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Validity of cardiac implantable electronic devices in assessing daily physical activity

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ABSTRACT

Background: Data on physical activity assessed by cardiac implantable electronic devices (ICD/CRT) have been used for prognostic implications in heart failure patients, but no study has ever compared these data to validated external accelerometers.
Methods: 73 ICD/CRT recipients (age 60 ± 20 years, 21% female) received a validated external accelerometer over a period of 7 days. Thereafter, data on physical activity of both ICD/CRT and external accelerometers were retrieved and compared using Spearman's rank correlation coefficient and Bland Altman plots.
Results: Mean total daily activity was 276 ± 85 min (range 72–462) as assessed by the external accelerometers and 237 ± 105 min (28–575) as assessed by the ICD/CRT activity sensors ($p<0.001$). A strong, significant intra-individual correlation ($r>0.7$) between the two measurements was observed in a majority (70%) of patients ($p<0.05$ each). However, a Bland Altman plot revealed a broad variation of total daily activity between both methods (95% limits of agreement −225 to 147 min), resulting in differences in the duration of daily activity up to several hours. In multivariate regression analysis, no influence of age, NYHA functional class, left ventricular ejection fraction, underlying disease or type of device on these differences was observed.
Conclusions: As compared to a validated external accelerometer, daily physical activity assessed by ICD/CRT devices shows strong intra-individual correlations, but differs substantially regarding the absolute amount of daily activity. Thus, using ICD/CRT activity data for more precise clinical or prognostic information without prior validation is of limited value.

1. Introduction

Regular physical activity and exercise improve quality of life and exercise tolerance in heart failure patients, whereas a decrease in physical activity indicates disease progression [1–6]. Hence, monitoring physical activity is important in the clinical management of these patients. Implantable cardioverter-defibrillators and cardiac resynchronization therapy devices (ICD/CRT) are routinely equipped with activity sensors in order to adjust heart rates during patient activity. Thus, data on daily physical activity assessed by these sensors can easily be obtained on ICD/CRT interrogation. This information is available irrespective of the activation of the rate response function. Several studies have used these data to monitor physical activity and to derive prognostic information [7–10]. However, no study has so far evaluated the activity amounts assessed by ICD/CRT devices regarding their clinical applicability. Therefore, the aim of this study was to compare data on daily physical activity assessed by ICD/CRT devices to activity data measured by a validated external accelerometer [4,11] in heart failure patients.

2. Materials and methods

The study was a prospective analysis of consecutive male and female heart failure patients of all ages who had received Medtronic ICD/CRT devices for primary or secondary preventive purposes ≥6 months earlier. Participants were recruited in the outpatient clinic of the German Heart Center in Munich from June to December 2010. Only clinically stable, medically optimally treated patients were included; no cut-off value for left ventricular ejection fraction was used. Patients with physical disabilities who seemed not able to perform adequate and measurable physical activities were not included ($n=7$). In addition, only patients with ICD/CRT devices assessing daily activity on a similar technical background were included; the vast majority carried Maximo, InSync or Marquis devices. All patients gave written informed consent; the study protocol was approved by the university's ethical board. No financial support was provided by Medtronic or Aipermon. The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology.

Participants received an external accelerometer (AiperMotion 440, Aipermon, Munich, Germany) over a period of 7 full days, attached to the trousers in an anterior–posterior direction. The AiperMotion has been validated previously in heart failure patients in showing strong and highly significant correlations to 6 min walking distance and peak oxygen uptake and in predicting NYHA functional classes [4,11]. It carries a three-dimensional accelerometer, assessing five different modes of physical activity: passive (resting), active (body movement without steps), slow walking (up to 5 km/h), fast walking (5–7 km/h), and running (>7 km/h). Total daily activity means the sum of active, walking and running modes. During the passive mode no activity signals are detected. Activity data are recorded continuously, verified every 4 s, and categorized into the different

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modes every 60 min. The final results are provided in activity minutes per day, separated into the different modes. The AiperMotion does not allow any change of activity thresholds, resulting in the same sensitivity in assessing body movement in all patients. Individual step length was programmed according to standard recommendations in the manual. Patients were told not to change any mode or turn off the accelerometer during the study period. In addition, they were told to wear the AiperMotion throughout the whole day, keeping periods without wearing the accelerometer such as taking a bath or shower to a minimum.

Detailed information on the function of the Medtronic ICD/CRT activity sensors could not be obtained due to the company's privacy policy. Basically, in all models evaluated in the present study frequency and intensity of physical activity are detected by three different internal activity thresholds with different g values (1 g = 9.81 m/s^2) and a minimum of 0.04 g. An activity count is registered if at least one of the thresholds is exceeded and, thereafter, the zero line is crossed again. These counts are weighted in intervals of 2 s and summarized every minute. Total activity increases if the sum of detected activity signals exceeds the programmed activity threshold. It has been reported that in InSync III devices an "active" minute corresponds to a walking rate of approximately 70 steps/min [5]. Similar to the AiperMotion, the ICD/CRT activity data are provided in activity minutes per day after retrieval, but no different modes are calculated. In all but 2 patients the default settings regarding the ICD/CRT activity thresholds (medium/low) had not been changed since the time of implantation; to ensure consistency in detecting physical activity within the study population the thresholds were also set to medium/low in the remaining 2 patients during the study period.

After 7 full days, AiperMotion (using AiperMotion software) and ICD/CRT activity data were retrieved. Anonymous ICD/CRT data were decoded by a blinded Medtronic employee, and both data sets were analyzed by a blinded local study investigator. To ensure sufficient comparability, days with an AiperMotion wearing time of <10 h and the corresponding ICD/CRT measurements were not analyzed.

Data were analyzed using the PASW statistical package version 19.0 (IBM, Chicago, USA) and R version 2.9.0 (R foundation, Vienna, Austria) and are presented as mean ± standard deviation. Student's t-tests and analysis of variance were used to test for differences between activity measurements of both devices and differences among NYHA class subgroups. Activity data were compared intra-individually using Spearman's rank correlation coefficient; Bland Altman Plots were applied to compare means and differences of both methods [12]. Multivariate regression analysis was performed to evaluate the influence of age, left ventricular ejection fraction, underlying disease, type of device and NYHA functional class on the differences in activity measurements. A two-sided level of significance of $p<0.05$ was used for all statistical tests.

3. Results

A total of 73 patients were included; baseline characteristics are shown in Table 1. Mean total daily activity of all participants was 276 ± 85 min as assessed by the AiperMotion and 237 ± 105 min as assessed by the ICD/CRT activity sensor, resulting in a mean difference between both measurements of 39 ± 83 min ($p<0.001$). The average time spent in the different activity modes of the AiperMotion was distributed as follows: "active" 177 ± 54 min, "slow walking" 82 ± 36 min, "fast walking" 6 ± 12 min, "running" 0 min. A total of 496 days were available for analysis with a mean wearing time of the AiperMotion of 13.7 h/day (range 11–20); 15 days in n = 9 patients had to be excluded due to a low wearing time.

Table 1
Baseline characteristics of study population.

Characteristic	Value
n	73
Age, years	60 ± 20
Female, %	21
Reason for device implantation, %	
Primary prevention of rhythm disorders	44
Secondary prevention of rhythm disorders	56
Cardiac resynchronization therapy, %	41
Etiology, %	
Ischemic cardiomyopathy	62
Dilated cardiomyopathy	22
Hypertrophic cardiomyopathy	12
Non-compaction cardiomyopathy	1
Progressive muscular dystrophy	3
Left ventricular ejection fraction, %	31 ± 14
NYHA functional class, %	
I	32
II	43
III	26

Figures for age and ejection fraction are mean ± standard deviation.

AiperMotion and ICD/CRT measurements of daily activity showed strong, significant correlations regarding both mean total daily activities of all patients ($r = 0.64$; $p<0.001$) and daily measurements in each individual with a coefficient of $r>0.7$ in 70% of participants ($p<0.05$ each; Fig. 1; for distribution of all intra-individual coefficients, see Fig. 2). However, a Bland Altman plot (displaying differences of daily AiperMotion and ICD/CRT measurements against their means) revealed a symmetrical, but very broad variation of total daily activity (95% limits of agreement considering multiple observations in the same subjects −225 to 147 min), resulting in differences in the duration of daily activity up to several hours (Fig. 3). In multivariate regression analysis, no significant influence of age, ejection fraction, NYHA functional class, underlying disease or type of device on these differences was observed (Table 2). Similar results were

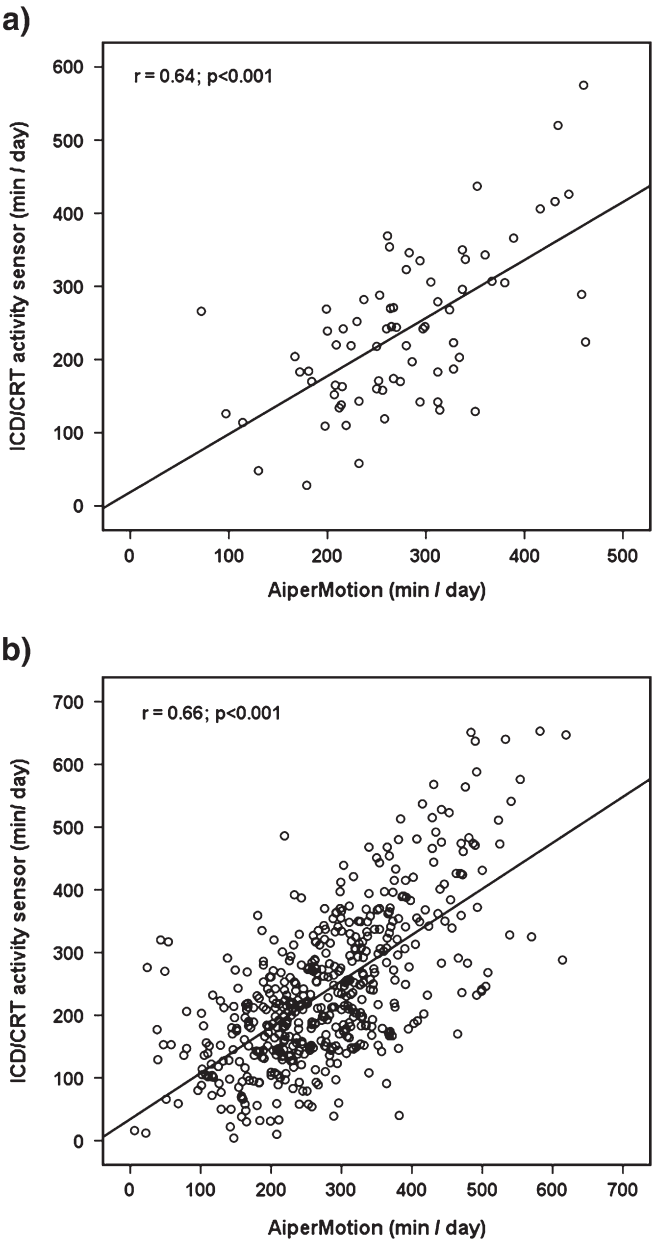

Fig. 1. Scatter plots of the correlations between (a) mean total daily activity measurements in each patient and (b) all individual daily activity measurements of ICD/CRT and AiperMotion.