Body mass index, airflow obstruction, dyspnea, and exercise index is not modified after 6 months therapy with roflumilast in a cohort of patients with chronic obstructive pulmonary disease

Sir,

Roflumilast is an oral phosphodiesterase-4 selective inhibitor with anti-inflammatory action targeting the systemic inflammation associated with chronic obstructive pulmonary disease (COPD). Several studies have recently evaluated the clinical efficacy and safety of roflumilast in the treatment of COPD, showing its capacity in reducing exacerbations and hospital admissions in patients at risk of frequent and severe exacerbations despite conventional inhaled therapy with inhaled corticosteroids, long-acting beta-agonists, and long-acting muscarinic antagonist.[1,2]

The body mass index, airflow obstruction, dyspnea, and exercise (BODE) index is a validated multidimensional scoring system for COPD patients to predict long-term pulmonary and systemic outcomes.[3] It has been clearly demonstrated that BODE index is a better predictor of the risk of death from respiratory and/or systemic causes than is the forced expiratory volume in 1 s (FEV1) alone.[3,4]

In this study, we aimed to assess the variation of BODE index in eligible patients with COPD before and after 6 months of therapy with roflumilast.

Twenty-six patients with severe and very severe COPD (FEV1 <50% pred) with a history of frequent exacerbations [GOLD C and D, Table 1][5] were recruited in the outpatient clinics of our two participating centers in Italy. Exclusion criteria were the following: (a) subjects with any kind of exacerbation in the 4 weeks before testing. (b) All exclusion conditions for therapy with roflumilast as indicated in the drug information sheet. (c) Subjects who discontinued therapy with roflumilast for side effects (weight loss and gastrointestinal disturbances) or for personal reasons.

During the first visit (T1) selected patients performed the following measurements: anthropometric data (height, weight, and body mass index), flow-volume spirometry with bronchoreversibility, COPD assessment test (CAT), modified Medical Research Council (mMRC) dyspnea scale, 6 min walking test and BODE index was calculated. Roflumilast 500 mcg/day was then prescribed to all the participants in addition to their current inhaled therapy. The second visit (T2) was scheduled 6 months after beginning of therapy with roflumilast and all the above measurements were repeated.

Table 1: Subject demographics and clinical characteristics of the total cohort

	T1	T2	*P*
Patients (*n*)	20	/	/
Sex (male/female)	20/0	/	/
Age (years)	67.3±9.82	/	/
BMI	25±3.55	24.1±2.48	0.902
CAT	16.3±6.7	13.75±5.19	0.096
mMRC	2.08±0.99	1.50±1.16	0.367
FEV1% post	34±10	40.9±17.9	0.585
BODE index	4.75±1.91	4.17±2.72	0.33
Exacerbations (*n*/6 months)	2.5±0.79	1.08±1.16	0.001

Values are expressed as mean±SD. Significance was determined by ANOVA analysis. SD: Standard deviation, BMI: Body mass index, CAT: COPD assessment test, COPD: Chronic obstructive pulmonary disease, BODE: Body mass index, airflow obstruction, dyspnea, and exercise, FEV1: Forced expiratory volume in 1 s, mMRC: Modified Medical Research Council

We used ANOVA to compare mMRC, CAT; FEV1% pred postbronchodilator, BODE index and a number of exacerbation in the last 6 months at T1 with those obtained at T2. $P < 0.05$ was considered as statistically significant.

Results are showed in Table 1. Twenty patients out of 26 completed the study. The number of exacerbations in T2 was significantly lower than T1 whereas BODE index, FEV1% CAT, and mMRC did not differ between T1 and T2.

This study confirmed that a relatively short period (6 months) of therapy with roflumilast is sufficient to significantly reduce the number of exacerbations in frequent exacerbators with COPD. Moreover, all clinical, functional, and prognostic parameters, including BODE index remained unaltered between the study period. This is likely to be a positive effect of the medication because its anti-inflammatory effect may have slowed the disease evolution as reflected by the stability of BODE index, which is the best health status indicator for COPD.[6] Undoubtedly, further evaluations with a longer study period and with larger sample sizes are warranted to encourage the use of this therapeutic option in specific phenotypes of COPD.

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Conflicts of interest
There are no conflicts of interest.

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