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CLINICAL RESEARCH | Clinical Trial

The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) Trial

The Value of Wireless Remote Monitoring With Automatic Clinician Alerts

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Objectives The primary objective was to determine if wireless remote monitoring with automatic clinician alerts reduces the time from a clinical event to a clinical decision in response to arrhythmias, cardiovascular (CV) disease progression, and device issues compared to patients receiving standard in-office care. A secondary objective was to compare the rates of CV health care utilization between patients in the remote and in-office arms.

Background In addition to providing life-saving therapy, implantable cardioverter-defibrillators collect advanced diagnostics on the progression of the patient's heart disease. Device technology has progressed to allow wireless remote monitoring with automatic clinician alerts to replace some scheduled in-office visits.

Methods The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) study was a multicenter, prospective, randomized evaluation involving 1,997 patients from 136 clinical sites who underwent insertion of an implantable cardioverter-defibrillator (including cardiac resynchronization therapy devices) and were followed up for 15 months. Health care utilization data included all CV-related hospitalizations, emergency department visits, and clinic office visits.

Results The median time from clinical event to clinical decision per patient was reduced from 22 days in the in-office arm to 4.6 days in the remote arm ($p < 0.001$). The health care utilization data revealed a decrease in mean length of stay per CV hospitalization visit from 4.0 days in the in-office arm to 3.3 days in the remote arm ($p = 0.002$).

Conclusions Wireless remote monitoring with automatic clinician alerts as compared with standard in-office follow-up significantly reduced the time to a clinical decision in response to clinical events and was associated with a significant reduction in mean length of CV hospital stay. (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision [CONNECT]; NCT00402246) (J Am Coll Cardiol 2011;57:1181–9) © 2011 by the American College of Cardiology Foundation

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy with defibrillation (CRT-D) have been shown to improve survival beyond that afforded by optimized drug therapy (1–3). Since the acceptance of indications for primary prevention of sudden cardiac death (1,3,4), the numbers of defibrillator implantations have increased. In 2007, an estimated 1 million cardiac devices were implanted, with at least 4 million annual follow-up visits in the U.S. (5,6). The standard of care for defibrillator follow-up is an in-person evaluation 1 month after implant, again 2 months later, and every 3 to 6 months thereafter (6). This volume of visits adds burden to clinicians and creates the need for a more cost-effective solution for the follow-up of these patients.

Defibrillators have evolved so that they not only deliver life-saving therapy for ventricular arrhythmias, but also

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Abbreviations and Acronyms

AF = atrial fibrillation
AT = atrial tachycardia
CRT-D = cardiac resynchronization therapy-defibrillator
CV = cardiovascular
ED = emergency department
HCU = health care utilization
ICD = implantable cardioverter-defibrillator
LOS = length of stay

continuously collect diagnostic information pertaining to the function of the ICD and the clinical status of the patient, such as the number of shocks delivered and atrial arrhythmias.

Patients with defibrillators are at high risk for atrial fibrillation (AF) and atrial flutter, which predispose them to embolic events and worsening of congestive heart failure (7–10). Atrial arrhythmias can also cause inappropriate shocks (11,12). The accuracy of atrial arrhythmia detection has been established (13,14). Rapid awareness of AF is important in that practice guidelines allow for cardioversion of AF without the need for a transesophageal echocardiogram procedure or anticoagulation therapy during the first 48 h after onset (15). Clinical events including AF events can trigger an auditory signal to the patient. However, a limitation of this alerting approach is that decreased auditory acuity of elderly patients may lead to under-recognition of that signal (16).

Defibrillators now have remote monitoring capabilities that allow clinicians to have remote access to the complete device diagnostic information. In response to clinician request or a predefined schedule, patients transmit diagnostic information from the device to a central server through standard phone lines by holding a wand physically connected to a home monitor. Clinicians can access the patient transmitted diagnostics through a secure Internet interface. Remote monitoring has been shown to be easy to use for patients and comparable to in-office device interrogations (17). It has also been demonstrated to be efficient (5). In addition, the PREFER (Pacemaker Remote Follow-Up Evaluation and Review) study showed that remote monitoring in pacemakers led to quicker and more frequent detection of clinical events than standard of care (18). The latest defibrillators have wireless technology that can automatically transmit data from a patient's defibrillator to the home monitor and central server without any patient action. The transmissions include regularly scheduled checks and automatic clinician alerts in response to clinical events.

The purpose of the CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) study is to determine the impact of wireless remote monitoring with automatic clinician alerts on the time from clinical events to clinical decisions and on health care utilization.

Methods

Study design. The CONNECT study was a multicenter, prospective, randomized evaluation of wireless remote monitoring in a population of 1,997 adult patients implanted with a Medtronic (Minneapolis, Minnesota) wireless ICD or CRT-D system utilizing the Medtronic CareLink Network. Institutional review boards approved the protocol at all 136 participating U.S. centers. Details of the study design were previously reported (19). In summary, the study was designed to evaluate the impact of remote monitoring with automatic clinician alerts (wireless remote monitoring) on how quickly clinicians became aware of a clinical event and formulated a corresponding clinical decision regarding a plan of action. Over a 15-month period, the effect of wireless remote monitoring was compared directly with standard in-office device follow-up. Patients were enrolled after signing an informed consent form and an authorization to use and disclose health information. After successful insertion of an ICD or CRT-D, patients were randomly assigned in a 1:1 manner, stratified by device type, to wireless remote monitoring or in-office care. Inclusion criteria included: 1) being able and willing to replace regularly scheduled in-office follow-ups with remote follow-ups; and 2) being able to attend all required follow-up visits. Patients were excluded for: 1) permanent AF (constant AF for which there were no plans to attempt to restore sinus rhythm); 2) chronic warfarin therapy; 3) having had a previous ICD, CRT device, or pacemaker; 4) being <18 years of age; and 5) having a life expectancy <15 months.

Objectives. The primary objective was to determine if wireless remote monitoring with automatic clinician alerts reduces the time from a clinical event to a clinical decision in response to arrhythmias, cardiovascular (CV) disease progression, and device issues compared to patients receiving standard in-office care.

The primary outcome, time to clinical decision, is defined as the time from device detection of a clinical event to a decision being made in response to the event, as reported by the clinician or as evidenced by device data obtained at interrogation. Clinical events are defined in Table 1. The definitions of events were applied equally to both arms regardless of whether an automatic clinician or audible patient alert occurred.

The key secondary objective was to compare cardiovascular health care utilization (HCU) rates between arms for each HCU type (hospitalizations, emergency department [ED], and unscheduled clinic office/urgent care visits). Length of hospital stay (LOS) and actions taken at each HCU event were also compared between arms.

Programming. Tachycardia and bradycardia therapy and detection programming was left to the clinician's discretion. Programming related to the defibrillator, lead, and clinical management alerts were controlled (Table 1). To limit the number of device transmissions sent in the remote arm, a conservative approach was taken when selecting alert thresholds. Only values warranting clinician attention and possible intervention were specified. Specifically, the atrial tachycardia (AT)/AF burden threshold was programmed to 12 h/day, and the rapid ventricular rate during AT/AF alert