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Tele-accelerometry as a novel technique for assessing functional status in patients with heart failure: Feasibility, reliability and patient safety☆,☆☆

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ABSTRACT

Background: The six-minute walk test (6MWT) is an established measure of functional exercise capacity associated with clinical prognosis in Chronic Heart Failure (CHF). The aim of this study is to evaluate the employment of tele-accelerometry for the remote assessment of 6MWT in CHF.
Methods: 155 patients were subjected to tele-accelerometry in form of monthly 6MWTs in their home surroundings. Accelerometer output included steps/6 min and walking speed. Data was directly transferred via mobile network to the Telemedicine Centre subsequent to test completion. 6MWT distance was measured by hand wheel and steps were counted with a digital hand-counter at baseline (Test 1) and at 12 months follow-up (Test 2).
Results: Accelerometer accuracy was within the 99th percentile. There was a significant correlation between step count, walking speed and measured 6MWT distance (Test 1: steps: $r = 0.80$, $P < 0.001$; Test 2: steps: $r = 0.90$, $P < 0.001$ and Walking Speed Test 1: $r = 0.80$, $P < 0.001$; Walking Speed Test 2: $r = 0.86$, $P < 0.001$). The reproducibility of tele-accelerometry was within 95% margin for all performance parameters, which showed stronger associations to quality of life questionnaire (Short Form - 36) Physical Component Score (PCS) than New York Heart Association (NYHA) functional class.
Conclusion: Tele-accelerometry is feasible in patients with CHF and output parameters are indicative of exercise capacity. The benefit of this approach lies in its simplicity under every day circumstances by enabling routine performance testing to assess patients' functional status.

1. Introduction

The expectations in telemedicine (TM) to manage patients with chronic diseases continue to grow. Patients with chronic heart failure often serve as the primary reference population in order to investigate whether the information gained by continuous TM offers additional value in the management of other chronic diseases. There is a variety of telemedical concepts ranging from basic telephone support to complex technologies involving transmission of vital parameters such as electrocardiogram (ECG), weight, blood pressure and subjective well-being, from the patient's home directly to a TM Centers [1,2]. These parameters are used in order to assess a given patient's clinical status, however, there is a paucity of data showing prognostic significance. Incorporating objective assessment of functional exercise capacity, a parameter associated with clinical prognosis, has not been aspired using TM in heart failure thus far [3].

The use of accelerometers to measure exercise capacity in heart failure and other chronic diseases has found widespread application in literature, however is rarely applied in actual clinical praxis. Previous studies have employed accelerometers to measure ambulatory activity over several days and were able to demonstrate tight associations

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with functional exercise capacity suggesting its surrogate utility to clinical exercise testing [4–7]. In addition, all modern implantable cardiac devices are also equipped with accelerometers. Unfortunately, these captured activity logs are often difficult to interpret and are of limited use in routine clinical patient evaluation [8].

In this study, accelerometer based six-minute walk testing (6MWT) was implemented into patients' home environment as part of a more complex telemedical patient monitoring system. The aim of this investigation was to demonstrate the validity of tele-accelerometry in providing reliable information regarding 6MWT performance. Another major aspect of this analysis was to compare objectively measured exercise capacity with patient perception of physical status (SF-36) and study physicians' interpretation in assigning New York Heart Association (NYHA) functional class.

2. Methods

This is a sub-analysis evaluating the functionality of remote exercise testing via tele-accelerometry in patients recruited in the TIM-HF trial (clinicaltrials.gov identifier: NCT00543881), a large multi-center clinical trial including 710 patients with chronic systolic heart failure. TIM-HF study sites incorporated four German federal states, Berlin, Brandenburg, Saxony-Anhalt and Baden-Württemberg. Patients were randomized to a telemonitoring (TM) group (N = 354) or to a control group (N = 356) in an intention-to-treat-principle [9]. Home based TM included daily body weight, blood pressure, ECG, subjective well-being and monthly 6MWT in a subgroup of TM patients. Wireless data transfer was conducted from the patients' homes directly to the TM Centers located at the Charité - Universitätsmedizin Berlin and at the Robert Bosch Hospital in Stuttgart, Germany.

To be eligible for the TIM-HF study, patients had to be at least 18 years of age, be diagnosed with chronic systolic heart failure according to NYHA class II-III on the basis of clinical history and meet echocardiographic criteria for heart failure diagnosis according to guidelines issued by the European Society of Cardiology (ESC) with a left ventricular ejection fraction (LVEF) ≤ 35 % [10]. In addition, patients had to have at least one heart failure decompensation episode that resulted in hospitalization maximally 24 months prior to randomization or LVEF ≤ 25 % measured twice within the past six months. Patients were followed for a minimum of 12 months, with outpatient visits at randomization, 3, 6, 9 and 12, 18 and 24 months including clinical evaluation, laboratory analysis and quality of life (SF-36 [11]). Detailed results of the TIM-HF trial can be found elsewhere [9].

The analysis of remote exercise testing via tele-accelerometry in a pre-stratified subgroup of TIM-HF patients was a defined tertiary end-point of the TIM-HF study protocol [12]. However, incoming exercise data were not used to guide disease management in the TIM-HF trial, but were collected in a double-blinded fashion to the patient and the medical staff at the TM Centers and analyzed for subsequent analysis. The study was carried out in accordance with the principles of the Declaration of Helsinki (1996), International Conference on Harmonization Good Clinical Practice and approved by the local ethics committee (Ethics Number EA1/052/07). Written informed consent was obtained from all participating patients.

2.1. Sub-study initiation and patient selection

Due to the fact that exercise data were blinded to the decision making in patient treatment and did not have any impact on the analysis of the trial's primary and secondary endpoint, the initiation of baseline exercise testing (**Test 1**) was delayed until 5 months after randomization. Reasons included a 4-month period during which patient training with technical devices dominated our resources. This made it impossible to initiate tele-accelerometry simultaneously to TIM-HF study commencement.

Only a subgroup of the TM group (155/354 patients, 43.8 %) was targeted for tele-accelerometry. As a consequence of the delay between TIM-HF randomization and sub-study begin 21 patients were lost to tele-accelerometry due to premature death. Thirteen patients also expressed unwillingness to participate in TM after randomization in general. Twenty-six patients were actively excluded due to contraindications to exercise testing according to ESC guidelines [13], physical limitations preventing them from walking for six minutes or unwillingness to use the accelerometer. Physical limitations included peripheral artery disease (N = 20), severe angina pectoris (N = 8), resting dyspnea (NYHA IV, chronic obstructive pulmonary disease GOLD IV, severe asthma; N = 8) and the inability to walk without any sort of assisting device (N = 29). Sixty-seven patients were also excluded due to local infrastructure logistics, meaning no availability of a suitable walking path from their homes to walk continuously on a flat concrete surface for six minutes without street crossings and/or traffic junctions. This eventually resulted in our study population of N = 155. The majority of patients (N = 129) targeted for tele-accelerometry were from Berlin area because these regions are consistently flat. A total of twenty-six patients were lost over the 12-month follow-up including death (N = 8), discontinued TM (N = 10), met exclusion criteria (N = 5), and were unwilling to continue activity monitoring (AM, N = 3). This left 129/159 patients for the 2nd 6MWT.

2.2. 6MWT testing procedure and patient assessment

Tele-accelerometry was measured at baseline (**Test 1**) and on a monthly basis during follow-up. Initiation of exercise testing entailed home visits by the nurses to each patient in order to find a suitable walking path that met 6MWT recommendations [13]. To assure consistency, patients were familiarized with the testing procedures under nurse guidance and asked to use the same walking path throughout the entire study period. To reference accelerometer data output, 6MWT distance (meter) was also measured with a measuring wheel during the first valid baseline test. In addition, total steps in six minutes were counted with a digital hand-counter in order to retrospectively re-assure accelerometer accuracy and reliability. The nurses in the field were blinded to accelerometer output. Encrypted accelerometer data were automatically transmitted to the TM Centers via mobile network after completion of each 6MWT. After baseline testing, patients were asked to perform the 6MWT once a month on their own for the remaining follow-up period. Patients were told to complete the 6MWT on their own in order to determine their own walking pace however the presence of an accompanying person was encouraged.

The device used for tele-accelerometry (AiperMotion 300 PfH, Aipermon GmbH & Co. KG, Munich, Germany) is a three dimensional accelerometer customized especially for recording data during the 6MWT with a "start 6MWT" button and automatic end of data recording after 6 minutes. The device is matchbox sized and worn on hip level attached to the belt via a pocket pouch. Data output includes total steps and percentage of time spent in different walking intensity categories during the six minutes. Walking speed is divided into 5 subcategories W1–W5. W1 < 60 steps/min, W2 60–79 steps/min, W3 80–99 steps/min, W4 100–120 steps/min, W5 > 120 steps/min. This device type has been previously validated in terms of its measurement accuracy in patients with heart failure under laboratory conditions as well as in a field based setting [3].

At 12 months, the same testing procedure as described above during **Test 1** was repeated during the 6MWT finalization phase (**Test 2**) including a nurse based visit to the patient's home, manually counted 6MWT steps as well as distance walked. This was done in order to have a second reference point in time to account for test-retest variability regarding tele-accelerometry. No active exercise training was conducted over the 12-month follow up time between Test 1 and Test 2.

2.3. Patient safety

Routine procedure in the TIM-HF study entailed patients to measure daily ECG, blood pressure and body weight. To ensure patient safety, the medical staff at the TM Centers evaluated incoming data prior to each exercise test in order to look for possible contraindications. If data showed any contraindication, patients were told to pause exercise testing.

2.4. Statistical analyses

Statistical analysis was done using IBM SPSS Statistics software (version 20.0, IBM corp.). Patient baseline characteristics were categorized according to patients who received an accelerometer compared to those that did not. Data was descriptively analysed reporting mean ± standard deviation (SD) for quantitative measurements. Bivariate correlations of continuous variables were investigated using Pearson correlation coefficient (r). Scatter charts including linear regression lines as well regression equations were provided to illustrate and quantify correlations of relevant measurements. Differences were compared using two-tailed *t* test for normally distributed variables, Mann–Whitney U test for non-parametric variables and Chi^2-test for dichotomous variables. In all data analyses p-values less than 0.05 were considered as statistically significant and were reported in an explorative manner. Reproducibility of 6MWT data was assessed by repeated measures analysis of variance followed by Bland–Altman analysis in which individual test differences were plotted against their means. Mean bias and 95% confidence interval was calculated as mean ± 1.96 SD of between test differences.

3. Results

3.1. Overall patient characteristics of the telemedicine group

Baseline characteristics of TIM-HF study participants at randomization are shown in Table 1. In general, activity patients had significantly lower levels of mid-regional pro-atrial natriuretic peptide (MR-proANP) and mid-regional pro-adrenomedullin (MR-proADM) and a higher rate of implantable cardioverter defibrillators (ICD) compared to patients that did not participate in tele-accelerometry.

3.2. 6MWT

3.2.1. Step accuracy

All patients completed **Test 1** and 129/155 patients completed **Test 2**. The exact mean time gap between **Test 1** and **Test 2** was 364 ± 30.0 days. Accuracy of accelerometer based step count compared to hand counted steps was 99 % ($P = 0.5$) with a statistically