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Clinical Investigation

Efficacy of a Commercial Physical Activity Monitor in Longitudinal Tracking of Patients With Pulmonary Hypertension: A Pilot Study

Eliana Rosenzweig, BS[1]; Gerson Antonio Valencia Villeda, MD[1,3]; Sarah Crook, PhD[1]; Fatima Koli, MS[2]; Erika B. Rosenzweig, MD[1]; Usha S. Krishnan, MD[1]

[1]Division of Pediatric Cardiology, Department of Pediatrics, Columbia University Irving Medical Center–New York Presbyterian Hospital, New York, New York
[2]Data Science Institute, Columbia University, New York, New York
[3]The Heart Center at Orlando Health Arnold Palmer Hospital for Children, Orlando, Florida

Abstract

Background: Patients with pulmonary arterial hypertension have quality-of-life limitations, decreased exercise capacity, and poor prognosis if the condition is left untreated. Standard exercise testing is routinely performed to evaluate patients with pulmonary arterial hypertension but may be limited in its ability to monitor activity levels in daily living.

Objective: To evaluate the validity of the commercial Fitbit Charge HR as a tool to assess real-time exercise capacity as compared with standard exercise testing.

Methods: Ambulatory pediatric and adult patients were enrolled and given a Fitbit with instructions to continuously wear the device during waking hours. Patients underwent a 6-minute walk test, cardiopulmonary exercise test, and a 36-Item Short Form Health Survey on the day of enrollment and follow-up. Twenty-seven ambulatory patients with pulmonary arterial hypertension were enrolled, and 21 had sufficient data for analyses (median age, 25 years [range, 13-59 years]; 14 female participants).

Results: Daily steps measured by the Fitbit had a positive correlation with 6-minute walk distance ($r = 0.72$, $P = .03$) and an inverse trend with World Health Organization functional class. On the 36-Item Short Form Health Survey, 77% of patients reported improvement in vitality ($P = .055$). At follow-up, there was a strong correlation between number of steps recorded by Fitbit and role limitations because of physical problems ($r = 0.88$, $P = .02$) and weaker correlations with other quality-of-life markers.

Conclusion: The findings of this pilot study suggest activity monitors may have potential as a simple and novel method of assessing longitudinal exercise capacity and activity levels in patients with pulmonary hypertension. Further study in larger cohorts of patients is warranted to determine which accelerometer measures correlate best with outcomes.

Keywords: Pulmonary hypertension, accelerometry, physical activity, exercise tolerance

Introduction

Pulmonary arterial hypertension (PAH) is a rare disease characterized both by high mortality and morbidity and by continued disease progression despite targeted therapy. Patients with PAH present with multiple symptoms, including exertional dyspnea, chest pain, fatigue, syncope, exercise intolerance, and overall poor

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Corresponding author: Usha S. Krishnan, MD, Division of Pediatric Cardiology, Columbia University Medical Center, 3959 Broadway CH-2N, New York, NY 10032 (usk1@cumc.columbia.edu)

quality of life (QOL) caused by obstruction in the pulmonary arteries that limits perfusion and oxygen exchange in the lungs.[1] Often, as a result of generalized fatigue and fear of worsening disease, patients self-limit activities and become further physically deconditioned.[2] Historically, there has been concern that exercise could worsen right heart function or pulmonary vascular hemodynamics and lead to sudden cardiac-related death, which has led to patients being discouraged from exercising, but recent studies have shown that supervised exercise training can be performed by patients with PAH without adverse events.[3] Furthermore, there is increased awareness that exercise training is an important adjunct to pharmacologic therapy and an integral component of clinical management of PAH.[4] Exercise training programs have demonstrated improvements in maximum oxygen consumption, World Health Organization functional class (WHO FC) classification of disease severity, hemodynamics, and 6-minute walk distance (6MWD) across patients with PAH with various etiologies and functional classes.[5-7]

The 6-minute walk test (6MWT) is the most commonly used serial assessment of exercise capacity in patients with PAH. The 6MWT is a submaximal exercise test that was initially devised for patients with heart failure. The test has a strong independent association with mortality and correlates well with more extensive cardiopulmonary exercise testing.[8] The 6MWT has been validated as a tool to measure functional exercise capacity in patients with chronic respiratory disease.[9] The cardiopulmonary exercise test (CPET) is a stress test performed on a treadmill or a bike and is also used to determine exercise capacity. Both the 6MWT and CPET are important tools for evaluation, management, and prognostication in patients with PAH.[5]

With the expansion of pharmacologic armamentarium in recent years and the increase in innovative transcatheter and surgical interventions that can prolong the lifespan of patients with PAH, it is imperative to accurately predict prognosis. Even though these clinical assessments have been well validated, the 6MWT and CPET have some drawbacks. These exercise tests are typically administered once every few months, give an assessment at the point of evaluation, and can only be conducted in a hospital or expert clinical setting with trained staff. Thus, they may not accurately represent the activities of daily living in real time for patients, may miss a clinical decline between assessments, and may not be broadly available for many patients. Furthermore, the 6MWT is less likely to detect clinically significant changes in patients with a WHO FC of II or less, given their tendency to exhibit less severe symptoms.[10] Additional limitations of the 6MWT may include a patient's individual motivation, body habitus, patient cooperation, shoe choices, and daily conditions.[10] A multitude of less tangible factors, such as comorbid illnesses or anxiety, can also alter patients' distance walked during the 6MWT and their ability to reliably perform exercise during the CPET.

The quantitation of daily activity and sedentary time using accelerometry is a relatively novel end point for PAH management.[11] Accelerometers are well-validated, easy-to-use instruments that quantitate patterns of daily physical activity.[12] With the modern development of wearable technology, many activity trackers are commercially available and are commonly used in day-to-day life. Physical activity monitors can track steps per day, distance walked per day, calories burned, physical activity levels throughout the day, and other measures. They have the potential to incentivize patients to advocate for their personalized care and may allow health care professionals to gain real-world assessments of patients' daily activity patterns.[13] The SenseWear armband (BodyMedia Inc), a multiparameter activity tracker used in clinical settings, has been found to correlate

Key Points

- Daily steps positively correlate with the standardized 6MWT and inversely correlate with WHO FC.
- Patients with PAH perceived an improvement in QOL—specifically, experiencing more vitality after wearing a Fitbit accelerometer for at least 3 weeks.
- Patients who walked more daily steps according to Fitbit accelerometry experienced fewer limitations caused by physical problems.
- The Fitbit activity monitor may help predict long-term exercise capacity outcomes and help patients with PAH experience a better QOL.

Abbreviations and Acronyms

6MWD	6-minute walk distance
6MWT	6-minute walk test
CPET	cardiopulmonary exercise test
MET	metabolic equivalent
PAH	pulmonary arterial hypertension
QOL	quality of life
SF-36	36-Item Short Form Health Survey
VE/V̇CO2	ventilation equivalent for carbon dioxide
WHO FC	World Health Organization functional class

with 6MWT data in individual patients as well as with most QOL scores.[14] The Fitbit activity tracker (Fitbit) is a commercially available monitor that has been validated in multiple studies and is one of the most widely used monitors in wearable technology.[15]

The primary objective of this study was to determine whether there is a relationship between the physical activity data acquired from the Fitbit Charge HR and the results of standard exercise tests and QOL surveys in patients with PAH to gain more insight into the feasibility of using the activity monitor as an assessment of real-world exercise capacity.

Patients and Methods

Study Population and Design

Patients who were older than 13 years of age, ambulatory, and attending the Pulmonary Hypertension Comprehensive Care Center at the Columbia University Irving Medical Center–New York Presbyterian Hospital with a confirmed diagnosis of PAH and a WHO FC of I, II, or III between September 1, 2016, and July 31, 2017, were deemed eligible for the study. Patients with WHO FC IV were excluded because of the inability to perform serial exercise testing reliably. Potential participants were excluded from the study if they were unable to provide informed consent or assent (as applicable based on age). Patients were also excluded from the study if they had reported use of a Fitbit or other wearable physical activity trackers in the 6 months prior to enrollment. The study was approved by the Columbia University Irving Medical Center Institutional Review Board (IRB #AAAQ9188). Informed consent and assent (in children aged 13-18 years) were obtained at the time of enrollment.

Enrolled participants were given a Fitbit with instructions to wear the device during waking hours, with the option to wear the device during sleeping hours. Participants were followed for 1 to 2 follow-up visits, each 3 to 4 months apart, for a total of 6 to 8 months of accelerometry tracking. This timeline varied slightly depending on patient compliance and visit availability. The Fitbit was set up at the Pulmonary Hypertension Comprehensive Care Center before the initial visit and tailored to the patient during the first visit. The patient's name and email were deidentified, and each participant received a number and password that was randomly assigned to their Fitbit. Participants were asked to log in to their account weekly to upload data automatically to a secure cloud-based platform created for the purpose of this study. To obtain the most accurate information about unencouraged, real-world baseline activity levels, participants were not given instructions regarding how much exercise or daily physical activity to complete. Patients were not enrolled at the time of new PAH medication initiation.

Baseline Assessment

During the initial visit, participants underwent a 6MWT and CPET. Data from right heart catheterization and echo assessments performed within 6 months of enrollment were included. All visits were performed as part of standard of care. Patients did not alter their medication regimen. Participants also filled out the 36-Item Short Form Health Survey (SF-36), which measures self-reported physical and mental health QOL using the following 9 scales: (1) physical functioning, (2) role limitations caused by emotional problems, (3) emotional well-being, (4) general health, (5) change observed in health, (6) pain, (7) social functioning, (8) vitality, and (9) role limitations caused by physical problems.

Follow-Up Assessments

Participants had their post–study enrollment follow-up visit after 3 to 4 months as part of their routine clinic follow-up visit. During the follow-up visit, participants underwent standard testing, including the 6MWT and CPET, as well as a transthoracic echocardiogram (if indicated as part of standard care). Participants also filled out the SF-36 QOL questionnaire again at the first follow-up after enrollment. The present study focused on the data collected at baseline (specifically the first 2 weeks of wearing the Fitbit) and the first follow-up visit.

Accelerometry

The primary measurement collected was the number of steps per day recorded by the Fitbit activity monitor. The Fitbit calculates exercise intensity and classifies activity levels according to metabolic equivalents (METs), taking into account body mass, heart rate, and physical activity to measure the rate of energy expended during periods of physical activity compared with the energy expended during rest. Sedentary activity is measured as 1.0 to 1.5 METs, light activity as 1.6 to 3.0 METs, fair activity as 3.1 to 6.0 METs, and vigorous activity as greater than 6.0 METs.[16,17] According to Ainsworth et al,[18] sedentary time typically includes activities such as

sitting quietly, sleeping, and watching television. Lightly active time includes cooking, bathing, and walking 2.0 miles per hour on a level surface. Fairly active activities can include walking a dog, food shopping, and caring for a child. Vigorous activities include swimming, jogging or running, and carrying groceries upstairs.

Statistical Methods

To assess the association between daily physical activity and clinically relevant end points, Spearman correlation was used. Scatterplots of individual patient steps and key variables were created to further assess the association. To evaluate changes between baseline and follow-up, Wilcoxon signed-rank tests were used to compare differences in steps and other clinically relevant end points. Wilcoxon signed-rank tests were used as a nonparametric alternative to paired *t* tests because of the small sample size and the differences not being normally distributed, thus not meeting the assumptions of the paired t test. Statistical analyses were conducted using Stata, version 16, statistical software (StataCorp LLC). $P<.05$ was considered statistically significant. The number of steps at baseline and follow-up were calculated as the median number of steps from the 14 days following enrollment and the follow-up visit, respectively. Four days was determined to be the minimum amount of time required to get a valid median of a participant's true activity. Patients with at least 4 days of steps in the first 2 weeks of enrollment were included in this data analysis. Days with fewer than 100 steps per day were not included in the restricted sample (Supplementary Table I). The restricted sample eliminated potentially skewed data from noncompliant users if there was no or virtually no activity for a given day and no other accelerometer variables were collected.

Results

Baseline Demographics

The baseline demographics of participants are shown in Table I. Twenty-seven participants with PAH were originally enrolled in the study, and 21 with sufficient baseline and follow-up data were included in the final analysis. This was further restricted to 16 participants for analysis of daily steps after excluding potentially erroneous residual values (<100 steps). Of the 6 participants who were excluded, 1 withdrew from the study because of a rash on the wrist area, 2 did not wear the Fitbit for the first 2 weeks, and 3 did not have enough coherent Fitbit data to produce conclusive results. Wearable devices can be difficult to set up and maintain remotely from a clinical standpoint, and this difficulty would likely increase when working with older patients. This was known to be the case for at least 1 of the excluded participants. Because most variables were not normally distributed, the median was used to observe the participants' demographics.

As shown in Table I, 14 female participants (66.7%) and 7 male participants (33.3%) were included in the study. Fifty-six percent of participants had associated PAH, and 44% had idiopathic PAH. The median (IQR) age of the participants was 25 (13-59) years. At baseline, 5 (23.8%) were in WHO FC I, 9 (42.9%) were in WHO FC II, and 7 (33.3%) were in WHO FC III. For the baseline period of activity tracking, the Fitbit was worn for a median (IQR) of 14 (11.5-14.0) days.

Table II shows the median daily steps, exercise testing data, and SF-36 scores at baseline and follow-up, along with sample size collected for each end point (Table II). The maximum respiratory exchange ratio increased from 1.09 to 1.13, ventilatory equivalent for carbon dioxide ($VE/\dot{V}CO_2$) changed from 40.0 to 41.0, and median daily steps measured by the Fitbit improved from 4,877.0 to 5,324.0. Additionally, median steps increased by 1,223.5 steps on average from baseline to follow-up.

Activity Levels

Activity levels measured by the Fitbit were compiled for the first 2 weeks from baseline to determine the amount

TABLE I. Baseline Demographics

Variable	Value (n=21)
Age, median (IQR), y	25 (13-59)
Sex, No. (%)	
Female	14 (66.7)
Male	7 (33.3)
Height, median (IQR), cm	162.0 (157.0-168.0)
Weight, median (IQR), kg	57.7 (54.0-74.0)
Body mass index, median (IQR)	21.8 (20.5-28.0)
Body surface area, median (IQR), m^2	1.65 (1.56-1.87)
WHO FC, No. (%)	
I	5 (23.8)
II	9 (42.9)
III	7 (33.3)

WHO FC, World Health Organization functional class.

of time each day that was spent in each activity level. The median daily activity level of each participant was calculated, and the average number of minutes spent in each activity level classification was recorded. On average, patients spent approximately 82% (920 minutes) of the day in sedentary level and 186 minutes, 11 minutes, and 8 minutes in light, fair, and vigorous daily activity levels, respectively. This equates to 16% of the day

TABLE II. Exercise and SF-36 Variables at Baseline vs Follow-up

Variable	Median (IQR)[a,b]			
	Baseline (n = 21)	Follow-up (n = 16)	Change	*P* value
Fitbit				
Steps (≥4 d)	4,877.0 (3,418.5-7,327.0)	5,324.0 (4,804.5-8,422.5)	1,022.5 (–138.5 to 2,200.0)	.08
Steps (≥7 d)	5,081.0 (3,288.3-7,898.3)	5,534.0 (4,902.0-8,422.5)	1,022.5 (807.0-2,189.0)	–
Exercise testing				
6MWD, m	480.5 (434.0-526.0)	473.0 (427.5-569.5)	–21.0 (–68.0 to 13.5)	.19
6MWT, steps	635.0 (584.0-722.5)	–	–	–
Borg dyspnea score	2.0 (0.5-3.0)	2.0 (0.5-3.0)	0 (-0.5-0.0)	.256
$\dot{V}O_2$max, mL/kg/min	16.5 (14.0-21.1)	18.7 (15.0-28.8)	–0.4 (–1.5 to 0.6)	.82
$\dot{V}O_2$max, % predicted	47.0 (36.5-57.5)	53.0 (41.0-67.0)	–1.0 (–6.0 to 2.0)	–
Watts	75.0 (49.0-96.0)	51.5 (42.0-89.0)	–3.0 (–4.0 to 1.0)	.25
Watts, % predicted	52.5 (35.0-60.0)	35.0 (33.0-58.0)	–2.0 (–2.0 to 1.0)	–
Maximum respiratory exchange ratio	1.09 (1.05-1.20)	1.13 (1.10-1.19)	0.10 (0.01-0.12)	.08
$PetCO_2$, mm Hg	28.0 (23.5-33.5)	24.5 (22.8-31.0)	–0.8 (–1.5 to 2.5)	–
$VE/\dot{V}CO_2$	40.0 (35.0-44.0)	41.0 (35.0-47.0)	4.5 (2.0-7.0)	–
O_2 saturation at rest, CPET, %	97.0 (96.0-98.0)	96.5 (94.5-98.0)	0.5 (–1.5 to 1.0)	–
O_2 saturation during exercise, CPET, %	94.0 (92.0-97.0)	91 (80.0-100.0)	–11.0	–
O_2 saturation at rest, 6MWT, %	98.0 (96.0-98.0)	98.0 (97.0-98.0)	1.0 (0.0-2.0)	–
SF-36				
Physical functioning	70.0 (45.0-90.0)	80.0 (45.0-85.0)	–	.999
Role limitations caused by physical problems	50.0 (0.0-100.0)	75.0 (75.0-75.0)	–	.50
Role limitations caused by emotional problems	100.0 (100.0-100.0)	83.3 (66.7-100.0)	–	.75
Vitality	57.5 (50.0-65.0)	62.5 (55.0-65.0)	–	.055
Emotional well-being	80.0 (72.0-80.0)	72.0 (64.0-88.0)	–	.999
Social functioning	75.0 (50.0-87.5)	100.0 (62.5-100.0)	–	.50
Pain	93.8 (57.5-100.0)	93.8 (67.5-100.0)	–	.50
General health	35.0 (30.0-65.0)	30.0 (25.0-70.0)	–	.84
Health change	50.0 (50.0-50.0)	75.0 (50.0-75.0)	–	.999

6MWD, 6-min walk distance; 6MWT, 6-min walk test; CPET, cardiopulmonary exercise test; $PetCO_2$, partial pressure of end tidal CO_2; SF-36, 36-Item Short Form Health Survey; $VE/\dot{V}CO_2$, ventilation equivalent for carbon dioxide; $\dot{V}O_2$max, maximum oxygen consumption; Watts, exercise resistance.

[a]The overall sample was used for baseline data. Follow-up data and change scores used the restricted sample, which reflected a smaller sample size, eliminating potentially erroneous data from noncompliant users if there was virtually no activity for a given day and no other accelerometer variables were collected. Change score represents the median of individual change scores.

[b]Refer to Supplementary Table I for sample sizes for each variable. Measurements of Watts and $\dot{V}O_2$ also included % predicted, which compares patient scores with the healthy standard for their demographic (age, sex). The sample size used to compile baseline data was 21 patients. Because of noncompliance as well as some participants not receiving all testing (ie, CPET), the follow-up sample size was slightly lower (n = 16), and the *P* value could not be calculated for these particular parameters. $P < .05$ was considered statistically significant.

spent performing light activity and approximately 1% of the day performing fair and vigorous activity. Although there is no general consensus on the average time spent in sedentary activity given the variation in populations across the globe, most individuals spend less than 82% of their time in sedentary activity.

There was a trend toward fewer daily steps as WHO FC increased in severity (Fig. 1). When median daily steps were compared to the WHO FC of each participant, class I had the broadest range of median daily steps. The mean number of daily steps was 6,440 for WHO FC I, 6,121 for WHO FC II, and 4,902 for WHO FC III. From WHO FC I to II, the mean number of steps taken each day decreased by 319 steps per day, or by approximately 5%; from WHO FC II to III, the mean number of steps taken decreased by 1,219 steps per day, or by approximately 20%. The mean line also supports an overall decrease in steps with increasing PAH severity, with greater decrease from FC II to FC III.

Quality of Life

The results of the SF-36 questionnaire at baseline and at the 3- to 4-month follow-up were compared in 13 patients who completed their follow-up surveys. Self-reported physical functioning, role limitations caused by emotional problems, emotional well-being, general health, and change observed in health were not significantly improved. As seen in Table II, however, perceived pain, social functioning, vitality, and role limitations caused by physical problems improved, but because of limited numbers, these changes did not reach statistical significance. Vitality scores improved the most in the nonrestricted sample from baseline to follow-up, with 77% of patients reporting improvement in their vitality scores (Fig. 2) ($P = .055$). The average score was 57.5 and improved to 62.5 at follow-up. Self-reported physical function scores improved in 38% of participants, with an average baseline physical function score of 70.0 and an increased score of 80.0. Seventy-seven percent of participants reported either an improvement in role limitations caused by emotional problems or no change, with a baseline score of 100 and a follow-up score of 83.3. Fifty-four percent of participants reported no change or improvement in role limitations caused by physical health. Approximately 70% of participants reported an improvement or no change in their social functional QOL score, with the average score improving from 75.0 at baseline to 100.0 at follow-up. Participants perceived an improved average overall health change score from 50.0 at baseline to 75.0 at follow-up.

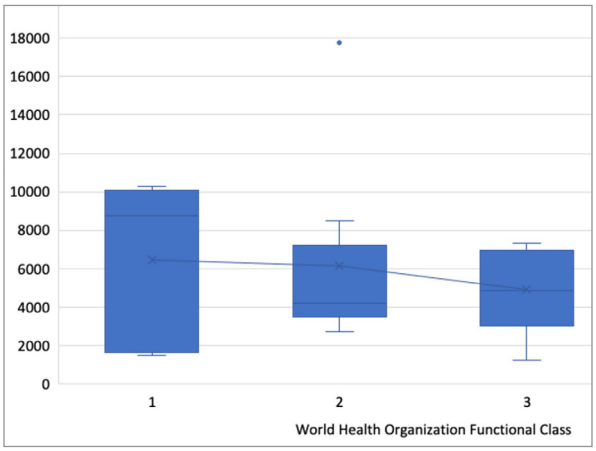

Fig. 1 The average daily step count of each participant was plotted over the first 2 weeks of monitoring and graphed against World Health Organization functional classes I, II, and III. The average daily steps for each respective functional class are represented by the X and connected blue lines to represent the trend of daily steps across functional classes. The median is represented by the horizontal line inside each box, with the upper and lower edges representing the upper and lower quartiles, respectively. The horizontal lines on the top and bottom of each whisker represent the upper and lower end of the range, respectively. The blue circle above the upper limit of functional class II represents an upper bound outlier.

Exercise

The Spearman correlation was used as a pairwise analysis to determine whether steps measured by the Fitbit correlate with exercise parameters measured by CPET and 6MWT or the SF-36 QOL questionnaire. The correlation coefficients between steps and other clinical end points are presented in Table III. The 6MWT measured the distance walked in meters, also called the 6MWD, and it was found to have a strong positive correlation with steps measured by the Fitbit Charge HR. The Spearman rank correlation coefficient was determined to be 0.72 at follow-up ($P = .03$). A trend can be observed between the meters walked during the 6MWT and steps measured by the Fitbit (Fig. 3). Participants who were able to walk more meters during the 6MWT frequently walked more steps per day as measured by the Fitbit monitor. There were fewer participants analyzed at follow-up; however, the correlation between 6MWD and steps measured by the Fitbit is noticeably stronger at follow-up (Fig. 3, Fig. 4). In fact, a majority of other clinical end points had a stronger correlation at follow-up than at baseline, including Borg dyspnea score, VCO_2, Watts, and O_2 saturation as well as all SF-36 classifications (Table III).

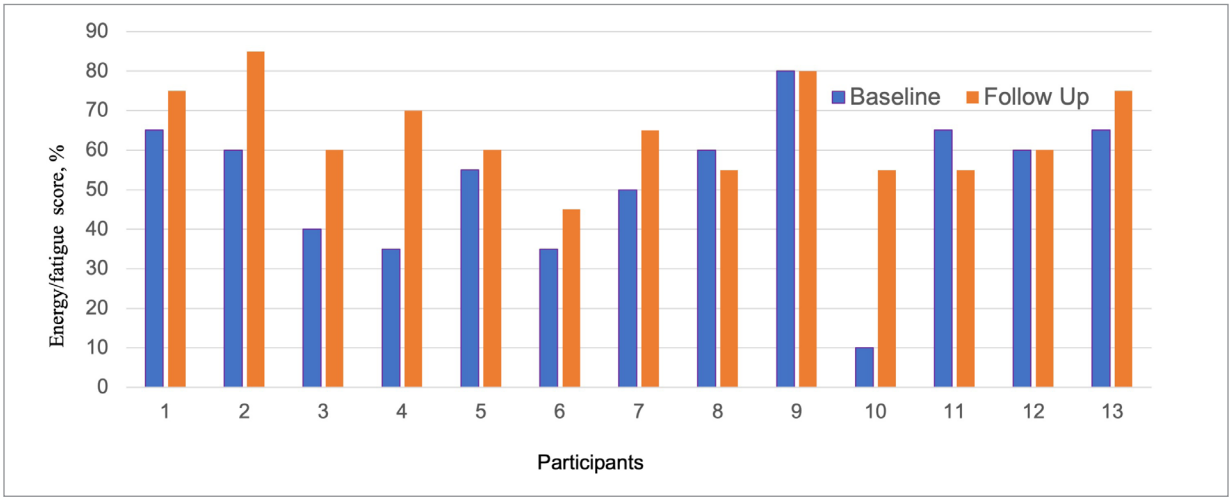

Fig. 2 Self-reported vitality scores, as measured by the 36-Item Short Form Health Survey, were compared in 13 participants at baseline and follow-up.

TABLE III. Spearman Correlation (Pairwise) of Exercise and Survey Variables at Baseline and Follow-Up

Variable	Baseline		Follow-up		Change	
	r	*P* value[a]	*r*	*P* value[a]	*r*	*P* value[a]
6MWD, m	0.37	.16	0.72	.03	−0.46	.26
6MWT, steps	0.33	.18	–	–	–	–
Borg dyspnea score	0.29	.26	0.32	.40	−0.41	.31
$\dot{V}O_2$max, mL/kg/min	0.02	.95	0.12	.76	−0.17	.67
$\dot{V}O_2$max, % predicted	−0.18	.45	0.33	.38	−0.17	.67
Watts	0.23	.38	0.37	.46	−0.35	.50
Watts, % predicted	0.18	.49	0.38	.46	−0.21	.69
Maximum respiratory exchange ratio	0.44	.052	−0.17	.66	−0.40	.29
$PetCO_2$	0.27	.25	0.20	.62	−0.25	.55
$VE/\dot{V}CO_2$	0.38	.32	−0.03	.95	−1.00	.999
O_2 saturation at rest, CPET	0.11	.65	−0.22	.60	−0.12	.77
O_2 saturation during exercise, CPET	−0.14	.78	−0.80	.20	–	–
O_2 saturation at rest, 6MWT	0.00	.99	−0.12	.82	−0.30	.62
O_2 saturation during exercise, 6MWT	0.37	.46	−0.40	.50	–	–
Physical functioning	0.22	.35	0.41	.42	−0.62	.19
Role limitations caused by physical problems	−0.09	.72	0.51	.30	0.88	.02
Role limitations caused by emotional problems	−0.27	.26	0.37	.47	0.58	.23
Vitality	−0.04	.88	0.71	.11	0.03	.96
Emotional well-being	−0.22	.35	0.56	.32	0.70	.19
Social functioning	0.05	.82	0.52	.29	0.20	.75
Pain	−0.04	.85	0.27	.60	0.29	.58
General health	0.39	.092	0.52	.29	−0.31	.55
Health change	0.07	.77	0.22	.71	−0.26	.67

6MWD, 6-min walk distance; 6MWT, 6-min walk test; CPET, cardiopulmonary exercise test; $PetCO_2$, partial pressure of end tidal CO_2; $VE/\dot{V}CO_2$, ventilation equivalent for carbon dioxide; $\dot{V}O_2$max, maximum oxygen consumption; Watts, exercise resistance.

[a]$P < .05$ was considered statistically significant. The change in role limitations caused by physical problems was statistically significant.

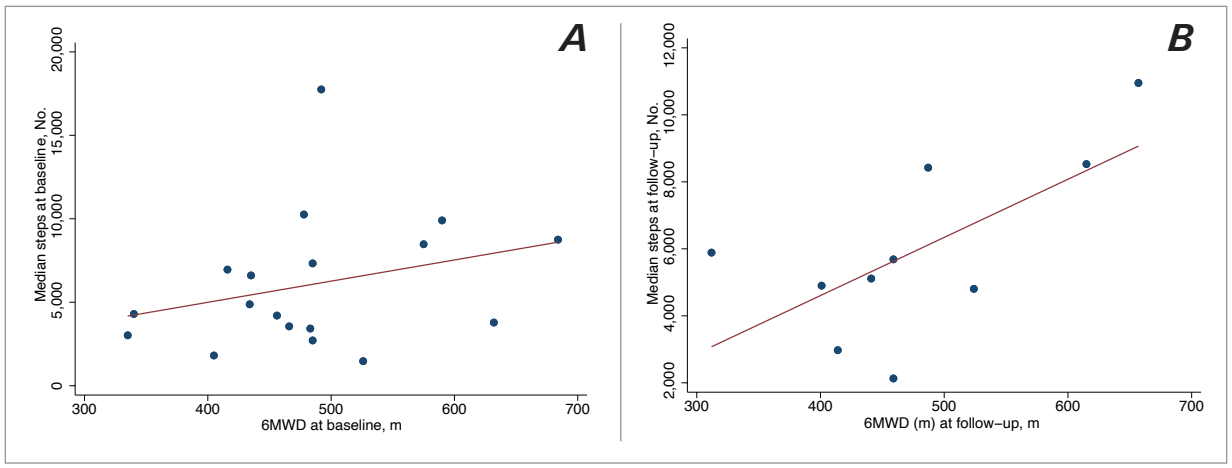

Fig. 3 A) 6-Minute walk distance in meters was graphed in a scatterplot against median steps at baseline (first 2 weeks of Fitbit monitoring). **B**) 6-Minute walk distance in meters was graphed in a scatterplot against median steps at follow-up (2 weeks of Fitbit monitoring after 3-4 months).

6MWD, 6-minute walk distance.

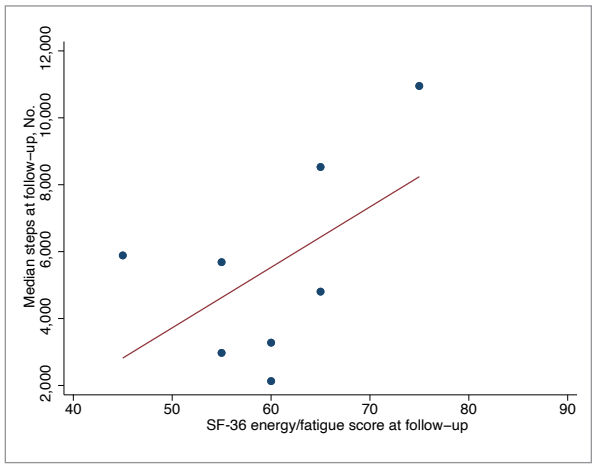

Fig. 4 Median Fitbit-measured steps at follow-up (2 weeks of Fitbit monitoring after 3-4 months) was graphed in a scatterplot against 36-Item Short Form Health Survey self-reported vitality.

SF-36, 36-Item Short Form Health Survey.

The SF-36 survey found a strong positive correlation between steps and vitality at follow-up, with an *r* correlation of 0.71. This correlation is demonstrated in Figure 4 by the positive linear trend of Fitbit steps plotted against vitality at follow-up. In addition, there was a significantly strong correlation of 0.88 for the change between baseline and follow-up for role limitations caused by physical problems ($P = .02$). Physical functioning and general health showed moderate correlation to steps walked at follow-up, with correlation coefficients of 0.41 and 0.52, respectively. The Spearman correlations were weaker between steps and health change, pain, and role limitations caused by emotional problems, with correlations of 0.22, 0.27, and 0.37, respectively. Social functioning and emotional well-being showed moderate correlations of 0.52 and 0.56, respectively.

Discussion

Patients with PAH face significant compromises in activities of daily living. Use of New York Heart Association classification or WHO FC can be inadequate as patients with chronic illness often do not have great insights into their exercise capacity because of lifelong self-limitation of activity.[15] Thus, exercise testing measures such as 6MWD and CPET have been valuable tools for this population to measure their exercise capacity at baseline and in response to therapy. These tests, however, measure exercise capacity at a given point in time, whereas activity monitors can measure exercise capacity for a period of time, including during activities of daily living. A wearable accelerometer, even a commercial physical activity tracker such as Fitbit, can provide fairly valid and measurable real-time assessment of a patient's effort, tolerance, and activity levels and can prove a valuable tool for clinical management as well as a measurable validated end point for therapeutic research. A recent study published by Zijlstra et al[19] found that accelerometry may provide clinically meaningful end points in children with PAH. This may be of value

when evaluating pediatric patients' response to therapy and interventions.

Despite patients with PAH having markedly decreased exercise capacity and compromised respiratory function in this study, a strong correlation was observed between the 6MWD and real-life exercise variables in patients older than 13 years of age, including steps measured by the activity monitor as well as self-reported health-related QOL, most noticeably vitality.[20] The SF-36 survey showed a stronger correlation to variables of role limitation caused by physical problems than emotional problems from baseline to follow-up and a strong correlation with self-reported vitality at follow-up. Interestingly, this sample included participants from the nonrestricted group, who may have used the Fitbit less than daily yet still reported an improvement in their perception of their fatigue level during follow-up. The predictability of the activity monitor for exercise parameters was supported by strong correlations with variables such as 6MWD and O_2 saturation during exercise. The correlations between 6MWD and exercise and SF-36 survey variables strengthened at follow-up compared with baseline, which suggests the usability of the Fitbit activity tracker as a longitudinal measure of exercise capacity, with improved correlation suggesting more consistent use and, possibly, an incentive to be more active while wearing a measurable activity tracker.

As expected, the average 6MWD and measured steps by the Fitbit were lower than the normal reference point for healthy participants and were further decreased with each level of WHO FC.[21,22] The 6MWD (in meters) showed a strong positive correlation to Fitbit measured steps, indicating that Fitbit steps can be a potentially valid real-time tracking tool. Participants who could walk more meters during a 6MWT typically recorded more steps on the Fitbit. Additionally, participants with more follow-up data were shown to have a stronger correlation between steps measured by the Fitbit and the 6MWD. As the Fitbit activity tracker accrues more data, the data can potentially be more reflective of the disease state in conjunction with exercise and QOL parameters. This finding supports the potential usability of activity tracking as a longitudinal measure of real-time daily tracking for patients with PAH as opposed to short-term standard exercise tests, which have limitations in a clinical setting and are also considered to be indirect outcome measures in the context of clinical trials for patients with PAH.[10,12,23] Chowdhury et al[22] reported similar results using the Fitbit Charge HR, corroborating the correlation of steps to 6MWT end points, ultimately favoring the use of a long-term wrist-worn accelerometer for patients with PAH.

Prior studies have found a correlation between sedentary activity levels and QOL, whereas the current study found a correlation between some QOL physical variables and steps on the activity tracker, suggesting a need for further exploration into the exact relationship between these variables.[9] Some end points measured by the SF-36 QOL questionnaire were strongly correlated to the steps measured by the Fitbit at follow-up, including the measurement of vitality. The vitality score was comparable to the Borg dyspnea score on the 6MWT, with vitality as a longer-term variable or the end point of perceived respiratory function. Lima et al[23] highlighted poor QOL as a significant factor affecting patients with PAH. The SF-36 questionnaire was observed to have a lower overall correlation in less related areas, including role limitations caused by emotional problems and pain, and was more strongly correlated with physical activity outcomes, including role limitations caused by physical pain from baseline to follow-up and vitality reported at follow-up. These findings suggest the Fitbit tracker may be useful as a potential clinical tool to track perceived fatigue during or after physical activity, which is a commonly reported symptom of PAH.

Activity monitor data correlated more strongly to physical activity parameters, such as 6MWD, rather than those dependent on ventilatory function, such as $V\dot{E}/V\dot{C}O_2$. As in the current study, these variables representative of ventilatory function or other physiological variables have not been studied extensively or found to be significant in previous studies.[13,16] In addition, the significantly strong correlation between activity tracked steps and role limitations caused by physical activity from baseline to follow-up suggests that the Fitbit may be a valid predictor of exercise capacity over time and physical activity outcomes in patients with PAH. In addition, correlation measurements with 6MWD were stronger at follow-up, suggesting that long-term accelerometry in patients with PAH may be more beneficial than short-term use. A study done by Okumus et al[15] observed an association between 6MWD and physical activity as well as QOL using a SenseWear arm band activity tracker. In the present study, the average steps taken daily measured by the Fitbit decreased with increased WHO FC, further suggesting the value of tracking daily steps as a potential marker of disease severity and a more accurate way to measure functional class to help in risk stratification and prognostication for people with PAH (Fig. 1).

Participants were not given any instructions regarding expectations of physical activity output to determine whether the Fitbit activity tracker alone would motivate patients with PAH to exercise. Although most changes in exercise testing outcomes were insignificant, when exercise tests were analyzed at baseline vs follow-up, it was observed that some participants individually did improve their scores. Surprisingly, the 6MWD decreased from baseline to follow-up, while the daily steps measured by the Fitbit increased during this period, though neither was statistically significant (Table II). Patients did not change medication regimens throughout the study. In only 3 to 4 months, which was used as the main period of analysis to ensure the reliability of accelerometry results, a significant improvement in exercise parameters was not altogether expected, but a lack of decline is in itself of clinical importance. Self-reported end points of the SF-36 survey, including vitality and role limitations caused by physical activity, did improve, which suggests that participants may perceive an improvement before one can be detected by standard exercise testing. In previous studies, exercise training has been seen to significantly improve QOL, 6MWD, WHO FC, $\dot{V}O_2$, systolic pulmonary artery pressure, and overall exercise capacity in patients with pulmonary hypertension.[4,6,21] To clarify whether the Fitbit can stand alone as a motivator for patients to exercise, there is a need for clinical intervention, such as an exercise program that could be paired with a Fitbit or other activity tracking technology as a comparison. Thus, it is too early to say whether the Fitbit alone can be a motivational factor of clinical improvement in physical activity and disease outcomes.

Limitations

This study is limited by the relatively small sample size; larger multicenter studies are required to further investigate the utility of activity monitors in pulmonary hypertension. Certain trends—specifically, measurements at baseline and follow-up—may not have been statistically significant because of a small sample size. Future studies would likely benefit from a larger sample size to both confirm results and obtain a better picture of whether longitudinal monitoring is feasible in a population of patients with PAH. The study took a noninterventional approach whereby follow-up visits were dependent on routine evaluation. Therefore, if a patient did not schedule or attend their office visit, the QOL and exercise test data were unable to be used for comparison against activity tracking for that time. Most lack of follow-up data after 3 and 6 months was the result of noncompliance. It was difficult, however, to discern why specific participants were noncompliant. For future studies, it would be useful to add a specific section to the QOL questionnaire or have a separate questionnaire regarding satisfaction with the Fitbit device or a space to elaborate on their experience wearing the device itself. Because the study sought to look at a commercially available physical activity monitor, the study may also be limited by the variables provided by the Fitbit, as opposed to standardized measurements provided by other accelerometers built for research purposes. Moreover, the participants analyzed were somewhat heterogeneous, with both children and adults included, so there may be differences in activity levels that should be explored separately in these groups to determine any significant differences.

Conclusion

In summary, the correlation between Fitbit-measured steps and 6MWD suggests that the Fitbit has potential benefit as an effective way to monitor exercise capacity in patients with PAH or even as an adjunct to short-term 6MWT and CPET exercise tests and could be an excellent exploratory end point for future studies. Future studies utilizing a larger sample size or an exercise intervention are warranted to determine whether daily activity monitoring has an important role in the assessment and management of patients with pulmonary hypertension and other cardiovascular diseases.

Article Information

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Co-senior Authors: Erika B. Rosenzweig, MD; Usha S. Krishnan, MD.

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