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ORIGINAL ARTICLE

Physical Activity in Cardiac Implantable Electronic Device Recipients During the COVID-19 Pandemic

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Abstract

Objective: To characterize the physical activity (PA) level in patients with a cardiac implantable electronic device (CIED) during the coronavirus disease 2019 (COVID-19) pandemic and compare PA level during the pandemic in 2020 with the year 2019.

Methods: We performed a retrospective analysis of PA activity in individuals implanted with a CIED enrolled in the BIOTRONIK CERTITUDE Registry. Mean daily and weekly PA from January to August 2020 was compared with 2019.

Results: A total of 21,660 individuals met eligibility criteria, with mean age of 72.6±11.6 years, and 12,411 (57.3)% were males. A significant decline in daily PA was noted following the pandemic declaration in 2020, with a maximum mean reduction of -24.5±36.3 minutes ($P<.0001$) observed in April 2020 compared with 2019. PA in 2020 increased from April to May (120.6±67.4 to 129.2±70.9 min/d). PA was lower for all months in 2020 compared with 2019. The decrease in PA was observed in all prespecified groups based on age, sex, type of device, and region of the country.

Conclusion: After the declaration of the coronavirus disease 2019 pandemic, a significant decline in daily PA was observed in individuals with a CIED. Future investigation to establish the impact of this reduction on short and long-term cardiovascular outcomes is required.

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The World Health Organization declared the coronavirus disease 2019 (COVID-19) a global pandemic on March 11, 2020.[1] To curb the disease's spread, varying degrees of social distancing guidelines have been established. Although the time frame, adoption, and enforcement of these restrictions have varied, these restrictions are anticipated to reduce physical activity (PA) among the general population.[2] Patients with chronic heart diseases and related comorbidities are particularly vulnerable to severe COVID-19 and, consequently, it is strongly recommended they adhere to public health guidelines to avoid contracting the disease.[3,4]

Cardiac implantable electronic devices (CIEDs) implanted in patients with bradyarrhythmia, ventricular tachyarrhythmias, and heart failure collect daily PA data using an implanted sensor.[5,6] Prior studies have shown that CIEDs detected increased PA correlating with reduced incidence of implantable cardioverter-defibrillator (ICD) shocks, improved heart failure outcomes, and survival.[7] The reduction of PA in patients with CIEDs, specifically during the pandemic, may result in deleterious effects on long-term mortality and morbidity. We sought to characterize the PA level and differences in activity level during the COVID-19 pandemic compared with the year 2019 in recipients of CIEDs enrolled in the BIOTRONIK CERTITUDE registry.

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METHODS

Data Sources

The CERTITUDE program was established to analyze data for US patients implanted with a BIOTRONIK CIED collected via the BIOTRONIK Home Monitoring remote cardiac device monitoring system (BIOTRONIK SE & Co. KG, Berlin, Germany), which gained initial US Food and Drug Administration approval in 2001, and has been described previously.[8] The CERTITUDE registry consists of approximately 50,000 US patients implanted with 60,000 market-released BIOTRONIK implantable loop recorder, pacemaker, cardiac resynchronization therapy with a pacemaker (CRT-P), ICD, and cardiac resynchronization therapy with a defibrillator (CRT-D) devices with BIOTRONIK Home Monitoring capability. These patients have provided authorization for the use of their data for research purposes. The Advarra Institutional Review Board (Columbia, MD) reviewed and approved the CERTITUDE program, which granted a Waiver of Informed Consent and a Full Waiver of Health Insurance Portability and Accountability Act Authorization. A steering committee of independent physicians reviews investigator-initiated CERTITUDE proposals before execution. A charter establishes the conduct of the CERTITUDE Steering Committee and BIOTRONIK personnel.

The CERTITUDE registry dataset consists of remote monitoring transmission data for these 60,000 CIEDs, supplemented by device registration and demographic data obtained from the BIOTRONIK US device-tracking database. Remote monitoring data from January 2019 to August 2020, including PA, atrial arrhythmia burden (atrial tachycardia/atrial fibrillation burden), heart rate variability, mean ventricular heart rate, and corresponding demographic and device registration data were evaluated for this study.

Study Population

Individuals from the CERTITUDE registry implanted with a BIOTRONIK pacemaker, CRT-P, ICD, or CRT-D on or after January 1, 2010, were eligible for inclusion in this analysis. Patients with an eligible device implanted after December 31, 2018, patients without at least one remote transmission per month in January to August of 2019 and 2020 (eg, missing remote transmission, patient death, and device explant without replacement), and patients who underwent a procedure to change device type during the study time period (eg, ICD to CRT-D) were excluded.

Home Monitoring Parameters

Patient PA is reported daily as a percentage value, representing the time in a state of "activity" determined by comparing the acceleration measured by a capacitive single-axis accelerometer at ∼0.4 Hz to a threshold value. The accelerometer collects PA data independent of the programming of rate-responsive mode. PA values were converted to minutes per day, and activity data obtained within the first 45 days of the device implant were excluded due to potential restrictions on activity for patients immediately after the implantation. Heart rate variability is assessed based on the standard deviation of the 5-minute mean normal to normal interval over the recorded time based on the atrial P-P rate. Mean ventricular heart rate reports the daily mean ventricular rate calculated using sensed ventricular events, paced ventricular events, premature ventricular contractions, and ventricular rate stabilization events. The atrial arrhythmia burden (atrial tachycardia/atrial fibrillation burden) is reported as a percentage value, representing the time per day spent in device-detected atrial tachyarrhythmia.

Statistical Analysis

Continuous variables were reported using means with SD, whereas categorical variables were reported using frequencies with percentages. Paired *t* tests (two-tailed) were used to compare continuous variables between months for 2020 and 2019. Using a reduction threshold of 10 min/d between 2019 and 2020, subjects were classified as above or below the threshold, and a two-tailed binomial proportional test was conducted to determine if a majority of subjects had higher reductions between the periods. Plots of weekly averages were generated for continuous variables across the study's total

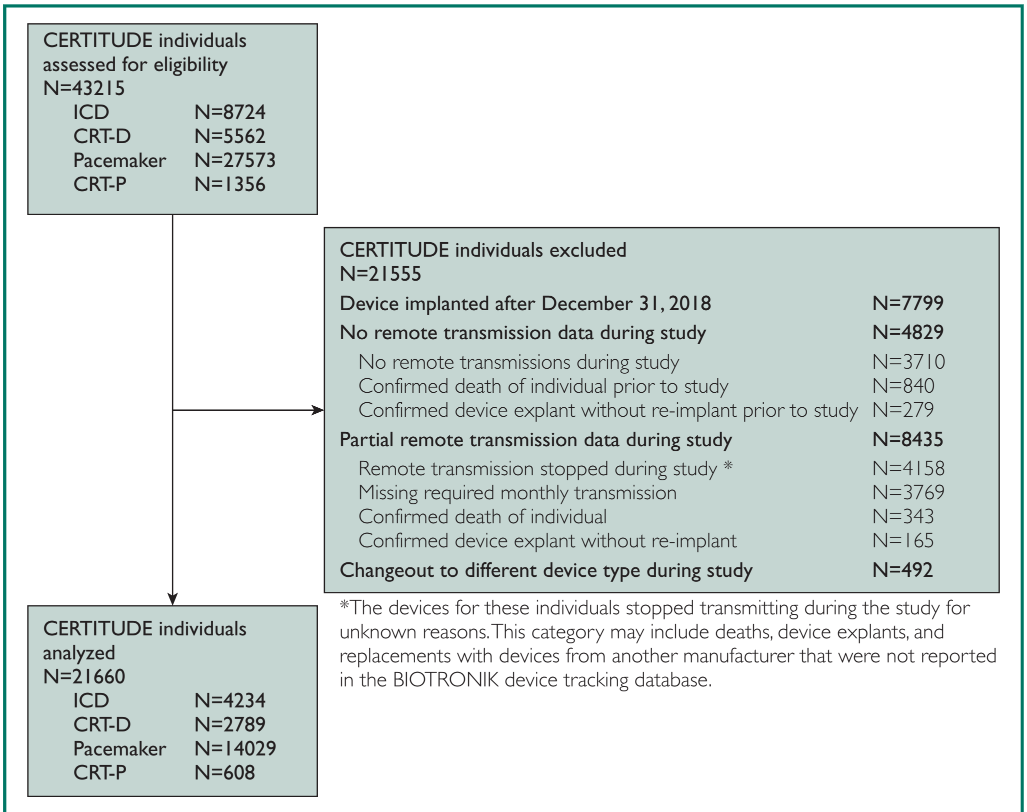

FIGURE 1. Flow chart showing the derivation of the study cohort. CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter-defibrillator.

time frame (January 1, 2019, to August 31, 2020), and for January to August, stratified by year. Spearman's rank-order correlation was used to assess the correlation between PA and atrial arrhythmia burden in each month of 2020. All statistical analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC) using a significance level of 0.05.

RESULTS

Physical Activity

A total of 21,660 individuals from the CERTITUDE registry were implanted with a BIOTRONIK pacemaker, CRT-P, ICD, or CRT-D, meeting all eligibility requirements. Figure 1 details the derivation of the study cohort. The baseline characteristics of the cohort are presented in Table 1. The mean age of the cohort was 72.6±11.6 years, and 12,411 (57.3%) were male. The mean follow-up duration, defined as first-to-last remote transmission, was 1.66±0.01 years (607.0±3.64 days), and a total of 12.3 million days with transmission were analyzed. The mean transmission number of days per individual was 568.66±3.64 days, and the mean transmission completeness per individual during the follow-up period was 93.5%. The mean daily and weekly duration spent being physically active in January through August in 2020 is compared with 2019 in Table 2 and Figure 2A, respectively. A significant decline in time spent being physically active was noted following the pandemic declaration in 2020, with a maximum mean reduction of -24.5±36.3 minutes ($P<.0001$) observed in April 2020 compared with 2019. PA in 2020 increased from April to May, with PA for all months in 2020 at lower levels than 2019. More than half of the cohort experienced a reduction in PA of 10 minutes or more in March through August 2020, consistent with widespread effect across the cohort (Table 2).

PA declined in both men and women in this period (Figure 2B). A similar degree of decline in PA was observed in all strata of age in March and April 2020. However, individuals older than 80 years notably showed less rebound in the subsequent months. A reduction in activity was noted from June through August 2020 (Figure 2C and Table 3). A similar trend in reduction in PA was noted across different device types (Figure 2D). PA data were stratified by the country's region and are presented in Figure 3.

Heart Rate, Heart Rate Variability, and Atrial Arrhythmia Burden

Corresponding to the decline in PA, we noted a small reduction in the ventricular rate following the pandemic declaration (Supplementary Table 1, available online at http://www.mayoclinicproceedings.org). Heart rate variability represented by variability in the atrial rate was lower in March through August 2020 than corresponding months in 2019 (Supplementary Table 1). However, these changes were small and of unknown clinical significance. The burden of atrial arrhythmia progressively increased throughout the study (Supplementary Figure, available online at http://www.mayoclinicproceedings.org). There was no correlation between PA and atrial arrhythmia burden in each month of the pandemic (Supplementary Table 2, available online at http://www.mayoclinicproceedings.org).

TABLE 1. Baseline Characteristics of the Cohort[a,b]

Characteristic	N = 21,660
Age at enrollment, y	
Mean ± SD	72.6±11.6
Range	9.2 to 102.5
Sex	
Male	12,412 (57.3)
Female	8054 (37.2)
Unknown	1194 (5.5)
Implant type	
ICD	4234 (19.6)
CRT-D	2789 (12.9)
Pacemaker	14,029 (64.8)
CRT-P	608 (2.8)
Geographic region	
Midwest	5195 (24.0)
Northeast	2788 (12.9)
South	8148 (37.6)
West	5436 (25.1)
Unknown	93 (0.4)
Implant year	
2010 to 2013	307 (1.4)
2014 to 2015	990 (4.6)
2016	3548 (16.4)
2017	9313 (43.0)
2018	7502 (34.6)

[a]CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter-defibrillator.
[b]Values are n (%) unless otherwise stated.

DISCUSSION

Using data from a large patient cohort from the BIOTRONIK CERTITUDE registry, we report a significant decrease in device-detected PA following the global COVID-19 pandemic declaration in March 2020, compared with the same period in 2019. This decline in PA was noted across all sexes, ages, regions, and device types.

The global COVID-19 pandemic declaration in March 2020 was followed by social distancing guidelines and various degrees of restrictions on daily activities.

The corresponding reduction in PA in individuals with CIEDs may be secondary to decreased daily activity such as exercise. Our findings parallel those of Tison et al,[2] who reported a 27% decline in the average PA at 30 days following the pandemic declaration across the globe using data from a smartphone-based application. Sassone et al[9] also reported a 25% reduction in PA in a small cohort of Italian patients with ICDs in the first 40 days of government-imposed quarantine. Self-reported vigorous physical activity decreased by 17% in an adult cohort in Spain in the months of March and April 2020.[10]

There were regional differences in the type of restrictions (spanning from the closure of all non-essential activities and

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TABLE 2. Comparison of Daily PA (Minutes Per Day) in January Through August[a]

Month	N[b]	2019 − mean PA ± SD, min/d	2020 − mean PA ± SD, min/d	Difference (2020 − 2019)	*P* (paired Student *t* test), two sided	% Individuals with reduction in PA of 10 min/d or more in 2020	Binomial proportion test (Ho: % difference = 50%)
January	20,999	135.6±68.5	131.9±68.7	-3.7±33.0	<.0001	38.0	<.0001
February	21,034	137.4±69.2	133.2±69.6	-4.3±33.9	<.0001	38.5	<.0001
March	21,047	141.5±70.4	126.4±67.7	-15.0±33.2	<.0001	56.6	<.0001
April	21,037	145.1±71.4	120.6±67.4	-24.5±36.3	<.0001	69.0	<.0001
May	21,049	147.0±72.5	129.2±70.9	-17.8±35.1	<.0001	60.3	<.0001
June	21,042	146.5±72.8	132.0±72.2	-14.5±34.6	<.0001	55.8	<.0001
July	21,043	143.0±71.4	129.1±71.6	-13.9±34.0	<.0001	55.0	<.0001
August	21,036	142.5±71.8	127.7±71.3	-14.8±33.9	<.0001	55.7	<.0001

[a]PA, physical activity.
[b]Remote transmissions with 0%, 100% ,or missing PA values were excluded from the analysis. Therefore, the total number of transmissions analyzed per month are variable and less than the total number of patients in the analyzed cohort.

quarantine to limits to social gatherings), enforcement, and the timeline of lifting restrictions. Besides, the timing and severity of the COVID-19 infection peak have also varied between states. Despite these variations from state to state, we observed a parallel reduction in PA in all regions of the country. However, the majority of the states had stringent restrictions in the months of March and April compared with the rest of the study period, which corresponded to the most significant decline in recorded PA. This observation may be secondary to self-imposed quarantine in patients with chronic

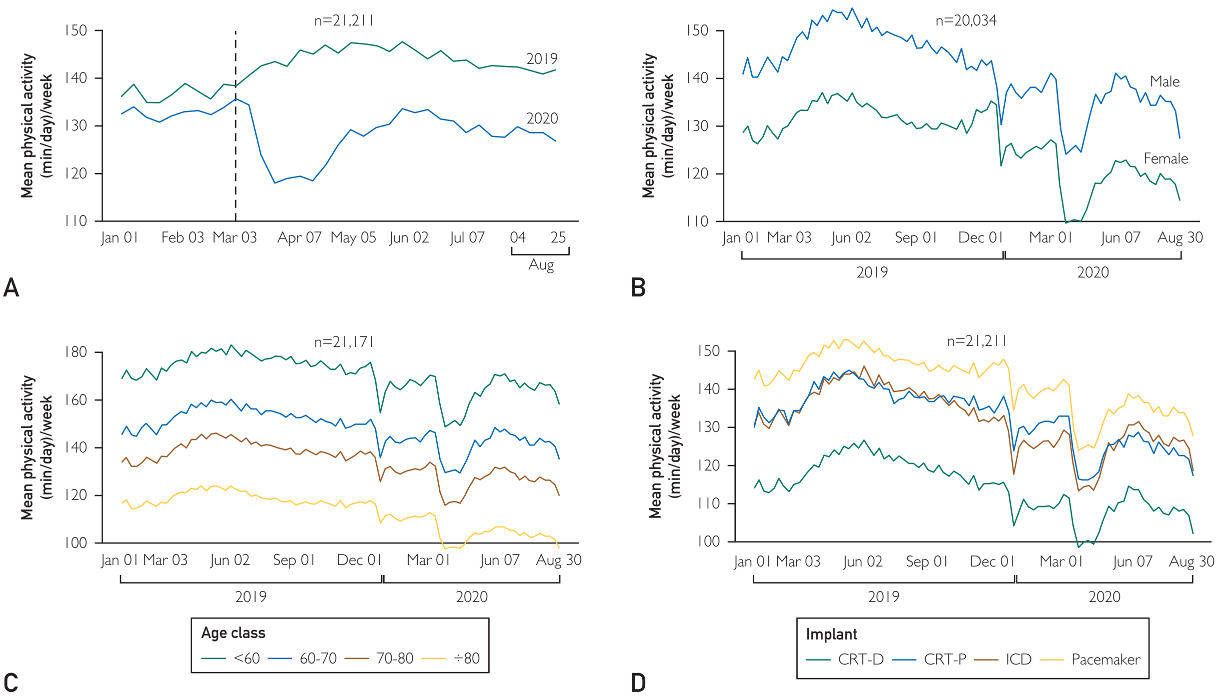

FIGURE 2. Mean physical activity (minutes per day) in the year 2020 compared with 2019 in the (A) entire cohort and stratified by (B) sex, (C) age, and (D) device type.

TABLE 3. Reduction in Mean Daily PA in 2020 Compared With 2019 in Different Strata of Age[a,b]

Month	Age, y <60[b]	60–70[b]	70–80[b]	>80[b]
January	-3.6±40.3	-2.8±36.7	-3.1±30.8	-5.5±27.1
February	-3.6±42.0	-3.8±38.1	-3.9±31.3	-5.4±27.7
March	-14.7±42.1	-14.7±36.3	-15.1±31.0	-15.5±27.2
April	-25.6±45.8	-24.5±39.6	-24.4±33.8	-24.3±29.8
May	-15.7±44.7	-16.4±38.1	-18.0±32.6	-19.8±28.6
June	-12.4±43.3	-12.5±37.6	-14.6±32.4	-17.4±38.4
July	-11.3±42.4	-12.0±36.9	-14.6±32.4	-16.2±27.3
August	-12.8±44.4	-13.6±35.7	-14.8±31.4	-16.9±28.1

[a]PA, physical activity.
[b]The mean ± SD reduction in daily PA (minutes per day) in 2020 compared to the corresponding month in 2019 is presented.

diseases due to public knowledge of the reported higher mortality and need for intensive care unit support in individuals older than 60 years and those with known cardiovascular diseases.[11,12] For instance, Guo et al[13] reported that patients with pre-existing cardiovascular diseases had higher mortality and a higher likelihood of myocardial injury with COVID-19 infection. Another potential reason for the noted reduction in PA may be related to COVID-19 illness in some patients in the cohort, although this could not be ascertained from the registry.

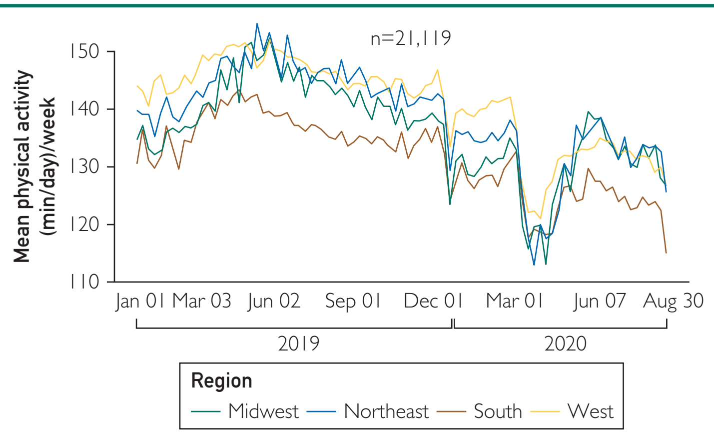

FIGURE 3. Mean physical activity (minutes per day) stratified by region of the country.

A significant cardiovascular involvement is reported with COVID-19.[14] Early data suggest an increased risk of myocarditis, myocardial infarction, heart failure, and arrhythmias.[15] The potential effects of restricted PA during quarantine periods on cardiovascular outcomes have not been widely reported but cannot be ignored. The cardiovascular and mental health benefits of exercise are well established in patients with known cardiovascular diseases such as heart failure. Reduction in PA in patients with ICD and CRT-D devices has been associated with an increased risk of death and heart failure hospitalizations.[16−19] Kelly et al[17] reported a four-fold increased risk of death and heart failure hospitalization with a 10-minute reduction in PA within a particular patient. Furthermore, reduced PA has also been shown to be associated with a higher burden of atrial arrhythmia.[20] As a corollary, patients with heart failure and ICD undergoing exercise training have a lower risk of ICD therapies.[21] Although we report an increase in atrial arrhythmia burden during 2020 compared with 2019, it does not correlate with a decrease in PA. Potential reasons include the aging of the population, limited access to health care, and anxiety.

The current study does not explore the health-related consequences of reduced PA in patients with a CIED, which should be the subject of future investigation. Future studies should be designed to combine patient-specific CIED data from remote monitoring with other clinical data sources to assess the risks associated with changes in activity and the impact on short- and long-term cardiovascular outcomes as well as interventions to mitigate this risk. To identify significant population-level effects, large-scale studies such as designs using real-world data sets may be preferred over reports of single-center experience or other small-scale studies.

Study Limitations

This study has limitations inherent to the observational study design. Although a reduction in PA is demonstrable, the

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database does not have data regarding the cause and effects of this reduction. The dataset does not contain clinical data regarding COVID-19 infection or cardiovascular outcomes such as heart failure hospitalization and death. Our study is limited to individuals with a CIED with underlying cardiac disease and predominantly included individuals older than 60 years of age. Hence, these findings cannot be generalized to healthy individuals or younger populations. PA data were not obtained using a gold standard external accelerometer. However, prior studies have reported on the reliability of CIED-derived PA data. For example, Pressler et al[22] reported an excellent intra-individual correlation between a CIED PA sensor and an external accelerometer. Subsequently, several studies have used CIED sensor—derived data to assess PA and to predict early worsening of heart failure, establishing the validity of this technique.[23,24]

CONCLUSION

Following the declaration of the COVID-19 pandemic, a significant decline in daily PA was observed in individuals with a CIED. Future investigations to establish the impact of this reduction on short- and long-term cardiovascular outcomes is necessary.

POTENTIAL COMPETING INTERESTS

Camden Harrell and Jacob Hicks are salaried BIOTRONIK employees. Dr Cha has received a research grant from Medtronic. Dr Asirvatham receives royalties for work licensed through Mayo Clinic to a privately held company for contributions related to the use of nerve signal modulation to treat central, autonomic and peripheral nervous system disorders, including pain (Mayo Clinic receives royalties and owns equity in this company — the company does not currently license or manufacture any drug or device in the medical field); co—patent holder for technique to minimize coagulum formation during radiofrequency ablation; inventions/startup companies include Nevro, Aegis, and the Phoenix Corp; has received honoraria/speaker fees from Abiomed, Atricure, BIOTRONIK, Blackwell Futura, Boston Scientific, Medtronic, Medtelligence, Spectranetics, St Jude, and Zoll; and has received consulting fees from Aegis, ATP, Nevro, Sanovas, Sorin Medical, and FocusStart. Dr Madhavan serves on the steering committee of CERTITUTDE, BIOTRONIK, Inc. The remaining authors report no potential competing interests.

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SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at http://www.mayoclinicproceedings.org. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviations and Acronyms: **CIED**, cardiac implantable electronic device; **COVID-19**, coronavirus disease 2019; **CRT**, cardiac resynchronization therapy; **ICD**, implantable cardiac-defibrillator; **PA**, physical activity

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