Data deluge from remote monitoring of cardiac implantable electronic devices and importance of clinical stratification



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BACKGROUND Remote monitoring (RM) has been accepted as a standard of care for follow-up of patients with cardiac implantable electronic devices (CIEDs). However, the resulting data deluge poses major challenge to device clinics.

OBJECTIVE This study aimed to quantify the data deluge from CIED and stratify these data based on clinical relevance.

METHODS The study included patients from 67 device clinics across the United States being remotely monitored by Octagos Health. The CIEDs included implantable loop recorders, pacemakers, implantable cardioverter-defibrillators, cardiac resynchronization therapy defibrillators, and cardiac resynchronization therapy pacemakers. Transmissions were either dismissed before reaching the clinical practice if they were repetitive or redundant or were forwarded if they were either clinically relevant or actionable transmission (alert). The alerts were further classified as level 1, 2, or 3 based on clinical urgency.

RESULTS A total of 32,721 patients with CIEDs were included. There were 14,465 (44.2%) patients with pacemakers, 8381 (25.6%) with implantable loop recorders, 5351 (16.4%) with

implantable cardioverter-defibrillators, 3531 (10.8%) with cardiac resynchronization therapy defibrillators, and 993 (3%) with cardiac resynchronization therapy pacemakers. Over a period of 2 years of RM, 384,796 transmissions were received. Of these, 220,049 (57%) transmissions were dismissed, as they were either redundant or repetitive. Only 164,747 (43%) transmissions were transmitted to the clinicians, of which only 13% (n = 50,440) had clinical alerts, while 30.6% (n = 114,307) were routine transmissions.

CONCLUSION Our study shows that data deluge from RM of CIEDs can be streamlined by utilization of appropriate screening strategies that will enhance efficiency of device clinics and provide better patient care.

KEYWORDS Data deluge; Cardiac implantable electronic device; Remote monitoring; Remote transmissions; Alerts; Efficiency

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Introduction

Remote monitoring (RM) has been accepted as standard of care for follow-up of patients with cardiac implantable electronic devices (CIEDs) and has a class 1 recommendation in all major guidelines. He are RM has seen a logarithmic growth since the COVID-19 pandemic, with up to 63-fold increase in Medicare telehealth utilization had 555% increase in RM as compared with prepandemic times. Rapid growth of RM has brought a paradigm shift in the management of patients with CIEDs and has resulted in improved patients'

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safety and convenience, reduced overall cost, and improved patient satisfaction. ^{10–12} The overall impact and benefits of RM have established it as an essential component of healthcare delivery in the 21st century, which will continue to grow in volume in the future. ¹³

While RM of CIEDs is convenient and cost-effective and improves patient outcomes, it poses several challenges. ^{12,14,15} Some of the major challenges include poor connectivity to remote monitors especially in rural or remote areas, data security, integration with electronic medical records, device clinic staffing issues, and large volume of alerts. ^{16–18} The purpose of this study is to objectively quantify the number of transmissions from the RM of CIEDs, classify these transmissions based on their urgency, and propose a systematic approach to improve triaging these transmissions in order to reduce the data deluge.

KEY FINDINGS

- The retrospective study included 32,721 patients with cardiac implantable electronic devices being monitored remotely at 67 device clinics across the United States.
- Transmissions either were dismissed before reaching the clinical practice if they were repetitive or redundant or were forwarded if they were clinically relevant or an actionable transmission (alert).
- The alerts were further classified as level 1, 2, or 3 based on clinical urgency. Over a period of 2 years, 384,796 transmissions were received, of which 220,049 (57%) were dismissed.
- Only 167,747 (43%) transmissions were transmitted to the clinicians, of which only 13% (n = 50,440) had clinical alerts.

Methods Study data

The study included remote transmissions from all CIEDs from 67 device clinics throughout the United States, monitored by Octagos Health (Houston, Texas)—a private thirdparty platform that provides RM solutions to several device clinics in the United States. Transmissions from RM received from April 24, 2020, to June 30, 2022, were included in the study. The CIEDs included implantable loop recorders (ILRs), pacemakers, implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy defibrillators (CRT-Ds), and cardiac resynchronization therapy pacemakers (CRT-Ps). De-identified data were obtained from the data repository of Octagos Health. The study was deemed exempt by the Institutional Review Board committee and patient consent was waived because of de-identified data. The research reported in this article adhered to the Helsinki declaration as revised in 2013.

Remote transmission workflow and statistical analysis

Data from RM of CIEDs consisted of routine transmissions and alert transmissions. Routine device transmissions were scheduled every 91 days for ICDs and pacemakers and every 31 days for ILRs. Routine transmissions for heart failure status from ICDs/CRT-Ds were transmitted every 31 days. The frequency of routine device transmissions was in accordance with the recommendations from the 2015 Heart Rhythm Society expert consensus statement and Center for Medicare and Medicaid Services guidelines. Octagos Health had limited access to medical history of the enrolled patients, which included presence of a left atrial appendage closure device as well as medications including anticoagulants. The alert transmissions from the CIEDs were transmitted as they were generated. All transmissions were initially reviewed by a team of technicians who were employed by Octagos Health located at a core study center based in Houston, Texas. The technicians were certified by International Board of Heart Rhythm Examiners, who verified, classified, and prioritized these transmissions and forwarded them to the respective device clinics for review and confirmation. Additionally, at random, 15% of the transmissions were reviewed for accuracy by a board-certified electrophysiologist. Moreover, a board-certified electrophysiologist was available for correct adjudication of the transmissions on a daily basis in case of lack of clarity from International Board of Heart Rhythm Examiners—certified technicians. Descriptive statistics were performed on SPSS, version 28 (IBM Corporation, Armonk, NY). Categorical variables are described as a percentages.

Device setting at baseline

Outside of customer-specific specifications or exceptions, all devices of the same type across all vendors are programmed to a standardized nominal. Alert settings for ILRs are programmed in the vendor portals in an attempt to filter out clinically irrelevant data while maintaining patient safety.

All critical alerts for device functionality (battery status, device reset occurrence, etc.) are programmed "on," along with alerts for arrhythmia detection including pauses and high ventricular rates. Alerts for the detection of atrial fibrillation (AF) and bradycardia are programmed based on indication for implant/monitoring and vary based on duration and/or rate thresholds.

In a similar way, alert settings for permanent pacemakers/ CRT-Ps and ICDs/CRT-Ds are programmed with alerts "on" for those parameters monitoring device, battery, and lead functionality/integrity. The following device-specific settings (on/off) vary based on clinic preferences: for pacemakers, the settings are % right ventricular (RV) pacing, mode switch episode duration, mean ventricular heart rate; for defibrillators, the settings are % RV pacing, mode switch episode duration, mean ventricular heart rate, and nonsustained high ventricular rate events detected outside of programmed ventricular fibrillation zone; and for CRT/ biventricular devices, the settings are % biventricular pacing, mode switch episode duration, and mean ventricular heart rate.

Categories of alerts from CIEDs and their escalation

An alert was defined as an abnormal transmission either due to arrhythmia or other device-related issues. The alert transmissions were broadly categorized into 3 categories based on urgency: level 1, 2, or 3. If the alert was legitimate and not noise then it was categorized as follows.

Level 1 alerts were defined as alerts that did not need any clinical action or intervention at the time of receiving the transmission—for example, any rate-controlled AF recorded on a device in a patient who was already on oral anticoagulation or had a left atrial appendage closure device in place. These were forwarded as routine notification to the RM team in the clinics.

Table 1 Definitions of the alerts

Table 1 Level 1 Level 2 Level 3

Common to all devices

- AF/AFL recorded on device that is rate controlled in a patient who is already on OAC or with LAAC in place
- Tachycardia: sinus tachycardia, frequent SVTs in a patient with h/o SVTs
- Bradycardia: any true bradycardia episodes detected (diurnal/ nocturnal)
- Other: PVCs, flat histograms, or anything nonurgent

ICD/pacemaker/CRT-D/CRT-P

- Pacing %: RV pacing >50% or recent increase in RV pacing
- Advisory: patient's leads or device are currently under an advisory per the vendor
- Parameter: note suggesting to reprogram any setting
- Common to all devices
- AF/AFL with rapid ventricular response in a patient with prior history
- Sustained SVT at high rates
- NSVT or VT in conjunction with level 3 review alert
- Pause: any pause detected (diurnal/ nocturnal)
- Other: alert that does not fit any other alert category but needs attention/nonurgent

ICD/pacemaker/CRT-D/CRT-P

- ♦ BiV pacing <90%
- HF data indicating possible fluid accumulation

Common to all devices:

- ♦ VT
- New-onset AF
- ERI/EOS detected for the first time ICD/pacemaker/CRT-D/CRT-P
- Device: lead values out of range (sensing, impedance, thresholds), any electrical reset, device error
- Review: manually added either in conjunction or without additional flags
- ERI/EOS: attached once ERI is first detected
- Shock: any arrhythmia treated with shock(s)
- ATP: any arrhythmia treated with ATP(s)

AF = atrial fibrillation; AFL = atrial flutter; ATP = antitachycardia pacing; BiV = biventricular; EOS = end of service; ERI = elective replacement indication; LAAC = left atrial appendage closure; OAC = oral anticoagulation; PVC = premature ventricular contraction; RV = right ventricular; RVR = rapid ventricular response; SVT = supraventricular tachycardia; NSVT = nonsustained ventricular tachycardia; VT = ventricular tachycardia.

Level 2 alerts included the observations that needed actions or interventions that were not urgent—for example, <90% biventricular pacing identified on CRT-Ps or CRT-

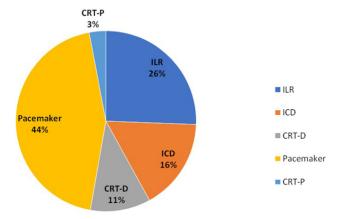


Figure 1 Distribution by device type. CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder.

Ds, or nonsustained ventricular tachycardia. These were forwarded as semi-urgent e-mail notifications, along with flags on the RM Octagos platform urging reasonably quick action.

Level 3 alerts were defined as transmissions that needed to be addressed urgently, such as sustained ventricular tachycardia, new-onset AF, ICD shocks, or antitachycardia pacing therapies. These alerts were forwarded as urgent, with a notification to the physician, patient, and red alert on the RM Octagos platform warranting immediate action. A comprehensive list of the alert types within each category is elaborated in Table 1.

Results

Data from 32,721 patients implanted with CIEDs resulted in 384,796 transmissions generated over a period of approximately 2 years (797 days). Among all the implanted CIEDs, 14,465 (44.2%) were pacemakers, 8381 (25.6%) were ILRs, 5351 (16.4%) were ICDs, 3531 (10.8%) were CRT-Ds, and 993 (3%) were CRT-Ps (Figure 1A and 1B). Distribution by device type is shown in Table 2.

Out of 384,796 total transmissions generated, 220,049 (57%) of the transmissions were adjudicated to be dismissed, as they were redundant, repetitive, or a result of noise with device sensing. Out of 167,747 (43%) of the transmissions that were not dismissed, only 50,440 (13%) had alerts, while 114,307 (30.6%) were routine transmissions (Figure 2A).

There were 9.1 transmissions per device per year with ILRs and 6.6 transmissions per device per year with ICDs and CRT-Ds, whereas there were 3.7 transmissions per device per year with pacemakers and CRT-Ps. When stratified for the type of device, there were a total of 153,117 transmissions generated from ILRs, of which 91,556 (60%) were dismissed. Only 23,183 (15%) of the total transmissions were forwarded to the providers with alerts, while 38,378 (25%) transmissions were routine transmissions without alerts (Figure 2B). There were 116,874 transmissions from ICDs and CRT-Ds, of which 61,095 (52%) were dismissed. Only 14,578 (13%) had clinical alerts, while 41,201 (35%) were

Table 2 Device distribution by type

	Loop (n = 8381)	Pacemaker $(n = 14,465)$	ICD (n = 5351)	CRT-D (n = 3531)	CRT-P (n = 993)	Total by manufacturer (n = 32,721)
Manufacturer 1	400 (4.8)	1570 (10.9)	1031 (19.3)	526 (14.9)	120 (12.1)	3647 (11.1)
Manufacturer 2	2131 (25.4)	4262 (29.5)	1535 (28.7)	1142 (32.3)	333 (33.5)	9403 (28.7)
Manufacturer 3	1502 (17.9)	2308 (16)	969 (18.1)	520 (14.7)	125 (12.6)	5424 (16.6)
Manufacturer 4	4348 (51.9)	6325 (43.7)	1816 (33.9)	1343 (38)	415 (41.5)	14,247 (43.5)

Values are n (%).

CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; ICD = implantable cardioverter-defibrillator.

routine transmissions (Figure 2C). Similarly, out of 114,805 transmissions from pacemakers and CRT-Ps, 67,398 (59%) were dismissed, 12,679 (11%) were forwarded with alerts, and 34,728 (30%) were routine transmissions without alerts (Figure 2D). Table 3 summarizes the alert levels for each device category. The majority of the clinical alerts were level 1 or level 2, which did not require urgent attention. ICDs and CRT-Ds had the highest percentage of level 3 alerts (25.4%)

and 20.5%, respectively), followed by pacemakers (8%), CRT-Ps (7.2%). and ILRs (6.4%).

The details of the clinical alerts (levels 1–3) in both dismissed and forwarded transmissions are shown in Figure 3A to 3C. The majority of the level 3 alerts were either due to ICD therapies or device reaching elective replacement indication or end of life. Some of these transmissions were dismissed after acknowledgement from the clinical staff, as

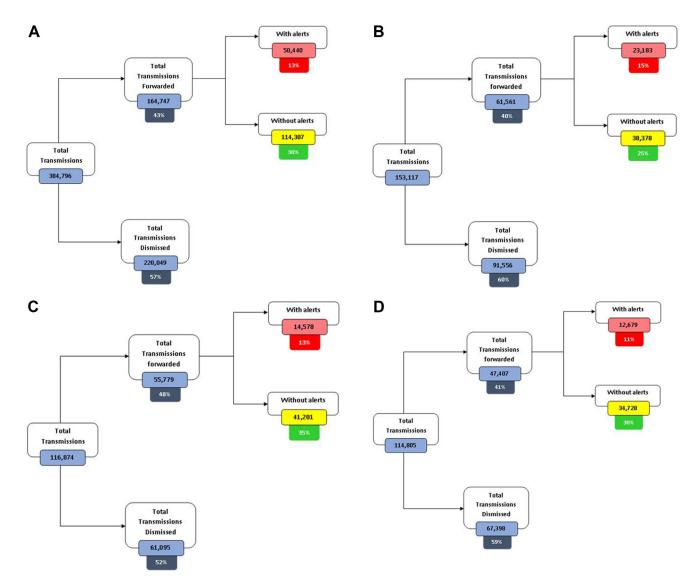


Figure 2 A: Total transmissions from all devices. B: Transmissions from Loop Recorders. C: Transmissions from implantable cardioverter-defibrillators and cardiac resynchronization therapy defibrillator. D: Transmissions from pacemaker and cardiac resynchronization therapy pacemakers.

Table 3 Distribution of alerts by level of acuity

	Loop	Pacemaker	ICD	CRT-D	CRT-P	Total
Level 1	29,106 (36.6)	18,039 (65.9)	9253 (44.0)	4144 (18.9)	1000 (25.3)	61,542 (40.0)
Level 2	45,270 (59.8)	7136 (26.1)	6449 (30.6)	13,320 (60.6)	2661 (67.4)	74,836 (48.6)
Level 3	5128 (6.4)	2192 (8.0)	5348 (25.4)	4507 (20.5)	286 (7.2)	17,461 (11.4)
Total	79,504	27,367	21,050	21,971	3947	153,839

Values are n (%) or n.

CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; ICD = implantable cardioverter-defibrillator.

they were already aware of them either due to a prior clinic visit or due to a repetitive transmission after an appropriate clinical decision making process had already been put in place. Based on workflow estimation, a dismissed transmission took around 1 to 2 minutes per transmission as compared with 3 to 6 minutes per forwarded transmission. This is a rough estimate and may vary based on a number of factors such as type of alert, device manufacturer, responsiveness of the receiving clinic, learning curve of the technician, etc.

Discussion

There are several important findings from our study. First, RM of CIEDs generates a large volume of transmissions, which contributes to data deluge and therefore needs effective and efficient triage to identify alerts in which active clinical intervention is needed. Second, the majority of the transmission alerts were either level 1 or 2, which were not urgent. ILRs resulted in the highest number of transmissions per device per year, whereas most of the urgent (level 3) alerts were seen with ICDs or CRT-Ds.

To the best of our knowledge, our study represents the largest cohort of patients with CIEDs to objectively quantify the remote transmissions and classify them based on the clinical relevance. Several studies have reported alert burden and data deluge from CIEDs as a challenge in the practice of electrophysiology. However, very few studies have quantified these transmissions into actionable and nonactionable subtypes. In a study of 26,713 patients, O'Shea and colleagues¹⁹ reported that 40.2% of the transmissions had alerts and 59.8% were routine transmissions, whereas in our study only 32% of the transmissions had alerts. The study further divided the alerts in 2 categories based on urgency and all alerts were forwarded to the physicians for adjudication. We divided the alerts into 3 categories based on urgency, and a smaller proportion of those transmissions were forwarded to the device clinics, whereas the rest were dismissed. 19 Several studies have shown higher false positive transmissions with ILRs as compared with other CIEDs because of the diagnostic nature of the device requiring higher sensitivity as a trade-off for specificity, with atrial tachycardia/AF being the major culprit. 20-22 This phenomenon was also seen in our study, which showed the highest number of transmissions per device per year, substantiating the findings from prior studies.

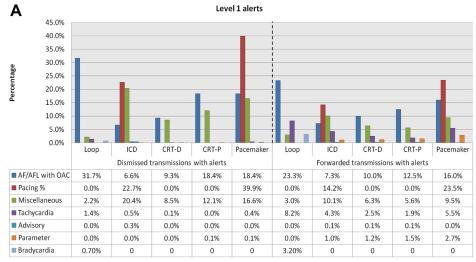
RM is an essential component of the care of CIED patients, which has been shown to improve patient outcomes. However, the RM data obtained from the CIEDs poses a sig-

nificant burden on the device clinics and providers who have to spend a sizable portion of their time and energy on triaging these data and identifying and responding to clinically relevant and actionable alerts while dismissing data that are redundant and repetitive. Clinics and hospital systems have adopted different strategies to import, manage, and review the CIEDs transmissions, some of which include hiring a third-party data management system, training in-house staff to respond to the transmissions, and triaging alerts based on actionable, nonactionable, urgent, or nonurgent transmissions. Alert-based follow-up rather than calendar based follow-up for ICDs has also been studied and shown to generate high clinical value while reducing transmission burden. Another strategy that could be particularly effective for managing the data deluge from ILRs include setting the device to low sensitivity to avoid an excessive number of false positive alerts.²³ These strategies are not mutually exclusive and could be combined for efficient workflow optimization and providing quality care.

Artificial intelligence (AI) and machine learning (ML) can potentially be used to manage the data deluge from remote transmissions of CIEDs. There are 2 levels of AI that can be deployed for implantable devices: (1) automatic interpretation of the transmissions without signal analysis and (2) automatic interpretation of the transmissions with signal analysis. With the former option, the AI platform relies on the analysis from the device. This may be more helpful in adjudicating the routine transmissions without alerts.²⁴ The second AI platform, which also analyzes the signals, can potentially adjudicate all the transmissions.^{25–27}

Limitations

Our study must be interpreted in the context of some limitations. First, this is a retrospective observational study that provides a snapshot of the data deluge from CIEDs. Therefore, it may not account for the effect of various strategies employed in programming of the CIEDs on the number of transmissions. However, due to the large sample size from multiple centers, the data are representative of real-world device clinics with different programming strategies. Second, the study reflects stratification of remote transmissions by a third-party RM company, which may not be replicated by other companies or device clinics. The interpretation and categorization of the transmissions relies heavily on a strong technical team, good interface between the RM system, and electronic health records so that clinical data including the anticoagulation status and in-person clinic visit can be assessed.





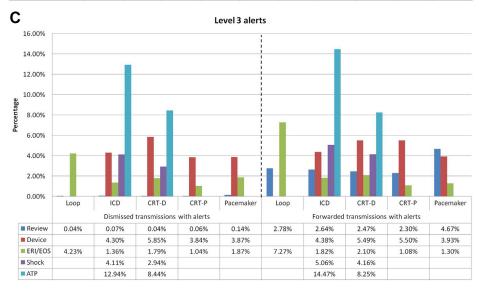


Figure 3 A: Distribution of level 1 alerts by type and device. **B:** Distribution of level 2 alerts by type and device. **C:** Distribution of level 3 alerts by type and device. AF = atrial fibrillation; AFL = atrial flutter; ATP = antitachycardia pacing; BiV = biventricular; CRT-D = cardiac resynchronization therapy defibrillator; CRT-P = cardiac resynchronization therapy pacemaker; EOS = end of service; ERI = elective replacement indication; HF = heart failure; ICD = implantable cardioverter-defibrillator; OAC = oral anticoagulation.

This was based on the fact that the RM third party had access to patients' medical records, which may not the case with several other RM companies. An integral part of this process is quality control and frequent auditing of transmitted/dismissed data. Finally, while categories of clinical alerts (levels 1–3) were used in this study, these can be modified based on the preference of the device clinics. Last, due to a wide range of clinical practices and health systems and the retrospective nature of the study, it was impossible to track all the alerts that resulted in in-person clinic or emergency room visits and/or led to reintervention.

Future directions

While remote CIED monitoring is a very attractive clinical tool in maximizing efficiency, reducing costs, and improving the safety of clinical care for those patients with CIEDs, automation of these screening and classification protocols requires rigorous testing and confirmation of highest reproducible performance. Continued improvements in the AI/ML algorithms could enable the ability of the RM software with appropriate human oversight. This can lead to significant strides in the evolution of this space.²⁸

Conclusion

While RM of CIEDs is an integral part of clinical electrophysiology practice that has shown to improve patient outcomes, the data deluge adds significant burden and inefficiency to electrophysiology device clinics. Our study showed that appropriate use of screening and stratification strategies can effectively triage these data so that the device clinics are not overwhelmed and identify the urgent clinical alerts in a timely manner so that appropriate clinical interventions can be instituted. AI and ML can potentially be used to screen and triage RM data from CIEDs, thereby reducing the burden on healthcare providers and device clinics and thus improving the patient care in a more dynamic fashion. Further studies are needed to look at clinical outcomes with stratification of remote monitoring transmissions.

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