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J. Am. Coll. Cardiol. 2009;54;2012-2019
doi:10.1016/j.jacc.2009.10.001

This information is current as of November 16, 2009

The online version of this article, along with updated information and services, is located on the World Wide Web at:
<http://content.onlinejacc.org/cgi/content/full/54/22/2012>

JACC

JOURNAL of the AMERICAN COLLEGE of CARDIOLOGY



QUARTERLY FOCUS ISSUE: HEART RHYTHM DISORDERS

Clinical Benefits of Remote Versus Transtelephonic Monitoring of Implanted Pacemakers

George H. Crossley, MD,* Jane Chen, MD,† Wassim Choucair, MD,‡ Todd J. Cohen, MD,§ Douglas C. Gohn, MD,|| W. Ben Johnson, MD,¶ Eleanor E. Kennedy, MD,# Luc R. Mongeon, PhD,** Gerald A. Serwer, MD,†† Hongyan Qiao,** Bruce L. Wilkoff, MD,‡‡ for the PREFER Study Investigators
Nashville, Tennessee; St. Louis, Missouri; Corpus Christi, Texas; Mineola, New York; Lancaster, Pennsylvania; Des Moines, Iowa; Little Rock, Arkansas; Minneapolis, Minnesota; Ann Arbor, Michigan; and Cleveland, Ohio

- Objectives** The purpose of this study was to evaluate remote pacemaker interrogation for the earlier diagnosis of clinically actionable events compared with traditional transtelephonic monitoring and routine in-person evaluation.
- Background** Pacemaker patient follow-up procedures have evolved from evaluating devices with little programmability and diagnostic information solely in person to transtelephonic rhythm strip recordings that allow monitoring of basic device function. More recently developed remote monitoring technology leverages expanded device capabilities, augmenting traditional transtelephonic monitoring to evaluate patients via full device interrogation.
- Methods** The time to first diagnosis of a clinically actionable event was compared in patients who were followed by remote interrogation (Remote) and those who were followed per standard of care with office visits augmented by transtelephonic monitoring (Control). Patients were randomized 2:1. Remote arm patients transmitted pacemaker information at 3-month intervals. Control arm patients with a single-chamber pacemaker transmitted at 2-month intervals. Control arm patients with dual-chamber devices transmitted at 2-month intervals with an office visit at 6 months. All patients were seen in office at 12 months.
- Results** The mean time to first diagnosis of clinically actionable events was earlier in the Remote arm (5.7 months) than in the Control arm (7.7 months). Three (2%) of the 190 events in the Control arm and 446 (66%) of 676 events in the Remote arm were identified remotely.
- Conclusions** The strategic use of remote pacemaker interrogation follow-up detects actionable events that are potentially important more quickly and more frequently than transtelephonic rhythm strip recordings. The use of transtelephonic rhythm strips for pacemaker follow-up is of little value except for battery status determinations. (PREFER [Pacemaker Remote Follow-up Evaluation and Review]; NCT00294645) (J Am Coll Cardiol 2009;54:2012-9)
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Pacemakers have been used for several decades to treat patients with sinus node dysfunction and disorders of the cardiac conduction system. The follow-up of pacemaker patients has evolved over this period from in-person evaluation of pulse generators with little or no programmability to transtelephonic monitoring (TTM), which allows remote but limited assessment of device function.

The current standard of care is for a pacemaker system to be evaluated annually in the office with a full interrogation

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and then periodically by TTM. The frequency of the TTM is typically every 3 months with increased frequency every 1

From the *St. Thomas Research Institute and University of Tennessee College of Medicine, Nashville, Tennessee; †Department of Internal Medicine, Cardiovascular Division, Washington University School of Medicine, St. Louis, Missouri; ‡Cardiology Associates of Corpus Christi, Corpus Christi, Texas; §Department of Medicine, Winthrop University Hospital, Mineola, New York; ||The Heart Group, Lancaster, Pennsylvania; ¶Iowa Heart Center, Des Moines, Iowa; #Heart Clinic Arkansas, Little Rock, Arkansas; **Medtronic, Inc., Minneapolis, Minnesota; ††Department of Pediatrics, University of Michigan Congenital Heart Center, University of Michigan Health System, Ann Arbor, Michigan; and the ‡‡Department of Cardiovascular Medicine, Cleveland Clinic, Cleveland, Ohio. A list of the PREFER investigators can be found in the Online Appendix. This study was supported by

Medtronic Inc., Minneapolis, Minnesota. Dr. Crossley is on the advisory board for Medtronic and receives income from research and lecturing for Medtronic, and receives research support from Boston Scientific and St. Jude Medical. Dr. Chen receives honoraria and fellowship support from Medtronic. Dr. Cohen receives honoraria from Medtronic. Drs. Johnson and Serwer serve as consultants for Medtronic. Dr. Mongeon and Ms. Qiao are employees of Medtronic and hold Medtronic stock. Dr. Wilkoff receives honoraria for being a consultant and a physician advisory committee member, receives royalty payments for a patent from Medtronic, and receives research support from Medtronic.

Manuscript received June 14, 2009; revised manuscript received October 1, 2009, accepted October 1, 2009.

to 2 months as the device battery nears the elective replacement indicator voltage.

Early on, the longevity of the implantable pulse generators was very limited and the reliability was significantly less than today, creating the need for increased surveillance. There was little programmability or diagnostic information, and in-person evaluation was the only option for follow-up. Over time, the device longevity increased, and TTM was developed for the remote evaluation of the rudimentary functions of pacing systems.

The transtelephonic transmission of electrocardiographic data for the purpose of following pacemaker patients was first described by Furman et al. (1) in 1971 and has been used since that time for remote evaluations of patients with pacemakers (2). TTM allows the assessment of the battery status and the analysis of sensing and stimulation function; that is, one is usually able to determine whether capture is present, intermittent, or absent and whether sensing is present, intermittent, or absent. TTM also provides a limited electrocardiogram rhythm strip that does offer a small window of information about the patient's rhythm at the time of the transmission. It has been the standard of care since the 1970s (3).

Pacemakers have evolved so that current models not only provide heart rate support, but also continuously collect a myriad of diagnostic information. The diagnostics provide ongoing performance data about the pacing system such as sensing and stimulation function, rate response history, lead and battery impedances, and battery capacity. Additionally, there is the ability to report clinical information such as the presence and nature of atrial arrhythmias, the percentage of atrial and ventricular pacing, and the presence of potentially lethal ventricular arrhythmias. These data have the potential to assist in clinical decision making for the management of underlying cardiac disease. For a decade or more, this information was only available during an in-office evaluation. Unfortunately, with the current standard of care (an annual visit plus TTM performed quarterly), these data are not seen in a timely fashion. Remote systems now allow the acquisition of these data stored in the implanted device's memory from the convenience of the patient's home. These data are transmitted to a central server that the patient's caregivers can access via a secure Internet-based interface. Similar systems have been used for several years with defibrillators (4-7). The drivers of this move to remote follow-up of defibrillator patients include the dramatic expansion of the defibrillator patient population, the development of tools in the defibrillators that facilitate disease management such as heart failure and arrhythmia diagnostics, and the need for a more cost-effective follow-up solution. In the future, there will likely be push technology available in pacemakers as is currently available in wireless implantable cardioverter-defibrillators that will further reduce the data lag.

Previous studies have demonstrated that there is a significant rate of clinical events, such as the presence of atrial tachycardia/

atrial fibrillation (AT/AF), in pacemaker patients (8,9). Before the availability of remote interrogation, these events were typically discovered only at a standard device follow-up, which may not occur until 6 months after device implantation of a dual-chamber pacemaker or after 1 year for a single-chamber pacemaker. Infrequent access to these data has limited their clinical usefulness and the clinician's ability for timely intervention.

To test the hypothesis that an Internet-based remote pacemaker interrogation system would be useful to identify clinically actionable information sooner than the current standard practice of TTM and in-office follow-up, a prospective, randomized study was undertaken.

Methods

The PREFER (Pacemaker REmote Follow-up Evaluation and Review) study was a prospective, randomized, parallel, unblinded, multicenter, open-label clinical trial to determine the utility of remote pacemaker interrogation for the earlier diagnosis of clinically actionable events (CAEs) compared with the existing practice of TTM and routine office visits. The study design was discussed previously in detail (10). The study was conducted at 50 centers in the U.S. Institutional review board approval of the protocol was obtained from all centers, and all participants provided written informed consent.

CAEs were defined as events that required a clinical decision to be made for potential alteration of the patient's medical management and/or required further medical assessment. These events, as defined in Chen et al. (10) and listed in Table 1, collectively increase stroke risk, predispose the patient to congestive heart failure, and may warrant further evaluation depending on clinical factors. Indicators

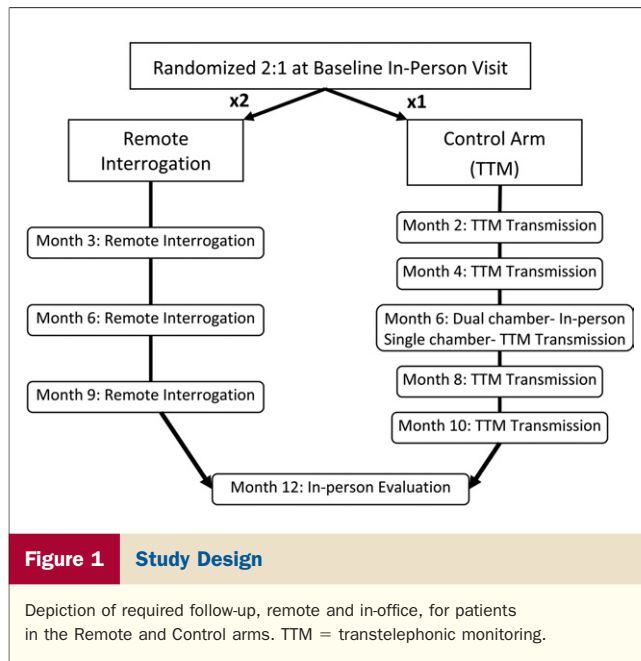
Abbreviations and Acronyms

AT/AF = atrial tachycardia/atrial fibrillation
CAE = clinically actionable event
TTM = transtelephonic monitoring

Table 1 Clinically Actionable Events

AT/AF episodes ≥ 48 h (defined as 2 consecutive days in which the device records at least 18 h of AT/AF per day)
New-onset AT/AF in patients with no history of AT/AF
Sensed ventricular rate of ≥ 100 beats/min during atrial arrhythmia for at least 20% of the time since previous device interrogation
Ventricular pacing that has increased by 30% since the last device interrogation
Nonsustained ventricular tachycardia ≥ 5 beats
Loss of capture*
Increase in pacing voltage threshold ≥ 1 V compared with the previous interrogation*
Significant changes in atrial or ventricular lead impedance, defined as impedance < 200 or $> 2,000$ Ω , unstable lead impedance deemed to be clinically actionable, $\geq 50\%$ change in lead impedance since last interrogation*
Elective replacement indicator or end of life present*

*Not used for analysis due to low numbers of events.
AT/AF = atrial tachycardia/atrial fibrillation.



of problems with the pacing system may also be noted, including a significant increase in stimulation threshold, changes in lead impedance, and indicator of battery depletion. Each CAE requires, at minimum, physician diagnostic action and could require the addition of a medication or surgical revision of the pacing system. Timeliness of this diagnostic activity or lack of activity entirely could result in a diminished prognosis for the patient.

Primary objective. The primary objective of the study was the incidence of first diagnosis of a CAE in patients whose pacemakers were followed by remote interrogation (Remote) as opposed to those whose pacemakers were followed per standard of care with office visits augmented by TTM (Control). The goal was earlier identification of events that were likely to require intervention and had the potential to affect the patient’s clinical course.

Patient selection. Patients, as described in Chen et al. (10), were required to have a pacemaker compatible with the Medtronic CareLink Network remote monitoring system and were enrolled after the implantable pulse generator system was deemed stable. Patients with both single- and dual-chamber pacemakers were enrolled. All patients underwent an in-office evaluation on study entry including pacing system evaluation, cardiovascular medical and surgical history, and arrhythmia history.

Study design. Patients were randomized in a 2:1 manner to the Remote arm or the Control arm (Fig. 1). A permuted block randomization scheme was used. Pacemaker programming was at the discretion of the responsible physician with the exception of 3 parameters. The atrial high rate episode value was set to “rolling,” so that the most recent data were always saved; the ventricular high rate episode value was set to “rolling,” and the ventricular minimum detection duration was set to 5 beats. Patient data for those

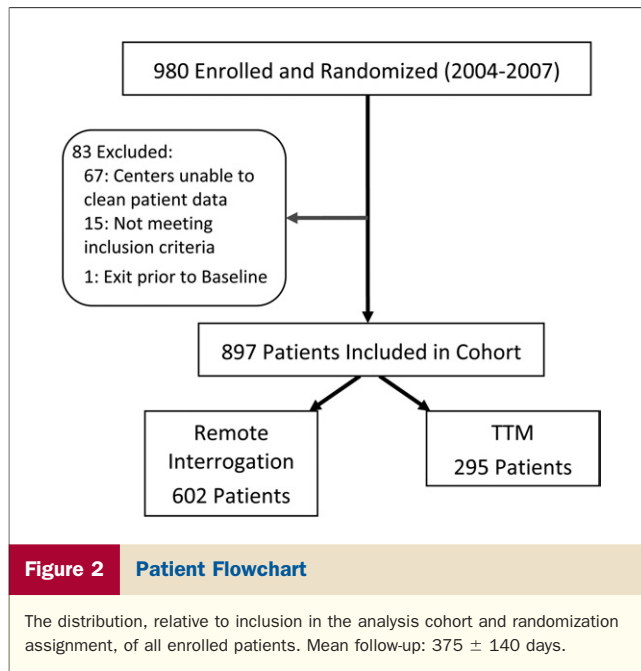
in the Remote arm were remotely transmitted at 3, 6, and 9 months. The Control arm patients performed a TTM transmission at 2, 4, 8, and 10 months. At 6 months, dual-chamber patients were seen in person, and a TTM transmission was performed in single-chamber patients. The study concluded with an in-office visit at 12 months, as shown in Figure 1. This TTM schedule was carried out at the maximally permitted interval as described in the Centers for Medicare & Medicaid Services guidelines (11). Un-scheduled transmissions and in-person evaluations were included in the analysis. Data collected at all transmissions and in-person evaluations included medication changes, CAE collection, and clinician actions taken. Additionally, on full pacemaker interrogation conducted remotely or in person, battery voltage, stimulation thresholds, impedances, and all stored data were collected. A parallel design was used because it was anticipated that patients would prefer to stay with the more convenient remote telemetry arm than the less convenient TTM arm.

Statistical analysis. SAMPLE SIZE METHODS AND ASSUMPTIONS. For the purposes of sample size calculation, simulations were run to determine the sample size necessary to evaluate the primary objective while following patients through quarterly CareLink transmissions compared with TTM transmissions and in-office visits per the Control arm schedule. The sample size was chosen to achieve 80% power and $\alpha = 0.05$. Only the first 5 actionable events listed in Table 1 were examined in estimating the time to first CAE for the PREFER study.

Data from the A-HIRATE (Atrial High Rate Episodes in Pacemaker Patients Trial) were used to estimate the event rates for patients in the Remote and Control arms of the PREFER study (8,9). The A-HIRATE trial was chosen because it was a study of pacemaker patients (many of whom had no history of documented AT/AF) with an implanted Kappa 700 or 900 device. These patients had scheduled follow-up visits at 1, 6, and 12 months post-implantation.

For the purposes of event rate estimation, each patient’s scheduled 6- and 12-month visits and any unscheduled visits occurring during the period from their 1-month visit to 13 months after the 1-month visit were used to determine the event rate as if they were randomized to the Control arm. In addition, for each patient, a 3- and 9-month CareLink transmission date was randomly generated.

ANALYSIS OF PRIMARY OBJECTIVE. The time to first diagnosis of a CAE was determined for each randomized patient. Patients without a CAE were censored at the exit date (death, lost to follow-up, or study closure). The Peto and Peto modification of the Gehan-Wilcoxon test was performed (12). An intent-to-treat analysis was performed. Only events diagnosed by the clinician counted toward the primary objective. A p value <0.05 indicated that the freedom from first diagnosis of CAE was significantly different when patients were followed with remote interro-



gation (Remote) compared with those being followed with TTM and having scheduled in-office visits (Control).

Results

Participant flow, recruitment, and demographics. Study enrollment occurred from May 24, 2004, to March 30, 2007. A total of 980 participants provided consent and were screened. Of these, 83 were excluded from the cohort and the remaining 897 were randomized in a 2:1 manner to either the Remote (n = 602) or Control (n = 295) arm (Fig. 2). Summary statistics for the entire cohort are given in Table 2. There were no statistically significant differences in baseline characteristics between the 2 arms.

Primary objective results. There were 382 patients with at least 1 CAE, 111 patients in the Control arm and 271 in the Remote arm. Over an average follow-up of 375 ± 140 days, CAEs were detected earlier in the Remote arm than in the Control arm (p < 0.0001). The mean and median times to first CAE in the Remote arm were 5.7 and 4.9 months, respectively, whereas in the Control arm, the mean was 7.7 months with a median of 6.3 months. The Kaplan-Meier survival curve in Figure 3 shows the survival analysis of time to the first diagnosis of a CAE for both arms. This reflects the data that were obtained for each patient, including data obtained both in-person and remotely. The stepwise appearance of the event curves reflects the information obtained during interrogations, which produces a sudden increase in the event rate during each interrogation. Importantly, only 3 (2%) of the 190 events in the TTM arm were detected during a TTM transmission. All others were found during the in-office evaluations. In contrast, 446 (66%) of 676 total events were detected during remote interrogation follow-up in the Remote arm of the study.

CAE summary. There were 866 CAEs reported in 382 patients in the study. A summary of the number of CAEs experienced per patient can be found in Table 3. The most frequent CAE reported was nonsustained ventricular tachycardia, followed by AT/AF episodes lasting 48 h or longer. Figure 4 displays the number of CAEs per year by either home (Remote) or clinic for both arms. As can be seen, the number of CAEs discovered by TTM per year in the TTM arm was very small (0.01). Most of the CAEs in this group were discovered at the time of the in-office evaluations.

Discussion

TTM was introduced in the early days of cardiac pacing. The primary functions of this monitoring technique were to evaluate the pacing system for sensing and to capture and to evaluate the status of the pacemaker battery. Although this technology has been the standard of care since the 1970s, there have always been technical difficulties in the analysis of the acquired data. It is often difficult to assess whether capture and/or sensing are present (13). There are also other difficulties associated with TTM, including the logistics of arranging phone calls, attachment of electrocardiography equipment, and the need to follow phone instructions in a patient population that is elderly and often hearing or visually impaired.

The secondary function of TTM is evaluation of the electrocardiogram rhythm strip for the presence of arrhythmias. This function is quite limited for paroxysmal arrhythmias because the tracing is quite brief.

Beginning about the year 2000, pacemakers started recording data that were useful in the clinical follow-up of the patient. These data eventually included a full evaluation of the device, information about lead function, and a detailed arrhythmia log. These data are typically presented in a trended fashion rather than a point in time. Unfortunately, this information was only available to the physician when the patient was seen in the office and a programmer was able to extract the data. The utility was, therefore, somewhat limited as there could have been 6 to 12 months between event occurrence and event discovery by the clinician.

Similarly, the critical analysis of a patient's rhythm is often not possible given the resolution of TTM tracings. The new Internet-based remote interrogation follow-up system leverages all the power and memory of the new pacemaker devices by interrogating the pacemaker at home and then transmitting the data to a central computer. These Internet-based systems reflect the natural progression of the TTM technology.

The results of the PREFER study demonstrate the overwhelming superiority of the Internet-based full-disclosure remote management approach over the traditional TTM approach for early identification of CAEs. These data are displayed in the survival curves of Figure 3. The survival curves demonstrate a step function behavior at every remote follow-up when full device data are available.

Table 2 Patient Demographics			
	Remote (n = 602)	Control (n = 295)	p Value (Remote vs. Control)
Sex, male	312 (52)	142 (48)	0.3
Age, yrs	68 ± 16.7	69 ± 16.9	0.51
Left ventricular ejection fraction, %	57 ± 10.5	58 ± 10.2	0.38
Cardiovascular history			
Congestive heart failure	88 (15)	40 (14)	0.67
Coronary artery disease	195 (32)	88 (30)	0.44
Diabetes	130 (22)	51 (17)	0.13
Coronary artery disease	195 (32)	88 (30)	0.44
Diabetes	130 (22)	51 (17)	0.13
Hypertension	382 (63)	191 (65)	0.71
Myocardial infarction	82 (14)	37 (13)	0.65
Acute (≤6 months)	12 (2)	8 (3)	0.49
Chronic (>6 months)	68 (11)	26 (9)	0.25
Syncope	204 (34)	108 (37)	0.42
Atrial arrhythmias			
None	39 (6)	25 (8)	0.28
Atrial fibrillation	261 (43)	129 (44)	0.92
Paroxysmal	183 (30)	90 (31)	0.97
Persistent	53 (9)	23 (8)	0.61
Permanent	33 (5)	18 (6)	0.71
Atrial flutter	82 (14)	37 (13)	0.65
Atrial tachycardia	55 (9)	28 (9)	0.86
Sinus node dysfunction			
Sinus bradycardia	18 (3)	15 (5)	0.25
Sick sinus syndrome	30 (5)	15 (2)	0.95
Brady-tachy syndrome	115 (19)	63 (21)	0.43
Chronotropic incompetence	30 (5)	5 (2)	0.95
Heart block			
Mobitz I	26 (4)	12 (4)	0.86
Mobitz II	60 (10)	20 (7)	0.12
Third-degree block	180 (30)	80 (27)	0.39
Ventricular arrhythmias			
None	222 (37)	113 (38)	0.68
Premature ventricular complexes	115 (19)	53 (18)	0.68
Nonsustained ventricular tachycardia	38 (6)	25 (8)	0.23
Sustained ventricular tachycardia	1 (0)	0 (0)	>0.99

Values are presented as n (%) or mean ± SD.

This is an artifact of the remote systems that requires patients to initiate a device data transmission. There would be an advantage to a pacemaker system that could alert a clinician via the remote interrogation system at the time of an event occurrence, as is currently the case with defibrillators that use wireless telemetry to communicate with the remote follow-up system. One would expect an enhanced level of care for these patients, with potential improved outcomes. There is a potential for a reduction in overall clinic workload as the focus changes to exception-based management and device checks, which only provide limited information, decrease. This approach could, however, affect the current workflow of a device clinic, thus needing further consideration if it is to be incorporated into practice.

The most significant result of the PREFER study is that only 3 events were identified in the Control arm patients by

TTM. The remaining 190 events identified in the Control arm were identified by the scheduled in-office evaluations. This verifies the long-held suspicion that TTM, although useful for analysis of the pacemaker battery, may not be very useful for the clinical follow-up of the patient. It is hoped that the early notification of events such as AT/AF and increased ventricular pacing can aid in the detection or prevention of disease states such as stroke and progression to congestive heart failure. Remote pacemaker interrogation could potentially decrease the need for routine in-office patient visits. This may potentially translate into positive benefits for clinic efficiency and an increase in patient convenience.

This was the second study that provided clear evidence that pacemaker patients were not free of CAEs. Interestingly, the event rates in this study were lower than

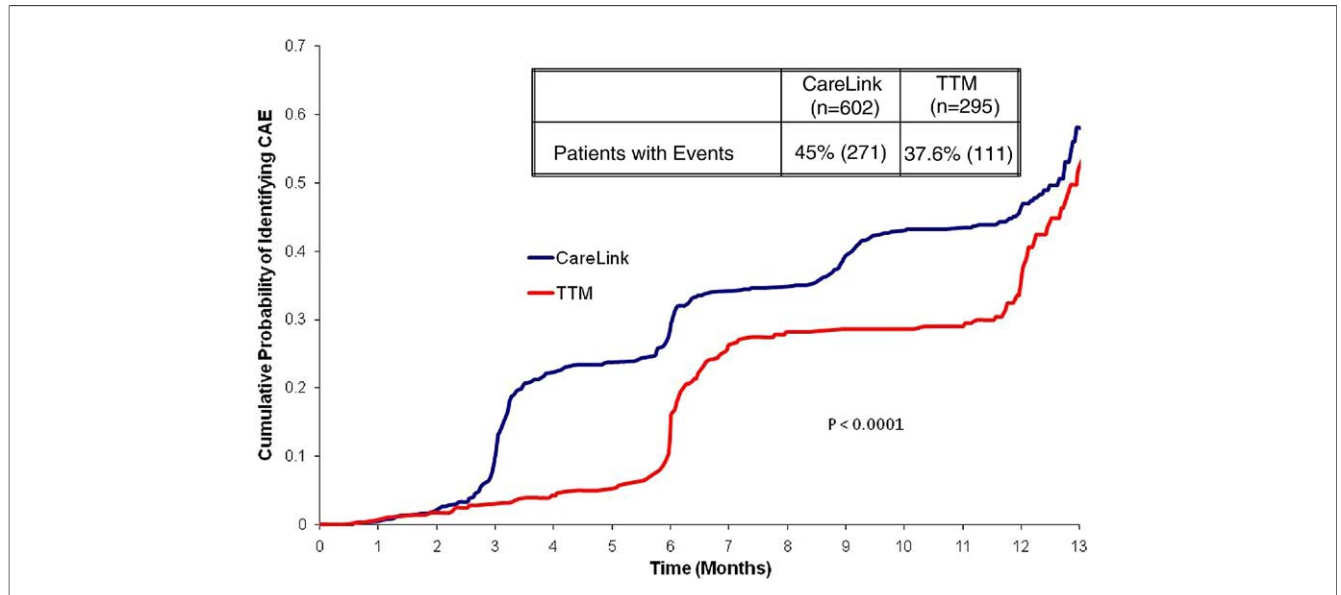


Figure 3 Composite CAE

Survival curves represent the difference in probability of clinically actionable event (CAE) identification between the Remote and Control arms. TTM = transtelephonic monitoring.

what was seen in the A-HIRATE trial. Lower event rates might have been due to different patient selection, different drug regimens, or the fact that end points for the current study were only clinician-defined relevant events. Some events in the A-HIRATE trial might not have met the criteria for CAEs as used in this study. The A-HIRATE analysis used the device records to identify all events retrospectively.

At this time, there is still an important need for TTM. There is still a significant number of patients who have devices not supported by remote telemetry systems. TTM technology has evolved to be compatible with all devices, whereas Internet-based systems are manufacturer spe-

cific. TTM is not expected to be completely replaced in the short term because many legacy devices are not capable of remote transmission. Although TTM has limited value in the evaluation of arrhythmias and device function, there is value in following the battery status of older pacemakers that are approaching battery depletion. Further, we do not anticipate that remote interrogation will fully supplant in-office follow-up. Certain procedures can only be done in person such as the examination of the wound and reprogramming. In the future, if regulatory hurdles are overcome, we may even be able to further enhance follow-up and achieve remote reprogramming of pacemakers for problem solving. Remote programming

Table 3 CAE Summary

Event	No. of Events Reported per Patient	
	Remote Arm	TTM Arm
Composite CAEs	1.123	0.644
NSVT	0.517	0.308
AT/AF >48 h	0.198	0.105
Sensed ventricular rate >100 beats/min during AT/AF	0.188	0.098
Ventricular pacing ↑ 30%	0.101	0.064
New-onset AT/AF	0.061	0.037
Increase in ventricular pacing voltage threshold ≥ 1 V	0.018	0.017
Change in ventricular lead impedance	0.012	0.003
Loss of ventricular capture	0.010	0.000
Change in atrial lead impedance	0.010	0.003
Increase in atrial pacing voltage threshold ≥ 1 V	0.005	0.003
ERI/EOL	0.003	0.000
Loss of atrial capture	0.000	0.003

AT/AF = atrial tachycardia/atrial fibrillation; CAE = clinically actionable event; ERI/EOL = elective replacement indicator/end of life; NSVT = nonsustained ventricular tachycardia; TTM = transtelephonic monitoring.

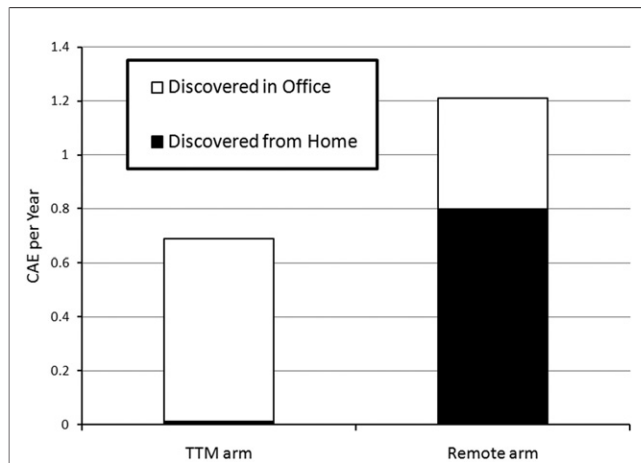


Figure 4 CAE Rate by Source

The number of clinically actionable events (CAEs) by their source. The number of CAEs discovered by transtelephonic monitoring (TTM) per year in the TTM arm was very small (0.01).

will never replace the periodic direct evaluation of the patient that is done now with both TTM and remote evaluation. It is important to realize that remote interrogation does not prevent the acquisition of historical information from the patient. It is standard practice in most centers for the arrhythmia nurse to call the patient, albeit after the remote transmission, take his or her history, and deliver the results of the remote evaluation.

What these data suggest is that the future of pacemaker follow-up is changing. Devices are becoming more sophisticated as they can now monitor their own operations and detect clinical events. It is clear that the use of remote follow-up allows a more timely recognition of these events due to the ease with which a clinic can gain access to these data. This study supports the conclusions of the Heart Rhythm Society/European Heart Rhythm Society expert consensus document that supports the use of remote follow-up to achieve the goals of pacemaker follow-up (14). New reimbursement codes (CPT) are now in use in the U.S. These codes allow reimbursement for remote interrogation follow-up procedures. With the clear improvement in data and the practicality of reimbursement, we certainly hope that there will be a rapid transition from the relatively inefficient TTM to the more efficacious remote interrogation follow-up.

Study limitations. This study was not powered to detect a decrease in the clinical end points of stroke and congestive heart failure. A larger study would be required to have the power to detect these benefits if they are present. This study involved only the Medtronic CareLink system. Several other manufacturers have remote follow-up systems. The applicability of our findings to those systems is unknown. These findings are only applicable to devices for which remote follow-up is available. There remain many legacy

devices implanted for which there is no remote follow-up available.

Conclusions

The strategic use of remote pacemaker interrogation follow-up detects clinically important and actionable events more quickly and frequently than transtelephonic rhythm strip recordings. The value of TTM rhythm strips for pacemaker follow-up is limited to battery status determinations. Remote device interrogation technology continues to improve patient care.

Acknowledgments

The authors acknowledge the following individuals for their undying support during this study: Julianne Herr and Terri Wright, for providing overall clinical study management as well as reviewing and editing the manuscript, and Amie Buckska and Betsy Crossley, for also reviewing and editing the manuscript.

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: pacemaker ■ follow-up ■ remote follow-up.

 **APPENDIX**

For a list of the PREFER investigators, please see the online version of this article.

Clinical Benefits of Remote Versus Transtelephonic Monitoring of Implanted Pacemakers

George H. Crossley, Jane Chen, Wassim Choucair, Todd J. Cohen, Douglas C. Gohn, W. Ben Johnson, Eleanor E. Kennedy, Luc R. Mongeon, Gerald A. Serwer, Hongyan Qiao, Bruce L. Wilkoff, for the PREFER Study Investigators

J. Am. Coll. Cardiol. 2009;54;2012-2019

doi:10.1016/j.jacc.2009.10.001

This information is current as of November 16, 2009

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