

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable

ACTIVE INGREDIENT: Not applicable

Study No: NIS-REU-DUM-2007/1

Patient perception of symptom variability. A cross-sectional study of patients with severe COPD

Developmental phase: Not applicable

Study Completion Date: LSLV = 19 March 2009

Date of Report: 03 Dec 2009

OBJECTIVES:

The primary objective was patient's perception of the variability of symptoms due to severe stable state COPD throughout the day, the week and the year.

Secondary objectives were to describe : the impact of symptoms (and variability of symptoms) on the patient's morning & daily living activities and sleep quality; how patient use their COPD treatment and factors that may influence the patient's perception of symptom variability.

METHODS:

This was a Pan-European, cross-sectional, observational study conducted in 17 countries. Patients were selected by GPs or respiratory physicians during a routine visit and asked to consent for being interviewed over the phone by a trained operator, independent from the physician, the company in charge of study coordination and the study sponsor. Each physician was asked to include the first 4 consecutive patients meeting the eligibility criteria and consenting to participate in the study. The inclusion/exclusion criteria were designed to select subjects suffering from severe COPD (according to spirometric classification) and in a stable state. During the interview, patients were asked to recall their chest symptoms during the past 7 days.

RESULTS:

Description of patients in the study

Of 3642 patients initially recruited by 802 physicians, 2441 patients had both telephone interview and all necessary data available (completed by the physician), and were therefore eligible for analysis

The study population showed a male predominance (78.5%) with a mean age of 67.3 years and a mean BMI of 26 kg/m². The mean time since COPD diagnosis was 8.9 years and 24.2% of them were current smokers. Patients' lung function data showed a mean FEV₁ (forced expiratory volume in one second measurement) of 38.8% of the predicted value and the mean Medical Research Council dyspnoea score of participants at inclusion was 2.9. Overall, 98.4% of patients were prescribed at least one COPD medication. In the 12 months preceding study enrolment, 61.6% of patients had experienced at least one COPD exacerbation (defined as a worsening of the disease leading to hospitalization and/or emergency room visit and/or prescription of antibiotics/steroid tablets). Comorbidities were reported for 76.2% of patients, and hypertension was the most frequently reported (present in 42.8% of the patients).

A total of 92.5% of patients reported experiencing at least one COPD symptoms in the 7 days prior to telephone interview. Breathlessness was the most frequently reported symptom among the study participants (72.5%), followed by phlegm (63.6%), cough (58.7%) wheezing (41.7%) and chest tightness (28.3%).

Response to the primary objective

Of the patients reporting any symptoms, 44.7% experienced variability (a little or a lot) in one or more symptom(s) throughout the day and 54.4 % throughout the week. Overall, 62.7% perceived some symptom variability throughout the day and/or the week.

Breathlessness and chest tightness are the two symptoms that vary the most, both during the day and during the week.

Regarding variations throughout the year, 59.5% of patients reported seasonal variations in their respiratory symptoms.

Winter was the period reported as the most troublesome (55.9% of patients), followed by autumn (18.6%), summer (17.2%) and spring (8.3%).

When asked how many days of the previous week their symptoms affected them the most; for every symptom, the two most common responses were 1–3 days (24.2%–42.5%, depending on the symptom) or every day (33.6%–50.1%, depending on the symptom).

The morning period (upon waking and/or later in the morning) was identified by patients as the most troublesome period of the day, whatever the symptom reported by the patient. For patients who reported breathlessness, 45.4% mentioned upon waking and/or later in the morning as most troublesome: for patients reporting cough, 60.1%; phlegm, 70.1%; chest tightness, 45.4% and wheezing, 43.4%.

Response to the secondary objectives

The activities that patients felt were most affected by their COPD symptoms were: going up and down stairs (82.5%), doing heavy household chores (56.9%), going shopping

(43.1%), washing (41.0%), dressing (40.7%), drying (36.2%), doing sport or hobbies (35.9%) and getting out of bed (35.4%).

Regarding sleep, 26.5% of patients reported that their chest symptoms affected the quality of their sleep.

Therapeutics use: 92.7% of the patients reported to take a regular daily medication and 59.6% a rescue inhaler to relieve their chest symptoms. When symptoms worsen during the day 51.3% continue using their medicines in the same way (others vary the dose and/or frequency). Similarly, 38.7% of patients declared that their use of medication doesn't change when chest symptoms worsened over several days.

Common factors associated with variability of breathlessness ($p < 0.05$) during the day and week included younger age, the severity of symptoms during the previous week and whether patients were treated by a GP or specialist.