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Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry

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Aims The HomeGuide Registry was a prospective study (NCT01459874), implementing a model for remote monitoring of cardiac implantable electronic devices (CIEDs) in daily clinical practice, to estimate effectiveness in major cardiovascular event detection and management.

Methods and results The workflow for remote monitoring [Biotronik Home Monitoring (HM)] was based on primary nursing: each patient was assigned to an expert nurse for management and to a responsible physician for medical decisions. In-person visits were scheduled once a year. Seventy-five Italian sites enrolled 1650 patients [27% pacemakers, 27% single-chamber implantable cardioverter defibrillators (ICDs), 22% dual-chamber ICDs, 24% ICDs with cardiac resynchronization therapy]. Population resembled the expected characteristics of CIED patients. During a 20 ± 13 month follow-up, 2471 independently adjudicated events were collected in 838 patients (51%): 2033 (82%) were detected during HM sessions; 438 (18%) during in-person visits. Sixty were classified as false-positive, with generalized estimating equation-adjusted sensitivity and positive predictive value of 84.3% [confidence interval (CI), 82.5–86.0%] and 97.4% (CI, 96.5–98.2%), respectively. Overall, 95% of asymptomatic and 73% of actionable events were detected during HM sessions. Median reaction time was 3 days [interquartile range (IQR), 1–14 days]. Generalized estimating equation-adjusted incremental utility, calculated according to four properties of major clinical interest, was in favour of the HM sessions: +0.56 (CI, 0.53–0.58%), $P < 0.0001$. Resource consumption: 3364 HM sessions performed (76% by nurses), median committed monthly manpower of 55.5 (IQR, 22.0–107.0) min × health personnel/100 patients.

Conclusion Home Monitoring was highly effective in detecting and managing clinical events in CIED patients in daily practice with remarkably low manpower and resource consumption.

Keywords Pacemakers • Implantable cardioverter defibrillators • Remote monitoring • Telemedicine

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Introduction

Remote monitoring of cardiac implantable electronic devices (CIEDs) has been suggested as a new standard for patient follow-up and it has been accepted as an alternative to the majority of scheduled follow-up visits in the international guidelines.[1,2] Expected benefits include reduction of outpatient clinic workload, better patient quality of life, improved implanted system surveillance, continuous patient monitoring to early detect harmful clinical events, and to improve patient outcome. Some studies have demonstrated favourable effects of remote monitoring on device and patient management with potential benefits on clinical outcome,[3–7] but few data are available in daily practice.[8] Furthermore, introduction of telemedicine in outpatient clinic for CIED patients needs deep changes in workflow, but to date an optimal organizational model is still to be defined.

The HomeGuide Registry is an Italian multicentre study, designed to provide an organizational model for implementing remote monitoring of CIEDs in daily clinical practice. The aim was to estimate the effectiveness of device remote monitoring in clinical event detection and management and to analyse the associated outpatient clinical workload and impact on resource consumption.

Methods

The HomeGuide Registry is an investigator-initiated, prospective, multicentre observational study (ClinicalTrials.gov identifier NCT01459874), evaluating the effectiveness of an outpatient clinic workflow model implementing remote monitoring for detection and management of unselected cardiovascular events in patients with class I/II indications for pacemaker (PM) or implantable cardioverter defibrillator (ICD), either with or without cardiac resynchronization therapy (CRT). The study was designed by a coordinating investigator and reviewed by a steering committee, which included the study coordinator, five investigators, one representative nurse, one statistician, and one Biotronik representative. HomeGuide was approved by an institutional review board and conducted in 75 Italian sites recruiting patients after obtaining written informed consent to study participation. Biotronik Italy offered technical support but did not sponsor the study. The steering committee members had direct access to and queried the study database.

Study design and objectives

The primary objective of the HomeGuide Registry was to collect and document all major cardiovascular events (MCE; as better defined below) that are normally observed and managed in the participating outpatient clinics to assess the rate of the events that Home Monitoring (HM) allowed to remotely detect and treat during patient follow-up. The secondary objective was to measure healthcare source consumption.

Eligible subjects were patients indicated to first implantation or upgrade of PM or ICDs with or without CRT.

Remote monitoring was accomplished with the Biotronik HM system (Biotronik SE & Co. KG) based on ultra-low power daily or event-triggered transmissions in the MICS (Medical Implant Communication Service) band, from the implanted device to a mobile patient unit, forwarding data via GSM (Global System for Mobile Communications) with GPRS (General Packet Radio Service) protocol to a Service Centre with encrypted access.[9,10]

In this study, HM was routinely implemented in the outpatient clinics of the participating sites according to an organizational model setting roles, responsibilities, and workflow. This model (the HomeGuide model) derived from a previous pilot experience[8] and has been accepted as a national standard by the Italian Association of Arrhythmology and Cardiostimulation.[11] The model is applicable to all the currently available remote monitoring systems. Yet, practical feasibility and clinical effectiveness of such model have never been assessed on a large-scale clinical trial.

HomeGuide model workflow of outpatient clinics

The HomeGuide model is essentially based on a cooperative interaction between the roles of an expert reference nurse and a responsible physician with an agreed list of respective tasks and responsibilities. Each nurse–physician pair, within one outpatient clinic, is exclusively dedicated to an assigned subgroup of remotely controlled patients.

Physicians' and nurses' tasks are detailed in the *Figure 1* along with action items and responsibilities. Centres underwent an extensive training programme before starting study participation.

Home Monitoring transmissions were reviewed by the nurse within two working days upon HM notifications of critical events flagged for attention. In case of no alerts, patient data were checked every 3 months. Custom software was implemented to measure and record the duration of all the HM sessions conducted by the nurse and the physician.

Nurse communications to individual patients were triggered by: HM transmission interruptions for more than 7 days, recall for an unscheduled in-clinic visit or a skipped scheduled in-clinic visit, assessment of patient compliance, and clinic status after medical actions. In-clinic visits were scheduled at post-implant discharge, at 1 month and then once in a year. Cardiac resynchronization therapy patients only had in-person visits every 6 months. Unscheduled in-clinic visits were further classified in: visits required by the patients (including visits following an emergency department admission) or triggered by HM notifications, reports, and trend reviews.

Event definition and classification

Major cardiovascular events were defined as any untoward cardiovascular occurrence, disease or signs (including abnormal device findings) faced in an outpatient CIED clinic whether or not related to the implanted device. Such definition was broad enough to encompass a large class of significant events, including arrhythmias, worsening heart failure (HF), device-related complications, as well as events that are not supposed to be detected by CIEDs or remotely transmitted via HM (such as strokes or acute myocardial infarctions). From early detection to final decision, MCEs were tracked by a custom made software. When a MCE was a combination of multiple events, a multiple diagnosis was allowed in the electronic case report forms.

Major cardiovascular events were classified by the investigators according to specific guidelines developed by the steering committee, according to the following properties:

- Source of information (HM session, in-person visit, or other circumstances);
- Home Monitoring-witnessed: a MCE was considered as HM-witnessed if HM is technically able to detect the event;
- Appropriateness of initial diagnosis;
- Absence of associated symptoms;
- Corrective action required.

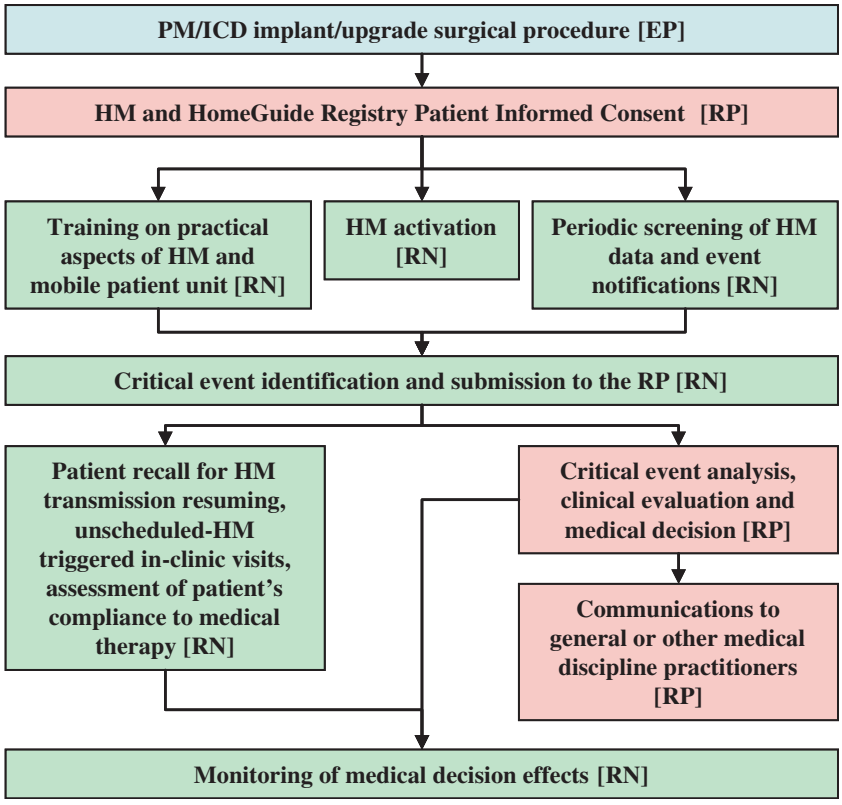

Figure 1 HomeGuide model workflow with action items and responsibilities. EP, electrophysiology/cardiac pacing laboratory; ICD, implantable cardioverter defibrillator; HM, Home Monitoring; PM, Pacemaker; RN, responsible nurse; RP, responsible physician.

Investigators' classifications were reviewed and adjudicated by an independent five-member board, blinded to the investigational sites and investigators.

Home Monitoring indexes of worsening heart failure

The implanted study devices were equipped with several indexes for HF monitor, depending on the device type and model. The HomeGuide protocol did not provide reaction algorithm, programming or threshold setting recommendations which were left to investigators' discretion. Therefore, the results represent current standard practice at the present stage of clinical experience and HM technology development.

Sensitivity, positive predictive value and expected utility of major cardiovascular event detection by Home Monitoring

To provide estimates of sensitivity and PPV of HM event detection, adjudicated MCEs were divided in: true-positive (events detected during periodic or alert-triggered HM sessions); false-negative (events actually occurred but not detected with HM for any reason); false-positive (false events notified by automatic HM alerts and/or misinterpreted).

Home Monitoring sensitivity and PPV were then estimated as usually by the ratios of the number of true-positive events over the number of true documented events and the number of events detected during HM sessions, respectively. Estimates were reported as percentages with the respective 95% confidence interval (CI) boundaries. Generalized estimating equation (GEE) models were used to adjust sensitivity and PPV estimates for within-individual repeated MCEs. Home Monitoring sensitivity was further estimated for specified subclasses of MCEs. Deaths were excluded from calculations.

It is worth noting that the broad definition of MCE, assumed in the HomeGuide Registry, and the particular characteristics of HM as a diagnostic tool, may impair practical significance of sensitivity and PPV. We therefore sought to develop an index, derived from the expected utility concept normally used in Markov processes[12] and based on the rate of some properties of interest shown by MCEs. The latter may in fact be considered as a measure of the utility of the follow-up strategy by which the MCE was first detected (HM sessions or in-person visits/other circumstances), and assumed as a score. The sum of the products of the scores by the respective probabilities is normally known as an expected utility value and can be easily estimated for both monitoring strategies with experimental data. An incremental utility (IU) index can be defined as the difference between the respective expected utilities of both follow-up strategies returning a numerical value in the $(-1, 1)$ range, that can be estimated with its 95% CI and tested against the hypothesis of $IU = 0$ (with our assumptions, a positive IU value was in favour of a higher expected utility of the HM strategy). Generalized estimating equation models may be used as well to adjust for within-individual repeated events correlation.

In principle, calculations may be performed for each set of arbitrarily chosen properties, or according to the clinical interest of the particular

aspect analysed. We considered a set of four properties: HM-witnessed; correct initial diagnosis; asymptomatic events; corrective action required (actionability). Expected utilities and IU were calculated with respect to this set of properties.

Statistics

The HomeGuide Registry was 90% powered to reject the null hypothesis that sensitivity of HM MCE detection was $\leq$70% at an one-sided test with a significance level of $P = 0.025$. Simulations showed that *a priori* assuming a sensitivity value of 75% would have required 844 adjudicated MCEs. With such a collection of MCEs it was also estimated that there was a 97% power available to reject the null hypothesis that the HM PPV was $\leq$80% assuming a PPV of 85%. It was then predicted that 55% of enrolled patients would have experienced one valid MCE during at least follow-up of 1 year. With a hypothesized patient dropout rate of 10%, the required population size was estimated in 1650 patients. The prediction of 55% MCE rate per patient proved false, as it resulted remarkably higher at the end of the study. The Steering Committee decided to terminate patient follow-up after the target population was enrolled and the last patient in reached the 3-month follow-up.

Continuous variable distributions were checked for normality with the Shapiro–Wilk test and reported as mean $\pm$ SD if the normality hypothesis could not be rejected. Median and interquartile range (IQR) were used in the opposite case. Proportions were reported as percentages along with the exact 95% CI. Statistical significance was set at $P = 0.05$ level. To account for the bias deriving from repeated MCEs in individual patients (=unadjusted), HM sensitivity, PPV, and IU were adjusted using GEE models with a first-order autoregressive correlation. Generalized estimating equation-adjusted and unadjusted values were reported. Stata 11.1 software package (StataCorp) was used.

Results

On the whole, 1650 patients, mean age 69.5 $\pm$ 11.4 years, 76% male, were enrolled in 75 Italian centres (22 enrolments per site on average, range 1–221) from March 2008 to September 2011. Almost one-fifth of the patients actually implanted in the participating sites during standard clinical practice were selected for enrolment, with similar rates among implant types. Implanted devices were single-chamber ICDs in 444 patients (27%), dual-chamber ICDs in 359 (22%), cardiac resynchronization therapy defibrillators (CRT-D) devices in 399 (24%), single-chamber PMs in 4 (0%), dual-chamber PMs in 417 (25%), and cardiac resynchronization therapy pacemaker devices in 27 (2%). Among PM patients, sinus node dysfunction was the main indication in 45%, atrioventricular block in 40%, vasovagal syncope in 8%, and HF requiring CRT in 6%. Among ICD patients, implant indication was primary prevention in 77%. Population baseline characteristics and pharmacological therapies at implant are reported in *Tables 1* and *2*, respectively. The majority of enrolled patients (66%) had emergency department visits or hospitalizations because of cardiovascular events within 1 year prior to device implantation.

During a mean follow-up of 20.4 $\pm$ 12.6 months, 3364 HM sessions were performed (74% by the nurse), during which 15 984 patient reports were reviewed. Each session had a median duration of 5.5 (2.0–11.1) min to review three (1–6) patient reports, if conducted by the nurse; and 4.6 (1.8–10.5) min to review two (1–4) patient reports, if conducted by the physician. Overall, with the HomeGuide model workflow, HM required a median manpower of 55.5 (22.0–107.0) min $\times$ health personnel per month every 100 patients.

Two thousand four hundred seventy-one MCEs were detected in 838 patients (51%), with a median of 2.0 (1.0–3.0) events each: 2033 events (82%) were detected during HM sessions, 165 (7%) during in-person visits, and 273 (11%) in other circumstances. False-positives were 60 (57 during HM sessions, 1 during in-person visits, and 2 in other circumstances). The 2411 true-positive single and multiple MCEs generated 2848 event classifications: 134 deaths; 5 strokes; 6 myocardial infarctions; 137 worsening HF episodes; 19 syncope episodes; 868 atrial arrhythmias; 612 sustained or non-sustained ventricular arrhythmias; 318 effective/ineffective/inappropriate ventricular therapies; 433 device-related issues; 8 pocket/device infections; and 351 other events. Further details are provided in *Table 3*.

Among the 2411 true MCEs, 1976 events were detected during HM sessions, resulting in an unadjusted sensitivity estimate of HM in MCE detection of 81.9% (95% CI, 80.3–83.5%); GEE-adjusted, 84.3% (82.5–86.0%). Unadjusted HM positive predictive value (PPV) was 97.2% (96.4–97.9%); GEE-adjusted, 97.4% (96.5–98.2%). Among the 435 true events detected during in office visits or in other circumstances, 262 (60%) were not witnessed by HM, while 173 (40%) could have been potentially documented by HM but they actually were not. Maximum unadjusted estimated sensitivity of HM, including potentially HM-witnessed events, could reach 89.1% (87.8–90.3%); GEE-adjusted, 91.3% (90.0–92.6%). One thousand four hundred eighty-seven events detected during HM sessions (75%) were asymptomatic, vs. 87 (20%) asymptomatic events not detected during HM sessions. Seven hundred twenty-three events detected during HM sessions (37%) were actionable, vs. 262 (60%) of those detected not during HM sessions. On the whole, 73% of actionable events were detected during HM sessions with a median reaction time (defined as the period from detection to clinical decision) of 3 days (IQR, 1–14 days). Reactions to clinical events are reported in detail in *Table 4* (events could have required multiple reactions). Oral anticoagulation introduction, antiarrhythmic therapy starting or adjustment, β-blockers titration, and diuretic dosage increasing were the most commonly reported drug therapy changes.

Incremental utility of HM, calculated according to four properties (HM witnessed, appropriate detection, asymptomatic events, and actionability), was 0.53 (95% CI 0.51–0.55); GEE-adjusted, 0.56 (0.53–0.58) $P < 0.0001$. In *Figure 2*, GEE-adjusted HM sensitivity, PPV and IU, as well as HM sensitivity estimates for each group of MCEs are represented. Home Monitoring sensitivity was >90% for atrial and ventricular arrhythmias and device-related issues, while it was <35% for stroke, syncope, and acute coronary syndromes. An intermediate HM sensitivity value was found for early detection of HF impairment (59%), with a maximum estimated sensitivity of 87%.

Discussion

The main results of our study showed that using HM within the HomeGuide outpatient clinic workflow model, 82% of all MCEs observed in normal daily practice were detected remotely, with

Table 1 Population characteristics

	All patients (1650)	PM (448)	ICD (803)	CRT-D (399)
Mean age (years)	69.5 ± 11.4	73.7 ± 10.3	67.0 ± 12.2	69.9 ± 9.5
Male	1261 (76%)	282 (63%)	660 (82%)	319 (80%)
HD				
No HD	183 (11%)	168 (38%)	15 (2%)	0 (0%)
Cardiomyopathy	851 (53%)	30 (7%)	496 (62%)	325 (81%)
Ischaemic HD	689 (43%)	82 (18%)	421 (52%)	186 (47%)
Valvular HD	107 (7%)	20 (4%)	63 (8%)	24 (6%)
Channelopathies	27 (2%)	0 (0%)	27 (3%)	0 (0%)
Congenital HD	9 (1%)	3 (1%)	5 (1%)	1 (0%)
Others	5 (0%)	3 (1%)	2 (0%)	0 (0%)
NYHA class				
I	309 (19%)	189 (42%)	112 (14%)	8 (2%)
II	751 (46%)	181 (41%)	456 (57%)	114 (29%)
III	553 (33%)	73 (16%)	220 (27%)	260 (65%)
IV	37 (2%)	5 (1%)	15 (2%)	17 (4%)
QRS width (ms)	120 (100–142)	100 (87–120)	108 (98–120)	146 (125–160)
LVEF (%)	30.0 (25.0–42.0).	60.0 (50.0–60.0)	30.0 (26.0–38.0)	28.0 (25.0–30.0)
Ventricular tachyarrhythmias	447 (27%)	4 (1%)	355 (44%)	88 (22%)
Supraventricular tachyarrhythmias[a]	416 (25%)	135 (30%)	186 (23%)	95 (24%)
AT	93 (6%)	34 (7%)	37 (4%)	22 (6%)
AF	356 (22%)	118 (26%)	160 (20%)	78 (20%)
Paroxysmal	155 (44%)	72 (61%)	53 (33%)	30 (38%)
Persistent	71 (20%)	33 (28%)	27 (17%)	11 (14%)
Permanent	130 (37%)	13 (11%)	80 (50%)	37 (47%)
Bradyarrhythmias	538 (33%)	354 (79%)	92 (11%)	92 (23%)

HD, heart disease; LVEF, left ventricular ejection fraction; AT, atrial tachycardia/flutter; AF, atrial fibrillation.
[a]Individual patients could have multiple supraventricular arrhythmias.

Table 2 Baseline pharmacological therapy

Drug	All (1650)	PM (448)	ICD (803)	CRT-D (399)
ACE-inhibitor	971 (59%)	177 (40%)	479 (60%)	315 (79%)
ARBs	244 (15%)	81 (18%)	81 (10%)	82 (21%)
β-Blockers	1056 (64%)	126 (28%)	573 (67%)	357 (89%)
Diuretics	1050 (64%)	171 (38%)	536 (67%)	343 (86%)
Spironolactone	237 (14%)	17 (4%)	101 (13%)	119 (30%)
Calcium channel blockers	161 (10%)	82 (18%)	53 (7%)	26 (7%)
Vasodilator	231 (14%)	43 (10%)	111 (13%)	77 (19%)
Digitalis	131 (8%)	11 (2%)	62 (8%)	58 (15%)
Antiplatelets	741 (45%)	174 (39%)	383 (48%)	184 (46%)
Anticoagulants	467 (28%)	102 (23%)	241 (30%)	124 (31%)
Antiarrhythmics	386 (23%)	103 (23%)	181 (23%)	102 (26%)
Class I	49 (3%)	40 (9%)	8 (1%)	1 (0%)
Amiodarone	312 (19%)	54 (12%)	162 (20%)	96 (24%)
Sotalol	25 (2%)	9 (2%)	11 (1%)	5 (1%)

ARBs, angiotensin II receptor blockers; ACE, angiotensin-converting-enzyme.

Table 3 Classifications of 2411 true-positive MCEs

Event description	All	During HM sessions
Deaths	134	0
Strokes	5	0
Acute myocardial infarctions	6	2
Worsening heart failures	137	74
Syncope events	19	5
Atrial arrhythmias	868	808
Sustained ventricular arrhythmias	434	394
Unsustained ventricular arrhythmias	178	170
Effective/ineffective ventricular device therapies	246	223
Ineffective maximal energy shocks	10	7
Inappropriate device therapies	62	57
Sensing failures	193	174
Capture failures or threshold raises	134	103
Out-of-range impedances	43	41
Suboptimal device programming	59	40
Battery depletion or device error status	4	4
Pocket/device infections	8	0
Others	351	276

Table 4 Clinical reactions to actionable events

Clinical reaction	All	During HM sessions number (%)
Pharmacological therapy optimization	381	297 (78%)
Therapy compliance recommendation	48	44 (92%)
Device reprogramming	315	244 (77%)
Device replacement	17	8 (47%)
Implantation surgical revision	73	47 (64%)
Device upgrading	12	5 (42%)
Pharmacological AF cardioversion	6	4 (67%)
Electrical AF cardioversion	35	26 (74%)
Radiofrequency ablation	21	15 (71%)
Further diagnostics exams	28	21 (75%)
Hospitalizations	151	69 (46%)
Others	69	58 (84%)

AF, atrial fibrillation.

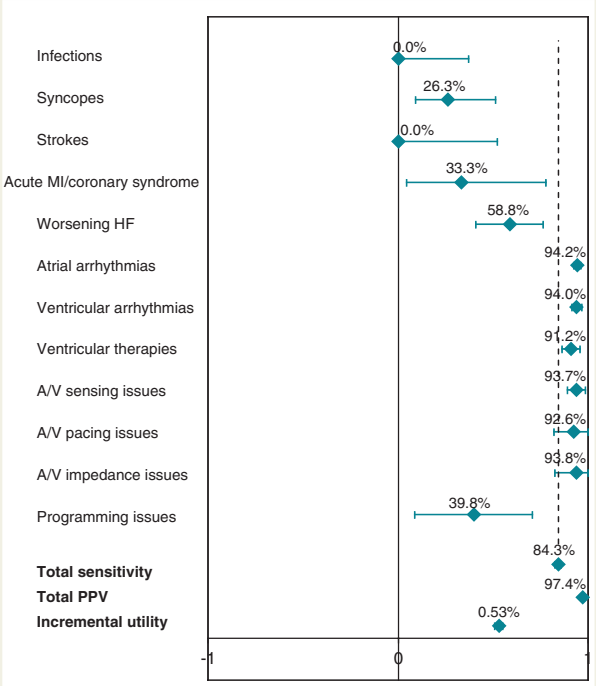

Figure 2 Generalized estimating equation-adjusted overall HM sensitivity, PPV, and IU. Home Monitoring sensitivity estimates for subgroups of MCEs are also displayed.GEE, generalized estimating equation; HM, Home Monitoring.

early clinical reaction, by devoting <1 h healthcare personnel per month every 100 patients.

Remote monitoring is rapidly becoming the standard of care for patients with CIEDs with the aim to enhance patient clinical management and to reduce healthcare source consumption. Remote monitoring has been introduced in the international guidelines[1] and, accordingly, it may replace the majority of in-person follow-up visits. The TRUST Study has demonstrated that remote monitoring safely reduces healthcare source consumption and shortens the reaction time to clinical events.[3] Early detection of adverse events and prompt reaction to them may lead to major clinical benefits, particularly in patients with device or lead malfunction.[13,14] Remote monitoring has been also associated to a reduced hospitalization rate for atrial fibrillation and a potential lower risk for stroke,[7,15] to less appropriate and inappropriate ICD shocks[16] and to shorter hospitalization stays for HF.[4–5]

The HomeGuide Registry is the first large registry that investigated the impact of remote monitoring of CIEDs on patient management and clinical event detection and treatment in daily practice. A predefined organizational model, deeply involving Allied Professionals, was applied in all 75 participating Italian centres and the data were homogeneously collected by using custom made software.

The results of the registry showed a high effectiveness of remote monitoring in detecting clinical events. Almost three out of four events needing clinical intervention were remotely detected and reaction time to events was short (median 3 days). The most common clinical reaction was drug therapy adjustment; oral anticoagulation introduction in patients with asymptomatic atrial fibrillation at high risk for stroke and HF therapy titration were the most clinically significant. The impact of Home Monitoring-guided anticoagulation on stroke risk in patients with ICD and CRT-D devices is being evaluated in the ongoing randomized IMPACT trial, with a target population of more than 2700.[17]

Sensitivity and PPV concepts have been applied to HM detection of generic cardiovascular events, excluding deaths, with no further restrictions to those normally detected by an implanted device.

The scope was to stress the evaluation of the event detection performance by HM when embedded in the HomeGuide workflow model: therefore the 82% sensitivity obtained (84%, GEE-adjusted) returns an estimate of the conditional probability that for any cardiovascular event a patient experienced, the outpatient clinic personnel became aware of it remotely. Events detected outside HM sessions included both events not expected to be detected by an implanted device (infections, strokes, myocardial infarctions, etc.) and events not detected with HM due to technical or organizational reasons. Including the latter class of events led to a maximum sensitivity estimate of 89% (91% GEE-adjusted). These estimates appear remarkably high in the light of the special meaning of sensitivity assumed here. Similarly, the 97% PPV estimate returned the conditional probability that a remote notification of an event by HM was trustworthy.

Due to the broad definition of MCE assumed in the HomeGuide Registry encompassing such a large variety of unpredictable events, sensitivity, and PPV concepts may however appear incomplete to assess HM detection performance, since events may have several characteristics or properties with completely different clinical and practical significance. The IU, based on the expected utility concept and derived from the Game Theory, may be regarded as an additional index introducing a qualitative differentiation among events. Although calculations may be performed for any set of arbitrarily chosen properties of interest, the method does not introduce any difference between the clinical or practical significance of properties. With the set of four properties we chose (HM-witnessed, correct diagnosis, asymptomatic, and actionable) the events collected during HM sessions were associated with a significantly positive IU of +0.56 (unadjusted, +0.53; $P < 0.0001$) as compared with the events detected during in-person visits/in other circumstances. Roughly speaking, this means that for any event detected during an in-person visit showing one of the considered properties, there was an event detected during a HM session showing on average two properties more. This gives an extra value to HM; as a matter of fact, HM allowed early reaction mainly to asymptomatic events which could have lead to serious adverse events if missed or late detected.

Home Monitoring sensitivity was calculated also for event types. As expected, sensitivity for atrial and ventricular arrhythmias, for device therapies, and for implanted system malfunctions (including pacing, sensing, and lead impedance issues) was very high (>90%). On the contrary, a modest sensitivity (<35%) was observed for events such as stroke or acute coronary syndromes, for which direct event detection is not currently in the system capability and it may be only indirectly suspected (e.g. an episode of ventricular tachycardia due to myocardial ischaemia). In patients with syncope, HM could identify the cause (for instance ventricular fibrillation), only in 26%.

Progression of HF was early detected only in about 60% of cases. This result may be basically due to suboptimal efficiency of the currently available HF predictors, as well as to a still imperfect interpretation of them during normal clinical practice. Continuous monitoring of markers of HF status has been demonstrated to help identifying patients at higher risk of developing acute HF.[18,19] However, an algorithm combining all data in a score index capable of alerting the physician is still lacking.

It should be noted that despite the HomeGuide organizational model may be applied to any remote monitoring system, our results cannot be generalized as, unlike other systems, the HM is essentially characterized by daily device-to-server transmissions providing a patient-independent continuous data flow.

Finally, data on healthcare resource consumption should be taken into account. Since the preliminary studies, remote monitoring has consistently shown ability to reduce patient visits (almost 50%), time required for patient follow-up, physician time, costs of patient transport, and hospital incurred costs[20] without compromising safety.[3] The results of the HomeGuide Registry confirmed that continuous remote monitoring of patients with CIEDs may be obtained in standard clinical practice with a very low manpower and resource consumption.

Conclusion

The HomeGuide Registry is the first large registry, providing a model for implementing CIED remote monitoring in daily clinical practice, which evaluated the impact on detection and treatment of MCEs. Home Monitoring sensitivity and PPV were very high. The large majority of the events were detected during HM sessions and were asymptomatic and actionable. Impact on outpatient clinic workload and resource consumption was remarkably low.

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Appendix

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