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Maximum Daily Six Minutes of Activity (M6min): An index of functional capacity derived from actigraphy, Application to older adult patients with heart failure

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Abstract

Objective—To evaluate the correlation of the maximum six minutes of daily activity (M6min) with standard measures of functional capacity among older adults with heart failure (HF) in comparison to younger subjects and its prognostic utility.

Design—Prospective, cohort study.

Setting—Tertiary care, academic HF center.

Participants—Sixty, ambulatory, adults, NYHA Class I-III, stratified into young (51±10 years) and older cohorts (77±8 years).

Intervention—Continuous actigraphy monitoring on the non-dominant wrist.

Measurements—Correlation between M6Min and measures of functional capacity (6 minute walk distance; 6MWT) and with peak VO₂ by cardiopulmonary exercise testing in a subset. Survival analysis was employed to evaluate the association of M6Min with adverse events.

Results—Compliance with actigraphy was high (90%) and did not differ by age. The correlation between M6min and 6MWT was higher in subjects ≥65 years of age than those <65 years of age ($r=0.702$, $p=0.0002$ vs. $r=0.490$, $p=0.002$). M6min was also significantly associated with peak VO₂ ($r=0.612$, $p=0.006$). During the study, 26 events occurred (2 deaths, 10 hospitalizations, 8 emergency room visits and 6 intercurrent illnesses). The M6min was significantly associated with subsequent events (Hazard ratio of 2.728; 95% CI: 1.099–6.775, $p=0.031$) independent of age, gender, ejection fraction, NYHA class, brain natriuretic peptide, and 6MWT.

Conclusions—The high compliance with actigraphy and association with standard measures of functional capacity and independent association with subsequent morbid events suggests that it may be a useful for monitoring older adults with heart failure.

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Keywords

Heart Failure; Actigraphy; Functional Capacity

Introduction

A principal feature of many chronic conditions that affect older adults, including heart failure (HF), is a significant decrease in patient's physical activity tolerance and exercise capacity. Assessments of functional limitations are a routine part of clinical evaluation and have been shown to be one of the strongest determinants of morbidity and mortality in subjects with heart failure.¹ In addition, there is a significant negative impact on their quality of life.²

Among multiple available measures of functional capacity, the six-minute walk test (6MWT) is an objective, practical and simple test for evaluating submaximal functional capacity in patients with heart failure. It has been shown to be sensitive to treatment interventions³ predict morbidity and mortality⁴ and provide information that may be a better index of the patient's ability to perform daily activities than other exercise based tests of performance⁵. Typically, the 6MWT is performed in a clinical setting on an intermittent. As a result, the 6MWT only demonstrates a patient's submaximal capacity at a single point in time and provides limited insight into a patient's functional performance over longer periods of time.

Actigraphs can quantify and monitor activity counts and estimate energy expenditure over an extended period of time. These devices contain an omni-directional accelerometer that records activity, which can be employed using various algorithms to estimate energy expenditures including metabolic equivalents (METs), a measure of oxygen consumption. Previous uses of actigraphy have primarily focused on evaluation of sleep disorders^{6, 7} and quantification of physical activity predominantly among children and teenagers^{8, 9}. Only limited applications of actigraphy have been reported for monitoring daily activities of patients with HF^{10, 11}.

In order to evaluate the feasibility and clinical utility of actigraphy in subjects with HF of various phenotypes, we performed a prospective, longitudinal cohort study. The major aims of the current study were to evaluate: (1) compliance with continuous monitoring using actigraphy in order to determine if meaningful data could be collected to effectively monitor a subject's functional capacity over prolonged period of time, (2) the associations of a measure of the peak daily six minutes of activity (termed the M6min) with standard measures of functional capacity, and (3) if the M6min would be independently associated with intercurrent morbid events and hence have prognostic utility in this population.

Methods

Study Subjects

Consecutive subjects from the Advanced Cardiac Care Center of Columbia University Medical Center, who had a clinical diagnosis of heart failure, were approached regarding participation in this observational study if they met the inclusion and exclusion criteria. Inclusion criteria included: 1) outpatients, 2) New York Heart Association Class I-III, 3) ambulatory, including with a walker, and 4) living in a traditional residence, apartment, or non-communal adult home where they move about freely and frequently and are primarily responsible for scheduling their sleep and daily activities. The diagnosis of heart failure was based on the criteria developed by Rich et al¹², which require a history of acute pulmonary

edema or the occurrence of two of the following that improves with diuretic therapy without another identifiable cause: dyspnea on exertion, paroxysmal nocturnal dyspnea, orthopnea, bilateral lower extremity edema, or exertional fatigue. Additionally, for those subjects with an ejection fraction greater than 50%, the European Society of Cardiology criteria¹³ were employed to further adjudicate the diagnosis. Subjects were not eligible if they reported problems with skin or extremities that would limit their ability to wear an actigraph 24hrs/day for the study duration, were on continuous intravenous inotropes or mechanical circulatory support, or could not provide informed consent. Subjects were also excluded if they lived more than 60 miles from the Medical Center, as this would prevent the study coordinator from making the pre-specified monthly visits. The Columbia University Medical Center Institutional Review Board approved the protocol and informed consent was obtained from all subjects.

Study Design

This was a nine-month prospective cohort study conducted by Columbia University Medical Center and GE Global Research. Heart failure patients were provided an Actical actigraph device (Minimitter Inc, Respironics, Bend, Oregon) and instructed to wear it continuously on their non-dominant wrist. At baseline and at every three months, for a total of four visits, each subject underwent a targeted physical exam including review of concomitant medications, co-morbid diagnoses, measure of serum b-type natriuretic peptide (BNP) and measures of functional capacity. They were also asked to complete several survey instruments including the Anergia Scale¹⁴, SF-12¹⁵ and the Minnesota Living with Heart Failure Questionnaire¹⁶. On a monthly basis, the study coordinator downloaded data from the actigraph during a personal home visit and recorded any intercurrent illnesses, emergency room visits and hospitalizations.

Functional Performance

This was quantified by clinical assessment of New York Heart Association functional class along with the 6MWT, as has been previously described⁵. In a subset of patients (n=18), cardiopulmonary exercise tests were reviewed for data delineating functional capacity as determined by peak VO₂ in ml/kg/min.

Actigraphy

The Actical® (MiniMitter, Respironics, Inc, Bend, Oregon) is a small, wristwatch-like omni-directional accelerometer that provides real-time ambulatory monitoring and can quantify energy expenditure based on activity counts at various epochs. Patients wore the device on the non-dominant wrist on a continuous basis, including during sleep. Data was recorded using a 1-minute epoch, generating an activity count for each minute of the day. Previous research using actigraphy has employed measures that record either the maximum or minimum level of activity performed by the subject in a given length of time over the course of a day. Such measures include the M10¹⁷, which is the average activity counts per hour for the most active 10 hours of the day, and the L5¹⁸, the average activity counts per hour for the least active 5 hours of the day. These measures will be referred to here as M10hr and L5hrs. In addition, we explored other measures of peak activity using shorter epochs: the M60min, M15min, and M6min, which quantify activity during the most active 1 hour, 15 minutes, and 6 minutes of the day, respectively.

Activity counts for each epoch were converted to METs (Metabolic Equivalents) using the Actical software provided by Minimitter. The software uses single and double regression models developed using minute-by-minute data from an Actical and a portable metabolic system in 24 adults¹⁹. The single regression model was selected for this work. A MET value is calculated for each 1-minute epoch activity count by the formula $METs = 2.384 +$

0.0007341*Activity counts. M0.1 is equal to the sum on the activity counts in each of the six minutes.

Intercurrent Events

Serious intercurrent events were self-reported by study subjects or their next of kin on a monthly basis to study personnel. Such events included deaths, hospitalizations, emergency room visits and intercurrent illnesses (e.g. febrile illnesses requiring antibiotics such as urinary tract infections, pneumonias and zoster) and outpatient procedures (e.g. cardioversion and surgical interventions). These events were subsequently evaluated as either elective or non-elective, with the latter used in time to event analyses, delineated below.

Statistical Analysis

The actigraph measures were computed per patient per day. In order to determine compliance with wearing the watches, a 24-hour period was considered useable if fewer than 4 hours of data were missing. For month-long data, at least 21 of 28 days were required in order to be considered valid. The average was computed for total activity counts and the derived variables M10hrs, M1hr, M30min, M15min, M6min and L5hrs over the first 28 days¹⁸. Various actigraphy parameters were compared to the 6MWT distance using Pearson's correlation coefficient. Similar associations between actigraphy measures and peak VO₂ were computed and were compared among subjects <65 and ≥65 years of age.

Associations between first non-elective events and the M6min were evaluated by time to event survival analysis. Since actigraphy parameters in this population have not been previously delineated, we performed exploratory analyses to evaluate the values of various actigraphy parameters and their relationship to non-elective morbid events. The m6min above or below a value of 22 METS-min emerged as the most robust actigraphy parameter with a sensitivity of 82.8% and a specificity of 54.8% for subsequent non-elective events. Accordingly, the M6min (measured in METs-min during the first week of the study as either <22 or ≥22) was used in a multivariate Cox proportional hazard model along with other risk factors including age, gender, NYHA class, ejection fraction, brain natriuretic peptide, 6MWT distance at baseline, Anergia(No/Yes) at baseline to evaluate for associations with intercurrent events. Event Free Survival was calculated and the risk factors entered into the multivariate model using a backward elimination approach. SPSS (Version 11, Chicago, IL) was used for all analyses and a p value of < 0.05 was considered significant.

Results

Sixty subjects were studied. The study population was older adult women and men who on average had NYHA class II heart failure and several other co-morbid conditions. Forty six percent of the sample had an ejection fraction > 50%. Older adults in comparison to younger subjects had a worse functional capacity as evidenced by a lower 6MWT distance and lower peak VO₂ but had a higher ejection fraction, consistent with the epidemiology of heart failure in older adults. Additionally, older adult subjects were more often hypertensive and diabetic than the younger subjects (Table 1).

Over the 9-month study period, 54 of 60 (90%) subjects wore the device for the duration of the study period (average length 9.0±2.6months). Subjects who prematurely discontinued wearing the Actical did not differ significantly from the overall cohort in terms of age, gender or other clinical or demographic characteristics. Based on predefined criterion (see methods), subjects remaining enrolled in the study were compliant an average of 90±6.28% of the days they participated.

The correlation between the 6MWT distance and several measures derived from actigraphy is shown in Figure 1. As demonstrated in the figure, the correlation between the 6MWT distance and the actigraphy measures increased as the period of time measuring activity counts decreased. Specifically, the correlation between 6MWT and M6min was greater ($r=0.613$, $p<0.0001$) than the other comparisons. Additionally, the correlation between peak VO₂ (measured in a subset of the participants, $n=19$) and the 6MWT was $r=0.398$, $p=0.092$ while the correlation between VO₂ and M6min was higher, $r=0.612$, $p=0.006$. When stratified by age ($\geq$ or < 65 years) the correlation between 6MWT and M6min was higher ($r=0.702$, $p=0.0002$ vs. $r=0.490$, $p=0.002$) as was the correlation between peak VO₂ and M6min ($r=0.824$, $p=0.176$ vs. $r=0.556$, $p=0.03$) for the subjects equal to or older than 65 years of age compared to those younger than 65 years of age.

During the course of the study, 26 non-elective events occurred including 2 deaths, 10 hospitalizations, 8 emergency room visits and 6 intercurrent illnesses of which 17 were cardiac related. The median Event Free survival was 9.64 months (Confidence Interval: 7.77 to 11.50 months). Event Free Survival at 3, 6 and 9 months was 86%, 70% and 52% respectively. Multivariate analysis indicated that M6min remained a significant predictor of subsequent events with a Hazard ratio of 2.728 (CI: 1.099–6.775), $p=0.031$ (Figure 2), whereas age, gender, EF, NYHA class, BNP, and 6MWT were not significantly associated with subsequent events in this model.

Discussion

The results of this study show that M6min, an actigraphy-based measure of the peak six minutes of daily physical activity is significantly associated with the more traditional measures of both submaximal and maximal functional capacity (e.g. 6MWT distance and peak VO₂) and these associations are higher for older as compared with younger heart failure subjects. Additionally, the M6min measured in metabolic equivalents per minute (METs-min) was found to be an independent risk factor for subsequent morbid events (death, hospitalization, emergency room visits, and intercurrent illness) in multivariate analysis. Coupled with the high rate of compliance over the nine month study period, these data suggest that actigraphy may have utility in monitoring of older adult patients with heart failure.

In recent years the use of the actigraphy as a research and clinical tool has increased^{11, 20–22} and practice guidelines have been issued regarding its use²³. However, the typical data collection periods for the use of this device in these studies, range from 2 to 26 days with most studies employing the device for relatively short (e.g. less than a week) time periods. Compliance with wearing these devices during more prolonged periods was presumed to be high, but not reported previously. We have shown that such devices are readily adopted by patients with heart failure, at least in the context of a clinical trial, with compliance rates of 90%, which exceeds most reports of adherence in clinical trials of drugs²⁴ devices²⁵ or lifestyle interventions^{26, 27}. With such rates of compliance, a subject's functional capacity could be monitored by employing such measures as the M6min on a day to day basis. Although this low drop-out rate may be attributed to a number of factors, including the relatively non-invasive and unobtrusive nature of the current devices, we cannot exclude monthly home visits and constant contact between study subjects and the two research coordinators over the course of the study as possible contributors to the high compliance observed.

The 6MWT has emerged as a standard approach employed by health care providers as a measure of functional capacity that has a high correlation with data derived from cardiopulmonary exercise testing and can be used serially with limited cost and clinical

expertise⁴. Despite its ease of measurement, the 6MWT is still usually confined to use in the context of research studies or as part of evaluation of patients with cardiopulmonary disease being considered for advanced therapies. Since actigraphy allows for continuous monitoring of physical activity, thereby allowing patients to continue with uninterrupted daily routines, we sought to develop a useful parameter would be analogous to the 6MWT. Because the period of six minutes is a current standard time period for assessment of sub-maximal functional capacity and is a typical duration of exercise tests, we hypothesized that a measure of peak daily activity counts during this time period would have clinical utility and could facilitate clinical application.

The M6min was determined to be the actigraphy variable that had the highest correlation with both maximal and submaximal exercise variables in this cohort of older adults with heart failure. The average metabolic equivalents consumed during the peak six minutes of activity was ~3.5 METS/minute. This is similar to the consumption of energy that occurs during the performance of light housework, walking two blocks, or climbing a flight of stairs.²⁸ Additionally, independent of several standard measures used to evaluate prognosis in patients with heart failure including age, gender, NYHA class, ejection fraction, B-type natriuretic peptide, 6MWT distance and self reported lack of energy¹⁴, M6min in METS-min ($<22/\geq 22$) was independently associated with a greater than two fold increased risk of adverse subsequent events. To our knowledge, this is the first study to risk stratify heart failure patients using actigraphy.

Future studies should compare use of the actigraphy with other less expensive and less intrusive method of monitoring such as daily diaries of activity in order to determine if they have additional clinical utility. While we hypothesize that these latter data would be confounded by reporting biases that would be overcome with actigraphy, this should be proven by prospective investigation. We chose the Actical and not another commercially available device because of its bioengineering features that would allow recording a broad range of physical motions that can be used to monitor sleep as well as low, medium and high intensity physical activity. However, such investigation is not restricted to this device, nor is there evidence of one device's superiority in this context.

This is a small, but prospective study among subjects with heart failure from an urban community, in which some but not all subjects were of the age to be cared for by geriatricians. Larger studies in solely older adults should be performed to confirm these preliminary findings. Additionally, subjects were recruited from the Advanced Cardiac Care Center of our institution and thus the generalizability of these data to patients with less advanced disease is not clear. The current analysis was restricted to baseline data. Future analyses of these and other datasets using actigraphy could examine the clinical utility of longitudinal data for quantifying functional capacity and predicting morbid events. As the actigraphy device employed was developed and originally validated as a trunk-worn device, the use as a wrist-worn device may confound the estimates of caloric expenditure provided by the manufacturer. Nevertheless, our data suggest that despite these limitations, the proposed measure of the maximum six minutes of activity may have clinical utility. Several of the clinical examinations (e.g. echocardiograms and cardiopulmonary exercise tests as well as 6MWT distances) were performed as part of routine clinical care in close proximity but not on the same day as the assessments of actigraphy variables, and thus the effect of intervening time between assessments is a potential confounder. The methodology to define the M6min has high content and clinical validities, good consistent reliability, as well as well as concurrent and predictive validity for future morbidity, as demonstrated by these data. However, this variable should be viewed as one of many variables that can be determined from actigraphy. The most useful variable(s) may emerge from future properly designed prospective investigations depending of the purpose of the monitoring program.

Finally, questions about the need to control for artifacts and the duration of actigraphy recording have been raised, which will need to be addressed by data cleaning algorithms such as those which we employed, in order to providing reliable measures that can capture important variations across time.

In summary, we found that compliance with actigraphy amongst older adult patients with heart failure is high; suggesting that chronic monitoring of patients is feasible. Among the available measures to monitor patients, the M6min (maximum six minutes of daily activity) has a strong correlation with standard measures of functional capacity and independently associated with subsequent morbid events. Future studies employing this measure will determine its utility in continually monitoring and treating patients with heart failure.

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Figure 1.

Correlation between actigraphy parameters including total daily activity counts (panel A), average of the maximum ten hours of activity per day, M10hrs (panel B) and the average of the peak 6 minutes of activity per day, M6min (panel C) and the six minute walk distance.

Figure 2. Survival analysis showing the difference in subsequent non-elective events between heart failure subjects with a high M6min (>22 METs-min) versus subjects with a reduced M6min (<22 METs-min). See text for details.

Table 1

Demographics/Clinical characteristics

Parameter	Overall (n=60)	Age <65 Years (n=37)	Age 65 Years (n=23)
Age (years)	61±15	51±10	77±8 [†]
Gender (% female)	48%	49%	43%
BMI	28±6	29±7	28±4
Regular Exercise	27%	27%	26%
VO2 (ml/kg/min) [*]	17±3	18±3	15±5 [†]
BNP (pg/ml)	379±544	346±529	401±571
Six-Minute Walk Test (meters)	386±116	412±113	338±104 [†]
Ejection Fraction (%)	43±16	40±15	48±15 [†]
NYHA Class	2.0±0.6	2.0±0.6	2.1±0.5
SF-12			
-Physical	39±11	39±12	39±10
-Mental	50±11	48±11	51±9
Minnesota Living with HF			
-Overall	37±24	40±25	35±23
-Physical	17±10	18±11	16±10
-Emotional	8±7	8±7	7±7
Anergia (%)	39	39	39
Epworth Sleepiness Scale	8±5	7±5	9±5
Co-Morbidities (%)			
-Hypertension	54	41	78 [†]
-Diabetes	23	14	39 [†]
-Sleep Disorder	13	14	13
-Depression	13	16	9
-Hypothyroidism	15	14	17
-Anemia	26	26	27
-Chronic Pain	16	11	26
-COPD	15	14	17

[†] p <0.05 for comparison of older versus younger individuals,

^{*} data for 19 subjects