





ORIGINAL RESEARCH

Real-World Disparities in Remote Follow-Up of Cardiac Implantable Electronic Devices and Impact of the COVID-19 Pandemic: A Single-Center Experience

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BACKGROUND: Remote monitoring (RM) of cardiac implantable electronic devices has been shown to improve cardiovascular morbidity and mortality. To date, no studies have investigated disparities in use and delivery of RM. This study was performed to investigate if racial and socioeconomic disparities are present in cardiac implantable electronic device RM.

METHODS AND RESULTS: This was a retrospective observational cohort study at a single tertiary care center in the United States. Patients who received a newly implanted cardiac implantable electronic device or device upgrade between January 2017 and December 2020 were included. Patients were classified as RM positive (RM+) when they underwent at least ≥ 2 remote interrogations per year during follow-up. Of all eligible patients, 2520 patients were included, and 34% were women. The mean follow-up was 25 months. Mean age was 71 ± 14 years. Pacemakers constituted 66% of implanted devices, whereas 26% were implantable cardioverter-defibrillators, and 8% were cardiac resynchronization therapy with implantable cardioverter-defibrillators. Most patients (83%) were of European American ancestry. During follow-up, 66% of patients were classified as RM+. Patients who were younger, European American, college-educated, lived in a county with higher median household income, and were active on the hospital's patient portals were more frequently RM+. In an adjusted regression model, RM+ remained associated with the use of the online patient portal (odds ratio [OR], 2.889 [95% CI, 2.387–3.497]), presence of an implantable cardioverter-defibrillator (OR, 1.489 [95% CI, 1.207–1.835]), advanced college degree (OR, 1.244 [95% CI, 1.014–1.527]), and lastly with European American ancestry ($P < 0.05$). During the years of the COVID-19 pandemic, the number of RM+ patients increased, whereas the association with ancestry and ethnicity decreased.

CONCLUSIONS: Despite being offered to all patients at implantation, significant disparities were present in cardiovascular implantable electronic device RM in this cohort. Disparities were partly reversed during COVID-19. Further studies are needed to examine health center- and patient-specific factors to overcome these barriers, and to facilitate equal opportunities to participate in RM.

Key Words: cardiac implantable electronic devices ■ health care disparities ■ heart failure ■ pacemaker ■ remote monitoring ■ social determinants of health

The use of cardiovascular implantable electronic devices (CIEDs), including pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy devices with defibrillators has significantly expanded over the past decade.^{1,2} Remote

monitoring (RM) has emerged as an invaluable tool for device follow-up by allowing for provider and patient-triggered transmission of stored CIED data for review by health care professionals.³ RM has been associated with reduced hospitalizations, shorter hospital stays, and

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CLINICAL PERSPECTIVE

What Is New?

- Remote monitoring of cardiac implantable electronic devices has in the past been shown to improve cardiovascular morbidity and mortality.
- Multiple disparities on the use of the online patient portal, education, and ancestry were present in patients who were remotely monitored and those who were not in this remotely monitored patient cohort from a large academic US hospital system.

What Are the Clinical Implications?

- Despite being offered to all patients at implantation, significant disparities were present in remotely monitored cardiac implantable electronic devices in this cohort, and thus further studies are needed to examine health center- and patient-specific factors to overcome these barriers and to facilitate equal opportunities to participate in remote monitoring.

Nonstandard Abbreviations and Acronyms

MHI	median household income
RM	remote monitoring

lower hospital costs,^{4–6} and has been shown to be complementary to in-person office visits.^{7,8}

Despite its use being recommended as a standard of care by major professional societies,⁹ RM continues to remain underused.¹⁰ Therefore, enrollment in RM programs may be underused among different patient groups such as uninsured patients and marginalized groups.^{11–13} As the use of RM continues to expand, health care providers must ensure that RM use remains equitable and accessible to vulnerable populations. However, limited data are available on the use of RM and device interrogation rates among patients with low socioeconomic status or marginalized groups with CIEDs.

During the COVID-19 pandemic, the model of virtual care delivery has significantly shifted, with telemedicine and remote device interrogation being increasingly important to quality care. Current guidelines strongly urged for the use of RM in most circumstances during the pandemic to reduce nonurgent clinic visits.¹⁴ These recommendations, in conjunction with the current underuse of RM, may further foster health care disparities for underserved populations with CIEDs.

The goal of this study was first to understand general and sociodemographic characteristics of patients

with CIEDs that are remotely followed at Massachusetts General Hospital. Second, we aimed to determine if these characteristics impact the likelihood for successful remote monitoring follow-up. Finally, we aimed to determine the impact of the COVID-19 pandemic on observed disparities.

METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study Population

This was a retrospective observational cohort study of patients who received a newly implanted CIED or device exchange at Massachusetts General Hospital between January 2017 and December 2020. CIED was defined as any kind of pacemaker (single lead, 2 leads, and leadless), cardiac resynchronization pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy with an implantable defibrillator. Patients had to be >21 years of age.

Sociodemographic patient characteristics were obtained from the electronic medical record including age, sex, ancestry, preferred language, insurance type/primary payer, patient portal enrollment, and county-code-linked median household income (MHI). MHI used in this study was paired to the primary patient residence and was acquired from the 2019 data from the US Census Bureau. Patients residing in the following New England states were included: Maine, Vermont, New Hampshire, Massachusetts, Connecticut, and Rhode Island. Patients who received an implantable loop recorder were excluded.

Remote Interrogation Data

During the timeframe of this study, every patient who received a newly implanted device or device exchange, independent of the implanted device brand, received a remote home monitoring system. A remote monitoring home system allows for wireless communication with the implanted device and sends the device data in various ways to the monitoring physician without requiring the physical presence of the patient in a hospital or clinic. Patient remote interrogations occurring between January 1, 2017 and May 31, 2021 were included into the study.

Data Extraction

All clinical data, including age, sex, insurance type, ancestry, ethnicity, education level, language spoken, address and county, patient portal access, date of device implantation and diagnosis, death, and hospitalizations

were extracted from the electronic medical record using Massachusetts General Hospital's D4Q clinical data warehouse. Therefore, specific informed consent for this particular study protocol was not required. These data were complemented by the device clinic data that had been gathered during in-person and remote interrogations, and stored in PACEART Optima (Medtronic, Minneapolis, MN). The protocol was reviewed by Massachusetts General Hospital's institutional review boards and met the board's criteria for exemption (45 CFR 46) as a secondary research protocol.

Outcome Measures

Patients were deemed to be remote monitoring positive (RM+) if they had ≥ 2 successful remote interrogations per calendar year after device implantation. The primary outcome measure was the RM+ rate. All included patients had to survive a period of 160 days, because the RM assignment was contingent upon survival of the initial implantation surgery and hospitalization. The secondary outcome was all-cause mortality. The overall study design is depicted in [Figure 1](#).

Statistical Analysis

We compared RM+ and RM-negative patients by using χ^2 tests for categorical variables and Mann-Whitney *U* test for continuous variables that were of nonnormal distribution (shown as median and range), and a 2-sided *t* test in case of a less skewed distribution

(shown as mean \pm SD). We used a multivariate logistic regression analysis to identify patient factors associated with remote follow-up. The model included variables for age, sex, European American ancestry compared with minoritized racial groups and Latinx, county of residence, education, income, and access to the online patient portal. In a subanalysis, we aimed to determine the impact of the COVID-19 pandemic. Therefore, we included patients who received a device before 2019 into this part of the analysis and compared their RM status in the prepandemic years to the pandemic years and performed a logistic regression. We were not able to determine from these data how many patients elected to follow up at a different hospital system or clinic. Therefore, we conducted a sensitivity analysis in which we excluded all patients who did not follow up in person at Massachusetts General Hospital for ≥ 2 times after device implantation with persistence of the major determinants of RM+. Here, 369 patients who did not fulfill this criterion were excluded.

A 2-tailed *P* value of <0.05 was considered to indicate statistical significance for all tests. All analyses were performed using IBM's SPSS statistics package version 28 (IBM, Armonk, NY).

RESULTS

[Table 1](#) shows the baseline characteristics of the study population. Within the time frame of the study, 2520 patients who had undergone implantation or generator change of a CIED were identified and included into the study.

Of these, 34% ($n=884$) patients were women. The mean patient age was 71.0 ± 13.5 years. Most patients (85%, $n=2146$) were of European American ancestry, whereas the other portions were minoritized racial groups or Latinx ([Table 1](#)). Pacemakers constituted 66% ($n=1655$) of the implanted devices, whereas 34% ($n=861$) were ICDs and cardiac resynchronization therapy with defibrillators. Over the time of follow-up, 67% ($n=1693$) of patients were classified as RM+. Included patients underwent a mean follow-up of 25.20 ± 12.24 months. [Figure 2](#) shows the RM+ rate per year of device implantation, which was around 70% for all years. Of note, the percentage decreased for devices implanted in 2020 given the shorter follow-up period in the study.

Patients who were White ($P=0.003$), college educated ($P<0.001$), and active on the hospital's patient portal ($P<0.001$) were associated with RM+ status. In addition, patients who were of a younger age ($P<0.001$) and lived in a county with a higher MHI ($P=0.006$) were more likely to be RM+. In addition, RM+ patients more frequently had commercial insurance as opposed to Medicare or Medicaid ($P=0.004$) and more commonly had ICDs/

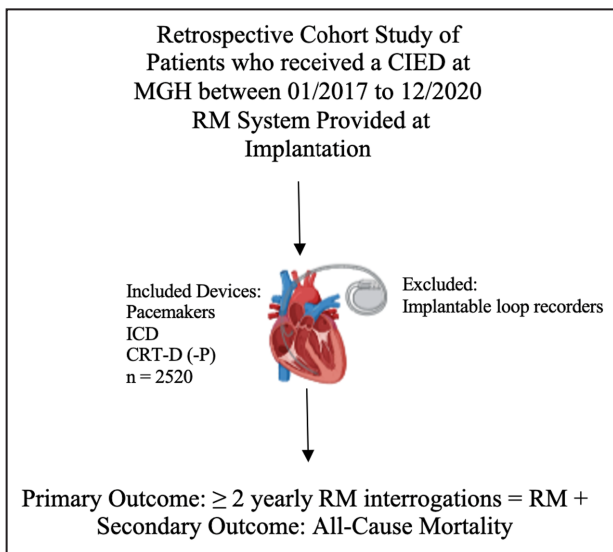


Figure 1. Overview of the study design.

Study design of this retrospective cohort study that included all patients who received a cardiac implantable electronic device (CIED) at Massachusetts General Hospital (MGH) between 2017 and 2021. CRT-D indicates cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter-defibrillator; and RM, remote monitoring.

Table 1. Baseline Characteristics of the Patient Population

Characteristic	All patients, n=2520	Remote monitoring positive, n=1693	Remote monitoring negative, n=827	P value
Mean age, y, mean±SD	71.0±13.5	70.0±13.2	72.1±14.1	<0.001
Female sex, n (%)	884 (34)	574 (35)	310 (33)	0.403
Pacemaker, n (%)	1655 (66)	1042 (63)	620 (67)	<0.001
ICD and CRT-D, n (%)	861 (34)	615 (36)	231 (28)	<0.001
Minoritized racial groups, n (%)	374 (15)	228 (13)	146 (18)	0.003
English speaking, no translation service required, n (%)	2283 (90)	1551 (68)	732 (88)	0.020
Median time to first in-person outpatient interrogation, median d (minimum–maximum)	39 (24–50)	38 (23–49)	41 (27–53)	0.021
Median time to first remote outpatient interrogation, median d (minimum–maximum)	92 (59–146)	92.5 (57–140)	93 (65–165)	0.017
Completed college education, n (%)	823 (33)	607 (36)	216 (26)	<0.001
Patient portal, n (%)	1570 (64)	1226 (72)	375 (45)	<0.001
Median income, US dollars (SD)	88668.1 (14751.1)	89201.3 (14521.7)	87544.6 (15247.9)	0.006
Commercial insurance, n (%)	671 (27)	481 (28)	190 (23)	0.004
Noncommercial insurance, n (%)				
Medicaid	152 (5.9)	91 (5)	60 (7)	
Medicare	1729 (67)	1112 (66)	571 (69)	
Uninsured	4 (0.2)	3 (0.1)	1 (0.1)	

The table presents the univariate characteristics of the patient population. All variables are unadjusted. CRT-D indicates cardiac resynchronization therapy with defibrillator; and ICD, implantable cardioverter-defibrillator.

cardiac resynchronization therapy with defibrillators compared with pacemakers ($P<0.001$, Table 1). Table 2 shows the median number of RM interrogations per device and year of device implantation across all groups,

indicating that the median number of remote interrogations increased over the course of the study period.

In a multivariable binary logistic regression model that was adjusted for the significant covariables

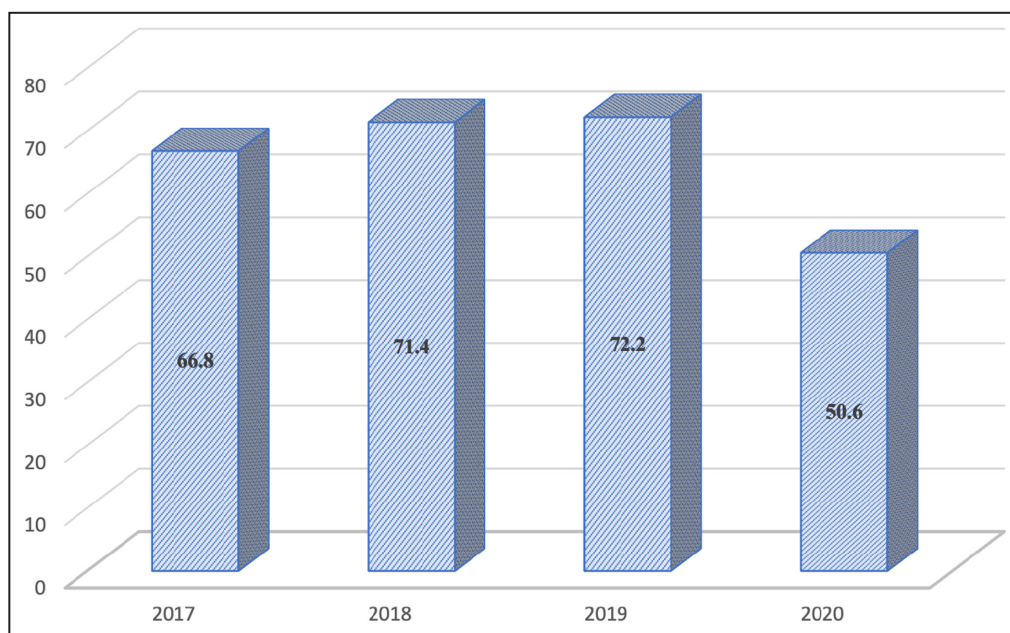


Figure 2. Percentage of remote monitoring positive (RM+) patients by year of device implantation. Patients who received a device in 2020 had a shorter follow-up period and thus had slightly lower allocation into the RM+ group.

Table 2. Median and Quartiles (in Parentheses) of Yearly RM Interrogations and Year of Device Implantation in Patients per Year

Device implantation, y	Median RM, 2017 (range)	Median RM, 2018 (range)	Median RM, 2019 (range)	Median RM, 2020 (range)	Median RM, 2021 (range)
2017	1 (0–2)	3 (1–5)	3 (0–5)	3 (0–5)	3 (0–5)
2018	*	2 (1–5)	4 (1–7)	4 (0–6)	4 (0–5)
2019	*	*	3 (1–7)	5 (1–8)	4 (0–6)
2020	*	*	*	4 (1–7)	4 (2–6)

RM indicates remote monitoring.

*Not an applicable value.

above, patient portal enrollment (odds ratio [OR], 2.889 [95% CI, 2.387–3.496]; $P < 0.001$), presence of an ICD (OR, 1.489 [95% CI, 1.207–1.835]; $P < 0.001$), college education (OR, 1.244 [95% CI, 1.014–1.527]; $P = 0.036$), and European American ancestry (OR, 1.305 [95% CI, 1.259–1.602]; $P = 0.011$) remained significantly associated with remote follow-up, whereas MHI did not remain significantly associated ($P = 0.057$; Table 3).

Lastly, we aimed to determine the impact of the COVID-19 pandemic on the RM status. Here, 1275 patients received a device before 2019 and were thus included in this part of the analysis. In the combined years of 2017 and 2018, 68.2% of patients were RM+, which increased to 70.0% in the years of 2019 and 2020 ($P < 0.001$). In addition, there was a significant increase in the median number of RM interrogations between these groups of patients in the pre-pandemic year 2018 and the COVID-19 pandemic year 2020 (median RM 2018, 3.0 [range, 89] versus median RM 2020, 4.0 [range, 93]; $P = 0.001$). In a regression analysis to predict RM+ status for the pandemic years 2019 and 2020, patient portal enrollment (OR, 3.954 [95% CI, 2.774–5.635]) remained statistically significantly associated with RM+, whereas age, device type, ancestry or ethnicity, and income did not.

Table 3. Adjusted OR to Predict Remote Monitoring Positive Status

Characteristic	OR (95% CI)	P
Age, y	0.988 (0.989–1.008)	0.734
ICD	1.489 (1.207–1.835)	<0.001
European American ancestry	1.305 (1.259–1.602)	0.011
English speaking, no translation service required	1.048 (0.732–1.411)	0.787
College education	1.244 (1.014–1.527)	0.036
Patient portal enrollment	2.889 (2.387–3.497)	<0.001
Median income, US dollars	1.093 (0.997–1.197)	0.057
Commercial insurance	0.825 (0.610–1.115)	0.210

Units were as follows: age = y, median income = US dollars, and all other variables were binary and yes/no. ICD indicates implantable cardioverter-defibrillator; and OR, odds ratio.

DISCUSSION

Given the benefits of RM of CIEDs, it is crucial to understand barriers to successful RM implementation. To date, there are limited data available on this topic. The findings of our study show that several clinical and socioeconomic factors were associated with RM in our patient population with CIEDs at a large academic medical center. First, we found that presence of an ICD and enrollment into the hospital’s online patient portal were strongly and independently associated with successful RM over a mean follow-up of 2 years. Second, socioeconomic variables, such as college education and European American ancestry, were associated with RM+ status. There was also an association of RM positivity with a home address in a county with a higher MHI; however, this did not persist in the multivariate model. Last, during the COVID-19 pandemic, patient portal enrollment remained significantly associated with RM, whereas other disparities did not.

It has been shown that marginalized parts of the US population, such as minoritized racial groups, through adverse social and environmental conditions, as for instance, decreased access to health care, lower-quality education, and nonequal employment opportunities, are predisposed to poor outcomes in cardiovascular disease forming the basis of structural racism that further concentrates power among already privileged groups.^{15–18} In this regard, compared with nonmarginalized adults, minoritized racial groups are more likely to die from heart disease and have the highest risk of heart failure.^{15,19} Similarly, Latinx patients have been found to have a higher risk for hospitalization compared with patients of European American ancestry in the United States.¹⁹ In a recent study, lower MHI was associated with adverse events in patients with atrial fibrillation.²⁰ There are also abundant data reporting that marginalized groups are less likely to receive a primary prevention ICD.^{21–23} However, data on disparities in RM remain scarce. In a recent study, Chew et al studied the clinical and economic outcomes associated with RM, and similar to the present study found that patients who were constantly remotely followed were of younger age and also more likely to have an

ICD in place.⁶ This process is likely multifactorial and includes decreased/lack of digital literacy and hesitancy to adopt new health technologies, visual impairment, and cognitive dysfunction in elderly patients. In our present data, RM was significantly associated with college education and European American ancestry, indicating that despite being offered to all patients at the time of implantation, significant barriers for usage of RM remain present in our health care system.¹⁵ This appears particularly important because RM devices in the present study were provided to all patients at the time of implantation. Therefore, this finding reflects multiple different aspects of our health care system, which are leading to disadvantages for certain groups of patients. Institutions and device clinics must ensure that remote care remains accessible to all patients. Our data show that even when this is attempted, patients are facing significant challenges. Our future task will be to use support systems that assist patients facing challenges and barriers for RM. This should span from pure technical support to understanding and education about these systems, to the appropriate devices needed, and finally to further actions against structural racism and implicit bias leading to the described status quo.

The COVID-19 pandemic has led to a large increase in the use of different forms of telemedicine or virtual care delivery. Recent studies have indicated that telemedicine might improve access to care overall; in one study the authors speculated that as long as access to the necessary technologies can be guaranteed, telemedicine access will be more equitable compared with general access to the US health care system.²⁴ Importantly, our data support this statement because disparities in the use of RM improved during the COVID-19 pandemic. However, only half of the study population was included into this portion of the analysis, and therefore this conclusion should be viewed with caution. In addition, during the time of the COVID-19 pandemic it was made policy at our institution that device care is to be performed remotely. This likely explains why some disparities did not remain present during the COVID-19 pandemic.

Limitations

First, this analysis was a single-center study based on observational, administrative claims data, and therefore the findings of this analysis are subject to coding and reporting bias. As an example, it is unclear how ancestry and ethnicity were assessed and in how many cases it was truly self-reported by the patient. Second, we used a county-code-linked MHI data approach that likely lacks precision for individual or patient-based MHI, which might significantly deviate from the value used. Nevertheless, we were still able

to detect a significant difference using this approach in RM+ and RM-negative patients. Third, 82% of the patients included in the study were White, which is reflective of the general population in the New England states, and particularly Massachusetts, which may limit generalizability to other medical centers with more diverse patient populations. Fourth, we did not have other data on other potential confounders in this analysis, such as medical comorbidities, medications, and device indications, that are important covariates of social determinants of health, and thus could influence outcomes as well. Fifth, this is an observational study, and thus we can only speculate on causation of the observed patterns. Sixth, our analyses determining the impact of the COVID-19 pandemic because of the time relationship were only performed in half of the study population, and we therefore cannot exclude that this portion of the analysis was underpowered. Seventh, in this study, we did not perform any comparison analyses between different RM systems, and further data are needed to identify if there are any differences in the user patterns between these technologies. Last, from these data we do not know how many patients from the initial cohort elected to follow up at a different hospital system; in this case, these data might overreport RM-negative patients. Therefore, we conducted a sensitivity analysis in which we excluded all patients who did not follow up in person for ≥ 2 times after device implantation with similar major determinants of RM+. This is the first analysis to determine general and socioeconomic predictors of CIED RM follow-up in a large academic medical center and determine the impact of the COVID-19 pandemic.

CONCLUSIONS

Despite being offered to all patients at the time of implantation, significant disparities persisted in RM of CIEDs in this single-center cohort. Disparities decreased during the COVID-19 pandemic. Further studies are needed to examine health center- and patient-specific factors to overcome these barriers, and to facilitate equal opportunities to participate in RM.

ARTICLE INFORMATION

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Disclosures

None.

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