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Original Article

Examination of the Effective Utilization of the CARELINK® Remote Monitoring System after its Introduction

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Background: Japan started using the CARELINK® (Medtronic, Inc, Minneapolis, MN, USA) remote monitoring system in April 2009. However, in some cases, the device failed to transmit a message after registration or according to schedule. We investigated the difference between patients who could make effective use of CARELINK® system and those who could not.

Subjects and Method: Sixty patients who had registered until December 2009 at our institution were analyzed. These patients were divided into two groups: those who were able to use the device effectively (group G, n = 49) and those who were not (group F = 11). Patient background, automatic or manual telemetries, new or existing implant patient, presence of adverse events, and the use or non-use of a checklist at the time of introduction were compared between the two groups.

Results: In group G, more patients used a checklist at the time of introduction than that in group F (use of checklist/total, 31/49 in group G vs. 3/11 in group F; P, 0.029). No significant difference was observed in other factors between the two groups.

Conclusion: We consider that the method used to explain the system are important to make the patients understand handling methods of CARELINK® system. The number of patients introduced to remote monitoring of implantable devices will continue to increase in the future; therefore, we must continue to develop innovative approaches for their effective use. (J Arrhythmia 2011; 27: 126–130)

Key words: Implantable Devices, Remote Monitoring, Checklist

Introduction

Pacemakers (PM) and implantable cardioverter defibrillators (ICD) have been used to treat patients with symptomatic bradycardia and those at risk for sudden death due to ventricular arrhythmia.[1)] Furthermore, cardiac resynchronization therapy with a defibrillation function (CRT-D) has become

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more popular for treating patients with systolic dysfunction and left ventricular dyssynchrony; thus, the number of patients with implants has increased.[2–4)]

Patients with implanted devices must have the condition of the devices checked and receive medical examination from a physician on a regular basis, although the frequency of follow-up checkups varies depending on the implant type and disease. Patients implanted with ICD as primary prevention for cardiac arrhythmia events do not always feel motivated to visit the ICD clinic regularly.[5–9)] In addition, in some cases of asymptomatic cardiac arrhythmia, the arrhythmia events were not detected until the next outpatient visit. However, a quick intervention is possible if we can identify these events using remote monitoring.

To solve these problems, a remote monitoring system (CARELINK®; Medtronic, Inc., Minneapolis, MN, USA) has become available. Through this system patients can view accumulated data on a dedicated web site using a telephone line at home, and obtain information similar to that obtained from a device checkup conducted at an outpatient visit.[4)] An improvement in patient care has been recognized in various clinical studies conducted on this remote monitoring system.[10–13)]

Japan lags behind Europe and the US in the use of this remote monitoring system. In our institution, we introduce the CARELINK® system to patients soon after they are admitted. However, some patients could not use this system effectively, i.e., the device failed to transmit a message after registration or according to schedule. To take advantage of the CARELINK® remote monitoring system, we investigated the difference between patients who could make effective use of the CARELINK® system and those who could not.

Methods

Sixty patients who completed registration between April 2009 and December 2009 were included in the study. Eleven patients were implanted with PM (7 Adapta, 4 EnRhythm); 44 with ICD (21 Maximo, 15 Virtuoso, 8 Secura); and 5 with CRT-D (5 Concerto). All devices used were manufactured by Medtronic, Inc. Patients were divided into two groups: those who could use the device effectively (group G) and those who could not (group F). Group G comprised 49 patients and group F comprised 11 patients. We compared patient background, gender ratio, age, device type, and differences in interrogation between the two groups.

All PM models required manual data reading and transmission by the patient each time. Of the ICD, only the Maximo required manual data reading and transmission. The remaining devices were automatic such that they required manual data reading and transmission by the patient during its first use, and after the second use, the device automatically read and transmitted the data via an antenna incorporated in the device.

After regular checkup at a periodic outpatient visit and when the existing implant device was deemed compatible with the CARELINK® system, the patient received an explanation about the CARELINK® system from the physician during a consultation. The patient returned to the room where the device checkup was conducted and received an explanation about installation and handling of the device from the clinical engineering technologist. The patient then returned to the consultation room and obtained the physician's signature on a written consent to complete the procedure.

In our institution when a patient receives an implantation for the first time, a checkup is conducted a week after implantation. Such a patient receives an explanation about the CARELINK® system at the first checkup and obtains the physician's signature on a written consent. For new implants, the patient does not have to travel between rooms, unlike those with existing implants.

The presence of atrial or ventricular arrhythmia events was recorded and a checklist was presented to the patient during the explanation (**Figure 1**).

The checklist for the explanation details provided to the patients was not used during the period from April 2009 until July 2009, and was used during the period from August 2009 until December 2009.

Statistical Analysis

The unpaired *t*-test and 2×2 chi-square test were used. $P < 0.05$ was considered statistically significant.

Results

No significant difference was observed in patient background or devices used between the two groups. Furthermore, no significant difference was observed for other examination factors, i.e., difference in interrogation, difference upon introduction of the CARELINK® system, and presence of atrial arrhythmias. In group G, the percentage of patients who were using the checklist at the time of introduction was significantly higher than that in

	Check factor	Contents／Matters that require attention
Necessary part / name of each part	☐Confirmation of a necessary part ☐Explanation of a button switch ☐Explanation of a lamp	•Main body (an antenna) / telephone cord / power adaptor •A start･stop button / a line changeover switch •Power supply ON・Off/a lamp during the transmission and reading
About environment / the establishment*	☐Confirmation of using a telephone ☐Confirmation of the presence of a telephone ☐Confirmation of connection methods ☐Confirmation of a phone line	•Black telephone NG (IP**/ light : OK) •Is an establishment place living environment 3 m range; (a bedroom best) •Only telephone connection/Confirmation of internet line connection •tone (T), pulse (P) line :In the case of a light line a tone (T) There are many cases of a tone (T)
Data reading / transmission	☐Confirmation of a power supply ☐Data reading ☐A downlink	•A lamp turns on*** •The reading that is worked by hand/Automatic reading**** (the first time) (completed in around 2 minutes) •Transmission methods and transmission completion (Even if an antenna is separated, during the transmission, there is not no problem. Afterwards, transmission completion is confirmed)
About an alert	☐Confirmation of an alert sound ☐Setting of an alert	•Convey that alarm sounds from machinery***** Have you heard the sound at Demo (High or Low) •Make setting of Clinical Management Alerts / Lead/Device Integrity Alerts On
Troubleshooting	☐A transmission error ☐At the time of staying out	•Change setting of a phone line (T/P)･Confirmation of connection •When we are away from home for a long term, a setting change is necessary(care alert Off)

Figure 1 Checklist
A pamphlet was used to explain the contents of the checklist to each patient. The contents of the checklist was describe to the patient. After the checklist was described, the following items were explained.
*The device is operational as soon as it arrives and the first time it transmits a message.
**An IP telephone may be used.
The device is automatically set the first time it is used after it has been off-line.
***The light indicates that the power is on.
****In the manual mode, the data is transmitted before coming to the hospital
*****Contact the hospital when an alarm sounds.

Table 1 Comparison of group G and group F for each factor

	Group G	Group F	P value
Sex ratio (male : female)	38 : 11	10 : 1	0.316
Age (means ± SD)	58 ± 15	50 ± 22	0.112
Device type (PM : ICD/CRT-D)	9 : 40	2 : 9	0.988
Difference in Interrogation (Manual type : Automatic type)	25 : 24	8 : 3	0.190
Difference Upon Introduction of CARELINK (*outpatient : inpatient)	33 : 16	8 : 3	0.728
Presence of Events (existence : nothing)	14 : 35	5 : 6	0.276
Use of Checklist upon Explanation (use : mint condition)	31 : 18	3 : 8	0.029

P value is shown comparing the patient who could utilize the CARELINK system versus those who could not. Unpaired t-test was used for the statistical analysis. $P < 0.05$ is considered significant.
*Implanted devices in the case of a CARELINK supported model

group F (use of checklist/total = 31/49 in group G vs. 3/11 in group F, P = 0.029) (**Table 1**).

The problems faced by the 11 patients who could not use the device effectively were as follows: the device failed to transmit the first message (5 cases); failed to transmit messages according to the schedule (4 cases); delay in transmission (1 case); and mechanical problem (1 case).

Discussion

The number of patients with PM, ICD, and CRTD, and those attending PM clinics is annually increasing. Patients implanted with ICD as primary prevention for cardiac arrhythmia events do not always feel motivated to visit the ICD clinic regularly.[5–9] In addition, in some cases with asymptomatic cardiac

arrhythmia, arrhythmia events were not detected until the next outpatient visit. If these events are detected immediately, we can intervene as soon as possible. To solve these problems, the CARELINK® remote monitoring system is now available. However, Japan lags behind Europe and the US in the use of this remote monitoring system. In our institution, we introduced the CARELINK® system soon after patient admission. However, some patients could not use this system effectively, i.e., the device failed to transmit a message after registration or according to schedule. To take advantage of the CARELINK® remote monitoring system we investigated the possible causes of such problems in patients who could use the device effectively and those who could not. As a result, using a checklist when the CARELINK® system is introduced is important to ensure its effective utilization.

We created a checklist and began using it as a tool for staff members to standardize the explanation procedure during CARELINK® introduction. According to some reports, the use of a checklist is effective not only for those explaining the system but also for the patients who receive the explanation. We cannot exclude the possibility from repeating an explanation or staff explanation methods improving, but introducing the CARELINK® system was valuable, hence, we can exclude habituation effects.

The reason patients could not perform the transmission for the first time after the device was introduced was because they forgot the data uptake method. A checklist may make the use of the CARELINK® system more easily understandable. The patient in whom transmission of a message failed according to schedule forgot to switch the instrument on. We believe that this error would decrease with the use of a checklist as it indicates that a green light comes on when the device is operational. In cases of instrument problems, the patients were unable to use a phone line because their phones were on IP lines.

The patient must manually perform data reading and transmission at the first transmission, which is a burden. However, operation is simple and easy, and no significant difference was observed in transmission methods as previously reported.[14)]

Furthermore, no difference was observed in the interrogation methods. For the manual type of device, all patients were required to manually perform data reading and transmission each time. With the automatic type, patients were required to manually perform data reading and transmission at the first use, and transmission was automatic via an antenna incorporated in the device from the second use. No difference was presented between the manual and automatic types because they used the manual transmission of data at the first use, and the method was easy.

Furthermore, no differences were observed between the time of introduction of the CARELINK® system at the inpatient versus the outpatient clinic. This may be because patients faced the same situation with little knowledge of the remote monitoring system.

No significant difference was observed in the presence or absence of adverse events, possibly because the patients failed to notice the occurrence of adverse events in the absence of shock therapy. Therefore, in the cases in which the manual CARELINK® type was used, the problem would not be discovered until the next outpatient checkup.[15–22)] However, in the future, an automatic type of the remote monitoring system will be widely used, and hence, the system will be more effective.

Conclusion

The patients using the CARELINK® system had to set up telecommunication equipment at the time of first use and communicate via the equipment by themselves. Therefore, we consider that the methods of explanation are important to make the patients understand how to handle the CARELINK® system correctly. The number of patients introduced to remote monitoring of implantable devices will continue to increase in the future; therefore, we must develop innovative approaches for their effective use.

Study Limitations

We retrospectively investigated possible causes of problems in patients who could not effectively use the CARELINK® monitoring system. The use of a checklist at the time of device introduction was suggested as a factor for the effective use of the CARELINK® system.

References

1) Kusumoto F, Goldschlager N: Remote monitoring of patients with implanted cardiac devices. Clin Cardiol 2010; 33(1): 10–17
2) Abraham WT, Fisher WG, Smith AL, Delurgio DB, Leon AR, Loh E, et al: Cardiac resynchronization in chronic heart failure. N Engl J Med 2002; 346(24): 1845–1853
3) Cleland JG, Daubert JC, Erdmann E, et al: The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005; 352(15): 1539–1549

4) Burri H, Senouf D: Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators. Europace 2009; 11(6): 701–709
5) Winters SL, Packer DL, Marchlinski FE, et al: Consensus statement on indications, guidelines for use, and recommendations for follow-up of implantable cardioverter defibrillators. PACE 2001; 24(2): 262–269
6) Gregoratos G, Abrams J, Epstein AE, et al: ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: Summary article: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). Circulation 2002; 106: 2145–2161
7) Bernstein AD, Irwin ME, Parsonnet V, et al: Report of the NASPE policy conference on antibradycardia pacemaker follow-up: Effectiveness, needs, and resources. North American Society of Pacing and Electrophysiology. PACE 1994; 17(11): 1714–1729 [Remark 4]
8) McGrory-Usset ME, Stanton MS: Use of Implantable Cardioverter Defibrillator (ICD) Therapy and ICD Guidelines Around the World. In IE Ovyshcher ed: New Development in Cardiac Pacing and Electrophysiology. Armonk, NY: Futura Publishing Company Inc., 2002, p. 81–90
9) Wilkoff BL, Auricchio A, Brugada J, et al: HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. Heart Rhythm 2008; 5(6): 907–925
10) Schoenfeld MH: Follow-up of the Paced Patient. In KA Ellenbogen et al eds: Clinical Cardiac Pacing and Defibrillation, 2nd edition. Philadelphia, PA, WB Saunders Company, 2000, p. 895–929
11) Dressing TJ, Schott R, McDowell C, et al: Transtelephonic ICD follow-up is better: more comprehensive, less intrusive and more desirable. (abstract) PACE 2002; 25: 219
12) Igidbashian D, Stellbrink C, Hartmann A, et al: Benefit of permanent pacemaker follow-up with home monitoring. PACE 2002; 25: 47
13) Stellbrink C, Hartmann A, Igidbashian D, et al: Home monitoring for pacemaker therapy: intermediate results of the first European multicenter study. PACE 2002; 25: 655
14) Mark H. Schoenfeld, Compton SJ, et al: Remote monitoring of implantable cardioverter defibrillators: a prospective analysis. PACE 2004; 27[Pt. I]: 757–763
15) Varma N, Stambler B, Chun S: Detection of atrial fibrillation by implanted devices with wireless data transmission capability. PACE 2005; 28(suppl 1): S133–136
16) Hauser RG, Kallinen L: Deaths associated with implantable cardioverter defibrillator failure and deactivation reported in the United States Food and Drug Administration manufacturer and user facility device experience database. Heart Rhythm 2004; 1(4): 399–405
17) Maisel WH, Kramer DB: Implantable cardioverter-defibrillator lead performance. Circulation 2008; 117(21): 2721–2723
18) Kleemann T, Becker T, Doenges K, et al: Annual rate of transvenous defibrillation lead defects in implantable cardioverter defibrillators over a period of >10 years. Circulation 2007; 115(19): 2474–2480
19) Neuzil P, Taborsky M, Holy F, et al: Early automatic remote detection of combined lead insulation defect and ICD damage. Europace 2008; 10(5): 556–567
20) Spencker S, Coban N, Koch L, et al: Potential role of home monitoring to reduce inappropriate shocks in implantablecardioverter-defibrillator patients due to lead failure. Europace 2009; 11(4): 409–411
21) Hammill SC, Kremers MS, Stevenson LW, et al: Review of the Registry's second year, data collected, and plans to add lead and pediatric ICD procedures. Heart Rhythm 2008; 5(9): 1359–1363
22) Ricci RP, Morichelli L, Santini M: Remote control of implanted devices through home monitoring technology improves detection and clinical management of atrial fibrillation. Europace 2009; 11(1): 54–61