AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A
ACTIVE INGREDIENT: N/A

Study No: NIS-RKR-DUM-2009-1
***SYMBOL* study** (Patients perception in **SY**mptom related to **M**orning activity **B**ased on chronic **O**bstructive **L**ung disease)

Developmental phase: Marketed
Study Completion Date: 2009-12-07
Date of Report: 2010-01-20

OBJECTIVES:

Primary objectives
• To assess the perception of COPD Patients in symptoms related to morning activities

Secondary objectives
• To assess the patient's perception of the variability of symptoms
• To describe the impact of symptoms on sleep quality
• To describe how patients use their COPD treatments
• To investigate factors that may influence the patient's perception of symptom variability (such as patient characteristics, COPD treatments, co morbidities, etc…)

METHODS:

Design

Prospective, Observational, Multi-center, non-interventional study

Target subject population

The inclusion/exclusion criteria were designed to select subjects suffering from severe COPD (according to spirometric classification, GOLD stage III and IV) and in a stable state.

Inclusion criteria

For inclusion in the study subjects should fulfil all of the following criteria:

- COPD outpatients over 45 years old
- Lung function: **FEV1 < 50%**
- Current or ex-smoker ≥ 10 Packs per year.
- Patients who were not had medication of ISC/FC at least 2weeks.
- Patients who will be received medication of ISC/FC by physician's scientific decision
- Signed Informed Consent.

Exclusion criteria

Any of the following was regarded as a criterion for exclusion from the study:

- Ongoing exacerbation of COPD or within the previous 3 months.
- History of asthma or allergic rhinitis.
- Lung cancer or any other significant respiratory disease such as bronchiectasis, lung fibrosis, interstitial lung disease, tuberculosis, sarcoidosis.
- Current participation in an interventional clinical trial.

Result variables

- **Primary variables:** patient questionnaire(Symptom and Morning activity) at baseline and last visit
- **Secondary variables:** score change in patient questionnaire(Symptom and Morning activity), All relevant factors that may influence the variability of symptoms

Statistical Analysis

Primary evaluation

• The following descriptions were based on data collected in the patient questionnaire. 95% confidence intervals were added where relevant.

- Patient's perception of the impact of symptoms on morning activities was described

Secondary evaluation

• The impact of symptom on the patient's sleep quality was described

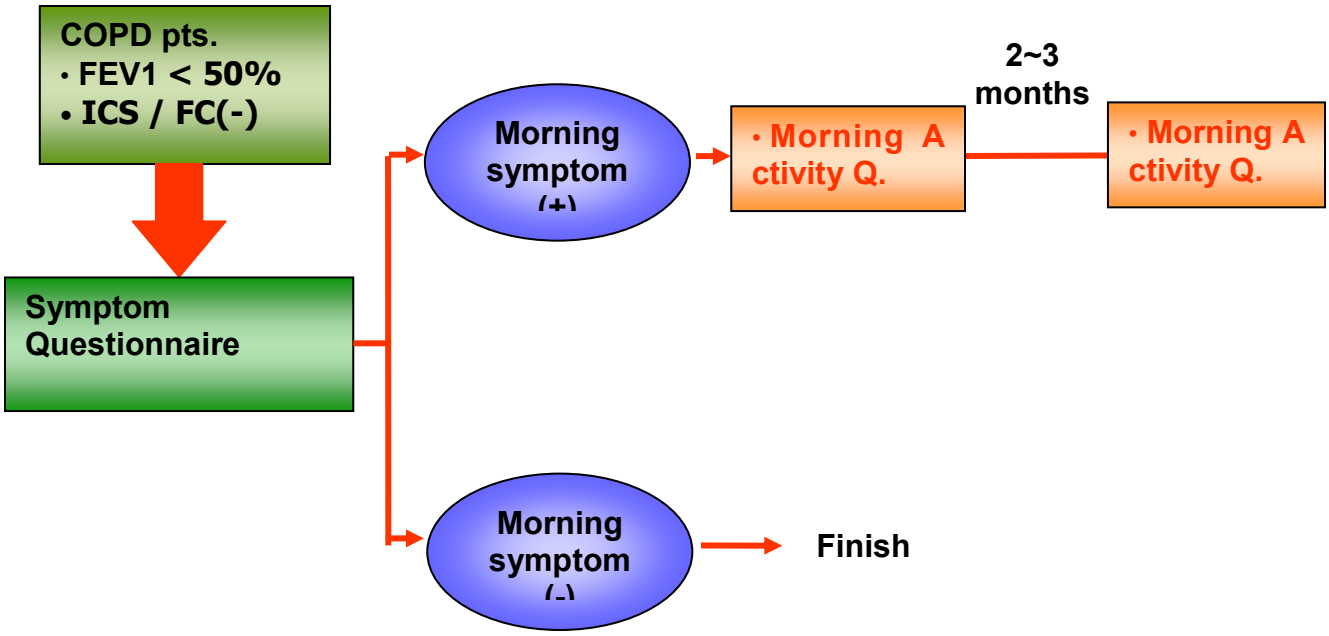
• Data on therapeutic behaviour of the patient was described

• All relevant factors that might influence the variability of symptoms was described and compared according to the variability of symptoms. An ANCOVA/logistic regression was performed for significantly related factors (threshold 20%).

TIME SCHEDULE

	Baseline	Endpoint After 2~3months
Demographics		
Gender	X	
Date of Birth	X	
Medical history		
Smoking history	X	
Diagnosis	X	
FEV_1	X	X
Symptom Questionnaire	X	
Morning Activity Questionnaire	X	X
Medication	X	X
Concomitant medication	X	X

Overall Study Design and Flow Chart



RESULTS:

A total of 142 patients from 6 centers participated in this study, of whom 137 were included in the analysis set. The reason why 5 patients were excluded from the analysis set was that they did not meet the inclusion and/or exclusion criteria.

Of 137 patients in the analysis set, 129(94.2%) were males and 8(5.8%) were females and the mean age was 67.4 years. The GOLD stage of 116 patients (90.6%) was stage III. The average number of pack per day was 1.15 pack and the average pack year was 38.2 years. The mean of post-FEV1(% pred) was 39.6 and the mean of post-FEV1(L) was 1.0.

At baseline, 78(56.9%) patients had at least one or more morning symptoms. The most frequent morning symptom was short of breath (91.1%), followed by excessive sputum production (77.9%). Waking up and washing or showering are two most difficult morning activities scored with 5.2 (SD 2.7), 5.5 (SD 2.4), respectively. At the end of the study after treatment, the scores of all items of morning activity except preparing breakfast were significantly reduced, while no significant relation between the degree of improvement of FEV1 and the changes of scores of all items of morning activity were observed.