The Maugeri daily activity profile: a tool to assess physical activity in patients with chronic obstructive pulmonary disease

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Abstract

Patients with chronic obstructive pulmonary disease (COPD) report reduced physical activity (PA). There are only few tools available to assess PA and sedentary behavior in these patients, and none of them aims to differentiate between sedentary and active patterns. Aim. To evaluate an easy tool to profile daily activity time in a cohort of patients with COPD, compared to healthy subjects. Design: interventional. Setting: Istituti Clinici Scientifici Maugeri (ICS), IRCCS of Tradate and Lumezzane, Italy, and Ente Ospedaliero Cantonale Novaggio, (Italian Speaking) Switzerland. Population: Inpatients with COPD, healthy subjects. The items of the Maugeri Daily Activity (MaDA) profile were chosen based on literature, interviews with patients and health professionals. Time spent during sleep (ST), when awake (AT), active (ACT) or in sedentary behavior (SET) were recorded. Lung function tests, arterial blood gases, the modified Medical Research Council (mMRC), the six-minute walking distance test (6MWD), the COPD Assessment Test (CAT), and the body-mass index, airflow obstruction, dyspnea, and exercise capacity (BODE) index were also assessed in patients. Sixty patients with COPD and 60 healthy controls filled in the questionnaire. As compared to controls, patients showed longer AT and SET. Active time of patients was significantly correlated with mMRC, CAT, Bode Index and 6MWD, but not with demographics, anthropometrics or stages of disease. Using this tool, we found that patients with COPD spent longer time awake and in sedentary behavior. The MaDA may be useful to evaluate PA in patients with COPD.

Key words: Chronic respiratory diseases, physical activity, rehabilitation

Introduction

Physical activity (PA), defined as any body movement produced by skeletal muscles resulting in energy expenditure, is characterized by type, intensity, duration, patterns and symptoms experience. It includes, but is not limited to, exercise, leisure-time, domestic and occupational activities [1,2]. It has been calculated that elimination of physical inactivity would avoid between 6 and 10% of the major non communicable diseases, coronary heart disease, type 2 diabetes, breast and colon cancers, and increase life expectancy, whereas higher levels of PA increase healthy and chronic disease-free years [3,4]. Daily PA of patients with chronic obstructive pulmonary disease (COPD) is reduced in the early phases of disease as compared to healthy age-matched controls and worsen over time, with important clinical consequences [5].

Pulmonary rehabilitation (PR) that is a ''comprehensive intervention to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health enhancing behaviours" [6], sought strategies to improve PA in COPD [7]. It has been speculated that increases in exercise capacity in combination with behavioral changes may also have the potential to increase physical activity in patients with COPD, however so far, the studies have yielded inconsistent results [8].

Several methods are able to measure the amount of PA (i.e. metabolic rate, number of daily footsteps) [2]. These instrumental assessments require dedicated equipment which provide different information. Some of those are inexpensive and easy to use. Up today, they are not regularly used to evaluate the usual PA of COPD subjects. A profiling tool, able to differentiate sedentary or active patterns, could allow to acquire information useful to identify and customize the optimal components of the rehabilitation (i.e. provide an educational intervention aimed at the subject's habits and not hypothetical-usual habits) [9]. The aim of this study was to evaluate a tool to profile daily activity time in a cohort of COPD patients, compared to healthy subjects.

Methods

The study was carried out at Istituti Clinici Scientifici Maugeri (ICS), IRCCS of Tradate and Lumezzane, Italy, and Ente Ospedaliero Cantonale Novaggio, (Italian Speaking) Switzerland. The ICS Maugeri Ethics Committee approved the study protocol (2067 CE, September 26, 2016). Informed consent was obtained from all subjects.

Participants

All patients with COPD admitted since October to December 2018 to undergo pulmonary rehabilitation were consecutively recruited. The Maugeri Daily Activity profile (MaDA) was administered within two days since admission. Patients were eligible for inclusion if they fulfilled the following criteria: a) diagnosis of COPD (post-bronchodilator forced expiratory volume in 1s (FEV1)/forced vital capacity (FVC) < 0.7)14; b) age $\geq$ 65 years; c) Italian speaking; d) smoking history $\geq$10 pack/years, e) clinical stability (pH range: 7.38 - 7.42, without any change in respiratory medications in the previous 7 days); f) ability to perform the six-minute walking distance test (6MWD); g) ability to sign the informed consent.

Exclusion criteria were: other concomitant pulmonary diseases, hospitalization in the 30 days prior enrollment, being on long term oxygen therapy and/or home mechanical ventilation,15,16 any diagnosis of neurological or neuromuscular diseases and any other condition limiting ambulation, memory or comprehension problems.

Control healthy adults of comparable age and gender distribution underwent the administration of the MaDA.

Construction of MaDA

The active and sedentary activities were administered according a prespecified checklist. The MaDA profile was designed according to the TAxonomy of Self-Reported Sedentary behavior Tools (TASST) framework 10. According to TASST four domains were included: *i*-type of assessment: self-reported; *ii*-recall period: the last week preceding the interview; *iii*-temporal unit: hour; *iv*-assessment period: week. MaDA construction was performed following two steps:

Items selection

Preliminary items were chosen based on available literature 11-13. A team of experts including pulmonologists (DV, AZ, AS), a bioengineer (AG), respiratory therapists (EZ, MP, GLB), a psychologist (GB) and a psychometrist (AI) defined the instructions to administer the pilot version. Subjects had to recall how a specific activity (i.e. gardening) and/or a sedentary behavior (i.e. watching television) was frequent (number of times in a week) and for how long (hours) on average in the week preceding the interview, without any distinction between week and weekend days.

Revision

In June 2018, 10 patients were administered a preliminary version, afterwards the focus group gave comments, and discussed the relevance and comprehensiveness of the items according to the consensus-based standards for the selection of health measurements instruments (COSMIN) checklist.14 Some items were reworded when unclear or removed if not relevant. The resulting items were included into the final version. The final version of MaDA assesses the time spent during sleep (average numbers of hours per day), the sedentary activities (such as reading, watching television or using computer, sitting on a public transport: 14 items) and motion activities (such as homeworks, walking or cycling, leisure time: 10 items). The final version was submitted face to face, individually by trained staff and checked for completeness by the psychometrist. The full English and Italian versions of the MaDA profiler are available as Supplementary Materials.

Scoring method

In order to compute the profile, according to TASST, the duration in hours of the assessment period (one week = WH) was divided in Sleep (ST) and Awake Time (AT), with the latter subdivided in Active (ACT), Sedentary Time (SET) and time spent in other or unreported activities (OTH) as shown on Figure 1. Sleep Time was obtained by multiplying the reported average daily sleep duration in hours by 7. Awake Time was calculated by adding up time the patient declared to spend in ACT, SET and OTH. Activity time and SET were easily calculated by multiplying the frequency (number of times in a week) for the duration (hours) of the time spent for each item investigated and then summing the results. OTH was a calculated measure and represents the weekly time spent in very short activities, in transitions from a behavior to another one, in activities not included in MaDA or time incorrectly reported due to rounding effects:

OTH= WH - (ST + SET + ACT)

All periods of time reported during the day are expressed as absolute time and % of the total awake time.

Measurements

Demographics, anthropometrics, level of education and employment were recorded in both patients and controls;

In patients, the following data were recorded or assessed:

- Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages15 and reported number and severity of exacerbations in the previous 12 months;
- Static and dynamic lung volumes by means of a body plethysmograph according to the American Thoracic Society [16], using the predicted values of the European Respiratory Society [17];
- Arterial blood gases by means of automatic analyzers on samples from the radial artery with the patient in sitting position, breathing room air;
- Subjective sensation of dyspnoea by means of the modified Medical Research Council (mMRC) scale [18];
- Exercise tolerance assessed by means of the 6MWD according to accepted guidelines [19]: the predicted values were by Enright and Sherrill [20+. At the beginning and at the end of walking, subjective sensations of dyspnoea and leg fatigue were assessed by means of a modified Borg scale [21];
- Symptoms burden on health status by the COPD Assessment Test (CAT) [22];

- The composite and multi-dimensional body-mass index, airflow obstruction, dyspnea, and exercise capacity (BODE) index [23].

Statistical analysis

The effect size for the correlation between MaDA and measured parameters was expected medium to high (r ~ 0.4). In order to detect departure from the hypothesis (i.e. small effect size, r < .1), the required sample size involved at least 60 subjects (alpha = 0.05, beta = 0.8, one sided test).

Descriptive statistics were performed reporting means and standard deviations [mean (SD)] for continuous variables, numbers (n) and percentages (%) for categorical variables. Student's *t*-test for non-paired values was used to compare the means of groups for quantitative variables. For categorical variables, the Chi-squared test or Fisher's exact test, if necessary, was employed.

Student's *t*-test was used to compare ST and AT, duration and percentage of ACT and SET differences between healthy subjects and patients. ANOVA test was used to assess differences among GOLD stages.

The relationship between the percentage of time spent in activities (%ACT) as estimated by MaDA and patients' clinical status and conditions was investigated using Spearman's rank correlation for ordinal data (GOLD stages, CAT, mMRC, Bode Index) and linear correlation for continuous variables.

The data were analyzed by using StataCorp Stata 13.1 software

Results

The selection procedure is shown in Figure 2. Sixty patients and 60 healthy subjects were enrolled and answered the questionnaire. Thirty-six patients and controls were enrolled at Tradate, 14 at Lumezzane, and 10 at Novaggio.

Characteristics of patients and controls are shown in Table 1. The only difference between groups was the higher level of education in controls.

Physiological and clinical characteristic of all patients ~~and according to centers~~ are shown in Table 2. GOLD severity stages 2 and 3 according to airway obstruction and groups B and D according to the new classification15 accounted for more than 75% of patients. There was only one potentially relevant difference in physiological parameters among centers (residual volume (RV) ,% predicted: 140.8 ± 51.4, 187.8 ± 41.9, 152.2 ± 38.0 for Tradate, Novaggio and Lumezzane respectively: p = 0.0291).

The comparison of activity time in patients and healthy subjects is shown in Table 3. As compared with controls, patients spent significantly less time sleeping (47.3 ± 9.9 vs 50.1 ± 2.1 hours respectively, p=0.03) and more time awake (120.6 ± 9.9 vs 117.8 ± 2.0 hours respectively, p= 0.03) and in sedentary (49.2 ± 21.0 vs 41.2 ± 15.7 hours, respectively, p=0.01) behavior. There were no significant differences among GOLD stages either classified on airway obstruction (p = 0.140) or according to the new definition (p = 0.277).

Figure 3 shows the values of assessed measures according the time spent in activity, whereas Table 4 shows that ACT but not SET of patients was significantly correlated with mMRC, CAT, Bode Index, 6MWD and Borg fatigue perceived after 6MWD, but not with demographics, anthropometrics or levels of airway obstruction. There was no correlation with education level in any group.

Discussion

We propose a tool to profile the time of daily activity in patients with COPD. The lack of a simple tool pushed us to evaluate a profiler to be used to address the rehabilitative intervention. Furthermore, as most of the available questionnaires report the amount of PA, we aimed to develop a tool able to evaluate different periods of activity and time spent in sedentary behavior. Low to moderate correlation observed on country level suggests that cross country comparison is difficult even if the same self-report instrument is used [24]. Since lifestyles are strongly influenced by medical, environmental, cultural and social conditions, we need instruments specifically tailored to the population under study, in Italian language.

The MaDA profiler revealed that, as compared to healthy controls, patients with COPD spent significantly more time awake and in sedentary behavior. The awake time spent in activities was significantly correlated with levels of dyspnoea, symptom burden, exercise capacity but not with the severity of airway obstruction.

No difference was observed between patients with COPD and controls as regards the time spent in PA, while the difference was in the sleeping time and in the time spent in sedentary activities. This lack of difference: it might be due to the self-reported description of the activities performed by the single persons. Physical activity, as per definition [1,2] reflects "what a patient is actually doing", whereas exercise capacity, is a measure of "what a patient can do". Publications about tools for measurement of PA in patients with COPD has increased exponentially since Pitta *et al*. [25] reported the first characterization of the PA of these patients using an objective measurement. Multiple questionnaires exist to measure PA. A systematic review concluded that there were 104 different questionnaires available to measure PA or

related constructs in elderly or chronically ill populations [26]. From the questionnaires identified in this systematic review, 15 were developed for patients with COPD. Validity was assessed in 85% of these instruments, test-retest-reliability in 69% and responsiveness in only 19%, and none of the instruments was based on a conceptual framework [27]. Several questionnaires have been included in validation studies in patients with COPD [28-33], in comparison with activity monitoring. In general, the accuracy of questionnaires to estimate the individual PA of a patient is poor, nevertheless, because they are able to identify 'extremes' in PA they can be used in large epidemiological studies. The accuracy of using self-report is influenced by overestimation of the PA [34], recall bias and tendency to provide socially desirable information. Questionnaires used to measure symptoms and health status containing a domain related to PA cannot be used for an individual measure of PA [35].

The only difference between characteristics of patients and controls of our study was the higher level of education in healthy subjects, which is unlikely to have influenced differences in answers, as the time spent in activity showed no correlation with education level in either group. Residual volume was the only significant difference in physiological data among center. We are confident that this difference has not influenced results as the prevalence in GOLD stages either classified on airway obstruction or according the new definition was not different.

As compared with controls, patients spent significantly more time awake and in sedentary behavior. In the general adult population, sleep disorder symptoms increase with age and usually are greater in women. Furthermore, there is an increased prevalence of sleep symptoms among patients with COPD [36]. Chronic obstructive pulmonary disease is frequently associated with sleep-related breathing disorders, including sleep-related hypoxaemia, obstructive sleep apnoea, central sleep apnoea, respiratory effort-related arousals, and sleep-related hypoventilation. These sleep-related breathing disorders may be associated with non-restorative sleep and daytime sleepiness and fatigue and reduced exercise capacity [37,38].

The time spent in activities of our patients was significantly correlated with dyspnoea, as assessed by mMRC, with symptom burden as assessed by the CAT, with Bode Index, and with exercise capacity as assessed by means of 6MWD, but not with levels of airway obstruction. These results confirm those by Pitta *et al.* [25] obtained with activity monitors. As compared with healthy controls, patients in that study [25] showed lower walking time, standing time, and movement intensity during walking, as well as higher sitting time and lying time. Walking time was highly correlated with the 6MWD and more modestly to maximal exercise capacity, lung function, and muscle force. At difference, a study evaluating PA patterns and clusters in more than 1000 patients with COPD showed that age, Body Mass Index (BMI), dyspnoea grade

and age, dyspnoea and airflow obstruction (ADO) index were associated with PA measures and hourly patterns. Five clusters were identified which accounted for 60% of variance of the data. The most inactive cluster was characterized by higher BMI, lower FEV1, worse dyspnoea and higher ADO index compared to other clusters [35].

It has been reported that using different questionnaires shifts the patient distribution and results in different clinical characteristics, including PA [39]. In our study ACT was inversely correlated with measures such as CAT and mMRC. The CAT measures the impact of COPD on health status22, a score ≥ 10 is defined as having "high" symptoms in the GOLD strategy. The mMRC assesses the disability due to breathlessness18 where an mMRC grade ≥ 2 points indicates having "high" symptoms. Our results on mMRC are in line with those by Hayata *et al*. [40].

We did not find any significant correlation of SET with levels of airway obstruction and there were no significant differences in assessed periods among GOLD stages. This may be due to the fact that patients were not evenly distributed among all stages but were concentrated in stages 2 and 3 or B and D. According to other studies, the GOLD classification showed a gradual but substantially overlapping decline in level of PA as assessed by step counters, and accordingly a linear increase in proportion of inactive patients in the more severe levels of airway obstruction [5,39,41], whereas Pitta e*t al.* [25] found only a slight correlation with lung function. Our data confirm those questionnaires and objective measures of activity such as step counters give different information about PA.42 Also, a study by Paneroni *et al*. [43] reported that in patients with COPD and chronic hypoxia, daily steps showed a strong correlation with 6MWD, and only a moderate correlation with airway obstruction.

Clinical implications

There is insufficient evidence that incentives to increase PA in patients with a history of COPD exacerbations may affect improvements in acute care use or survival [44], nor the recognized benefits of exercise training do always translate into enhanced PA levels [8,45]. However public health guidelines developed for the general population recommend people who have chronic conditions such as COPD, seek advice from health care providers to adequately manage their condition [46] and reducing time spent in sedentary behavior has demonstrated positive effects [47-50]. Therefore, knowledge of patients' behavior profile may be useful in planning individualized self-induced or supported programs of changes in lifestyle. However we did not find any cut-off to distinguish active vs non active patients, and the description of the time spent in active and sedentary activities may be only suggestive of some potential interventions.

Limitations the study

Results of MaDA were neither compared with those of objective measurements of activity such as step counters, or of a specific assessment for the cognitive capacity, or test-retest-reliability and responsiveness were assessed. Self-report measures of sedentary time may have resulted in large bias, poor precision and low correlation with an objective measure of sedentary time [47]. The MaDA would be maybe difficult to be self-administered to elderly people with mild cognitive impairment, which is a frequent condition, especially among patients with chronic diseases. On the other hand, the advantages for using a profiler are the inexpensive and practical use, the easy analysis and fast results and further studies will cover these flaws.

Conclusions

The MaDA profiler may be a useful aid to distinguish patients with COPD in active and sedentary. However we did not find any cut-off to distinguish active vs non active patients, and the descritpion of the time spent in active and sedentary activities may be only suggestive of some potential interventions. Nonetheless, using this tool, we found that patients with COPD spend longer time awake and in sedentary behavior, these features make MaDA a suitable tool for the profiling of the PA when a basic evaluation must be performed, without being able to use technological devices (e.g. pedometer, *etc*). Further studies on larger sample sizes, comparing the results of MaDA with those of objective measurements of activity and evaluating test-retest-reliability and responsiveness are needed.

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Figure 1. Domains assessed by MaDA.

Weekly hours	WH	Sleep Time	ST*		
		Awake Time	AT*	Active Time	ACT*
				Sedentary time	SET*
				Other activities Time	OTH°

WH: one week, ST: Sleep Time, AT: Awake Time, ACT: Active Time, SET: Sedentary Time, OTH: Other Time, * Direct measure, ° Derived measure
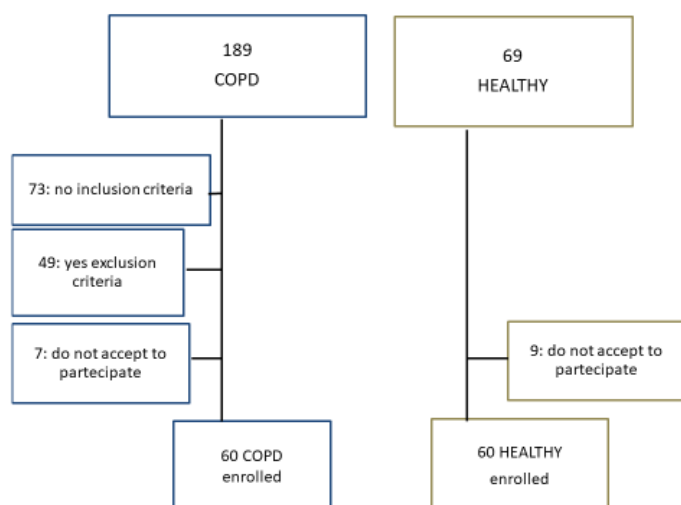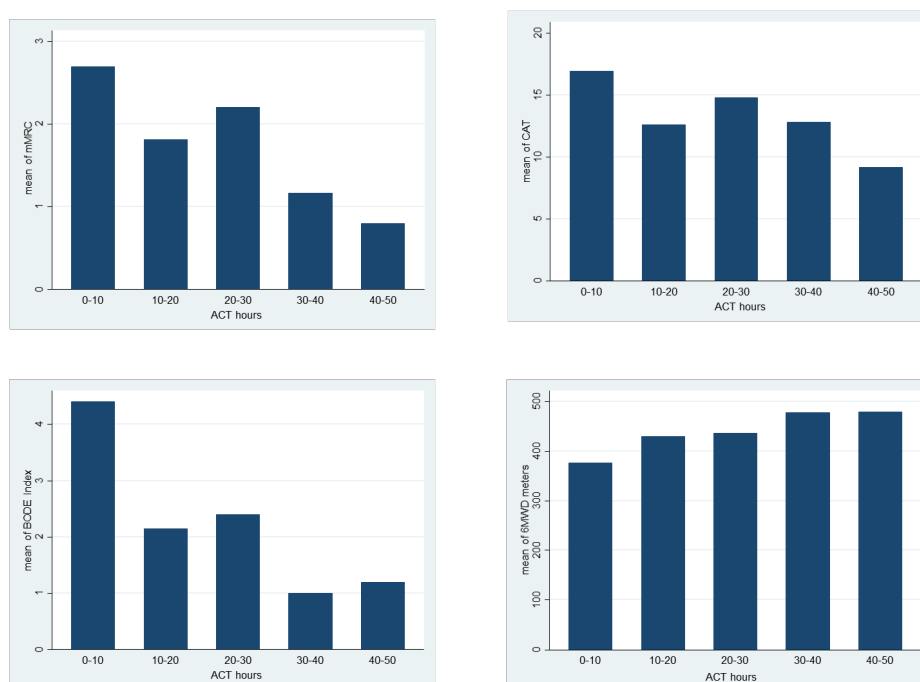
Figure 2. Selection procedure.

Figure 3. Values of assessed measures according to time spent in activity

mMRC: modified Medical Research Council; CAT: COPD Assessment Test; BODE Index: The Body-Mass, Airflow Obstruction, Dyspnea, Exercise Index; 6MWD: Six minutes walking test.

Table 1. Demographics and social data.

Variables		COPD	Controls	p
N		60	60	-
Male, n (%)		38 (63.3)	39 (65)	0.849
Age, years		70.5±7.3	71.2±7.1	0.293
Subjects with walking problems, n (%)		12 (20.0)	17 (28.3)	0.286
Subjects use of walking device, n (%)		3 (5.0)	6 (10.7)	0.298
Educational level, n (%)	None	1(1.67)	-	
	Primary school	20 (33.3)	12 (20.1)	
	Secondary school	24 (40.0)	14 (23.3)	0.005
	High school	11 (18.3)	17 (28.3)	
	University	4 (6.7)	17 (28.3)	
Marital status, n (%)	Married	37 (61.7)	49 (81.6)	
	Divorced	6 (10.0)	4 (6.7)	
	Widowed/er	10 (16.7)	4 (6.7)	0.100
	Single	7 (11.6)	3 (5)	
Employment, n (%)	Employed	6 (10.0)	6 (10.0)	
	Never employed/housewife	5 (8.4)	8 (13.3)	
	Retired	47 (78.4)	44 (73.3)	0.698
	Invalid	1 (1.6)	-	
	Unemployed, at present	1 (1.6)	2 (3.4)	
Living, n (%)	Alone	15 (25)	6 (10.0)	
	With other	45 (75)	54 (90.0)	0.111

Table 2. Anthropometrics, physiological and clinical characteristics of patients with COPD.

Variables			
BMI, Kg/cm2 n ± SD			25.8 ± 5.8
GOLD Stage	FEV1 ≥ 80% pred, n (%)	1	6 (10.0)
	50% ≤ FEV1 < 80% pred, n (%)	2	30 (50.0)
	30% ≤ FEV1 < 50% pred, n (%)	3	18 (30.0)
	FEV1 < 30% pred, n (%)	4	6 (10.0)
GOLD stages n (%)		A	10 (16.7)
		B	29 (48.3)
		C	3 (5.0)
		D	18 (30.0)
FEV1 L			1.4 ± 0.6
FEV1 % pred			55.1 ± 18.7
FVC L			2.8 ± 0.8
FVC % pred			85.5 ± 17.6
FEV1/FVC %			48.5 ± 12.5
RV % pred			151.2 ± 50.2
PaO2 mmHg			72.7 ± 8.5
PaCO2 mmHg			37.1 ± 4.1
pH			7.40 ± 0.0
mMRC			2.0 ± 1.1
CAT			14.0 ± 6.4
BODE Index			2.8 ± 2.1
6MWD meters			422.4 ± 98.5
6MWD % pred			88.8 ± 20.5
Post 6MWD Borg dyspnea			3.7 ± 2.4
Post 6MWD Borg fatigue			2.6 ± 2.2

: BMI: Body Mass Index; BODE Index: The Body-Mass, Airflow Obstruction, Dyspnea, Exercise Index; CAT: COPD Assessment Test; FEV1: Forced Expiratory Volume at First second; FVC: Forced Vital Capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; mMRC: modified Medical Research Council; PaCO2: Arterial Carbon Dioxide Tension; PaO2: Arterial Oxygen Tension; RV: Residual Volume; 6MWD: Six minutes walking test.

Table 3. Comparison of activity time between patients and healthy subjects.

		COPD n=60	Controls n=60	p
ST		47.3 ± 9.9	50.1 ± 2.0	0.03
AT		120.6 ± 9.9	117.8 ± 2.0	0.03
ACT	hours	18.2 ± 15.8	18.5 ± 13.4	0.93
SET		49.2 ± 20.9	41.2 ± 15.7	0.01
OTH		53.1 ± 25.7	58.0 ± 20.0	0.25
%ACT	% AT	15.0 ± 13.2	15.7 ± 11.4	0.25
%SET		40.1 ± 15.7	35.1 ± 13.4	0.03
%OTH		44.9 ± 20.1	49.2 ± 17.0	0.21

ACT: Active time; AT: Awake time, COPD: Chronic Obstructive Pulmonary Disease; OTH: Other time; %ACT: percent of Active time; %AT: percent of Awake time; %OTH: percent of Other time; %SET: percent of Sedentary time; SET: Sedentary time; ST: Sleep time

Table 4. Correlation between ACT and SET, expressed as mean time (hours) or percentage, and clinical\functional parameters; a) for ordinal and b) for continuous parameters, in COPD subjects. ρ Spearman's rank correlation coefficient, R Pearson correlation coefficient.

a)	ACT		SET		%ACT		%SET	
	ρ	p	ρ	p	ρ	p	ρ	p
mMRC	-0.51	0.000	0.01	0.96	-0.51	0.001	0.03	0.83
CAT	-0.34	0.009	0.09	0.50	-0.36	0.006	0.06	0.69
BODE Index	-0.54	0.000	0.06	0.64	-0.55	0.001	0.07	0.60

b)	ACT			SET			%ACT			%SET		
	R2	Coeff.	p	R2	Coeff.	p	R2	Coeff.	p	R2	Coeff.	p
6MWD meters	0.174	2.605	0.001	0.049	-1.042	0.089	0.161	2.984	0.001	0.041	-1.263	0.123
6MWD % pred	0.144	0.494	0.003	0.007	-0.084	0.516	0.147	0.594	0.003	0.002	-0.053	0.757
Post 6MWD Borg fatigue	0.171	-0.058	0.001	0.003	0.006	0.686	0.158	-0.067	0.002	0.004	0.009	0.648

ACT: Active time; BODE Index: The Body-Mass, Airflow Obstruction, Dyspnea, Exercise Index; CAT: COPD Assessment Test; mMRC: modified Medical Research Council; %ACT: percent of Active time; %SET: percent of Sedentary time; SET: Sedentary time; 6MWD: Six minutes walking distance.