

Technical Reliability and Clinical Safety of a Remote Monitoring System for Antiarrhythmic Cardiac Devices

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Introduction and objectives. In recent years, physicians have experienced a huge increase in workload associated with cardiac devices. Remote monitoring enables these devices to be monitored at a distance and could reduce the number of hospital visits. The aim of this study was to assess the technical reliability and clinical safety of the Home Monitoring™ remote monitoring system (Biotronik GmbH, Germany).

Methods. The study included 162 patients: 115 with pacemakers, 44 with implantable cardioverter-defibrillators (ICDs) and 3 with ICDs incorporating cardiac resynchronization therapy (CRT). Patients were followed up for a mean of 303 (244) days. We compared the survival time free of event alerts in patients with pacemakers and in those with ICDs. The remote monitoring system's reliability was evaluated by comparing the data it transmitted with clinical observations made immediately afterwards.

Results. The mean percentage of days monitored was 88.2%. The incidence of event alerts was higher in pacemaker than ICD patients (45% vs 34%; $P=.01$). Event alerts preceded the following hospital visit by 76 (47) days. In the ICD group, the data sent by the monitoring system were judged as true-positives in 42% of cases, as true-negatives in 57% and as false-positives in 1%. No false-negative was observed. In the ICD group, the remote monitoring system had a sensitivity of 100% and a specificity of 97% (positive predictive value 96%, negative predictive value 100%).

Conclusions. Remote monitoring was a reliable and safe method for following up patients with cardiac devices. Its routine use could enable the early detection of device malfunctions or arrhythmic events.

Key words: Pacemaker. Defibrillator. Remote monitoring.

Fiabilidad técnica y seguridad clínica de un sistema de monitorización remota de dispositivos cardíacos antiarrítmicos

Introducción y objetivos. En los últimos años se ha producido una sobrecarga de trabajo en las consultas de dispositivos cardíacos. La monitorización remota permite su evaluación a distancia y podría reducir el número de visitas hospitalarias. Los objetivos del estudio han sido evaluar la fiabilidad técnica y la seguridad clínica del sistema Home Monitoring™ (HM, Biotronik GmbH, Alemania).

Métodos. Hemos evaluado a 162 pacientes portadores de marcapasos (115), DAI (44) y DAI-TRC (3), durante un seguimiento medio de 303 ± 244 días. Se comparó la supervivencia libre de sucesos de alarma entre los pacientes portadores de marcapasos y DAI. La fiabilidad del HM fue analizada comprobando los datos transmitidos con la evaluación clínica presencial inmediatamente posterior.

Resultados. El porcentaje medio de días monitorizados fue el 88,2%. La incidencia de sucesos de alerta fue mayor en el grupo de marcapasos que en el de DAI (el 45 frente al 34%; $p = 0,01$). Los sucesos de alerta precedieron a la siguiente visita programada en 76 ± 47 días. En el grupo de DAI los datos transmitidos por el HM fueron juzgados como verdaderos positivos en el 42%, como verdaderos negativos en el 57% y como falso positivo en un 1% de los casos. No observamos ningún falso negativo. El HM mostró en el grupo de DAI sensibilidad y especificidad del 100 y el 97% (VPP, 96%; VPN, 100%).

Conclusiones. El HM es una herramienta fiable y segura para el seguimiento de los pacientes con un dispositivo cardíaco. Su utilización rutinaria permitiría detectar precozmente anomalías del funcionamiento del dispositivo o sucesos arrítmicos.

Palabras clave: Marcapasos. Desfibrilador. Monitorización remota.

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INTRODUCTION

The implantation of pacemakers (PM), implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy (CRT) devices involves the subsequent follow-up of patients and the devices themselves. During follow-up, various

ABBREVIATIONS

CRT: cardiac resynchronization therapy
 EGM: electrogram
 ICD: implantable cardioverter-defibrillator
 PM: pacemaker
 VF: ventricular fibrillation
 VT: ventricular tachycardia

electrical parameters are analyzed and adjusted to verify their correct operation, increase their longevity, and to improve the quality of life of the patient and prolong survival. In recent years, there has been an exponential increase in the number of cardiac devices implanted, as well as in their technological complexity and the software used to run them. As a result, there has been a huge increase in workload associated with patient follow-up, to which device and lead safety alerts have recently contributed. Parallel to the increase in the complexity of follow-up procedures, there have been new and recent developments in the remote monitoring of cardiac devices.¹ The possibility of remotely monitoring patients and their devices has been proposed as a solution to these increasingly complex follow-up procedures.²⁻⁷ Furthermore, the advantages of remote monitoring would include the capacity to more rapidly detect the presence of arrhythmic and clinical events or device malfunction, the possibility of monitoring any treatment administered, the prevention of inappropriate ICD therapies,⁸ improvements in the efficacy of follow-up and, finally, reductions in follow-up costs.^{1,9}

The remote monitoring systems currently available have various limitations; for example, it is impossible to either program the device remotely or physically examine the patient. Furthermore, doubts remain concerning the safety of conducting follow-up without the physical presence of the patient and which involves relying on the data transmitted by the system.^{1,5} For these reasons, recently published guidelines advise in-hospital patient follow-up at least once a year.¹⁰

The Home Monitoring™ system (Biotronik, Germany) was one of the first remote monitoring systems available for PM and ICD. This system automatically provides daily information on the patient's cardiac disorder and correct functioning of the device.

The aim of the present study was to evaluate the technical reliability and safety of the Home Monitoring™ remote monitoring system in patients fitted with PM, ICD, and CRT.

METHODS

The study included 162 patients in whom a Biotronik device had been consecutively implanted between January 2003 and June 2004 and between March 2005 and January 2008. During these periods, a dual-chamber PM was implanted in 115 patients, an ICD in 44 patients, and an ICD-CRT in 3 patients. A total of 69% were men and mean patient age was 62 (13) years in the ICD group and 73 (14) years in the PM group. Table 1 shows the characteristics of the population included in the study.

Home Monitoring System™

The Home Monitoring™ system enables cardiac devices that are equipped with a telemetry system to be monitored and automatically provides stored diagnostic information on a daily basis. It is wireless and does not involve the patient in its operation. This system is available in dual-chamber PM, PM-CRT, ICD, and ICD-CRT.

TABLE 1. Clinical Characteristics of the Population Evaluated

	Pacemaker (n=115)	ICD (n=47)
Age, mean (SD), y	73 (14)	62 (13)
Sex (men/women), n	68/47	44/3
Hypertension	68	58
Diabetes mellitus	30	33
Dyslipidemia	36	44
Smoking	31	57
Obesity	45	35
Pulmonary disease	12	6
Kidney failure	2	6
Atrial fibrillation	10	29
LVEF, mean (SD), %	61 (7)	36 (15)
Indication for pacemaker		
AVB	48	NA
SND	40	NA
Neurally mediated syncope	12	NA
Indication for ICD		
Primary prevention	NA	36
Secondary prevention	NA	64
Structural heart disease		
Ischemic heart disease	12	71
Dilated cardiomyopathy	0	19
Hypertrophic cardiomyopathy	0	6
Channelopathy	0	4
Device		
Single chamber	0	58
Dual chamber	100	36
Triple chamber (CRT)	0	6

AVB indicates atrioventricular block; CRT, cardiac resynchronization therapy; DCM, dilated cardiomyopathy; ICD, automatic implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction; NA, non-applicable; SND, sinus node disease. Values are expressed as percentages, unless otherwise indicated.

TABLE 2. Alarm Events Generated by the Devices in the Home Monitoring™ System

Pacemaker	ICD/CRT
ERI	ERI
Imp A and/or Imp RV outside range (<200 Ω - >3000 Ω)	Imp A and/or RV outside range (<200 Ω - >3000 Ω)
Increased RV threshold (>V) ^a	A/RV detection <mV ^a
Inactivated ACC	RV pacing margin <V ^a
A/RV detection margin <50% programmed value	Imp shock outside range (<25 Ω - >110Ω)
Increase/decrease RV pacing threshold >1 V	RV pacing >% ^a
Mode change	AF episode
Duration of mode change	Duration of mode change
VES (4-8 beats)	VT1/VT2/VF detection
USVT (>8 beats)	Ineffective shock
	Mean frequency >90 beat/min
	VES/h >% ^a
	Periodic EGM
	Imp LV outside range (>200 Ω - >3000Ω)
	LV pacing margin <V
	LV detection <mV
	CRT pacing <%

ACC indicates automatic capture control; AF, atrial fibrillation; CRT, cardiac resynchronization therapy; ERI, elective replacement index; Imp A, atrial pacing impedance; Imp RV, right ventricle pacing impedance; LV, left ventricle; TV2, programmed ventricular tachycardia in the second window ("fast VT"); USVT, unsustained ventricular tachycardia; VES, ventricular extrasystoles; VF, ventricular fibrillation; VT1, programmed ventricular tachycardia in the first window ("slow VT").

^aThe magnitude of the variables set up to activate alarms can be modified from the Home Monitoring™ system webpage.

The information emitted by the device is received by the transmitter (CardioMessenger™), which should be located between 20 cm and 2 m from the patient. The CardioMessenger™ is a dedicated mobile telephone that transmits the information from the device to an analysis center in Erlangen (Germany) via the GSM (Global System for Mobile Communication) network. After decoding and analyzing the transmitted information, the center—which provides international coverage—creates a cardiology report that is sent to the acting physician or hospital center via Internet, fax, or SMS. Monitoring is initiated in the cardiac device by programming the home monitoring algorithm.

The system transmits 3 types of messages. First, periodic messages are issued daily at a previously programmed hour. The most recent ICD models permit the periodic transmission of 30 s of electrogram (EGM) (every 2, 3, or 4 months depending on the programming). The second type of messages are event alerts (Table 2). When the PM or ICD detects a clinical problem or an anomaly in the device, it will issue a message that will be transmitted when the patient is within the reception radius of the CardioMessenger™. In the event of an unnoticed disconnection, intermittent breaks in mobile phone coverage or anything impeding the link between the device and the CardioMessenger™, alert messages are transmitted from the moment the link between the device and the transmitter is

reestablished. Furthermore, the most recent ICD models can evaluate the intracardiac EGM of arrhythmic episodes. Finally, some messages can be activated by the patient by placing a magnet over the PM; the device has to be appropriately programmed for this option to be available.

Phases of Inclusion in the Registry

The study began in January 2003 with ICD patients. A total of 17 patients fitted with the first version of the Home Monitoring™ system were followed up in this phase which was characterized by fewer parameters being evaluated, fewer alerts sent by fax to the hospital and less access to the information stored by the device.

The second phase of the study began in March 2005 and included the remaining patients who were monitored with the second version of the Home Monitoring™ system. This version can analyze the different alerts (Table 2) and the evaluated parameters via a webpage which is accessed by 3 keys.

Device Implantation, Programming, and Follow-up

After the device is implanted, it is programmed according to the clinical situation of the patient and standard programming guidelines. The patients

underwent routine follow-up, that is, 3 months after implantation and then every 6 months in the case of ICD and every 12 months in the case of PM. The schedule of hospital visits was not modified.

The wireless remote monitoring function was activated during the hospital visit in the third month after implantation to avoid the lead run-in period, obtain the long-term electrical parameters, and verify correct functioning of the system. The daily data transmission was programmed to occur at 04:00 h. Finally, the patient was told how the CardioMessenger™ worked and, after obtaining informed consent, the patient was included in the Home Monitoring™ registry.

The information transmitted via the Home Monitoring™ system was evaluated on a daily basis for event alerts by the physicians responsible for the arrhythmia unit. In the case of events judged as clinically relevant, the patient was telephoned and asked to visit the hospital. The information stored by the Home Monitoring™ system for patients without alert messages was analyzed every 3 months in the case of ICD and every 6 months in the case of PM. The use of the Home Monitoring™ system did not replace any scheduled visit.

Statistical Analysis

Data are expressed as mean (standard deviation). The incidence of event alerts between the PM group and ICD group was compared using the χ^2 test. Survival free of event alerts in the total group and in the PM and ICD groups was evaluated using the Kaplan-Meier method with the log-rank test for between-group comparisons.

To evaluate the safety of the Home Monitoring™ system in the ICD and ICD-CRT groups of patients, the transmitted data were compared to those obtained during the hospital visit. The outcome of the comparison was used to classify each transmission as true or false (positive) and its absence as true or false (negative). This classification was used to construct a table to calculate sensitivity, specificity, and the positive and negative predictive values that the Home Monitoring™ system presented in our series.

RESULTS

Incidence of Event Alerts During Follow-up

The 162 patients included in the study were followed up for 49 086 days (average, 303 [244] days; interval, 1-1484 days). The average follow-up time was 464 (296) days in the 44 ICD patients, 243 (191) days in the 115 PM patients and 247 (130) days in the 3 ICD-CRT patients.

During follow-up, 69 (43%) patients presented some alert event. The PM patients issued a higher percentage of alert messages than the ICD patients (45% vs 34%; $P=.01$); 2 of the 3 ICD-CRT patients (67%) presented event alerts during follow-up.

Figure 1 shows survival free of event alerts in the total group (Figure 1A) and in the PM and ICD groups (Figure 1B).

In the PM group, 52 of the 115 patients issued a total of 1991 alert messages which were mainly due to problems related to device programming (safety margins related to atrial and ventricular detection) (Figure 2A).

In the ICD group, 15 of the 44 patients issued a total of 472 messages; the bulk of these were from a single patient who presented 371 alerts due to frequent ventricular extrasystoles. Most event alerts were due to ventricular arrhythmias. As shown in Figure 2B, 29% of the patients suffered a ventricular tachycardia (VT) and 20%, a ventricular fibrillation (VF). In 2 patients, a 30-J ineffective shock message was sent, corresponding to one of the programmed shocks. In both cases, the message was issued at the time the data transmission was activated (third month after implantation). In 2 patients the Home Monitoring™ system warned of a life-threatening situation that preceded the next scheduled hospital visit by 61 days and 122 days, respectively. Finally, the event alerts in the ICD group preceded the following scheduled visit by an average of 76 (47) (12-180) days.

The ICD-CRT group consisted of 3 patients. One patient presented alerts due to VT and VF, as well as heart failure monitoring alerts that included a high mean heart rate and left ventricular pacing of 76%. A second patient presented an alert due to VT.

Home Monitoring™ System Data Transmission: Technical Reliability

During follow-up, a total of 42 265 daily messages and 1663 alert messages were sent. The mean percentage of monitored days was 88.2%, with a slightly higher percentage in PM group than in the ICD group (90% vs 87%, nonsignificant difference). A total of 60% of the patients were monitored for more than 90% of the total number of days, and nearly all the patients were monitored for more than 50% of the total number of days (Figure 3). The most frequent cause of interruptions in transmission were due to the patient not carrying the transmitter (CardioMessenger™), the unnoticed disconnection of the transmitter and, to a lesser extent, intermittent breaks in coverage.

In 3 (1.7%) cases, the patients did not issue any message due to mobile phone coverage problems and these were excluded from the study.

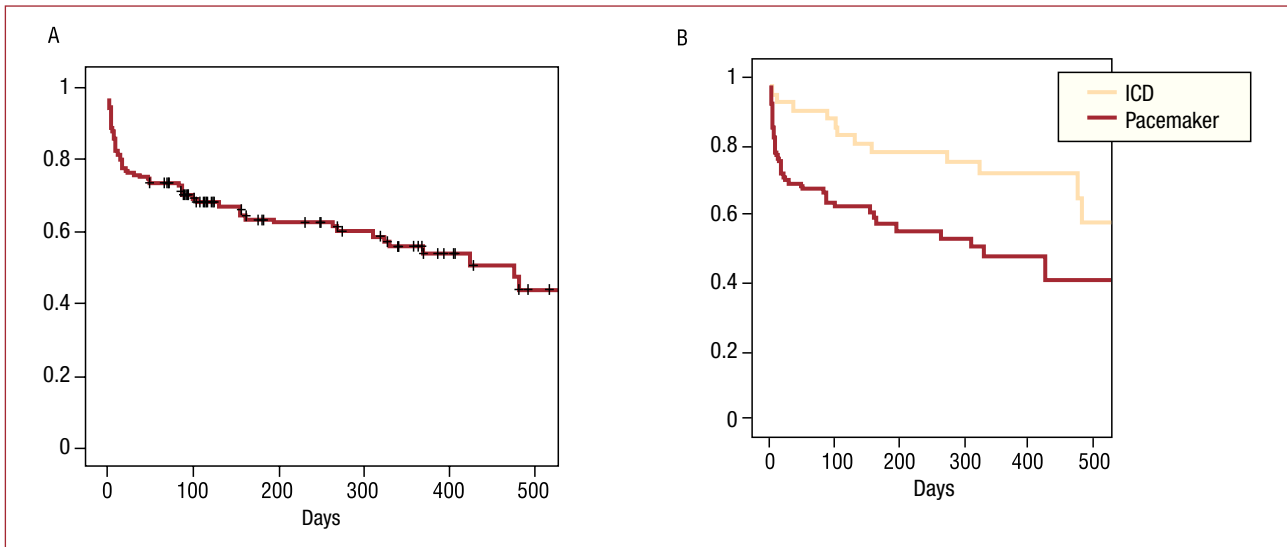


Figure 1. Cumulative survival free from alarm events. A: cumulative survival free from alarm events in the total group of patients included in the study. B: comparison of event-free survival between pacemaker patients (PM) and implantable cardioverter-defibrillator (ICD) patients (difference: log rank; $P=.01$).

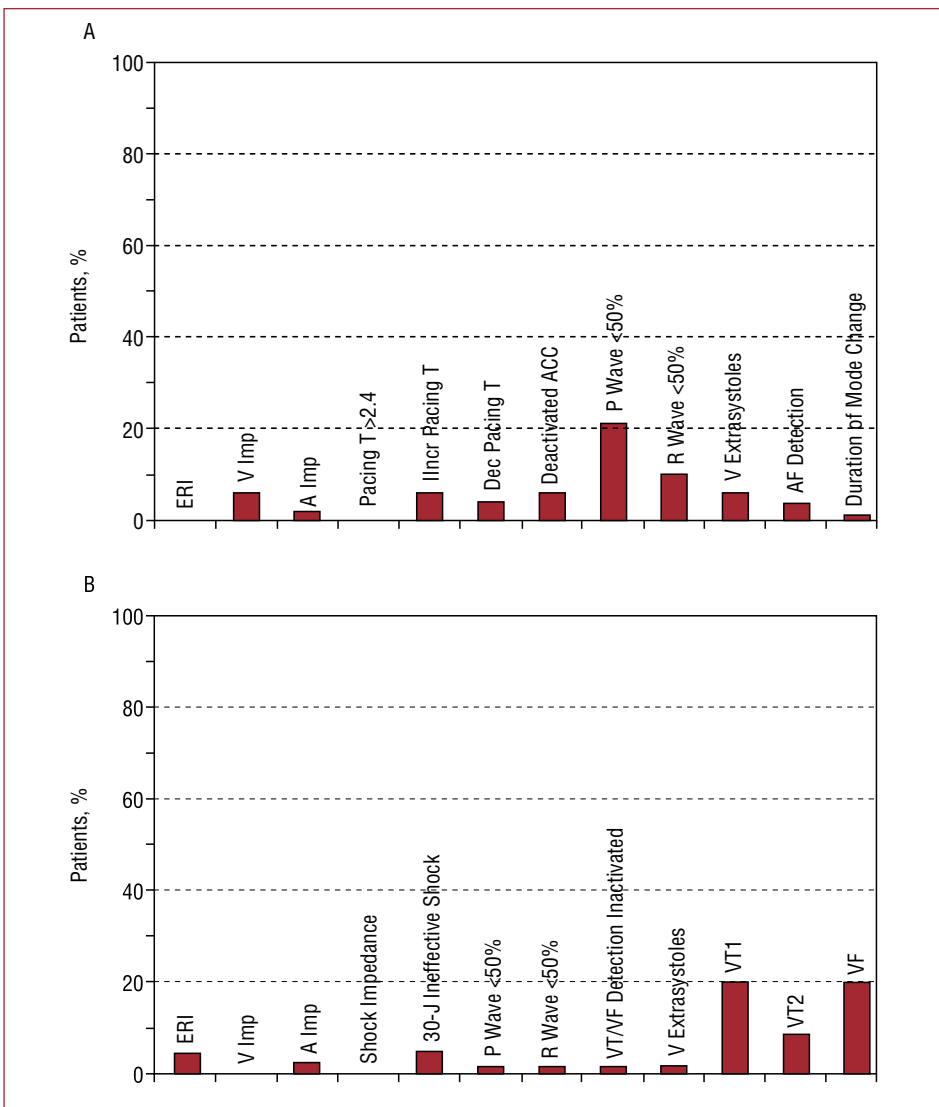


Figure 2. Percentage of patients with alarm events. A: pacemaker patients (PM). B: ICD and ICD-CRT patients. AF detection indicates atrial fibrillation detection; Deactivated ACC, deactivated automatic capture control; A Imp, atrial impedance outside range ($<200 \Omega$, $>3000 \Omega$); Dec pacing T, decrease in pacing threshold >1 V; ERI, elective battery replacement index; Incr pacing T, increase in pacing threshold 1 V; Pacing T >2.4 , ventricular pacing threshold >2.4 V; P wave $<50\%$, margin for P wave detection $<50\%$ compared to programmed sensitivity; R wave $<50\%$, margin for R wave detection $<50\%$ compared to programmed sensitivity; Shock Imp, shock impedance; V extrasystoles, consecutive ventricular extrasystoles; VF, detection of an episode in the ventricular fibrillation window; V Imp, ventricular impedance outside range ($<200 \Omega$, $>3000 \Omega$); VT1, detection of an episode in the first ventricular tachycardia window; VT2, detection of an episode in the second ventricular tachycardia window (fast VT).

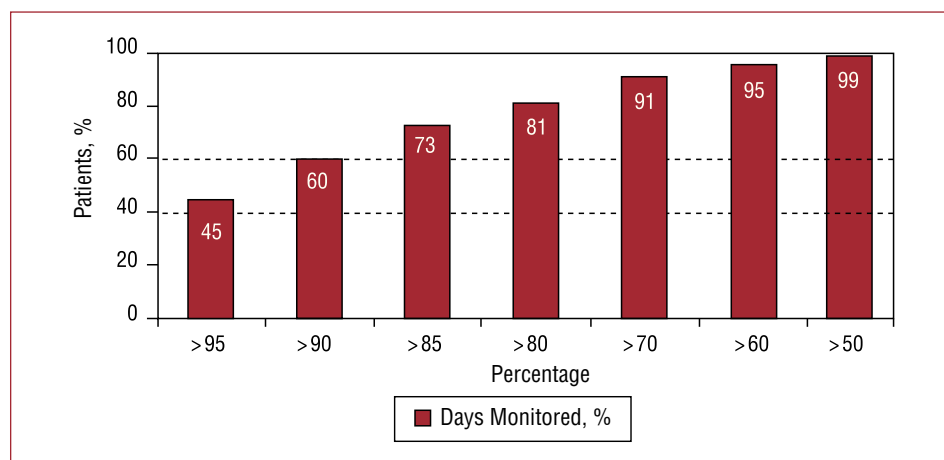


Figure 3. Distribution of the patients in relation to the percentage of days monitored with the Home Monitoring™ system.

The transmission of the intracardiac electrograms stored by the ICD (only available in the latest devices), was successfully completed in 100% of the cases. In all cases, the EGM sent by the system was compared to the one obtained by the device during hospital visits for arrhythmia. In one case, the transmitted EGM erroneously classified as VF was diagnosed as T-wave oversensing (Figure 4).

Diagnostic Reliability of Remote Monitoring

The diagnostic reliability of the Home Monitoring™ system was evaluated in the group of patients with ICD or ICD-CRT (47 patients). In this group, each alert event transmitted by the system was compared to that obtained from the device during the hospital visit. Furthermore, if no alert was issued, the absence of events was confirmed by later examination in the hospital. Thus, at the end of follow-up, 120 pairs of interrogations were obtained corresponding to the information transmitted through the Home Monitoring™ system and that obtained during the hospital visit. The case of the patient with numerous alert messages due to ventricular extrasystoles was only included once.

In 68 (57%) patients, the comparison was judged as a true negative, that is, the Home Monitoring™ system did not issue any alert message and the device did not identify any significant event during the hospital visit. In 50 (42%) of patients, the comparison was classified as a true positive, that is, alerts sent by the Home Monitoring™ system were confirmed by the device during the hospital visit. In 2 patients, the transmitted event alerts were not confirmed during the hospital visit, which would result in 1% being confirmed

as false positive. These 2 cases corresponded to a detection message indicating an R wave lower than 2 mV in patients dependent on ventricular pacing. Finally, in no case was a significant event detected during device interrogation during the hospital visit for which the remote monitoring system had failed to provide an alert, and which would indicate an absence of false negatives.

According to these results, the diagnostic reliability of the Home Monitoring™ system for following-up ICD patients had a sensitivity of 100%, a specificity of 97%, and positive and negative predictive values of 96% and 100%, respectively.

DISCUSSION

Currently, ICD patients are evaluated in hospital every 3-6 months and PM patients every 6-12 months. The great increase in the number and complexity of implanted devices and the increasingly frequent safety alerts for generators and leads have led to a huge increase in workload for the physicians and nurses responsible for the cardiac device and subsequent follow-up. Remote monitoring may be a solution to the current overload in hospital visits for device follow-up. The results of this study show that the Home Monitoring remote monitoring system is technologically reliable and safe for following-up PM or ICD patients.

Potential Role of Remote Monitoring Systems

Previous studies have shown that a significant number of patients do not require changes in device programming after implantation after the first

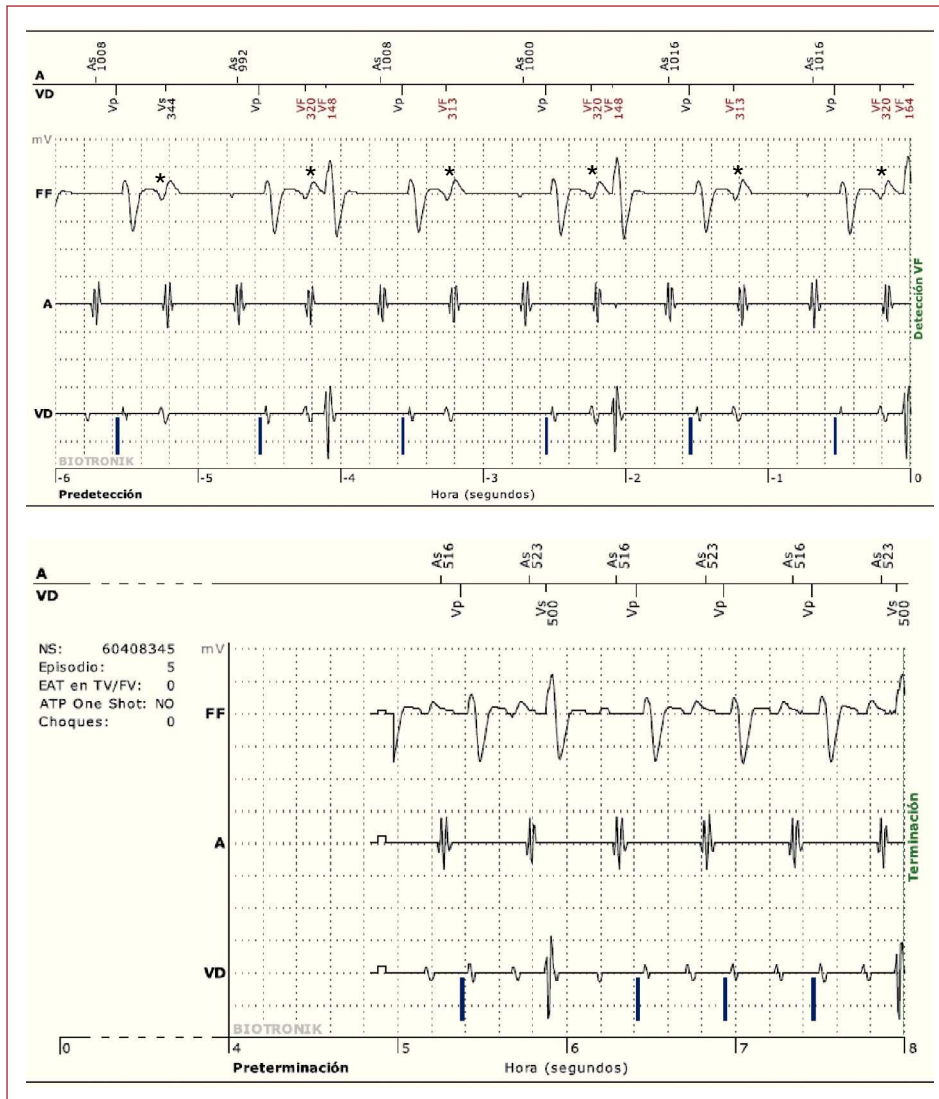


Figure 4. Electrogram included in an alert message due to detected ventricular fibrillation. As can be seen, this is not a ventricular fibrillation (VF) episode, but involves T-wave undersensing. The marker channel indicates paced ventricular activity and T-wave oversensing in the stimulated beats (asterisks), together with correct detection of ventricular extrasystoles. This situation leads the ICD to classify the episode as VF (8/12 beats <320 ms). T-wave oversensing is spontaneously interrupted and, after the capacitors have charged, the device reconfirms the absence of intervals in the VF window, and so it cancels therapy.

visit.^{11,12} In our study, more than half of patients included did not present any type of alarm event during follow-up. This means that the implanted device did not detect any malfunction, pacing or detection problems related to the electrical parameters or to arrhythmic events.

Several works have been recently published that have analyzed the frequency of follow-up among PM and ICD patients and what percentage require a change in programming. The FollowPace¹³ study included 1526 PM patients with an average follow-up of 394 days. The PM parameters were modified in 23% of the patients based on the hospital visit at 12 months. The parameter that most frequently needed reprogramming was the pacing voltage.

Heidbüchel et al¹⁴ retrospectively analyzed programmed and urgent visits in 169 ICD patients for an average of 5.3 years. A total of 1739 visits were evaluated, 88% of which were scheduled and 12% unscheduled. Device interrogation indicated significant findings (arrhythmic or device related) in 21.8% of the scheduled visits and in 80% of the unscheduled ones. The authors considered that a remote monitoring system that had the features of the available systems would have currently detected more than 99.5% of all arrhythmic or device-related findings. If the system automatically adjusted the pacing voltage, the theoretical reliability of this system would be 100%.

These data reveal 2 facts: a) a high percentage of the device parameters remain constant during follow-

up and do not require reprogramming; and *b*) the availability of automatic algorithms to adjust pacing energy should reduce the number of reprogramming sessions. Thus, a huge number of hospital visits could be prevented by remote monitoring. This situation would involve a series of changes in the organization of follow-up hospital visits and among the health personnel responsible for this work.

Reliability of the Home Monitoring™ System

The results of this study show that the Home Monitoring™ system offers great technical reliability. The percentage of days monitored was almost 90% and the data transmitted by the device was available every day on the webpage. Significantly, 100% of the intracardiac EGMs of ventricular arrhythmia events and periodic reports were transmitted without incident. Subsequent evaluation in the hospital confirmed that the transmitted EGM perfectly matched that obtained during direct interrogation of the ICD. Failure to transmit any message due to problems in mobile phone coverage occurred in only 1.7% of all the patients.

A study by Ricci et al⁷ reported similar percentages of monitored days and emission failures (90% and 2.5%, respectively) due to a lack of mobile phone coverage.

These results show that the main technical limitation in the use of the Home Monitoring™ system is mobile phone coverage. Other remote monitoring systems—such as Carelink™, Medtronic; Lattitude™, Boston; and House Call™, St. Jude—use standard analogue telephone lines for data transmission.¹ The main technical limitation of these systems is the availability of fixed telephone lines, which in some countries, such as Finland, only reach 50% of the population. In a probable future scenario in which remote monitoring is in common use, access to one type of telephony or another may be determined by the choice of implanted device.

The second point to take into account is the risk to the patient involved in relying on remote follow-up instead of routine hospital visits. A previous study⁶ that used the first version of the Home Monitoring™ system in ICD patients, found that the transmitted data were judged as true negative in 67% of cases, true positive in 16%, false positive in 3% and, significantly, false negative in 14%. Based on these results, the authors provided a working protocol that integrated remote monitoring and recommended that the following situations required a hospital visit: the first routine follow-up after device implantation; when there was already a history of electrical malfunction in the lead (including threshold pacing problems); following

hospitalization; and in the presence of symptoms or arrhythmic episodes.

In our study, most patients were monitored using the second version of the Home Monitoring™ system. In ICD patients, the transmitted data were regarded as true negative in 57% of cases, true positive in 42%, and false positive in 1% of cases. We did not identify any significant event that had not been detected previously, which indicates high diagnostic capacity and a sensitivity for the detection of relevant events close to 100%. The fundamental differences between our study and the former study are that the second version of the Home Monitoring™ system transmits a greater amount of data, of which the availability of intracardiac EGM is especially noteworthy. Furthermore, the patients were monitored after the first post-implantation visit, when the few problems associated with the pacing threshold were diagnosed and solved. These 2 facts appear to confirm the reliability shown by the Home Monitoring™ system in our series. The incorporation of new devices with automatic pacing voltage adjustment will make remote follow-up even safer.

Clinical Benefit of Remote Follow-up

The fundamental aims of monitoring cardiac devices¹⁰ include the early detection of possible device malfunction, as well as monitoring cardiac arrhythmias and other biological parameters.

The Home Monitoring™ system has the unique feature of automatically transmitting data on a daily basis and whenever relevant events occur, with around 90% of follow-up time being monitored. This is of interest in the case of safety alerts involving generators and leads. Specifically, it would make it possible to adopt a conservative strategy, maintaining strict clinical follow-up via remote monitoring without the need for shortening follow-up time between hospital visits. The Home Monitoring™ system transmits data on the following adverse events, among others: circuit malfunction; battery exhaustion; lead malfunction; or ineffective defibrillation shocks. These are indicators that tend to be affected in the case of device and lead safety alerts.

Remote monitoring could improve the quality of medical care by enabling the early detection of arrhythmias, device malfunction, and even changes in the clinical situation of the patient.¹ In our study, the alarm events transmitted by the Home Monitoring system preceded the following scheduled visit by more than 2 months on average. Similar to other published works,^{2,3,7} the most frequent alarm events were triggered by atrial fibrillation episodes,

ventricular arrhythmias, and ICD therapies. In our study, an alert event due to atrial fibrillation was transmitted in 7% of the PM patients and 5% of the ICD patients. In the series studied by Ricci et al,⁷ an alert due to atrial fibrillation was transmitted in 28% of the monitored patients and in half of the cases the arrhythmia was unknown before implantation. This made it possible to initiate anticoagulation therapy in a large proportion of cases. The potential for the immediate diagnosis of atrial fibrillation opens up the issue of how to apply indications for anticoagulation therapy within a remote monitoring context.

Several works have identified the role that remote monitoring systems may play in reducing the number of inappropriate ICD therapies.^{8,15} Among the patients monitored in our study, a case of inappropriate VF detection due to intermittent T-wave oversensing was identified, and this was diagnosed promptly thanks to the EGM of the episode which was transmitted by the Home Monitoring™ system.

Finally, the alert messages transmitted via remote monitoring could have an impact on the survival of patients fitted with the device.¹⁶ In our series, in 2 ICD patients, an alert was transmitted by the Home Monitoring™ system due battery exhaustion which had not been identified in the previous hospital visit. Early detection of battery end-of-life made it possible to refer the patient for an immediate change of generator.

CONCLUSIONS

This study confirms that the Home Monitoring™ system is an effective, reliable, and safe system for following up patients fitted with PM and ICD. The capacity of the system to immediately detect the onset of atrial or ventricular arrhythmias, device malfunction or heart failure events would enable optimizing patient management and the prevention of severe cardiac complications.

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