Validation of a medically certified, wrist-worn sensor for the assessment of heart rate and energy expenditure during daily activities in patients with chronic heart failure, coronary artery disease and recreational athletes

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Ignace L. J. De Lathauwer[1, 2] MD; Valerie A.A. van Es[3] MSc; Mayke M.C.J. van Leunen[1, 2] MD; Steven Onkelinx[4] PhD; Rutger W.M. Brouwers[1, 2] MD, PhD; Danny A.J.P. van de Sande[1] MD, PhD; Mathias Funk[2] PhD; Hareld M.C. Kemps[1, 2] MD, PhD

[1]Department of Cardiology Máxima Medisch Centrum Veldhoven NL
[2]Department of Industrial Design Eindhoven University of Technology Eindhoven NL
[3]MoMiLab research unit IMT School for Advanced Studies Lucca Lucca IT
[4]Department of Allied Health Professions Fontys University of Applied Sciences Eindhoven NL

Corresponding Author:
Ignace L. J. De Lathauwer MD
Department of Industrial Design
Eindhoven University of Technology
5612 AZ Eindhoven
Eindhoven
NL

Abstract

Background: Exercise capacity and lifestyle have proven to be important prognostic factors for cardiovascular patients. Both can be ameliorated through different preventive interventions. Cardiac rehabilitation (CR) and remote patient monitoring (RPM) have proven to reduce cardiac events and cardiovascular mortality. One of the most important goals of CR and RPM is improving physical fitness and monitoring of cardiovascular parameters which could predict cardiac deterioration. In order to monitor cardiac patients successfully, reliable and non-obtrusive devices to assess physical activity (PA) and cardiovascular parameters need to be available.

Objective: The aim of this validation study was to determine the accuracy of the Philips health band (PHB), a non-invasive, wrist-worn, medically certified device, for the assessment of heart rate (HR) and energy expenditure (EE) in chronic cardiovascular patients and recreational athletes.

Methods: Assessment of HR and EE by the PHB was compared with indirect calorimetry (Oxycon Mobile (OM)) during an activity protocol, consisting of daily activities. Three groups were assessed: patients with heart failure with reduced ejection fraction (HFrEF), patients with stable coronary artery disease (CAD) with preserved left ventricular ejection fraction (LVEF) and recreational athletes (RA).

Results: A total of 57 patients were included: 19 with CAD, 19 with HFrEF and 19 recreational athletes. HR assessment in the HFrEF and CAD group was significantly underestimated over the entire protocol by the PHB as compared to the OM, with poor and fair reliability respectively. No significant difference in HR was found between the PHB and OM over the entire protocol for the RA group, with a good reliability (HFrEF: mean difference 2.97, $p<0.001$, ICC 0.36; CAD: mean difference 2.65, $p<0.001$, ICC 0.55; RA: mean difference 0.78, ICC 0.60). Assessment of EE showed an underestimation over the entire protocol for the RA and CAD group, with poor and fair reliability respectively. The HFrEF group showed no significant difference in EE assessment over the entire protocol, with a poor reliability. (HFrEF: mean difference 0.09, ICC 0.32; CAD: mean difference 0.29, $p<0.001$, ICC 0.46; RA: mean difference 0.79, $p<0.001$, ICC 0.26). The responsiveness, to detect within patient changes in activity intensity, of the PHB was moderate for the HFrEF and CAD group, and acceptable for the RA group.

Conclusions: HR and EE assessment of a medically certified non-invasive sensor, using PPG and accelerometer, showed poor accuracy and moderate responsiveness during an activity protocol reflecting daily living activities in patients with stable CAD and chronic HFrEF. Accuracy of HR in recreational athletes was good and responsiveness for both HR and EE acceptable. This research confirms prior research and stresses the need for better patient specific algorithms in non-invasive sensors, taking cardiovascular pathology and medication usage into account, for assessing HR and EE, before implementing them in patient

care.

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1. Department of Cardiology, Máxima Medical Centre, Veldhoven/Eindhoven, the Netherlands
2. Department of Industrial Design, Eindhoven University of Technology, the Netherlands
3. MoMiLab research unit, IMT School for Advanced Studies Lucca, Italy
4. Department of Allied Health Professions, Fontys University of Applied Sciences, Eindhoven, the Netherlands

Corresponding author:

Ignace De Lathauwer

Department of cardiology, Máxima Medical Centre

De Run 4600

5504 DB Veldhoven

The Netherlands

Email: Ignace.de.lathauwer@mmc.nl

Telephone number: +31 40 888 8000

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Abstract

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Exercise capacity and lifestyle have proven to be important prognostic factors for cardiovascular patients. Both can be ameliorated through different preventive interventions. Cardiac rehabilitation (CR) and remote patient monitoring (RPM) have proven to reduce cardiac events and cardiovascular mortality. One of the most important goals of CR and RPM is improving physical fitness and monitoring of cardiovascular parameters which could predict cardiac deterioration. In order to monitor cardiac patients successfully, reliable and non-obtrusive devices to assess physical activity (PA) and cardiovascular parameters need to be available.

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The aim of this validation study was to determine the accuracy of the Philips health band (PHB), a non-invasive, wrist-worn, medically certified device, for the assessment of heart rate (HR) and energy expenditure (EE) in chronic cardiovascular patients and recreational athletes.

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A total of 57 patients were included: 19 with CAD, 19 with HFrEF and 19 recreational athletes. HR assessment in the HFrEF and CAD group was significantly underestimated over the entire protocol by the PHB as compared to the OM, with poor and fair reliability respectively. No significant difference in HR was found between the PHB and OM over the entire protocol for the RA group, with a good reliability (HFrEF: mean difference 2.97, $p<0.001$, ICC 0.36; CAD: mean difference 2.65, $p<0.001$, ICC 0.55; RA: mean difference 0.78, ICC 0.60). Assessment of EE showed an underestimation over the entire protocol for the RA and CAD group, with poor and fair reliability respectively. The HFrEF group showed no significant difference in EE assessment over the entire protocol, with a poor reliability. (HFrEF: mean difference 0.09, ICC 0.32; CAD: mean difference 0.29, $p<0.001$, ICC 0.46; RA: mean difference 0.79, $p<0.001$, ICC 0.26). The responsiveness, to detect within patient changes in activity intensity, of the PHB was moderate for the HFrEF and CAD group, and acceptable for the RA group.

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HR and EE assessment of a medically certified non-invasive sensor, using PPG and accelerometer, showed poor accuracy

and moderate responsiveness during an activity protocol reflecting daily living activities in patients with stable CAD and chronic HFrEF. Accuracy of HR in recreational athletes was good and responsiveness for both HR and EE acceptable. This research confirms prior research and stresses the need for better patient specific algorithms in non-invasive sensors, taking cardiovascular pathology and medication usage into account, for assessing HR and EE, before implementing them in patient care.

Key words

Cardiac diseases – Non-invasive device - Smartwatch – Validation studies

Introduction

Exercise capacity is known to be an important prognostic factor in patients with cardiovascular disease. Coronary artery disease (CAD) and Heart Failure (HF) are two of the most prevalent cardiovascular diseases, affecting millions of people worldwide.[1] In CAD patients, regular moderate intensity physical activity is associated with an increase in peak aerobic capacity and a reduction in all-cause mortality.[2] Research has shown a similar effect for HF patients, indicating that decreased exercise capacity is linked to an increased risk of atrial arrhythmias, mortality and hospitalizations due to HF exacerbations.[3] A study demonstrated that, even after adjusting for age, exercise capacity remains the strongest predictor for risk of death in both cardiovascular patients and healthy individuals undergoing exercise testing. Because of this, exercise capacity is a more powerful predictor for mortality among men than other established risk factors for cardiovascular disease.[4]

Over the years several preventive interventions have emerged to enhance prognosis of cardiovascular patients by coaching and/or monitoring their health status.[5] Firstly, exercise based-cardiac rehabilitation (CR) after an acute coronary syndrome is associated with a reduction of the risk of repeated cardiac events and cardiovascular mortality.[6, 7] Despite the benefits of CR, participation rates remain low due to factors such as long distances to CR facilities and patient age.[8] Consequently, telerehabilitation has been proposed as an innovative solution. Secondly, research has demonstrated that remote patient monitoring (RPM) of HF patients is effective in reducing mortality and HF-related hospitalizations.[9, 10, 11] Current RPM interventions use spot measurements of weight, blood pressure and heart rate (HR) to monitor patients. In order to optimize RPM interventions and enable telerehabilitation, non-invasive sensors are needed for continuous monitoring of cardiovascular parameters.

It is essential for a monitoring device to be accurate and responsive if implemented in patient care. The accuracy of a device is defined as the closeness of agreement between the monitoring device measurement and the true value.[12] Responsiveness of a device is defined as its ability to detect within-patient changes of exercise intensity or cardiovascular parameters over time and is therefore highly important in cardiac patients to monitor progression or their overall health status.

Previous trials, investigating commercially available sensors in healthy populations, have shown mixed results.[13-16] The results of these trials also could not be extrapolated to cardiac patients since they do not take in account the impaired cardiac function of chronic cardiac patients or their medication use, which influences cardiac chronotropic competence. This emphasized the need of validation trials of wrist-worn activity trackers, that can measure physical activity (PA) and

cardiovascular parameters, in chronic cardiac patients. Herkert et al. demonstrated that two commercially available wrist-worn devices had low accuracy in estimating energy expenditure (EE) in patients with HF with reduced ejection fraction and CAD. Both devices also showed poor performance to detect within-patient changes in the low-to-moderate exercise intensity domain. These findings highlight the need for population-specific devices and algorithms.[17] A more recent trial, investigating the accuracy of an Apple Watch Sport (first generation) in estimating HR and EE in cardiac patients, showed a clinically acceptable accuracy for HR during exercise but an overestimation of EE.[18] A recent systematic review, investigating the accuracy of wearable activity trackers, showed that Fitbit devices were consistently accurate in assessing step count and the Apple Watch for measuring HR. However, none of the tested devices proved to be accurate in measuring EE. Additionally, the majority of devices were not validated with cardiac patients.[19] The above-mentioned studies demonstrate that technical progress is being made, but there is still significant room for improvement before activity trackers, such as wristwatches, can be effectively implemented in patient care.

The aim of this validation trial is to investigate the accuracy and responsiveness of a medically certified wrist-worn sensor, the Philips health band (PHB) for the assessment of HR and EE in three patient populations: HF patients with reduced ejection fraction, stable CAD patients with preserved left ventricular ejection fraction and recreational athletes. If the PHB shows sufficient accuracy and responsiveness for measuring HR and EE, and thus PA levels, it could be implemented in clinical care (e.g. telerehabilitation, secondary prevention and RPM) to provide healthcare workers with continuous cardiovascular data and give patients insights in and promote their PA in daily life.

Methods

Study population

Patients were included based on their diagnosis to form three patient groups: heart failure patients with reduced ejection fraction (HFrEF), patients with stable CAD and preserved left ventricular ejection fraction (LVEF), and recreational athletes (RAs) who have visited a sports cardiologist before. RAs were defined as men or women, > 35 years of age, who perform sports at least 30 weeks a year, with a minimum of 2,5 hours of the same sport or 1,5 hours of different sports each week.[20] All three groups were analyzed separately. Patients were recruited via their cardiologist in the outpatient clinic of the Máxima Medical Centre, the Netherlands. Eligible patients were contacted by the principal investigator, who provided verbal and written information about the validation study. Patients were excluded from the study if they suffered from permanent atrial fibrillation, hemodynamic significant valvular disease, neurological or orthopedic conditions impairing physical exercise capacity, severe pulmonary disease impairing exercise capacity, peripheral

vascular disease and/or cognitive impairment. Patients had to be able to speak Dutch to be included. Written informed consent was provided by all patients. The validation study was approved by the local medical ethical committee of the Máxima Medical Centre and was conducted in accordance with the declaration of Helsinki.

Protocol

Patients completed a laboratory activity protocol consisting of daily household activities reflecting real life situations (cooking, table cleaning, vacuuming), walking on a treadmill and cycling. All activities were low-to-moderate intensity. The activity protocol was based on 2 similar studies in CV patients, where it appeared to be functional and feasible in these patient groups.[17, 21] The protocol was adjusted based on the patient population. Activity intensities were highest for RAs, since they are in good condition and used to sports at higher intensities, while they were lower for CAD patients and the lowest for HFrEF patients. Cycling was done on 3 different loads, while walking was done at 3 different speeds and inclination angles, all depending on the different patient groups. The duration of the entire protocol was around one hour. An overview of the protocol is shown in **Table 1**. The protocol was performed at the physical therapy department in the Máxima Medical Centre under supervision of a medical doctor.

Table 1. Activity protocol

Activity type and activity	**Duration (min)**	**Resting (min)**
Sedentary activities		
Sitting	5	/
Standing	2	/
Household activities		
Cooking	3	1
Cleaning	3	1
Vacuuming	3	3
Cycling (ergometer); load		
HFrEF[A] 0 Watt; CAD[B] 0 Watt; RA[C] 0 Watt	3	3
HFrEF 25 Watt; CAD 40 Watt; RA 50 Watt	3	3
HFrEF 50 Watt; CAD 70 Watt; RA 100 Watt	3	3
Walking (treadmill); speed - inclination		
HFrEF 2km/h; CAD 4km/h; RA 4km/h - 5%	3	3
HFrEF 4km/h; CAD 5,5km/h; RA 5,5km/h - 5%	3	3

HFrEF 2km/h – 5%; CAD 4km/h – 5%; RA 4km/h – 10%	3	3
Stairs		
Ascending	1	1
Descending	1	1

[A]CAD: coronary artery disease, [B]HFrEF: heart failure with reduced ejection fraction, [C]RA: recreational athletes

Criterion measure

A CareFusion Oxycon Mobile (OM) device was used during the entire protocol to measure breath-by-breath oxygen (VO_2) uptake and carbon dioxide (VCO_2) production. This is a light-weighted mobile device consisting of a facemask with a gas analyzer and a 12-lead ECG sensor. The 12-lead ECG sensor was attached to the gas analyzer unit and strapped on a backpack, worn by the patient. The OM was connected to a computer where real time data was gathered. Gas and volume calibration and ambient conditions were verified before the start of the protocol. The OM provides a reliable criterion measure as it has been validated before by comparing it with the golden standard of EE measurements, the Douglas Bag.[22]

Device

The Philips Health Band (PHB), is a CE-marked medical class IIa, wrist-worn device that measures and tracks movement and physiological parameters of the wearer. The PHB consists of different sensors including a photoplethysmography (PPG) sensor, an altimeter, and a tri-axial accelerometer. HR can be assessed through the PPG signal, while EE is estimated by an algorithm including basal metabolic rate (based on the wearer's gender, age, height and weight), activity and HR. Patients wore the PHB on their non-dominant wrist. The PHB was connected to the Philips Actigraphy Server System (PASS). The PASS includes a mobile phone app and a Philips Health Suite Data Platform, where the data can be viewed and extracted by the authorized clinician. The PASS was supplied with the most recent firmware updates.

Data analysis

Raw data from the breathing and HR analysis of the OM (sample rate 0.5 Hz) and the processed HR and EE data of the PHB (sample rate 0.0167 Hz) were exported and imported into a custom-made MATLAB analysis program (R2023b [23.2.0.2409890], MathWorks). The entire activity bounds were analyzed.

Firstly, the EE was calculated from the OM breath-by-breath measurements using the Weir equation[23]:

$$EE = [(3.941 \times VO_2) + (1.11 \times VCO_2)] \times 1.1440$$

Outliers (e.g., abrupt movements) in the HR and EE data were detected using a Hampel filter. Values exceeding three standard deviations from the median, calculated over the data point itself and up to three neighboring elements, were considered outliers and replaced with the median of this local window..[24] Afterwards, the OM data was down-sampled to 0.0167 Hz to enable a correct comparison between the PHB data and the OM data. Then, the HR and EE data of the criterion measure (OM) and the device (PHB) were matched according to the timestamps corresponding to the activities of the protocol as represented in **Table 1**, and were ready for comparison.

Statistical analysis

To achieve 80% power to detect an intraclass correlation coefficient (ICC) of 0.75 (H0), which is considered to indicate excellent agreement, a sample size of 19 subjects per study group was calculated. This applies under the alternative hypothesis that an ICC of 0.4 (H1) corresponds to poor agreement in the groups HFrEF, CAD and RA.

Descriptive statistics were used to describe the population according to baseline clinical characteristics. Normality of the data was assessed by visual inspection of histograms and by interpreting skewness and kurtosis.[25] The accuracy of the PHB was assessed by calculating the mean ± standard deviation, mean differences, and mean average percentage error (MAPE) in HR and EE obtained from the PHB compared with the criterion measure, the OM. These values were calculated per activity and over the entire protocol, including resting time.

One-sample t-tests were performed using mean differences (between the PHB and the OM) compared with zero (H_0) to identify agreement between the PHB and the criterion measure within reasonable limits (set at a 10% error zone). Additionally, Bland-Altman plots were created to illustrate the level of agreement between the estimated HR and EE, and the HR and EE from the criterion measure, with mean bias and 95% upper and lower limits of agreement (LoA).Data falling outside the LoA were inspected but did not meet any predefined exclusion criteria, such as extreme physiological values, poor signal quality, or documented device malfunctions. While there may be systematic errors under specific conditions (e.g., high-intensity activities), these data were retained to ensure the analysis reflects the full range of real-world conditions encountered in the dataset.

To assess the reliability of the PHB for each activity and the entire protocol, the ICC using 2-way mixed models with absolute agreement was used. The ICC was considered poor below 0.4, fair between 0.4 and 0.59, good between 0.6 and

0.74, and excellent above 0.75.[26] The responsiveness of the OM and the PHB was assessed using a paired t-test during cycling at different speeds, and walking at different speeds and inclination angles. All data analyses were performed using MATLAB (R2023b [23.2.0.2409890], MathWorks).

Results

A total of 57 patients were included and completed the activity protocol. The patients were equally divided in three groups; HFrEF patients (n=19, age 69.47 years, SD 9.28 years), CAD patients (n=19, age 63.74 years, SD 8.11 years) and RAs (n=19, age 58.84 years, SD 10.70 years). Included patients in all groups were mainly male, with an exception of one female in the HFrEF group and two in the CAD group. The majority of HFrEF and CAD patients were using drugs affecting HR (19/19 HFrEF patients, 100%; 18/19 CAD patients, 94,74%), compared to only 5 in the RA group (26.32%). Additional patient characteristics can be found in **Table 2**.

All data from the PHB of one RA patient was lost due to a synchronization problem and all data from the OM of one HFrEF patient was lost due to technical problems. Stair walking activities of 5 RA patients, 5 CAD patients, and 2 HFrEF patients were excluded from the analysis due to failure in OM measurement.

Table 2. Patient characteristics

	HF (n = 19)	CAD (n = 19)	RA (n = 19)
Age (years), mean (SD)	69.47 (9.28)	63.74 (8.11)	58.84 (10.70)
Gender, n (%)			
Male	18 (94.74)	17 (89.47)	19 (100)
Female	1 (5.26)	2 (10.53)	0
LVEF (%), mean (SD)	37.74 (7.52)	58.79 (6.48)	61.79 (3.59)
HF etiology, n (%)			
iCMP	9 (47.37)	-	-
non-iCMP	10 (52.63)	-	-
Medication, n (%)			
Beta-blocker	17 (89.47)	11 (57.89)	2 (10.53)
Calcium channel blocker	2 (10.53)	7 (36.84)	3 (15.79)
Amiodaron	3 (15.79)	0	0
Ivabradine	1 (5.26)	0	0

LVEF: Left ventricular ejection fraction, iCMP: ischaemic cardiomyopathy, SD: standard deviation, HF: heart failure,

CAD: coronary artery disease, RA: recreational athletes

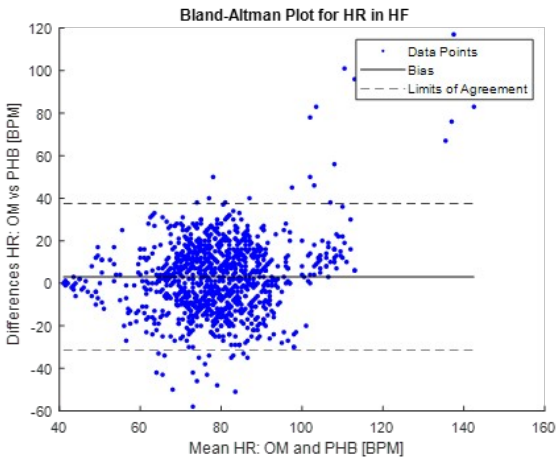
Accuracy

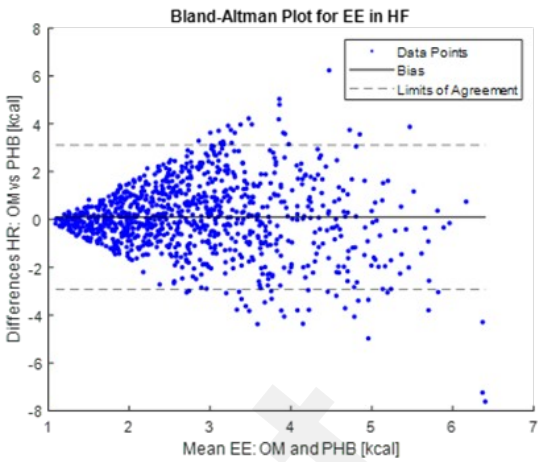
HFrEF patients

Appendix Table A illustrates the accuracy of HR and EE measurements by the PHB for HFrEF patients. For HR, the Mean ± SD over the entire protocol in the HFrEF group was 80.03 ± 16.94 BPM for OM and 77.05 ± 13.63 BPM for PHB. The PHB significantly underestimated HR over the entire protocol, with a mean difference of 2.97 BPM ($p<0.001$), showing a similar underestimation pattern for moderate-intensity household activities, cycling, and walking. For resting and low-intensity household activities, there were no significant differences between HR assessed by PHB and OM, except for standing, showing an underestimation of 3.19 BPM ($p<0.05$). Bland-Altman plots for total HR measurements showed the PHB's underestimation, with wide LoA (lower LoA -30.73 BPM, upper LoA 36.68 BPM) (**Figure 1**). The bias was smaller for resting values (e.g., for sitting, lower LoA -27.10 BPM, upper LoA 29.27 BPM) and increased with higher HR levels (e.g., for cycling at 70 W, lower LoA -23.69 BPM, upper LoA 42.10 BPM). The ICCs for the total protocol indicated poor reliability, with a value of 0.36. The MAPE ± SD was 16.62 ± 13.86%.

The EE results for the HFrEF group showed a Mean ± SD over the entire protocol of 2.86 ± 1.24 kcal for OM, and 2.76 ± 1.35 kcal for PHB (mean difference: 0.09 kcal, $p = 0.06$). However, significant underestimations were observed during climbing and walking down the stairs and cycling at 50 W, with mean differences of 0.54 kcal ($p<0.05$), 1.04 kcal ($p<0.05$), and 0.67 kcal ($p<0.001$), respectively. It is important to note that resting and low-intensity household activities showed non-significant overestimations of EE, in contrast to other activities that were underestimated. Bland-Altman plots for total EE measurements indicated an underestimation by PHB, with a wide LoA for the total protocol (lower LoA -2.86 kcal, upper LoA 3.04 kcal) (**Figure 1**). The bias for resting values was smaller (e.g., for sitting, lower LoA -1.08 kcal, upper LoA 1.0 kcal), but increased towards EE values around 3 kcal, then stagnated (e.g., cycling at 50 W, lower LoA -2.18, upper LoA 3.04). The ICCs for the total protocol indicated poor reliability, with a value of 0.32. The MAPE ± SD was 41.07 ± 40.53%.

Figure 1. Bland-Altman plots HR and EE in HFrEF patients





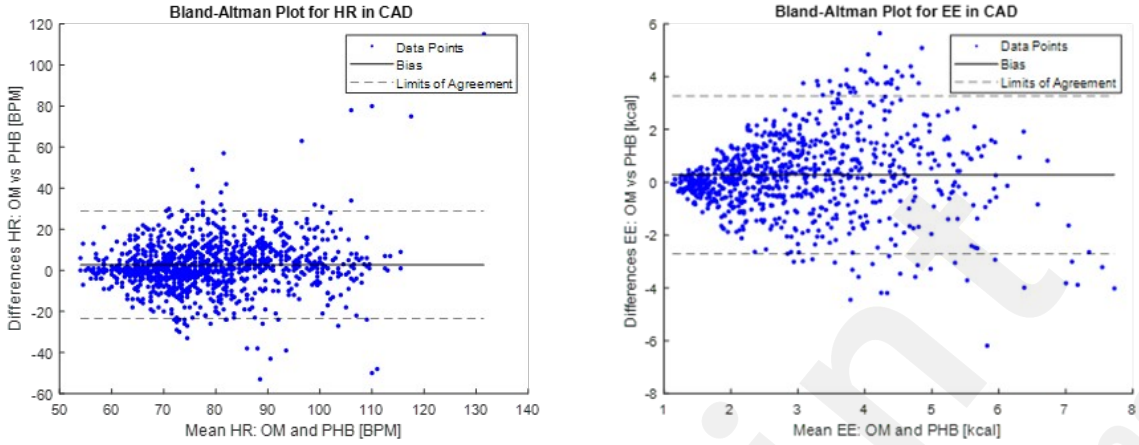
CAD patients

Appendix Table B demonstrates the accuracy of HR and EE measurements by the PHB for CAD patients. For HR, the Mean ± SD over the entire protocol in the CAD group was 80.37 ± 15.18 BPM for OM and 77.72 ± 13.34 BPM for PHB. The PHB significantly underestimated HR over the entire protocol, with a mean difference of 2.65 BPM ($p<0.001$), showing a similar underestimation pattern across all activities except for sitting, cleaning the table, and cycling at 0 W, with mean differences of 0.86 BPM, 1.68 BPM, and 0.78 BPM, respectively ($p>0.05$). Bland-Altman plots for total HR measurements illustrated the PHB's underestimation, with medium wide LoA (**Figure 2**). The PHB exhibited LoA from -23.11 BPM to 28.41 BPM. The bias was smaller for resting values (e.g., for sitting, lower LoA -13.75 BPM, upper LoA 15.47 BPM) and increased with higher HR levels (e.g., for cycling at 70 W, lower LoA -29.29 BPM, upper LoA 48.95 BPM). The ICCs for the total protocol indicated fair reliability, with a value of 0.55. The MAPE ± SD was 10.82 ± 10.65%.

The EE results for the CAD group showed a Mean ± SD over the entire protocol of 3.16 ± 1.48 kcal for OM and 2.88 ± 1.41 kcal for PHB. The PHB significantly underestimated EE across the entire protocol, with a mean difference of 0.29 kcal ($p<0.001$). A similar underestimation pattern was observed for moderate-intensity household activities (except for climbing the stairs) and walking (except for walking at 4 km/h). For resting, lower intensity household activities, and cycling, the PHB showed non-significant differences compared to OM. Bland-Altman plots for total EE measurements indicated an underestimation by PHB, with wide LoA for higher EE values and narrow LoA for lower EE values (**Figure 2**). The PHB exhibited LoA from -2.63 kcal to 3.20 kcal for the total protocol. The bias for resting values was small (e.g., for sitting, lower LoA -0.74 kcal, upper LoA 0.84 kcal) and increased with higher EE levels (e.g., cycling at 70 W, lower LoA -3.71 kcal, upper LoA 4.09 kcal). The ICCs for the total protocol revealed fair reliability, with a value of 0.46. The

MAPE ± SD was 35.66 ± 34.83%.

Figure 2. Bland-Altman plots for HR and EE in CAD patients



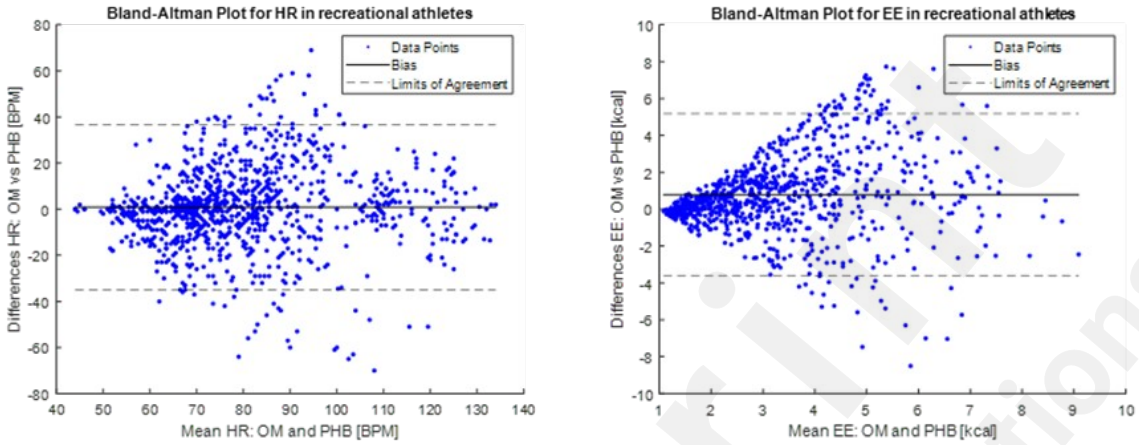
Recreational athletes

Appendix Table C demonstrates the accuracy of HR and EE measurements by the PHB for RAs. For HR, the Mean ± SD over the entire protocol in the RA group was 80.97 ± 20.78 BPM for OM and 80.19 ± 19.54 BPM for PHB. The PHB showed non-significant ($p>0.05$) underestimations over the entire protocol, with a mean difference of 0.78 BPM. Significant underestimations were found only for walking at all speeds, cycling (except at 0 W), and standing. For the other activities, there were non-significant ($p>0.05$) differences between HR measurements by OM and PHB. Bland-Altman plots for total HR measurements illustrated the PHB's underestimation, with LoA from -34.46 BPM to 36.01 BPM (**Figure 3**). The bias was smaller for resting values (e.g., for sitting, lower LoA -14.08 BPM, upper LoA 13.55 BPM) and increased with higher HR levels (e.g., for cycling at 70 W, lower LoA -22.33 BPM, upper LoA 43.98 BPM). The ICCs for the total protocol indicated good reliability, with a value of 0.60. The MAPE ± SD was 16.20 ± 17.21%.

The EE results for RAs showed a Mean ± SD over the entire protocol of 3.80 ± 2.11 kcal for OM and 2.96 ± 1.71 kcal for PHB. The PHB significantly underestimated EE across the entire protocol, with a mean difference of 0.79 kcal ($p<0.001$). This underestimation pattern was consistent across most activities, with only non-significant ($p>0.05$) underestimations for standing (mean difference of 0.08 kcal), cooking (mean difference of 0.04 kcal), and cycling at 0 W (mean difference of 0.18 kcal). Bland-Altman plots for total EE measurements indicated an underestimation by PHB, with wide LoA for higher EE values and narrower LoA for lower EE values (**Figure 3**). The bias increased until EE expenditures were around 5 kcal and then decreased. The PHB exhibited LoA from -3.53 kcal to 5.10 kcal for the total

protocol. The bias for resting values was small (e.g., for sitting, lower LoA -0.93 kcal, upper LoA 1.55 kcal) and increased with higher EE levels (e.g., cycling at 100 W, lower LoA -3.66 kcal, upper LoA 6.41 kcal). The ICCs for the total protocol revealed poor reliability, with a value of 0.26. The MAPE ± SD was 42.87 ± 38.51%.

Figure 3. Bland-Altman plots for HR and EE in RAs



Responsiveness

Appendix Table D shows the ability of PHB to detect within patient changes in cycling and walking activities.

HFrEF patients

For HR responses, the PHB was able to detect within-patient changes when cycling at 25 W versus 50 W (mean difference -1.28 BPM, p=0.02) and when walking at 2 km/h versus 4 km/h (mean difference -3.78 BPM, p=0.009). Note that differences in HR between cycling at 0 W versus 25 W were non-significant as measured by the OM. For EE responses, the PHB detected within-patient changes for cycling at 0 W versus 50 W (mean difference -0.44 kcal, p<0.001) and at 25 W versus 50 W (mean difference -0.42 kcal, p<0.001). However, the PHB was not able to detect within-patient changes in EE for walking. It should be noted that differences in EE were non-significant for cycling at 0 W versus 25 W and for walking at 2 km/h versus 2 km/h with a 5% slope, as was measured by the OM

CAD patients

For HR responses, the PHB was able to detect within-patient changes when cycling at 0 W versus 70 W (mean difference -4.32 BPM, p=0.003) and when cycling at 40 W versus 70 W (mean difference -3.76 BPM, p<0.001). For walking, the PHB was able to detect within-patient changes when walking at 4 km/h versus walking at 4 km/h with a 5% slope (mean

difference -4.26 BPM, p<0.001). Note that there were no significant differences between waling at 5.5 km/h versus walking at 4 km/h with a 5% slope, as measured by the OM. For EE responses, the PHB can detect within-patient changes when cycling at 0 W versus 70 W (mean difference -0.74 kcal, p<0.001) and when cycling at 40 W versus 70 W (mean difference -0.57 kcal, p<0.001). However, the PHB was not able to detect within-patient changes in EE for walking at different speeds and slopes. It should be noted that there were no significant changes in EE when walking at 5.5 km/h versus walking at 4 km/h with a 5% slope, as measured by the OM.

Recreational athletes

For HR responses, the PHB was able to detect within-patient changes for cycling and walking at different watts, speeds, and slopes, except when cycling at 0 W versus 50 W. However, no significant differences were present when walking at 5.5 km/h with a 5% slope versus walking at 4 km/h with a 10% slope. For EE responses, the PHB detected within-patient changes for cycling and walking at different watts, speeds, and slopes, except for walking at 4 km/h with a 5% slope versus walking at 5.5 km/h with a 5% slope. There were no significant differences between walking at 5.5 km/h with a 5% slope versus walking at 4 km/h with a 10% slope, as measured by the OM.

Discussion

This validation trial demonstrated poor accuracy of the PHB for monitoring HR in HFrEF and CAD patients, while there was no significant difference between the PHB and OM in the RA group, showing its ability to correctly measure HR in a healthier population. For all three groups there was a pattern of underestimating HR and EE during more intense activities. EE was significantly underestimated in patients with CAD and RAs over the entire protocol. Responsiveness of the PHB demonstrated mixed results. The PHB was able to detect within patient changes in HR and EE in RAs for almost all cycling loads and walking speeds. In CAD and HF patients, the PHB demonstrated moderate to poor responsiveness to changes in cycling loads or walking speeds.

Accuracy

Our study showed that the PHB demonstrates poor accuracy for measuring HR in patients with HF and CAD during moderate intensity activities. This is in contrast with previous studies, investigating commercially available wrist-worn PPG sensors. Blok et al.[27] investigated the accuracy of heartbeat detection using PPG sensors in CV patients. They concluded that PPG sensors can determine HR with high accuracy in CV patients. However, these measurements were made in resting state. During activities PPG signals are often contaminated by motion artifacts and noise, which

deteriorate the signal quality and pose significant challenges on HR monitoring. This has led to different research suggesting algorithms for accurate HR tracking even in the presence of motion artifacts and noises.[28] Novel PPG based sensors are integrated with algorithms for HR estimation even during activities. Kim et al.[29] validated two new commercially available smartwatches for the assessment of HR during a cardiopulmonary exercise test in patients with CAD. They concluded that these newer devices show a high concordance with the gold standard-ECG measurement. These results are also in contrast with the findings from our validation trial. A possible explanation for this might be the difference in activity protocol. While Kim et al.[29] validated the PPG sensors during a cardiopulmonary exercise test, we tried to validate the PHB sensor during an activity protocol with household activities reflecting real life situations. These household activities included cooking, table cleaning, and vacuuming, which require more wrist movements. The placement of the PPG sensor on different body parts affects the severity of motion artifacts. Wrist placement is convenient since the PPG sensor can be integrated into smartwatches and fitness trackers, but the wrist is more prone to motion artifacts and sensor detachment due to hand movement.[30] Moreover, the skin on the wrist moves more than other body parts, affecting sensor stability, likely influencing signal quality.[30] Conversely, placing the PPG sensor higher on the under arm or on the upper arm could reduce motion artifacts, since these areas experience less motion during daily activities, and skin movement is minimal compared to the wrist.

Another finding demonstrates a significant difference in accuracy of HR between HFrEF and CAD patients compared to the RA group. A possible explanation for this difference might be the patient's medication use and their cardiovascular pathology. Almost all patients in both HFrEF and CAD groups used drugs affecting their HR. In the RA group only 26% of participants used drugs affecting HR. Additionally, HF patients often suffer from chronotropic incompetence, which might affect HR estimation by the algorithm analyzing the PPG signal. This stresses the need for more patient specific algorithms for assessing HR through PPG signals.[31]

Our trial demonstrated that the PHB significantly underestimated EE over the entire protocol for CAD patients and RAs. Gemini et al.[19] conducted a systematic review examining studies that investigated the accuracy and acceptability of commercially available smartwatches. Of the 24 included studies, 22 assessed PA using EE as the outcome measure. Overall, all sensors demonstrated a MAPE of over 30%, indicating poor accuracy across all devices for assessing EE. The underestimation of EE by non-invasive sensors has also been observed in other studies. This aligns with our findings. All three groups showed an increase in underestimation with increasing activity intensity. This is in contrast with the findings from Herkert et al.[17], who investigated two commercially available activity trackers in patients with

CAD and HFrEF. They observed an overestimation of EE over the entire protocol and an increase in overestimation when the activities intensify. This difference may possibly be explained by the variation in algorithms used to estimate EE. An alternative explanation for the underestimation of EE and its increase with intensified activities possibly lies within the HR sensor. Most algorithms for predicting EE in wrist-worn sensors are based on HR and accelerometer measurements. During this trial, we observed that the PHB significantly underestimated HR in HFrEF patients and patients with CAD. Since these HR measurements are used to predict EE during these activities, it is expected that the underestimation would also be reflected in the EE prediction. Another explanation could be the simulation of use of walking aids, which restrict arm movement in patients, by holding the handlebars of the treadmill. This restriction leads to decreased accelerometer measurements, resulting in a lower prediction of EE during those activities.

Responsiveness

The PHB was able to detect some changes in both walking and cycling loads in HFrEF and CAD patients. However, responsiveness of the PHB in RAs was a lot better compared to HFrEF and CAD patients. Research investigating responsiveness of wrist worn devices is scarce, especially in CV patients, almost all trials focus their research solely on accuracy. While responsiveness is an important feature of smart devices for monitoring exercise activities at home. Herkert et al.[17] investigated the responsiveness of two commercially available wrist-worn devices in HFrEF and CAD patients. They concluded that both sensors showed poor performance to detect within-patient changes in the low-to-moderate exercise intensity domain. These findings are confirmed by our validation trial. Even though the PHB showed better responsiveness, there is still a lot of room for improvement, stressing the need for better algorithms for detecting within-patient changes during exercises for CV patients.

Future perspectives

Our study clearly shows that even measurements of medically certified devices, using PPG and accelerometer to assess HR and EE, should be interpreted with caution for CV patients. More studies with CV patients and non-invasive sensors, using PPG and accelerometer, for assessing HR and EE should be done to enhance algorithm development. It is crucial that these trials extract raw PPG and accelerometer signals for better algorithm development. Additionally, it is important that the validation of these new algorithms is conducted using an activity protocol that reflects the patients' daily lives, rather than solely during exercises test or rest measurements. Furthermore, future validation studies should not only focus on accuracy but also on the responsiveness of the sensors, as this is crucial for detecting within-patient changes throughout the day.

Lastly, to address existing barriers that hinder the utilization of mHealth solutions and to assist healthcare professionals in evaluating the level of available evidence, a task force initiated by the ESC regulatory affairs committee formulated both general and specific criteria through a consensus process. These criteria should be consulted prior to considering the implementation of non-invasive devices in healthcare settings to ensure patient safety.[32]

Strengths and limitations

A strength of this trial is that both chronic CV patients as recreational athletes are included. In the results there is a significant difference between the accuracy of the PHB for RA and for CV patients in both accuracy and responsiveness. Stressing the need for algorithms taking into account both CV pathology of the patients and medication usage. A limitation of this trial is the fact that patients were tested in a laboratory setting even though the activity protocol consists of activities reflecting patients' daily life. This means that the results might not be able to be extrapolated to free living conditions. Another limitation lies within the patient population. The majority of patients were men, making it possible that these results are not applicable for females.

Conclusion

HR and EE assessment of a medically certified non-invasive sensor, using PPG and accelerometer, showed poor accuracy and moderate responsiveness during an activity protocol reflecting daily living activities in chronic cardiac patients (HFrEF and CAD). High accuracy was obtained for HR in RA, while responsiveness was acceptable. This research confirms prior research and stresses the need for better patient specific algorithms, taking CV pathology and medication usage into account, for assessing HR and EE.

Conflict of interest

Authors declare no conflict of interest.

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Supplementary Files

Multimedia Appendixes

The appendix file contains the tables wih the results from the statistical analysis.
URL: http://asset.jmir.pub/assets/ff2c89f2e8bf6870b6fcb8b7c33fdbec.docx