Validation of an Organizational Management Model of Remote Implantable Cardioverter-Defibrillator Monitoring Alerts

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Background—Implantable cardioverter-defibrillators (ICDs) are a standard means of sudden cardiac death prevention. Compared with ambulatory visits, remote monitoring (RM) of ICD recipients has improved the quality of health care and spared its resources. Few studies have addressed the organization of RM. We optimized and validated our institutional model of RM organization for ICD recipients.

Methods and Results—This observational study of 562 ICD recipients compared 2 RM periods consisting of iterative, qualitative, and quantitative (1) device diagnostic evaluations by nurses and cardiologists; and (2) selected decisional trees. The main study end points were the professional interventions prompted by, and times allocated to, RM alerts. During the first period, 1134 alerts occurred in 427 patients (286 patient-year), of which 376 (33%) were submitted to cardiologists’ reviews, compared with, 1522 alerts in 562 patients (458 patient-year), of which 273 (18%) were submitted to cardiologists’ reviews during the second period (P<0.001). An intervention was prompted by 73 of 376 (19.4%) alerts in the first versus 77 of 273 (28.2%) in the second period (P=0.009). The mean time to manage an alert was 4 minutes 31 s in the first versus 2 minutes 10 s in the second period (P<0.001). The annual numbers of alert-related hospitalizations were 10.8 versus 8.1 per 100-patient-year (P=0.230), and annual numbers of alert-related visits were 9.8 and 6.1 per 100-patient-year (P=0.081), respectively.

Conclusions—An optimized RM organization based on automated alerts and decisional trees enabled a focus on clinically relevant events and a decrease in the consumption of resources without compromising the quality of ICD recipients’ care. (Circ Cardiovasc Qual Outcomes. 2015;8:403-412. DOI: 10.1161/CIRCOUTCOMES.114.001433.)

Key Words: death, sudden, cardiac ◼ defibrillators, implantable ◼ models, organizational ◼ remote monitoring ◼ telemedicine
WHAT IS KNOWN

• Decision trees aimed at managing alerts triggered by the remote monitoring of implantable cardioverter-defibrillators have been neither described nor tested.
• Because it has become an important component of the routine follow-up of implantable cardioverter-defibrillators, remote monitoring must be the object of an in-depth and detailed organization.
• We describe our experience with the development and optimization of a model of remote monitoring, and the validation of decision trees using methodology adapted to the challenge at hand.

WHAT THE STUDY ADDS

• Our organizational model decreased the time devoted to remote monitoring by >50% and significantly decreased its variability.
• The efficacy and safety of our trees were confirmed by ≈60% fewer unnecessary interventions in response to remote monitoring alerts without increase in the rate of hospitalizations.
• This unique and original organizational model may optimize the time dedicated to follow-up of patients with implantable cardioverter-defibrillators.

Methods

Study Design
We used an iterative, phased approach that harnesses qualitative and quantitative methods, as recommended for the design of research on complex interventions to improve health care. This prospective, single-center study was designed to evaluate and optimize the use of resources and the remote management of ICD recipients as part of the standard clinical practice of a French, regional university hospital.

Our institutional ethics committee reviewed and approved the protocol of the study, which was performed in compliance with the declaration of Helsinki. All patients (1) were explained that their ICD RM information might be used for scientific research and (2) granted their informed consent.

Patient Population
We enrolled consecutive patients who, between February 2004 and August 2011, had undergone implantation of an ICD for primary or secondary prevention of sudden cardiac death according to current professional practice guidelines.

Technical and Organizational Aspects of RM
RM of ICD recipients is based on the transmission of data from the implanted device to a transmitter and, subsequently, to the healthcare provider. Communication between the ICD and the patient’s transmitter is via wireless telemetry. In case of scheduled, event-triggered or patient-initiated transmission, the information is collected by the patient’s transmitter and then transmitted to a network via a phone line or cellular connection, for analysis by the caregivers, who can access the data on the internet.

The RM pathway consists of several steps, including (1) securing the patient’s informed consent, (2) educating the patients on the use of RM, (3) programming the ICD for event-triggered transmissions, (4) adding the patient to the RM Website, (5) programming scheduled transmissions, (6) supplying patients with the RM monitor, (7) verifying the success of a first transmission, and (8) managing all transmissions and alerts. This study focused on the technical, organizational, and clinical management of RM transmissions and alerts.

Study Phases and RM Organization
The organizational flow chart of the study is shown in Figure 1. Phase 1 of the study consisted of a qualitative assessment by an engineer (L.F.) specialized in the collection, management, and analyses of investigative data, acting as an external observer evaluating the management of RM transmissions, tracking the various components of the RM organization (who, what, where, and when), investigating the logical pathways behind the RM organization, and determining how decisions are made, without personal participation in patient care. The outside observer worked side by side with the nurses and cardiologists, measured the times spent on each task, and entered that information in dedicated forms. The nurses and cardiologists did not participate in these measurements. The alerts were handled during working hours by the outside observer, who was constantly available during these hours. The objective of this run-in phase was to define the components of transmission management and to design a quantitative data collection form for the following phases of the study.

The study was then composed of 2 quantitative observational phases (phases 2 and 4), separated by a second qualitative phase (phase 3). During phase 2, which lasted from September 2009 to August 2010, nurses and cardiologists evaluated the transmitted data. Using independent judgment, the nurses referred most technical or clinical alerts of concern directly to cardiologists. The outside observer measured the time spent by the caregivers in the management of RM transmissions and tracked the alerts that prompted a reaction of any kind, although not necessarily a change in the patient management. The main objective of phase 2 was to provide the cardiologists involved in the study with both qualitative and quantitative data to optimize the management of RM transmissions by assigning new roles and designing the decisional trees. Optimization of this RM management was the aim of phase 3.

During phase 4, the second quantitative phase of the study, in accordance with the new decisional trees, only subgroups of alerts were referred to the cardiologists. The decisional trees were accessible by the nurses who could scrutinize each type of alert. In this last phase, which lasted from September 2010 to August 2011, the external observer again (1) measured the times required for the management of RM transmissions based on the newly defined roles and decisional trees and (2) tracked the reactions to alerts.

Follow-Up and Alert Programming
As recommended in current guidelines, the ambulatory visits were scheduled within 3 months after the ICD implants and at least every 12 months thereafter. In between visits, the patients were followed up remotely. RM systems from 4 different manufacturers were
used, including Home Monitoring (Biotronik Inc, Berlin, Germany), Latitude (Boston Scientific, Marlborough, MA), Carelink (Medtronic Inc, Minneapolis, MN), and Merlin.net (Saint Jude Medical, St Paul, MN). With the Home Monitoring and Merlin.net systems, which provide a variety of event-triggered automatic transmissions, and alerts in case of transmission failure, RM was performed using only these automatic transmissions and alerts. With the Latitude and Carelink systems, besides the event-triggered transmissions, RM was performed with 3-month scheduled transmissions to not miss technical or clinical events triggering inappropriate antitachycardia pacing therapy as the latter is not a trigger of transmission with these systems. These scheduled transmissions also confirmed that the system was operational for event-triggered transmissions because Carelink does not send alerts in case of transmission failures.

Objectives and End Points
We sought to evaluate and optimize the management of RM transmissions to follow and treat ICD recipients in the setting of a regional university hospital. The end point of the study was to compare 2 RM organizational models from the standpoints of (1) number of transmissions, (2) time spent in the management of transmissions by caregivers, (3) reactions to alerts, and (4) clinical outcomes. Clinical data were collected from patient records at the time of enrolment in the study, during reviews of RM transmissions and following patient contacts. Data on resource use were collected by the external observer during daily RM activities. Reactions prompted by the alert transmissions were classified as (1) patient contacts to inquire about event-related symptoms or medical compliance, (2) family physicians or cardiologists contacts to discuss modifications in the treatment plan, and (3) event-related ambulatory visits or hospitalizations.

Statistical Analysis
Descriptive statistics are reported as means±SD or medians (25th to 75th percentiles) where appropriate. The normality of distribution was tested, using q–q plots and Shapiro–Wilks test. Categorical variables are expressed as counts and percentages. Between-group comparisons of continuous measurements were made by Student t test for normal and nonparametric Mann–Whitney U test for non-normal distributions. Normality was examined by means of Shapiro–Wilks test. Categorical variables were compared using the χ² test. Rates of alerts were calculated per 100-person-year and 95% confidence interval. Exposure was measured in months. Rates were compared by means of Poisson exact test for pairs of samples. An F test was used to examine differences in variances between 2 populations. The SAS statistical software (SAS Institute Inc, Cary, NC) was used to perform all analyses. The tests were 2-sided, and P values of <0.05 were considered statistically significant.

Results
Study Population
During a mean follow-up of 16±7 and median of 17 (11–24) months, 562 patients were enrolled. The baseline characteristics of the study population are shown in Table 1. The flow of patients along the 2 quantitative phases is shown in Figure 2. At the beginning of phase 2, 175 patients were enrolled who were already remotely monitored, and 252 patients were added, for a total of 427 patients included in that phase, and followed up for a median of 286 cumulative years of follow-up. At the beginning of phase 4, 400 patients remained remotely monitored, and 135 patients were added, for a total of 535 patients included during that phase, and followed up for a median of 365 (365–365) days, corresponding to 458 cumulative years of follow-up.

Decisional Tree Design
During phase 1, the 5 steps of transmissions management were (1) control of RM transmissions and alerts for transmission failure on internet sites, (2) preparation of transmission reports, (3) evaluation of transmitted data, (4) contact with patients or caregivers, as needed, and (5) management of patient records. In our institution, these functions are performed by nurses and cardiologists with extensive RM experience. The nurses accessed the Websites to scrutinize the nature of event-triggered or patient-initiated transmissions, as well as scheduled and failed transmissions. They classified these events as administrative, or as technical (lead- or device-related) or clinical alerts (Table 2). Patient-initiated and scheduled transmissions were classified as administrative alerts, as the majority was not technical or clinical. Administrative alerts, including transmission failures, were managed by nurses. Patient-initiated or scheduled transmissions of clinical or technical issues were referred to the cardiologist. Reports of selected alerts were printed, and the patient’s history and medical management were retrieved from the records, before being submitted to the RM supervising cardiologist, who determined whether an intervention was needed. The identification of these various steps of transmission management enabled the engineer to design a form (Appendix I in the Data Supplement), which was subsequently used in the qualitative analysis of the activity and for the data collection during the 2 quantitative phases of the study. The form items allowed to (1) characterize the type and subtype of alerts, (2) record the time spent by the nurses in completing the file, including the reports of clinical and technical alerts and patient’s most recent medical report, (3) record the time spent by the cardiologist in diagnosing the event and, perhaps, contact the patient, the family physician or the treating cardiologist, and (4) indicate whether the alert has prompted a change in the patient’s care (intervention) and the nature of such change. These measurements were made and compiled by the engineer.

Table 1. Characteristics of the 562 Patients

<table>
<thead>
<tr>
<th>Category</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>458 (81)</td>
</tr>
<tr>
<td>Age, y</td>
<td>63±15</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>329 (59)</td>
</tr>
<tr>
<td>Dilated</td>
<td>111 (20)</td>
</tr>
<tr>
<td>Hypertrophic</td>
<td>26 (5)</td>
</tr>
<tr>
<td>Others</td>
<td>96 (17)</td>
</tr>
<tr>
<td>Atrial tachycardia/fibrillation</td>
<td>157 (28)</td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>54 (10)</td>
</tr>
<tr>
<td>Persistent</td>
<td>49 (9)</td>
</tr>
<tr>
<td>Permanent</td>
<td>54 (10)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>35±14</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>305 (54)</td>
</tr>
<tr>
<td>Cardioverter defibrillator</td>
<td></td>
</tr>
<tr>
<td>Single chamber</td>
<td>247 (44)</td>
</tr>
<tr>
<td>Dual chamber</td>
<td>200 (36)</td>
</tr>
<tr>
<td>Cardiac resynchronization</td>
<td>115 (20)</td>
</tr>
</tbody>
</table>

Values are means±SD or numbers (%) of observations.
In phase 3, the qualitative analysis of the data collected in phase 2 revealed that the cardiologist devoted nearly no time to certain types of alerts that did not warrant a change in patient management. This observation allowed to no longer submit nearly all alerts for review by the cardiologist in phase 4. Specifically, technical and clinical alerts (Table 2) were divided in 3 categories: (1) alerts systematically submitted to the cardiologist, including elective replacement indicator, ventricular tachycardia/ventricular fibrillation classification disabled, safe mode enabled, ventricular tachycardia, ventricular fibrillation, successful antitachycardia pacing, shock delivery, unsuccessful shock delivery at maximum energy, and proarrhythmic therapy; (2) alerts never submitted to the cardiologist, including nonsustained ventricular tachycardia, >100 ventricular extrasystoles per hour, and right ventricular stimulation >40%; and (3) alerts reviewed by the cardiologist only when indicative of serious abnormality and impending critical event. Variables that might have been associated with abnormal, though noncritical changes were right atrial lead impedance, signal amplitude sensed by the right atrial lead, right ventricular lead impedance, signal amplitude sensed by the right ventricular lead, left ventricular lead impedance, signal amplitude sensed by the left ventricular lead, safety margin of right ventricular stimulation threshold, safety margin of left ventricular stimulation threshold, shock impedance, ventricular rate >100 bpm, ventricular rate at rest >80 bpm, and <80% biventricular pacing. Atrial tachycardia/fibrillation-related alerts, such as >6-hour burden or prolonged episode of atrial tachyarrhythmia, supraventricular tachycardia episode, and ventricular rate during atrial tachyarrhythmia >100 bpm, were considered important only when new in onset or when developing in the absence of oral anticoagulation. The qualitative analysis of the data used by the cardiologists in their decision making allowed the drawing of decisional trees (Appendix II in the Data Supplement), which were used by the nurses during phase 4 of the study. With respect to the Carelink RM system, each alert was submitted to a cardiologist who scheduled an ambulatory visit to reset the alert with the programmer, short of which further similar events might not trigger an alert.

RM Alerts
An alert of any kind was recorded in 100% of patients, whereas a technical, a clinical, or both alerts were recorded in 260 of the 562 patients (46%). During phase 2, 1134 alerts occurred in 427 patients (286 patient-year), corresponding to an annual rate of 3.96 alerts per 100-patient-year, whereas during phase 4, 1522 alerts occurred in 562 patients (458 patient-year), corresponding to an annual rate of 3.32 alerts per 100 patient-years \( (P<0.001) \). Figure 3 shows the annual alert rates by types during phases 2 and 4. The cardiologist was submitted 376 of 1134 alerts (33%) during phase 2 and 273 of 1522 alerts (18%) during phase 4 \( (P<0.001) \). A reaction was prompted by 73 of 1134 (6.4%) and 77 of 1522 (5.1%) alerts in phases 2 and 4, respectively \( (P=0.151) \). An intervention ensued after 73 of 376 alerts (19.4%) were submitted in phase 2 and after 77 of 273 alerts (28.2%) were submitted in phase 4 \( (P=0.019) \). The types (administrative, technical, or clinical) and number of alerts, number and proportions of submitted alerts, and number and proportions of reactions to alerts during phases 2 and 4 are shown in Table 3.

Time Spent By Caregivers in the Management of RM Alerts
The total time spent in the management of alerts was 85 hours 39 minutes in phase 2 and 55 hours 12 minutes in phase 4. The time spent by nurses was 61 hours 34 minutes and 34 hours 50 minutes and that spent by the cardiologist was 24 hours 05 minutes and 20 hours 22 minutes, in phases 2 and 4 (Figure 4), respectively.

The time spent per alert was 4 minutes 31 s during phase 2, decreasing significantly to 2 minutes 10 s during phase 4, a 52% decrease \( (P<0.001) \). The time spent in RM activities is shown in Figure 5. On the basis of the number of alerts that occurred in phase 4 and the average time spent managing alerts in phase 2, 114 hours 30 minutes instead of 55 hours 12 minutes would have been spent during phase 4 in the absence of optimization.

The variability in total time (SD, 5.4 versus 6.9; \( P<0.0001 \)) and nurses’ time (SD, 3.0 versus 4.9; \( P<0.0001 \)) spent reviewing and managing alerts was significantly lower in phase 4 than in phase 2.
We observed no differences in the consumption of healthcare resources as a function of specific patient populations or type of implanted single, dual, or triple chamber ICD.

### Classification of Types and Subtypes of Alerts

<table>
<thead>
<tr>
<th>Category</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative</td>
<td>No message for 14 days*</td>
</tr>
<tr>
<td></td>
<td>First message received</td>
</tr>
<tr>
<td></td>
<td>Reminder of a past alert</td>
</tr>
<tr>
<td></td>
<td>Patient-initiated transmission</td>
</tr>
<tr>
<td></td>
<td>Scheduled transmission</td>
</tr>
<tr>
<td>Technical</td>
<td>Elective replacement indicator</td>
</tr>
<tr>
<td></td>
<td>Ventricular tachycardia/fibrillation classification disabled</td>
</tr>
<tr>
<td></td>
<td>Safe mode enabled</td>
</tr>
<tr>
<td>Lead-related</td>
<td>Right atrial lead impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Right atrial lead sensed signal amplitude out of range</td>
</tr>
<tr>
<td></td>
<td>Right ventricular lead impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Right ventricular lead sensed signal amplitude out of range</td>
</tr>
<tr>
<td></td>
<td>Right ventricular stimulation threshold out of range*</td>
</tr>
<tr>
<td></td>
<td>Safety margin of right ventricular stimulation*</td>
</tr>
<tr>
<td></td>
<td>Left ventricular lead impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Left ventricular lead sensed signal amplitude out of range</td>
</tr>
<tr>
<td></td>
<td>Safety margin of left ventricular stimulation*</td>
</tr>
<tr>
<td></td>
<td>Shock impedance out of range</td>
</tr>
<tr>
<td></td>
<td>Lead integrity alert*</td>
</tr>
<tr>
<td>Clinical</td>
<td>Atrial tachycardia/fibrillation</td>
</tr>
<tr>
<td></td>
<td>Atrial burden&gt;threshold</td>
</tr>
<tr>
<td></td>
<td>Long atrial episode</td>
</tr>
<tr>
<td></td>
<td>Episode of atrial fibrillation</td>
</tr>
<tr>
<td></td>
<td>Supraventricular tachycardia*</td>
</tr>
<tr>
<td></td>
<td>Ventricular rate during atrial tachycardia/fibrillation&gt;threshold</td>
</tr>
<tr>
<td>Ventricular tachyarrhythmias</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td></td>
<td>Ventricular fibrillation</td>
</tr>
<tr>
<td></td>
<td>Successful antitachycardia pacing*</td>
</tr>
<tr>
<td></td>
<td>Delivered shock</td>
</tr>
<tr>
<td></td>
<td>Unsuccessful shock at maximum energy*</td>
</tr>
<tr>
<td></td>
<td>Poirhythmic therapy*</td>
</tr>
<tr>
<td></td>
<td>Nonsustained supraventricular tachycardia</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>Ventricular extrasystoles/h, &gt;100*</td>
</tr>
<tr>
<td></td>
<td>Ventricular rate, &gt;100 bpm*</td>
</tr>
<tr>
<td></td>
<td>Ventricular rate at rest, &gt;80 bpm*</td>
</tr>
<tr>
<td></td>
<td>Resynchronization therapy, &lt;80% stimulation</td>
</tr>
<tr>
<td></td>
<td>&gt;40% right ventricular stimulation</td>
</tr>
</tbody>
</table>

*Alerts common to all remote monitoring systems are grouped under a single term. Alerts specific to 1 system have been assigned their own identification. *Alerts specific to 1 system.

### Ambulatory Visits and Hospitalizations

RM alerts prompted 28 ambulatory visits during phase 2, corresponding to an annual rate of 9.8 per 100-patient-year, and 28 ambulatory visits during phase 4, corresponding to an annual rate of 6.1 per 100-patient-year (P=0.081). Moreover, RM alerts prompted 31 and 37 hospitalizations in phases 2 and 4, respectively, corresponding to annual rates of 10.8 and 8.1 hospitalizations per 100-patient-year, respectively (P=0.230).

In phase 2, 20 of 73 alerts (27%) submitted to the cardiologist prompted no change in patient management, compared with 9 of 77 (12%) in phase 4, corresponding to a 56% decrease in unnecessary reactions to alerts.

### Deaths and End of Study

The annual death rate was 6.6 per 100 patient-year in phase 2 and 4.1 per 100 patient-year in phase 4, corresponding to 19 deaths in each phase 2 and 4 of follow-up. Furthermore, 8 patients in phase 2 and 25 in phase 4 exited the study prematurely. The reasons for premature termination were (1) the transfer of 26 patient follow-ups to another health center, including 2 in phase 2 and 20 in phase 4, (2) the deactivation of a single ICD in each phase, (3) the explantation of 2 ICDs in phase 4, (4) 2 patients declining further follow-ups in phase 4, and (5) a single cardiac transplantation in phase 2.

### Discussion

**Rationale for Our Study**

RM multiplies the data available to the caregivers and distributes them via electronic media that are accessible everywhere. Although it was intuitively perceived to be a progress in the organization of healthcare, it might, in fact, turn out to be counterproductive by (1) wasting time by diverting the physicians’ attention toward an overload of information that might not be useful and clinically pertinent, (2) perverting the traditional clinical thought process by the multitude of data, and (3) disorganizing the day-to-day medical practice by its pervasive intrusion everywhere, any time. This challenge, underscored by Varma, incited our rational and scientific reconsideration of the organization and application of RM of ICD recipients. To the best of our knowledge, this is the first study to examine objectively the strategy of RM and ascertain its effect on the delivery of health care. We used an original multiphasic approach particularly suited for the evaluation of complex interventions, such as those related to the behavior and organization of healthcare professionals. The multidisciplinary methodology, using external observer and statistician, optimized the data quality and increased the likelihood of obtaining unbiased results.

**Main Contributions of the Management Model**

The attribution and definition of a key role played by a nurse specialist and the creation of decision trees toward the management of alerts (1) decreased the number of clinical and technical alerts per patient by 21%, to an average of 1.53 alerts per patient per year, (2) cut in half the time spent per alert, to an average of 48 s of medical time and 1 minute 22 s of...
nurses’ time, and 3) lessened the variability of the overall time spent and of the time spent by nurses. The trigger of a certain proportion of alerts is the crossing of a threshold by a numeric variable. The baseline value of this variable, in some patients, often oscillates near this threshold, triggering frequent alerts that are not contributory. The inclusion, in decision trees, of a need, in some instances, to adjust the alert threshold has considerably contributed to moderating the inevitable rise in the incidence of technical alerts caused by the gradual decay of the implanted material, thus limiting the rate of irrelevant alerts. The decrease in the number of clinical alerts was attributable to the deactivation, in selected patients, of the alerts.

### Table 3. Alert Types and Subtypes and Reactions

<table>
<thead>
<tr>
<th>Type</th>
<th>Subtype</th>
<th>Total</th>
<th>Brought to Cardiologist’s Attention</th>
<th>Prompting a Reaction</th>
<th>Contacts</th>
<th>Introduction to Cardiologist</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative</td>
<td>Transmission</td>
<td>570</td>
<td>19 (3.3)</td>
<td>2 (0.4)</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Technical</td>
<td>Device-related</td>
<td>9</td>
<td>9 (100.0)</td>
<td>8 (88.9)</td>
<td>8</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Technical</td>
<td>Lead-related</td>
<td>71</td>
<td>44 (62.0)</td>
<td>10 (14.1)</td>
<td>8</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Clinical</td>
<td>Atrial tachycardia/fibrillation</td>
<td>131</td>
<td>75 (57.3)</td>
<td>4 (3.1)</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Clinical</td>
<td>Ventricular tachycardia/fibrillation</td>
<td>182</td>
<td>145 (79.7)</td>
<td>40 (22.0)</td>
<td>35</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Clinical</td>
<td>Miscellaneous</td>
<td>171</td>
<td>84 (49.1)</td>
<td>9 (5.3)</td>
<td>4</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>1134</td>
<td>376 (33.2)</td>
<td>73 (6.4)</td>
<td>58</td>
<td>5</td>
<td>12</td>
</tr>
</tbody>
</table>

427 patients in phase 2 of the study

<table>
<thead>
<tr>
<th>Type</th>
<th>Subtype</th>
<th>Total</th>
<th>Brought to Cardiologist’s Attention</th>
<th>Prompting a Reaction</th>
<th>Contacts</th>
<th>Introduction to Cardiologist</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative</td>
<td>Transmission</td>
<td>805</td>
<td>40 (5.0)</td>
<td>5 (0.6)</td>
<td>5</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Technical</td>
<td>Device-related</td>
<td>22</td>
<td>20 (90.9)</td>
<td>20 (90.9)</td>
<td>19</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Technical</td>
<td>Lead-related</td>
<td>236</td>
<td>29 (12.3)</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Clinical</td>
<td>Atrial tachycardia/fibrillation</td>
<td>198</td>
<td>34 (17.2)</td>
<td>2 (1.0)</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Clinical</td>
<td>Ventricular tachycardia/fibrillation</td>
<td>195</td>
<td>122 (62.6)</td>
<td>48 (24.6)</td>
<td>42</td>
<td>3</td>
<td>22</td>
</tr>
<tr>
<td>Clinical</td>
<td>Miscellaneous</td>
<td>66</td>
<td>28 (42.4)</td>
<td>2 (3.0)</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>1522</td>
<td>273 (17.9)</td>
<td>77 (5.1)</td>
<td>68</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

535 patients in phase 4 of the study

Values are numbers (%) of observations.

*P = 0.024; **P < 0.001

**Figure 3.** Annual rates of each type of alert per 100-patient-year in phases 2 and 4.
caused by frequently recurrent atrial fibrillation, as well as to the absence of these recurrences after modifications of the patient management by pharmaceuticals, reprogramming of the ICD, radiofrequency ablation, and other successful therapeutic interventions.

The overall medical time spent in the management of alerts was shortened because of the ≈50% decrease in the percentage of alerts referred to the cardiologist. This decrease consisted of a large proportion of unnecessary alerts, as a third of those referred to the cardiologist did not prompt a medical intervention, which allowed a reallocation of the time spent in favor of clinically relevant alerts. The notable increase in mean medical time spent in the management of device-related, technical alerts in phase 4 might be explained by (1) a skewed distribution of a small number of observations and (2) the greater amount of time available and less pressure on the cardiologist in phase 4, as fewer alerts needed to be handled. The average medical time spent in the management of lead-related technical alerts decreased in phase 4 because the decisional trees enabled a speedy triage, sparing the cardiologist and nurses much wasted time in the handling and analysis of clinically equivocal and time-consuming data. The absence of interventions (as defined in the Methods) after ≈70% of the alerts referred to the cardiologist is explained by our insistence that all alerts prompted by the delivery of a therapy for ventricular tachycardia or ventricular fibrillation be referred to the cardiologist. The small amount of time spent to confirm that antitachycardia pacing was appropriate is negligible, if one considers the clinical benefit conferred by the detection of inappropriate antitachycardia pacing. As shown in the Effectiveness and Cost Of ICD Follow-Up Schedule With Telecardiology (ECOST) trial, an early detection contributes to a decrease in the incidence of inappropriate shocks, an objective that is worth pursuing meticulously.22

Main Organizational Points
The decision trees had major repercussions on the nurses’ interventions at the levels of (1) the time spent by the decrease in the number of alerts, (2) the 58% decrease in time spent on each alert, and (3) especially in a decrease in the variability of the time spent, which was partially attributable to the time needed to reflect on the means of treating an alert and, more precisely, on whether it needed to be referred to the cardiologist. This decrease in variability of the management of RM is of particularly great importance because RM probably increases the survival.15

The level of performance of RM and its contribution to an accurate diagnosis and appropriate decision hinge on the importance, relevance and individual tuning of the alerts,
as well as on the access to the most recent medical records and up-to-date medical treatment. As a consequence, the nurses play a key role in the management and triage of the alerts and their presentation to the cardiologist along with the latest medical report. Ricci et al\(^1\) have described a similarly close interaction between nurse specialists and cardiologists. In that system, the nurses continuously monitor the flow of RM data, filter critical events or unclear interpretations, and prepare special files for further evaluation by the cardiologist. They reported that 133 of 2249 RM transmissions (5.9%) were submitted to the cardiologist, of which 66 (2.9%) prompted a reaction. In their study, Ricci et al\(^1\) included alerts from 88 pacemaker recipients of 117 patients. These alerts are clinically less pertinent than ICD-triggered alerts. Furthermore, the nurses accessed the internet at 2-week intervals to evaluate all data which, unless event-occurred, rarely require an analysis by a physician. This might explain the lower rate of review and reaction by the cardiologist in their study than in ours. In our study and that of Ricci et al\(^1\), the cardiologists chose to intervene in \(\approx 30\%\) of the events they reviewed. We think that the management of clinical and technical alerts is the responsibility of the paramedical and medical staff, whereas the administrative alerts can be referred to the RM service provider to relieve the caregivers’ burden.

We found that, for a mean follow-up of 16±7 months, technical or clinical events occurred in \(<50\%\) of patients, confirming indirectly that a follow-up strategy based on RM and automatic alerts is more efficient than scheduled follow-ups.\(^{21-24}\) Additional personalization of the alert programming, based on the clinical profile of each patient at the time of ICD implantation, evolving with the evolution of the disease, might further optimize RM. It is noteworthy that the medical response brought about changes in patient management in 92% of instances, representing a high return.

Clinical Implications

The efficient use of the RM ICD data in clinical practice requires from the cardiology services to tailor their organization to the resources of the hospital and its staff and to the specific needs of RM. This represents the undertaking of new tasks, including the daily visiting of telecardiology Websites, the evaluation of transmissions, and the management of relevant clinical and technical observations. An optimized organization of RM enables the cardiologists to focus their attention on arrhythmias and potential technical issues, to which more time can be devoted, instead of to routine, scheduled, often futile ICD interrogations, which can be discontinued. It was opined by Sutton\(^1\) that routine interrogations that are not followed by clinical interventions no longer represent standard of care. On the other hand, a similar study might optimize the management of RM pacemakers by developing specific decision trees toward the surveillance of pacemaker recipients.

Limitations of Our Study

This single-center study was not randomized. We think, however, that comparing the new RM model tested in the 4th phase with the model applied in the 2nd phase was reliable. We used a historical control group because most patients were the same in both phases, who were followed up by the same hospital staff. We cannot exclude that our findings were influenced by a learning effect, despite the absence of significant temporal changes in the use of resources and considering our 10-year experience with the use of RM. Neither can we exclude that the optimization of medical management and device programming promoted by alerts and the aging of the devices changed the types of alerts in phase 4 and influenced the total time spent on RM. The overall improvements, however, including patient management, would remain a consequence of the progress made in our organization. On the other
hand, the decrease in mean time spent managing most of the specific types of alert is confirmatory of the positive role played by the decision trees in the optimization of the organization of RM. Furthermore, by multiple variable analysis, we found an independent association between decision trees and outcomes, taking into account the phase of the study and type of alert.

Our observations are linked to the choice of alerts offered by the RM system at the time of the study. Thus, the general applicability and reproducibility of our results may partially depend on the similarity of cardiology departmental organizations, patient populations, and other factors. The results of our qualitative research reflect the specific RM organization of our regional hospital. This organization, however, is similar among most cardiology departments, where clinically relevant events needing the attention of a cardiologist are being screened.

Conclusions

An optimized RM strategy based on automatic alerts, detailed triage rules, and decisional trees has reduced our utilization of healthcare resources and enabled us to focus on clinically relevant events without compromising the quality of health care. More generally, the use of telemedicine involves a reorganization of medical practices because it modifies the diagnostic armamentarium and its use.

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References


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Appendix 1- Data collection form

✓ Patient:
  • Name
  • Date of birth

✓ Alert:
  • Date
  • Type of alert
  • Subtype of alert

✓ Preparation of alert report:
  • Date
  • Start time (h : min)
  • End time (h : min)
  • Name of nurse

✓ Preparation of patient’s last medical report:
  • Start time (h : min)
  • End time (h : min)
  • Name of nurse

✓ Alert management by cardiologist:
  • Start time (h : min)
  • End time (h : min)
  • Name of cardiologist
  • Patient called (yes or no)
  • Patient’s family physician called (yes or no)
  • Patient’s family cardiologist called (yes or no)
  • Ambulatory follow-up (yes or no)
  • Hospitalization (yes or no)

✓ Modification of patient care:
  • Medication change (yes or no)
  • ICD programming change (yes or no)
  • Date of patient’s admission
  • Date of patient’s discharge
  • Final diagnosis
Appendix 2

Decisional trees for the management of alerts

Adminstrative alerts
➢ Transmission
   Transmission without event
   No Cardiologist review
   Transmission with event
   Cardiologist review according to event decisional tree

Technical alerts
➢ Device-related
   All alerts
   Cardiologist review

➢ Lead-related
   RA and LV lead impedance out of range and sensed signal amplitude out of range
   RV stimulation threshold out of range
   First alert
   Next alerts
   Significant variation
   Insigificant variation
   Check tomorrow
   Cardiologist review
   Discuss alert threshold with cardiologist
   Other leads
   Lead under advisory
   Significant variation
   Insigificant variation
   Check tomorrow
   Cardiologist review
   Discuss alert threshold with cardiologist

RV lead impedance out of range and sensed signal amplitude out of range
   First alert without other lead-related issue
   First alert with other lead-related issue or next alerts
   Other leads
   Lead under advisory
   Significant variation
   Insigificant variation
   Check tomorrow
   Cardiologist review
   Discuss alert threshold with cardiologist

Safety margin of RV or LV stimulation
   Pacemaker-dependent patient
   Cardiologist review
   Pacemaker non-dependent patient
   Measure the threshold
Clinical alerts

- **Supraventricular tachycardia**
  
  Atrial arrhythmia burden > threshold
  Long atrial episode: episode of atrial fibrillation

- **Ventricular tachycardia and fibrillation**

- **Miscellaneous**