA lead failure, n (%)	3 (27.3)	3 (30)	NS
RV lead failure, n (%)	7 (63.6)	6 (60)	NS
Shock impedance out of range, n (%)	1 (9.1)	1 (10)	NS
All treatment actions by clinical abnormalities or events, n (%)	12 (52.2)	15 (60)	NS
Mode switch counter above limit, n (%)	8 (66.7)	10 (66.7)	NS
Episode with fastest ventricular rate			
SVT/VT, n (%)	5 (41.7)	4 (26.7)	NS
CRT pacing below limit, n (%)	1 (8.3)	1 (6.7)	NS

Abbreviations: AE, adverse events; CRT, cardiac resynchronisation therapy; NS, not significant; RA, right atrial; RV, right ventricular; SVT, supraventricular tachycardia; VT, ventricular tachycardia.

Data were compared; the P values indicate the difference between the active group and control group.

led to outpatient treatment in 2 patients. The occurrence of ventricular tachycardia requiring immediate treatment was reported in 4 patients in the SM-AG and in 3 patients in the SM-CG, respectively. A total of 2 (AG, $n = 1$; CG, $n = 1$) clinically related adverse messages reflected low percentage of CRT pacing, and led to early reprogramming of the atrioventricular interval within 2 weeks in the AG and 4 weeks in the CG (Table 4).

3.5 | Cost analysis

The cost calculations were based on the direct hospital costs and on consultation fee for cardiologist. Expenses related to the Biotronik service center were provided by the manufacturer. The mean costs for the duration of the trial were 22% to 25% lower per patient for 217 patients assigned to the AG vs the mean costs for 147 patients assigned to the CG ($P < 0.001$).

3.6 | Quality-of-life estimates

The mean psychological, physical, and overall scores between groups were all statistically nonsignificant.

4 | DISCUSSION

An increasing number of patients receive CIEDs with RM functionality.⁸ Early detection of adverse clinical or technical events by implant-based RM might enable early discharge and a postoperative period at home shortly after ambulatory CIED implantation, but the evidence is weak.^{12,13} We performed the Home Ambulance Pilot Study and retrospectively evaluated the incremental benefit of the HM system for patients, who were discharged on the day of implantation, in the first hours and days, with extremely high risk of complications following ambulatory primary implantation of a CIED. Furthermore, we investigated the HM system as a medically important and economic way of shortening the hospital stay, especially during the immediate postoperative period after ambulatory implantation of a CIED. Nearly 90% of the patients in the AG were discharged from the hospital within 7.5 ± 1.5 h, whereas 29.3% of the patients managed by standard methods were discharged from the hospital within 24 h. Although the importance of RM for shortening hospital stays after CIED implantation is well known, and overnight hospitalization after first implants and ambulatory replacement of SM generators is a well-established standard procedure,¹⁴ the mean postoperative hospital stay of 7.5 ± 1.5 h in the AG indicated that these practices did not represent standard care.

The overall number of AEs was similar in both groups (47 in the AG and 52 in the CG) (Tables 3 and 4). The proportion of patients with a treatment-related AE was not significantly lower in the CG than in the AG (Table 4). The higher number of treatment-related AEs in the AG might be attributable to the early detection of technical or clinical anomalies, which otherwise might have remained unnoticed without the HM system's surveillance. It is also noteworthy that, in both groups, approximately 70% of the AEs occurred within the first week after implantation of the CIED and could have been detected

with the assistance of the HM system without a hospital stay. This even distribution between the 2 groups satisfied the primary objective of the study, which was to confirm that the HM system allowed a significant shortening of the postprocedural hospitalization, while preserving a safety level similar to that associated with standard patient care. Thus, early discharge (within 7.5 ± 1.5 h) with the HM system after ambulatory CIED implantation in our study was safe and not inferior to the classic medical procedure.

Although the HM system is sensitive in the detection of technical complications and arrhythmic episodes, its sensitivity is lower with respect to medical AEs related to the surgical procedure, such as pulse generator pocket complications or development of a pneumothorax. However, in the AG, after discharge from the hospital and up to 4 weeks of follow-up, 13 AEs with device dysfunction were detected, which gives an impression of the acute nature of possible problems (Table 4). Within the first week after implantation, revisions must be planned individually before system failure causes clinical symptoms. On the other hand, high or rising ventricular thresholds followed daily help to delay unnecessary lead revisions (Table 3). Furthermore, AE messages may be nonspecific, as a single anomaly may trigger several different kinds of messages. From this perspective, the HM system is not an automatic surveillance system, and its data must be critically reviewed by the cardiologists. On the other hand, lead failure was reported as a significant alert in ICD patients, perhaps because this is a failure in which RM has a clear advantage over the usual care.^{6,14,15}

This retrospective analysis does not address the link between reported alerts and patient outcomes. However, the alerts reported by cardiologists are those that are likely to influence clinical outcomes. These included early detection of atrial fibrillation, ventricular arrhythmias, lead failure, loss of biventricular capture, and inappropriate shocks. However, in the AG, after discharge from the hospital and after up to 4 weeks of follow-up, 47 messages prompted the early detection of 17 AEs with clinical abnormalities (Table 3). The relatively high number of detected rhythm disturbances in the immediate postoperative period might be, in some cases, the first indication of an early complication. These clinically related parameters indicate further diagnostic steps, for example, an early electrophysiology study or medical modification.

The HM system can reflect the actual situation of patients in their everyday life, not only at in-clinic visitations, and with additional equipment necessary to perform specific examinations.⁸ We further analyzed the data from our pilot study and investigated the clinical benefit and positive effect of the HM system on patient psychology, because early discharge and early identification of peri-interventional complications and critical situations assists the close follow-up of decisions for or against changes in further treatment. Finally, we showed that the HM system of CIEDs had no negative effect on the patients' quality of life.

Physicians report that the HM system has clinically significant applications, and that its implementation has led to reductions in in-office visits.^{8,14} This, however, has been achieved at the expense of an increased workload without appropriate reimbursement. The cost issue of RM of CIEDs is a controversial subject.¹⁶⁻¹⁹ Some regional studies in individual countries have shown that the RM of patients with CIEDs is a cost savings.¹⁶⁻¹⁸ The mean costs for the duration of

our trial were approximately 22% to 25% lower per patient for 217 patients assigned to the AG. Follow-up periods could be prolonged up to 1 year in a few unproblematic patients, instead of the usual 3 to 6 months. Thus, the HM system for CIEDs in our study decreased the duration of postoperative hospitalization by nearly 80% compared with the usual practice, and the decrease in the overall costs associated with this shortening of the hospital stay was statistically significant. Finally, together with the possibility of emergency transmissions throughout the day within the perioperative period at home and lower costs, the HM system and modifications would be a useful extension of the present concepts for ambulatory implanted CIEDs.

4.1 | Limitations

Retrospective analysis has by nature inherent limitations. Consequently, we cannot necessarily assume that our findings are generalizable to the whole European community. In addition, we have not assessed patient outcomes, and therefore we cannot assume that the benefit perceived by physicians necessarily reflects a true benefit. Additionally, although we have detailed information about patients at the time of implantation, we do not have information about changes in patient status and medical therapy during the follow-up period. Finally, analyses were restricted to patients receiving the Biotronik devices. Most CIEDs have the capacity for RM, the technology differs across manufactures, and the extent to which our findings are generalizable to other devices was not investigated.

5 | CONCLUSION

This study reveals that RM of CIEDs is a feasible useful and safe technology and should be used in clinical practice for patients with ambulatory implanted primary CIEDs. The HM system has led to significant benefits for patients, with a reduction in hospital stay and in-office consultations, as well as for healthcare, with lower cost shortly after ambulatory implantation of CIEDs. These data further support decision making regarding treatment options and outpatient follow-up. As a result, electrophysiology studies, system revisions, adaptation of medication, modification of programming, reduction of physical activity, and postponement of system revisions can be decided on the history of an individual dataset. Revealing acute and upcoming problems unapparent to the patient, telemetric surveillance increases the safety of device therapy, especially in patients with ambulatory implanted CIEDs. Importantly, however, RM is perceived as increasing workload, particularly in the ambulatory praxis. This survey indicates that there is interest in the HM system for CIEDs among the European cardiology community, particularly for the follow-up of patients with ambulatory implanted primary ICDs and CRT devices.

ACKNOWLEDGMENTS

The authors thank Mr. Jonnas Klütz, Home Monitoring Manager, and Ms. Büsra Memis, Clinical Research Associate, for their assistance in conducting this trial.

Conflicts of interest

The authors declare no potential conflicts of interest.

REFERENCES

1. Burri H, Senouf D. Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators. *Europace*. 2009;11:701–709.
2. Chen J, Wilkoff BL, Choucair W, et al. Design of the Pacemaker Remote Follow-up Evaluation and Review (PREFER) trial to assess the clinical value of the remote pacemaker interrogation in the management of pacemaker patients. *Trials*. 2008;9:18.
3. Dubner S, Auricchio A, Steinberg JS, et al. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). *Europace*. 2012;14:278–293.
4. Brignole M, Auricchio A, Baron-Esquivias G, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the Task Force on Cardiac Pacing and Resynchronization Therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). *Europace*. 2013;15:1070–1118.
5. Nielsen JC, Kottkamp H, Zabel M, et al. Automatic home monitoring of implantable cardioverter defibrillators. *Europace*. 2008;10:729–735.
6. Mabo P, Victor F, Bazin P, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial). *Eur Heart J*. 2012;33:1105–1111.
7. Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation*. 2012;125:2985–2992.
8. Hindricks G, Taborsky M, Glikson M, et al; IN-TIME Study Group. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet*. 2014;384:583–590.
9. Ricci RP, Morichelli L, D'Onofrio A, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry. *Europace*. 2013;15:970–977.
10. Lazarus A. Remote, wireless, ambulatory monitoring of implantable pacemakers, cardioverter defibrillators, and cardiac resynchronization therapy systems: analysis of a worldwide database. *Pacing Clin Electrophysiol*. 2007;30:S2–S12.
11. Burri H, Sticherling C, Wright D, et al. Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK. *Europace*. 2013;15:1601–1608.
12. Mairesse GH, Braunschweig F, Klersy K, et al. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association. *Europace*. 2015;17:814–818.
13. Vogtmann T, Stiller S, Marek A, et al. Workload and usefulness of daily, centralized home monitoring for patients treated with CIEDs: results of the MoniC (Model Project Monitor Centre) prospective multicentre study. *Europace*. 2013;15:219–226.
14. Crossley GH, Boyle A, Vitense H, et al. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol*. 2011;57:1181–1189.
15. Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. 2010;122:2359–2367.
16. Guédon-Moreau L, Lacroix D, Sadoul N, et al. Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter

- defibrillators in the randomized ECOST study; ECOST trial Investigators. *Europace*. 2014;16:1181–1188.
17. Burri H, Sticherling C, Wright D, et al. Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK. *Europace*. 2013;15:1601–1608.
 18. Ricci RP, D'Onofrio A, Padeletti L, et al. Rationale and design of the health economics evaluation registry for remote follow-up: TARIFF. *Europace*. 2012;14:1661–1665.
 19. Heidebuchel H, Hindricks G, Broadhurst P, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net

financial impact of follow-up with or without remote monitoring. *Eur Heart J*. 2015;36:158–169.

How to cite this article: Parahuleva MS, Soydan N, Divchev D, Lüsebrink U, Schieffer B, Erdogan A. Home monitoring after ambulatory implanted primary cardiac implantable electronic devices: The home ambulance pilot study. *Clin Cardiol*. 2017;40:1068–1075. <https://doi.org/10.1002/clc.22772>