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Children with wearable cardioverter defibrillators: Examining activity levels via accelerometer

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ABSTRACT

The wearable cardioverter defibrillator can be used to protect against sudden cardiac arrhythmic death in at risk children. The wearable cardioverter defibrillator provides clinicians with multiple types of information such as activity level while wearing the device. The current study examined physical activity in pediatric populations while wearing the wearable cardioverter defibrillator and compared age, sex, and diagnostic groups in activity levels. The study sample included 231 children, aged 8–17, who wore a wearable cardioverter defibrillator between 2009 and 2017. All device based information and activity counts were retrieved from the data sent via remote monitoring. Pediatric patients were active for 73 min per day, with a median step count of 7361. These data were collected during their average of 39 days of wear time over an average of 21 h daily. There were no associations between sex, diagnostic groups, or end of use reason and wear time or activity; however, age was negatively associated with changes in activity level for patients aged 8–11. Results indicated significant increases in step count over the first three weeks of wear in all ages χ_F^2 (3, n = 50) = 34.27, p < .001. Pediatric patients are relatively active and increase levels of physical activity over the first month of use. These results are encouraging in that pediatric patients with wearable cardioverter defibrillator are potentially improving both physically and mentally over time with the wearable cardioverter defibrillator.

1. Introduction

Sudden cardiac arrest occurs in approximately 1 to 8 of every 100,000 children [1,2], with sudden cardiac death occurring in 1 to 4 of every 100,000 children [2,3]. Childhood survival rates from sudden cardiac arrest have increased from 13.0% in the 1980s to 40.2% in 2009 [2]. The prevention of cardiac arrest and the resumption of activities to the fullest extent possible as based on diagnosis remains a central goal in pediatric cardiology. In 2015, the FDA approved use of the wearable cardioverter defibrillator in appropriately sized children.

The current literature suggests that children prescribed a wearable cardioverter defibrillator were compliant in wearing the device [4,5]. Beyond potentially life-saving defibrillation, the wearable cardioverter defibrillator can provide objective data on patient activity levels that can aid in patient management of both physical and mental health. In the broader cardiac literature, children with a cardiac condition or implanted cardioverter defibrillator were physically active at or above the recommended level [6–9]. Research suggests that male gender [7], younger age [9], and device experiences (e.g., shocks) [8] were associated with higher levels of activity and increased disease severity is associated with lower levels of activity [8]. It is thought that similar patterns of physical activity levels and influencing factors would be seen in pediatric patients with a wearable cardioverter defibrillator due to the overlap in diagnoses. Because rates of activity level in children wearing wearable cardioverter defibrillators has not been studied, the current clinical utility of activity data is limited because quantitative normative data on activity in children has not been reported previously. The current study aimed to fill these gaps and expand the clinical utility of this information by examining physical activity in pediatric populations while wearing the wearable cardioverter defibrillator and compared groups by age, sex, and diagnostic type on activity levels.

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2. Methods

2.1. Participants

A retrospective study sample was drawn from a company database of all pediatric users of the wearable cardioverter defibrillator from December 2009 to December 2017. The initial analysis of the entire pediatric population, aged 3–17, was reported by Spar and colleagues (2018). For the purposes of measuring activity in this manuscript, the ages were limited to 8–17. In total, 231 adolescents, aged 8–17, were prescribed a wearable cardioverter defibrillator with accelerometers during this time. De-identified data used for this study were collected electronically by the device, which is programmed to upload usage, activity, and treatment (e.g., shock) data regularly to a server maintained by the device company (ZOLL LifeVest, Pittsburgh, PA). All patients provided consent to use their data for quality monitoring and research. Data was linked across subjects but de-identified for research. This study was approved by the institutional review board at participating academic institutions.

2.2. Measures

2.2.1. Demographics

Information on the age, sex, indication, and wearable cardioverter defibrillator discontinuation reason were coded by manufacturer. Information on patient demographics was collected at the time of device prescription. Prescription indications were grouped into the top three reasons based on similar disease pathophysiology. The top three indications for wearable cardioverter defibrillator use were cardiomyopathy (requires an EF < 35%), congenital heart disease, and implanted cardioverter defibrillator dysfunction.

2.2.2. Device usage

Device wear time was measured with two different variables, number of days worn and average hours of use on days the device was worn. End of use reason was coded as compliant or non-compliant, to classify if an individual's reason for terminating wearable cardioverter defibrillator use was considered to be compliant with medical recommendations. A patient's end of use reason was considered “compliant” if it was approved by medical team (e.g., implanted cardioverter defibrillator placed, ejection fraction improvement, physician decision). A patient's end of use reason was considered “noncompliant” if it was unlikely or unconfirmed that the end of use decision was approved by medical team (e.g., noncompliant, equipment returned – unspecified reason, patient decision). Of note, not all reasons for receiving a noncompliant classification are equivalent but were clustered to most accurately classify compliant patients for end of use. Within this study, compliance does not refer to an individual's daily wear time or length of wear.

2.2.3. Activity

Activity data was collected using an accelerometer embedded in the wearable cardioverter defibrillator. Two activity variables were measured. The first method assessed minutes active; specifically, a segment was considered “active” if the accelerometer registered 120 or more steps within a 5-min period of time. This “activity cut-off” was used to approximate activity in a manner consistent with similar accelerometers. These 5-min periods were summed to create total time active per day. The second measurement, average daily step count, was defined as number of total steps divided by days worn. Of note, daily steps were normalized for the proportion of the day that the wearable cardioverter defibrillator was worn.

2.3. Analyses

The SPSS 24 statistical package was used for all statistical analyses.

Table 1
Demographics.

	Categorical variables		
	Full sample N = 231	Pre-adolescent sample N = 25	Adolescent sample N = 206
Age	14.83 (SD = 2.27) range = 8–17	10 (SD = 1.00) range = 8–11	15.41 (SD = 1.57) range = 12–17
Sex			
Male	138 (59.7%)	11 (44%)*	127 (61.7%)
Female	88 (38.1%)	14 (56%)*,	74 (35.9%)
Unknown	5 (2.2%)	0 (0%)	5 (2.4%)
Indication reason			
Cardiomyopathy	86 (37.2%)	6 (24%)	80 (38.8%)
CHD	50 (21.6%)	9 (36%)	41 (19.9%)
ICD dysfunction	29 (12.6%)	4 (16%)	25 (12.1%)
End of use reason			
Compliant	189 (81.8%)	18 (72%)	171 (83%)
Noncompliant	42 (18.2%)	7 (28%)	35 (17%)

CHD – Congenital Heart Disease, ICD – Implanted Cardioverter Defibrillator.
*p < .05.
**p < .01.

Descriptive statistics of each variable were reported. Continuous variables were described using means or medians, standard deviations, and range. Dichotomized variables were described using frequencies and percentiles. Analyses were completed to examine differences between the pre-adolescent (range = 8–11; n = 25) and adolescent group (range = 12–17; n = 206). Correlation analyses were completed to examine the influence of sex, age, and end of use reason on wearable cardioverter defibrillator usage and physical activity levels. Four separate one-way analysis of variance were run to examine changes in wearable cardioverter defibrillator usage and physical activity based on indication reason. To assess changes over time in physical activity, Friedman's tests were run to examine differences at start of use and the 30 and 60-day marks. Additional analyses were run to further examine differences in physical activity, as measured by steps.

3. Results

3.1. Descriptive statistics

There were 231 pediatric cardiac patients (59.7% male) aged 8–17 years, with a mean age of 14.83 (SD = 2.27; Table 1). The most common indication reasons for wearable cardioverter defibrillator use were Cardiomyopathy (37.2%), congenital heart disease (21.6%), and implanted cardioverter defibrillator dysfunction (12.6%). Of the total sample, 81.8% reported an end of use reason that was considered compliant. Non-compliant end of use reason was not significantly related to complaints of alarms, discomfort, or fear of therapy. There were no significant demographic differences between the two age groups.

3.2. Activity data

Patients were active for 73 min a day (SD = 0.94, range = 4.8–301.2) and had an average of 7361 steps a day (SD = 5708, range = 96.07–43,056.26). No differences in daily physical activity were found between the two age groups. Activity data can only be obtained if the patient is wearing the wearable cardioverter defibrillator and patients wore the wearable cardioverter defibrillator for a median of 39 days (range = 1–999; Table 2) and a median of 20.73 h per day (range = 0.65–23.79). No differences in daily usage were found between the two age groups.

Table 2
Usage and activity.

	Continuous variables		
	Median	Interquartile range	Full range
WCD usage			
Days worn	39	13–89	1–999
Daily wear time (hours)	20.73	17.68–22.56	0.65–23.79
Physical activity			
Time active (minutes)	72.6	41.4–118.2	4.8–301.2
Daily steps	7361	4274-10,577	96–43,056[a]

WCD – Wearable Cardioverter Defibrillator.
[a] Based on normed step data

Table 3
WCD usage correlations.

	Sex	Age	EOUR	Days worn	Daily wear time
Sex	1	0.129	−0.055	−0.035	−0.113
Age		1	−0.010	−0.016	−0.138*
EOUR			1	0.062	0.109
Days worn				1	0.420**
Daily wear time					1

EOUR – End of Use Reason.
* p < .05.
** p < .01.

4. Influencing factors

Analyses were completed to examine the influence of sex, age, end of use reason on the usage of a wearable cardioverter defibrillator and physical activity levels (Tables 3 & 4). Age was significantly correlated with average hours of WCD wear (r(231) = −0.138, p = .036). Within the pre-adolescent group, age was significantly correlated with time active per day (r(24) = −0.521, p = .009) and average steps (r (25) = −0.548, p = .005), but not in the adolescent group (Table 5). Of note, the strongest significant correlations were still modest in strength. One-way analysis of variance revealed no significant effect of indication reason on wearable cardioverter defibrillator usage or physical activity. No other demographic or disease factors were related to usage or physical activity.

5. Changes over time in activity

Mean physical activity (e.g., steps) variables were created for 76 patients with 60 days of usage or more. This cut off was selected based on previous literature, which suggested that device patients take 60–90 days to increase physical activity after receiving their device [10]. While these populations have different restrictions, this is the most comparable "cut off" in literature currently. Time point 1 data was created by averaging daily data from days 1–7. The second time point data was created by averaging daily step data from days 24–30. Time point 3 data was created by averaging daily step data from days 54–60.

Table 4
Activity correlations overall sample.

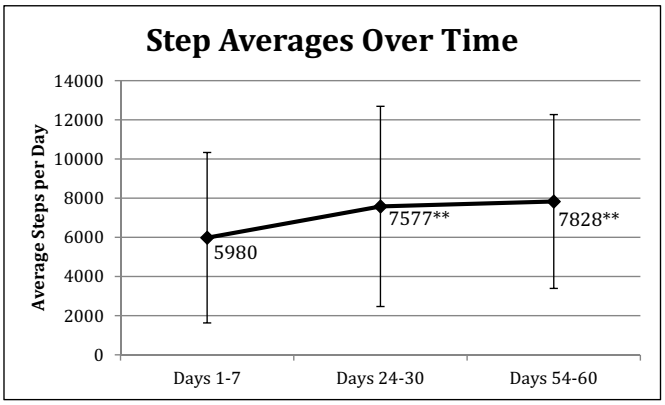
	Sex	Age	EOUR	Time active	Daily steps
Sex	1	0.129	−0.055	0.101	0.105
Age		1	−0.01	−0.125	0.003
EOUR			1	−0.018	−0.058
Time active				1	0.688**
Daily steps					1

EOUR – End of Use Reason.
*p < .05.
**p < .01.

Table 5
Activity correlations pre-adolescent sample (n = 25).

	Sex	Age	EOUR	Time active	Daily steps
Sex	1	−0.237	0.014	0.296	0.391
Age		1	0.059	−0.521**	−0.548**
EOUR			1	0.166	0.012
Time active				1	0.949 > **
Daily steps					1

EOUR – End of Use Reason.
*p < .05.
**p < .01.



* $p < .05$ ** $p < .01$

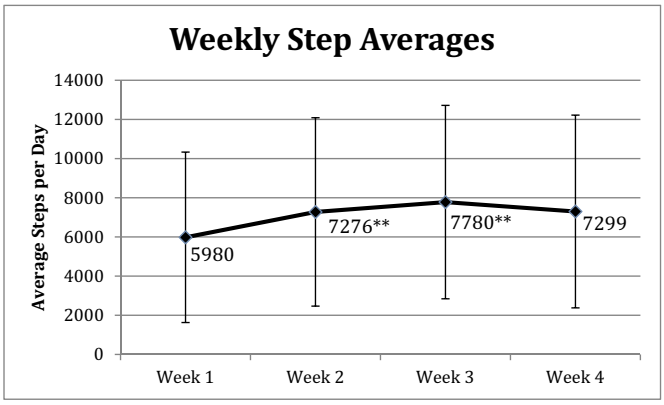
Fig. 1. Step averages days 0–60.

Mean number of steps was 5980 (SD = 4352) for time point 1, 7577 (SD = 5112) for time point 2, and 7828 (SD = 4439) for time point 3. Friedman's ANOVA indicated that physical activity was significantly affected by length of wear at the monthly level, $\chi_F^2(2, n = 47) = 14.34$, p = .001. A Wilcoxon signed-ranks test indicated that pediatric patients wearing a WCD took significantly more steps at the 30-day mark (M = 29.98, s = 1259.00) than they did at the beginning of wear (e.g., time point 1; M = 21.62, s = 281.00), $Z(N = 55) = -4.097$, p < .001 (Fig. 1). A second Wilcoxon signed-ranks test indicated that pediatric patients also took significantly more steps at the 60-day time point (M = 27.75, s = 999.00) than they did at the beginning of wear (M = 19.71, s = 276.00), $Z(N = 50) = -3.490$, p < .001.

In order to further understand the changes in activity over time given the previous findings, additional analyses were completed at the weekly level for the first 4 weeks of wear. Time points for each week of step data were created in a manner consistent with description above. Friedman's ANOVA indicated that physical activity was significantly affected by length of wear at the weekly levels, χ_F^2 (3, n = 50) = 34.27, p < .001 (Fig. 2). A Wilcoxon signed-ranks test indicated that pediatric patients wearing a WCD took significantly more steps during the second week of wear (M = 28.44, s = 1280) than they did the first week of wear (M = 22.78, s = 205), $Z(N = 54) = -4.628$, p < .001. A second Wilcoxon signed-rank test indicated that pediatric patients also took significantly more steps during week 3 of wear (M = 33.47, s = 1272) than they did during the second week of wear (N = 23, M = 26.91, s = 619), $Z(N = 61) = -2.345$, p = .019. There was no significant difference between week 3 and 4.

6. Discussion

The current study sought to provide normative data on the typical physical activity levels of pediatric patients while using the wearable cardioverter defibrillator, as well as influencing factors within this pediatric population. Pediatric cardiac patient activity levels averaged 73 min of activity daily, with an average step count of 7361 steps per



* $p < .05$ ** $p < .01$

Fig. 2. Weekly steps averages.

day during an average of 39 days of wear and approximately 21 h of wear time per day. These data suggest that pediatric cardiology patients maintain a level of physical activity consistent with national recommendations, [11] while wearing a wearable cardioverter defibrillator. Data surrounding usage were generally comparable to that in adult wearable cardioverter defibrillator populations [12,13]; however, some inconsistency is present amongst studies surrounding adult usage rates in relation to wear time.

Our results suggested that of the limited demographic and disease information collected few were associated with wearable cardioverter defibrillator recorded physical activity. Related to activity, our results indicated that as age increased in the pre-adolescent group physical activity levels decreased; however, the same pattern was not found in the adolescent group or overall sample. Specifically, these results suggest that age related declines in physical activity plateau during adolescence. Previous literature indicates that declines in physical activity levels in pediatric cardiac patients occurs across developmental stages continuing into adolescence as age increases [7–9]; therefore, these differences suggest that patients with a wearable cardioverter defibrillator initially follow a similar pattern of decline but reductions in physical activity stop around adolescence.

Finally, the study examined changes in physical activity over time. Initial analyses examining changes over a 60-day period found that average daily steps increased significantly from the beginning of wear to the 30 and 60-day mark. Follow up analyses revealed a significant increase in average daily steps from start of wear to the second week of wear, as well as a significant increase in steps from week 2 to week 3 of wear. Such findings suggest that pediatric patients wearing a wearable cardioverter defibrillator significantly increase physical activity over the first three weeks of wearing the device and then typically maintain that level of physical activity for the duration of wear. This increase in activity could represent an improvement in clinical status, as well as adjustment to wearable cardioverter defibrillator.

There were several limitations to this study to consider in interpretation of its findings. The first limitation to this study is the limited demographic and disease information available for the project. Research suggests that both ethnicity and socioeconomic status influence physical activity levels in pediatric patients [14]. Additionally, further disease information could have led to more telling findings about the influence of disease state on wearable cardioverter defibrillator usage and physical activity levels. Due to the variation in disease presentation and disease impact, it is likely that having more specific disease information and comorbid conditions would provide more accurate examination of the influence of disease factors on wearable cardioverter defibrillator usage and physical activity in pediatric cardiac patients. Additionally, while literature has often debated the most feasible and accurate way of assessing physical activity [15] research has suggested that accelerometers, when worn, were a valid and reliable measure of physical activity [16]; however, there is still inconsistency in assessing activity. Specifically, activity cut offs and step algorithms are inconsistent across devices and can influence the ability to compare across devices. Notably, the activity metric used for this study was chosen to be comparable to other accelerometer-based devices and does appear to provide results consistent with other studies. Additionally, the accelerometer data of wearable cardioverter defibrillators has yet to be "validated" in comparison to alternative forms of objective activity assessment. Within this populations, activity data can only be accurately collected while the patient is wearing the wearable cardioverter defibrillator. Therefore, the data was normalized based on the wearable cardioverter defibrillator wear time to help provide the most comprehensive data feasible, as the patients were not always wearing the device. This could have impacted the accuracy of these variables within this dataset; however, despite these limitations the data appeared to be consistent with the majority of previous research.

7. Conclusions

This study indicated that pediatric cardiology patients were engaging in physical activity at relatively appropriate rates, with a significant increase in activity over the first 30 days of wearable cardioverter defibrillator wear. These increases in activity could be a potential mark of clinical improvement and general adjustment. Given this potential, the first 2–3 weeks of wearable cardioverter defibrillator use is a critical time for monitoring and implementing interventions to improve physical activity if engagement is low. Despite these encouraging findings, according to the findings there were still a sizeable group of patients (e.g., ~18%) not effectively engaging in the potentially life-saving treatment provided by wearing a wearable cardioverter defibrillator due to ending use prematurely. Therefore, future research might also further examine patterns in compliance and activity to identify those pediatric patients at greatest risk for non-compliance or physical inactivity. Additionally, research focused on clinical outcomes and treatment based differences associated with wearable cardioverter defibrillator and physical activity engagement could be beneficial.

Disclosures

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