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Data Transmission Delay in Medtronic Reveal LINQ™ Implantable Cardiac Monitor: Clinical Experience in 520 Patients

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ABSTRACT

Background: The Implantable Cardiac Monitor (ICM) is an invaluable tool for detecting cardiac arrhythmias by providing physicians. Critical to the success of ICMs depends on how quickly and accurately the data can be transmitted to a physician's office after an arrhythmic event. Then, the clinical event can be analyzed and the treatment will be provided accordingly. However, no reports have been published as to how efficiently the ICM data is transmitted. *Methods*: There is a retrospective review of 520 patients who received a Medtronic Reveal LINQ™ between 2/01/2015 and 6/01/2017. The time from the arrhythmic event to the time of physician notification was calculated and reason for delay was noted. *Results*: One hundred and twenty patients out of 520 patients (23%) had arrhythmic events transmitted over a mean follow up of 14 ± 4 months. The mean time between cardiac events and physician notification was 15 ± 8 days. Sixty-three percent (63%) of data transmission delay (defined as >24 hours) was due to the MyCareLink™ Monitor not being in proximity to the patient. Connection failure between the monitor and the network accounted for 34% of data transmission delay. *Conclusion*: Significant delay in data transmission from Medtronic Reveal LINQ™ cardiac monitor occurs frequently impacting patient care. Newer generations of the implantable cardiac monitors utilize Bluetooth technology, enabling immediate transfer of data from ICM to a patient's cellular phone and subsequently to their physician's office. This technology could potentially improve efficiency and reliability eliminating the issues of proximity and connectivity.

1. BACKGROUND

Implantable cardiac monitors (ICM) are an invaluable tool for diagnosing cardiac Arrhythmias [1]. Cryptogenic stroke, unexplained syncope and arrhythmia surveillance are the most common indications for implantation of a long term ICM [1-3]. Previous reports of older generation ICMs, demonstrated its benefit in atrial fibrillation (AF) surveillance for patients who underwent AF ablation [2]. The use of ICM has also been established in long term atrial arrhythmia monitoring in patients at risk of atrial fibrillation [4-6]. The CRYSTAL-AF study showed the value of ICMs in detecting occult AF in cryptogenic stroke patients [7]. The benefit of these ICM rests on the ability of physicians to receive timely reports about potential arrhythmias that may not have been detected by traditional means or in an otherwise asymptomatic patient. By implanting a small ICM in patients, physicians are given around the clock cardiac monitoring which can help diagnose disease and dictate management.

While ICMs do provide continuous cardiac monitoring, the data do not always immediately sent a health care provider. Most current ICMs on the market require multiple steps to ensure the transmission of the intracardiac data to a physician's office. Once the ICM has been implanted, the patient also receives an additional external monitor that will assist in delivering the data securely. Medtronic's reveal LINQ ICM functions in this way as data transmission consists of a two-step process. The data is firstly downloaded into the MyCareLink™ monitor on a daily basis at 0200. The MyCareLink™ monitor will then attempt to connect to a 3G cellular network for data transmissions (**Figure 1**). It has been recommended by Medtronic that the MyCareLink™ monitor should be within 6 feet of the patient during the 0200-daily download [8-10]. This reliance on using an external monitor to transmit data is also used in other companies of ICMs including Biotronik's Home Monitoring, Abbot's Merlin@home™ transmitter and Boston Scientific's Latitude Home Monitoring [11-13].

Despite its ability to provide constant cardiac monitoring and their ability to transmit data on a daily basis, no study has been done to explore the timeliness of data transmission from ICMs. The main indications for the implantation of ICMs include life-threatening arrhythmias and any delay in data transmission may have serious consequences. The aim of this study was to investigate the average time from the occurrence of an arrhythmic event to physician notification in a patient with an ICM.

2. METHODS

We retrospectively reviewed the charts of 520 consecutive patients who received a Medtronic Reveal LINQ™ ICM between 2/01/2015 and 6/01/2017 at Sparrow Hospital (Lansing, Michigan, USA). All investigators were in compliance with Sparrow Hospital Institutional Review Board (IRB) regulations. All patients who received an ICM, did so under the latest guidelines for ICM implantation, which includes cryptogenic stroke, arrhythmia surveillance and unexplained syncope [3]. ICM was set to make the reader understand the classification of events. The ICM setting was not adjusted for the indication for ILR implantation. In addition, the device alert detection was set at the nominal setting for all patients. Yellow alert events include pause episodes, patient activated episodes and higher-than-threshold AF/AT more than 6 hours per day.

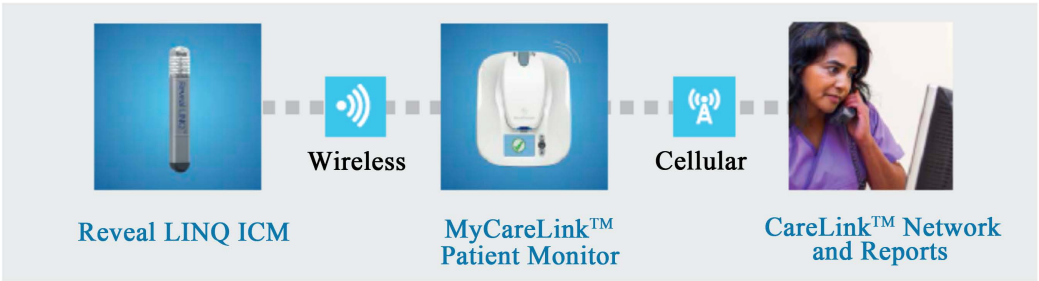

Figure 1. Reveal LINQ working steps; from event detection to health care provider notification.

Data related to time of arrhythmic events or patient activated events, and office notification was collected through Medtronic's MyCareLink™ portal. Any physician action based off of the ICM notification was also recorded based off of EMR (GEMMS and EPIC) analysis. The Reveal LINQ™ device automatically triggers a recording with any pauses over 3 seconds and any tachy-arrhythmia over 200 beats/min. Patients were also instructed to activate a patient triggered recording when they experience any usual cardiac symptoms including any severe lightheadedness, sensation of tachycardia or chest pain [9]. All events, both device and patient triggered, were classified into life-threatening and nonlife-threatening arrhythmias. Life-threatening arrhythmias were defined as pauses over 5 seconds, high-grade AV block over 5 seconds and any tachy-arrhythmias over 220 bpm (Table 1). Non life-threatening events were classified as those events picked up by the device or that were patient activated that did not fall under the definition of life-threatening by our criteria. Atrial fibrillation, one of the most common etiology of stroke that ILR was placed for, was classified as a non life-threatening event. Every ECG striped were also reviewed by authors to ensure that they correctly were identified by the device.

The time between an arrhythmic event and the time of physician's office notification in each patient was calculated and the reason of delay was noted. This was done by comparing the timestamps of generated the arrhythmia recordings within the Medtronic's MyCareLink™ portal with the timestamps of when the recordings were delivered to the physician's office. Any lag time greater than 24 hours was classified as a delay. Any events that were identified as delay was individually assessed for an attributable reason and was documented.

3. RESULTS

We reviewed 520 patients with a mean follow up 14 months. Indication for ILR implantations were cryptogenic stroke, syncope, palpitation and AF management (58%, 29%, 9% and 5% respectively). Twenty-three percent of patients (120/520) had arrhythmic events transmitted through the intracardiac monitor during this period. Of those 120 events, 13 events were classified as a life-threatening event and 107 events were classified as non life-threatening (Figure 2, Table 2). Of those patients with life threatening event, 1 event were patient activated while 12 events were automatically recorded by the device. In the non life-threatening event, 34 events were patient activated and the remaining 73 were recorded automatically by the device (Table 6). Symptom-related patient activations were palpitation, dizziness, syncope and fatigue/shortness of breath (40%, 17%, 9% and 9% respectively).

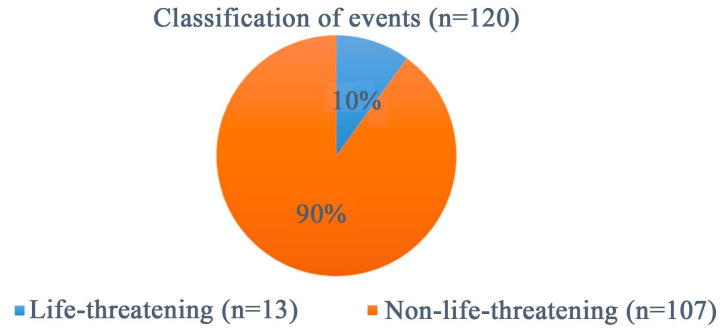

Figure 2. Relative frequencies of events classified by severity (n = 120).

Table 1. Definition of life-threatening events.

Pauses greater than 5 seconds
High Grade AV Block greater than 5 seconds
Any tachyarrhythmias greater than 220 beats per minute

Table 2. **Classification of all events.**

Life-Threatening	13 (10.8%)
Non Life-Threatening	107 (89.2%)
Total Number of Events	**120**

The mean time from all events to physician notification was 15.3 ± 8 days (Table 3). Out of the 120 events, the majority of them were transmitted between 3 - 10 days (40.8%). 35.8% of the events transmitted with a delay longer than 10 days, 1 event taking as long as 95 days. Only 12% all events (14/120) were transmitted without a delay (within 24 hours).

In patients with life-threatening arrhythmic events, the mean duration from event to physician notification was 13.2 ± 6 days (Table 4). Figure 3 shows duration between event and health care provider notification in life-threatening event group. Of the 13 life-threatening events, 2 (15.4%) of them were transmitted without delay, with 38.4% and 30.8% of the events taking between 3 - 10 days and greater than 10 days, respectively. The vast majority of these life-threatening events (84.6%) were identified as pauses greater than 5 seconds in duration (Table 5).

The mean time from patient-activated events to office notification was 18.7 ± 8 days (Table 6) with the shortest being in 1 day and the longest taking 95 days. Of the 35 patient activated events recorded, none of them were triggered within 24 hours, with 7 events (20.0%) taking 1 - 2 days to transmit, 11 events (31.4%) taking 3 - 10 days to transmit and 17 events (48.6%) taking greater than 10 days to transmit (Table 7).

Of all transmitted events, 11.7% (14/120) were delivered without any delay (defined as <24 hours) (Table 7). 66 events were delayed due to the patient not being near the vicinity of the ICM during it regularly scheduled upload time of 0200, while an additional 40 events were delayed due to connectivity issues from the ICM to the 3G cellular network.

Most of the patients having a delay transmission issue eventually received appropriate treatments including catheter ablation, permanent pacemaker/ICD implantation and oral anticoagulation for stroke prevention. Of note, no mortality event was reported in our studied population.

4. DISCUSSION

Implantable cardiac monitor has become the standard of care for evaluating patient with unexplained syncope and arrhythmia and it is also widely used as AF surveillance in patients with cryptogenic stroke [4, 14, 15]. The benefits of having continuous cardiac monitoring with ICMs have been demonstrated among multiple patient groups in different studies [1-3, 7]. This can be attributed to knowing when patients are having arrhythmia related symptoms which can be detected by the ICMs. Being able to diagnose arrhythmias earlier in their clinical course can help dictate and change management for those affected.

This study aimed to demonstrate that despite these advances in being able to monitor patients remotely with ICMs, the data and event reports that are being generated are not being delivered to physicians in a timely manner which can impact patient care. Almost a quarter (23%) of the patients implanted with an ICM had event generated within the observational period in this study. Out of all of these events the average time from event generation to physician notification was greater than 2 weeks at 15.6 days. This delay is even greater when looking at patient triggered events as the average time to physician notification was 18.6 days. This is a particularly troubling statistic as ICMs are commonly implanted to try and correlate patient symptoms with their rhythm. A 3 weeks delay between initial event occurrence and physician notification increases the risk of future episodes occurring without any physician intervention. Perhaps, what is even more concerning is that there is still a major delay of 13.2 days, when life-threatening events are considered. A total of 13 life-threatening events were identified with 9 of them taking longer than 3 days to transmit to the appropriate physician's office. While, most of the events in the study were

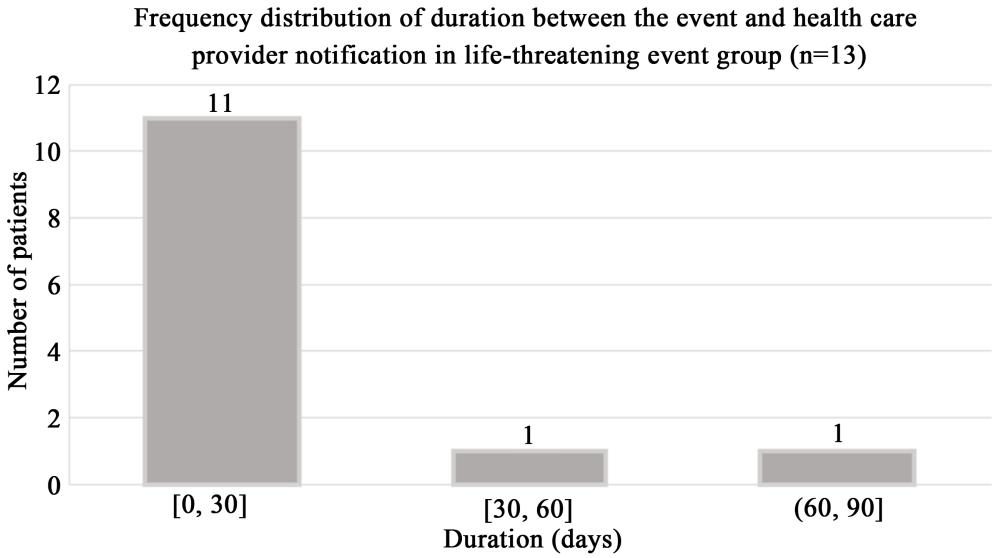

Figure 3. **Distribution of duration from event to health care provider notification in life threatening group (n = 13).**

Table 3. **Notification timing for all events (n = 120).**

Shortest Time till Notification	Within 24 hours
Average # of Days till Notification	15.26 Days
Longest Time till Notification	95 Days

Table 4. **Notification timing for life-threatening events (n = 13).**

Shortest Time till Notification	Within 24 hours
Average # of Days till Notification	13.23 Days
Longest Time till Notification	65 Days

Table 5. **Identification of life-threatening events (n = 13).**

Pauses greater than 5 seconds	11 (84.6%)
High Grade AV Block greater than 5 seconds	1 (7.7%)
Tachyarrhythmias greater than 220 beats per minute	1 (7.7%)
Total Number of Events	**13**

Table 6. **Notification timing for patient activated events (n = 35).**

Shortest Time till Notification	1 Day
Average # of Days till Notification	18.68 Days
Longest Time till Notification	95 Days

Table 7. Notification timing.

	Notification Timing for All Events (n = 120)	Notification Timing for Life-Threatening Events (n = 13)	Notification Timing for Patient Activated Events (n = 35)
Within 24 hours	14 (11.7%)	2 (15.4%)	0 (0.0%)
Duration 1-2 days	14 (11.7%)	2 (15.4%)	7 (20.0%)
3 - 10 days	49 (40.8%)	5 (38.4%)	11 (31.4%)
>10 days	43 (35.8%)	4 (30.8%)	17 (48.6%)
Total Number of Events	**120**	**13**	**35**

transmitted within 3 - 10 days of initial event occurrence, there was still a large proportion of events (35.8%) that took longer than 10 days. With only 14 (11.7%) events being transmitted within 24 hours; the vast majority of events had a delay in data transmission.

The two main issues with data transmission were identified as connectivity trouble between the ICM and the 3G cellular network, as well as the patient not being in the vicinity of the ICM during the regular upload time 0200. Connection issues could be explained in part if patients either live far away from major cellular towers to connect or conversely if patients live in a highly dense population with tall buildings blocking the ability of the ICM to find an adequate signal. Patients who fail to connect during the early morning upload times could be due a number of reasons including patients who work at night, patients going on vacation and leaving their ICM behind or patients simply not being at home during the scheduled download time.

Few data are available for the interval of interest provided by ILR. Furukawa and colleague study the efficacy and acceptance of remote monitoring in the management of patients with syncope and palpitation with ILR. They found that the mean time between implantation to the first true EKG-related event was 28 ± 49 days. This study did not provide the data regarding time of the event to health care provider notification which is the information that we aim to study [16]. We believe that the duration in our study directly represented greater clinical implication than prior studies. What clinicians really want to know is how long does it take from the actual event, not at the time of implantation, to their recognitions.

There are few different feasible techniques that may help patient transferring the data in case of failure to connect. Firstly, patient should be provided contact person or office in case of urgent situation requiring data transmission to figure out what was happening but connection failure occurred. Secondly, patient should be educated to be familiar with the system and its troubleshoot if some technical issue occurs. The alerting system if any issues arise with the device data transmission lead the patient to seek medical attention would also help the problem to be solved sooner. This is the way ICD or Pacemaker patients usually get a troubleshooting from any kind of device malfunction. Finally, patient education to realize which symptoms are really needed to be evaluated by emergency physician as soon as possible rather than waiting to contact the officer to solve connection problem. We believe these basic tools, mainly with patient education, would help patients to get access a timely medical care and prevent any unwanted events.

Over the past decade, multiple cardiac monitoring devices have been released. Accuracy and rapid detection are paramount qualities to this device. Consistent data demonstrated an increased diagnostic yield for unexplained syncope by these long-term cardiac monitoring devices [3]. However, these benefits may be lost when the data transmission to physicians is severely delayed. Given the limitations in the current generation ICMs with their requirement to have an additional external monitor and its reliance on a 3G cellular network, a significant number of events can still take weeks for a physician to be notified. The results of our study confirmed a similar pattern of duration between events to health care provider across all subgroup of patients which include the non life-threatening event group, the life-threatening event

group and patient-activated group. These imply that patient factors do not contribute to this delay in data transmission.

5. STUDY IMITATIONS

There are several limitations that we acknowledge within the study. Although our study represents the first real-world and large study population looking into the ICM transmission data, the study was conducted at a single center facility which may reduce the ability to generalize the data to a broader population. Additionally, only one brand of ICMs was studied, specifically Medtronic's MyCareLink™ monitor which may not be entirely reflective of general transmission times across all patients with different brands of implantable cardiac monitors. The data that was collected implies that all events that occurred were actually transmitted. The number of events that transmitted may in fact be an under representation as some patients who do not transmit at all during the observational period would have been missed entirely and not included in the final counts. Further studies are needed to assess if the delay in data transmission is an industry wide problem and future directions should be focused on how we can decrease that gap [17-19].

6. CONCLUSION

Over the past decade, technological advancements in the cardiac rhythm management industry have provided physicians with more tools than ever to help diagnose and treat potentially fatal arrhythmias. The ability for devices to not only rapidly and accurately detect arrhythmias is crucial but their efficiency in getting that information in the hands of a clinician is also paramount in its value. Our study is the first to show a surprisingly significant delay in data transmission from Medtronic Reveal LINQ™ cardiac monitor to physician notification which may impact patient care. Newer generations of implantable cardiac monitor utilize Bluetooth technology transferring data from ICM to patient phone and subsequent transmission to physicians which could be one of potential solutions to improve reliability. Further clinical studies are necessary to compare the efficiency of data transmission between companies and identify ways to reduce this lag time.

AUTHORS' CONTRIBUTIONS

All authors had access to the data and a role in writing the manuscript.

COMPLIANCE WITH ETHICAL STANDARDS

Funding: This study was not funded by any grant.

Ethical approval: For this type of study, formal consent is not required. This article does not contain any studies with human participants performed by any of the authors.

CONFLICTS OF INTEREST

Dr. John Ip has received research grants from St. Jude Medical, Medtronic and Biotronik. Dr. John Ip has received a speaker honorarium from St. Jude Medical. Other authors declare that they have no conflict of interest.

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