e-Cardiology/Digital Health, Remote Patient Monitoring and Telehealth

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

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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 and cardiovascular parameters need to be available.

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

Methods: HR and EE assessment by the PHB was compared with indirect calorimetry (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 (RAs).

Results: A total of 57 patients were included: 19 with CAD, 19 with HFrEF and 19 RAs. 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.

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 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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Bland-Altman plots for HR and EE