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

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Short title: Patient perspective and safety of remote monitoring of ICDs

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All authors have been included in Medtronic “CareLink” Network Evaluation Registry.
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Abstract

Background: Remote monitoring of Cardiovascular Implantable Electronic Devices allows for the assessment of the effectiveness of the system, the occurrence of arrhythmia and indirectly for 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 the operation of the system.

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

Methods: Finally, 176 patients in 10 sites were analysed (84.1% men). The mean age (SD) of the patients was 60.7 (12.5) years (20 - 86 years), and mean follow-up period was 405 days (131 to 723 days).

Results: A total of 354 at the outpatient and 514 remotely follow-up visits were conducted. During the study period episodes of arrhythmias, device malfunctions were detected with similar frequency as in the outpatient and remote visits.

During the study period patients’ sense of safety significantly increased. More patients preferring joined remote and outpatient visits as the optimal health care model. In the patients’ opinion, the greatest benefit of the "CareLink" network was fast intervention in case of problems 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 one year just to confirm the proper functioning of the implantable cardioverter defibrillators.

Key words: implantable cardioverter defibrillator, registry, remote monitoring
What’s New?

The majority of visits, for the cardiovascular implantable electronic devices patients, both scheduled and urgent can be successfully replaced by remote visits.

Increasing the patient's sense of security can be the most important argument for using remote monitoring.
**Introduction.**

The constantly increasing number of Cardiovascular Implantable Electronic Devices (CIEDs) in use, the degree of their complexity and elongation of life in this group of patients have led to a dramatic increase in the workload of device monitoring clinics. In addition, the analysis of data stored on the device and the need to make therapeutic decisions prolong the duration of a follow-up visit in selected patients. The guidelines on the frequency of monitoring visits in accordance with the EHRA recommendations require the ever increasing involvement of medical personnel and the requirement for suitable premises; it is very difficult now to maintain 6 - 12 month deadlines for follow-up visits for those patients with implanted pacemakers (PM) and 3 - 6 month deadlines for patients with cardioverter-defibrillators (ICD) [1]. The majority of outpatient visits end with only a confirmation of the effectiveness of the system and does not result in any changes to the operating parameters of the device. The recommendations of international scientific societies consider the system balanced if the follow-up visits in an office 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 an implanted pacemaker and about 66% in patients with ICD. As a result, more time can be devoted to the direct monitoring of patients who actually require it. Remote monitoring allows for the assessment of the effectiveness of the system (analysis of the basic electrical parameters of the system), the occurrence of arrhythmia and indirectly for 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 the operation of the system. Even early studies analysing the effectiveness of remote device monitoring care show that there is no deterioration in prognosis, there is a reduction in inadequate discharges, extending of the battery life, the earlier diagnosis of abnormalities in system operation, the identification of asymptomatic atrial fibrillation and implementation of
a suitable anticoagulation therapy [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 lack of the ability to make changes to the device program. In most cases, the need to change the parameters of the system takes place during the first 6 months after implantation [11].

The primary endpoint of the study was the effectiveness of the remote monitoring of implantable cardioverter defibrillators in an outpatient setting during 12 months follow-up. In addition, there was an evaluation of the usefulness of the telemedical method for unscheduled visits caused by the occurrence of distressing symptoms and high-energy interventions.

**Methods.**

A multicentre, non-randomized, prospective registry was conducted in ten sites in Poland. The study protocol was approved by the Bioethics Committee of Institute of Cardiology in Warsaw.

The study included patients who, in a period from thirty days to one year before joining the registry, received an ICD or CRT-D implant enabling communication with the “CareLink” network (Medtronic Minneapolis USA), each of whom gave their informed consent. The patient exclusion criteria included: under the age of 18 years, non-compliant or those who did not give their consent to participate in the program.

The study protocol for each patient included both outpatient visits at the device monitoring clinic (at the beginning and end of the study), and remote device monitoring through the “CareLink” network in the following periods: 3 - 4, 6 - 8 and 9 - 12 months of the follow-up period. The outpatient and remote visit were performed by the physician participating in the study. The 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 data on the subjective evaluation of “CareLink” network.

After the first and the last transmission in the study the feasibility and acceptance of the remote monitoring model of care was provided by using self-assessed patient survey.

Statistical analysis.

Statistical analysis was performed with the SAS 8.2 (SAS, Institute Inc, Cary, NC, USA). Continuous data were presented in the form of means and standard deviation (SD) in case of a normal distribution or medians and the interquartile range with no compliance to a normal distribution. The frequency and percentage of the distinguished units of nominal features were also used. The study of nominal variables involved the use of contingency tables, and the distribution of features was analysed first by Pearson’s chi-squared test. In cases where the expected value of the observation in the cell was less than 5, Fisher’s exact test was additionally used. The Shapiro-Wilk test verified the compliance of the distribution of continuous variables with a normal distribution. To compare significance of differences the t-test or Cochran-Cox test were used respectively. Homogeneity of variance was analysed with the F-test. The level of statistical significance was \( \alpha \leq 0.05 \).

Results.

The study involved 178 patients in 10 sites, with between 5 and 30 per site (average of 18). 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 analysed, including 148 men (84.1%) (Figure 1). Single or dual-chamber ICD was in 121 (68.8%) patients, and a
CRT-D device in the remaining 55 (31.3%) patients. The mean (SD) age of the patients was 60.7 (12.5) years (20 - 86 years), and mean follow-up period was 405 days (131 to 723 days).

**Follow-up.**

A total of fourteen (7.9%) patients prematurely ended their participation in the program, including two (1.1%) patients who discontinued the participation due to technical reasons (data transmission problems), contact was lost with seven (4.0%) patients and five (2.8 %) patients died during the follow-up period. The causes of death included: exacerbation of heart failure in three patients, peritonitis related to past malignant cancer of the sigmoid colon in one patient and the cause was not specified in one patient. These deaths were not related to participation in the program.

**Follow-up visits.**

For each patient telemetric visits and outpatient visits were planned in a 3 : 2 ratio. 91% of the 352 scheduled outpatient visits and 82% of the 528 scheduled remote visits were carried out. That gives 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 (13.4%) visits were unscheduled visits - 35 (30.2%) outpatient and 81 (69.8%) remote visits. (Figure 1). The mean age of the patients who participated in the remote unscheduled visits was higher than the mean (SD) age of those who made outpatient visits: 61.5 (11.1) and 54.7 (15.7), respectively, \( P = 0.02 \).

During the scheduled visits, episodes of arrhythmias, both ventricular and supraventricular, were detected with similar frequency as in the outpatient visits, 101 (31.7%) and remote visits, 159 (36.7%), \( P = 0.15 \). 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 episodes, respectively. In the case of outpatient visits, incorrect diagnosis was related to ventricular arrhythmias in only 2 (0.6%) patients, including 1 case that required lowering the VT detection threshold, whereas in the case of remote visits, it concerned 4 (1%) cases and did not require changes to the program parameters. According to the doctors monitoring the data stored in the device memory, both during outpatient and remote visits, they allowed for the correct assessment of arrhythmia in all patients.

During the unscheduled follow-up visits, both carried out in the office and remotely, arrhythmias, both ventricular and supraventricular, were detected significantly more often than in the case of 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 detected during 8 (11%) outpatient visits and 54 (12.5%) remote visits. The differences in the incidence of arrhythmia between the outpatient visits and remote visits were not significant. During 3 (2.6%) visits, both ventricular and supraventricular arrhythmias were recorded. Most of arrhythmic episodes (77%) were correctly treated by the device, although this percentage was lower than in the case of 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 statistically significant, $P < 0.01$ for outpatient visits and $P = 0.02$ for remote visits, respectively). In the case of outpatient visits, incorrect diagnosis and procedure were related to ventricular arrhythmia in one case (6.7%) and was the reason for changing the ICD program, and in the case of remote visits this occurred in 4 (16%) cases and did not require changes in the program but only a recommendation to change the drug therapy in 2 cases.

As for the scheduled visits, device malfunctions were detected both during outpatient and remote visits only in single patients, 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), wave-T oversensing (1 patient), and resistance alarm in 2 cases. In the case of the outpatient visits, there was a threshold increase in 1 patient and damage to an electrode in 2 cases. As for the unscheduled visits, there was only 1 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 requiring additional outpatient checks of the device were detected only during 6 (1.4%) outpatient visits. Additional checks of a device was necessary in relation with 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 for 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's anxiety, with 77.7% reports in total. A detailed description of the reasons for the visits, with division into outpatient/hospital and remote visits, is presented in Table 2.

The 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 taken 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: 125 such answers out of 132 (94.7%) and after the last transmission: 139 out of 149 (93.3%). This assessment did not change significantly in the course of the program.

Only 12.1% (16 patients) during the first and 16.8% (25 patients) during the last transmission required the assistance of other people.

It also appears that using the "CareLink" network provides a sense of safety, observed in the follow-up period. The majority of patients stated that their sense of safety significantly increased (Table 3).

Experience with the "CareLink" network resulted in more patients preferring joined remote and outpatient visits as the optimal health care model. After the first transmission there were 117 such answers out of the 132 surveys and after the last transmission 107 answers out of the 149 surveys, 98.6% and 71.8%, respectively. The group of patients with no preference increased.

In the patients' opinion, the greatest benefit of the "CareLink" network was fast intervention in case of problems and an increased sense of safety. This opinion did not change significantly during the whole period of the registry process. A lower but also significant number of patients also reported the additional benefits of saving time and saving costs related to the visit (Table 4).

Discussion.

The main finding of this study is that remote control of ICD and CRT-D devices with the Medtronic “CareLink” network is feasible and safe and thus allows to one perform routine outpatient visits once a year with patients with having Cardiovascular Implantable Electronic Devices. 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 malfunc
tions throughout the whole follow-up period. The majority of scheduled visits were successfully performed both in a conventional manner and remotely (91 and 82% respectively). According to the opinion of the physicians who performed the conventional, one year follow-up visit at the outpatient clinics in as many as 75.8% of cases the telemetric visit would have been sufficient and satisfactory as the only way of monitoring the Cardiovascular Implantable Electronic Devices. These findings were in line with current HRS 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 here was that 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 changes, additional consultations, an 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 technology, which allows every patient to actively participate in remote monitoring of the transmissions at every opportunity. Of note is that those patients who initiated an unscheduled transmission were significantly older than those who waited until the scheduled visits (61.5 (11.1) and 54.7 (15.7) 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, suffer from 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 the 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/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 is the fact that 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, every 3 - 6 month visits to the outpatient clinic, just to confirm the proper functioning of the implanted devices.

Several recently published papers 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]. However, significantly, it has been recently proven that remote monitoring does reduce mortality in HF patients. These fundamental findings were initially observed in large non-randomized, observational registries, like ALTITUDE or MERLIN [6,21], and finally confirmed in a prospective, randomized clinical IN-TIME trial [10]. It has been shown for the first time that daily-based remote monitoring improves survival in comparison to 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 surveillance over the patient depends directly on both the adherence to the therapy and the time spent on being constantly monitored [21]. Recently published study suggested also that remote monitoring of heart failure patients with implanted ICD or CRT-D significantly reduced the hospitalization rate in the RC arm [22].
These observations encouraged the role of remote monitoring to be strongly supported by recently published opinion of Polish experts of telemedicine [23].

**Limitations:**

The main limitation of this study is the lack of comparison between remote and conventional follow-up. Analysing remote monitoring provided by only one company might affect 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 one year just to confirm the proper functioning of the implantable device. The trial revealed moreover that more than two thirds of the unscheduled visits were telemetric and in a third of cases additional medical intervention was required. As this trial did not compare patients monitored remotely vs. those who were followed up in a conventional way, as all the study patients were equipped and used the Medtronic “CareLink” network transmitter, we cannot make a conclusion with respect to the superiority of any of the methods presented in this study. However, bearing in mind that no major issues concerning the remote monitoring appeared throughout the whole study period, the telemetric control of CIEDs could become the routine, standard type of follow-up care in Poland.

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

| Interventions                        | Scheduled visits | Unscheduled visits | Scheduled vs. unscheduled |
|--------------------------------------|------------------|--------------------|---------------------------|
|                                      | Outpatient (n = 319) | Remote (n = 433) | P | Outpatient (n = 35) | Remote (n = 81) | P | 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 | 1.00   |
| Ordering further diagnostics         | 4 (1.2%)         | 0                 | 0.03 | 1 (2.9%)        | 2 (2.5%)         | 1.00 | 0.40  | 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 | 1.00  | 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  | 1.00   |
Table 2. Causes of additional visits (multiple choice answers: in 14 patients there was more than one (two or three) cause); groups are not separable.

|                                | Total     | Outpatient clinic / hospital | Remote    | P        |
|--------------------------------|-----------|-----------------------------|-----------|----------|
| 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 (6.0%)  | 2 (5.7%)                    | 5 (6.2%)  | 1.00     |
| 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's anxiety              | 19 (16.4%)| 1 (2.9%)                    | 18 (22.2%)| 0.01     |
| Deteriorated well-being        | 1 (0.9%)  | 0                            | 1 (1.2%)  | 1.00     |
| Assessment of heart rate       | 2 (1.7%)  | 0                            | 2 (2.5%)  | 1.00     |
| 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         | 0.30     |

Abbreviations — see Figure 2
Table 3. Subjective patients' sense of safety on the basis of the given answers ($P = 0.02$)

|                  | Week 1     | 12m       |
|------------------|------------|-----------|
| 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         |

Table 4. Patients' opinion on the benefits of using a telemedic system to control ICD.

|                          | Week 1   | 12 month | $P$  |
|--------------------------|----------|----------|------|
| 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%) | 0.37 |
| Flexibility              | 21 (15.9%) | 21 (14.3%) | 0.71 |
| Other                    | 4 (3.0%)  | 24 (14.3%) | 0.001|

Abbreviations — see Figure 2
Figure 1: Patients and visits flow chart.
Figure 2. Frequency of arrhythmia detection during ICD monitoring, both outpatient and remote, scheduled n=752, and unscheduled visits, n=116.

Abbreviations — (ICD implantable cardioverter defibrillator, VT/VF ventricular tachycardia/ventricular fibrillation, Others included non-sustained ventricular tachycardia, supraventricular tachycardia, atrial tachycardia and atrial fibrillation).