CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES

COMPLEX CASE STUDY

Wireless LINQ™ Loop Recorders' Premature Battery Depletion Status: One Clinic Experience

MARTHA FERRARA, DNP, RN, CCDS, FHRS

The Arrhythmia Institute, Valley Health System, Ridgewood, NJ

ABSTRACT. Daily wireless transmissions from implantable loop recorders (ILRs) have become part of the arsenal in the field of arrhythmia surveillance and detection. Daily alerts from these devices allow for prompt medical patient management. Any device malfunction potentially affects clinical management. This case presentation highlights a device alert for premature battery depletion in LINQ™ loop recorders (Medtronic Inc., Minneapolis, MN).

KEYWORDS. LINQ™, loop recorders, wireless.

ISSN 2156-3977 (print)
ISSN 2156-3993 (online)

© 2016 Innovations in Cardiac
Rhythm Management

Introduction

Remote monitoring (RM) has come of age. The promise of proficient patient care due to arrhythmia surveillance, early alerts, and faster plans of care on “actionable events”¹ is possible with the current RM technology in cardiovascular implantable electronic devices (CIEDs), allowing clinicians to manage CIED patients with more confidence.² Although many barriers have been identified in RM patient follow-up,³ no doubt should exist to the utility of implementing and maintaining an RM program in device clinics.^{4–7} CIED advisories, such as Fidelis and RIATA leads, can be successfully managed to a large measure by implementing intensified RM surveillance,⁸ aligning with manufacturers’ suggestions. Clinic RM workflow is challenging but can be successfully accomplished.⁹ The use of wireless, injectable implantable loop recorders (ILRs) (LINQs™, Medtronic Inc., Minneapolis, MN) places immediate clinical data workflow concerns and any detected device malfunction adds burden to RM patient management.

The author reports no conflicts of interest for the published content. Manuscript received August 29, 2016, Final version accepted September 26, 2016.

Address correspondence to: Martha Ferrara, APN, Valley Health System, EP Office, 1 Linwood Avenue Ste 2, Paramus, NJ 07652. E-mail: mayanrn@optonline.net

Case report

Patient 1

One of the very first ILR patients, for atrial fibrillation (AF) management, at 1-week post implant wound check follow-up in February 2014, had reached “end of service” (EOS) status. Engineers from Medtronic, after studying submitted data, were able to reset the battery to normal status via the programmer in the device clinic. Routine daily wireless transmissions resumed for this patient.

At that time, the decision was made to program *all* LINQ™ care alerts to red alert under “low battery voltage recommended replacement time” (RRT) status for this 36-month battery longevity device via the Carelink (Medtronic Inc., Minneapolis, MN) website (**Figure 1**).

Patient 2

An RRT status alert was detected in our clinic in October 2015 via the red alerts in a patient implanted for AF management, within 15 months of implantation (**Figure 2**). This was our index premature RRT alert. To the best of our knowledge, our clinic reported the first cases of premature RRT status in LINQ™ ILRs to the manufacturing company.

Discussion

LINQ™ loop recorders received FDA approval in February 2014 and are implanted for diverse diagnoses,

Reveal LINQ Wireless Device Alert Conditions

Hide Alert Group Conditions

Note: Any alert condition group setting may be overridden for an individual patient. Customized settings are assigned within the Patient Profile.

☐ Display descriptions of alert conditions

Clinical Management Alerts

	Red Alert	Yellow Alert	Website-only Alert	No Alert
Symptom (Patient Activated) Episode	☐	☐	☐	☒
Symptom (Patient Activated) + Detected Episode	☐	☒	☐	☐
Tachy Episode	☐	☐	☒	☐
Pause Episode	☐	☒	☐	☐
Brady Episode	☐	☐	☒	☐
AF Episode	☐	☐	☐	☒
AT Episode	☐	☐	☐	☒
AT/AF Daily Burden > Threshold	☐	☒	☐	☐
Time: 6 hrs/day				
Average Ventricular Rate during AT/AF	☐	☐	☐	☒
Time: Not in Use V Rate: Not in Use				
Maximum Episode Count Met	☐	☐	☐	☒
Maximum Symptom (Patient Activated) Count Met	☐	☐	☐	☒
Low Battery Voltage Recommended Replacement Time *	☒	☐	☐	
Electrical Reset *	☒	☐	☐	

Note: Alerts identified with an asterisk () cannot be programmed as "No Alert."

Figure 1: Reveal LINQ™ alert conditions warns of a red alert under "low battery voltage recommended replacement time" via the Carelink website.

Figure 2: A recommended replacement time status alert detected via the red alerts within 15 months of implantation.

i.e. syncope, palpitations, cryptogenic stroke, and long-term AF management. The CRYSTAL-AF trial demonstrated their applicability and potential impact on meaningful patient care.¹⁰

As of this report, over 650 LINQ™ loop recorders have been implanted by our physicians at the Valley Health System, NJ, since FDA approval. All patients are paired with MyCareLink (Medtronic Inc., Minneapolis, MN) remote monitors prior to discharge. Care alerts are tailored and programmed at implant by the implanting physician, allowing for more appropriate patient alert management and decrease potential “alert fatigue,” which may affect workflow efficiency and patient safety.¹¹

The initial LINQ™ ILR patient cohort (20%) was added to our regular “virtual” clinic device group, under “ILR Patients.” Incoming daily wireless data resulted in data avalanche and RM management challenges, necessitating a strategy for categorizing specific diagnoses alerts to streamline data and provide appropriate clinical follow-up care. Subsequent ILR patients’ diagnoses and the corresponding tailored-care alerts are as follows: 1) cryptogenic stroke (19%), 2) ventricular tachycardia (1%), 3) syncope (17%), 4) anticoagulation management (13%), and 5) AF/ablation management (30%). As of May 2016, a total of 33 premature RRT status ILR patients had

been reported in our clinic. Initially, a root cause analysis was conducted by clinic staff to elucidate potential obvious reasons.

In February 2016, Medtronic Inc. issued an advisory on premature RRT alerts with an observed occurrence rate of 0.45%. The Reveal LINQ™ Model LNQ11 premature RRT alerts are a software malfunction (false alert). An Urgent Field Safety Notice indicated an error of “sensitivity of an algorithm used” with ILRs affected 200 days after implant.¹² Daily voltage and impedance change measurements surveil battery longevity; three daily consecutive 2.75 V values signal replacement time; 16 consecutive impedance differences or fluctuations per day would signal replacement time. This is the benchmark testing used in the “laboratory” environment before “real-world” experience at 200 days. RRT ILRs, per their normal function, signal “end of service” (EOS) status after 1 month of reaching RRT, losing wireless telemetry functionality then. At EOS, manual transmissions for data download are necessary. Patient clinical management may be compromised if a false RRT status is flagged as a red alert. A letter was designed to inform patients of the advisory and potential workflow changes (Figure 3). Mid-level practitioners were designated to speak to patients when they presented to clinic to outline the issues and

Figure 3: Letter designed to inform patients of the advisory and potential work flow changes of their LINQ™ loop recorder.

Figure 4: LINQ™ loop recorders with early recommended replacement time status in one clinic experience compared with the United States.

potential plan of care previously discussed with their respective implanting physician.

In May 2016, after a regulatory submission for a software update from Medtronic to the FDA, a software “patch,” which sets impedance fluctuation measurements per day more broadly to correct this performance malfunction, was approved and made available by Medtronic, thus correcting error and resetting the Reveal LINQ™ battery status, thereby resuming normal functionality with no need for ILR explant/re-implant. Uploading this software patch keeps the same RRT error from recurring. This patch download can be done in the office via a programmer or via the MyCareLink monitor, although, to date, this functionality is not yet available in the United States.¹²

Conclusion

Thus far, premature RRT status in ILRs remains a low percentage in our clinic (5%) and in the United States (Figure 4), as initially reported by Medtronic in their advisory MD letter. In our patient cohort, only the index RRT patient underwent an explant and re-implant; all others remain implanted after receiving the patch upload and “Good” reported on the battery status. Our clinic continues to have a few RRT care alerts. These patients are scheduled for software patch upload immediately, thus experiencing no daily transmission interruptions. As it is not yet possible to predict which ILRs will reach a false RRT status, programming parameter alert conditions at red alert for “low battery voltage recommended replacement time” status in all ILRs, for closer observation of this advisory and monitoring system, should remain a priority in RM

device clinics to ensure appropriate follow up and patient care.

References

1. Crossley GH, Chen J, Choucair W, et al. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. *J Am Coll Cardiol*. 2009;54(22):2012–2019.
2. Movsowitz C, Mittal S. Remote patient management using implantable devices. *J Interv Card Electrophysiol*. 2011;31(1): 81–90.
3. Halligan D. Barriers to incorporating remote monitoring into clinical practice: Allied health professional perspective. *EP Lab Digest*. 2016;16(7):6–9.
4. Slotwiner D, Varma N, Akar JG, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. *Heart Rhythm*. 2015;12(7):e69–e100.
5. Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. 2010;122(23):2359–2367.
6. Varma N, Epstein AE, Irimpen A, Schweikert R, Love C; TRUST Investigators. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: The Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial. *Circulation*. 2010;122(4):325–332.
7. Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH; CONNECT Investigators. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: The value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol*. 2011;57(10):1181–1189.
8. Varma N. Automatic remote home monitoring of implantable cardioverter defibrillator lead and generator function: A system that tests itself everyday. *Europace*. 2013;15(Suppl. 1):i26–i31.
9. Slotwiner D. Wireless remote monitoring: The new standard of care. *EP Lab Digest*. 2016;16(6):32–33.

10. Sanna T, Diener HC, Passman RS, et al; CRYSTAL AF investigators. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. 2014;370(26):2478–2486.
11. Walsh-Irwin C, Jurgens CY. Proper skin preparation and electrode placement decreases alarms on a telemetry unit. *Dimens Crit Care Nurs*. 2015;34(3):134–139.
12. Premature RRT alert in some LINQ devices. Reveal LINQ Model LNQ11. Original Date of Advisory: February 2016. http://wwwp.medtronic.com/productperformance/document.html;jSESSIONID_productperformance=9cvGZgQNd4YyKBT0v26dXtqSz6CXpXW2hljqklGm20xhmjvddhql-2139304115!-1970462919?id=750064 (accessed July 31 2016).