Online supplementary data

Characterisation and impact of reported and unreported exacerbations: results from ATTAIN

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Methods

Statistical analyses

Analyses were performed in the intent-to-treat population (all patients who received ≥1 dose of study medication and had baseline and post-baseline forced expiratory volume in 1 second [FEV_1] data [baseline defined as mean pre-treatment FEV_1 on Day 1]). The annualised exacerbation event rate was calculated using Poisson regression with correction for over-dispersion, with treatment group, gender and baseline airflow limitation as factors and age as a covariate, adjusting for the log of the corresponding total exposure time in years for a given patient. Logistic regression, including treatment group and baseline airflow limitation as explanatory variables, was used to analyse the percentage of patients with ≥1 exacerbation

event. The kappa index was calculated to assess the agreement between the EXAcerbations of Chronic obstructive pulmonary disease Tool (EXACT) and healthcare resource utilisation (HCRU) methods. Time to first EXACT event and first HCRU event were assessed by Kaplan-Meier estimates and using the Cox proportional hazards model with placebo as a reference group. St George's Respiratory Questionnaire (SGRQ) total score and trough FEV_1 were analysed using analysis of covariance with treatment group and gender as factors and age and baseline values as covariates. The percentages of patients with clinically significant improvements in SGRQ (decrease of ≥4 units) [1] were analysed using logistic regression, with treatment group, gender, age and baseline value as covariates.

Results

Effects of aclidinium on EXACT-identified and HCRU events

Annualised HCRU event rates were 0.60, 0.43 and 0.40 in the placebo arm, aclidinium 200 μg and aclidinium 400 μg treatment arms, respectively. There was no significant difference between the two aclidinium doses in the reduction in HCRU events (rate ratio 0.94 [95% CI 0.66–1.34]; p=0.741).

Annualised EXACT-identified event rates were 1.39, 1.00 and 0.98 in the placebo, aclidinium 200 μg and aclidinium 400 μg treatment arms, respectively. There was no significant difference between the two aclidinium doses in the reduction in EXACT-indentified events (rate ratio 0.98 [95% CI 0.74–1.30]; p=0.888).

REFERENCE

1. Jones PW. St George's Respiratory Questionnaire: MCID. *COPD* 2005; 2: 75–79.