ORIGINAL ARTICLE

Evaluation of a Wearable Body Monitoring Device During Treadmill Walking and Jogging in Patients With Fibromyalgia Syndrome

Diego Munguía-Izquierdo, PhD, Alfredo Santalla, PhD, Alejandro Legaz-Arrese, PhD

ABSTRACT. Munguía-Izquierdo D, Santalla A, Legaz-Arrese A. Evaluation of a wearable body monitoring device during treadmill walking and jogging in patients with fibromyalgia syndrome. Arch Phys Med Rehabil 2012;93:115-22.

Objective: To evaluate the reliability and validity of a body monitoring device against measures obtained from indirect calorimetry (IC) in patients with fibromyalgia syndrome (FMS) during various incremental exercise intensities.

Design: Cross-sectional reliability and validity study.

Setting: Testing was completed in a university exercise physiology laboratory.

Participants: Women (N=25) with FMS, with a mean age ± SD of 48.6±8.4 years and a median symptom duration of 15 years (25th–75th percentiles, 10–23y), were recruited to the study.

Interventions: Not applicable.

Main Outcome Measures: Patients walked and jogged on a treadmill at 4 intensities (50m·min^{-1}, 0% grade [n=25]; 83.3m·min^{-1}, 0% grade [n=25]; 116.7m·min^{-1}, 0% grade [n=21]; 116.7m·min^{-1}, 2.5% grade [n=13]) during 2 measurement conditions, while IC and a multiple-sensor body monitor measured energy expenditure (EE). The differences between the readings (test 1 – test 2) and the SD of the differences, intraclass correlation coefficient (ICC), 95% confidence interval (CI) for the ICC, coefficient of repeatability, intrapatient SD, standard error of mean (SEM), minimal detectable change, Wilcoxon signed-rank test, and Bland-Altman graphs were used to examine reliability. The magnitude of the associations between IC and the body monitoring device, ICC, 95% CI for the ICC, paired *t* tests, and Bland-Altman graphs were used to examine the validity of the body monitoring device versus the IC.

Results: Moderate to excellent test-retest reliability was found for the 4 bouts of exercise (ICC=.73–.76). The SEM and minimal detectable change were satisfactory for the 4 bouts of exercise (.54–1.18kcal·min^{-1} and 1.51–3.28kcal·min^{-1}, respectively). The differences mean between test and retest were lower than the SEM for the 4 bouts of exercise, varying from –.17 to .14kcal·min^{-1}. No significant differences were found between test and retest for any bout. The Bland-Altman plots and the coefficients of repeatability indicated that the differences between repeated tests would lie within 2 SDs in 95% of the cases for the 4 bouts of exercise. Significant associations were found between the body monitoring device and IC measurements of EE for the 4 bouts of exercise (r=.87–.99). The differences for all bouts between the 2 methods were nonsignificant, except for the second bout (P<.001). The ICCs and Bland-Altman plots of EE for the 4 bouts showed high agreement (ICCs=.84–.99) and sufficient accuracy for quantifying EE during exercise in patients with FMS.

Conclusions: The body monitoring device provided a valid and reliable estimate of EE in patients with FMS during walking on horizontal and inclined surfaces in a laboratory setting across various exercise intensities.

Key Words: Exercise; Fibromyalgia; Rehabilitation.

FIBROMYALGIA IS CHARACTERIZED by the concurrent existence of chronic, widespread musculoskeletal pain and multiple sites of tenderness.[1] Core symptoms include sleep disturbance,[2] debilitating fatigue,[1] and joint stiffness,[3] and patients may also experience conditions such as cognitive disturbances,[4] anxiety, and depression.[5]

Patients with fibromyalgia syndrome (FMS) show lower functional capacity for daily activities and health-related quality of life than healthy age- and sex-matched people.[6] One of the most important aspects for patients with FMS is the impairment of daily functional performance,[7] and it can be explained by the reduced physical activity level caused by the symptoms[8] or due, at least in part, to metabolic disturbances that have been postulated.[9] Therefore, the assessment of physical activity and energy expenditure (EE) in this clinical population is very important to provide information about the relationship between health and physical activity.

For this reason, the use of measuring instruments (both objective and subjective) in patients with FMS has gained importance.[9-11] Among these, the most commonly used technique to assess physical activity is the administration of self-report questionnaires because they are easy and inexpensive to administer and are nonreactive (ie, they do not influence the behavior of the respondent).[12] In this sense, most studies have reported physical activity levels in patients with FMS with

List of Abbreviations

CI	confidence interval
EE	energy expenditure
FMS	fibromyalgia syndrome
IC	indirect calorimetry
ICC	intraclass correlation coefficient
MDC	minimal detectable change
SEM	standard error of mean
SWA	SenseWear Armband

From the Section of Physical Education and Sports, University Pablo de Olavide, Seville (Munguía-Izquierdo, Santalla); and Section of Physical Education and Sports, University of Zaragoza, Zaragoza (Legaz-Arrese), Spain.

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Address correspondence to Diego Munguía-Izquierdo, PhD, Departamento de Deporte e Informática, Universidad Pablo de Olavide, Carretera de Utrera, Km. 1, s/n, 41013, Sevilla, España (Spain), e-mail: *dmunizq@upo.es*. Reprints are not available from the authors.

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retrospective self-reported data.[11,13] However, this method often leads to an underestimation or overestimation of events.[14,15] Also a very few studies have used newer technologies such as pedometers[16] or actigraphy[13,17] to document objective physical activity levels in patients with FMS.

There is growing interest in functional performance assessment by the indirect but objective measurement of physical activity. Several methods for measuring daily activity have been described that have shortcomings, including being cumbersome, inaccurate, or expensive. The most accurate and commonly used criterion standard in the exercise laboratory is indirect calorimetry (IC) for the determination of EE during acute bouts of exercise[18,19]; in addition, doubly labeled water is used for the determination of EE over time.[18,20] Neither of these techniques are always available or easily applicable in all settings because they are expensive and technologically complex, and they also require trained personnel and specialized laboratory equipment. In addition, radioisotope methodology is time-consuming and intrusive, and it cannot provide information on the specific patterning of activity. In contrast, pedometers, which comprise the simplest method,[21] measure walking fairly well in active groups,[22] but they are unable to accurately measure body movement during nonwalking activities or slow walking,[23] which are activities particularly relevant in severely affected patients with FMS. Direct observation is both time-consuming and intrusive, and self-report questionnaires and diaries that rely on memory are imprecise, especially in subjects with cognitive deficiency such as patients with FMS.[4]

Each method has specific strengths and limitations regarding accuracy, reliability, expense, and portability. Consequently, none provides a simple, accurate, inexpensive, and practical approach for determining EE during an array of exercise and physical activities, including activities involved in daily living and recreational tasks.

A wearable body monitoring device for the assessment of EE has been recently introduced and validated in healthy subjects[24,25] and various clinical populations.[26-28] The portability, patient acceptability, low cost, and the basic skill required by users and the administering personnel are the strengths of this body monitoring device in clinical practice.[25,26] Thus, its use may be of benefit to patients with FMS. However, to our knowledge, no information about the reliability, validity, or feasibility of this new method in such a population has yet been provided.

The purpose of the present study was to evaluate the reliability and validity of this body monitoring device by using measures obtained from IC in patients with FMS during walking and jogging across various levels of incremental exercise intensities.

METHODS

Participants and Study Design

We contacted a local association of patients with FMS in Seville (Spain), and an invitation to participate in the study was sent to all women aged 18 to 60 years (n=250). Twenty-five potentially eligible patients responded. All gave their written informed consent after receiving detailed information in a meeting about the aims and study procedures. Informed consent was never obtained on the day of the meeting. There was a period of at least 1 week between when the information was provided in the meeting and the obtaining of the informed consent. The exclusion criteria included a history of morbid obesity, known cardiopulmonary diseases, uncontrolled endocrine or allergic disturbances, severe trauma, orthopedic or musculoskeletal limitations that precluded ambulation, frequent migraines, inflammatory rheumatic diseases, and severe psychiatric illness according to the criteria of the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.[29] In addition, subjects with any type of tremor, subjects with other diseases that prevent physical loading, and subjects who were pregnant were also excluded. The Spanish version[30] of the revised Physical Activity Readiness Questionnaire[31] was also administered to identify persons at risk for adverse events while exercising. In addition, all patients were instructed to refrain from consuming any food or performing any exercise for 3 hours before testing to ensure that EE would not be elevated.

The research protocol was reviewed and approved by the Committee on Biomedical Ethics of the University Pablo de Olavide. The study was developed following the ethical guidelines of the Declaration of Helsinki, last modified in 2000.[32] Two measurement conditions, separated by 1 week, were performed in a sample of patients with FMS during appointments that took place at the university to estimate the validity, reliability, and stability of the SenseWear armband[a] (SWA), a wearable body monitoring device for the assessment of EE. During the first appointment, the medical records of the patients and anthropometric measurements were examined by a physician, and a diagnosis of FMS was confirmed as per the American College of Rheumatology classification criteria.[1] In addition, patients completed an incremental staggered test in random order. During the second appointment, the patients were carefully interviewed to ensure that they were not restricting caloric intake during the study period. They completed the same incremental staggered test in the same order as the first session.

EE at Different Workloads of Exercise

After a 3-minute warm-up period at a speed of $50 m \cdot min^{-1}$, the patients performed 4 bouts of exercise during an incremental test, starting at $50 m \cdot min^{-1}$, with an increase of $33.3 m \cdot min^{-1}$ every 3 minutes up to $116.7 m \cdot min^{-1}$. After that, a 2.5% slope inclination was included. The testing protocol was performed for walking and jogging on a treadmill.[b] Gas exchange data were continuously collected during the test through an automated breath-by-breath system,[c] and EE was measured with the SWA. In this study, EE during each test was estimated by applying a generalized proprietary algorithm (SenseWear Professional Software version 6.1[a]) developed by the manufacturer. For the last 2 minutes of each bout of exercise, EE ($kcal \cdot min^{-1}$) was computed by multiplying the oxygen uptake ($L \cdot min^{-1}$) by the nonprotein caloric equivalent based on the respiratory exchange ratio.[33]

Anthropometry

All anthropometric measurements were performed by the same operator according to the Anthropometric Standardization Reference Manual.[34] Weight was measured to the nearest 100g, and height was measured to the nearest 0.1cm using an electronic balance with an incorporated stadiometer,[d] with subjects in their underwear. Body mass index was calculated as body mass (kg) divided by height (m) squared.

Skinfolds were measured with a caliper.[e] Skinfold thicknesses (biceps, triceps, subscapular, suprailiac, calf, and midthigh) were measured to the nearest millimeter using calipers on the right-hand side of the body.[34] The sum of the 6 skinfold thicknesses was used as an indicator of total body fat. All skinfold measurements were repeated 3 times, and the 3 values were averaged.