Impact of Comorbidity Prevalence and Cardiovascular Disease Status on the Efficacy and Safety of Nebulized Glycopyrrolate in Patients with COPD

Putcha N, et al. *Int J Chron Obstruct Pulmon Dis* 2021;16:1061–1073

KEY FINDINGS

The majority of patients with COPD in the GOLDEN-3 and -4 studies had multiple comorbidities, with CVD being common in those with high comorbidity count. GLY improved FEV_1 and SGRQ total score in individuals with COPD and had a good safety profile, independent of their comorbidities or CVD status.

OBJECTIVE

To quantify patients' comorbidities in the GOLDEN-3 and -4 studies and assess their impact on treatment efficacy and safety of nebulized GLY 25 µg BID (FDA-approved dose)

STUDY DESIGN

Pooled data from GOLDEN-3 and -4 Phase III clinical trials

Patients aged ≥40 years with moderate-to-very-severe COPD, grouped by number of comorbidities (≤2, >2) and CVD status

Randomized 1:1:1 to **placebo**, **GLY 25 µg BID**, or **GLY 50 µg BID**

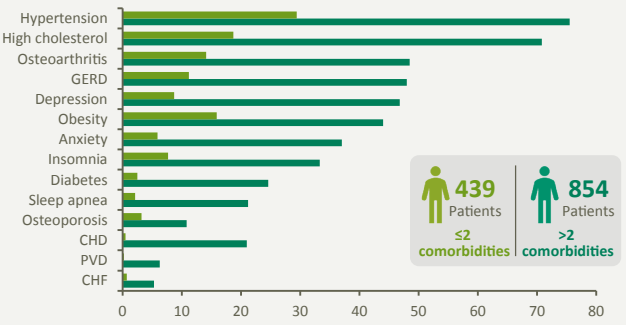
Screening 1–3 weeks → **Double-blind treatment period** 12 weeks → **Follow-up** 5–7 days

Continuation of background LABA ± ICS permitted

RESULTS

COMORBIDITIES DISTRIBUTION

Prevalence (%) of comorbidities in the pooled population



BASELINE DEMOGRAPHICS

Participants with ≤2 comorbidities

62 Mean Age | 57.6% Smoker | 37.8% Women

SGRQ total mean score 46.48

Participants with >2 comorbidities

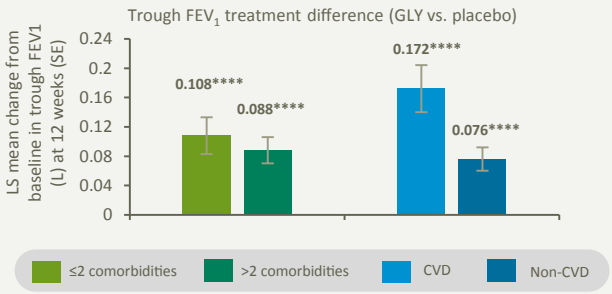
64 Mean Age | 50.5% Smoker | 47.2% Women

SGRQ total mean score 50.20

Baseline SGRQ total score was higher in patients with >2 comorbidities than those with ≤2, indicating worse health status among participants with high number of comorbidities.

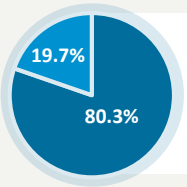
LUNG FUNCTION

Trough FEV_1 improved with GLY vs. placebo regardless of comorbidity prevalence or CVD status



CVD SUB-ANALYSIS: BASELINE DEMOGRAPHICS

To understand the impact of CVD comorbidities on GLY 25 µg treatment, a subanalysis by baseline CVD status* was performed



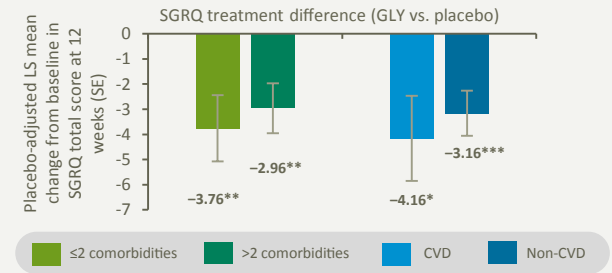
In the CVD vs. Non-CVD group

More males | Lower % of current smokers | Higher use of concomitant medications

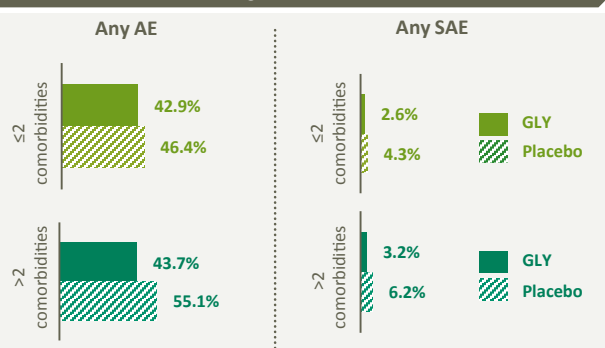
*CVD defined as the presence of CHD, CHF or PVD

PATIENT-REPORTED OUTCOMES

SGRQ total score improved with GLY vs. placebo regardless of comorbidity prevalence or CVD status



SAFETY



*p<0.05; **p<0.01; ***p<0.001; ****p<0.0001 vs placebo.

Abbreviations: AE, adverse event; BID, twice daily; CHD, coronary heart disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; FEV_1, forced expiratory volume in one second; GERD, gastroesophageal reflux disease; GLY, nebulized glycopyrrolate; ICS, inhaled corticosteroid; LABA, long-acting β2-agonist; LS, least squares; PVD, peripheral vascular disease; SAE, serious adverse event; SE, standard error; SGRQ, St George's Respiratory Questionnaire.