Synopsis

NIS Code: NIS-RCN-XXX-2012/1
Date: Date：08 July 2014

Study title：

Perception of Symptom Variability in Chinese COPD Patients

Participating sites：

11 sites across Chinese mainland.

Study duration：

12 months

Date of Fist Subject Enrolled: 20 December 2012

Date of Last Subject Completing Observation: 28 November 2013

Objective：

(1) Primary objective: To assess COPD patient's perception on the variability of symptoms throughout the day due to moderate and above airflow limitation

(2) Secondary objectives: To assess the impact of COPD symptoms and symptoms' variability on patient's daily quality of life

Study design：

Cross-sectional, observational study

Inclusion criteria：

Patients who:

(1) Provision of subject informed consent;
(2) Out-patient, male or female aged 40 years and over;
(3) Clinical diagnosis of COPD for at least 6 months;
(4) Lung function based on data available within 3 months in medical records confirming FEV1<80% normal predicted (post-bronchodilator) and FEV1/FVC<0.7 (post-bronchodilator).

Exclusion criteria：

Patients who:

(1) Participation in any interventional study involving investigational drugs
(2) Ongoing exacerbation of COPD or exacerbation within the previous 3 months. An exacerbation is defined as a worsening of COPD symptoms leading to a treatment with antibiotics and/or a short course of system steroids and/or hospitalisation or emergency room visit.
(3) History of asthma and/or allergic rhinitis
(4) Lung cancer or any other significant respiratory disease such as bronchiectasis, lung fibrosis, interstitial lung disease, tuberculosis, sarcoïdosis
(5) Patient inability to understand the study procedures or inability/reluctance to answer

questionnaire

Number of subjects：
1058 COPD patients

Efficacy variables：
Not applicable.

Safety variable：
Not applicable.

Efficacy assessment criteria：
Not applicable.

Statistical methods：
All the results were described. Quantitative variables were presented by mean, SD, median, quartiles 1 and 3, max, min and number of missing data. Qualitative variables were described by the absolute and relevant frequencies (%) of each variable and the number of missing data. Counts that are zero are displayed as "0". Percentages were calculated based on non-missing data, unless otherwise specified. Where applicable, statistically tests were performed. The maximal probability of type-1 error rate α was set at 5%.
Where possible, a logistic regression model fitting the factors including severity of airflow limitation, CAT and MMRC scores, gender, COPD treatments, complications was to be used to explore the influencing factors for patient's perception on symptom variability. Results were presented by the odds ratio (OR) and the corresponding 95 % CI and P value.
The two classifications, GOLD A/B/C/D classified by CAT/MMRC and GOLD I/II/ III/IV classified before 2010, were compared by consistency test (Kappa test), which used to evaluate the consistency of the different GOLD classifications.

Results：
Primary variable —— the variability of symptoms due to COPD throughout the day
COPD symptoms: Dyspnoea, chest tightness, coughing, wheezing, sputum production;
Among the 1032 patients, 7 had no typical symptoms of COPD, variability of COPD symptoms throughout the day was reported in 518 (50.2 %) patients. Among these patients "on waking(39.3 %)" and "at night(21.3 %)" were the most likely occurring time and "on waking (35.3%)" and "at night (24.1%)" were also the most troublesome time.
Secondary variables
— The impact of the COPD symptoms on the patient's daily living activities and quality of sleep

Among the 1032 patients, 34 did not perceive any impact of COPD symptoms on the daily activities, 263 (25.5 %) had "going up and down stairs, doing exercise" as the daily living activities most affected by the COPD symptoms, and 257 (24.9 %) had "going up and down stairs, going out shopping, doing exercise, doing housework" as the daily living activities most affected by the COPD symptoms.

Among the 1032 patients, 308 (29.8 %) had poor sleep, which was mostly manifested by "frequent waking during night" and the most commonly caused by "COPD symptoms impact on quality of sleep".

— Impact of COPD symptoms on morning activities

Based on a scale of 0 to 5 assessing the impact of COPD symptoms on individual morning activities, morning getting out of bed score, morning dressing score, washing score, eating breakfast score, morning activities after breakfast score and morning outdoor activities score were 0.4, 0.4, 0.4, 0.3, 0.9 and 1.5, respectively, with the mean total score 3.8.

— Patient's perception on COPD or COPD treatment

46 patients had the answer missing, 541 "maintained on daily medications", and 445 "Seek for treatment only when symptoms occurred/worsened". With regard to the question "Do you know how and when to use the drugs prescribed by the doctor?" 47 patients had the answer missing, and 275 (27.9 %) did not know how and when to use the drugs prescribed by the doctor.

In the multi-factor Logistic regression model, CAT score (CAT＜10 vs. CAT ≥ 10) was statistically significant for patient's perception on variability of COPD symptoms ($p <$ 0.0001); BMI (18 ≤ BMI ≤ 25 vs. BMI ＞ 25) was statistically significant for patient's perception on the time of the occurrence of COPD symptoms ($p = 0.0216$); BMI (18 ≤ BMI ≤ 25 vs. BMI ＞25) was statistically significant for the most troublesome time of COPD symptoms ($p = 0.0200$).