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Standardizing the Analysis of Physical Activity in Patients With COPD Following a Pulmonary Rehabilitation Program

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BACKGROUND: There is a wide variability in measurement methodology of physical activity. This study investigated the effect of different analysis techniques on the statistical power of physical activity outcomes after pulmonary rehabilitation.

METHODS: Physical activity was measured with an activity monitor armband in 57 patients with COPD (mean ± SD age, 66 ± 7 years; FEV_1, 46 ± 17% predicted) before and after 3 months of pulmonary rehabilitation. The choice of the outcome (daily number of steps [STEPS], time spent in at least moderate physical activity [TMA], mean metabolic equivalents of task level [METS], and activity time [ACT]), impact of weekends, number of days of assessment, post-processing techniques, and influence of duration of daylight time (DT) on the sample size to achieve a power of 0.8 were investigated.

RESULTS: The STEPS and ACT (1.6-2.3 metabolic equivalents of task) were the most sensitive outcomes. Excluding weekends decreased the sample size for STEPS (83 vs 56), TMA (160 vs 148), and METS (251 vs 207). Using 4 weekdays (STEPS and TMA) or 5 weekdays (METS) rendered the lowest sample size. Excluding days with < 8 h wearing time reduced the sample size for STEPS (56 vs 51). Differences in DT were an important confounder.

CONCLUSIONS: Changes in physical activity following pulmonary rehabilitation are best measured for 4 weekdays, including only days with at least 8 h of wearing time (during waking hours) and considering the difference in DT as a covariate in the analysis.

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ABBREVIATIONS: DT = duration of daylight time; ICC = intraclass correlation coefficient; METs = metabolic equivalents of task; METS = mean metabolic equivalents of task level; STEPS = daily number of steps; TMA = time spent in at least moderate physical activity

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In patients with COPD, physical inactivity is believed to play a crucial role in the development of comorbidities (ie, skeletal muscle weakness, osteoporosis, depression, exercise intolerance, cardiovascular disease).[1-3] Moreover, physical inactivity is an independent predictor of adverse outcome[4,5] and affects quality of life.[6,7] Increasing physical activity has become a patient-centered goal for the treatment of patients with COPD. Unfortunately, the literature suggests that after following a pulmonary rehabilitation program, an enhancement of physical activity is not guaranteed.[8,9] The lack of statistically significant improvements can be due to a failure of interventions to achieve behavioral changes or to the conduct of underpowered studies unable to account for the variability in the outcome measure.

Physical activity is characterized by large variability because it is measured under unstandardized conditions. Recommendations identify the need for optimal activity monitor schedules in field research.[10] Factors affecting standardization are related to intrinsic differences in physical activity levels from day-to-day, extrinsic variability (ie, climatologic conditions, seasons[11,12]); the measurement itself (ie, the monitor, the number of days of assessment, the number of hours of measurement); and postprocessing (ie, days and time use in the analysis). Minimizing the noise around the measure of physical activity can enhance the statistical power of studies, whereas minimizing the number of days and hours of assessment reduces the burden to patients, which may contribute to study compliance.

The aim of the present study was to find a standardized method of physical activity measurement and data analysis to improve the power of physical activity-related outcomes, predominantly by reducing the variability of the outcomes and optimizing the effect size. We explored the following research questions: What is the impact of (1) the chosen outcome, (2) the exclusion of weekends, (3) increasing the number of days of assessment, and (4) altering the postprocessing analysis techniques (eg, time set used, definition of valid days according to wearing time, correction for daylight time)?

We hypothesized that the variability in physical activity can be reduced by excluding weekends, using more assessment days, comparing the same days of the week at both time points, using a fixed time frame for physical activity analysis (eg, 7:00 AM-8:00 PM), and omitting days with a low monitor wearing time. Previous studies[13-17] identified the number of days of assessment through cross-sectional data analysis. The present study compared the impact of different techniques of analysis on the intervention effect after rehabilitation.

Materials and Methods

Study Subjects and Design

The baseline and 3-month data of a rehabilitation study (Clinical Trials registry No.: NCT00948623; approved by UZ Leuven Medical Ethics Committee [B32220095599]) were used to investigate variability in physical activity. Patients with stable COPD[2] (no exacerbations in preceding 4 weeks) referred for outpatient pulmonary rehabilitation were randomly assigned to a conventional rehabilitation group (described in detail elsewhere[18]) or a conventional rehabilitation plus counseling group. In the present analysis, both groups are combined. The sample size calculation of the original study was based on the primary aim of the rehabilitation study; hence, the present sample should be seen as a convenience sample and was judged to be appropriate for the present (sub)analysis. This judgment was based on a sensitivity analysis where random patients were left out of the analysis, which showed no change in mean and SD of the effect (e-Appendix 1). In addition, the present study sample is one of the larger samples analyzing the (objectively measured) physical activity of patients undergoing pulmonary rehabilitation.[9] Fifty-seven of the subjects already had accelerometer data files both at baseline and after 3 months. These data were retrieved for this investigation. Informed consent was obtained prior to the start of the study. More information can be found in e-Appendix 1.

Clinical Measurements

All subjects underwent spirometry (Jaeger MasterScreen Body; CareFusion Corp) according to European Respiratory Society and American Thoracic Society standards. The results were referred to the predicted normal values proposed by Quanjer et al.[19] A 6-min walk test was performed in a 50-m corridor, and the best of two tests was used.[20]

Physical activity was measured before and immediately after rehabilitation for 7 consecutive days with the SenseWear Pro armband (BodyMedia, Inc), which detects wearing time directly by skin contact.[21] The SenseWear Pro armband has been thoroughly validated.[22-24]

Subjects were asked to wear the monitor whenever awake. They refrained from their rehabilitation program in the week of the physical activity assessment. The minute-by-minute output of the number of steps and metabolic equivalents of task (METs) was exported for further analysis using SenseWear Professional, version 6.0 software (BodyMedia, Inc).

The variables chosen for this analysis were the total daily number of steps (STEPS); daily time spent in at least moderate physical activity (TMA), defined as any activity ≥ 3 METs[25]; and daily mean METs level (METS). Active time was also defined at lower thresholds (between 1 and 3 METs) using a 0.1-MET increase (e-Appendix 1).

Data Treatment

The full analysis set comprised all available minute-by-minute data before and after rehabilitation. From the full analysis set, several datasets were constructed to test various hypotheses (e-Appendix 1).

Duration of daylight time (DT) has been suggested as a proxy for seasonality. DT of each measured day was predicted using the CSIRO (Commonwealth Scientific and Industrial Research Organisation) Biosphere model, with a day length coefficient of 0.8333 and latitude of 50.78° (Fig 1).[26]

Statistics

Minute-by-minute datasets were analyzed with SAS, version 9.3 (SAS Institute Inc) statistical software. Two different approaches were used to identify the impact of standardization: