Immediate and long-term effects of the COVID-19 pandemic and lockdown on physical activity in patients with implanted cardiac devices

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Abstract

Background: Physical activity (PA) is an important determinant of cardiovascular health that may be affected the COVID-19 pandemic. Therefore, we examined the immediate and long-term effects of the pandemic and lockdown on PA in patients with established cardiovascular risk.

Methods: Objectively-measured daily PA data was obtained from cardiovascular implantable electronic devices (CIEDs) from 3453 U.S patients (mean and standard deviations [SD] age, 72.65 [13.24] years; 42% women). Adjusted mixed-effects models stratified by device type were used to compare daily PA from periods in 2020: pre-lockdown (March 1–14), lockdown (March 15 to May 8), and the reopening phase of the pandemic (May 9 to December 31) versus 2019. Patient characteristics and events associated with inactivity during lockdown and the proportion of patients who returned to their 2019 PA-level by the end of reopening phase (December 31, 2020) were examined.

Results: Daily PA was significantly lower during the lockdown compared to the same period in 2019 (-15%; p < .0001), especially for pacemaker patients, adults aged <65, and patients more active prior to lockdown. Non-COVID hospitalization and ICD shock were similarly associated with low PA during lockdown (p = .0001). In the reopening phase of the pandemic, PA remained 14.4% lower in the overall sample and only 23% of patients returned to their 2019 PA level by the end of follow-up.

Conclusions: In this large cohort of patients with CIEDs, PA was markedly lower during the lockdown and remained lower for months after restrictions were lifted. Strategies to maintain PA during a national emergency are urgently needed.

KEYWORDS

arrhythmia, exercise, implantable cardioverter-defibrillator, pacemaker

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1 | INTRODUCTION

Physical activity (PA) is an important factor for prevention and management of cardiovascular disease (CVD)¹ that has been greatly affected by the outbreak of a novel coronavirus in 2019 (SARS-CoV-2) and public health strategies to reduce the global burden of COVID-19. Among the general population, preliminary data from a study of 185,000 US adults showed a 48% decrease in daily PA during a nationwide lockdown (March through April 2020).² Sedentary behaviors such as time spent using the computer, lying down, and watching television also increased substantially in the U.S and in other countries during mandatory lockdowns.^{2,3} These trends are concerning, as even relatively short periods of reduced PA (1-14 days) can promote metabolic, inflammatory and hemodynamic alterations that increase risk for cardiovascular morbidity, mortality, and arrhythmogenic complications in patients with underlying cardiac dysfunction. 1,4 Longer durations of inactivity (≥4 weeks) have also been associated with decreased exercise tolerance, increased pulmonary congestion, and a higher risk of hospitalization in patients with heart failure. 5,6 Considering that millions of adults with underlying CVD may self-isolate for a longer duration due to a heightened risk of morbidity and mortality from COVID-19,7 it is paramount to identify patients who may benefit from close monitoring and referral to PA interventions to prevent clinical deterioration.

Accordingly, we sought to describe and quantify the effects of the COVID-19 pandemic and the statewide lockdown in North Carolina on daily PA in a large, well-characterized cohort of patients with implanted cardiac devices. Since longitudinal PA is automatically collected by implanted cardiac devices and is routinely integrated into electronic health records (EHR), these devices provide a unique opportunity for analysis of PA trends before, during, and after the lockdown in a population of patients with pre-existing CVD who are typically older with multiple comorbidities. We also examined patient characteristics and clinical events associated with inactivity during the lockdown and assessed the extent to which reductions in PA persisted after restrictions were lifted. Lastly, we identified subgroups of patients at risk for worse health outcomes due to prolonged inactivity during the COVID-19 pandemic.

2 | METHODS

2.1 | Study design

To contain the spread of COVID-19, the Governor of North Carolina issued a series of executive orders beginning on March 15, 2020 that strongly encouraged residents to stay home, and closed schools, restaurants, gyms, and other non-essential businesses. A statewide, stay-at-home order was issued on March 30, 2020 until April 23, 2020, and later extended until May 8, 2020. On May 9th non-essential businesses, public parks, and eventually restaurants and some schools reopened at a reduced capacity.

We examined daily PA from January 1, 2019 to December 31, 2020. Prepandemic data from 2019 were used to establish long-term PA

trends and control for seasonal variation in activity.⁸ The average number of minutes of PA per day from March 1, 2020 to March 14, 2020 were used to calculate a prelockdown level of PA for each patient, allowing us to control for baseline PA in our analysis. We defined the COVID-19 lockdown period as March 15, 2020 to May 8, 2020 and the reopening phase of the pandemic as May 9, 2020 through December 31, 2020 (end of study follow-up). Daily PA during the COVID-19 lockdown and reopening phase of the pandemic were compared with data from the corresponding periods in 2019. This study design and analytic approach has been used previously to assess potential adverse health impacts of the COVID-19 pandemic.⁹

The institutional review board at the University of North Carolina (UNC) at Chapel Hill School of Medicine approved the study and waiver of informed consent. The manufacturers of devices used in this study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The data that support the findings of this study are available from the corresponding author upon reasonable request.

2.2 | Patient cohort and data sources

The study cohort was derived from patients enrolled in the University of North Carolina Cardiovascular Device Surveillance Registry (UNC CDSR), a prospective, multicenter clinical research registry for all cardiovascular implanted electronic devices (CIEDs), including pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implanted cardiac monitors (ICMs), implanted at the UNC Medical Center and eight affiliated hospitals from 2010 to present. Figure 1 shows the geographic distribution of participating hospitals and patients (using zip code of residence). The registry captures information from remote monitoring transmissions and routine follow-up clinic visits for all CIED implants, upgrades, and replacements. As of January 2021, > 90% of all CIED patients implanted at participating centers were enrolled in remote monitoring (most at the time of implant), suggesting that the UNC CDSR captures a high rate of longitudinal device data from a diverse patient population in a large geographic area.

All patients in the registry who were at least 18 years old with Medtronic (Minneapolis, MN, USA) or Boston Scientific (Marlborough, MA, USA) cardiac devices (ICM, ICD or pacemaker) implanted prior to January 30, 2019 and who had continuous device data throughout the study period were eligible for inclusion. Our analyses were restricted to these two manufacturers to facilitate PA data comparisons, as they use similar methodology for PA assessment. Individuals not meeting study criteria and those who underwent device reprogramming or replacement with a change of manufacturer during follow-up were excluded.

Daily PA data were obtained from the accelerometer embedded in the CIED generator. The process of PA data collection by CIED accelerometer and a summary of validation studies are available in a recently published review. ¹⁰ Briefly, as the patient moves or accelerates, internal sensors detect changes in the frequency and amplitude

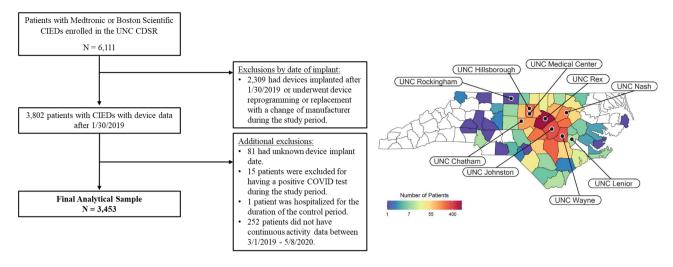


FIGURE 1 Study Cohort [Color figure can be viewed at wileyonlinelibrary.com]

of body motion, generating an electrical signal that is proportional to patient movement. ¹¹ Patient acceleration that meets or exceeds a preprogrammed threshold is considered an active minute and the total minutes of PA per day are automatically stored in device memory. PA is recorded similarly by Medtronic and Boston Scientific devices and would be considered light-intensity PA that is equivalent to walking at a slow pace (details provided in the Data Supplement). ¹²

As in previous studies, 13 PA data from the first 30 days postimplant were excluded from analysis to account for procedural recovery. In addition, data on all episodes of ICD shock were obtained from the registry because prior studies have shown a significant reduction in PA after ICD shock. 14 Electrograms for all arrhythmia episodes treated by ICD shock were adjudicated by a board-certified electrophysiologist in a blinded manner.

Sociodemographic information, clinical history, medications, and hospitalizations were abstracted from outpatient and inpatient EHR notes using automated computer algorithms and standard methodology. Sociodemographic information was collected closest to the pre-COVID period. Comorbidities were considered present and assumed to persist if the International Classification of Diseases, Tenth Revision (ICD-10) code for that specific condition was recorded in the EHR prior to January 1, 2020. Individuals with laboratory confirmed diagnoses of COVID-19 during follow-up (n=55) were excluded from the study, as the virus may have unique behavioral effects on PA. Additionally, because individuals may alter their behavior, and thus PA, in response to local disease transmissibility, data on new confirmed cases of COVID-19 in North Carolina were obtained from publicly available datasets for the period March 1 through December 31, 2020. 18

2.3 | Statistical analysis

Descriptive statistics were used to summarize the sample characteristics, and comparisons were made with Student t test or by Pearson's Chi-Squared tests, as appropriate. Sample characteristics were also compared by quartiles of prelockdown PA. Continuous variables

are expressed as means and standard deviations (SD) for continuous variables, and frequency (percentage) for categorical variables. A two-sided p value of less than .05 was considered significant. All analyses were performed with R software, version 3.6.1 (R Core Team, 2019).

In the main analysis, PA was stratified by device type to account for known variation in activity patterns, clinical features, and potential exposures that impact PA in patients with various types of implanted cardiac devices (e.g., ICD shock). We used linear mixed-effects models with daily PA values as the unit of analysis and a random intercept for each patient to estimate trajectories of PA during the COVID-19 lockdown and re-opening phase of the pandemic (May 9, 2020 to December 31, 2020) relative to the corresponding periods in 2019. This analysis allows for correlations between repeated measurements on the same individuals. Effects are reported with 95% confidence intervals (CI). The base model included variables for time since implant as a piecewise linear covariate and adjusted for quartiles of prelockdown PA. All days when an ICD shock occurred and days during hospitalization were initially excluded. Subsequent analyses were performed by adding covariates to the base model. Covariates were selected a priori based on previous literature. 19 Analyses were initially adjusted for age (≥65 years), sex, race/ethnicity (white vs. non-white/all others), and BMI. The larger numbers of patients with pacemakers and ICDs allowed us to further adjust for additional CVD risk factors in those analyses.

Since prior studies have shown a significant effect of hospitalization and ICD shock on PA in device patients, ¹⁴ separate analyses were performed to assess the additional effects of hospitalization and ICD shock on PA during the COVID-19 lockdown period. Linear mixed-effects models with an indicator variable were used to estimate the average difference in PA between days when hospitalization did and did not occur with ICMs as the reference group. A similar procedure was used to estimate the effects of ICD shock on PA in those with ICDs, and a separate model assessed for the effects of appropriate versus inappropriate ICD shocks. In an additional sensitivity analysis, the primary analysis was repeated in persons with an ICD after excluding patients who experienced an ICD shock at any point during the follow-up period.

PA data from the reopening phase of the pandemic and the corresponding period in 2019 were used to identify and compare characteristics of individuals who did and did not return to their 2019 level of PA by the end of the follow-up period (December 31, 2020) using Student *t* test and Pearson's Chi-Squared tests, as appropriate. Additionally, daily PA from March 1, 2020 to December 31, 2020 were plotted in relation to new confirmed cases of COVID-19 in North Carolina to discern whether, and to what extent, PA patterns (a proxy for a behavioral response) may have been influenced by local spread of COVID-19.

3 | RESULTS

Of the 6111 patients with Medtronic or Boston Scientific devices enrolled in the UNC CDSR, 3453 met study inclusion criteria (Figure 1). Of those included in the final cohort, 175 (5.2%) had an ICM, 1594 had a pacemaker (46.2%) and 1681 had an ICD (48.7%). Cohort demographics, comorbidities, and medications according to device type are summarized in Table 1. Patients were predominantly older (mean age of 72.65 \pm 13.24 years) and white (74.7%) with multiple comorbidities. Patients with ICMs tended to be younger with fewer comorbidities relative to those with pacemakers and ICDs.

3.1 | Patient PA prior to the outbreak of COVID-19

In total, PA values were available for 3453 patients (mean days per patient = 657 days). During the prelockdown period, the average daily PA for the entire cohort was 133.7 ± 112 min per day (mean and SD). Table S1 of the Data Supplement presents the characteristics of the study cohort according to quartiles of prelockdown PA. Several baseline characteristics including sex, age, renal dysfunction, heart failure status, medications, and lifestyle factors were associated with PA levels prior to the lockdown period.

3.2 | Changes in PA during the COVID-19 lockdown versus non-COVID control period in 2019

In the overall study cohort (Figure 2), we observed significantly lower PA during the lockdown compared to the same period in 2019 (15% lower overall PA; p < .0001). Patterns were generally consistent when stratified by device type (Table 2 and Figure 3). Among patients with ICMs, daily PA was 9.5% lower during the lockdown relative to the 2019 control period ($-28.34 \, \text{min/day}$, CI: -38.36--17.91, p < .0001), and was 15% lower for patients with pacemakers ($-29.32 \, \text{min/day}$, CI: -30.67, -27.96, p < .0001) and those with ICDs ($-22.77 \, \text{min/day}$, CI: -23.93--21.62, p < .0001). The adverse effects of the lockdown on PA remained significant in multivariate models that were stratified by device type and adjusted for pre-COVID PA, time since implant, sociodemographic characteristics, clinical comorbidities, medications, and depression (all p's < 0.0001).

For all three device groups, the single most important factor associated with lower PA during the lockdown was prelockdown PA (Table 2 and Figure 4), with data suggesting that individuals having the highest PA immediately prior to the lockdown demonstrated the largest absolute decline in daily PA during the lockdown period. Similarly, men and adults age <65 demonstrated significantly lower PA during the lockdown relative to the 2019 control period.

3.3 | Effect of hospitalization and ICD shocks on PA during the COVID-19 lockdown

Overall, 137 (4.0%) patients were admitted to the hospital during the COVID-19 lockdown, which was associated with significantly lower PA during lockdown, after adjusting for device type and time since implant ($-54.27 \, \text{min/day}$, CI: -55.25--53.29, p < .0001). In analyses stratified by device groups, the data show that a hospital admission was associated with significantly lower PA in patients with pacemakers ($-31.14 \, \text{min/day}$) and ICDs ($-13.75 \, \text{min/day}$) relative to individuals with ICMs. Only one patient was admitted to the hospital for ICD shock during the lockdown.

In addition, 18 shocked episodes occurred in 17 patients (1.0% of patients with ICDs) during the lockdown. PA was significantly lower on days when patients experienced ICD shock (-11.24 min/day, CI: -17.96--4.52, p = 0.0001) after adjusting for time since implant. There was no difference in effect between individuals who received appropriate versus inappropriate shocks (p=.47). In post hoc analyses, exclusion of persons who experienced ICD shock at any point during the follow-up period did not significantly alter the primary findings (Table S2 of the Data Supplement).

3.4 Long-term PA trends during the reopening Phase of the pandemic

After the lockdown orders were lifted on May 9, 2020, average daily PA remained 14.4% lower in the overall sample during the subsequent reopening phase of the pandemic (May 9, 2020 to Dec 31, 2020), compared with the corresponding period in 2019 (-13.91 min/day, CI: -14.10-13.72, p<.0001). In analyses stratified by device groups, patients with ICMs had 3.6% lower PA during the reopening phase of the pandemic (-7.75 min/day, CI: -8.71-6.78, p<.0001). Similarly, patients with pacemakers had 17.2% lower PA (-15.58 min/day, CI: -15.86-15.30, p<.0001) and patients with ICDs had 12.5% lower PA (-12.99 min/day, CI: -13.26-12.72, p<.0001).

As shown in Table 3, only 819 out of 3453 patients (23%) returned to their 2019 PA level by the end of follow-up (December 31, 2020). Patients who returned to their previous level of PA tended to be younger (p < .0001), male (p < .0001), and were employed full-time (p = .04). They were also less likely to have a history of diabetes (p = .04) or stroke (p = .03). In addition, Figure 2 shows the potential impact of daily case rates of COVID-19 in North Carolina on overall PA trends. The data show an inverse association between new cases of COVID-19

 TABLE 1
 Cohort characteristics

	Total (N = 3453)	ICM (n = 178)	Pacemaker (<i>n</i> = 1594)	ICD (n = 1681)	p value
Sociodemographic characteristics					
Age (Years) ^a	72.65 (13.24)	64.92 (17.39)	77.59 (11.45)	68.77 (12.62)	<.001
Female sex	1431 (41.6%)	100 (56.8%)	800 (50.3%)	531 (31.8%)	<.001
Race/Ethnicity					<.001
Black or African American	707 (20.6%)	21 (11.9%)	198 (12.5%)	488 (29.2%)	
Hispanic or Latino	65 (1.9%)	4 (2.3%)	25 (1.6%)	36 (2.2%)	
White or Caucasian	2567 (74.7%)	144 (81.8%)	1318 (82.9%)	1105 (66.1%)	
Other	98 (2.9%)	7 (4.0%)	48 (3.0%)	43 (2.6%)	
Employment status					<.001
Full time	360 (13.8%)	43 (32.3%)	125 (9.4%)	192 (16.8%)	
Part time	61 (2.3%)	6 (4.5%)	26 (2.0%)	29 (2.5%)	
Retired	2182 (83.8%)	84 (63.2%)	1179 (88.6%)	919 (80.6%)	
Lifestyle factors					
Body mass index (BMI) ^a	29.78 (6.57)	29.53 (7.48)	29.10 (6.46)	30.46 (6.51)	<.001
Alcohol abuse	31 (0.9%)	0 (0.0%)	10 (0.6%)	21 (1.3%)	.07
Drug abuse	130 (3.8%)	5 (2.9%)	37 (2.3%)	88 (5.3%)	<.001
Smoking status					<.001
Current	250 (7.3%)	13 (7.6%)	75 (4.8%)	162 (9.8%)	
Former	1595 (46.9%)	65 (37.8%)	703 (44.6%)	827 (50.0%)	
Never	1558 (45.8%)	94 (54.7%)	798 (50.6%)	666 (40.2%)	
Device characteristics					
Device manufacturer					<.001
Boston scientific	1029 (29.8%)	1 (0.6%)	528 (33.1%)	500 (29.7%)	
Medtronic	2424 (70.2%)	177 (99.4%)	1066 (66.9%)	1181 (70.3%)	
Time since implant (Years) ^a	3.49 (1.91)	1.93 (0.60)	3.47 (1.86)	3.67 (1.97)	<.001
Clinical comorbidities	0.17 (1.71)	1.70 (0.00)	0.17 (1.00)	0.07 (1.77)	\001
Hypertension	3193 (93.0%)	143 (82.2%)	1462 (92.1%)	1588 (95.1%)	<.001
Previous myocardial infarction	2257 (65.8%)	66 (37.9%)	893 (56.2%)	1298 (77.7%)	<.001
Congestive heart failure	2413 (70.3%)	42 (24.1%)	762 (48.0%)	1609 (96.3%)	<.001
Coronary artery disease	2344 (68.3%)	78 (44.8%)	931 (58.6%)	1335 (79.9%)	<.001
				757 (45.3%)	< 0.001
Diabetes mellitus	1378 (40.2%)	47 (27.0%)	574 (36.1%)	· · · ·	
Obstructive sleep apnea	652 (19.0%)	34 (19.5%)	299 (18.8%)	319 (19.1%)	.96
Stroke/TIA	497 (14.5%)	30 (17.2%)	256 (16.1%)	211 (12.6%)	.01
Lipid disorders	2457 (71.6%)	95 (54.6%)	1111 (70.0%)	1251 (74.9%)	<.001
Peripheral vascular disease	1349 (39.3%)	60 (34.5%)	656 (41.3%)	633 (37.9%)	.06
Valvular heart disease	2323 (67.7%)	86 (49.4%)	1084 (68.3%)	1153 (69.0%)	<.001
Chronic kidney disease	521 (15.2%)	12 (6.9%)	202 (12.7%)	307 (18.4%)	<.001
COPD	1183 (34.5%)	57 (32.8%)	501 (31.5%)	625 (37.4%)	.002
Atrial fibrillation/atrial flutter	2561 (74.6%)	123 (70.7%)	1176 (74.1%)	1262 (75.6%)	.29
Prior sudden cardiac arrest	231 (6.7%)	5 (2.9%)	46 (2.9%)	180 (10.8%)	<.001
Left ventricular assist device	51 (1.5%)	2 (1.1%)	4 (0.3%)	45 (2.7%)	<.001
Medications					
ACE-inhibitor or ARB	2591 (75.4%)	82 (46.6%)	1049 (66.0%)	1460 (87.3%)	<.001
Beta-blocker	3053 (88.8%)	127 (72.2%)	1287 (81.0%)	1639 (98.0%)	<.001
Statin	2548 (74.1%)	95 (54.0%)	1108 (69.7%)	1345 (80.4%)	<.001

(Continues)

TABLE 1 (Continued)

	Total (N = 3453)	ICM (n = 178)	Pacemaker (<i>n</i> = 1594)	ICD (n = 1681)	p value
Calcium channel blockers	1790 (52.1%)	79 (44.9%)	919 (57.8%)	792 (47.4%)	.01
Anti-arrhythmic	1439 (41.9%)	70 (39.8%)	658 (41.4%)	711 (42.5%)	.69
Anticoagulation	2635 (76.7%)	105 (59.7%)	1242 (78.2%)	1288 (77.0%)	<.001
Antiplatelet agent/Aspirin	2956 (86.0%)	135 (76.7%)	1307 (82.3%)	1514 (90.6%)	<.001
Antidepressant	1421 (41.3%)	74 (42.0%)	651 (41.0%)	696 (41.6%)	.91
Psychiatric comorbidities					
Major depressive disorder	704 (20.5%)	40 (23.0%)	308 (19.4%)	356 (21.3%)	.28
Prior anxiety disorder ^c	159 (4.6%)	9 (5.2%)	76 (4.8%)	74 (4.4%)	.84

Abbreviations: ACE, = angiotensin converting enzyme; ARB, angiotensin receptor blocker; COPD, chronic obstructive pulmonary disease; ICD, implantable cardioverter defibrillator; TIA, transient ischemic attack.

^cA composite variable was created for any prior diagnoses of anxiety disorders: generalized anxiety disorder, post-traumatic stress disorder, acute stress disorder and panic disorder.

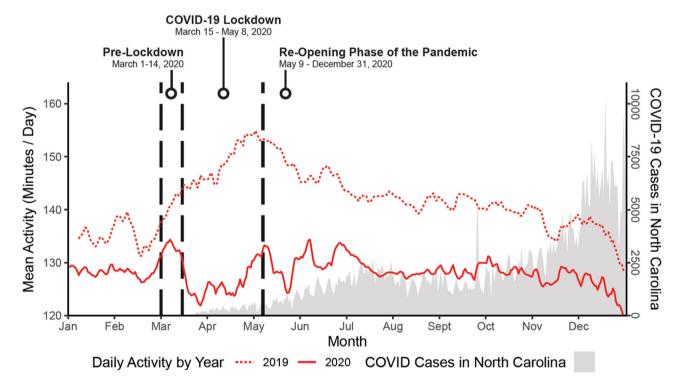


FIGURE 2 Impact of COVID-19 lockdown on daily PA relative to new confirmed cases of COVID-19 in North Carolina [Color figure can be viewed at wileyonlinelibrary.com]

in North Carolina and daily PA, suggesting that changes in PA during the reopening phase of the pandemic were often affected by fluctuations in COVID-19 infections.

4 | DISCUSSION

Until now, information on the secondary health impacts of the pandemic has been limited, especially in medically vulnerable popula-

tions, such as those with underlying CVD, who are more susceptible to acute changes in health status. The principal findings from this study include the following: (1) daily PA was significantly lower in the overall cohort (15%) during the mandatory lockdown in North Carolina relative to the same period in 2019, even when accounting for demographic factors, baseline PA, comorbidities, medications, and depression; (2) the effect on PA was greatest in the pacemaker group, adults <65 years of age, men, and for those who were more active prior to the lockdown period; (3) after the lockdown orders were

^aData are presented as mean \pm standard deviation (SD).

^b Antidepressant medications include selective serotonin reuptake inhibitors/serotonin and norepinephrine reuptake inhibitors.

 TABLE 2
 Changes in activity during the COVID-19 lockdown compared to the same period in 2019 stratified by device type

	ICM		Pacemaker		ICD	
Changes in daily activity during the COVID-19 lockdown (min/day) ³	-28.76 (-38.31, -17.78)	< 0.001	-29.02 (-30.35, -27.63)	< 0.001	-22.80 (-23.91, -21.64)	0.001
Time since implant (years)	0.04 (0.01, 0.07)	0.004	0.009 (0.01, 0.01)	< 0.001	0.01 (0.01, 0.02)	900.0
Pre-COVID PA level ^b						
Low quartile of activity	64.81 (43.87, 85.67)	< 0.001	52.71 (45.64, 59.76)	< 0.001	54.54 (48.57, 60.51)	<0.001
Mid quartile of activity	153.25 (131.91, 174.51)	<0.001	157.99 (150.81, 165.16)	< 0.001	133.8 (127.58, 140.02)	< 0.001
Highest quartile of activity	277.84 (251.53, 304.34)	<0.001	314.07 (304.94, 323.18)	< 0.001	266.38 (258.08, 274.68)	< 0.001
Sociodemographic characteristics						
Age (≥65 years)	-8.84 (-22.92, 5.07)	0.23	-22.58 (-30.93, -14.24)	< 0.001	-13.98 (-18.95, -9.02)	< 0.001
Female	-11.46 (-23.93, 1.01)	0.08	-13.37 (-18.35, -8.39)	< 0.001	-11.85 (-16.41, -7.29)	< 0.001
Non-white race/ethnicity	-4.54 (-21.51, 12.44)	0.61	-3.38 (-9.86, 3.10)	0.31	-1.85 (-6.26, 2.55)	0.42
Lifestyle factors						
Body mass index (BMI)	-5.77 (-11.64, 0.08)	90:0	-1.19 (-3.67, 1.28)	0.35	-3.67 (-5.82, -1.52)	< 0.001
Current smoker			-6.66 (-17.96, 4.61)	0.25	-4.42 (-11.82, 2.99)	0.25
Former smoker			-0.54 (-5.53, 4.46)	0.83	3.07 (-1.30, 7.45)	0.17
Clinical comorbidities and medications						
Atrial fibrillation/atrial flutter			-3.29 (-8.34, 1.77)	0.21	-4.16 (-8.37, 0.06)	90:0
Stroke/TIA			2.24 (-4.24, 8.73)	0.50	-7.26 (-13.40, -1.11)	0.02
Myocardial infarction			-0.94 (-14.67, 12.71)	0.89	-3.26 (-16.49, 9.96)	0.63
Congestive heart failure			-3.91 (-9.05, 1.21)	0.14	10.15 (-1.33, 21.61)	0.09
Coronary artery disease			3.13 (-10.63, 16.94)	99:0	-4.83 (-18.61, 8.98)	0.50
Diabetes mellitus			-2.03 (-7.19, 3.13)	0.44	-3.03 (-7.23, 1.17)	0.16
ACEs/ARBs			2.91 (-2.24, 8.04)	0.27	-3.78 (-10.19, 2.63)	0.25
Beta blockers			1.11 (-5.34, 7.56)	0.73	4.45 (-11.02, 19.92)	0.58
Psychiatric comorbidities			1.09 (-4.97, 7.14)	0.73	-1.49 (-6.50, 3.51)	0.56
Major depressive disorder			1.09 (-4.97, 7.14)	0.73	-1.49 (-6.50, 3.51)	0.56

 $^{^{}a}$ Mean changes in activity (min/day). b Coup) based on the average number of minutes of activity per day recorded by their implanted cardiac device between March 1, 2020 and March 14, 2020.

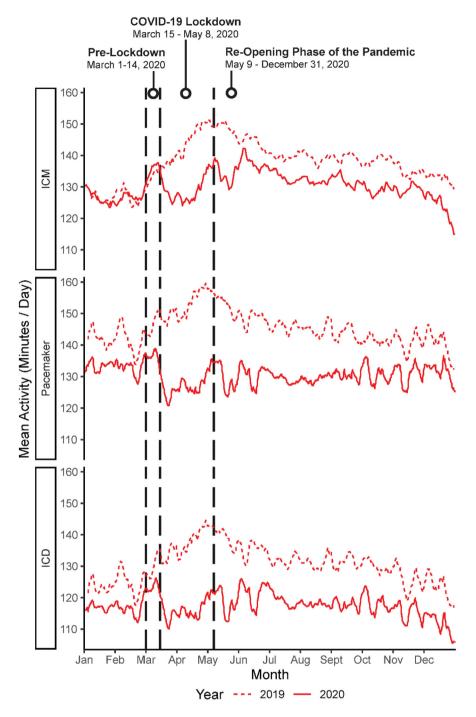


FIGURE 3 Daily PA during the COVID-19 lockdown and the same period in 2019 stratified by device type [Color figure can be viewed at wileyonlinelibrary.com]

lifted, PA initially increased but often declined as cases of COVID-19 increased in North Carolina; (4) our results further suggest that nearly 1 year into the COVID-19 pandemic-7 months after the lockdown orders were lifted-77% of patients in this study had not returned to their previous level of PA from the same period in 2019. These findings suggest that targeted strategies should be developed to maintain the health and wellness of vulnerable populations during the current pandemic and may help us prepare for future public health emergencies.

Early studies of ICD patients in Italy suggested that PA modestly declined during a 40-day national lockdown. Similar trends have been reported in a sample of U.S adults with pacemakers and ICDs, and in pediatric device patients. When the studies were generally limited to small samples of predominantly male patients with devices from a single manufacturer and did not adequately control for risk factors known to affect PA in persons with implanted cardiac devices (e.g., comorbidities, hospitalization and ICD shocks). Consequently, their data do not identify sub-groups of patients who may benefit from

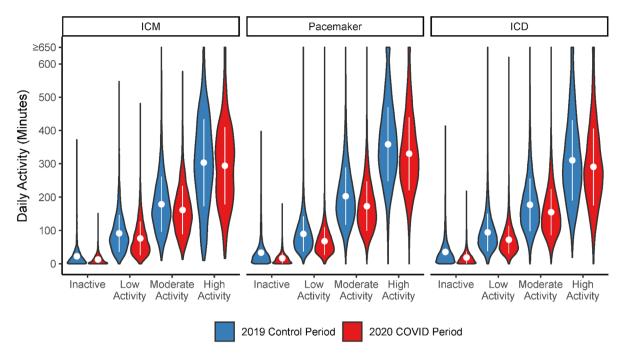


FIGURE 4 Changes in daily PA during the COVID-19 lockdown according to pre-lockdown levels of PA [Color figure can be viewed at wileyonlinelibrary.com]

targeted strategies to maintain PA during a public health emergency. Our findings extend this work by illustrating longitudinal PA trends over a 2-year period in a heterogenous population of patients with CIEDs with continuous PA monitoring and included a wide range of implanted cardiac devices from multiple manufacturers. Moreover, the large size of our dataset and the integration of multiple sources of high-dimensional health data allowed us to comprehensively assess the immediate and long-term impact of the lockdown on daily PA with greater precision.

Results from the current study demonstrate concerning trends in PA among a high-risk group of cardiac patients, especially those with pacemakers and ICDs. Similarly, individuals who were more active immediately prior to the COVID-19 pandemic, adults < 65 years of age, and men experienced significantly lower PA during the lockdown and may benefit from targeted interventions to maintain health-promoting behaviors during the pandemic. We also showed that adverse clinical events, such as hospitalization or ICD shock, had an immediate and detrimental effect on PA during lockdown. This finding may reflect that patients perform very little or no PA during hospitalization.²⁴ Alternatively, patients may experience anxiety and engage in behavioral avoidance after ICD shock. 14 More importantly, reductions in PA did not significantly differ between those who received appropriate versus inappropriate shocks. This finding is consistent with data from a prior study, 14 and suggests that the experience of ICD shock-not the underlying arrhythmia-triggered the behavioral response (i.e., immediate reduction in PA). These results suggest that there may be opportunities to leverage PA data obtained from CIEDs to proactively identify patients at risk for adverse outcomes due to prolonged inactivity and link them to interventions that can facilitate patients' recovery, and

return to activity following critical events, such as a global pandemic, lockdown, ICD shock, or even a prolonged period of time spent at home.

In addition, this study advances our understanding of the long-term effects of the pandemic and lockdown on an important modifiable risk factor for CVD. Although there was an initial increase in PA after the statewide lockdown orders were eased in May 2020, we saw evidence of persistently lower PA for months after restrictions were lifted compared to PA trends from 1 year earlier. This pattern of prolonged inactivity was observed in patients representing a broad clinical spectrum of CVD - from younger patients with ICMs, who presumably have less cardiovascular risk compared to those with ICDs and pacemakers, to those with CRT-D devices and advanced heart failure. Given the robust associations between inactivity and the risk of CVD morbidity and mmortality, 1,4 and the likely increase in other cardiovascular risk factors during the pandemic, ²⁵ ongoing surveillance of these issues should be considered to prevent potential increases in primary and secondary care presentations for CVD in the months and years ahead.

4.1 | Implications of findings

PA is an effective preventive measure that can reduce CVD progression and mortality.¹ Thus, early and ongoing education about the health benefits of PA and the risks of prolonged inactivity is essential to optimize CVD self-management.^{26,13} Patients may also benefit from specific guidance from their healthcare providers regarding strategies for exercising safely during the pandemic.^{27,28} Moreover, it is clear that cost-effective, widely-scalable, technology-based tools

TABLE 3 Characteristics of patients who did and did not return to their 2019 activity levels during the reopening phase of the COVID-19 pandemic

	Did not return to previous activity level (n = 2633)	Returned to previous activity level ($n = 819$)	Total (N = 3453)	p value
Sociodemographic characteristics	(11 – 2000)	activity level (II = 017)	10tal (14 = 0430)	pvalue
Age (Years) ^a	73.698 (12.791)	69.291 (14.068)	72.654 (13.237)	<.001
Female sex	1140 (43.5%)	291 (35.7%)	1431 (41.6%)	<.001
Race/Ethnicity			(,	.67
Black or African American	536 (20.4%)	171 (21.0%)	707 (20.6%)	121
Hispanic or Latino	53 (2.0%)	12 (1.5%)	65 (1.9%)	
White or Caucasian	1961 (74.8%)	605 (74.3%)	2566 (74.7%)	
Other	72 (2.7%)	26 (3.2%)	98 (2.9%)	
Employment status	7 2 (2.770)	20 (0.270)	70 (2.770)	.04
Full time	264 (13.0%)	96 (17.0%)	360 (13.8%)	.01
Part time	47 (2.3%)	14 (2.5%)	61 (2.3%)	
Retired	1727 (84.7%)	454 (80.5%)	2181 (83.8%)	
Device characteristics	1/2/ (04.//0)	TJT (UU.J/0)	2101 (03.070)	
Device type				.13
ICM	132 (5.0%)	14 /E 40/\	178 (5.2%)	.13
Pacemaker		46 (5.6%)		
	1261 (47.9%)	420 (51.3%)	1681 (48.7%)	
ICD	1261 (47.9%)	420 (51.3%)	1681 (48.7%)	07
Device manufacturer	005 (00 (0))	000 (07 00/)	4000 (00 00)	.07
Boston scientific	805 (30.6%)	223 (27.2%)	1028 (29.8%)	
Medtronic Time visual and O'Compa	1828 (69.4%)	596 (72.8%)	2424 (70.2%)	00
Time since implant (Years) ^a	3.492 (1.923)	3.462 (1.866)	3.485 (1.910)	.98
Lifestyle factors	000454444	00.570 // 050	00 704 ((5 (0)	4.7
Body mass index (BMI) ^b	29.845 (6.664)	29.572 (6.250)	29.781 (6.569)	.47
Alcohol abuse ^c	22 (0.8%)	9 (1.1%)	31 (0.9%)	.48
Drug abuse ^c	93 (3.6%)	37 (4.6%)	130 (3.8%)	.19
Smoking status				.31
Current	184 (7.1%)	66 (8.2%)	250 (7.3%)	
Former	1209 (46.5%)	386 (48.1%)	1595 (46.9%)	
Never	1206 (46.4%)	351 (43.7%)	1557 (45.8%)	
Clinical comorbidities				
Hypertension	2445 (93.4%)	748 (92.1%)	3193 (93.1%)	.23
Previous myocardial infarction	1719 (65.6%)	538 (66.3%)	2257 (65.8%)	.75
Congestive heart failure	1843 (70.4%)	570 (70.2%)	2413 (70.3%)	.93
Coronary artery disease	1787 (68.2%)	557 (68.6%)	2344 (68.3%)	.85
Diabetes mellitus	1076 (41.1%)	301 (37.1%)	1377 (40.1%)	.04
Obstructive sleep apnea	502 (19.2%)	150 (18.5%)	652 (19.0%)	.66
Stroke/TIA	399 (15.2%)	98 (12.1%)	497 (14.5%)	.03
Lipid disorders	1882 (71.9%)	574 (70.7%)	2456 (71.6%)	.52
Peripheral vascular disease	1045 (39.9%)	304 (37.4%)	1349 (39.3%)	.21
Valvular heart disease	1790 (68.3%)	533 (65.6%)	2323 (67.7%)	.15
Chronic kidney disease	401 (15.3%)	120 (14.8%)	521 (15.2%)	.71
COPD	900 (34.4%)	283 (34.9%)	1183 (34.5%)	.79

(Continues)

TABLE 3 (Continued)

	Did not return to previous activity level (n = 2633)	Returned to previous activity level (n = 819)	Total (N = 3453)	p value
Atrial fibrillation/atrial flutter	1961 (74.9%)	599 (73.8%)	2560 (74.6%)	.53
Prior sudden cardiac arrest	180 (6.9%)	51 (6.3%)	231 (6.7%)	.56
Left ventricular assist device	37 (1.4%)	14 (1.7%)	51 (1.5%)	.53
Medications				
ACE-inhibitor or ARB	1965 (74.9%)	625 (76.8%)	2590 (75.4%)	.29
Beta-Blocker	2321 (88.5%)	731 (89.8%)	3052 (88.8%)	.31
Statin	1956 (74.6%)	591 (72.6%)	2547 (74.1%)	.26
Calcium channel blockers	1381 (52.7%)	409 (50.2%)	1790 (52.1%)	.23
Anti-Arrhythmic	1083 (41.3%)	356 (43.7%)	1439 (41.9%)	.22
Anticoagulation	2020 (77.0%)	614 (75.4%)	2634 (76.7%)	.34
Antiplatelet agent/Aspirin	2264 (86.3%)	691 (84.9%)	2955 (86.0%)	.29
Antidepressant	1079 (41.2%)	342 (42.0%)	1421 (41.4%)	.66
Psychiatric comorbidities				
Major depressive disorder	536 (20.5%)	168 (20.7%)	704 (20.5%)	.89
Prior anxiety disorder ^d	120 (4.6%)	39 (4.8%)	159 (4.6%)	.79

Abbreviations: ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; COPD, chronic obstructive pulmonary disease; ICD, implantable cardioverter defibrillator; TIA, transient ischemic attack.

and telemedicine interventions need to be developed to supplement traditional in-person care. Preliminary data from a remotely-delivered intervention for patients with atrial fibrillation that was rapidly developed and deployed during the COVID-19 lockdown demonstrated the feasibility and acceptability of this type of intervention, as well as improvements in mood and disease self-management. Whether a similar approach can be used to improve health and health outcomes in other patient populations during routine care or in future public health emergencies requires further investigation.

4.2 | Limitations

This study has some limitations. First, although the UNC CDSR captures data from multiple centers and hospitals located throughout North Carolina, this is a study of patients from a single healthcare system. Second, information on some clinical parameters were not available for this study including NYHA (New York Heart Association) heart failure classification, ejection fraction, and data on lifestyle factors (e.g., adherence to medical therapies, sleep and diet). This is a common limitation of registry-based studies that utilize administrative data. Information on device indication was also not available and PA patterns may differ according to underlying cardiovascular etiology. However, in prior studies, PA measured by CIEDs has not been found to differ among primary and secondary prevention patients after correcting for

device type. ¹⁴ Thus, we stratified our analyses by device type. Third, CIED sensors are highly sensitive to the onset of PA but they are less sensitive to short bursts of movement or vibrations, ³⁰ and they are not able to determine the type or intensity of PA performed (i.e., light, moderate vigorous), ¹⁰ and the data cannot be used to compute metabolic equivalent tasks (METs). ³¹ Thus, data from CIEDs may not generalize to data obtained from other wearable PA devices. Developing CIED-specific PA thresholds will enhance the utility of these data. Finally, we did not have sufficient statistical power to investigate whether reductions in PA during the pandemic were associated with subsequent increases in hospitalizations or deaths. Larger studies are required to ascertain the association between reduced PA during the pandemic and health outcomes.

5 | CONCLUSIONS

In this longitudinal study of North Carolina adults with implanted cardiac devices, PA was significantly lower during the COVID-19 lockdown than during a comparable period 1 year earlier. During the subsequent reopening phase of the pandemic, PA did not return to prepandemic levels for a great majority of patients. Whether technology-based tools can proactively identify patients at risk of low PA and link them to interventions to prevent clinical deterioration during a national emergency or improve secondary pre-

^aData are presented as mean \pm standard deviation (SD).

^bAlcohol and drug abuse diagnoses were obtained from the EHR.

^cAntidepressant medications include selective serotonin reuptake inhibitors/serotonin and norepinephrine reuptake inhibitors.

^dA composite variable was created for any prior diagnoses of anxiety disorders: generalized anxiety disorder, post-traumatic stress disorder, acute stress disorder and panic disorder.

vention of CVD in routine care is an important avenue of future research.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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