Workload and usefulness of daily, centralized home monitoring for patients treated with CIEDs: results of the MoniC (Model Project Monitor Centre) prospective multicentre study

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Aim
Automated, daily Home Monitoring (HM) of pacemaker and implantable cardioverter-defibrillator (ICD) patients can improve patient care. Yet, HM introduction to routine clinical practice is challenged by resource allocation for regular HM data review. We tested the feasibility, safety, workload, and clinical usefulness of a centralized HM model consisting of one monitor centre and nine satellite clinics.

Methods and results
Having no knowledge about patients’ clinical data, a telemonitoring nurse (TN) and a supporting physician at the monitor centre screened and filtered HM data in 62 pacemaker and 59 ICD patients from nine satellite clinics for over 1 year. Basic screening of arrhythmic and technical events required 25.7 min (TN) and 0.7 min (physician) per working day, normalized for 100 patients monitored. Communication of relevant events to satellite clinics per email or phone required additional 4.3 min (TN) and 0.4 min (physician). Telemonitoring nurse also screened for abnormal developments in longitudinal data trends weekly for 3 months after implantation, and then monthly; one patient session lasted 4.0 ± 2.9 min. To handle transmission-gap notifications, TN needed additional 2.8 min daily. Satellite clinics received 231.3 observations from the monitor centre per 100 patients/year, which prompted 86.3 patient contacts or intensive HM screening periods by the satellite clinic itself (37.3% response rate), 51.7 extra follow-up controls (22.3%), and 30.1 clinical interventions (13.0%).

Conclusion
Centralized HM was feasible, reliable, safe, and clinically useful. Basic screening and communication of relevant arrhythmic and technical events required a total of 30 min (TN) and 1.1 min (physician) daily per 100 patients monitored.

Keywords
Centralized Home Monitoring • Telemonitoring nurse • Monitor centre • Implantable cardioverter-defibrillator • Pacemaker • Remote monitoring • Workflow

Introduction
Remote monitoring of patients treated with implantable cardioverter-defibrillators (ICDs) or pacemakers enables early detection and prompt evaluation of relevant events, including asymptomatic arrhythmias and technical problems that may remain concealed for extended periods with conventional follow-up.1–6 The growing number and complexity of implantable devices and

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What’s new?

- We tested, for the first time, a centralised Home Monitoring model, in which one monitor centre screened and filtered daily, automatic Home Monitoring data in pacemaker and ICD patients from nine satellite clinics, to forward relevant data per email and communicate highly important data by phone.
- We found this model to be feasible, safe, and clinically useful. It may help smaller centres fully utilise Home Monitoring technology despite limited workforce and low patient numbers that may hamper development of dedicated, experienced, single-centre Home Monitoring teams.
- This was only the second study so far to measure workload needed to control Home Monitoring data flow on a daily basis. Per 100 patients monitored, the telemonitoring nurse at the monitor centre spent 30 min daily for basic screening, filtering, and communication of critical events, while the physician supporting her needed 1.1 min daily.

Telemonitoring concepts challenge the organization of remote monitoring practice at outpatient clinics. These problems may be overcome by introducing a centralised remote monitoring system.

In a centralized remote monitoring system, a specialized centre (the ‘monitor centre’) could screen and filter remote monitoring data in patients referring to several ‘satellite clinics’. The monitor centre would pass seemingly relevant data to the satellite clinic per email and communicate highly important data additionally by phone. The specific challenge faced by the monitor centre would be judging on the relevance of remote monitoring data while having no access to patients’ clinical data.

The present study was designed to test the workflow of a centralised remote monitoring model in real life, focusing on its safety, feasibility, logistical effort, workload, and impact on follow-up of patients and their medical treatment.

Methods

The Model Project Monitor Centre (MoniC) study was a prospective, non-randomized, multicentre, observational study. The monitor centre was located in Berlin, Germany (Charite Universita¨tsmedizin Berlin, Campus Mitte) serving nine satellite clinics in Germany and Austria (see Appendix). Ethics committee approval was obtained for the study. All recruited patients provided written informed consent. The study was conducted according to the Good Clinical Practice Guidelines and the Declaration of Helsinki.

Remote Monitoring System

Unlike other remote monitoring systems for cardiac pacing devices, the Home Monitoring technology by Biotronik SE & Co. KG (Berlin, Germany) offers fully automated, daily data transmissions, enabling almost continuous arrhythmia and device surveillance. The diagnostic data recorded by the devices are automatically transferred to a bedside transmitter either time-triggered (e.g. each day at 2 AM when most patients are asleep) or event-triggered (e.g. by arrhythmia).

The bedside transmitter relays the data via standard GSM mobile phone links to the Biotronik Home Monitoring Service Centre (HMSC) for further computed processing.

Following data processing in the HMSC, event notification reports and patient’s status reports are generated automatically and delivered to the patient’s physician (or, in the MoniC study, to the monitor centre). These reports can be configured individually in each patient, to indicate potentially relevant arrhythmia episodes and technical events, including intracardiac electrocardiograms in last generation devices. The HMSC thereafter posts all HM data and generated reports on a secured webpage for online review by the patient’s physician. This online archive contains parameter trends, plotted with a temporal definition of 24 h, showing technical device and medical diagnostic data.

Patient Selection

To be enrolled in the MoniC study, patients had to have an indication for an ICD or a dual-chamber pacemaker, to be reachable by phone, and willing to attend all follow-ups. The patients were not admitted to the study if they had life expectancy <12 months or age <18 years. Further exclusion criteria were pregnant or breast-feeding woman, participation in another clinical study, inability to use the bedside transmitter, or living in an area without sufficient mobile phone coverage needed for the automated data transmission.

Study Protocol

Within the study, we distinguished between basic and extended screening of HM data. The basic follow-up was concerned daily with event notification reports. The extended follow-up was concerned with the analysis of data trends on a weekly basis for the first 3 months after implant and then monthly, thus resembling regular remote follow-up procedure without patient participation.

The monitor centre was on duty from Monday to Friday between 8 AM and 4 PM. Two trained nurses and two physicians were available at the centre to cover all working days including vacations. In order to maximize the input information, most of the customizable event notification reports were enabled in the devices. At the time of our study, the software platform in the HMSC did not integrate the traffic light concept, which is now available (see Discussion). Therefore, a trained study nurse (the ‘telemonitoring nurse’ (TN)) classified HM data manually, into the following three categories:

- Red—highly important events, to be communicated to the satellite clinic both over phone (physician to physician) and by email;
- Yellow—potentially important events; report forwarded to satellite clinic per email only; and
- Green—a notification of the participating cardiology department is unnecessary

All classification rules were defined before study beginning as decision-tree algorithms adjusted to the individual characteristics of implantable devices eligible for the study. For the extended data screening, observations of interest were marked changes in longitudinal trends related to lead impedance, percent of paced/sensed activity, mean heart rate, mode-switch, and several other parameters.

Whenever a prolonged (>7 consecutive days) interruption of HM data transmission occurred, the TN attempted to reach the patient by phone up to five times within 1 week, to find out the underlying reason and help the patient re-establish HM function. If this measure was not successful, the TN informed the satellite clinic per email of the continued transmission gap and the need for further action.
Results of the MoniC (Model Project Monitor Centre) study

Figure 1 Information flow in the MoniC study. Labelled arrows: (1) automated daily transmission of diagnostic data from implanted devices to the Biotronik Home Monitoring Service Centre; (2) Home Monitoring Service Centre sent event notification reports and patient’s status reports to the monitor centre per email, and posted Home Monitoring data online; (3) monitor centre called patients in case of a 7-day gap in Home Monitoring data transmission, but did not give any medical advice. If the phone support was ineffective, monitor centre informed the satellite clinic about the continued transmission gap per email; (4) monitor centre screened and filtered Home Monitoring data to inform satellite clinics of seemingly important findings (email) or highly important findings (phone + email); (5) satellite clinics had free access to the online Home Monitoring data archive, to elucidate situations of interest; (6) satellite clinics approached patients for discussion or treatment as needed; and (7) satellite clinics described measures they had undertaken and concluded on the importance of Home Monitoring findings forwarded by the monitor centre.

When unable to clarify herself an event notification report or a data trend, the TN consulted the responsible physician in the monitor centre. All activities at the monitor centre were documented, evaluated, and quantified in time, as needed to assess logistic efforts.

The information forwarded to satellite clinics could have had consequences for patient management. This might have been a phone call to the patient, an ambulatory visit, rescheduling of follow-up scheme, hospitalization, electrophysiological study, medication change, device reprogramming, or, at least, a closer look at HM data. Satellite clinics were free to decide on the follow-up scheme and device programming in all patients. Yet, they were bound to inform the monitor centre on patient management, and to provide telephone support to patients after prolonged transmission gaps. Satellite clinics approached patients for discussion or treatment as needed; and satellite clinics described measures they had undertaken and concluded on the importance of Home Monitoring findings forwarded by the monitor centre.

Normalization of study results
Messages forwarded to satellite clinics were counted and classified. The counts were normalized per 100 patients/year according to the formula:

\[ n_{100 \text{pts/year}} = \frac{n_{\text{total}} \times 365 \text{ days} \times 100 \text{ pts}}{\text{Total FU days for all pts}} \]

Where ‘\( n_{\text{total}} \)’ stands for the total number of certain message types, ‘pts’ denotes patients, and ‘FU’ denotes follow-up. The above formula was used also to normalize measures undertaken by satellite clinics. The numbers of event or trend analyses (‘\( n_{\text{total}} \)’) made by the TN were normalized per working day for 100 patients under HM as

\[ n_{100 \text{pts per working day}} = \frac{n_{\text{total}} \times 100 \text{ pts} \times 7 \text{ days}}{\text{(total FU days for all pts) 5 days}} \]

After replacing ‘\( n_{\text{total}} \)’ with ‘time total’, this formula was used to normalize the time expenditure of the nurse and of a supporting physician for different tasks.

Statistical methods
Descriptive statistics were used. Results are reported as normalized numbers either per 100 patients/year (for counts) or per working day for 100 patients (for time). In some cases the absolute numbers are provided, clearly denoted as such. Continuous variables are reported as mean ± SD.

Study objectives
The primary study objective was to evaluate the feasibility and safety of the described workflow for centralized HM. This included assessment of ‘false negatives’ that were defined as severe adverse events preceded by no warning from the monitor centre, despite potentially indicative HM data. The secondary endpoints were: (i) time effort of the monitor centre to analyse and communicate HM data to satellite clinics and to provide telephone support to patients after prolonged transmission gaps. (ii) consequences of forwarded messages for patient management, and (iii) value of forwarded messages as perceived by physicians at satellite clinics.

Results
Patients and implanted devices
A total of 128 patients were enrolled in the study at 10 satellite clinics. After exclusion of one clinic because of protocol violation and data incompleteness, the final analysis included 121 patients treated with 62 pacemakers (Philos II, Cylos) and 59 ICDs (Lumos, Lexos, Xelos, Kronos) (Biotronik SE & Co. KG).

The pacemakers were implanted to treat atrioventricular nodal disease (45%), sick sinus syndrome (44%), bionodal disease (8%), or else (3%). The ICDs, either alone (n = 57) or combined with cardiac resynchronization device (n = 2), were implanted in patients who fulfilled MADIT II criteria\(^1\) (36%), had other primary prevention indications (8%), survived a cardiopulmonary resuscitation (22%), or had another secondary prevention indication (34%). Pacemaker patients were older (mean age, 74 ± 9 vs. 67 ± 10 years) and more balanced in gender (45 vs. 15% female) than ICD patients. The ICD patients presented with ischaemic heart disease (48%), non-ischaemic dilated cardiomyopathy (29%), or other cardiomyopathies or channelopathies (24%). Approximately half of ICD patients were in 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 36 ± 15%.
Follow-up duration, transmission success
The mean follow-up was longer in the ICD group (445 ± 133 days) than in the pacemaker group (340 ± 160 days), reflecting the more common use of HM in ICD patients than in pacemaker patients at recruiting centres at the beginning of the study. The automatic HM data transmission was successful on 88.5% of all follow-up days (41 910/47 343 days).

Messages forwarded to satellite clinics
The TN received 1649 event notification reports per 100 patients/year. After applying the predefined algorithms, she forwarded 131.8 messages including 148.8 events to satellite clinics. Categorization of events into five main categories, shown in Table 1, reveals marked differences between pacemakers and ICDs in that atrial arrhythmias and pacing/sensing alerts prevailed in pacemakers and ventricular arrhythmias in ICDs. Overall, 68.6% of pacemaker events and 89.9% of ICD events were related to the underlying disease, and the remaining events were related to the device or its programming (Table 1). Furthermore, 1.1% of pacemaker and 5.6% of ICD events were classified as red. The underlying reasons for red events were ventricular fibrillation storm, ineffect-ive 30 J shock, and low ventricular impedance.

The monitor centre received 128 transmission-gap notifications per 100 patients/year. In 28.5 cases (22.3%) the transmission problem could not be resolved by transtelephonic support. In these cases, the nurse informed the satellite clinic about the continued transmission problem per email.

For the extended screening, the nurse performed scheduled analysis of online data trends 2264 times per 100 patients/year and forwarded observations as categorized in Table 1.

Measures undertaken by satellite clinics
In 37.3% of all messages received, satellite clinics undertook an action (Table 2). Follow-up control was carried out in 22.3% of all forwarded messages. This amounted to 51.7 additional checks annually per 100 patients, including 6.9 hospitalizations and 9.3 visits to the local cardiologist. Furthermore, device reprogramming, medication change, or another intervention was undertaken in 13.0% of all messages (30.1 interventions annually per 100 patients). Importantly, satellite clinics classified 72.3% of messages forwarded by the TN as valuable (Table 2).

Figure 2 compares clinical effects of forwarded events, trend observations, and unresolved transmission gaps. As seen, events generally had higher relevance and led to more follow-up controls and interventions than other kinds of forwarded data. Figure 3 illustrates the extent of data filtering by the monitor centre.

Of note, for event reports, 73.4% of all initial clinical reactions, 77.3% of clinical follow-up controls, and 70.4% of interventions were related to the underlying disease, and the remaining percents were related to the device or its programming. For trend observations, 60.0% of initial clinical reactions, 46.2% of clinical follow-up controls, and 57.1% of interventions were related to the underlying disease, and the rest to devices and their programming.

Screening and communication workload at the monitor centre
The TN analysed an event notification report for 4.1 ± 3.0 min, on average. This included log-in and access to the internet-based HM platform, analysis and classification according to the predefined rules, and internal communication with the physician. She spent 25.7 min daily on this activity per 100 patients. For the communication of relevant events to satellite clinics, she spent additional 4.3 min. The physician available for her support spent only 1.1 min per working day for events (Table 3).

Screening and communication of longitudinal data trends required 36.9 min daily from the nurse and 0.3 min from the physician (Table 3). On average, 22.6 scheduled trend analyses were performed per patient annually, representing a very intensive

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Category of events and trend observations forwarded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Event report*</td>
</tr>
<tr>
<td>PM</td>
<td>ICD</td>
</tr>
<tr>
<td>Total, n</td>
<td>148.8</td>
</tr>
<tr>
<td>Importance, n (%)</td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>1.7 (1.1)</td>
</tr>
<tr>
<td>Yellow</td>
<td>147.1 (98.9)</td>
</tr>
<tr>
<td>Category, n (%)</td>
<td></td>
</tr>
<tr>
<td>Atrial arrhythmia</td>
<td>102.1 (68.6)</td>
</tr>
<tr>
<td>Ventricular arrhythmia</td>
<td>0</td>
</tr>
<tr>
<td>Pacing/sensing alerts</td>
<td>43.2 (29.0)</td>
</tr>
<tr>
<td>Lead integrity alerts</td>
<td>3.5 (2.4)</td>
</tr>
<tr>
<td>HF indicator, heart rate control</td>
<td>0</td>
</tr>
<tr>
<td>Related to, n (%)</td>
<td></td>
</tr>
<tr>
<td>Underlying disease</td>
<td>102.1 (68.6)</td>
</tr>
<tr>
<td>Device or its programming</td>
<td>46.7 (31.4)</td>
</tr>
</tbody>
</table>

ICD, implantable cardioverter-defibrillator; HF, heart failure; PM, pacemaker.
*Incidence normalized per 100 patients/year [to restore non-normalized values, multiply with 0.579 (pacemakers) or 0.720 (ICDs)].
extended screening scheme. One patient session lasted for 4.0 ± 2.9 min.

To maintain a high HM data transmission success of 88.5%, the TN attempted an average of 2.3 ± 1.5 phone calls to the patient for each transmission-gap notification received. The majority of calls (53%) were answered, by the patient or by a relative. For these phone calls, the nurse needed 2.4 min per working day.

Table 2 Measures undertaken at satellite clinicsa

<table>
<thead>
<tr>
<th>Event report</th>
<th>Trend observation</th>
<th>HM gap ≥7 days</th>
<th>Totala</th>
</tr>
</thead>
<tbody>
<tr>
<td>Messages forwarded to SC, n</td>
<td>131.8</td>
<td>70.9</td>
<td>28.5</td>
</tr>
<tr>
<td>Initial clinical reaction, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone call to the patient</td>
<td>18.5 (14.0)</td>
<td>4.6 (6.5)</td>
<td>12.3 (43.2)</td>
</tr>
<tr>
<td>Face-to-face encounterb</td>
<td>28.5 (21.6)</td>
<td>8.5 (12.0)</td>
<td>5.4 (18.9)</td>
</tr>
<tr>
<td>Intensive screening of HM data</td>
<td>2.3 (1.8)</td>
<td>6.2 (8.7)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>49.3 (37.4)</td>
<td>19.3 (27.2)</td>
<td>17.7 (62.2)</td>
</tr>
<tr>
<td>Clinical follow-up control, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient clinic: device FU</td>
<td>22.4 (17.0)</td>
<td>5.4 (7.6)</td>
<td>7.7 (27.0)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>6.2 (4.7)</td>
<td>0.8 (1.1)</td>
<td>0</td>
</tr>
<tr>
<td>Ambulatory visit: cardiology</td>
<td>5.4 (4.1)</td>
<td>3.9 (5.4)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>33.9 (25.7)</td>
<td>10.0 (14.1)</td>
<td>7.7 (27.0)</td>
</tr>
<tr>
<td>Intervention, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device reprogramming</td>
<td>8.5 (6.4)</td>
<td>1.5 (2.2)</td>
<td>0.8 (2.7)</td>
</tr>
<tr>
<td>Medication change</td>
<td>10.8 (8.2)</td>
<td>3.9 (5.4)</td>
<td>0</td>
</tr>
<tr>
<td>Electrophysiological study</td>
<td>0.8 (0.6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lead revision</td>
<td>0.8 (0.6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Transmitter replacement</td>
<td>0</td>
<td>0</td>
<td>2.3 (8.1)</td>
</tr>
<tr>
<td>Transmitter relocation</td>
<td>0</td>
<td>0</td>
<td>0.8 (2.7)</td>
</tr>
<tr>
<td>Total</td>
<td>20.8 (15.8)</td>
<td>5.4 (7.6)</td>
<td>3.9 (13.5)</td>
</tr>
<tr>
<td>Value of FM to SC, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valuable</td>
<td>97.1 (73.7)</td>
<td>47.8 (67.4)</td>
<td>21.6 (75.7)</td>
</tr>
<tr>
<td>No value</td>
<td>34.7 (26.3)</td>
<td>23.1 (32.6)</td>
<td>6.9 (24.3)</td>
</tr>
</tbody>
</table>

FM: forwarded messages; FU: follow-up; HM, Home Monitoring; SC, satellite clinics.
aNormalized per 100 patients/year (to restore non-normalized values, multiply with 1.297).
bIncluding contact with general practitioner.

cEither straightforward (‘face-to-face encounter’ cases above) or after phone conversation (some of the ‘phone call to the patient’ cases above).

Figure 2 The effects of messages forwarded by the monitor centre to satellite clinics (for definitions, see Table 2). The numbers are rounded to integers.

Figure 3 Filtering of events, trends, and transmission-gap notifications in the monitor centre, in conditions when nearly all event options were enabled to receive maximum information for screening. The numbers are normalized per 100 patients/year and rounded to integers. Approximately 8% of events and 3% of trend analyses were forwarded to satellite clinics. Only unresolved transmission-gap problems after calling the patient were forwarded (22%).
She spent additional 0.4 min to notify satellite clinics of unresolved transmission gaps per email.

**Reasons for data transmission gaps**

In 46% of the gaps > 7 consecutive days, the underlying reason was a user error, as the transmitter was turned off, was not placed on a console connected to the power supply, or was out of reach of the implanted devices. The next most common reason was the patient’s absence from home (22%).

**Patient deaths, premature study discontinuations, and severe adverse events**

One pacemaker and three ICD patients died from non-cardiac (n = 2) and cardiac (n = 2) causes, including a case of lethal arrhythmia occurring in the setting of interrupted HM data transmission for > 4 weeks. Three patients discontinued the study prematurely on their own discretion, and two patients due to progressive dementia. The following severe device-related adverse events were reported: atrial lead dislodgment (n = 5), ventricular lead dislodgment (n = 4), surgical problems (n = 2, ICD dislodgment and late haematoma), and inadequate shock therapy caused by T-wave oversensing (n = 2). Data filtering at the monitor centre did not result in failing to forward additional HM data that would have provided incremental benefit to satellite clinics in foreseeing or earlier diagnosing these adverse events.

**Discussion**

Automated, daily HM can improve patient care, and is well accepted among pacemaker and ICD patients. Yet, the introduction of HM to routine clinical practice is challenged by resource allocation, especially in smaller clinics. This factor was first scrutinized by Ricci et al. in 2008, who proposed an organizational model based on close interaction between expert TN and responsible physician. The role of the nurse is to control HM data flow on a daily basis, and filter critical events or unclear interpretations to the physician. This model gained wide acceptance in high-volume centres. The MoniC study tested this approach in a multicentre setting.

**Clinical usefulness of centralized Home Monitoring**

The nine satellite clinics participating in MoniC rated 72.3% of messages received from the monitor centre as valuable, while reacting to 37.3%. By comparison, in the single-centre Ricci study, the physician reacted to 50% of messages forwarded by the nurse. In MoniC, satellite clinics undertook 30.1 interventions per 100 patients/year prompted by HM findings, mostly medication change (14.6) and device reprogramming (10.8). The centralized daily HM proved to be feasible, safe, and useful.

Clinical utility of the HM technology was confirmed by the large USA-based TRUST trial, which randomly assigned 1339 ICD patients to HM or conventional follow-up. TRUST unequivocally demonstrated that HM enables more rapid detection and evaluation of events than conventional follow-up. Moreover, the number of additional clinical visits in response to HM findings was considerably lower than the number of unnecessary clinical visits avoided owing to HM. This permitted a significant and safe reduction in the total number of yearly clinical visits (1.7 visits less per patient).

According to an expert consensus on the monitoring of cardiovascular implantable electronic devices, clinical visits can be partly omitted or drawn forward based on the individual (patient and implanted system) condition indicated by remote monitoring systems. It seems that a yearly number of additional clinical visits prompted by remote monitoring findings is inversely related to the yearly number of regular clinical visits. Thus, 3- to 6-month interval between regular clinical visits in MoniC was associated with 51.7 additional clinical visits per 100 patients/year, whereas the predominantly 12-month interval in TRUST or Ricci study led to 78 and 72.8 additional visits, respectively. 72.8 was not stated but derived from 53 additional visits during 26 559 days.

**Workflow in the monitor centre**

The HM system used in MoniC conveys detailed information on device operation and arrhythmic episodes that may be of great merit in patients receiving meticulous attention, but less so in an average patient. Data filtering was necessary. Approximately 8% of event reports and 3% trends analyses were forwarded to satellite clinics. This is in line with the Ricci study, where the TN forwarded 8% of 2249 analyses to the physician.

Basic data screening in MoniC (events) required negligible 1.1 min of the physician’s time daily, since the nurse covered data analysis (25.7 min) and standard communication with satellite clinics (4.3 min). In the Ricci study, the nurse and the physician spent together 21.9 min daily on data analysis and communication per 100

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**Table 3  Screening and communication workload at the monitor centre**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Telemonitoring nurse (min)</th>
<th>Physician (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analysis of event reports</td>
<td>25.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Communication of selected events to SC</td>
<td>4.3 @</td>
<td>0.4 (phone)</td>
</tr>
<tr>
<td>Total</td>
<td>30.0</td>
<td>1.1</td>
</tr>
<tr>
<td><strong>Extended screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scheduled analysis of online data trends</td>
<td>34.7</td>
<td>0.3</td>
</tr>
<tr>
<td>Communication of abnormal trends to SC</td>
<td>2.2 @</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>36.9</td>
<td>0.3</td>
</tr>
<tr>
<td>Transmission-gaps related communication</td>
<td>2.8 (phone, @)</td>
<td>0.0</td>
</tr>
</tbody>
</table>

SC, satellite clinics; @, email communication.

<sup>1</sup> Normalized per working day for 100 patients monitored, assuming each week has 5 working days.

<sup>2</sup> Event reports were customized in a way to cover almost all types of arrhythmia and technical events, to maximize the input information for the monitor centre.
patients monitored (derived from provided data). Several factors may have contributed to the increased daily workload in MoniC, the activation of nearly all types of event notifications, the use of more complex decision-tree algorithms, the multicentric approach with no access to patients’ clinical charts, and a higher proportion of ICD devices (49% MoniC vs. 25% Ricci), knowing that the analysis of intracardiac electrograms, frequently encountered in ICD patients, consume more time than review of other data.

Approximately three quarters of the time for analysis was spent on events and trends related to the underlying disease, and one quarter on data related to device or device programming. No significant difference was observed between these two groups in the percentage of messages leading to an action by satellite clinics.

The ambitious schedule for extended screening of longitudinal data trends consumed, however, more time and had less clinical implications than basic screening. It is therefore reasonable to limit extended screening in standard patients to, e.g., 3-month intervals. These intervals are commonly used with remote monitoring systems offering no automatic, daily data transmission and are currently recommended by the expert committee. Cutting the extended screening scheme in MoniC to 3-month interval would have resulted in ~7 min daily workload on top of basic screening.

Without a TN, the patient’s physician can filter HM data (i.e. reduce data inflow) by disabling unessential event notifications in individual patients. Moreover, the newest HMS Platform, Version 3.0, can prioritize data automatically and determine patient status according to a colour-coded traffic light concept. This concept integrates a score of classification rules tested in MoniC, and is aimed at improving the ease and comfort of the system by allowing a rapid overview of patients’ conditions.

Reliability of daily data transmission

The success of HM data transmission in MoniC of 88.5% (days covered) was similar to the success reported by other investigators using the same technology (89–96%). This enables an early detection of relevant clinical and technical events and ensures nearly daily dataflow for prospective automated algorithms to detect/predict cardiovasular events in heart failure patients, as described recently. Longer transmission gaps in MoniC were mostly caused by patient’s absence from home or inappropriate bedside transmitter operation due to patient’s oversight, which could usually be resolved by a phone call to the patient.

Importantly, in HM transmission gaps do not cause information loss in all cases, but merely postpone information delivery. The automated comparison of old and new data in the HMS Platform reveals all new events. By comparison, a recently published study with an alternative remote monitoring system reported transmission failure in 55% of alert triggering events. Thereby, up to 40% (229/575) of events did not trigger an alert because the alert was not reset. Such an in-office reset of an event is not needed in the HM system used in our study.

Study limitations

Arbitrary, albeit predefined, criteria for HM data filtering for satellite clinics was probably the major study limitation, in that definition of these criteria largely influenced study results. Furthermore, the HMS Platform 2.0 we used did not integrate the advanced colour-coded traffic light concept, now available in version 3.0. This newer platform would have been able to reduce workload of the monitor centre for data screening and filtering. Next, because we did not allocate patients randomly to centralized or standard (intraclinic) HM, we could not evaluate whether centralization compromises patient outcomes. Finally, MoniC covered only early life of devices, not addressing issues that may arise in the chronic phase.

Conclusion

Centralized HM was feasible, safe, and clinically useful, resting on a reliable automatic data transmission from the implanted devices (88.5% of days covered). For basic screening and communication of relevant arrhythmic and technical events, the TN needed a total of 30 min daily, whereas the supporting physician at the monitor centre needed negligible 1.1 min daily, per 100 patients monitored. Satellite clinics rated 73.7% of received basic screening messages as valuable; the reaction rate was 37.4%, with an impact on treatment in 15.8%. On the other hand, 67.4% of extended screening messages were rated as valuable, leading to a reaction rate of 27.2% and an impact on treatment in 7.6%. Accordingly, extended data screening for standard patients should be limited to, e.g., 3-month intervals to achieve a better workload–benefit balance. This model may help smaller centres utilize HM technology fully in pacemaker and ICD patients, despite limited workforce and low patient numbers that can hamper development of dedicated, experienced, single-centre HM teams.

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Conflict of interests:

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Appendix

Investigators and participating centres, according to the number of enrolled patients

M. Gomer (Diakoniekrankenhaus Mannheim, Germany); S. Stiller (University of Ulm Medical Center, cardiology Ulm, Germany); V. Kühlkamp (Herz- Zentrum Bodensee Konstanz, Germany); G. Zach (LKH Bruck, Austria); S. Löscher (Städtisches Klinikum St Georg Leipzig, Germany); G. Wiedmann and G. Huber (Donauspital im SMZ Wien, Vienna, Austria); F. Schminke (Klinikum Bernburg, Germany); B. Göttin
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