
Remote Patient Management of ICD: Of What Value Is It in Clinical Practice?

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Introduction

The benefits of the implantable cardioverter-defibrillator (ICD) have been established in the primary and secondary prevention of ventricular arrhythmias and sudden cardiac death. Patients with ICDs require regular monitoring to ensure that the implanted device is working appropriately. At present monitoring is undertaken at a pacemaker centre with equipment and experienced staff. The number of ICD implantations is growing rapidly, underlining the necessity of developing new methods for patient- and doctor-friendly control of their function. The standard follow-up protocol for patients who have received ICDs includes a first outpatient check-up 1 month after implantation and a quarterly device interrogation by radiotelemetry [1]. If patients experience any problems between check-up visits that may be related to the device, they generally have to return to the device clinic.

Most published studies demonstrated a cumulative incidence of adequate ICD-delivered therapy ranging from 20% to over 60% depending on the duration of follow-up (6 months to 4 years) [2–4]. In our experience, 73% of ICD patients implanted in secondary prevention and 42% in primary prevention received appropriate ICD therapy during a 5-year and 4-year follow-up respectively. The Canadian Implantable Defibrillator Study (CIDS), during an 11-year follow-up, showed that 70% of the ICD group had appropriate therapy [appropriate shock or appropriate antitachycardia pacing (ATP)] and 50% received inappropriate therapy, including ATP, one shock or more inappropriate shocks [5]. This causes a high number of event-related or symptom-related visits to add to routinely scheduled follow-up visits.

Based on the manufacturer's analysis and/or device interrogation, 72% of death events in ICD patients were associated with malfunctioning ICDs, leads, or both [6]. ICD follow-up systems should include methods that can identify defects before they cause catastrophic events.

In addition, patients who have received ICDs often need to be re-programmed several times on the basis of changes in their clinical status or concomitant anti-arrhythmic therapy that successfully modifies the frequency and recurrence of ventricular arrhythmias.

Efforts are being made to introduce remote device-based monitoring systems that can wirelessly transmit device information from the patient to the pacemaker clinic. Besides the money saving in healthcare costs by reducing outpatient visits and emergency admissions, the opportunity to follow the patient over an uninterrupted time period should improve patient care [7]. In addition, so much information, significantly increasing the communication between physician and patient, is useful for patients who may have concerns about the device or their cardiac health: this too contributes to improving patients' quality of life.

Available Technologies

Home Monitoring (HM) Service

Chiodi has described technical characteristics and some clinical benefits of the HM Service (Biotronik GmbH & Co., Berlin, Germany) [8]. This system uses an implanted chip that transmits diagnostic data from the ICD to a modified GSM mobile phone unit. The ICD is able to send the data over a distance of about 2.5 m to the receiver. The receiver, which is battery powered, can be placed in the loading tray beside the patient or can be carried around with him. The information transmitted includes the number of ventricular tachyarrhythmias detected in each different monitor zone and ATP and shock therapies delivered, besides data about battery voltage, pacing and shock impedance, and device status. The message is then forwarded as an encrypted short message via the standard SMS procedure to the remote Service Centre, i.e. the central data processing unit to which all implant data are sent. Data are generated and transmitted either at set times (automatically every 24 h), following an event (the termination detection after treatment), or as a patient-triggered message. At the Service Centre incoming messages are automatically decrypted, the contents are collected into a database, and a Cardio Report is then sent to the physician in charge of the patient. The entire process takes a few minutes and requires no involvement on the patient's part.

Several studies have been performed to explore the clinical benefits of

HM technology in patients who have received Biotronik ICDs [9–11]. Elsner et al. published an interim analysis of the collected data from 177 ICD patients followed for 232 ± 109 days [12]. On the basis of daily HM information, ventricular tachyarrhythmias were detected in 39% of patients, 36% of whom received ICD therapy. Detected arrhythmias included 550 ventricular tachycardia (VT) and 239 ventricular fibrillation (VF) episodes. Nine hundred and eighty-five ATP attempts were documented in 34 patients, with a mean success rate of 70.2% (one or more attempts). Three hundred and thirty-two shock therapies were initiated in 53 patients, 200 of which were aborted. The preliminary report from the WAMMI study [13] provided interim data analysis in 180 ICD patients who were followed for a mean of 9 months. Two hundred and fifty-two episodes of VT or VF were detected via HM, 98 of which were terminated by programmed ATP and 58 by shock. Additional reports have focused on the use of the HM Service to evaluate effects of drugs or to detect supraventricular tachyarrhythmias or lead/device defects [14–16].

Continuous monitoring of device-delivered therapies as soon as they occur, appropriate or inappropriate, their success rate, and the incidence of relevant tachyarrhythmias may contribute to optimising how the device can work to help modifying programming and drug therapy. Furthermore, the HM Service may allow prompt detection of lead- or ICD-related technical failures which can be catastrophic to the patient [17].

CareLink Patient Management Network

The CareLink (CL) monitoring and software package (Medtronic Inc., Minneapolis, Minn., USA) allows the physician to collect data via a website from patients with implanted Medtronic ICDs. The CL includes a portable monitor used by patients to self-interrogate their ICD. The data are automatically downloaded by the monitor and sent through a standard telephone connection, directly to the secure Medtronic CL Network where doctors view and analyse patient device data stored on the server [18]. The transmission includes all data within the device memory: stored episodes, device parameters, and diagnostics. A 10-s rhythm electrogram is available at the time of the interrogation. Clinicians access their patients' data by logging onto the clinician website from any internet-connected PC, and patients can also view information about their device and condition on their own personal website [19].

In the CareLink trial 59 patients from 10 follow-up clinics across the United States completed 119 transmissions [18]. Review of the data transmissions revealed several clinically relevant findings such as asymptomatic episodes of paroxysmal atrial fibrillation, atrial sensing failures, and VT. The quality of the web-accessed data was comparable to that of in-office device

interrogation. As a result, patients enjoy a timely and convenient connection to their care team and physicians may offer better patient care besides an improvement in the cost-effectiveness of clinic operations.

Housecall Plus Remote Patient Monitoring System

The Housecall Plus (HP; St. Jude Medical Co., Sylmar, Calif., USA) is a monitoring system to transmit complex ICD data: a full, in-office, programmer-based interrogation (electrograms, surface ECGs, delivered therapies and stored electrogram, etc.) in real time over standard telephone lines directly from patient to medical professional [20]. The patient must hold a transmitter over the ICD and the telephone is placed in a special cradle. Information is transmitted to a processing centre and then compiled and sent to the physician. During a 12-month study [21], 570 transmissions were received, revealing 54 delivered ICD therapies, 22 aborted therapies, and 30 episodes of non-sustained ventricular arrhythmias. In addition, 32 instances of trouble with the ICD or with the leads connected to the heart were revealed. Patients consider the transtelephonic ICD follow-up provided by HP satisfactory and easy to use, reducing the number of device clinic visits for routine follow-up and unwarranted trips to the emergency department.

Comment

All studies found high patient and physician satisfaction with the methods delivering remote monitoring of implanted devices. The ability to transmit information from any telephone connection means that patients have the comfort of knowing that their condition can be monitored wherever they are. Positive benefits include better use of resources including hospital-based staff, improved patient care, and the economic benefits associated with fewer unnecessary hospital admissions and patient transport costs [7]. The next step will be for these systems to allow the doctor to program the device without having the patient present [22].

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