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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

George H. Crossley, MD,* Andrew Boyle, MD,† Holly Vitense, PHD,‡ Yanping Chang, MS,§ R. Hardwin Mead, MD,‖ for the CONNECT Investigators

Nashville, Tennessee; Milwaukee, Wisconsin; Minneapolis, Minnesota; and Redwood City, California

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

From the *St. Thomas Research Institute and University of Tennessee College of Medicine, Nashville, Tennessee; †Division of Cardiology, Aurora St. Luke's Medical Center, Milwaukee, Wisconsin; ‡CRDM New Therapies and Diagnostics, Medtronic, Inc., Minneapolis, Minnesota; §CRDM Clinical Research, Medtronic, Inc., Minneapolis, Minnesota; and the ‖Sequoia Hospital, Redwood City, California. This study was supported by Medtronic Inc. Dr. Crossley is a consultant for Medtronic, Boston Scientific, and Cardiac Control systems; receives lecturing income from Medtronic, Boston Scientific, and Sanofi; and receives research support from Medtronic, Boston Scientific, and St. Jude Medical. Dr. Boyle serves on an advisory board for Medtronic. Dr. Vitense and Ms. Chang are employed by Medtronic. Dr. Mead receives consulting fees and honoraria from Medtronic, Proteus Biomedical, EBR Systems, and InnerPulse; has equity interests in Proteus Biomedical, EBR Systems, InnerPulse, and iRhythm; and serves as officer and director for iRhythm.

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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

Table 1 Protocol Required Alert Programming (Clinical Events)

Alert/Clinical Event	Remote Arm	In-Office Arm
Medtronic CareLink Home Monitor	Yes	No (not provided)
Clinical management alerts		
AT/AF daily burden	Automatic clinician alert (12 h/day)	Off
Ventricular rate during AT/AF	Automatic clinician alert (120 beats/min for ≥6 h AT/AF per day)	Off
Number of shocks delivered	Automatic clinician alert (2 shocks)	Off
All therapies exhausted in a zone	Automatic clinician alert (on)	Off
Lead/device integrity alerts		
Lead impedance out of range	Automatic clinician alert + audible patient alert (nominal ranges)	Audible patient alert (nominal ranges)
VF detection/therapy off	Automatic clinician alert + audible patient alert (nominal ranges)	Audible patient alert (nominal ranges)
Low battery voltage RRT	Automatic clinician alert + audible patient alert (nominal ranges)	Audible patient alert (nominal ranges)
Excessive charge time EOS	Automatic clinician alert + audible patient alert (nominal ranges)	Audible patient alert (nominal ranges)

AT/AF = atrial tachycardia/atrial fibrillation; EOS = end of service; RRT = recommended replacement time; VF = ventricular fibrillation.

was programmed to 120 beats/min for ≥6 h/day. Exactly 1 automatic clinician alert can be sent for any 1 clinical event between in-office device interrogations.

IN-OFFICE ARM. Only audible patient alerts associated with lead and device integrity were enabled for patients in the in-office arm (Table 1) because they are nominal settings and considered standard of care.

REMOTE ARM. All automatic clinician alerts were enabled for patients in the remote arm. Audible patient alerts were disabled with the exception of those related to lead and device integrity (Table 1).

Follow-up. All patients had study visits at 1, 3, 6, 9, 12, and 15 months post-implant. Patients in the remote arm received a home monitor, and their in-office visits at 3, 6, 9, and 12 months were replaced with remote visits, including a remote device transmission. Clinicians had access to the entire set of device-collected diagnostics for all study patients.

Statistical analysis. An intent-to-treat analysis served as the primary analysis for all objectives. An α-level of 0.05 was employed for each analysis. Poolability assessments were performed to ensure that the effect of wireless remote monitoring did not vary by device type.

The primary objective analysis included all analysis cohort patients who experienced at least 1 clinical event. Event onset was defined as the time when criteria for triggering an alert were met. The time between event onset and clinical decision was calculated for each event a patient experienced. The average time from event onset to clinical decision was determined for each patient so that each patient contributed 1 value to the analysis. If a patient experienced multiple events of a specific type (e.g., ≥12 h AT/AF burden in a day) between 2 consecutive evaluations, only the first of these was paired with the next device interrogation/visit and counted toward the analysis. The thought was that the onset of a specific event type is clinically meaningful and, left undetected by a clinician, it may persist (e.g., develop into chronic AF) until treated. In cases in which a subject experiences 24 h of AT/AF for 30 consecutive days until it is reported to a clinician, the authors did not believe that should constitute 30 unique events, as it is most likely 1 long AT/AF episode. However, defining the analysis cohort this way meant that if in-office subjects have 5 days over a 30-day period in which they experienced 12 to 24 h of AT/AF, only the first would count toward the analysis, whereas had the subject been in the remote arm, this might have resulted in 5 alerts and a shorter average time to decision.

A sensitivity analysis including all events was also performed. A Wilcoxon rank-sum test was used to compare the median time from event onset to clinical decision between treatment arms. All events from the day after randomization to patient exit/death were included, except AT/AF burden and ventricular rate during AT/AF events that occurred in patients after the physician had terminated a rhythm control strategy.

To allow for multiple HCU events per patient, an Andersen-Gill proportional hazards regression model was used to compare the hazard rates for each type of HCU event (hospitalization, ED, unscheduled office/urgent visit) between arms (20). All patients in the analysis cohort were included in this analysis, which was stratified by device type. A negative binomial model accounting for device type was fit to compare the LOS between arms (21).

A mixed model was fit with randomization arm and device type as predictors and a compound symmetry correlation structure to compare average cost for CV hospitalizations between arms. Because detailed economic data were not collected, national cost estimates for CV hospitalization based on data from the Medicare Limited Data Set Standard Analytic Files for 2002 to 2007 were assigned to each visit depending on LOS and whether the visit was deemed inpatient or outpatient. Based on Medicare rules, a patient can be hospitalized up to 3 days and still be considered outpatient. Hospitalizations of 3 days or less were assigned inpatient/outpatient status and the corresponding national cost estimate using Bernoulli distributions with prespecified probabilities depending on LOS (probability of being an inpatient visit for 1, 2, and 3 days is 70%, 89%, and 98%, respectively). A 95% 2-sided bootstrap confidence interval was generated for the difference (remote

Table 2 Baseline Demographics

	Remote (n = 1,014)	In-Office (n = 983)	Total (n = 1,997)
Sex, male	70.5%	71.7%	71.1%
Age, yrs	65.2 ± 12.4	64.9 ± 11.9	65.0 ± 12.1
LVEF, %	28.6 ± 10.0	29.2 ± 10.3	28.9 ± 10.2
NYHA functional classification			
No heart failure	5.3%	6.7%	6.0%
Class I	3.9%	4.7%	4.3%
Class II	40.9%	39.5%	40.2%
Class III	48.5%	47.5%	48.0%
Class IV	1.5%	1.5%	1.5%
Cardiovascular history			
Cardiomyopathy	96.1%	95.3%	95.7%
Ischemic	63.3%	61.5%	62.4%
Nonischemic	32.0%	33.5%	32.7%
Hypertrophic	1.8%	1.5%	1.7%
Dilated	28.0%	29.8%	28.9%
Hypertension	74.2%	76.9%	75.5%
Cerebrovascular accident	8.1%	7.3%	7.7%
Diabetes mellitus	34.8%	38.0%	36.4%
Atrial fibrillation	14.9%	13.3%	14.1%
Sustained monomorphic VT	6.5%	6.5%	6.5%
Sustained polymorphic VT	1.3%	1.9%	1.6%

Values are % or mean ± SD.
LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; VT = ventricular tachycardia.

minus in-office) in mean cost per visit using 10,000 simulations in which inpatient/outpatient status was assigned and a model fit for each simulation. Bootstrapping was similarly used to estimate mean cost per hospitalization visit in each arm.

Results

Study timelines and demographics. Patients were enrolled from November 2006 through May 2008. The last follow-up visit occurred in August 2009. There were 1,997 patients enrolled from 136 centers. There were 1,014 patients randomly assigned to the remote arm and 983 patients randomly allocated to the in-office arm. The remote and in-office arm patients had similar demographic data (Table 2). Of all enrolled patients, 1,980 met inclusion/exclusion criteria and make up the analysis cohort (remote arm = 1,005; in-office arm = 975). Seventeen randomized patients were excluded from the analysis cohort for the following reasons: permanent AF (n = 2), not implanted with a required study device (n = 9), previous defibrillator or pacemaker (n = 3), unwillingness to conduct CareLink follow-up visits (n = 2), and inability to attend all required follow-up visits (n = 1).

Primary objective. There were 317 patients with at least 1 clinical event, 172 (17%) in the remote arm and 145 (15%) in the in-office arm. A total of 966 clinical events occurred in those patients, with AT/AF burden (74%, n = 717) and ventricular rate during AT/AF (9%, n = 88) being the most frequent (Table 3). The median time from an event occurring to a clinical decision per patient was 4.6 days in the remote arm and 22 days in the in-office arm (Fig. 1). This resulted in a significant reduction from the time an event occurs to a clinical decision ($p < 0.001$), observed to be 17.4 days (79%). A sensitivity analysis including multiple events of the same type between an event onset and a device interrogation/visit also yielded a significant reduction ($p < 0.001$).

Automatic clinician alert transmissions. In the remote arm, there were 575 clinical events, and 329 of these events triggered an automatic clinician alert. There were 246 clinical events that did not trigger an automatic clinician alert because the alert was programmed off (7%) or the alert was not reset after being previously triggered (93%). For example, if an alert triggers for an AT/AF burden event, it will not trigger again until reset during an in-office interrogation. When an automatic clinician alert was triggered, 180 (55%) resulted in a successful transmission to the CareLink network. Automatic clinician alerts were triggered but not successfully transmitted for 149 (45%) clinical events, mainly because the home monitor was not set up and initiated to send out transmissions. Other reasons included circumstances where the patient was not home, or the monitor was unplugged or not connected to a phone line.

Table 3 Summary of Time to Decision by Alert Event Type

Device Event	No. of Events (No. of Patients)		No. of Days From Event Onset to Clinical Decision Median (Interquartile Range)	
	Remote	In-Office	Remote	In-Office
AT/AF burden at least 12 h	437 (107)	280 (105)	3 (1–15)	24 (7–57)
Ventricular rate during AT/AF 120 beats/min during at least 6 h AT/AF	41 (26)	47 (37)	4 (2–13)	23 (5–40)
At least 2 shocks delivered in an episode	44 (35)	32 (23)	0 (0–1.5)	0 (0–2)
Lead impedances out of range	26 (18)	12 (6)	0 (0–9)	17 (5.5–45)
All therapies in a zone exhausted for an episode	16 (12)	11 (6)	0 (0–1)	9 (0–36)
VF detection/therapy off	10 (10)	8 (8)	0	0 (0–84)
Low battery	1 (1)	1 (1)	30	0
Total	575 (172)	391 (145)	3 (0–13)	20 (4–52)

Abbreviations as in Table 1.

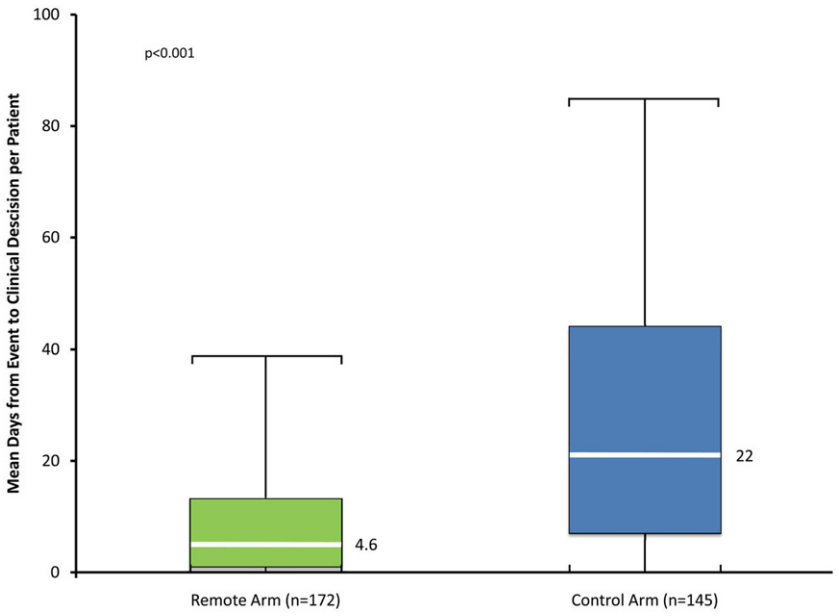

Figure 1 **Distribution of Time From Clinical Event to Decision per Patient**

Box-and-whisker plots show the quartiles with the medians labeled, and the **whiskers** extend to the fifth and 95th percentiles.

The timing of automatic clinician alerts in the clinical decision-making process could only be assessed for events that were successfully transmitted and used to make a clinical decision. Of the 180 successfully transmitted events, 40 were not viewed before clinical decision. For the remaining 140 events, the time from when an automatic clinician alert was triggered to when the transmitted information was viewed was <1.5 days in 70% of the cases. When time to clinical decision for these events was longer (e.g., ≥2 days) the majority of time fell between first viewing the alert and reporting a decision.

Automatic clinician alerts were classified by the clinician as "meaningful" 62% of the time and "timed appropriately" 84% of the time. Conversely, for 12% of automatic clinician alerts, clinicians thought "it could have waited longer," and for only 2%, clinicians "didn't want to know at all." At each routine in-office device check, clinicians were asked if "new and meaningful information" was obtained by the device interrogation: they reported "yes" for only 24% of the visits.

Health care utilization. There were 6,227 cardiovascular-related HCU visits. There was no statistical difference in the rates of any of the HCU types (Fig. 2), or in the rates of transesophageal echocardiograms (p = 0.67) between the 2 arms.

The mean LOS during a CV hospitalization was significantly reduced (18%, p = 0.002) in the remote arm (Fig. 3) after controlling for LOS differences between device types. The estimated mean LOS per hospitalization was 3.3 days in the remote arm and 4.0 days in the in-office arm. Among patients with a clinical event during follow-up, those in the remote arm had a significantly shorter mean LOS per hospitalization compared with in-office arm patients (3.2 vs. 4.3 days, p = 0.007) (Fig. 4).

Given that routine clinic visits were replaced by wireless remote monitoring in the remote arm, the observed rate of total clinic visits per patient year was higher in the in-office arm (6.3) than in the remote arm (3.9). The annualized rates of many of the specific actions taken at both scheduled and nonscheduled HCU visits were similar between the 2 arms (Fig. 5).

Mortality rates between arms were compared using the log-rank test and were not significantly different for ICD patients (p = 0.31) or CRT-D patients (p = 0.46).

Health care economics. As a result of the shorter hospital LOS for the remote arm as compared with the in-office arm, the estimated mean cost per hospitalization was significantly lower. A hospitalization in the remote arm was estimated at $8,114 compared with $9,822 for the in-office arm. After accounting for the impact of device type on cost, the mean difference between arms was estimated to be $1,793 (95% confidence interval: $1,644 to $1,940).

Discussion

This study demonstrated that wireless remote monitoring allows clinicians to make clinical decisions 17.4 days sooner when compared to the in-office arm. Remote arm patients with AT/AF events had a reduced median time from arrhythmia onset to a responsive clinical action (3 days vs. 24 days).

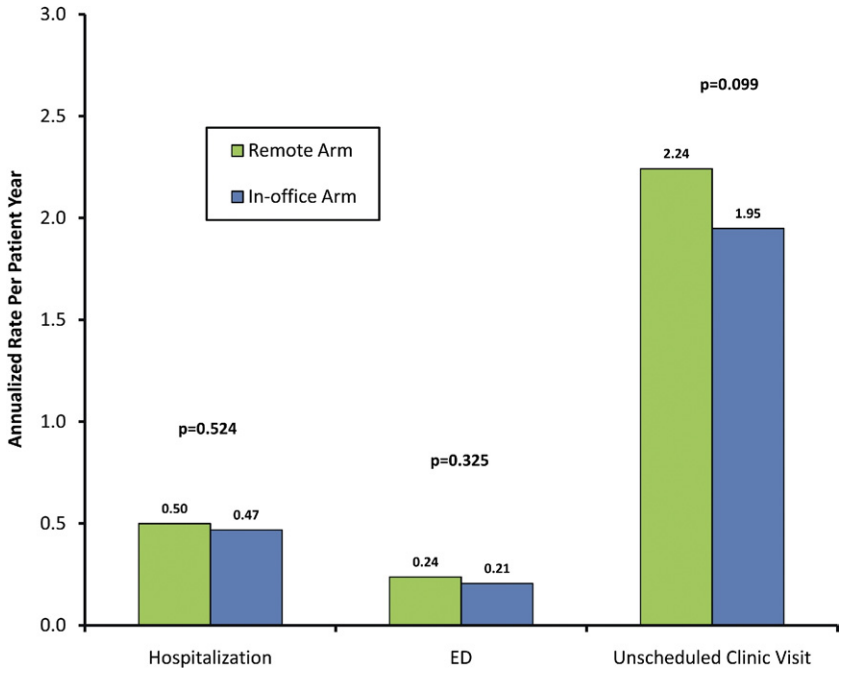

Figure 2 **Annualized Rate of Cardiovascular Health Care Utilization Visits per Patient-Year by Arm**

Annualized rate of cardiovascular health care utilization visits per patient-year by arm, and p values from Anderson-Gill proportional hazards regression model. There was a trend toward more unscheduled clinic visits, many of which were due to the need for the patient to come to the office to reset the alerts. **Green bars** indicate remote arm; **blue bars** indicate in-office arm. ED = emergency department.

Without wireless remote monitoring, AT/AF would only be detected at routine clinic visits or unscheduled visits related to symptoms, embolic events, or worsening heart failure. Other recent studies have also demonstrated positive benefits associated with remote monitoring (22,23).

Automatic clinician alerts were determined by clinicians to be meaningful and timely in 62% and 84% of cases, respectively. In contrast, only 24% of routine in-office device follow-ups provided new and meaningful information. Clinics often have a large infrastructure in place at significant expense to follow up patients with devices. Because a substantial number of scheduled in-office visits did not result in new and meaningful information, the impact of such an infrastructure on patient outcomes may be diminished. Findings from this study suggest that wireless remote monitoring with automatic clinician alerts may be a viable substitute for in-office visits.

No statistical difference was found between the remote arm and in-office arm for rates of mortality, CV clinic visits, ED visits, and hospitalizations, despite each alert having to be reset by interrogation. However, the observed rate of total clinic visits per patient-year was 2 days higher in the in-office arm (6.3) as compared with the remote arm (3.9). The time spent conducting remote device follow-ups would offset the in-office visits saved to some degree, but a precise calculation cannot be made as those data were not collected.

Remote arm patients experienced a significant reduction in the mean LOS for hospitalizations (3.3 days vs. 4.0 days), resulting in a lower cost, estimated to be $1,793. One explanation is that wireless remote monitoring, which afforded faster clinical decision making, could have a positive impact on patients' health. However, determination of the exact mechanism will require further investigation.

The effectiveness of a wireless remote monitoring system requires the attention of the patient and clinician. The patients must activate an initial monitor setup. In addition, patients who are away from their monitor for extended periods of time reduce the ability of automatic clinician alerts to transmit. Once the system was activated, a successful transmission led to a clinician viewing the data within 1.5 days 70% of the time. When the time to clinical decision for such events was at least 2 days, the majority of time was attributed to the time from first viewing the alert by a clinician to when a clinical decision was made. The wide range of days from event onset until clinical decision (interquartile range: 0 to 13 days) reveals that not all clinicians managing patients in the remote arm responded rapidly to automatic clinician alerts. In addition, many clinical events did not trigger automatic clinician alerts because it was not reset after the first occurrence in response to an event. Better deployment and utilization of the wireless remote monitoring system can result in more timely treatment decisions.

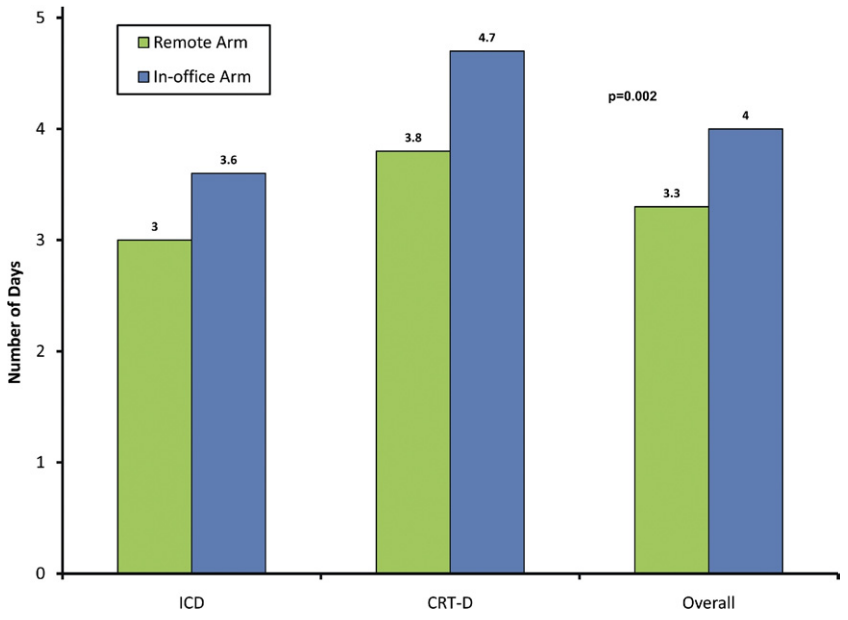

Figure 3 **Mean LOS per Hospitalization Visit by Arm and Device Group**

Estimated mean length of stay (LOS) per cardiovascular hospitalization by arm and device type using a negative binomial model. **Green bars** indicate remote arm; **blue bars** indicate in-office arm. CRT-D = cardiac resynchronization therapy-defibrillator; ICD = implantable cardioverter-defibrillator.

Study limitations. Although the study was designed to compare HCU rates, events were not adjudicated to verify relatedness to specific disease states. Only adverse events that resulted in a HCU were collected. Detailed cost data and status (inpatient vs. outpatient) were not collected for hospitalizations, necessitating cost estimations. The observed benefit of

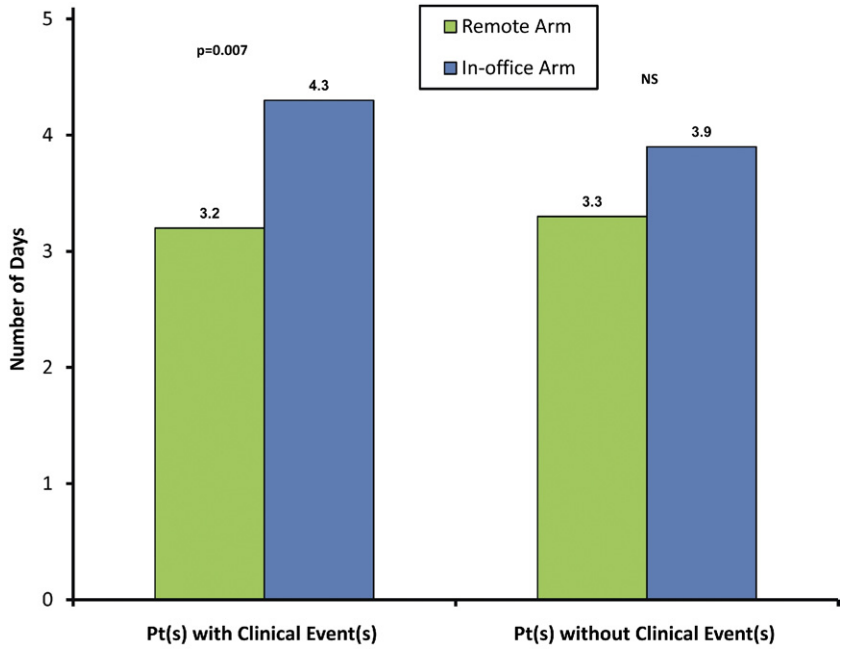

Figure 4 **Mean Length of Stay per Hospitalization by Arm and Whether Patient Had a Clinical Event**

Estimated mean length of stay per cardiovascular hospitalization determined by use of a negative binomial model.
Green bars indicate remote arm; **blue bars** indicate in-office arm.

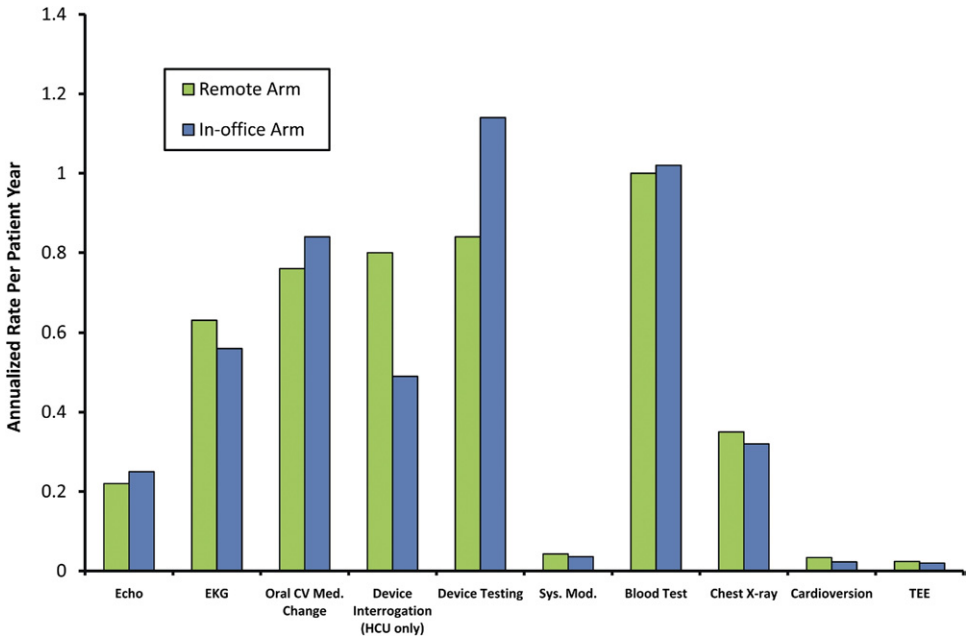

Figure 5 **Annualized Rate of Actions Taken per Patient-Year by Arm**

The annualized rates of many of the specific actions taken at both scheduled and nonscheduled health care utilization (HCU) visits were similar between the 2 arms. Displayed here are the actions that were tracked. **Green bars** indicate remote arm; **blue bars** indicate in-office arm. CV = cardiovascular; Echo = echocardiography; EKG = electrocardiogram; Sys. Mod. = system modification; TEE = transesophageal echocardiography.

the wireless remote monitoring system was constrained owing to an initial delay in monitors being activated in patient's homes and clinicians not resetting automatic clinician alerts.

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 hospital stay. Clinics employing wireless remote monitoring may expect fewer total clinic visits per year while not increasing the rate of ED visits or cardiovascular hospitalizations for their patients.

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Reprint requests and correspondence: Dr. George H. Crossley, St. Thomas Research Institute, Suite 400, 222 22nd Avenue North, Nashville, Tennessee 37203. E-mail: gcrossley@stthomasheart.com.

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Key Words: alerts ■ cardiac resynchronization therapy ■ clinician notification ■ health care economics ■ implantable cardioverter-defibrillator ■ remote patient monitoring.