Effect of daily remote monitoring on pacemaker longevity: A retrospective analysis

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BACKGROUND Energy demand of remote monitoring in cardiac implantable electronic devices has never been investigated. Biotronik Home Monitoring (HM) is characterized by daily transmissions that may affect longevity.

OBJECTIVE The aim of the study was to retrospectively compare longevity of a specific dual-chamber pacemaker model in patients with HM on and patients with HM off.

METHODS Hospital files of 201 patients (mean age 87 ± 10 years, 78 men) who had received a Biotronik Cylos DR-T pacemaker between April 2006 and May 2010 for standard indication were reviewed. In 134 patients (67%), HM was activated. The primary end point was device replacement due to battery depletion.

RESULTS The median follow-up period was 56.4 months (interquartile range 41.8–65.2 months). The estimated device longevity was 71.1 months (95% confidence interval [CI] 69.1–72.3 months) in the HM-on group and 60.4 months (CI 55.9–65.1 months) in the HM-off group ($P < .0001$). The frequency of inhospital visits with significant device reprogramming was higher in the HM-on group than in the HM-off group (33.3% vs 25.0%, respectively; $P = .03$). Lower ventricular pulse amplitude (2.3 ± 0.4 V vs 2.7 ± 0.5 V; $P < .0001$) and pacing percentage (49% ± 38% vs 64% ± 38%; $P = .02$), both calculated as time-weighted averages, were observed with HM on as compared with HM off. Patient attrition was significantly lower in the HM-on group (9.7%; 95% CI 3.0%–28.7%) than in the HM-off group (45.6%; 95% CI 30.3%–64.3%) ($P < .0001$).

CONCLUSION In normal practice, energy demand of HM, if present, was overshadowed by programming optimization likely favored by continuous monitoring. Pacemakers controlled remotely with HM showed an 11-month longer longevity. Patient retention was superior.

KEYWORDS Remote monitoring; Telemedicine; Pacemaker; Longevity; Battery; Device programming; Home Monitoring

ABBREVIATIONS **AV** = atrioventricular; **CI** = confidence interval; **ERI** = elective replacement interval; **HM** = Home Monitoring; **RR** = rate response; **TWA** = time-weighted average

Introduction

Device longevity is one of the most relevant characteristics in modern cardiac implantable electronic devices.[1] Device complexity has grown rapidly in the past decades owing to implementation of increasingly sophisticated diagnostic and therapeutic functions. While the clinical benefits of these functions are extensively evaluated, the associated energy demand has not been often investigated in detail.

Remote monitoring allows automatic remote controls of implanted devices through periodic telemetric transmissions to a central server. Therefore, remote monitoring is a particularly interesting case in terms of energy consumption: on one hand, it is an additional service potentially requiring a significant amount of energy owing to the frequent activation of long-range telemetry. On the other hand, it should favor optimization of device programming and therapy delivery,[2,3] which may result in a reduction in the energy demand in the long term. It is unknown which of the 2 trends is actually predominant in normal clinical practice in the long run.

Among the remote monitoring technologies currently available, Biotronik Home Monitoring (HM) is the only system characterized by daily transmissions and critical event-triggered messages. Therefore, despite the manufacturer's claim, HM could in principle be associated with a significant energy demand as the device battery should supply energy for >1800 expected long-range telemetry transmissions (excluding repetitions) in a 5-year service life in addition to all other diagnostic and therapeutic functions implemented in the devices.

The purpose of this retrospective analysis was to estimate longevity in normal clinical practice of a specific dual-

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chamber rate-response (RR) pacemaker model used in our institution from 2006 to 2010 by comparing subgroups of patients with and without HM.

Methods

Objectives and patient selection

The objective of our analysis was to investigate device longevity in patients monitored with HM in addition to scheduled inhospital visits compared with patients followed only through regular inhospital visits. We scanned the archive of our institution and reviewed patient files and inhospital follow-up reports of patients who had received a Biotronik Cylos DR-T dual-chamber pacemaker between April 2006 and May 2010 as a first implant or a replacement. To select a homogeneous pacemaker sample and to avoid bias induced by technical variability, we restricted our search to this particular device, as it was both provided with the HM technology and with a full set of the most common and advanced bradycardia therapeutic and diagnostic functions of that time. All the patients implanted in our institution and followed up during routine clinical activity were selected, if not included, in other interventional clinical studies.

The primary end point was device replacement due to battery depletion. For each included device, longevity was calculated as the time from the implant date to the replacement date. Data from devices prematurely replaced owing to a surgical implant revision or an upgrade to other systems before the elective replace interval (ERI) or end of service condition was censored at the date of the procedure.

Secondary end points were the total number of inhospital visits and the proportion of active follow-ups. The latter were defined as any inhospital visit that ended up with a significant device reprogramming. A device reprogramming was considered significant only if changes were introduced in at least one of the following parameters: (1) pacing mode; (2) lower pacing rate; (3) atrioventricular (AV) delay, including activation of algorithms for ventricular pacing minimization (ie, IRS Plus, AV hysteresis, etc); (4) activation/deactivation of RR function; (5) atrial or ventricular pacing pulse amplitude or duration (including activation of the automatic ventricular capture control and adjust feature). The time-weighted average (TWA) of atrial and ventricular pacing percentages, pulse amplitudes, and impedances during follow-up was calculated and reported as well.

Finally, patient compliance was evaluated in the study subgroups by estimating the patient loss rate: a patient was classified as lost to follow-up when no data were available for 18 months after the date of the last inhospital visit or the last remote HM message.

The study was conducted in accordance with the Declaration of Helsinki, and it was approved by the institutional ethics committee. Written informed consent to study participation was required before the enrollment.

Pacemaker model and HM

The Cylos DR-T pacemaker was a dual-chamber device with all the essential characteristics comparable with those of other competitor models at the time of production. It was a 6.4-mm-thick pacemaker equipped with a lithium/iodine battery of 2.8 V open-circuit voltage at the beginning of service and 1.3 Ah capacity. The device weight and volume were 31 g and 14 cm^3, respectively. As reported in the user manual,[4] the expected service life was 70, 89, and 105 months with a 100%, 50%, and 0% pacing (estimations based on the factory program, manufacturer's data, a lead impedance of 500 Ω, and an ambient temperature of 37°C). The manual reports a power consumption of 13 and 20 μA during 0% and 100% pacing at the beginning of service, but no information is given about the additional power required by the activation of HM for that particular pacemaker model. However, according to a manufacturer's claim, the HM feature should require $<2\%$ of the available battery energy during the entire service life of the device, despite the daily HM transmissions.[5]

As described earlier,[6] HM is an Internet-based system that uses the cellular phone network to transmit data from patients to a central server where physicians can log on with their own credentials. Periodic transmissions occur every day at a programmable time that is generally set during the night. The implanted device transmits data to a portable transmitter unit (CardioMessenger, Biotronik) using telemetry with the power and frequency range of Medical Implant Communication Service signals. Captured telemetry data are forwarded by the CardioMessenger to the central server using the conventional GSM network. In addition to periodic daily transmissions, unscheduled transmissions may be triggered by programmable critical events.

Follow-up

Both patients with and without remote monitoring followed quite similar inhospital visit schedules during the study period. Unless differently required by special conditions, patients without remote monitoring were visited 1 and 6 months after implantation and yearly thereafter. As the ERI condition approached, more frequent visits were scheduled according to the residual device service time (every 3 months generally).

Conversely, patients controlled remotely with HM were visited in hospital yearly after 1 month of follow-up, with no need for more frequent visits while approaching the ERI condition. HM remote follow-ups were performed in our outpatient clinic according to a standard model adopted by the Task Force for Telemedicine of the Italian Association of Arrhythmias and Cardiac Pacing.[7] As already described,[8,9] this model is essentially based on a univocal association between a patient and a responsible unit consisting of a nurse and a physician: the nurse is in charge of continuity of care, including patient training, online HM database management (HM activation/deactivation) and its periodical screening, notification of automatic alerts and critical events, as well as contacts with patients for different needs, including arranging an unscheduled inhospital visit or resuming interrupted transmissions. The physician is responsible for patient consenting, analysis of submitted critical events and medical