



## Original Article

## Prevalence and Perception of 24-h Symptom Patterns in Patients With Stable Chronic Obstructive Pulmonary Disease in Spain<sup>☆</sup>



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## ABSTRACT

**Introduction:** Few studies have examined the 24-h symptom profile in patients with chronic obstructive pulmonary disease (COPD). The main objective of this study was to determine daily variations in the symptoms of patients with stable COPD in Spain, compared with other European countries.

**Methods:** Observational study conducted in 8 European countries. The results from the Spanish cohort ( $n=122$ ) are compared with the other European subjects ( $n=605$ ). We included patients with COPD whose treatment had been unchanged in the previous 3 months. Patients completed questionnaires on morning, day-time, and night-time symptoms of COPD, the COPD Assessment Test (CAT), the hospital anxiety and depression scale (HADS), and the COPD and Asthma Sleep Impact Scale (CASIS).

**Results:** Mean age: 69 (standard deviation [SD]=9) years; mean post-bronchodilator FEV<sub>1</sub>: 50.5 (SD=19.4)% (similar in Spanish and European cohorts). The proportion of men among the Spanish cohort was greater (91.0% versus 60.7%,  $P<.0001$ ). A total of 52.5% patients experienced some type of symptoms throughout the day, compared to 57.5% of the other Europeans ( $P<.001$ ). Patients with symptoms throughout the day had poorer health-related quality of life (HRQoL) and higher levels of anxiety/depression than patients without symptoms. Patients with night-time symptoms had a poorer quality of sleep. Spanish patients with symptoms throughout the day had better CAT scores (16.9 versus 20.5 in the other Europeans,  $P<.05$ ).

**Conclusions:** Despite receiving treatment, more than half of patients report symptoms throughout the day. These patients have poorer HRQoL and higher levels of anxiety/depression. Among patients with similar lung function, the Spanish cohort was less symptomatic and reported better HRQoL than other Europeans.

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### Prevalencia y percepción de la variabilidad diaria de los síntomas en pacientes con enfermedad pulmonar obstructiva crónica estable en España

## RESUMEN

**Introducción:** Hay pocos estudios sobre la distribución circadiana de los síntomas de la enfermedad pulmonar obstructiva crónica (EPOC) durante las 24 h del día. El objetivo principal fue conocer la variabilidad diaria de los síntomas en pacientes con EPOC estable en España en comparación con otros países europeos.

## Palabras clave:

Enfermedad pulmonar obstructiva crónica

Calidad de vida relacionada con la salud

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**Métodos:** Estudio observacional realizado en 8 países europeos. Se presentan resultados de pacientes españoles ( $n=122$ ) versus resto de europeos ( $n=605$ ). Se incluyeron pacientes con EPOC, sin modificaciones en el tratamiento en los 3 meses anteriores. Los pacientes rellenaron: cuestionario de síntomas matutinos, diurnos y nocturnos de la EPOC, cuestionario *COPD Assessment Test* (CAT), escala de ansiedad y depresión hospitalaria (HADS) y escala del impacto del sueño por asma y EPOC (CASIS).

**Resultados:** Edad media: 69 (DE=9) años; FEV<sub>1</sub> posbroncodilatador medio: 50,5 (DE=19,4) % (similar en españoles y europeos). La proporción de hombres entre los españoles fue superior (91,0% versus 60,7%,  $p<0,0001$ ). El 52,5% experimentaron algún tipo de síntomas durante todo el día (57,5% resto europeos,  $p<0,001$ ). Los pacientes con síntomas durante todo el día tuvieron peor calidad de vida relacionada con la salud (CVRS) y niveles mayores de ansiedad/depresión que los pacientes sin síntomas. Los pacientes con síntomas nocturnos tenían peor calidad del sueño. Los pacientes españoles con síntomas durante todo el día mostraron una mejor puntuación en el CAT (16,9 versus 20,5 resto europeos,  $p<0,05$ ).

**Conclusiones:** A pesar de recibir tratamiento, más de la mitad de los pacientes refieren síntomas durante todo el día. Estos pacientes presentan peor CVRS, peor calidad del sueño y niveles aumentados de ansiedad/depresión. A igual función pulmonar, los españoles son menos sintomáticos y refieren mejor CVRS en comparación con otros europeos.

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## Introduction

The main symptoms of chronic obstructive pulmonary disease (COPD) are cough, expectoration, and dyspnea. Until recently, the general opinion was that COPD symptoms, unlike asthma symptoms,<sup>1</sup> did not change much over the course of the day. However, in recent years, it has become clear that COPD patients find that their respiratory symptoms vary over the course of the day.<sup>2–4</sup> Curiously, Kessler et al.<sup>2</sup> observed differences among different European regions in the perception of symptom variability, but this study only included patients with severe or very severe COPD (FEV<sub>1</sub><50% predicted).

Our group was involved in a recently published European observational study,<sup>5</sup> designed to determine the prevalence and severity of symptoms over a 24-h period in stable COPD patients with any level of airflow limitation seen in routine clinical practice (the ASSESS study). Since a large proportion of patients in this study were recruited from Spanish hospitals, we thought that it would be interesting to perform a subanalysis of this population, in order to define the prevalence and profile of 24-h respiratory symptom patterns in patients with any stage of COPD severity, compared to patients in other European countries.<sup>5</sup> Our secondary objective was to evaluate the relationship between COPD symptoms and health-related quality of life (HRQoL), anxiety and depression levels, quality of sleep, and COPD exacerbations.

## Methods

This was an epidemiological, observational, multicenter study performed in Spain and other European countries (Germany, Denmark, France, Netherlands, Italy, Sweden and United Kingdom) between April 2011 and November 2013. We present the results from patients included in Spain. Respiratory medicine specialists in 14 hospitals located throughout Spain (Cantabria, Castilla-La Mancha, Catalonia, Community of Valencia, Galicia, Balearic Islands, Madrid, Navarre, and the Basque Country) took part in this study.

Patients were  $\geq 40$  years of age with an accumulated history of smoking of  $\geq 10$  pack-years and a diagnosis of COPD of any severity (stages I to IV) according to GOLD criteria (2010).<sup>6</sup> To be included, they had to be stable, with no exacerbations in the previous month. Exclusion criteria were: modifications in COPD treatment regimen in the 3 months before the study visit, previous diagnosis of asthma, sleep apnea syndrome or chronic respiratory disease other than COPD, or any acute or chronic disease which, in the opinion of the investigator, would limit the patient's ability to participate in the study.

The study was performed according to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines of the International Conference on Harmonization. All patients gave their written informed consent before inclusion. The study was approved by the Clinical Research Ethics Committee of the Hospital Clínic de Barcelona.

## Data Collection

The following data were collected during the study visit: demographic, anthropometric and socioeconomic characteristics, smoking habit, data from the latest available spirometry (up to 12 months previously), disease severity according to the GOLD 2010 criteria, current treatment for COPD, exacerbations in the year before the visit. Patients were also asked to complete the following questionnaires:

- Night-time, morning and daytime COPD symptoms: a self-administered 33-item questionnaire, developed by the sponsor, on the frequency and severity of COPD symptoms (dyspnea, cough, expectoration, chest tightness, chest congestion, wheezing) during each time interval in the week before the visit, and in a normal week in the previous month (defined as the week considered by the patient as the most typical of the previous month). The questionnaires consist of 3 sections. The first (13 questions) addresses night-time symptoms (the time between the patient going to bed and getting up), the second (10 questions) asks about morning symptoms (between getting up and about 11 o'clock in the morning), and the third (10 questions) addresses daytime symptoms (from 11 o'clock in the morning until bedtime).
- COPD Assessment Test (CAT) questionnaire<sup>7</sup>: an 8-item questionnaire evaluating HRQoL in COPD with scores from 0 to 40, higher scores representing poorer HRQoL.
- Hospital Anxiety and Depression Scale (HADS)<sup>8</sup>: a self-administered 14-item scale measuring levels of anxiety and depression (with 7 questions in each respective subscale). Scores in each subscale range from 0 to 21, higher scores representing higher levels of anxiety and depression.
- COPD and Asthma Sleep Impact Scale (CASIS)<sup>9,10</sup>: a self-administered 7-item scale evaluating sleeping problems associated with COPD and asthma. Total score is from 0 to 100, higher scores representing greater sleep deterioration in the previous week.

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