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Original Article

Assessment of the clinical benefits of remote monitoring of cardiac-implanted devices: A single-center study in Japan

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ABSTRACT

Introduction: The clinical benefits of remote monitoring (RM) of cardiac-implanted devices have not been fully evaluated in Japan. We investigated the clinical benefits of RM in a single center in Japan.
Methods: Patients with pacemakers, implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy with defibrillators (CRT-D) were assigned to RM and non-RM groups. The outpatient wait times and times to notification of EVENTS that we defined sustained ventricular tachyarrhythmias, worsening heart failure, and inappropriate therapy for supraventricular tachyarrhythmias in this study, were compared between the 2 groups.
Results: A total of 416 patients (RM: 61; non-RM: 355) were evaluated. The outpatient wait time was 17.6 ± 22.1 min for the RM group and 35.6 ± 25.2 min for the non-RM group ($P < 0.001$). Seventy-seven and 306 EVENTS were observed in 38 and 256 patients during mean follow-up periods of 360 ± 22 days and 429 ± 10 days in the RM and non-RM groups, respectively. The times to notification of EVENTS were 8.1 ± 16.2 days for the RM group and 38.7 ± 33.2 days for the non-RM group ($P < 0.001$).
Conclusions: RM significantly shortened outpatient wait times and times to notification of EVENTS. Therefore, RM was clinically beneficial in a single center in Japan.

1. Introduction

Cardiac-implanted devices offer multiple programmable features and can store large amounts of diagnostic information related to the device function, arrhythmia frequency, hemodynamic or physiologic parameters, and patient activity. Traditional device follow-up requires direct interrogation of the device in order to view the programmed parameters and stored diagnostic data, identify and correct possible malfunctions, and optimize therapy by reprogramming the device [1]. As the use of implanted cardiac devices has expanded, the number of patients consulting device clinics has increased each year, extending the wait times at the clinic.

Remote monitoring (RM) systems for cardiac-implanted devices that transmit data from the implanted device from remote locations to the medical institution through analog or wireless telephones have recently been introduced in Japan. The transmitters are able to interrogate the device, either manually by the patient's use of a telemetry wand or automatically using wireless technology [2].

RM systems consist of data acquisition by the device on a scheduled basis followed by transmission of predefined alerts to the physician as necessary [1]. RM has been widely used in the U.S. and in European countries. Recent studies from these countries have demonstrated positive effects of RM [3–6], but the benefits of RM have not been fully evaluated in Japan. The objective of the present study was to investigate the clinical benefits of RM, particularly with respect to outpatient wait times and times to detection of EVENTS that we defined sustained ventricular tachyarrhythmic events, worsening heart failure, and inappropriate therapy for supraventricular tachyarrhythmias (SVT), in a single center in Japan.

2. Methods

2.1. Patients

This study was designed as a prospective evaluation of RM in patients with cardiac-implanted devices. All of the patients in the study population had had pacemakers, implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy with defibrillators (CRT-D) implanted at our institution. Patients

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divided into either the RM (using RM) or the non-RM (without RM) group. Either the CareLink system (Medtronic, Inc., Minneapolis, MN, USA; for pacemakers, ICDs, and CRT-Ds) or the Merlin.net system (St. Jude Medical, Inc., St. Paul, MN, USA; for ICDs and CRT-Ds) was used in RM patients. The 2 RM systems are compared in Table 1. The RM system was explained to all patients using newly implanted or generator-exchanged ICDs or pacemakers from Medtronic or St. Jude Medical. Patients from whom written informed consent could be obtained were enrolled in the RM group, while other patients with ICDs and pacemakers were assigned to the non-RM group.

The physician decided whether each patient was assigned to the CareLink system or Merlin.net system based on the patient's medical condition. The patients with history of congestive heart failure were generally given Medtronic devices due to the availability of OptiVol Monitoring. OptiVol Fluid Status Monitoring, which is available only in the CareLink system, measures the intrathoracic impedance between the implanted lead in the right ventricle (RV) and the device generator and provides early detection of worsening heart failure [7–9].

This study was approved by the ethics committees of Osaka City University. A written informed consent to participate was obtained from all patients.

2.2. Evaluation

The outpatient wait times and times to notification of EVENTS were compared between RM and non-RM patients. At our institution, patients with cardiac devices undergo medical examinations after their devices have been checked in another room. However, the patients using the CareLink system can skip the device check. Outpatient wait time was defined as the interval from the time of the appointment for the device check to the start of the medical examination.

The time to EVENTS notification was defined as the time from the onset of the EVENTS to the notification of the physician. The rates of EVENTS and emergency visits and data confirmation times (device check time or RM data confirmation time) were also compared between the RM and the non-RM groups. The precise day and time at which the alert events occurred could be identified only for EVENTS (alert events due to increased OptiVol index, shock therapy, or ATP [anti-tachycardia pacing] delivered for sustained VT or VF, including inappropriate therapy). Therefore, the times to notification of the EVENTS were evaluated and compared between the RM and non-RM groups. Patients were diagnosed with worsening heart failure based on their general conditions, including symptoms, chest radiography findings, blood test parameters, and OptiVol findings (OptiVol index >60 (ohm-days)).

The device check time in non-RM patients was defined as the interval from the interrogation of the implanted device using the programmer to the printing of all of the data at the clinic. The RM data confirmation time was defined as the interval from clicking on the web site to transmit the data to the printing of the data at the clinic. The transmitted alert data were checked at the clinic every weekday at 9 a.m., while the scheduled transmitted data were checked at the clinic a day before each scheduled visit.

2.3. Patient follow-up and data collection

Patients with pacemakers: both RM and non-RM patients were followed up at office visits every 6 months. The RM patients' device data were transmitted every 6 months on a scheduled basis.

Patients with ICDs or CRT-Ds: both RM and non-RM patients were followed up at office visits every 3 months. The RM patients' device data were transmitted every 3 months on a scheduled basis.

In addition, the contents of any inquiries to the RM call center for troubleshooting of the RM system and of the alert data were evaluated during the follow-up examinations of RM patients. The alert settings of the RM group are shown in Tables 2 and 3.

Table 2
Event trigger settings (CareLink system).

Electrical reset	Active can off
Excessive charge time End of Service	OptiVol index >60
Charge circuit timeout (30 seconds)	RV lead integrity
VF detection/therapy off	RV lead noise
RV pacing impedance $<200\,\Omega$, $>2500\,\Omega$	ERI
RV defibrillation impedance $<20\,\Omega$, $>200\,\Omega$	RA pacing impedance $<200\,\Omega$, $>2500\,\Omega$
SVC defibrillation impedance $<20\,\Omega$, $>200\,\Omega$	LV pacing impedance $<200\,\Omega$, $>2500\,\Omega$
All therapies in a zone exhausted	Number of shocks delivered in an episode
Pacing mode DOO, VOO or AOO	AT/AF daily burden >6 hours
Average ventricular rate during AT/AF >100 bpm (>6 hours)	

VF: ventricular fibrillation, RV: right ventricle, AT: atrial tachycardia, SVC: superior vena cava, LV: left ventricle, RA: right atrium, ERI: elective replacement indicator, AF: atrial fibrillation, bpm: beats per minute.

Table 1
Comparison of the RM systems.

	CareLink system (Medtronic, Inc.)	Merlin.net system (St. Jude Medical, Inc.)
Device	pacemakers, ICD, CRT-D	ICD, CRT-D
Characteristic	stationary	stationary
Data transmission	analog phone line	wireless, analog phone line
Transmission range	3 m	3 m
Home telemetry	pacemakers: wand ICD, CRT-D: Wireless[a]	wireless
Frequency of transmissions	scheduled follow-up, alert events	scheduled follow-up, alert events
Scheduled follow-up	at 3:00 a.m.	between 2 a.m. and 4 a.m.
Response to events	immediate transmission	immediate transmission
Retransmission	every 3 h for 3 days	every 2 h for 24 h
Physician notification	SMS, e-mail, smartphone	fax, e-mail, SMS text, smartphone
IEGM (arrhythmic episodes)	all recorded episodes	all recorded episodes
Special features	automatic RA, RV and LV pacing thresholds OptiVol Fluid Status Monitoring	alerts fully configurable online

SMS: short message service, IEGM: intracardiac electrocardiogram, RA: right atrium.
RV: right ventricle, LV: left ventricle.

[a] Except for the first transmission using wand-operated transmitters.