Improvement in health status of chronic obstructive pulmonary disease (COPD) patients with indacaterol/glycopyrronium therapy: Real-world evidence from an observational study in Ireland

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Introduction

In Ireland, approximately 500,000 people aged 40 years have chronic obstructive pulmonary disease (COPD), of whom 200,000 have moderate or severe disease1. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2019 recommends COPD management based on symptoms or health status and lung function assessments. It recommends the use of validated questionnaires including clinical COPD questionnaire (CCQ) for assessment of health status in routine clinical practice1.

COPD is a short (15-item), self-administered, disease-specific quality of life (HRQL) questionnaire consisting of symptoms, functional and mental domains.

- A reduction of 0.4 points in the CCQ total score indicates a minimal clinically important difference (MCID)4.

Indacaterol/glycopyrronium (IND/GLY) 110/50 µg once daily (o.d.) is a fixed-dose combination of long-acting β2 agonist-long-acting muscarinic antagonist (LABA/LAMA) approved in over 90 countries, including Ireland, for the management of COPD.

To date, there is no evidence on the effectiveness of IND/GLY 110/50 µg o.d. on Irish COPD patients on a real-world setting—The ANALY study aimed to evaluate the health status of Irish COPD patients initiated on IND/GLY 110/50 µg o.d. using the CCQ tool in a real-world primary care setting in Ireland.

Methods

Study design

- This was a prospective, open-label, multicentre, non-randomised, real-world study in different COPD groups (Figure 1): Patients were initiated on or switched to IND/GLY 110/50 µg o.d. irrespective of prior therapy and followed for 26 weeks.

Figure 1. Study design

Patients

Key inclusion criteria

- Men and women aged ≥40 years
- Smoking history of >10 pack-years
- Post-bronchodilator forced expiratory volume in 1 sec (FEV1)/forced vital capacity (FVC) < 0.7
- Patients initiated on IND/GLY 110/50 µg o.d. regardless of prior therapy for COPD

Key exclusion criteria

- Patients with previous or current diagnosis of asthma
- Patients with cardiac or respiratory diseases unrelated to COPD
- Patients with known sensitivity to the active ingredients or any excipients in IND/GLY 110/50 µg dosage form

Outcomes

- Change from baseline in the CCQ total score and the proportion of patients achieving MCID in reduction from baseline after 26 weeks of treatment with IND/GLY 110/50 µg o.d.
- Change from baseline in CCQ symptoms, functional and mental domain scores after 26 weeks of treatment with IND/GLY 110/50 µg o.d.
- Change in CCQ total score and responders on switch to IND/GLY 110/50 µg from baseline (Figure 2).

Safety

- Twenty percent of patients reported at least one AE, with exacerbation/infected COPD being the most common (n = 14), reported by 11 patients. IND/GLY 110/50 µg was discontinued by 57 patients during the study.
- In total, seven SAEs were reported in six patients. Three deaths due to myocardial infarction, unrelated cause, and pulmonary embolism occurred during the study period.
- No AEs were definitely caused by the study drug.

Conclusions

- In the real-world Irish setting, indacaterol/glycopyrronium 110/50 µg o.d. demonstrated a statistically significant and clinically meaningful improvement in health status.
- Majority of COPD patients initiated on indacaterol/glycopyrronium 110/50 µg o.d. were classified as CCQ responders.
- Majority (75%) of patients who completed the study continued treatment with indacaterol/glycopyrronium 110/50 µg o.d.
- Indacaterol/glycopyrronium 110/50 µg o.d. was well tolerated with safety profile similar to randomised clinical trials.

References

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