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DEVICES

The impact of CIEDs with automatic "wireless" remote monitoring on efficiency

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Abstract

Background: A benefit of automatically transmitting or "wireless" CIEDs (W-CIED) is the prompt detection of device malfunction and arrhythmias. We hypothesized that the use of W-CIEDs would improve the efficiency of remote monitoring by decreasing unnecessary CIED remote transmissions because of the automatic detection of abnormalities.

Objective: To compare the frequency of patient-initiated transmissions in patients with W-CIEDs versus non-wireless CIEDs (NW-CIED) at a single pediatric and congenital heart center.

Methods: Retrospective cohort study of patients with W-CIEDs followed over a 2-year period compared to a similar cohort of patients with NW-CIED. All CIED remote transmissions during were reviewed for indication and outcome.

Results: The W-CIED cohort had 87 patients; mean age 20 ± 13 years; NW-CIED cohort had 220 patients; mean age 22 ± (13) years. The mean number of symptomatic patient-initiated transmissions per patient was 0.93 ± 2.65 in the W-CIED cohort versus 0.39 ± 0.64 in the NW-CIED cohort ($p \leq .001$). The mean number of asymptomatic patient-initiated transmission sent per patient in the W-CIED cohort was 1.86 ± 2.59 versus 0.81 ± 1.41 in the NW-CIED cohort ($p \leq .0001$). Type of device, age, and presence of congenital heart disease were not significantly associated with the incidence of patient-initiated remote monitoring transmissions.

Conclusions: The frequency of patient-initiated transmission was higher in the W-CIED cohort, contradictory to the study hypothesis. This may reflect a lack of patient understanding of the benefit or functionality of W-CIEDs and may be mitigated by education to both providers and patients.

KEYWORDS
automated "wireless" remote monitoring, efficiency, implantable cardioverter defibrillator, pacemaker, pediatrics, remote monitoring

Abbreviations: CHD, congenital heart disease; CIED, cardiac implantable electronic device; ICD, implantable cardioverter defibrillator; ILR, implantable loop recorder; NW-CIED, "non-wireless" cardiac implantable electronic device; PAS, primary arrhythmia syndrome; RMT, remote monitoring transmission; W-CIED, "wireless" or automatic cardiac implantable electronic device

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1 | INTRODUCTION

Remotecardiac implantable electronic device (CIED) monitoring has evolved since it was introduced in 1971 from transtelephonic monitoring, to a patient-initiated, wand-based radiofrequency system, to the current system, which is fully automated and "wireless." With transtelephonic monitoring, a patient and recipient had to be present at a scheduled time to send and receive data. Radiofrequency wand monitoring allows for comprehensive data to be sent to a central repository and reviewed at any time but requires patient initiation of transmission either at scheduled time or with perceived concerns/symptoms. Although an improvement, asymptomatic device malfunction or arrhythmias could remain undetected until the next scheduled routine remote monitoring transmission, which is recommended every 3 months.[1]

With the introduction in the early 2000′s, automatic or "wireless" remote monitoring of CIEDs has significantly improved remote monitoring. The advantage of automatic remote monitoring is freedom from scheduling a specific time with provider and earlier detection of device or lead malfunction with automatic notifications to the provider team including battery status alerts, device/lead malfunction alerts and arrhythmia alerts.[2–6] Patients can continue to initiate manual remote monitoring transmissions (RMT) with symptoms or concerns. The burden on staff and physicians to interpret transmissions can be significant as there a large amount of data to review with each transmission, any reduction in unnecessary remotely monitored transmissions reduces work load, and in turn improves efficiency.[7] We hypothesized that the use of automatic or "wireless" CIEDs (W-CIED) would decrease unnecessary – defined as patient initiated transmissions with normal findings – CIED remote transmissions because of the automatic detection of abnormalities and real-time communication with the provider team.

2 | METHODS

This is a retrospective cohort study of patients with a wireless pacemaker or an implantable cardioverter defibrillator (ICD) followed over a 2-year period (2016-2018) at the University of Michigan Congenital Heart Center and enrolled in a manufacturer's remote monitoring program (Medtronic Carelink, Boston Scientific Latitude or St. Jude Merlin), compared to a cohort of patients followed during a similar time frame (2015-2017) with non-automatic or "non-wireless" CIED (NW-CIED) also enrolled in a remote monitoring program. This study was approved by the University of Michigan Medical School Institutional Review Board.

The primary outcome of interest was the frequency of patient-initiated transmissions. Each remote monitor transmission received during the study period, and relevant medical record was reviewed by a certified cardiac device specialist (BED) to determine if the transmission was initiated by the patient or sent "automatically" due to device or provider initiation. For purposes of the study, device/provider-initiated transmissions were defined as those sent automatically by the device due to detected abnormalities or for provider requested follow-up including routine scheduled surveillance (i.e., every 3 months). Patient-initiated transmissions were defined as those not scheduled by the medical team. These were categorized as asymptomatic or symptomatic transmission based on review of medical record documentation. An asymptomatic patient-initiated tracing had no identifiable patient symptom or concern documented or reported. A symptomatic patient-initiated transmission was associated with any documented symptom or concern from the patient. Symptoms were subjectively defined by the patients and varied widely – ranging from clear cardiac or device related symptoms to completely unrelated symptoms. For purposes of the study, the key feature of a symptom or concern was that it triggered the patient to send in the remote transmission; symptoms were not otherwise qualified. Patients were excluded if there were no remote monitor transmissions within the 2-year study period.

The typical clinical workflow for receiving and processing RMTs at the study institution includes reception and initial review of the transmission by a dedicated remote monitoring coordinator. Patients are contacted by phone whenever possible to elucidate the reason for the transmission when it is patient initiated. The transmission report and any relevant clinical data received from the patient are then communicated to the provider team for further management. An analysis of the effect of independent variables including type of device, patient age during the study period, and presence of congenital heart disease (CHD) on frequency of patient initiated remote monitoring for the wireless group is also included. Statistical analysis included t-test for continuous variables and chi-square analysis for categorical variables.

3 | RESULTS

There were a total of 307 pediatric or CHD patients included in the study- 87 patients in the wireless/automatic CIED (W-CIED) group and 220 patients in the NW-CIED group. In total, 2379 interrogations were reviewed, with analysis limited to the 1750 remote monitoring transmissions after removal of in-office device interrogations. Patient demographics and diagnosis by group have been summarized in Table 1. Notably, the percentage of non-CHD patients and ICD patients is higher in the wireless cohort.

Comparative device data between the two groups related to patient initiated RMTs are summarized in Table 2. These results are most notable for the higher frequency of patient-initiated transmissions in the W-CIED cohort, particularly the mean number of asymptomatic transmissions, which more than doubled in the W-CIED group. The frequency of an any abnormal result (typically arrhythmia or elective replacement indicator) from RMTs was higher in the non-wireless group compared to the wireless group.

Univariate analysis did not identify type of device (pacemaker versus ICD) ($p = .36$), patient age (< 18 years vs. > 18 years) ($p = .4$), or the presence of congenital heart disease ($p = .34$) as significantly associated with the frequency of patient-initiated RMTs.

TABLE 1 Patient demographics

Demographics	Wireless devices	Non-wireless devices
Patients	$n = 87$	$n = 220$
Age	20 ± 13 years	22 ± 13 years
Presence of CHD	39 (45%)	168 (76%)
Pacemaker	26 (29%)	219 (99%)
Heart block	20 (77%)	151 (69%)
Sinus node dysfunction	6 (23%)	63 (29%)
Other	_	5 (2%)
ICD	61 (70%)	1 (1%)
PAS or cardiomyopathy	36 (59%)	1 (100%)
CHD related arrhythmia	21 (34%)	_
Other	4 (7%)	_

Count (%) or Mean (±SD).
Abbreviations: CHD , congenital heart disease; PAS, primary arrhythmia syndrome (i.e., Long QT syndrome, CPVT, etc.).

TABLE 2 Device interrogation data

Device Data	Wireless Devices	Non-Wireless Devices	*p* value
Total Transmissions/interrogations[a]	904	1475	
Total # Remote monitor transmissions (RMT)	756 (83%)	994 (67%)	<.001
Total # of symptomatic RMTs	41 (11%)	85 (9%)	.13
Mean # RMTs per patient[b]	8.7 ± 5.7	7 ± 4	<.001
Symptomatic	0.93 ± 2.65	0.39 ± 0.64	<.001
Asymptomatic	1.86 ± 2.59	0.81 ± 1.14	<.001
Abnormality[c] noted on RMT	46 (6%)	93 (9.4%)	.0124

Count (%) or Mean (±SD).
[a]Includes in office interrogations.
[b]Mean (± SD) number of transmissions per patient for each category.
[c]Abnormality defined as any abnormal rhythm or device/lead malfunction.

4 | DISCUSSION

Efficiency is the ratio of useful input to total output. By decreasing the number of unnecessary RMTs, this ratio changes and leads to less workload overall improving efficiency in the device clinic. In this study, the mean number of symptomatic and asymptomatic patient-initiated transmissions per patient was significantly higher in the W-CIED cohort compared to the NW-CIED cohort, resulting in an overall higher frequency of RMTs that required review. Asymptomatic patient initiated RMTs are most likely unnecessary yet still require the same amount of work. Contradictory to the expectation that W-CIEDs would decrease patient initiated transmission, this study found that patient-initiated transmissions actually increased, thereby decreasing the efficiency of monitoring.

Automatic or "wireless" devices provide constant surveillance for lead/device malfunction or arrhythmia which should provide reassurance to families that their device is being closely monitored. In fact, the wireless group had a lower frequency of abnormality noted on remote monitoring transmissions despite sending a higher mean number of transmissions per patient. Families/patients may not recognize the constant surveillance because it does not require a patient to initiate the transmission. This could lead to anxiety or worry that the device is not being monitored and potentially be the cause of an increase in patient initiated and asymptomatic remote monitoring transmissions. Communication confirming data was received and the result is also essential for understanding and reassurance for the family. This type of telemedicine may add time to daily workload but in the long run will lead to higher quality patient care and better patient understanding of device function.[8] One key point of education during these encounters may be to review the tone/vibration alerts programmed for the device, which may remind the patient of these automated features.

Targeted patient/family education on the purpose, scope, and capabilities of wireless devices may lead to a decrease in the number of patient-initiated transmissions including asymptomatic transmissions. A recent study on improving the efficiency of implantable loop recorder (ILR) wireless remote monitoring focused on patient and provider

education as a means to reduce unnecessary transmissions.[9] Education about the purpose of devices with automatic remote monitoring was provided in clinic visits as well as with follow up phone calls. Improvements were made to written education that patients could continue to reference even at home. This change in workflow required a large investment of time up front but resulted in decreased unscheduled transmissions and overall improved efficiency of ILR remote monitoring.[9] A similar focus on patient and provider education related to pacemakers and ICDs will likely lead to a better understanding of the functionality of wireless monitoring which in turn could decrease the frequency of unnecessary transmissions.

Patient and family anxiety could be an explanation for unnecessary patient-initiated transmissions. ICDs, in particular, have been associated with anxiety, especially in patients who have experienced an ICD shock.[10] In this study, there were more ICDs in the wireless cohort. It could be the case that these patients may need more reassurance and may require more frequent monitoring, however this study did not demonstrate an association between the type of device and number of patient-initiated transmissions. Likewise, neither presence of CHD nor the patient being a young child led to an increase in frequency of patient-initiated transmissions. Even with a decrease in overall scheduled transmissions in a 2-year period, there was no increase in adverse events in a recent pediatric study,[7] suggesting that improved patient education and further reassurance of the capabilities of wireless devices may be helpful for all types of patients with pacemakers or ICDs. Education on the low frequency of abnormality found on RMTs may also help to decrease anxiety.

5 | LIMITATIONS

This is a retrospective study and patient symptoms and reason for sending RMTs are based on documentation from the medical records which may not be complete. This is a single-center study and may not be representative of all pediatric and CHD patients.

6 | CONCLUSIONS

Automatic or "wireless" CIEDs permit comprehensive CIED surveillance without patient intervention. Yet, this study found that the frequency of patient-initiated transmissions was higher in the W-CIED group compared to the NW-CIED group, contradictory to the study hypothesis. In addition, the frequency of abnormality's detected on remote monitoring was lower in the wireless-CIED group compared to the non-wireless group. We propose that these results may reflect a lack of patient understanding of the benefit or functionality of wireless monitoring, which could be mitigated by education to both providers and patients. Education intervention and future research on patterns of CIED remote follow up may be necessary to improve efficiency.

AUTHOR CONTRIBUTIONS

Ms Brynn Dechert was responsible for the concept/design, data collection, analysis and interpretation, drafting article, critical revision of article, and approval of article. Dr Martin LaPage was responsible for data analysis and interpretation, critical revision of article, approval of article and statistics. Dr David Bradley was responsible for critical revision of the article and approval of article. Dr Gerald Serwer was responsible for critical revision of the article and approval of article.

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