

Patient perspective and safety of remote monitoring of implantable cardioverter-defibrillators in the Polish Nationwide Multicenter Registry: the Medtronic CareLink network evaluation

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EDITORIAL

by De Filippo et al,
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Received: May 26, 2020.
Revision accepted:
August 7, 2020.
Published online:
August 14, 2020.
Kardiol Pol. 2020; 78 (11): 1115-1121
doi:10.33963/KP.15556
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ABSTRACT

BACKGROUND Remote monitoring of cardiovascular implantable electronic devices allows the assessment of system effectiveness, arrhythmia occurrence, and indirectly, clinical changes. Medical interventions can be performed earlier because of a faster transfer of information to the monitoring site, even in the case of asymptomatic arrhythmias or abnormalities in the operation of the system.

AIMS The aim of the study was to assess the effectiveness of remote monitoring of implantable cardioverter-defibrillators and evaluation in an outpatient setting during 12-month follow-up.

METHODS We analyzed 176 patients at 10 sites (men, 84.1%). The mean (SD) age of the patients was 60.7 (12.5) years (range, 20–86 years), and mean (SD) follow-up period was 405 (70) days (range, 131–723 days).

RESULTS A total of 354 outpatient and 514 remote follow-up visits were conducted. Episodes of arrhythmias and device malfunctions were detected with similar frequency in outpatient visits and in remote visits. During the study period, patient sense of safety increased. More patients preferred joined remote and outpatient visits as the optimal healthcare model. As the patient survey showed, the greatest benefit of the CareLink network was fast intervention and an increased sense of safety.

CONCLUSIONS The strategy of remote monitoring appeared to be feasible, safe, and patient friendly, demonstrating that the majority of patients do not require an additional in-person visit within 1 year from the device implantation just to confirm the proper functioning of the implantable cardioverter-defibrillators.

WHAT'S NEW?

The majority of visits of patients with cardiovascular implantable electronic devices, both scheduled and urgent, can be successfully replaced by remote visits. An increased patient sense of security is the most important argument in favor of remote monitoring.

KEY WORDS

implantable cardioverter-defibrillator, registry, remote monitoring

INTRODUCTION The constantly increasing number of cardiovascular implantable electronic devices (CIEDs) in use, the degree of their complexity, and elongation of life of patients with those devices have led to a dramatic increase in the workload of device clinics. In addition, analysis of data stored on the device and therapeutic decision-making process prolong the duration of a follow-up visit in selected patients. The guidelines on the frequency of follow-up visits in accordance with the recommendations of the European Heart Rhythm Association require the ever increasing involvement of medical personnel and suitable premises. This leads to difficulties in maintaining 6- to 12-month deadlines for follow-up visits in patients with implanted pacemakers and 3- to 6-month deadlines for follow-up visits in those with implantable cardioverter-defibrillators (ICDs).¹ The majority of outpatient visits end with only a confirmation of the effectiveness of the system and do not result in any changes to the operating parameters of the device. The recommendations of international scientific societies consider the system balanced if follow-up outpatient visits are held once a year, and the rest are carried out remotely.¹⁻³ This helps to reduce the number of outpatient visits by 30% in patients with implanted pacemakers and about 66% in patients with ICDs. As a result, more time can be devoted to the direct monitoring of patients who actually require it. Remote monitoring allows the assessment of system effectiveness (analysis of the basic electrical parameters of the system), arrhythmia occurrence, and indirectly, clinical changes. Medical interventions can occur earlier because of the more rapid transfer of information to the monitoring site, even in the case of asymptomatic arrhythmias or abnormalities in system operation. Even early studies analyzing the effectiveness of remote device monitoring care show that there was no deterioration in patient prognosis. Moreover, there was a reduction in inadequate discharges, prolonged battery life, and earlier diagnosis of abnormalities in system operation. Also, asymptomatic atrial fibrillation was detected more often and suitable anticoagulation therapy was implemented effectively.⁴⁻⁸ More recent registry and randomized studies indicate the benefits associated with a better prognosis (survival) in patients monitored remotely.⁹⁻¹⁰ Virtually, the only limit to remote device monitoring is the inability to make changes to the device program. In most cases, the need to change the parameters

of the system occurs during the first 6 months after the implantation.¹¹

The primary endpoint of the study was the effectiveness of the remote monitoring of ICDs in an outpatient setting during 12-month follow-up. In addition, we evaluated the usefulness of telemedical consultation for unscheduled visits caused by distressing symptoms and high-energy interventions.

METHODS A multicenter nonrandomized prospective registry was conducted at 10 sites in Poland. The study protocol was approved by the bioethics committee of the Institute of Cardiology in Warsaw.

The study included patients who, in a period from 30 days to 1 year before joining the registry, received an ICD or a cardiac resynchronization therapy device (CRT-D) enabling communication with the CareLink network (Medtronic, Minneapolis, Minnesota, United States). Every patient gave their informed consent. The exclusion criteria were as follows: younger than 18 years of age, noncompliance, or lack of consent to participate in the program.

The study protocol for each patient included both outpatient visits at a device monitoring clinic (at the beginning and end of the study), and remote device monitoring through the CareLink network in the following periods: 3 to 4, 6 to 8, and 9 to 12 months of the follow-up period. Outpatient and remote visits were performed by a physician participating in the study. Patients were also asked to contact the site in case of any distressing symptoms or the delivery of high-energy therapy. All unscheduled follow-up visits performed remotely and at the clinic were additionally recorded. Additional monitoring requested during any type of visit was classified as a continuation of a previous visit and not a new episode. During the visits, data were collected on arrhythmia, detected abnormalities, decisions made, methods of modifying the therapy, and patient subjective evaluation of the CareLink network. After the first and the last transmission in the study, feasibility and acceptance of the remote monitoring model of care were evaluated in a survey completed by the patients.

Statistical analysis Statistical analysis was performed with the SAS 8.2 (SAS, Institute Inc, Cary, North Carolina, United States). Continuous data with normal distribution were presented as means (SD) and data with nonnormal distribution, as medians and interquartile ranges. The frequency and percentage of distinguished units of nominal features were also used. The nominal variables were assessed with contingency tables, and the distribution of features was analyzed first by the χ^2 test. In cases where the expected

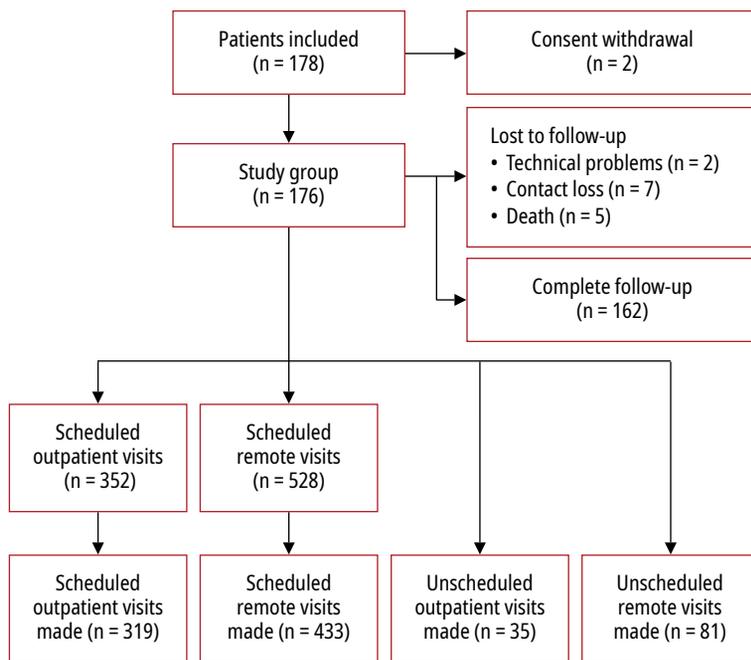


FIGURE 1 Flow chart of patients and visits

value of the observation in the cell was less than 5, the Fisher exact test was additionally used. The Shapiro–Wilk test was used to verify the compliance of the distribution of continuous variables with a normal distribution. To compare significance of differences, the *t* test or the Cochran–Cox test were used, depending on homogeneity or heterogeneity, respectively. The homogeneity of variance was analyzed with the *F* test. The level of significance was set at a *P* value of 0.05 or less.

RESULTS The study involved 178 patients from 10 sites, with between 5 to 30 patients per site (on average, 18 patients). Two patients withdrew their consent to participate in the study without giving any reason and they were not included in the analysis. Finally, 176 patients were included (men, 148 [84.1%]) (FIGURE 1). A total of 121 patients (68.8%) had a single- or dual-chamber ICD, and the remaining 55 (31.1%), a CRT-D device. The mean (SD) age of the patients was 60.7 (12.5) years (range, 20–86 years), and mean (SD) follow-up period was 405 (70) days (range, 131–723 days).

Follow-up A total of 14 patients (7.9%) prematurely ended their participation in the study, including 2 patients (1.1%) who discontinued the participation due to technical reasons (data transmission problems), contact was lost with 7 patients (4%), and 5 patients (2.8%) died during the follow-up period. The causes of death included exacerbation of heart failure in 3 patients, peritonitis related to past malignant cancer of the sigmoid colon in 1 patient. In 1 patient, the cause was not specified. These deaths were not related to participation in the study.

Visits For each patient, telemetric visits and outpatient visits were planned in a 3 to 2 ratio. In total, 91% of the 352 scheduled outpatient visits and 82% of the 528 scheduled remote visits were carried out. This translates into 752 visits preformed scheduled in the protocol, of which 319 (42.4%) were carried out at the outpatient clinic and 433 (57.6%), remotely. The remaining 116 visits (13.4%) were unscheduled visits, including 35 (30.2%) outpatient and 81 (69.8%) remote visits. (FIGURE 1). Patients who participated in the remote unscheduled visits were older than those in outpatient visits (mean [SD] age, 61.5 [11.1] years and 54.7 [15.7] years, respectively; *P* = 0.02).

During the scheduled visits, episodes of arrhythmias, both ventricular and supraventricular, were detected with similar frequency in the outpatient visits and remote visits (101 [31.7%] and 159 [36.7%], respectively; *P* = 0.15). Ventricular arrhythmias meeting the detection criteria were found during 35 (11%) outpatient visits and 54 (12.5%) remote visits. During 18 (2.4%) visits, both ventricular and supraventricular arrhythmias were recorded. The majority of arrhythmic episodes (93.5%) were correctly treated by the device (94.7% for outpatient visits and 92.7% for remote visits, respectively). In the case of outpatient visits, incorrect diagnosis was related to ventricular arrhythmias in only 2 patients (0.6%), including 1 case that required lowering the ventricular tachycardia detection threshold. Incorrect diagnosis occurred in 4 cases (16%) and did not require changes to the program but only a recommendation to change the drug therapy. According to physicians who monitored data stored in the device memory, these data allowed for the correct assessment of arrhythmia in all patients during both outpatient and remote visits.

During the unscheduled outpatient and remote follow-up visits, arrhythmias, both ventricular and supraventricular, were detected more often than during scheduled visits. Arrhythmias occurred during 15 (42.9%) out of 35 outpatient visits and 40 (49.4%) out of 81 remote visits, respectively. Ventricular arrhythmias meeting the detection criteria were identified during 8 outpatient visits (11%) and 54 remote visits (12.5%). There were no differences in the incidence of arrhythmia between the outpatient and remote visits. Both ventricular and supraventricular arrhythmias were recorded during 3 visits (2.6%). Most of arrhythmic episodes (77%) were correctly treated by the device, although this percentage was lower than in scheduled visits. The percentages were 66.7% for outpatient visits and 80.4% for remote visits (in comparison with the scheduled visits, the differences were *P* < 0.01 for outpatient visits and *P* = 0.02 for remote visits). In the case of outpatient visits, incorrect diagnosis and procedure were related to ventricular arrhythmia in

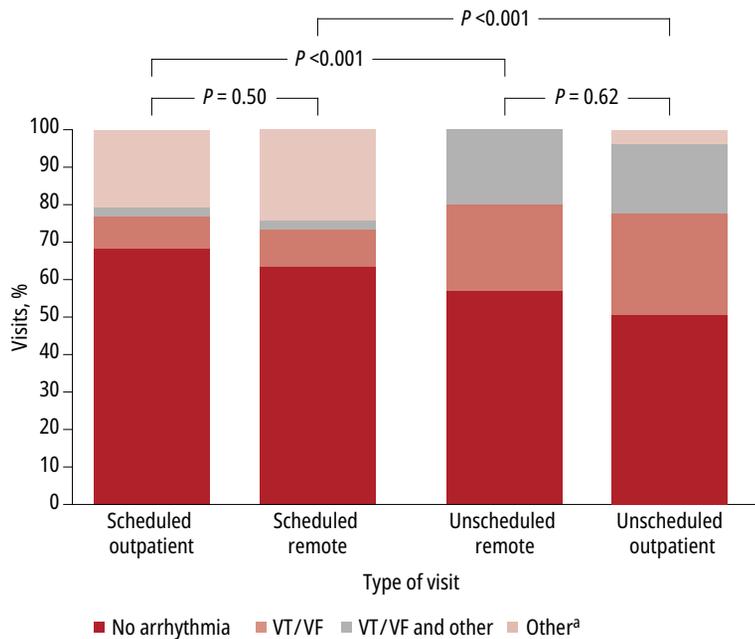


FIGURE 2 Frequency of arrhythmia detection during implantable cardioverter-defibrillator (ICD) monitoring, both outpatient and remote, scheduled (n = 752) and unscheduled (n = 116) visits.

a Other included nonsustained ventricular tachycardia, supraventricular tachycardia, atrial tachycardia, and atrial fibrillation

Abbreviations: VT/VF, ventricular tachycardia / ventricular fibrillation

one case (6.7%) and was the reason for changing the ICD program, and in the case of remote visits, this occurred in 4 cases (16%) and did not require changes in the program but only a recommendation to change the drug therapy in 2 cases (FIGURE 2).

As for the scheduled visits, device malfunctions were detected both during outpatient and remote visits only in few patients, that is,

3 (0.9%) and 4 (0.9%), respectively. In the case of remote visits these included: electromagnetic interference on the atrial electrode recorded by the device as arrhythmia (1 patient), T-wave oversensing (1 patient), and resistance alarm in 2 patients. In the case of the outpatient visits, there was a threshold increase in 1 patient and damage to an electrode in 2 patients. As for the unscheduled visits, there was only a single case of T-wave oversensing (0.9%) during a remote visit, which caused an additional outpatient visit.

During the scheduled visits, a necessity for a medication change, additional visit, or hospitalization resulting from the above observations of the device operation or arrhythmia was recorded with a similar frequency during outpatient and remote visits. Malfunctions of the device requiring additional outpatient checks were detected only during 6 outpatient visits (1.4%). Additional checks of the device were necessary in 1 outpatient visit (0.3%). Device reprogramming or referring for further diagnostics occurred more frequently. During unscheduled visits, the percentage of ordered interventions was comparable in remote and outpatient visits, except for device reprogramming, which took place more often during outpatient visits. The comparison of scheduled and unscheduled visits shows that a higher percentage of patients on unscheduled visits required intervention with respect to programming, medication change, and additional visits. A detailed comparison is presented in TABLE 1.

The most frequently reported reasons for remote additional outpatient visits were alarming symptoms, device alert, or patient anxiety,

TABLE 1 Interventions resulting from data collected during visits (more than 1 intervention in 6 patients of scheduled and 7 unscheduled visits)

Intervention	Scheduled visits			Unscheduled visits			P value (scheduled vs unscheduled)	
	Outpatient (n = 319)	Remote (n = 433)	P value	Outpatient (n = 35)	Remote (n = 81)	P value	Outpatient	Remote
No intervention	275 (86.2)	389 (89.8)	0.13	24 (68.6)	56 (69.1)	0.95	0.006	<0.001
Reprogramming	25 (7.8)	1 (0.2)	<0.001	7 (20)	0	<0.001	0.03	>0.99
Ordering further diagnostics	4 (1.2)	0	0.03	1 (2.9)	2 (2.5)	>0.99	0.4	0.02
Medication change	12 (3.8)	27 (6.2)	0.13	3 (8.6)	10 (12.3)	0.75	0.18	0.05
Additional outpatient control	1 (0.3)	6 (1.4)	0.25	2 (5.7)	3 (3.7)	0.64	0.03	0.16
Additional consultation	4 (1.25)	4 (0.9)	0.73	0	5 (6.2)	0.32	>0.99	0.006
Admission to hospital	5 (1.6)	1 (0.2)	0.09	1 (2.9)	7 (8.6)	0.43	0.47	<0.001
Others	1 (0.3)	8 (1.9)	0.09	1 (2.9)	1 (1.2)	0.51	0.19	>0.99

Data are presented as number (percentage).

TABLE 2 Causes of additional visits (multiple choice answers: in 14 patients there was more than 1 [2 or 3] cause); groups are not separable

Cause of additional visit	Total	Outpatient clinic / hospital	Remote	P value
Symptoms reported by patients	31 (26.7)	5 (14.3)	26 (32.1)	0.046
Appropriate discharge	17 (14.7)	4 (11.4)	13 (16.1)	0.52
Inappropriate discharge	7 (6)	2 (5.7)	5 (6.2)	>0.99
Device alert	20 (17.2)	1 (2.9)	19 (23.5)	0.007
Necessity of reprogramming	2 (1.7)	2 (5.7)	0	0.09
Patient anxiety	19 (16.4)	1 (2.9)	18 (22.2)	0.01
Deteriorated well-being	1 (0.9)	0	1 (1.2)	>0.99
Assessment of heart rate	2 (1.7)	0	2 (2.5)	>0.99
During outpatient visit due to another reason	34 (29.3)	25 (71.4)	9 (11.1)	<0.001
Arrhythmias without ICD intervention	3 (2.6)	0	3 (3.7)	0.55
Stimulation disturbances	1 (0.9)	1 (2.9)	0	0.3

Data are presented as number (percentage).

Abbreviations: ICD, implantable cardioverter-defibrillator

TABLE 3 Patient subjective sense of safety

Sense of safety	Week 1	Month 12
Much safer	40 (30.5)	66 (44.6)
Safe	75 (57.3)	75 (50.7)
No influence	15 (11.4)	7 (4.7)
Unsafe	1 (0.8)	0

Data are presented as number (percentage).

TABLE 4 Patient opinion on the benefits of using a telemedical system to control ICDs (multiple choice answers, groups are not separable)

Opinion	Week 1 (n = 132)	Month 12 (n = 147)	P value
Fast intervention in case of problems	98 (74.2)	99 (67.4)	0.21
Security / safety	59 (44.7)	60 (40.8)	0.51
Time saving	45 (34.1)	43 (29.2)	0.39
Cost saving	28 (21.2)	25 (17)	0.37
Flexibility	21 (15.9)	21 (14.3)	0.71
Other	4 (3)	24 (16.3)	0.001

Data are presented as number (percentage).

with a total of 77.7% of all reports. A detailed description of the reasons for the visits, with division into outpatient or hospital and remote visits, is presented in TABLE 2.

People monitoring the devices claimed that in the case of additional remote visits, as many as 31 cases (38.3%) would require additional outpatient visits, unless a remote visit could be performed. On the other hand, in the case of additional outpatient visits, as many as 25 cases (75.8%) could have been carried out remotely.

Subjective assessment of the CareLink network The majority of patients, both during the first and last transmission, found the handling of the monitor easy or very easy. After the first transmission, there were 125 such answers (94.7%) out of 132, and after the last transmission, 139 (93.3%) out of 149. This assessment did not change in the course of the program. Only 16 patients (12.1%) during the first and 25 patients (16.8%) during the last transmission required the assistance of other people. It

also appears that the CareLink network provided a sense of safety, observed in the follow-up period. The majority of patients stated that their sense of safety increased (Fisher exact test, $P = 0.02$ for trend) (TABLE 3).

Experience with the CareLink network resulted in more patients preferring joined remote and outpatient visits as the optimal healthcare model. After the first transmission, there were 117 such answers out of 132, and after the last transmission, 107 out of 149, 88.6% and 71.8%, respectively. The group of patients with no preference increased.

As the patient survey showed, the greatest benefit of the CareLink network was fast intervention in case of problems and an increased sense of safety. This did not change during the whole study period. A lower number of patients also reported additional benefits such as saving time and costs related to the visit (TABLE 4).

DISCUSSION The main finding of this study is that remote control of ICDs and CRT-Ds with the Medtronic CareLink network is feasible and safe, and thus, allows to carry out routine outpatient visits once a year in patients with CIEDs. No differences between the conventional and remote visits were observed with regard to proper detection of arrhythmic events as well as to the diagnosis of any device malfunctions throughout the whole follow-up period. The majority of scheduled visits were carried out successfully both in outpatient visits and remotely (91% and 82%, respectively). According to the opinion of physicians who performed the conventional 1 year follow-up visit at outpatient clinics, as many as 75.8% of telemetric visits would have been sufficient and satisfactory as the only way of monitoring CIEDs. These findings were in line with the current Heart Rhythm Society Expert Consensus Statement on remote interrogation and monitoring for CIED's.¹²

Secondly, as many as 13.4% of all study visits were unscheduled and, even more significantly, 69.8% of them were telemetric. Of note, the majority of unscheduled visits were patient-initiated as a result of anticipated symptoms, anxiety, or device alerts. Importantly, about a third of these unscheduled transmissions required medication change, additional consultation, outpatient visit, or even hospital admission (12.3%, 6.2%, 3.7%, and 8.6%, respectively). This reflects one of the greatest advantages of the Medtronic CareLink network, which allows every patient to actively participate in remote monitoring of the transmissions at every opportunity. Of note, patients who initiated an unscheduled transmission were older than those who waited until the scheduled visits (mean [SD] age, 61.5 [11.1] years and 54.7 [15.7] years, respectively). Taking into consideration

the fact that for over 96% of patients the use of the monitor was easy or very easy, it should not be a surprise that over 95% of the subjects felt safe or even more safe with the CareLink network. These findings are of particular importance as many patients with heart failure, in particular those with implantable devices, have depression and anxiety, and thus, their active participation in the treatment may exert a positive effect on the understanding of the disease as well as long-term outcomes.¹³⁻¹⁶

Third, scheduled remote transmissions, which were performed in line with the study protocol every 3 months, resulted in no intervention in 89.9% of cases. The most frequent intervention was medication change or dose up-titration (6.2%), while additional in-person consultations or acute hospital admissions were very infrequent (0.9% and 0.2%, respectively). Of note, the need for device reprogramming was necessary only in 0.2% of cases. These findings confirm that the majority of patients do not require routine visits to the outpatient clinic every 3 to 6 months just to confirm the proper functioning of the implanted devices.

Several recent studies confirmed that remote monitoring of implantable devices is not only safe and feasible but also allows early diagnosis of any device malfunctions, reduces the number of in-office visits as well as both inappropriate and appropriate shocks, and eventually contributes to lower costs of treatment.^{4-7,17-20} Moreover, it has been recently proven that remote monitoring reduces mortality in patients with heart failure. These fundamental findings were initially observed in large nonrandomized observational registries, like ALTITUDE or MERLIN,^{6,21} and finally confirmed in a prospective, randomized clinical trial, Implant-Based Multiparameter Telemonitoring of Patients with Heart Failure (IN-TIME).¹⁰ It was shown for the first time that daily, implant-based remote monitoring improves survival in comparison with conventional outpatient follow-up visits in patients with CIEDs.¹⁰ What is more, these observations seem to be true for remote follow-up visits for different kinds and modalities of CIEDs, including pacemakers, and that the real advantage of remote patient monitoring depends directly on both the adherence to therapy and time spent on being constantly monitored.²¹ A recent study also suggested that remote monitoring of patients with heart failure with implanted ICDs or CRT-Ds reduced the hospitalization rate in the remote monitoring care arm.²² These observations, which reinforce the role of remote monitoring, were strongly supported by the recently published opinion of Polish experts of telemedicine.²³

Limitations The main limitation of this study is lack of comparison between remote and conventional follow-up. Moreover, analyzing remote

monitoring provided by only 1 company might affected comparison between remote monitoring systems from different manufacturers.

Conclusions The strategy of remote monitoring appeared to be feasible, safe, and patient friendly, demonstrating that the majority of patients do not require an additional in-person visit within 1 year just to confirm the proper functioning of the device. The trial revealed more-over that more than two-thirds of the unsched-uled visits were telemetric and in a third of cas-es additional medical intervention was required. As this trial did not compare patients monitored remotely with those who were followed in a con-ventional way, since all the study patients were equipped with and used the Medtronic CareLink network transmitter, we cannot make a conclu-sion with respect to the superiority of any of the methods presented in this study. However, bearing in mind that no major issues concern-ing the remote monitoring appeared through-out the whole study period, the telemetric con-trol of CIEDs could become the routine type of follow-up care in Poland.

ARTICLE INFORMATION

ACKNOWLEDGMENTS This work was supported by Medtronic Poland as a Medtronic CareLink Network Evaluation Registry (ClinicalTrials.gov identifier, NCT01023022).

CONFLICT OF INTEREST All authors were included in the Medtronic Care-Link Network Evaluation Registry (ClinicalTrials.gov identifier, NCT01023022). AM received lecture fees and travel grants from St. Jude Medical, Medtronic, and Bio-tronik. PM received lecture fees and travel grants from Medtronic. MM received lecture fees and travel grants from Medtronic. MG received lecture fees and travel grants from Medtronic. MK received travel grants from Medtronic. RL received lec-ture fees from Medtronic, Biotronik, and St. Jude Medical.

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HOW TO CITE Maciąg A, Mitkowski P, Mazurek M, et al. Patient perspec-tive and safety of remote monitoring of implantable cardioverter-defibrillators in the Polish Nationwide Multicenter Registry: the Medtronic CareLink network eval-uation. *Kardiol Pol.* 2020; 78: 1115-1121. doi:10.33963/KP.15556

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