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The Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients

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ABSTRACT

BACKGROUND Remote monitoring (RM) technology embedded within cardiac rhythm devices permits continuous monitoring, which may result in improved patient outcomes.

OBJECTIVES This study used "big data" to assess whether RM is associated with improved survival and whether this is influenced by the type of cardiac device and/or its degree of use.

METHODS We studied 269,471 consecutive U.S. patients implanted between 2008 and 2011 with pacemakers (PMs), implantable cardioverter-defibrillators (ICDs), or cardiac resynchronization therapy (CRT) with pacing capability (CRT-P)/defibrillation capability (CRT-D) with wireless RM. We analyzed weekly use and all-cause survival for each device type by the percentage of time in RM (%TRM) stratified by age. Socioeconomic influences on %TRM were assessed using 8 census variables from 2012.

RESULTS The group had implanted PMs (n = 115,076; 43%), ICDs (n = 85,014; 32%), CRT-D (n = 61,475; 23%), and CRT-P (n = 7,906; 3%). When considered together, 127,706 patients (47%) used RM, of whom 67,920 (53%) had ≥75%TRM (high %TRM) and 59,786 (47%) <75%TRM (low %TRM); 141,765 (53%) never used RM (RM None). RM use was not affected by age or sex, but demonstrated wide geographic and socioeconomic variability. Survival was better in high %TRM versus RM None (hazard ratio [HR]: 2.10; $p < 0.001$), in high %TRM versus low %TRM (HR: 1.32; $p < 0.001$), and also in low %TRM versus RM None (HR: 1.58; $p < 0.001$). The same relationship was observed when assessed by individual device type.

CONCLUSIONS RM is associated with improved survival, irrespective of device type (including PMs), but demonstrates a graded relationship with the level of adherence. The results support the increased application of RM to improve patient outcomes. (J Am Coll Cardiol 2015;65:2601–10) © 2015 by the American College of Cardiology Foundation.

Remote monitoring (RM) of patients with cardiac electronic implantable devices (CIEDs) continues to evolve (1). Although originally devised to facilitate patient access and/or clinic efficiency by replacing the need for in-person follow-up evaluations, RM is now being explored as a method for improving patient outcomes (2–8). Newer technologies embedded in CIEDs permit daily monitoring with automatic early notification of changes in patient's clinical condition and device (mal)function (9). These notifications enable prompt clinical intervention, irrespective of follow-up

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ABBREVIATIONS AND ACRONYMS

CI = confidence interval

CIED = cardiac electronic implantable device

CRT = cardiac resynchronization therapy

CRT-D = cardiac resynchronization therapy with defibrillation capability

CRT-P = cardiac resynchronization therapy with pacing capability

HR = hazard ratio

ICD = implantable cardioverter-defibrillator

MIR = mortality incidence rate

MIRR = mortality incidence rate ratio

PM = pacemaker

RM = remote monitoring

RM None = never used remote monitoring

TRM = time in remote monitoring

%TRM = percentage of time in remote monitoring

schedule (4,6,10). However, whether these actions have a tangible effect on patient outcome remains an area of active investigation. First reports from studies using high-voltage CIEDs indicated improved survival among patients assigned to remote management in both an observational cohort (ALTITUDE) (11) and the randomized IN-TIME (Influence of Home Monitoring on Mortality and Morbidity in Heart Failure Patients with Impaired Left Ventricular Function) trial (5). Mechanisms remain unclear, but facilitation of ventricular arrhythmia/shock management has been proposed as one explanation.

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To better understand the influence of RM on outcomes, we hypothesized that survival would be better in patients with greater RM use and should apply to *all* types of CIEDs: patients with pacemakers (PMs) who have less cardiovascular risk as well as those with implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) with pacing/defibrillation capability (CRT-P/CRT-D). We tested this in a cohort of CIED patients, all receiving automatic RM devices, by leveraging "big data" from a nationwide RM system-generated proprietary database, which collects comprehensive longitudinal follow-up data in hundreds of thousands of patients.

METHODS

STUDY DESIGN AND PATIENT SELECTION. This retrospective, national, observational cohort study evaluated 371,217 consecutive patients receiving new implants of market-released PMs, ICDs, CRT-Ps, and CRT-Ds (St. Jude Medical, Inc., Sylmar, California). To assess the impact of RM use on outcome, patients whose implanted device did not support automatic daily monitoring were excluded (deemed not automatic RM capable) (**Figure 1**). The remaining patients with ICD/CRT-D devices implanted between October 2008 and December 2011 and PM/CRT-P devices implanted between October 2009 and December 2011 comprised the study cohort (automatic RM capable). Patients enrolled in another clinical trial or with follow-up time <90 days also were excluded. Included patients were followed until death or device replacement/removal through November 2013.

Study data were obtained from 4 sources: device implant registration, device RM, postal (ZIP) code sociodemographic data, and the U.S. Social Security Death Master File. Age, sex, device type, and follow-up duration were ascertained using manufacturer device tracking data. Remote monitoring status was determined from the Merlin patient care network (St. Jude Medical) and date of death from the U.S. Social Security Death Master File, with all death records through November 30, 2013. We added death reports through this date made directly to the device manufacturer's U.S. tracking system by health care providers or family members (this accounted for <1% of deaths). Socioeconomic data were gathered from the 2012 U.S. Census Bureau American Community Survey, 2008 to 2012, by individual ZIP code tabulation area, specifically, 4-year college degree, median income, below poverty level, telephone or cell phone service, employment status, health care insurance, and total urban/rural classification of population counts (12). The urban percentage for a region was computed as the ratio of urban to total population counts. We obtained data without patient identifiers from implant registration records of devices manufactured by St. Jude Medical, Inc. Data included date of implantation, age at implantation, sex, patient ZIP code, site ZIP code, and device model numbers. For patients enrolled in the Merlin patient care network remote monitoring, we obtained data without patient identifiers consisting of maintenance transmission dates linked to implant registration data.

Among RM-capable patients, RM service use was computed using weekly status data sent from each user of Merlin to the central server. A multiple-retry algorithm ensured the status data were communicated when an attempt to send data to the server failed. Those patients having had at least 1 transmission ever were classed as RM Any. RM adherence per patient was defined as the proportion of total follow-up weeks having at least 1 status transmission or percentage of time in RM (%TRM). To determine whether %TRM affected outcome, RM-capable patients were assigned to 1 of 3 groups based on extent of their RM use. Those with 0%TRM were designated as RM None. RM Any patients were further divided into high %TRM or low %TRM groups by a cut point of 75% use (this value approximated median %TRM) Thus, low %TRM patients were those sending weekly maintenance records to the server <75% (but >0%) of their follow-up time in this study, whereas high %TRM patients were those who sent weekly maintenances record to the server ≥75% of their follow-up time.

STATISTICAL ANALYSIS. The primary endpoint of this study was all-cause mortality, which was determined using unadjusted mortality incidence rates (MIRs) and adjusted survival via Cox proportional hazards survival models. The MIR ratio (MIRR), RM