Technical and practical aspects of remote monitoring of implantable cardioverter-defibrillator patients in Poland – preliminary results

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Abstract

Background: The aim of remote monitoring of implantable cardioverter-defibrillators (ICD) is to increase the patient's safety by early detection of technical or medical malfunctions and decrease the number of follow-up visits.

Aim: To evaluate the feasibility and reliability of internet-based home monitoring of ICD recipients in Poland.

Methods: Twenty-seven patients with ICD with remote monitoring options were evaluated; 20 (74%) patients had a single chamber ICD, 6 (22%) patients had a dual chamber ICD and one had an ICD with a resynchronisation therapy option. Medical and technical events reported by the remote monitoring system as well as interruptions in monitoring longer than 14 days were analysed.

Results: The patients were followed for 12.7 ± 10.5 months. Two of them died because of heart failure (6 and 13 months after ICD implantation, respectively). The remote monitoring system reported medical events in 13 (48%) patients. In total, we received 32 event reports (from 1 to 19 per patient, mean 2.6) which were generated due to the detection of ventricular tachycardia (VT) (17 events in 9 patients), ventricular fibrillation (VF) (9 episodes in 6 patients), ineffective defibrillation with the maximal energy (5 reports in 3 patients) and supraventricular tachycardia in the VT detection window (1). Two patients had more than 3 VT/VF episodes during 24 h. There were no reports on technical abnormalities of the ICD system. Interruptions in home monitoring longer than 14 days occurred in 5 (18.5%) patients and lasted 2 to 14 weeks (mean 2.8 ± 7.1). The longest break was caused by the patient's stay abroad. The remaining interruptions were caused by: journeys (5 episodes), hospitalisations (4), and a temporary stay in a place without sufficient GSM coverage (3). During the follow-up period there were no interruptions in monitoring caused by transmitter or ICD failure. All data received by the home monitoring system were confirmed during the follow-up visits.

Conclusion: Remote monitoring of ICD recipients in Poland does not present technical difficulties and enables early detection of serious events in ICD patients.

Key words: implantable cardioverter-defibrillators, remote monitoring, telecardiology

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Introduction

The number of implantable cardioverter-defibrillator (ICD) recipients has increased systematically in recent years [1-3]. Since the patients require regular and frequent follow-up visits, the workload of the health care system has also increased. According to the guidelines, regular follow-up visits should be performed at 3-6 month intervals [4]. In addition, unscheduled visits due to both appropriate and inappropriate ICD interventions are common. Furthermore, the number of potentially life-threatening ICD or lead failures is increasing [4, 5]. It should be noted that most of them are clinically silent and their first manifestation can be undersensing of ventricular tachycardia (VT) or ventricular fibrillation (VF) resulting in the absence of adequate therapy.

Regular follow-up visits could be troublesome for medical or economic reasons, especially for older patients or those with diseases limiting their travelling possibilities. Devices with the capability of remote monitoring via analogue or cellular phone lines have been available since 2001 [6, 7].

The aim of this study was to assess the feasibility and reliability of ICD remote monitoring in Poland.

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Methods

Patient population

Twenty-seven patients with a previously implanted ICD with remote monitoring features were included in the study. Clinical characteristics of the study group are presented in Table I. Indications for ICD implantation with the home monitoring function included the distance between the patient's home and clinic > 150 km and/or medical conditions limiting his travelling possibilities. In five patients, the device with remote monitoring was implanted during ICD exchange.

Implanted cardioverter defibrillators

All implanted devices were manufactured by Biotronik (Berlin, Germany). A single chamber ICD was implanted in 20 (74%) patients, dual chamber in 6 (22%), and one patient had an ICD combined with cardiac resynchronisation therapy. Nineteen (70.4%) devices belonged to the older generation of ICDs, that is to say, intracardiac electrogram (IEGM) transmission was impossible (Lexos VR-T, Lexos DR-T, Kronos LV-T). Eight patients received devices capable of transmitting IEGMs (Lumos VR-T, DR-T, Lumax 300 VR-T, Lumax 300 DR-T).

Remote monitoring principles

Cardioverter-defibrillators compatible with the Home Monitoring™ system have a built-in antenna enabling wireless transmission of the data from the ICD memory to the external transmitter (CardioMessenger, Biotronik, Berlin, Germany). The data from the CardioMessenger are forwarded via cellular phone lines to the Service Centre located in Berlin. Older devices use GSM (Global System for Mobile Communication) technology for data transmission, while the GPRS (General Packet Radio Service) standard is applied in the newer generation of ICDs (Lumax family). Data transmission occurs automatically once daily at a pre-programmed time, usually at night. In the Service Centre the data are decoded, archived and put on a secured website. The whole process is anonymous, as the information retrieved from the ICD and transmitted to the Service Centre do not contain patients' personal data, but only the identification number issued by the hospital. The medical staff is informed about events requiring notification by SMS, e-mail and/or fax. In our hospital, SMS and e-mails were used for that purpose.

Table I. Clinical characteristics of patients (n = 27)

Age [years]		52.9 ± 14.9
Gender [male %]		85%
Underlying heart disease [%]		
	CAD	12 (44)
	DCM	5 (19)
	HCM	3 (11)
	others	7 (26)
ICD indications [%]		
	primary prophylaxis of SCD	13 (48)
	secondary prophylaxis of SCD	14 (52)
ICD type [%]		
	single chamber	20 (74)
	dual chamber	6 (22)
	CRT	1 (4)
NYHA class [%]		
	I-II	19 (70)
	III-IV	8 (30)
LVEF [%]		36 ± 17.4
Permanent AF [%]		2 (7)

Abbreviations: CAD – coronary artery disease, HCM – hypertrophic cardiomyopathy, DCM – dilated cardiomyopathy, CRT – cardiac resynchronization therapy, AF – atrial fibrillation, SCD – sudden cardiac death, LVEF – left ventricular ejection fraction

Events and notifications

The data stored in the ICD memory and requiring notification can be divided into three groups:

- technical data: leads and device parameters,
- arrhythmias detected in VT/VF detection window,
- other parameters related to the heart rhythm: percentage of paced events, number of ventricular extrasystoles.

In all cases, standard settings for event notifications were activated. Additionally, in patients with activated VT detection and therapy, event reports included arrhythmias detected in that zone. The Home Monitoring system also sent a notification if the Service Centre did not receive data from the ICD in a preset period of time (usually 14 days).

In case of receiving an event notification, the event report was analysed on the Service Centre website by a responsible physician on the same day. On the basis of the event report analysis the decision concerning further actions was made. The reports on technical abnormalities of the ICD system (lead impedance out of range, deactivated VT/VF zones, ineffective maximum energy shock, ≥ 3 VT/VF episodes in 24 h) were regarded as the most dangerous and required immediate contact with the patient in order to recommend an in-hospital follow-up visit. In other cases, the decision about the time and method of contact with the patient was made on the basis of the patient's medical history and previous Home Monitoring reports.

Despite the lack of notifications, the reports on the website were reviewed every 10-14 days in order to check for arrhythmias or other events that did not require notification (e.g. permanent sinus tachycardia, atrial fibrillation with rapid ventricular response). The patients were also contacted in the case of interruption of data transmission longer than a preset period (usually 14 days).

ICD programming

Devices were programmed according to the current guidelines. The VF detection and therapy zone was activated in all cases. The VT zone was switched on in 22 (81%) patients. The bradycardia pacing settings were programmed in a way to avoid right ventricular pacing, if possible. The cardiac resynchronisation device was programmed to achieve > 90% of biventricular pacing.

Statistical analysis

The results are presented as mean ± standard deviation for normally distributed values or as median for other distributions.

Results

The mean follow-up was 12.7 ± 10.5 months. Two patients died during the follow-up due to heart failure (6 and 13 months after ICD implantation, respectively). Both deaths occurred in hospital. The Home Monitoring system was not used during the hospitalisation. The electromechanical dissociation was reported to be a terminal rhythm. One patient resigned from Home Monitoring after three months for personal reasons.

Home monitoring events requiring notification

Events reported by the remote monitoring system occurred in 13 (48%) patients. In total, 32 event reports were received (from 1 to 19 per patient, mean 2.6). Reasons for notification are listed in Table II and their time distribution after ICD implantation is presented in Figure 1. All events reported by the monitoring system were triggered by medical causes. There were no events caused by technical abnormalities (lead or generator failure).

Verification of reported events during in-hospital follow-up visits

The patients were asked to report for regular follow-up visits in the device clinic in the intervals recommended by international guidelines. There were 53 regular visits (from 1 to 8 per patient); an additional 6 visits were triggered by reports from the Home Monitoring system. They were caused by:

1. ineffective maximum energy defibrillation – 3 visits (2 patients),
2. ≥ 3 VT/VF episodes in 24 h – 2 visits and hospitalisations in two patients.

In one patient, we received in one day messages about ineffective maximum energy shock and more than three VT/VF episodes during 24 h.

Supraventricular and ventricular arrhythmias detection

Twenty-seven (84.3%) out of thirty-two events were triggered by arrhythmias. In two cases (supraventricular and ventricular tachyarrhythmia detected in the VF zone) remote verification of the diagnosis was possible by using transmitted IEGMs (Figure 2). In other cases the diagnosis by the Home Monitoring system was verified on the basis of IEGMs stored in the ICD memory. The diagnosis of the ventricular tachyarrhythmia was confirmed in 26 events, and one inappropriate diagnosis was caused by sinus tachycardia detected in the VF zone. Out of 17 arrhythmias detected in the VF zone, 12 terminated spontaneously before ICD therapy. Seven episodes of VT were terminated by anti-tachycardia pacing (ATP); in two cases ATP was unsuccessful and the arrhythmia was terminated by shock therapy.

Ineffective maximum energy defibrillation

Five alerts (in 3 patients) were generated due to ineffective maximum energy defibrillation. In two patients (four episodes), they were caused by sinus tachycardia recognized as VF. In a third patient, ventricular tachyarrhythmia was terminated by ICD shock, but recurred immediately and the therapy was automatically regarded as unsuccessful. The patient was admitted to the hospital with the diagnosis of electrical storm.

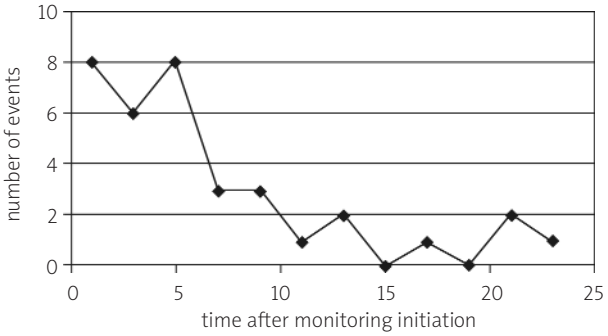
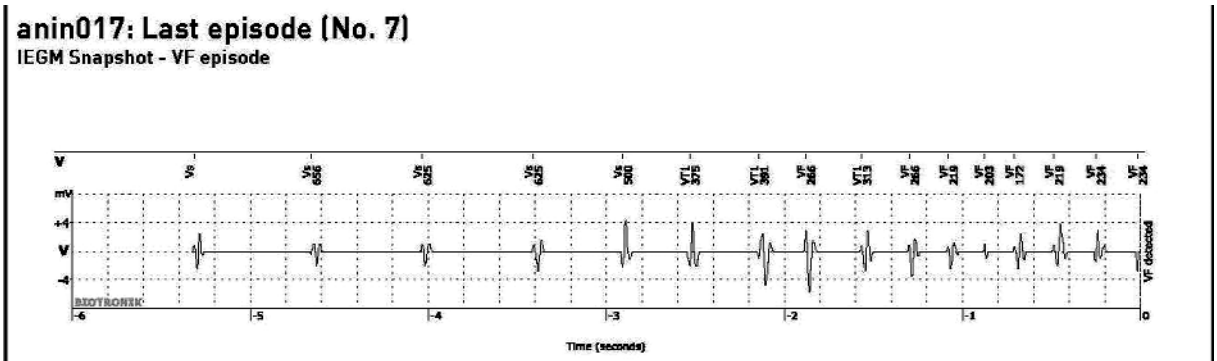


Figure 1. Number of medical and technical events reported by remote monitoring system

Table II. Reported events

Event	Number of reports	Number of patients with the event
Ventricular tachycardia detected	9	6
Ventricular fibrillation detected	17	6
Supraventricular tachycardia detected	1	1
Ineffective maximal energy defibrillation	5	3

In three patients arrhythmias were detected in both VT and VF zones



Episode details

Episode number	7
Detection	20-Nov-2008 12:17:13
Termination	20-Nov-2008 12:17:24
Duration	11 s
Detection in	VF
Redetection	0
Delivered ATPs	0
Delivered shocks	0
Remark	

Figure 2. Intracardiac electrogram received via the Home Monitoring system from a Lumax VR-T cardioverter-defibrillator (Biotronik). The IEGM presents the ventricular tachyarrhythmia detected in the VF detection window. The episode details are shown below. The arrhythmia terminated spontaneously before ICD therapy

Arrhythmias and technical abnormalities recognised during follow-up visits

During an in-hospital visit one VT episode which terminated with ATP was detected. It was not reported by the Home Monitoring system because the notifications for VT detection were inactive in this patient. However, the detection and delivered therapy were included in the daily report. There were no technical abnormalities encountered during the follow-up visits.

Temporary interruptions of data transmission

In five patients, there were 14 (from 1 to 5 per patient) interruptions in the data transmission longer than 14 days. They lasted from 2 to 12 weeks (mean 2.8 ± 7.1). The longest break was caused by a temporary stay abroad. The remaining interruptions were caused by: journeys (5 episodes), hospitalisations (4) and a temporary stay in a place without sufficient GSM coverage (3). During the follow-up period there were no monitoring interruptions caused by transmitter or ICD failures.

Discussion

The possibility of remote monitoring of ICD recipients seems to be an interesting solution aiming to increase patients' safety, as well as decrease the number of in-hospital ICD-related visits. The goal of our study was to assess the feasibility of ICD remote monitoring in Poland.

Data transmission

There were no monitoring interruptions caused by transmitter or ICD components' failures. The data transferred by the Home Monitoring system were confirmed during regular in-clinic visits. With the exception of one VT episode, there were no technical abnormalities or VT/VF episodes that were recognised during the follow-up visits but were not reported by the Home Monitoring system. Moreover, the lack of information about the VT episode was related to the programmed settings and not to technical problems.

Interruptions in remote monitoring occurred in five (18.5%) patients. They were usually caused by a prolonged stay outside the transmitter's coverage or its temporary switch off. Insufficient cellular network coverage occurred only in one case. In the Italian study during the follow-up of 227 ± 128 days, the patients were monitored for more than 90% of the days. Three patients were excluded from the study due to the lack of mobile phone coverage at their

Table III. Events requiring notification

ICD technical data	Detected arrhythmias	Other
Ventricular or atrial lead pacing impedance < 25 ohm or > 1500 ohm	VF	* ventricular intrinsic rhythm < 90%
* elective replacement indications (ERI)	VT1	mean heart rate > 90 bpm
* Abnormal system status (e.g. VT/VF zones deactivated)	VT2	mean heart rate at rest > 90 bpm
** P and R wave amplitude	SVT	
** High voltage leads impedance	ineffective maximal energy defibrillation	

Abbreviations: VF – ventricular fibrillation, VT1, VT2 – ventricular tachycardia, SVT – supraventricular tachycardia
** nonprogrammable parameters*
*** available only in Lumax family ICDs*

place of residence [8]. On the other hand, the study performed in Finland and assessing the Medtronic CareLink™ system based on analogue phone lines showed that 50% of patients were unable to use the remote monitoring because of the limited number of household phone lines in Finland, where cellular phones are three times more common. It seems that due to the development of the mobile phone network and increasing mobility of Polish society, remote monitoring of implantable cardiac devices will be a method of the future in Poland.

Home monitoring limitations and directions of further development

The majority of implanted devices (70.4%) belonged to the older generation of ICDs which can transmit a limited number of parameters. This concerns particularly the possibility of diagnosis confirmation on the basis of the IEGMs and other lead parameters, rather than just pacing impedance (pacing threshold, P and R wave amplitude, high voltage lead impedance). These limitations were eliminated in the newer devices (Table III) which can also transmit heart failure parameters such as heart rate variability, percentage of paced beats, number and duration of atrial arrhythmias, frequency of ventricular premature beats and intrathoracic impedance values. These parameters seem to be particularly useful in CRT recipients. The clinical value of remote monitoring of heart failure parameters is evaluated in the ongoing, multicentre study [10].

Bidirectional data transmission allowing remote device reprogramming remains controversial. It is technically possible, but there are several medical and ethical objections. Complete assurance of data safety on the internet still remains the most difficult and unrealistic issue.

Clinical usability

It is difficult to precisely assess whether, and to what extent, remote monitoring could reduce the number of follow-up visits. This issue is being evaluated in ongoing trial [11]. The economic aspect of remote monitoring should also be taken into consideration, as devices equipped with this system are more expensive. Some studies have shown the economic benefits of remote monitoring [9]. Its clinical usefulness depends mainly on the quantity and quality of transmitted data. There have been several reports on the detection of lead failures by remote monitoring [12, 13]. This system can also be applied to the assessment of the results of pharmacological or non-pharmacological (ablation) treatment of arrhythmias.

Limitations of the study

This is a retrospective study with all its limitations. The patients were selected for the ICD with Home Monitoring on the basis of the distance to the ICD clinic, coexisting morbidities limiting their ability to make regular follow-up visits, and the ability to use the system. Therefore, the data concerning mortality and number of arrhythmias cannot be extrapolated to all the patients with ICDs.

Conclusion

Remote monitoring of the implanted cardioverter-defibrillator in Poland does not present technical difficulties and enables early detection of serious events in ICD patients.

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Techniczne i praktyczne aspekty telemetrycznego monitorowania osób ze wszczepionym kardiowerterem-defibrylatorem w Polsce – wyniki wstępne

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Streszczenie

Wstęp: Monitorowanie domowe wszczepionych kardiowerterów-defibrylatorów (ang. *implantable cardioverter-defibrillator*, ICD) ma na celu zwiększenie bezpieczeństwa chorego i zmniejszenie liczby wizyt kontrolnych. Jego zadaniem jest wczesne wykrycie zarówno nieprawidłowości technicznych, jak i zagrożeń medycznych.

Cel: Ocena technicznych i praktycznych możliwości wykorzystania opartego na sieci Internet zdalnego monitorowania ICD w Polsce.

Metody: Badaniem objęto 27 osób ze wszczepionym ICD z możliwością telemetrii. Dwudziestu (74%) chorych miało wszczepiony jednojamowy ICD, 6 (22%) dwujamowy ICD i jeden chory miał wszczepiony ICD z opcją terapii resynchronizującej. Analizowano powiadomienia przesłane przez system monitorujący z powodów medycznych i technicznych oraz przyczyny przerw w monitorowaniu.

Wyniki: Średni okres obserwacji wynosił 12,7 ± 10,5 miesiąca. W tym okresie 2 chorych zmarło (odpowiednio 6 i 13 miesięcy po implantacji ICD). Przyczyną zgonów w obu przypadkach była niewydolność serca. Zdarzenia wymagające wysłania powiadomienia wystąpiły u 13 (48%) chorych. Łącznie zarejestrowano 32 powiadomienia (1–19 u jednego chorego, średnio 2,6). Ich przyczyną było: rozpoznanie migotania komór (VF) – 17 zdarzeń u 6 chorych, rozpoznanie częstoskurczu komorowego (VT) – 9 epizodów u 6 chorych, brak skuteczności defibrylacji maksymalną energią – 5 epizodów u 3 chorych, rozpoznanie częstoskurczu nadkomorowego w oknie detekcji VT – jedno zdarzenie. U 2 chorych wystąpiły więcej niż 3 epizody VT/VF w ciągu 24 godz. Nie było sytuacji alarmowych spowodowanych przyczynami technicznymi (awariami ICD lub elektrod). U 5 (18,5%) chorych wystąpiło 14 przerw w monitorowaniu trwających dłużej niż 2 tygodnie (1–5 u jednego chorego). Trwały one 2–12 tygodni (średnio 2,8 ± 7,1). Najdłuższa przerwa była spowodowana pobytem za granicą. W pozostałych przypadkach przerwy telemetrii były spowodowane: wyjazdami (5 przerw), pobytami w szpitalu (4 przerwy) oraz okresowym zamieszkaniem poza zasięgiem sieci telefonii komórkowej (3 przerwy). Nie wystąpiły przerwy spowodowane awariami nadajnika lub ICD. Wszystkie dane przekazane przez system monitorowania zostały potwierdzone w czasie standardowych wizyt kontrolnych.

Wniosek: Telemetryczne monitorowanie ICD w Polsce nie wiąże się z trudnościami technicznymi i umożliwia wczesne wykrycie zagrożeń.

Słowa kluczowe: wszczepialne kardiowertery-defibrylatory, telemedycyna, zdalne monitorowanie

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