

Clinical utility of remote monitoring for patients with cardiac implantable electrical devices

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Abstract

Background Remote monitoring of cardiac implantable electronic devices (CIEDs) offers practical and clinical benefits juxtaposed against burdens associated with high transmission volume.

Methods We identified patients receiving *de novo* pacemakers (PPMs) and implantable cardiac defibrillators (ICDs) at a single academic medical center (January 2016–December 2019) with at least 1 year of follow-up device care. We collected patient- and device-specific data at time of implant and assessed all remote and in-person interrogation reports for clinically actionable findings based on pre-specified criteria.

Results Among 963 patients (mean age of 71 (\pm 14) years, 37% female), 655 (68%) underwent PPM, and 308 (32%) underwent ICD implant. Median follow-up was 874 (627–1221) days, during which time patients underwent a mean of 13 (10–16) total interrogations; remote interrogations comprised 53% of all device evaluations; and of these, 96% were scheduled transmissions. Overall, 22% of all CIED interrogations yielded significant findings with a slightly higher rate in the PPM than in the ICD group (23% vs. 20%, p < 0.01). Only 8% of remote interrogations produced clinically meaningful results, compared with 38% of in-person ones. In adjusted models, routine, remote transmissions were least likely to be useful for both PPM and ICD patients (p < 0.001), whereas time from initial device implant was inversely associated with probability of obtaining a useful interrogation (p < 0.001).

Conclusions Routine remote interrogations constitute the majority of device evaluations performed, but uncommonly identify clinically actionable findings.

Keywords Remote monitoring · Pacemaker · Implantable cardiac defibrillator

Abbreviations

- CIED Cardiac implantable electrical devices
- PPM Permanent pacemaker
- ICD Implantable cardioverter-defibrillator
- CHF Congestive heart failure
- AF Atrial fibrillation

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1 Introduction

Remote monitoring of cardiac implantable electronic devices (CIEDs), including permanent pacemakers (PPM) and implantable cardiac defibrillators (ICDs), is growing in prevalence. Remote monitoring includes patient-initiated transmissions as well as programmed alerts, alongside routine interrogations performed at predetermined intervals based on clinical indications, practice guidelines, and reimbursement structures. The latter typically occur every 3–12 months for PPMs and every 3–6 months for ICDs [1].

Multiple studies illustrate the clinical benefits of remote monitoring, particularly as replacements for in-person evaluations [2–5]. Advantages include increased convenience, faster identification of dangerous arrhythmias or device malfunction, and timelier clinician responses. Remote monitoring may also reduce unnecessary in-person office visits, which can be cumbersome for patients with long travel times or difficult access to in-person care [6–9].

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However, the high volume of data flowing into clinician offices may complicate the "signal-to-noise ratio" of meaningful or clinically relevant findings [10]. Concerns about clinical and financial burdens on device monitoring programs and payors [11], respectively, raise questions about utilization of remote monitoring as currently implemented, particularly regarding routine, scheduled transmissions.

Accordingly, this study aimed to evaluate the incidence of clinically actionable findings identified through routine remote monitoring of CIEDs. In addition, we evaluated patient- and device-specific factors associated with clinically significant transmissions.

2 Methods

2.1 Data sources and extraction

This study was reviewed by the Beth Israel Deaconess Medical Center Institutional Review Board. Eligible patients were identified retrospectively by extracting procedural data from the Beth Israel Deaconess Medical Center electrophysiology lab clinical reporting system for procedures performed during the study period. Each case was manually reviewed for eligibility/inclusion.

Baseline demographic, clinical, and device-specific data were extracted from the electronic medical record (see *variables* below) specific to the date of their implantation procedure. Manual electronic chart review was then performed from date of implantation through end of the follow-up period for any in-person or remote interrogations performed.

All data were entered directly into standardized case report forms using the research electronic data capture system (REDCap).

2.2 Patient population and clinical pathway

All patients undergoing implantation of *new* PPMs and ICDs at BIDMC between January 1, 2016, and December 31, 2019, were eligible for inclusion. Single-chamber, dual-chamber, cardiac resynchronization therapy, leadless pacing systems, and subcutaneous ICDs were all eligible for inclusion. Exclusion criteria included age < 18 years and < 12 months of follow-up device care at BIDMC post-implantation.

Consistent with the observational nature of the study, clinical care of all patients was provided at the discretion of their treating physician. However, the standard of care for all CIED patients at BIDMC, as outlined in Fig. 1, includes enrollment in remote monitoring, preferentially with pairing performed during the initial encounter for device implantation. Post-implantation patients without any acute procedural complications are discharged home on the same day or next day according to patient preference or clinical discretion. All patients are scheduled for a post-operative wound check within 7–10 days post-discharge, at which time enrollment in remote monitoring is offered if not previously completed. A second scheduled post-operative visit at approximately 6 weeks includes additional education, refinement of programming as needed, removal of restrictions on arm motion or mobility if applicable to that patient's device type, and further opportunity to enroll in or troubleshoot remote monitoring as needed.

Following these post-operative appointments, patients typically were scheduled for at least one annual in-person evaluation with an electrophysiologist. Remote monitoring was specified to include automated transmissions every 90 days as well as upon patient initiation for symptoms or other concerns. Alerts were programmed according to vendor-specific parameters to identify unexpected changes in battery voltage, lead parameters, or arrhythmia burden.

2.3 Patient variables

Demographic and clinical characteristics as of the time of initial CIED implantation were extracted from the medical record. These included age, sex, hypertension, diabetes, history of coronary artery disease, history of peripheral vascular disease, history of prior ischemic stroke or transient ischemic attack, most recent serum sodium, lowest serum creatinine within preceding 6 months, most recent N-terminal pro-brain natriuretic peptide within preceding 12 months, most recent ejection fraction within preceding 12 months, history of congestive heart failure (CHF), baseline New York Heart Association (NYHA) functional class (if applicable), history of atrial fibrillation (AF), atrial flutter, atrial tachycardia, or other supraventricular tachycardia, use of specific antiplatelet and/or anticoagulant medications, and indication for initial CIED placement.

In addition, data regarding the implantation procedure and device abstracted included date of implantation, device manufacturer, model number, device type (PPM or ICD), and number of pacing leads (single-chamber, dualchamber, biventricular, leadless, or subcutaneous).

Subsequent procedures during the follow-up period were also recorded. These data included date of device change, indication for change (battery issues, lead-related issues, heart failure, infection, or other), and type of change made (generator change, lead implantation/replacement, cardiac resynchronization therapy upgrade, ICD upgrade, device extraction with or without re-implantation, or other), as well as information regarding new device type, manufacturer, and model number, if applicable.

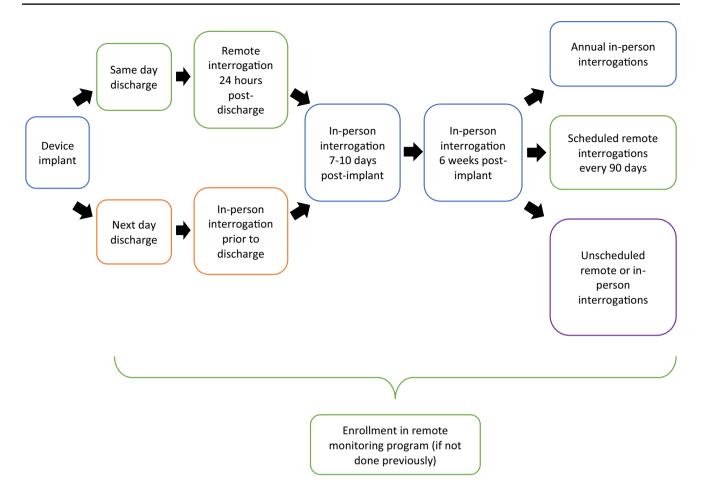


Fig. 1 Standard post-implantation device care follow-up. Clinical care of every patient was tailored to individualized needs and discretion of treating physician. Enrollment in remote monitoring offered continuously from implantation through duration of device care follow-up

2.4 Assessment of device interrogations

For each device-related encounter, we manually reviewed standardized device interrogations performed as part of routine clinical care and corresponding reports located in the electronic medical record. These notes used a standardized template and were completed by device clinic nurses, technicians, and advanced practice providers and were co-signed with comments by physicians. Each interrogation report also included summary PDF according to each manufacturer's format.

Data ascertained from each encounter included: date of interrogation, interrogation setting (clinic, inpatient/emergency department, or remote), and reason for interrogation (routine, peri-procedural, device alert-driven, symptomdriven initiated by either clinician or patient, or other). All scheduled interrogations—whether in-person or remote were considered routine. All other interrogations were considered non-routine.

In addition, we noted any changes or issues interpreted as significant by the evaluating clinician related to battery, percent pacing, sensitivity, pacing threshold, and impedance. Detection of new-onset AT/AF/AFL or high AT/AF/AFL burden (defined as > 12 h/day and/or > 50% overall burden, excluding permanent atrial arrhythmias without documented plans to restore sinus rhythm, or otherwise determined by evaluating clinician) was also captured, along with sustained ventricular arrhythmias and delivery of tachy-therapies, including anti-tachycardia pacing and defibrillation. Finally, any device settings or medical therapies adjusted at time of interrogation, particularly of anticoagulant, antiarrhythmic, or rate-control agents; additional patient contact resulting from interrogation findings (phone call, clinic visit, emergency department/hospital referral, or physical device change); and other clinically meaningful findings detailed by evaluating clinician were documented as well.

We a priori and intentionally defined "clinically useful" generously using the following criteria, incorporating those from previously published studies assessing remote CIED monitoring and designed with the goal of being inclusive (e.g., more sensitive than specific) [6, 12, 13]. Thus, we defined an interrogation to be clinically useful if any of the

following were identified by record review: (1) significant changes or issues pertaining to device parameters, new or high-burden of atrial arrhythmias, sustained ventricular arrhythmias, or delivery of tachy-therapies; (2) device settings or medical therapies were changed following data review; (3) additional patient contact was established; or (4) otherwise meaningful findings were detailed by evaluating clinician.

2.5 Statistical analysis

Categorical and continuous variables were compared between patient groups with the chi-squared and *t*-tests, respectively, and simple proportions calculated for categorical outcomes. A mixed-effects multivariable probit model was selected instead of alternate regression model in order to evaluate the probability rather than odds of having a clinically useful finding on an interrogation. Fixed effects in the model were whether the interrogation was routine and remote, routine and in-person, non-routine and remote, or non-routine and in-person; age; sex; device type (PPM or ICD); ejection fraction; and time since device implant. A per-patient random effect was included to account for clustering. The predicted probabilities of useful interrogation were computed for each device type at the population means of the other covariates. Two-tailed p values were taken to be significant at the 0.05 level. All analyses were performed using Stata 17 (StataCorp, College Station, TX).

3 Results

3.1 Cohort and device characteristics

Patient characteristics at time of device implantation are detailed in Table 1. Notably, a total of 963 patients underwent CIED implantation, of whom 655 (68%) received pacemakers and 308 (32%) received ICDs. At time of device implant, average age was 71 (\pm 14) years; 37% of patients were female; 38% had a known diagnosis of atrial fibrillation or flutter with a median CHADS2VASC score of 4 (3–5); and 35% were already on some form of oral anticoagulation prior to receiving a device. The most common indications for pacemaker and ICD placement were heart block (58%) and primary prevention of sudden death (72%), respectively.

Device characteristics are outlined in Table 2. Dualchamber devices comprised the majority of pacemakers implanted (86%), whereas single ventricular lead systems were most commonly placed (42%) among ICDs. Throughout the study period, a total of 97 (10.1%) devices were subject to additional procedural interventions. Lead-related issue was the most common indication (53%) for device change, and ventricular lead replacement accounted for 44% of these procedures. There were no significant differences between the PPM and ICD groups, except device extraction, which occurred more frequently within the ICD group (26% vs. 7.6%, p = 0.01).

3.2 Interrogations

Over a median follow-up was 874 (627–1221) days for all patients with CIEDs, and each patient underwent a mean of 13 (10–16) total interrogations (in-person and remote), without significant differences observed between patients receiving PPMs and ICDs. There were a cumulative 12, 745 interrogations performed, of which 8789 (69%) involved pacemakers and 3956 (31%) involved ICDs. Six thousand six hundred ninety nine (53%) of all device evaluations were conducted remotely, with the vast majority (96%) being routine or scheduled transmissions. Unscheduled remote transmissions were predominantly triggered by device alerts (1.7%) and patient symptoms (1.9%). In-person evaluations were also predominantly routine in nature (75%), with nonroutine evaluations performed largely for peri-procedural evaluation (19.9%) and patient-reported symptoms (5.8%).

In aggregate, 22% of all CIED interrogations were considered clinically useful according to our pre-specified criteria. Rates of useful interrogations were slightly higher among pacemakers than ICDs (23% vs. 20%, p < 0.01) and significantly lower among remote as compared with in-person interrogations (8% vs. 38%, p < 0.01). Sixty-eight percent of all useful device evaluations were considered clinically significant because changes were made to device settings subsequent to data review-by definition, these were all inperson interrogations. Specific changes made pertained to programmed mode (68%), pacing/threshold settings (47%), and sensitivity parameters (12%). Detection of atrial and/or ventricular arrhythmias (25%) was the next most common reason interrogations were considered useful, followed by additional patient contact (9%) and medication changes (6%) made as a result of interrogation findings. These data are further detailed by remote vs. in-person and by routine vs. nonroutine in Table 3. Notably, remote routine interrogations were least commonly associated with significant findings on device evaluation (5.9%) with detection of arrhythmias being the most frequent actionable item identified.

Significant arrhythmia-related findings consisted of high AT/AF/AFL burden (46%), new AT/AF/AFL (35%), and VT/VF (22%). These occurred at similar rates between remote and in-person device evaluations, except high AT/ AF/AFL burden, which was more frequent on in-person than remote interrogations (51% vs. 41%, p < 0.05). Notably, there was a higher proportion of pacemaker interrogations (70.4% vs. 67.6%, p < 0.01), and comparing pacemakers and ICDs, new and high burden of AT/AF/AFL was

Table 1 Patient characteristics

	Total (<i>N</i> =963)	Pacemaker ($N = 655$)	ICD (N=308)	
Age at implant, years (SD)	71 (14)	75 (11)	63 (14)	
Female gender, n (%)	356 (37%)	269 (41%)	87 (28%)	
Hypertension, n (%)	802 (83%)	525 (80%)	277 (90%)	
Diabetes, n (%)	267 (28%)	181 (28%)	86 (28%)	
Coronary artery disease, n (%)	323 (34%)	185 (28%)	138 (45%)	
Peripheral vascular disease, n (%)	98 (10%)	67 (10%)	31 (10%)	
Prior ischemic stroke/TIA, n (%)	114 (12%)	85 (13%)	29 (9.4%)	
History of atrial fibrillation or flutter, n (%)	366 (38%)	285 (44%)	81 (26%)	
CHADS2VASC score, median (IQR)	4 (3–5)	4 (3–6)	4 (3–6)	
Use of oral anticoagulation, n (%)	337 (35%)	244 (37%)	93 (30%)	
Warfarin	139 (14%)	91 (14%)	48 (!6%)	
Direct oral anticoagulant	198 (21%)	153 (23%)	45 (15%)	
Use of antiplatelet medication, n (%)				
Aspirin	500 (52%)	316 (48%)	184 (60%)	
P2Y12 inhibitor	81 (8.4%)	42 (6.4%)	39 (13%)	
Ejection fraction, % (SD)	48 (16)	56 (11)	35 (15)	
Baseline creatinine, mg/dL (SD)	1.1 (0.77)	1.1 (0.84)	1.1 (0.59)	
Heart failure, n (%)	382 (40%)	147 (22%)	235 (76%)	
Ejection fraction $< 40\%$, n (%)	225 (23%)	27 (4.1%)	198 (64%)	
NYHA class, n (%)				
Ι	51 (13%)	13 (8.8%)	38 (16%)	
П	157 (41%)	34 (23%)	123 (52%)	
III	55 (14%)	23 (16%)	32 (14%)	
IV	1 (0.3%)	0 (0%)	1 (0.4%)	
Unknown or not applicable	118 (30.8%)	77 (52.4%)	41 (17%)	
Baseline sodium value, mEq/L (SD)	140 (3.3)	140 (3.3)	140 (3.2)	
Recent proBNP, pg/mL (SD)	3348 (7474)	4906 (9884)	2074 (4278)	
Device indication, n (%)				
Sinus node dysfunction/tachy-brady syndrome	306 (32%)	286 (44%)	20 (6.5%)	
Heart block	393 (41%)	379 (58%)	14 (4.5%)	
Cardiac resynchronization therapy	144 (15%)	67 (10%)	77 (25%)	
Primary prevention of sudden cardiac death	223 (23%)	1 (02%)	222 (72%)	
Secondary prevention off sudden cardiac death	86 (8.9%)	0 (0%)	86 (28%)	

more common in the former (41% vs. 24%, p < 0.01; 59% vs. 19%, p < 0.01). Detection of VT and VF was more common in the latter (1% vs. 57%, p < 0.01; 0% vs. 9%, p < 0.01).

The coefficients of the multivariable probit model for the probability of a clinically useful interrogation are shown in Table 4. Routine interrogations were significantly less likely to be useful than non-routine ones. Routine remote interrogations were least likely to be useful (p < 0.001). This effect is stratified by device type in Fig. 2. Pacemakers and transmissions in older patients were somewhat more likely to have a useful interrogation than ICDs although the magnitude of these effects was small. For each 30 days since implant, the probability of useful interrogation decreased (change in *z*-score – 0.02 per 30 days, p < 0.001).

4 Discussion

This study aimed to comprehensively evaluate all interrogations performed following implantation of new PPMs and ICDs, with rigorous assessment of clinical utility applied to all in-person and remote interrogations. We found that routine, scheduled interrogations comprise the majority of all evaluations, but uncommonly identified clinically actionable findings even according to a relatively permissive pre-specified definition. These findings support prior work suggesting that growing CIED utilization, along with higher uptake of remote monitoring in accordance with clinical guidelines, while beneficial in many ways, may have a deleterious impact on CIED monitoring programs through increasing volumes of non-actionable information.

Table 2 Device information

	Total (<i>N</i> =963)	Pacemaker ($N = 655$)	Defibrillator ($N = 308$)	
Device type, <i>n</i> (%)				
Single atrial	3 (0.31%)	3 (0.46%)	0 (0%)	
Single ventricular	177 (18%)	47 (7.2%)	130 (42%)	
Dual-chamber	645 (67%)	561 (86%)	84 (27%)	
Biventricular	113 (12%)	34 (5.2%)	79 (26%)	
Subcutaneous	15 (1.6%)	0 (0%)	15 (4.9%)	
Leadless	10 (1%)	10 (1.5%)	0 (0%)	
Device manufacturer				
Medtronic	503 (49.9%)	363 (54.3%)	140 (41.1%)	
Boston Scientific	416 (41.2%)	226 (33.8%)	190 (55.7%)	
Abbott/St. Jude	86 (8.5%)	75 (11.2%)	11 (3.2%)	
Biotronik	4 (0.4%)	4 (0.01%)	0 (0%)	
Device revisions, <i>n</i> (%)	97 (10.1%)	66 (9.9%)	31 (10.1%)	
Type of change, <i>n</i> (%)				
Generator change	2 (2.1%)	1 (1.5%)	1 (3.2%)	
Atrial lead re-/placement	15 (15%)	12 (18%)	3 (9.7%)	
Ventricular lead re-/placement	43 (44%)	29 (44%)	14 (45%)	
Cardiac resynchronization therapy upgrade	14 (14%)	10 (15%)	4 (13%)	
ICD upgrade	8 (8.2%)	7 (11%)	1 (3.2%)	
Device extraction	13 (13%)	5 (7.6%)	8 (26%)	
Other	11 (11%)	7 (11%)	4 (13%)	
Indication for device change, n (%)				
Battery issue	1 (1%)	0 (0%)	1 (3.2%)	
Lead-related issue	51 (53%)	37 (56%)	14 (45%)	
Heart failure	16 (16%)	10 (15%)	6 (19%)	
Infection	13 (13%)	6 (9.1%)	7 (23%)	
Other	21 (22%)	14 (21%)	7 (23%)	

Table 3 Significant findings by location and setting

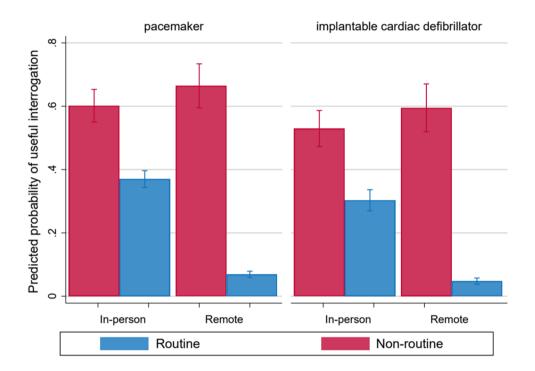
	Non-remote, non-routine $(N=1486)$	Remote, non-routine $(N=240)$	Non-remote, routine $(N=4560)$	Remote, routine $(N=6459)$	p value
Significant finding present	436 (29.3%)	152 (63.3%)	1885 (41.3%)	384 (5.9%)	< 0.01
Type of finding					
Battery issue	0 (0%)	0 (0%)	0 (0%)	1 (0.26%)	0.092
Settings change	320 (73%)	0 (0%)	1,626 (86%)	0 (0%)	< 0.001
Medication change	27 (6.2%)	25 (16%)	97 (5.1%)	29 (7.6%)	< 0.001
Pacing issue	7 (1.6%)	7 (4.6%)	17 (0.9%)	23 (6%)	< 0.001
Sensing issue	23 (5.3%)	5 (3.3%)	40 (2.1%)	43 (11%)	< 0.001
Threshold issue	30 (6.9%)	1 (0.66%)	43 (2.3%)	24 (6.3%)	< 0.001
Arrhythmia/s detected	86 (20%)	72 (47%)	293 (16%)	262 (68%)	< 0.001
Impedance issue	7 (1.6%)	7 (4.6%)	12 (0.6%)	16 (4.2%)	< 0.001
Tachy-therapies delivered	31 (7.1%)	55 (36%)	24 (1.3%)	26 (6.8%)	< 0.001
Additional patient contact made	33 (7.6%)	105 (69%)	40 (2.1%)	64 (17%)	< 0.001

Modern CIED management necessarily involves careful surveillance for device malfunction, expected changes in battery life over time, and review of ambient arrhythmias. The ability to remotely review and triage patient-initiated transmissions in response to symptoms provides clinical flexibility, particularly for patients unable to access

Table 4Probit modelcoefficients for probability ofuseful interrogation

	Coefficient	p value	95% confidence interval
Routine interrogation	-0.651	< 0.001	[-0.792, -0.511]
Remote interrogation	0.174	0.145	[-0.060, 0.409]
Routine remote interrogation	-1.436	< 0.001	[-1.684, 1.188]
Age at device implant (years)	-0.004	0.047	[-0.008, 0.000]
Male sex	-0.101	0.052	[-0.204, 0.001]
ICD (vs. PPM)	-0.266	< 0.001	[-0.408, -0.125]
Ejection fraction (%)	-0.004	0.074	[-0.007, 0.000]
Time since device implant (months)	-0.001	< 0.001	[-0.008, -0.001]

Fig. 2 Probit model for probability of useful interrogation, stratified by device type. Nonroutine and routine interrogations are represented respectively by magenta and blue bars. For both implanted pacemakers and implantable cardiac defibrillators, routine interrogations were less likely than non-routine ones to identify clinically actionable findings (p < 0.001). Among routine evaluations, remote device interrogations were also less likely than non-remote ones to contain clinically actionable findings (p < 0.001). Factors included in multivariable probit regression are detailed in Table 4



in-person care simply. Several studies have demonstrated that routine remote transmissions clearly can replace many of these in-office visits safely: For example, the RM-ALONE trial (N=445) found that scheduled remote monitoring reduced in-office visits by 80%, with no adverse impact on patient outcomes and substantial savings in clinician time and effort [14]. The AT-HOME trial (N=1274) also showed that remote monitoring replaced in-office visits with no harm to patients [15]. The TRUST study (N=1450) further noted that remote monitoring reduced non-actionable *in-office* device encounters by 80% and the CONNECT study (N=1997) demonstrated a marked reduction in time from CIED event detection to appropriate clinical response predominantly through an alert-driven model [7, 8, 11, 12].

Within these studies, however, the rate of actionable findings for scheduled device evaluations was low and comparable to those identified in our study—ranging from 1.4% among remote and 1.5% of in-office encounters in the AT-HOME trial to 6.6% among both groups in the TRUST

study. In contrast, CIED alert-driven device evaluations led to a modest increase in this rate—up to 17 and 15%, respectively, within the remote and in-person arms of the CONNECT study. These data, in concordance with ours, suggest that alert-based, rather than routine transmissions may drive much of the clinical benefit gained through remote CIED monitoring. As such, an alert-driven remote monitoring approach, paired with regular in-person visits as recommended in current guidelines, may prove to be equally as efficacious and safe as one reliant on routine remote transmissions. This and the ideal balance between alert-based transmissions and scheduled ones (if any) will need to be assessed in prospective randomized fashion.

An alert-driven device monitoring system would also help address the growing clinical and administrative demands associated with remote monitoring. With advances in cellular and Bluetooth technology facilitating ease of sending and receiving transmissions, cardiac device clinics are becoming inundated with a rapid influx of CIED-related data. An analysis of a large multi-center remote monitor cohort (N=26,713) revealed that over a period of 12 months, there were over 205,804 total transmissions received, including 82,000 triggered by automated device alerts and at least 1 transmission sent by over 50% of this patient population [16]. This tremendous volume of information to process and act upon certainly adds strain to any remote monitoring system. Reducing the number of routine remote device evaluations could greatly help to ameliorate this burden on device clinic staff and allow for more efficient resource utilization and clinical response. Furthermore, assuming a similar rate of identifying actionable findings as shown in prior studies as well as our own, this reduction would not result in compromised clinical care.

While our study does not directly address the question of cost-effectiveness, these findings do suggest that remote evaluations scheduled less frequently overall, particularly if buttressed by automated alert-based monitoring may help reduce unnecessary efforts and costs without compromising the benefits of remote monitoring. However, reimbursement models will invariably need to evolve to influence change in practice. In doing so, caution should be taken to maintain policies that continue encouraging remote monitoring as an instrumental element of CIED-related care. Potential ways to accomplish this include de-emphasizing per-unit reimbursements and shifting towards fixed or bundled models—for instance, annual payments made based on number of patients enrolled in remote monitoring programs rather than volume of transmissions performed.

With regard to limitations, our analysis was conducted using data from a single, academic, tertiary-care center. This may limit the generalizability of our findings to other clinical settings, in which practices surrounding remote monitoring and patient demographics may differ. However, our study population is enriched for more medically complex patients, who may be more likely to have clinically meaningful events such as ambient arrhythmias detected on CIED evaluation. This would suggest that our findings may, if anything, overestimate the utility of these interrogations. The retrospective, observational nature of our study also includes the possibility that unmeasured confounders may limit comparisons between patient and device groups. Furthermore, interrogation data were collected through manual review of standardized device evaluation notes within the electronic health record. As such, interrogations and transmissions-particularly focused ones performed to answer specific questions such arrhythmia burden or correlation with clinical symptoms as well as those documented in alternate formats-may not have been captured. These will be important to include in any future studies assessing alert-based remote monitoring. Our criteria for clinically significant findings were also intentionally broad in order to maximize captured events. Of interest, in-person device evaluations were considered significant if any settings changes were made during these encounters. This ostensibly engenders bias towards a higher rate of actionable findings on in-person interrogations as settings changes cannot be programmed remotely even if similar observations are made. However, this was felt to better reflect a valid inherent limitation of remote as opposed to in-person device evaluation. Additionally, temporal trends in care, including those related to the COVID-19 pandemic, were difficult to evaluate for within the constraints of our study. However, we note that the increasing reliance on remote, rather than in-person device evaluations and limited preventative care during initial months of the COVID-19 pandemic, may, if anything, have increased the frequency of actionable findings on remote transmissions, suggesting a regression to a natural mean may be observed subsequently.

5 Conclusions

In our single-center, cohort study, routine remote interrogations of PPMs and ICDs accounted for over half of all device evaluations but identified clinically salient findings in only a minority of cases. Remote monitoring, including routine scheduled transmissions, undoubtedly plays an important role in modern CIED management strategies, but also carries significant clinical, administrative, and financial costs. Our findings suggest opportunities to adjust routine scheduled encounters for patients consistently enrolled in remote monitoring. In addition, tuture randomized, multi-center studies are needed to prospectively evaluate the feasibility and effectiveness of an alert-based approach as an alternative monitoring strategy.

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Declarations

Ethics approval This study was approved by the Institutional Review Board of Beth Israel Deaconess Medical Center.

Informed consent N/A (retrospective chart review study).

Conflict of interest The authors declare no competing interests.

References

- Slotwiner D. HRS Expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015;12(7):32.
- Al-Khatib SM, Mi X, Wilkoff BL, Qualls LG, Frazier-Mills C, Setoguch S, Hess PL, Curtis LH. Follow-up of patients with new cardiovascular implantable electronic devices: are experts' recommendations implemented in routine clinical practice? Circ Arrhythm Electrophysiol. 2013;6(1):108–116.

- 3. Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. Heart Rhythm. 2012;9(12):1947–51.
- Hess PL, Mi X, Curtis LH, Wilkoff BL, Hegland DD, Al-Khatib SM. Follow-up of patients with new cardiovascular implantable electronic devices: is adherence to the experts' recommendations associated with improved outcomes? Heart Rhythm. 2013;10(8):1127–33.
- 5. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, Haves DL, Howlett JG, Kautzner J, Love CJ, Morgan JM, Priori SG, Reynolds DW, Schoenfeld MH, Vardas PE, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations: developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the American Heart Association. Europace: European pacing, arrhythmias, and cardiac electrophysiology: Journal of the Working Groups on Cardiac Pacing, Arrhythmias, and Cardiac Cellular Electrophysiology of the European Society of Cardiology. 2008;10(6):707-25.
- 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):325–32.
- Varma N, Love CJ, Michalski J, Epstein AE, TRUST Investigators. Alert-based ICD follow-up: a model of digitally driven remote patient monitoring. JACC Clin Electrophysiol. 2021;7(8):976–87.
- Varma N, Michalski J, Epstein AE, Schweikert R. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T safely reduces routine office device follow-up (TRUST) trial. Circ Arrhythm Electrophysiol. 2010;3(5):428–36.
- 9. Varma N, Piccini JP, Snell J, Fischer A, Dalal N, Mittal S. The relationship between level of adherence to automatic wireless remote monitoring and survival in pacemaker and defibrillator patients. J Am Coll Cardiol. 2015;65(24):2601–10.

- Diamond J, Varma N, Kramer DB. Making the most of cardiac device remote management: towards an actionable care model. Circulation: Arrhythmia and Electrophysiology. 2021 Mar;14(3):e009497. https://doi.org/10.1161/CIRCEP.120.009497.
- 11. Holtzman JN, Wadhera RK, Choi E, Zhao T, Secemsky EA, Fraiche AM, Shen C, Kramer DB. Trends in utilization and spending on remote monitoring of pacemakers and implantable cardioverter-defibrillators among Medicare beneficiaries. Heart Rhythm. 2020;17(11):1917–21.
- Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH. The CON-NECT (clinical evaluation of remote notification to reduce time to clinical decision) trial. J Am Coll Cardiol. 2011;57(10):1181–9.
- Crossley GH, Chen J, Choucair W, Cohen TJ, Gohn DC, Johnson WB, Kennedy EE, Mongeon LR, Serwer GA, Qiao H, Wilkoff BL, PREFER Study Investigators. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers. J Am Coll Cardiol. 2009;54(22):2012–9.
- 14. García-Fernández FJ, Osca Asensi J, Romero R, Fernández Lozano I, Larrazabal JM, Martínez Ferrer J, Ortiz R, Pombo M, Tornés FJ, Moradi KM. Safety and efficiency of a common and simplified protocol for pacemaker and defibrillator surveillance based on remote monitoring only: a long-term randomized trial (RM-ALONE). Eur Heart J. 2019;40(23):1837–46.
- 15. Watanabe E, Yamazaki F, Goto T, Asai T, Yamamoto T, Hirooka K, Sato T, Kasai A, Ueda M, Yamakawa T, Ueda Y, Yamamoto K, Tokunaga T, Sugai Y, Tanaka K, et al. Remote management of pacemaker patients with biennial in-clinic evaluation. Circ Arrhythm Electrophysiol. 2020;13(5):e007734.
- O'Shea CJ, Middeldorp ME, Hendriks JM, Brooks AG, Lau DH, Emami M, Mishima R, Thiyagarajah A, Feigofsky S, Gopinathannair R, Varma N, Campbell K, Sanders P. Remote monitoring alert burden. JACC: Clin Electrophysiol. 2021;7(2):226–34.

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