Frequency of CIED Remote Monitoring: A Quality Improvement Follow up Study

SHORT TITLE: Frequency of CIED Remote Monitoring

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Ms Dechert: designed the research concept/study, performed analysis and interpretation of the data, drafted the paper and approved of the final version

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Abstract:

Background: Based on the findings of a prior study of CIED (Cardiac Implantable Electrical Device) remote monitoring (RM) frequency at the same center, the University of Michigan Congenital Heart Center (UMCHC) instituted a quality improvement (QI) change to reduce the frequency of routine CIED RM from every 2 months to every 3 months. The objective of this study is to determine the impact of this QI initiative to reduce workload without compromising patient care.

Methods: This is a single center retrospective cohort study of all UMCHC patients with CIEDs followed via Medtronic CareLink CIED remote monitoring system from July 2015-June 2017; after the QI change in 2014. The primary outcome was success of transition to new monitoring schedule. Secondary outcomes included complications, incidence of actionable events (AES), patient compliance, and change in workload. Outcomes were compared to the prior study.

Results: There were 325 patients (mean age was 24 ± 14 years) included, of which 293 (90%) completely transitioned to the new RM schedule. During the study period 96 transmissions included AES (4% of total), of which 50 (52%) were asymptomatic and discovered on routine monitoring. No patient experienced a complication attributable to decreased RM frequency. The mean number of interrogations decreased by 1.6 per patient over the 2-year period compared to prior study.

Conclusions: This study demonstrated successful implementation of a QI initiative to reduce CIED monitoring frequency at a single center with no patient adverse events. The intervention reduced workload and potentially improved patient compliance with routine RM.

Key words: Pediatric

Remote monitoring of CIED

Quality improvement

Abbreviations:

CIED: cardiac implantable electronic devices

ERI: Elective replacement indicator

Introduction:

Based on remote monitoring guidelines[1], in 2014 the University of Michigan Congenital Heart Center instituted a change in the frequency of cardiovascular implantable electronic device (CIED) remote monitoring from an every 2-month schedule to an every 3-month schedule. This study published in the *Heart Rhythm Journal* by Dechert et al.[2] showed that the rate of actionable events, defined as requiring a clinical intervention, remained low with the change in schedule for both newly implanted and chronic devices. The goals of this change were to improve the quality of care by reducing workload without compromising patient care. Presented here is an assessment of the impact of that quality improvement change on workload and patient care.

Methods:

This is a retrospective cohort follow up study of all CIED patients followed between July 2015 and June 2017 at the University of Michigan Congenital Heart Center and enrolled in the Medtronic CareLink remote monitoring system. Patients without any remote monitoring transmissions were excluded from the study. This study was approved by the University of Michigan Medical School Institutional Review Board.

Patient and CIED data were collected from the medical records and from the Medtronic CareLink system by individual review of every in-office device interrogation and remotely monitored transmission obtained during the study period. Definitions of the types of transmissions were the same as the prior study[2]. Routine (i.e asymptomatic) CIED remotely monitored transmissions were scheduled to occur every 3 months and were considered compliant if received within 2 weeks before or after the scheduled date. Interrogations were also considered routine if the clinical team requested an early follow up interrogation based on prior clinical concerns. Symptomatic interrogations included any (remote or in-office) interrogation that was performed specially for patient symptoms. Non-routine remotely monitored transmissions were those that were sent in prior to the expected interval without reported symptoms.

The primary quality improvement outcome was successful implementation of the remote monitoring schedule change. Secondary outcomes included complications, incidence of actionable events - defined as CIED findings resulting in any clinical intervention, change in workload and patient compliance when compared to prior study[2]. Overall compliance was defined as the number of transmissions expected in 1 year, less those not sent by the patient divided by the total number expected. A routine transmission was considered "missed" if not received between 2.5 to 3.5 months after the prior. Data were compared to those from the previous study[2]. Statistical analysis included T-test for continuous variables and Chi-square for categorical variables.

Results:

There were 325 patients analyzed, having 2408 total CIED in-office interrogations or remotely monitored transmissions. There were 293 (90%) patients successfully transitioned to the new remote monitoring schedule; the remaining 30 (10%) remained on more frequent monitoring for at least part of the study period, and 2 never transitioned. Reasons for more frequent monitoring included 21 (65%) patients whose devices were nearing elective replacement (ERI), 7 (2%) for closer arrhythmia monitoring, and 2 (13%) for other clinical reasons. Two patients did not transition due to

significant anxiety surrounding the proposed change. Table 1 shows the demographic information and interrogation summary data from both the original study[2] and current data.

Actionable events: Actionable events were identified in 96 (4%) of the total interrogations (remotely monitored and in-office). Table 2 shows the type of actionable event including arrhythmia, device/lead malfunction and reaching elective replacement indicator (ERI) when compared to the prior study[2]. Of the 96 actionable events, 50 (52%) were noted on asymptomatic/routine remotely monitored transmissions, 36 (38%) were associated with symptoms and 10 (10%) were discovered on wireless/automatic transmissions. Incidence of and percentage of interrogations showing CIED at ERI was higher in the current study than the prior (Table 2).

Workload: Considering both in-office interrogations and remotely monitored, the mean decrease in total transmissions for all patients was 1.6 interrogations per patient over the 2-year study period (p value <0.0001 (95% CI 0.837-2.363).

Compliance: Compliance improved with the change in frequency of the remote monitoring schedule and is shown in table 3.

Discussion:

The primary goal of this study was to evaluate the successful implementation of a change in the frequency of CIED surveillance monitoring in a single center, implemented as a quality improvement initiative. This study showed that 90% of patients successfully transitioned to the new schedule. Failure to transition to the new schedule was most commonly due to recommendation by the clinical team for more frequent monitoring. Despite education and reassurance, 2 patients could not transition due to significant anxiety related to concerns with less monitoring.

Importantly, the decreased frequency of CIED monitoring was not associated with any significant increase in complications or actionable events. The intended benefit of this change was decreased staff/provider work effort dedicated to processing, reviewing, interpreting and documenting normal

and unnecessary remotely monitored transmissions, as well as improved patient compliance with surveillance. Data from the comparative prior study[2] showed a low rate (4% of overall transmissions) of actionable events identified by routine CIED remote monitoring. The current study continues to show a low rate of (2.5% of overall transmissions), and no increase in, actionable events; and most importantly – no recognizable complications from actionable events while on the reduced frequency monitoring schedule. The majority of the actionable events were due to arrhythmia requiring treatment or devices reaching elective replacement. The notable increase in percentage of interrogations showing ERI is likely due to 2 factors: 1) a greater incidence by chance of CIEDs reaching ERI during the study period; and 2) the decreased monitoring frequency would have necessarily decreased the denominator of CIEDs not at ERI, and thereby increased the percentage at ERI. Of the 96 actionable events, only 20 (20%) were related to device or lead malfunction and of these, 6 required revision. None were in device dependent patients or were life threatening.

Remote monitoring of CIEDs has been shown to decrease resource utilization of healthcare personnel in several large adult trials[3,4]. Despite the ease with which patients send remote interrogations, the amount of data produced from these reports is extensive. The time for staff to download and prepare these reports, follow up with patients via telephone, and providers to interpret these reports is significant and requires dedicated resources. Practices with a large number of devices are challenged to develop efficient processes for remote monitoring services because of the volume of data received[5]. Goals to balance high efficiency and high quality care can be challenging. A systematic approach focused on efficiency can decrease resource utilization, yet minimize impact on patient care[6]. This study highlights such an ongoing effort.

Based on our center's experience, it is estimated to require 15 minutes to process each normal remotely monitored transmission, which includes staff and physician time for processing, interpreting, reporting and patient notification. The reduction of a mean of 1.6 transmissions per

patient in this cohort therefore results in reduction of work load of 130 hours (15 minutes per report multiplied by the decrease in 1.6 interrogations per 325 patients) over the 2-year study period. The actual magnitude of decrease in remotely monitored transmission frequency was lower than expected, however. It was expected that CIED monitoring interrogations for patients should have decreased by a total of 4 in the 2-year period, with the decrease in frequency of remotely monitored transmissions. The reasons for this shortcoming in reduction was not achieved are likely multifactorial. First, 10% of the patients did not successfully transition to the new schedule either because of clinical concerns (ie arrhythmias, lead/device concerns, nearing ERI), or patient or provider resistance to the change. It is speculated that anxiety could have played a role with the increase in "non-routine yet asymptomatic tracings" compared to the prior cohort. Post-hoc analysis of the data did not show a difference when comparing the first year versus the second year of the study regarding number of non-routine sends. As familiarity with the new schedule increases, these non-routine remotely monitored transmissions are likely to decrease further. In addition, increasing availability of wireless/automatically transmitted data will alleviate physician and patient concerns. Further education and discussion with the patient prior to and during the change in schedule may also help alleviate anxiety. Second, patients are frequently encouraged by telephone triage personnel to send transmissions for a variety of complaints, including many highly unlikely related to their CIED. Secondary data collected in this quality initiative follow up assessed the symptoms associated with the transmissions and will feed back into the monitoring process to reduce these unnecessary remotely monitored transmissions.

Current guidelines[1] recommend device interrogation (remotely or in person) every 3–12 months for pacemakers and 3-6 months for ICDs. Based on these, a less frequent than every 3-month schedule would be acceptable and may be implemented in the future. However, the optimal monitoring schedule is likely dependent on individual patient parameters. One key to successful further reduction in monitoring frequency will be to fully define those risk factors that lead to asymptomatic

or serious actionable events, and assigning more frequent monitoring to those patients only. Future improvements in automated monitoring and transmission of abnormalities to the provider will also make routine transmissions obsolete.

Limitations:

This is a retrospective study, and patient symptoms and reason for sending remotely monitored transmissions were assessed from documentation in the medical record, which may not have been complete. This study and the prior were limited to patients enrolled in the Medtronic CareLink system because these patients constitute the majority of the patients followed by the University of Michigan Congenital Heart Center. In addition, this study compares to a prior study which only used patients in the Medtronic CareLink system. Patient compliance has improved but still remains suboptimal and may have affected the timing of symptoms and interventions needed.

Conclusions:

This study demonstrates the successful implementation of a quality improvement initiative to reduce CIED monitoring at a single center without demonstrable complications or negative effects on the patient population. This intervention potentially improved patient compliance with routine remote monitoring. Despite successful implementation of the intervention, the magnitude of effect was less than expected, demonstrating that quality improvements, such as this, may take extended time to fully be realized.

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Table 1: Patient and remote monitoring data (comparison)

Data	Prior Study (every 2 month)	Current Study (every 3 month)	p value
Total number of patients	286	325	
Congenital heart disease	196 (69%)	220 (68%)	
Wireless device	33 (12%)	83 (27%)	p=<0.0001
Age	21±13 years	24±14 years	p=0.006
Total number of interrogations	2614	2408	
In office	792 (28%)	711 (29%)	
Remote monitoring transmissions	1822 (70%)	1697 (70%)	
Routine/Asx	1441 (79%)	1164 (67%)	p=<0.0001
Nonroutine/Asx	229 (13%)	346 (20%)	p=<0.0001
Symptomatic	144 (8%)	167 (10%)	p=0.038
Wireless alert	8 (0.4%)	20 (1%)	p=<0.0001
Interval between transmission/patient	65.4±61.4 days	99±103 days	p=<0.0001
Mean remotely monitored transmission/patient	6±6	5±3.9	p=0.014
Mean in-office interrogations	3±2	2±1	p=<0.0001

*Data presented in total (%) or Mean (SD)
†p values >0.2 not listed

Table 2 Actionable Events (comparison)

Actionable events	Prior Study (every 2 month)	Current Study (every 3 month)	p value
Total	129 (5%)	96 (4%)	
Arrhythmia	66 (47%)	35 (36%)	p=0.1
Device/lead malfunction	37 (37%)	20 (20%)	p=0.36
Elective replacement indicator	26 (23%)	41 (43%)	p=<0.0001

*data presented in total (%)

Table 3: Compliance Data (comparison)

Compliance Data	Prior Study (every 2 month)	Current Study (every 3 month)	p value
Never missed a transmission	21 (7%)	53 (18%)	p=0.0002
Overall compliance (total expected –missed/total expected)	166 (58%)	244 (75%)	p=<0.0001

*data presented in total (%)