

Remotely monitored inactivity due to COVID-19 lockdowns

Potential hazard for heart failure patients

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ABSTRACT

الأهداف: دراسة تأثير حظر التجول أثناء جائحة COVID-19 على النشاط البدني المرضى قصور القلب المزروع بأجهزة إلكترونية قابلة للزرع (CIEDs).

المنهجية: كانت هذه دراسة استرجاعية من مركز واحد المرضى قصور القلب تم إدخالهم باستخدام جهاز المراقبة عن بعد (CIED). قمنا بتحليل البيانات المرسله للنشاط البدني وحالة حجم السوائل لجميع المرضى، قبل وأثناء فترات الإغلاق خلال الفترة من فبراير وأبريل 2020م. كما تم تقييم الحالة السريرية للمرضى.

النتائج: تم تقييم بيانات الجهاز من 429 مريضاً استخدموا جهاز CIED في البداية. واستبعد المرضى الذين يعانون من مسجل حلقة قابل للزرع، ومتلازمة بروجادا أو متلازمة QT الطويلة، والمرضى الذين يعانون من نقل غير كامل. بينما اشتملت الدراسة على 82 مريضاً يعانون من قصور القلب. كان متوسط العمر 65 عاماً (58-72)، وكانت نسبة الرجال 53 (64.6%). وجدنا انخفاضاً بنسبة 27.1% في النشاط البدني، ومتوسط النشاط البدني للمرضى بشكل ملحوظ من 2.4 إلى 1.8 ساعة/يوم ($p=0.000010$).

الخلاصة: تشير البيانات التي تم الحصول عليها عن طريق جهاز CIED للمراقبة عن بعد في مرضى قصور القلب إلى انخفاض كبير في النشاط البدني أثناء منع التجوال بسبب الوباء. الوعي بالمخاطر المستقبلية المحتملة في هذه المجموعة من المرضى له ما يبرره.

Objectives: To study the impact of curfews during the COVID-19 pandemic, on the physical activity in patients of heart failure implanted with cardiac implantable electronic devices (CIEDs).

Methods: This was a retrospective single-center study of heart failure patients inserted with remote monitoring (RM)-capable CIED. We analyzed the transmitted data of physical activity and fluid volume status of all patients, before, and during the lockdown periods between February and April 2020. The clinical status of the patients was also evaluated.

Results: Device data from 429 patients implanted with CIED capable of RM were initially evaluated. Patients with an implantable loop recorder, Brugada or Long QT syndromes, and patients with incomplete transmissions were excluded. Eighty-two patients with heart failure were included. The median age was 65 years (58-72), and 53 (64.6%) subjects were men. There was a 27.1% decline in physical activity, and the median physical activity of patients significantly declined from 2.4 to 1.8 hours/day ($p=0.000010$).

Conclusion: Data obtained by remotely monitored CIED in heart failure patients suggests a significant decline in physical activity during the country lockdown due to the pandemic. Awareness of the future potential hazards in this group of patients is warranted.

Keywords: COVID-19, CRT, ICD, physical activity, remote monitoring

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Cardiac implantable electronic devices (CIEDs) with remote monitoring (RM) capabilities might be beneficial in the clinical management of heart failure (HF) patients in the COVID-19 era. It allows early detection of arrhythmias, pre-clinical HF indicators, and technical device follow-up.¹ In addition, most of the recent generations of CIED continuously collect and store daily physical activity data through a built-in accelerometer, thus providing a new opportunity to assess the patient activity remotely.² Current evidence suggests that device-based measured physical activity combined with other device parameters are accurate and might predict the clinical outcomes in HF patients.³ The World Health Organization (WHO) has established clear guidelines on the minimal amount of physical activity necessary to maintain adequate health and fitness.⁴ In order to provide appropriate care for patients living with CIED while limiting exposure to the hospital staff during the COVID-19 pandemic, the Heart Rhythm Society COVID-19 Task Force update document stated that every effort should be made to perform CIED interrogation via RM rather than in-person visits.⁵

We objectively evaluate the impact of public health measures such as curfews and lockdowns due to the COVID-19 pandemic on physical activity in HF patients.

Methods. This was a retrospective single-center study conducted at Prince Sultan Cardiac Center, Riyadh, Kingdom of Saudi Arabia, including HF patients with reduced ejection fraction (<40%). The study was approved by our institution's Research & Ethics Committee (R20016), and conformed to the Declaration of Helsinki. Verbal informed consent was obtained before the interview during a telemedicine appointment at our institution's outpatient clinics.

Heart failure patients having a left ejection fraction less than 40% were implanted with various models of RM-capable CIED Medtronic devices (Medtronic, Dublin, Ireland) were recruited in the study. Patients who received implantable cardioverter defibrillators or cardiac resynchronization therapy (ICD/CRT) were included. Patients who had an implantable loop recorder, Brugada and/or Long QT syndromes, technical problems in device transmissions, history of

impaired physical limitation, poor mobility, or received ICD/CRT device less than 6 months ago were excluded. Medtronic ICD/CRT devices contain a single-axis accelerometer that records patient activity and is graphically reported as hours per day in the cardiac compass report.⁶

Data including patient demographics such as age, gender, residence, comorbidities, and the implanted device type, were collected. A structured questionnaire was developed by the investigators to determine the clinical status of patients during the period of lockdown such as New York Heart Association Class, palpitation, presence of dizziness or syncope, adjusted use of diuretics, unplanned hospitalization, and the amount of daily activity and exercise. Physical activity levels were defined as hours per day (hrs/day). Thoracic impedance (Ohms), and Optivol index reflecting the fluid status of patients were collected from the Medtronic CareLink® Network from February 2 to April 19, 2020. Device generated data were obtained across the following durations: pre-lockdown period from February 2, 2020 to March 12, 2020 while the lockdown period was from March 12, 2020 to April 19, 2020. Data was assessed in the center virtual device clinic, which has full access to all remotely monitored parameters. All remotely monitored variables before and throughout the lockdown periods were compared.

Statistical analysis was performed by comparing the changes in 2 different time periods: before and during implementation of the lockdown. Patient characteristics were summarized using descriptive statistics (**Table 1**). Categorical variables were reported as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation or median with the 25th and 75th percentiles. Visualization of Q-Q plots and Shapiro-Wilk test was used to assess the normality distribution of continuous variables. Differences in physical activity among males and females were compared using the Mann-Whitney U test. The difference in physical activity between the first and last day of the study period was assessed using the Related-Samples Wilcoxon Rank Signed test. All statistical and graphical analyses were performed using IBM-SPSS version 25 (IBM Corp., Armonk, N.Y.). A *p*-value of 0.05 was considered statistically significant.

Results. A total of 429 patients implanted with RM capable CIED in our center were initially evaluated. Eighty-two patients were included in the analysis after careful review of the inclusion and exclusion criteria. All patients had valid data transmitted throughout the study period. The median age of patients was 65 years

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(58-72), and 53 (64.6%) were men. Demographic data and comorbidities of the patients are summarized in **Table 1**.

Remotely monitored data. During the first week of the study, the median physical activity of male patients (2.5 [1.3-5.1] hrs/day) was higher than that of females (2 [1-3.9] hrs/day), although it was not statistically significant ($p=0.571$). However, during the last week of the study, both gender showed a relatively similar decline in physical activity, (1.8 [1-3.3] hrs/day) among males and (1.5 [0.8-3] hours/day) among females.

At the end of the study period, there was a 27.1% decline in the physical activity of HF patients. Comparing the first week of February 2020 and the last week of March of the same year until the end of the study period, the median physical activity of patients declined from 2.4 to 1.8 hrs/day ($p=0.000010$). The change in the trend of physical activity occurred in the first week of March 2020, which coincides with the implementation of social distancing measures around the country (**Figure 1**). The measured thoracic impedance and Optivol index did not show a significant change in the trend throughout the study period (**Figure 2**).

Patients' symptoms during curfew. The clinical status of the patients was assessed using a structured questionnaire. Twenty-seven (32.9%) patients were found to have NYHA class II and III. Eight patients (9.8%) reported emergency room visits and one (1.2%) patient had an unplanned hospitalization for HF symptoms. Ten (12.2%) patients required diuretic dose adjustment. Forty-two (51.2%) patients reported that

they maintained their level of exercise throughout the study period. None of the patients reported experiencing typical symptoms nor tested positive for COVID-19.

Discussion. Since its introduction, CIED remote monitoring has provided convenience and comparative

Table 1 - Demographic data and medical history of 82 patients.

Variables	n (%) or median (25 th , 75 th percentile)
Age, years	65 (58, 72)
Male	53 (64.6)
Weight, Kg	80.5 (72,90)
Diabetes	46 (56.1)
Hypertension	34 (41.5)
Ischemic heart disease	36 (49.9)
Ejection fraction, %	30 (23.8, 41.2)
Medications	
ACE inhibitors	28 (34.1)
Angiotensin II receptor blockers	43 (52.4)
Beta blockers	81 (98.8)
Anti-arrhythmic	21 (25.6)
Diuretic	71 (86.6)
Warfarin	9 (11.0)
NOAC	13 (15.9)

ACE: angiotensin converting enzyme, NOAC: non-vitamin K oral anticoagulants

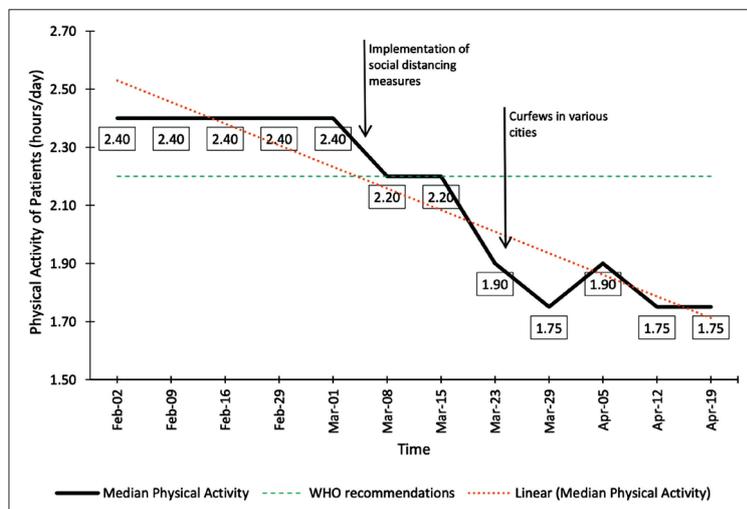
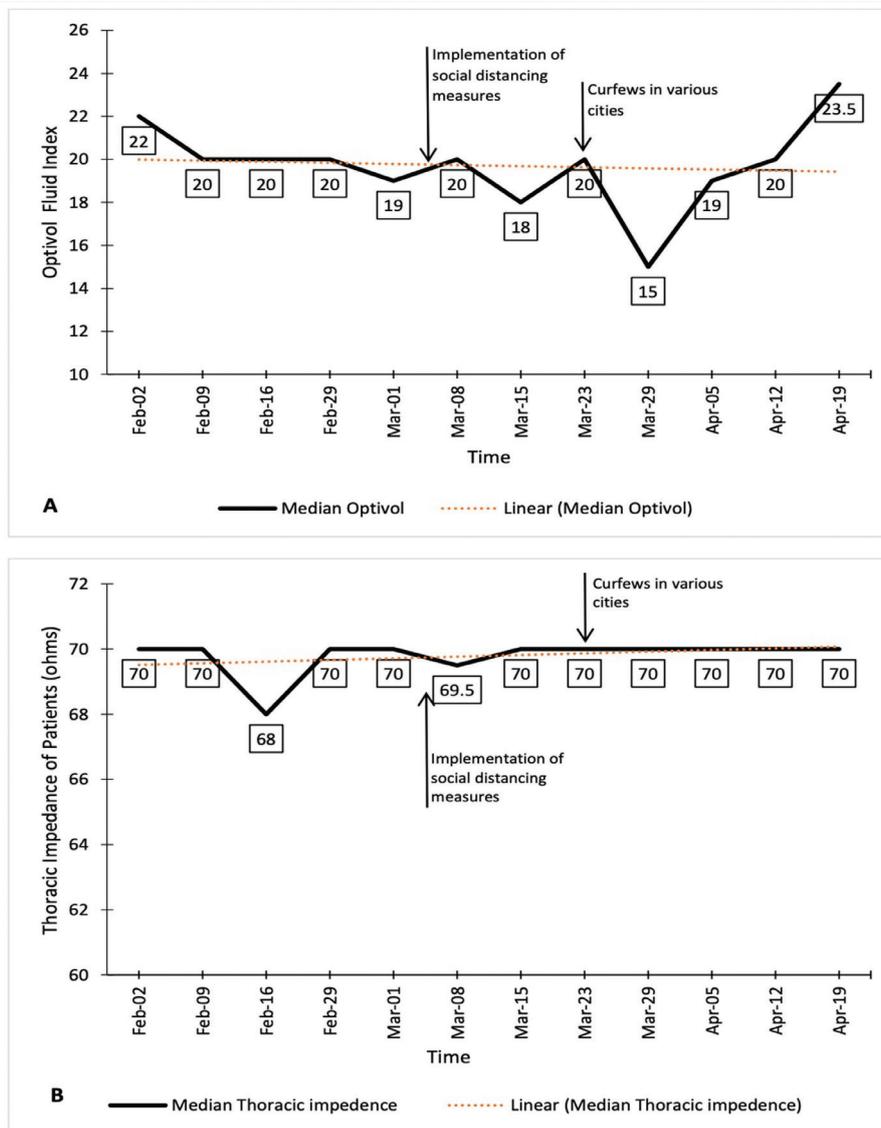


Figure 1 - Median plots of heart failure patients' average weekly activity from February to April 2020.

advantages over in-person evaluation, especially for patients with HF.⁷⁻⁹ It is feasible and has clear implications for the clinical follow-up of implantable devices as well as disease and medical management.¹⁰⁻¹² Patient's physical activity as assessed by ICD/CRT devices has intra-individual variation based on the mode of exercise.¹³ Various forms of lockdown have been implemented by governments in an attempt to prevent the spread of the novel coronavirus disease 2019 (COVID-19) worldwide.¹⁴ It is vital to understand the impact of such public health recommendations on

physical activity in HF patients as well as the expected consequences on their clinical outcome.¹⁵ Although the differences in overall physical activity might be attributed to seasonal variations, the decline in the activity of our patients coincides with the announcement of the social distancing recommendations and curfew in the country.^{16,17} In a very recent Canadian study, children with congenital heart disease had a significant decline in their daily physical activity assessed by step-count during the COVID-19 pandemic compared to that during the same season of the preceding year.¹⁸ Social



*OptiVol 2.0 fluid index is an accumulation of the difference between the daily and reference impedance

Figure 2 - Median plots of A) Optivol fluid index and B) thoracic impedance.

distancing measures were introduced in our country gradually in early March 2020, followed by curfew in most cities within 2 weeks.¹⁷ The impact of these public health recommendations was clearly reflected in our HF patients (Figure 1). Despite the significant decline in physical activity, the measured thoracic impedance and Optivol index were maintained and did not show a significant change throughout the study period (Figure 2). This could explain why only one patient required unplanned admission for HF symptoms, and few patients required diuretic dose adjustment. Yet, the long-term effect of such a situation is not clear. A significant drop in thoracic impedance sufficient to generate a fluid index maintained above the threshold level for more than 30 days per year was associated with significantly higher rates of hospitalization for acute decompensated HF.¹⁹ Low levels of physical activity in HF patients might also predispose to the development of atrial arrhythmia and increase the morbidity and mortality.^{20,21} In one study of CRT patients, a decline in the device measured physical activity of more than 40% was found to be a short-term predictor of mortality, HF events, and ventricular tachyarrhythmia.²² Activity reduced by 30 minutes per day in a given month has an estimated 48% higher risk of death at 4 years compared to a similar patient in the same month.²³

Study limitations. First, it is a single-center study, resulting in a limited number of patients recruited. A limited number of patients might contribute to a non-statistically significant result despite their clinical significance. Second, its retrospective design might have been affected by uncontrolled factors; therefore, a single factor affecting the physical activity of the patients might affect the data at any point during the study period.

In conclusion, in the light of a significant decline in physical activity during COVID-19 as evidenced by remotely monitored CIED, the potential long-term impacts of public health precautions in response to the pandemic, especially among patients with HF needs to be considered.

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