How Wireless Remote Monitoring Improves Clinical Benefits;

A CLINICAL CASE STUDY

Suneet Mittal, M.D., The Arrhythmia Institute at Valley Hospital, Ridgewood, NJ; New York, New York;
E. Martin Kloosterman, M.D., Boca Raton Regional Hospital, Boca Raton, FL

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CLINICAL BENEFITS OF WIRELESS REMOTE MONITORING OF PACEMAKER PATIENTS

INTRODUCTION

Transtelephonic monitoring of pacemakers has been available since the 1970s. The technology has continued to evolve and now not only enables near continuous monitoring of device status but can also provide clinically valuable diagnostic information (Table 1). Wireless remote monitoring is a standard feature on many currently available pacemakers including those from Abbott, Boston Scientific Corp. and Biotronik, Inc. The clinical value of remote monitoring (RM) has been demonstrated in multiple clinical studies.[1-3] Remote monitoring enables early access to clinically valuable information including earlier detection of arrhythmia- and heart-failure-related problems.[1,2] A utilization-related survival benefit[3] and a significant reduction in hospitalization and health care use have also been demonstrated for remote monitoring of pacemakers.[4]

The strong clinical evidence surrounding remote monitoring has led to changes in practice management guidelines to include Class 1A recommendations that all patients with CIED should be offered remote monitoring (Table 2).[5] Nevertheless, only a small percentage of patients with pacemakers are currently being followed remotely.[4] Given that pacemakers are the most widely implanted cardiac device, implementation of remote monitoring for these patients represents a significant but underutilized opportunity to improve patient outcomes.[5] This paper will address the clinical evidence for remote monitoring of pacemaker patients, especially in regard to the early detection and quantification of atrial fibrillation (AF), mortality and health care usage (Table 3).

HOW REMOTE MONITORING IS CHANGING OUR UNDERSTANDING OF AF

Given the availability of a whole range of diagnostic information about the patient's device function as well as arrhythmias, there has been an evolution in thinking about the value of remote monitoring for patients with pacemakers. Remote monitoring is changing our understanding of AF and has raised questions about the optimal medical treatment. The commonly held perception has been that AF starts with a limited number of sporadic episodes which become more frequent and persistent over time. However, the availability of long-term longitudinal data from remote monitoring has demonstrated that the natural history of AF can be quite variable and unpredictable. We also know that sick sinus syndrome and high-grade atrioventricular block have been linked to an increased prevalence of AF.[7,8] Therefore, remote monitoring can be useful in following the course of AF and in managing treatment.

TABLE 1. TYPES OF PACEMAKER REMOTE MONITORING

TYPE	TRANSTELEPHONIC	REMOTE INTERROGATION	WIRELESS REMOTE MONITORING
Key Indicators Monitored	Battery status Rhythm Sensing/capture	Battery status Rhythm Sensing/capture Diagnostics	Battery status Rhythm Sensing/capture Diagnostics Heart failure status
How it Works	Sends data via an analog transmission via a telephone landline	Scheduled remote device check at a discrete point in time; typically, the patient must activate the monitoring system and then make the connection with their device via a hand-held wand	Alerts: Data transmissions occur automatically; there is no need for one-to-one interaction between the health care provider and patient or patient action needed.

The term remote monitoring is often used to refer to both remote interrogation and wireless remote monitoring.

TABLE 2. 2015 HRS CONSENSUS STATEMENT[6]

CLASS 1A RECOMMENDATIONS	
Device Follow-Up Paradigm	**Device and Disease Management**
A strategy for remotely monitoring CIEDs, combined with at least an annual in-person evaluation, is recommended over a calendar-based schedule of in-person CIED evaluations alone (when technically feasible).	Remotely monitor device for surveillance of lead function and battery conservation.
All patients with CIEDs should be offered some type of remote monitoring as part of the standard follow-up management strategy.	Remotely monitor for early detection and quantification of atrial fibrillation (AF).

TABLE 3. CLINICAL VALUE OF REMOTELY MONITORING PACEMAKER PATIENTS

TRIAL STUDY DESIGN	NUMBER OF PATIENTS	PRIMARY ENDPOINTS	CONCLUSIONS
DETECT ARRHYTHMIC EVENTS EARLIER			
PREFER study[1] Crossley, et al. Randomized controlled trial	897 (602 in RI grp. and 295 in IPE grp.)	Mean time to the first diagnosis of a clinically actionable event (CAE).	• CAEs were found, on average, 2 months earlier with transtelephonic monitoring compared with standard of care office visits (5.7 vs. 7.7 months). • Transtelephonic monitoring found CAEs more quickly and frequently.
IMPROVED PATIENT OUTCOMES			
COMPAS[2] Mabo, et al. Randomized, controlled, non-inferiority trial	538 (269 in each grp.)	Assess the proportion of patients who experienced at least one major adverse event, including all-cause death and hospitalizations for device-related and cardiovascular events with wireless remote monitoring (RM) compared with standard of care. Margin for inferiority: 7%	• There were significantly fewer hospitalizations for atrial arrhythmias and strokes with RM group compared with standard of care, P < 0.05 at a mean follow-up of 18.3 months. • Interim ambulatory visits also decreased significantly with RM (56% lower, P < 0.001) compared with the standard care group. • Changes in pacemaker (PM) programming or drug regimens were made in 62% of RM group visits vs. 29% in standard of care visits, P < 0.001. • In a retrospective comparison, the median delay in medical intervention was significantly less in the RM group (17 days in the RM group and 139 days in the standard of care grp.).
IMPROVED SURVIVAL			
Varma, et al.[3] Retrospective analysis	269,471 consecutive patients with PM and ICDs (PM: n = 115,076)	Analysis of weekly use and all-cause survival for each device type by percentage of time in wireless RM stratified by age	RM was associated with improved survival across all device types and demonstrated a "dose response" dependent on the percentage of time in RM: • Survival was significantly better in patients with a higher percentage of time in RM vs. no time in RM (hazard ratio [HR]: 2.10, P < 0.001). • Higher percentage of time in RM vs. low time in RM (HR: 1.32; P < 0.001). • Low percentage of time in RM vs. no time in RM (HR: 1.58; p < 0.001).
Mittal, et al.[6] Retrospective analysis	106,027 (41% PM)	Determine if a mortality reduction is seen with prompt initiation of wireless RM (≤ 91 days post-implant)	• Mortality benefit was seen with PM patients who enrolled in RM ≤ 91 days post-implant compared with delayed initiation (3,480 vs. 4,010 per 100,000 patient years, P <0.001). • RM activation within 3 months of implant was associated with an 18% increase in survival during a mean follow-up of 2.6 years across all device types. • In PM patients, the early detection of atrial arrhythmias via RM may result in management that translates to fewer strokes and related hospitalizations.
REDUCED HOSPITAL ADMISSIONS			
Piccini, et al.[4] Retrospective analysis	92,586 (59% PM)	Assess the impact of RM on hospitalizations and health care utilization	• RM is associated with a reduced risk of all-cause hospitalization (adjusted hazard ratio 0.82; 95% confidence interval 0.80–0.84; P < .001) and shorter mean-length of stay (5.3 days vs. 8.1 days; P <.001). • RM associated with a 30% reduction in hospitalization costs

CAE: Clinically Actionable Event
RM: Remote Monitoring
PM: Pacemaker

CASE STUDY 1

EARLY DETECTION OF AF WITH REMOTE MONITORING

Background: An 84-year-old male with hypertension and coronary artery disease underwent implantation of an Abbott dual chamber pacemaker for the management of symptomatic sinus node dysfunction and advanced AV block. He was enrolled in remote monitoring at the wound check, one-week post-implant.

Alert: The patient's device underwent daily self-checks for the presence of mode switches or AT/AF events. An alert would be sent if an out-of-specification event occurred. Approximately 5.5 years after implant, we received an AT/AF alert for an AF episode that had started the previous day (Figure A). This was the first known episode of AF in this patient (Figure B). The peak A rate was 640 bpm; the V rate during the episode was 110 bpm for six hours, evaluated daily.

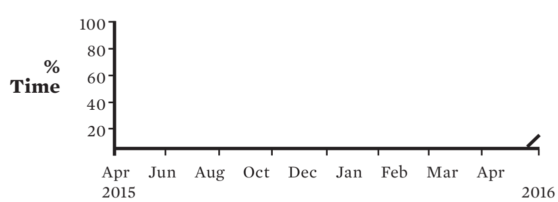
Figure A

AT/AF ALERT

AT/AF Alerts
Exceeded AT/AF Burden
Long AT/AF Episode(s)

KEY AMS LOG EPISODES	DATE AND TIME	PEAK A RATE	PEAK V RATE	DURATION (D:H:M:S)
Most Recent Episode	Apr 26, 2016 3:48 am	244 bpm	72 bpm	0:00:03:30
Peak V Rate Episode	Apr 25, 2016 5:50 pm	640 bpm	95 bpm	0:08:02:42
Longest Episode	Apr 25, 2016 5:50 pm	640 bpm	95 bpm	0:08:02:42

AT/AF Burden	<1%	Since Feb 2, 2016	**V Rates During AMS**	Since Feb 2, 2016
Total AT/AF Burden	<1%	Since Oct 6, 2010		



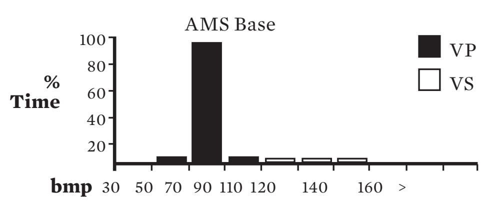
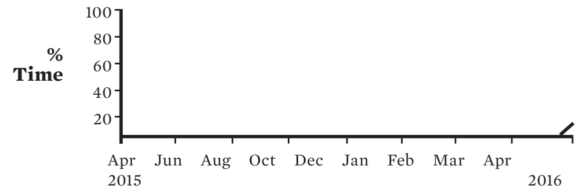


Figure B

AT/AF Burden	<1%	Since Feb 2, 2016
Total AT/AF Burden	<1%	Since Oct 6, 2010

(0m 0d sampled in AT/AF)



Week	D:H:M:S	%	Week	D:H:M:S	%
Apr 29, 2015	0:00:00:00	0	Nov 4, 2015	0:00:00:00	0
May 6, 2015	0:00:00:00	0	Nov 11, 2015	0:00:00:00	0
May 13, 2015	0:00:00:00	0	Nov 18, 2015	0:00:00:00	0
May 20, 2015	0:00:00:00	0	Nov 25, 2015	0:00:00:00	0
May 27, 2015	0:00:00:00	0	Dec 2, 2015	0:00:25:36	<1
Jun 3, 2015	0:00:00:00	0	Dec 9, 2015	0:00:00:00	0
Jun 10, 2015	0:00:00:00	0	Dec 16, 2015	0:00:00:26	<1
Jun 17, 2015	0:00:00:00	0	Dec 23, 2015	0:00:00:00	0
Jun 24, 2015	0:00:00:00	0	Dec 30, 2015	0:00:00:00	0
Jul 1, 2015	0:00:00:00	0	Jan 6, 2016	0:00:00:00	0
Jul 8, 2015	0:00:00:00	0	Jan 13, 2016	0:00:00:00	0
Jul 15, 2015	0:00:00:18	<1	Jan 20, 2016	0:00:00:00	0
Jul 22, 2015	0:00:00:00	0	Jan 27, 2016	0:00:00:00	0
Jul 29, 2015	0:00:00:00	0	Feb 3, 2016	0:00:00:00	0
Aug 5, 2015	0:00:00:00	0	Feb 10, 2016	0:00:00:00	0
Aug 12, 2015	0:00:00:00	0	Feb 17, 2016	0:00:00:00	0
Aug 19, 2015	0:00:00:00	0	Feb 24, 2016	0:00:00:00	0
Aug 26, 2015	0:00:00:00	0	Mar 2, 2016	0:00:00:00	0
Sep 2, 2015	0:00:01:52	<1	Mar 9, 2016	0:00:00:00	0
Sep 9, 2015	0:00:00:00	0	Mar 16, 2016	0:00:00:00	0
Sep 16, 2015	0:00:00:00	0	Mar 23, 2016	0:00:00:00	0
Sep 23, 2015	0:00:00:00	0	Mar 30, 2016	0:00:00:00	0
Sep 30, 2015	0:00:00:00	0	Apr 6, 2016	0:00:00:00	0
Oct 7, 2015	0:00:00:00	0	Apr 13, 2016	0:01:45:22	1.0
Oct 14, 2015	0:00:00:00	0	Apr 20, 2016	0:00:01:36	<1
Oct 21, 2015	0:00:00:00	0	Apr 26, 2016	0:16:28:00	12
Oct 28, 2015	0:00:00:00	0			

Actions: Given the patient's CHA$_2$DS$_2$-VASc score of 4, anticoagulation was initiated.

Results: Remote monitoring is ongoing. The AF episode terminated spontaneously and the patient's overall AF burden is being monitored to determine whether an antiarrhythmic medication is required.

Discussion: The patient experienced additional paroxysms of AF so anticoagulation has been continued. However, he has been entirely asymptomatic. Therefore, neither antiarrhythmic drug therapy nor catheter ablation have been pursued.

CASE STUDY 2:

OVERSENSING WITH PACING INHIBITION

Background: An 86-year-old white male with a history of hypertension underwent implantation of a dual-chamber pacemaker for the management of sinus node dysfunction with conduction system disease. The patient had a known history of limited paroxysmal atrial tachyarrhythmia and non-sustained ventricular tachycardia (NSVT) not requiring treatment. The patient was enrolled in remote monitoring at discharge and sent home with a remote monitoring unit for immediate use.

Alerts: A series of automatically generated alerts were received regarding high ventricular rate (HVR) events. A low RV lead impedance was also noticed. (Figure C and Figure D)

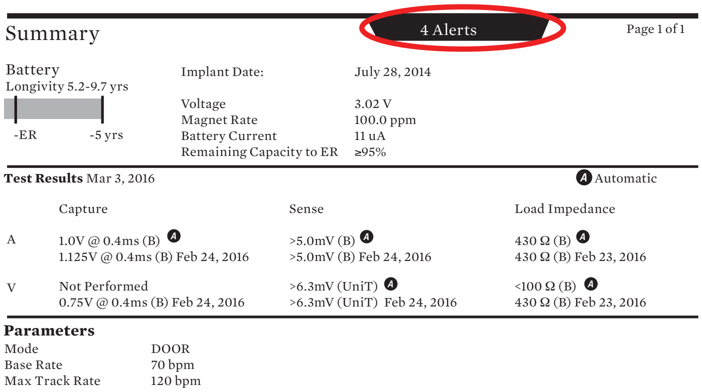
Upon closer analysis, it was discovered that the HVR events were electrical noise with pacemaker oversensing and pacing inhibition rather than NSVT — a sequence of events that occurred previously.

Actions: Based on the data, a new RV lead was implanted that day.

Results: A HVR event was again transmitted two months later. However, lead impedance was within range. In this case, the alert resulted from a long episode of NSVT. The patient was monitored closely in consideration of whether to initiate medical therapy.

Discussion: Remote monitoring provides actionable data enabling the timely diagnosis of arrhythmias or hardware malfunction requiring intervention. A well-organized home remote database, including a comments section with relevant clinical information, assists with managing patient alerts. All episodes triggering an alert should be examined closely without making assumptions based on the diagnostic labeling.

Figure C: 4 alerts and RV lead impedance < 100 Ω were noticed.



Summary — 4 Alerts — Page 1 of 1

Battery
Longivity 5.2-9.7 yrs
-ER -5 yrs

Implant Date:	July 28, 2014
Voltage	3.02 V
Magnet Rate	100.0 ppm
Battery Current	11 uA
Remaining Capacity to ER	≥95%

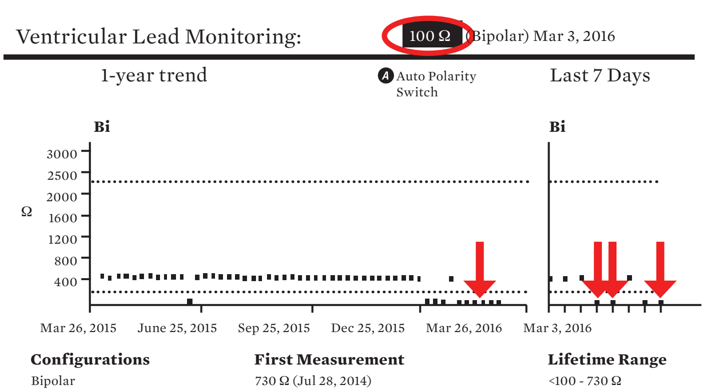
Test Results Mar 3, 2016 — (A) Automatic

	Capture	Sense	Load Impedance
A	1.0V @ 0.4ms (B) (A) 1.125V @ 0.4ms (B) Feb 24, 2016	>5.0mV (B) (A) >5.0mV (B) Feb 24, 2016	430 Ω (B) (A) 430 Ω (B) Feb 23, 2016
V	Not Performed 0.75V @ 0.4ms (B) Feb 24, 2016	>6.3mV (UniT) (A) >6.3mV (UniT) Feb 24, 2016	<100 Ω (B) (A) 430 Ω (B) Feb 23, 2016

Parameters

Mode	DOOR
Base Rate	70 bpm
Max Track Rate	120 bpm

Figure D: Evidence of recurrent RV low impedance illustrated in trend chart.



CONCLUSION

REMOTE MONITORING OF PACEMAKER PATIENTS ADDS CLINICAL VALUE

The clinical benefits of remote monitoring to pacemaker patients include the early detection and quantification of arrhythmic events, including AF. This benefit enables informed medication modifications, which has shown to improve patient outcomes with fewer hospitalizations and ambulatory visits.[9,10]

To harness the full clinical benefits of remote monitoring, the following steps should be considered:

- Monitor hardware function closely, including:
  - Impedance changes, increased thresholds and electrical noise.
  - Battery decay monitoring: Devices may offer generic rather than precise longevity estimation when approaching elective replacement. Remote monitoring allows for close monitoring without the need for an earlier than needed replacement.

- Tailor device follow-up to individual patient needs including more intense monitoring of patients with a need to stop anticoagulation perioperatively; who have undergone ablation or cardioversion procedures; or who have newly recognized symptoms or an arrhythmic event such as non-sustained ventricular tachycardia.

- Create a database that enables convenient access to defined groups of patients who may require additional follow-up regarding their alert status or alert parameters — physician advisories; changes in guidelines.

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