

## Observational, Concurrent Study to Assess Safety and Efficacy of Glycopyrronium and Arformoterol Home Nebulization in High-risk, Symptomatic Acute Exacerbation of Chronic Obstructive Pulmonary Disease Cases: SYMPTOM Study

Dr. Salil Bendre

KLS Memorial Hospital, Mumbai, India

### Abstract

**Background:** Chronic obstructive pulmonary disease (COPD) is one of the most important reasons for hospitalization worldwide with high 30-day readmission rates. Although the prognostic significance of early readmission is not fully understood, they are often associated with poor outcomes including high mortality rates of 4%–19% at 30 and 365 days, respectively. Similarly, in acute exacerbations of COPD (AECOPD) cases receiving emergency department care, current status on lung function and cardiovascular comorbidities are considered as best predictors for both 30- and 90-day COPD readmission rates. Dual bronchodilator strategy with long-acting muscarinic antagonist (LAMA)/long-acting beta-agonists (LABA) is therefore recommended by GOLD (2019) in the postdischarge phase following an acute exacerbation.

**Aim:** To further assess the clinical impact of dual bronchodilators including glycopyrronium and arformoterol as home nebulization in the post-discharge phase of AECOPD, the current postapproval, observational study was conducted.

**Materials and Methods:** An observational, concurrent, and non-inferiority study with glycopyrronium and arformoterol home nebulizing solutions on patients with moderate and severe COPD was conducted at two centers in India. An estimated sample size of 40 patients involving moderate and severe COPD cases was factored for per-protocol analyses with  $P < 0.05$  considered as statistically significant. A concurrent study analysis for the follow-up visit was conducted as per the principles of International Conference of Harmonization for Good clinical practice and Declaration of Helsinki while ensuring confidentiality during access of patient support registration sheets.

**Results:** Per protocol analyses for consecutive 46 cases from two centers receiving Nebulized glycopyrronium (25 mcg) and arformoterol (15 mcg), as separate formulations are given as admixed solution with follow-up visit for at least 4 weeks was carried out. Baseline demographics for the overall group showed exacerbation history (46, 100%), hospitalization for AECOPD (21, 45.6%); ED visit (25, 54.3%), forced expiratory volume in one second (FEV1)  $1.2 \pm 0.6$  L/min; FEV1/FVC  $64.8\% \pm 10.6$ ; reversibility  $8.4\% \pm 11.8$ ; CAT  $34.6 \pm 2.3$ ; and vibrating mesh nebulizer (46, 100%). The mean predose FEV1 ( $\Delta$ ) at the end of 4 weeks for overall, moderate and severe COPD cases were observed as of  $9.6 \pm 3.1\%$ ,  $11.8\% \pm 3.1$ , and  $8.4\% \pm 1.6$ , respectively ( $P < 0.0001$ ). Similarly, the mean CAT( $\Delta$ ) score at the end of 4 weeks was observed as of  $18.1 \pm 0.69$ ,  $20.6 \pm 0.69$ , and  $18.26 \pm 0.6$  for overall, moderate and severe COPD cases, respectively ( $P < 0.0001$ ). The intergroup differences for rescue medication use for a lone case with severe COPD (1, 2.04%) complied with the suggested non-inferiority margin between the groups. There were no other treatment-emergent adverse events or serious adverse events that warranted treatment modification or withdrawals in both groups.

**Conclusion:** Glycopyrronium and arformoterol home nebulization with Vibrating mesh nebulizer (VMN) offers bronchodilation that is clinically significant with successful use of the drugs as “Rescue Medication” in post-discharge high-risk symptomatic AECOPD cases.

**Key words:** Acute exacerbation of chronic obstructive pulmonary disease, Arformoterol, Glycopyrronium, Home nebulization, High risk COPD, Vibrating mesh nebulizer

### Biography

Dr Salil Bendre has completed his MBBS , MD in Pulmonary Medicine from a leading Medical College from Mumbai . Subsequently, he joined KJ Somaiya Medical College as a Lecturer .He continued Teaching and was then promoted as Prof and Head , Pulmonary Medicine . He has 17 years of Teaching Experience in Mumbai University. His interest is Interventional Pulmonary Medicine , Drug Resistant TB and HIV. He has presented papers on HIV and TB at National Conferences .He has conducted Respiratory Training workshops for over 1000 medical students .He is Currently Head of Dept of Pulmonary Medicine at Nanavati Superspeciality Hospital ,Mumbai. He has been featured in Television , Radio and Newspapers for Respiratory Talks and Interviews..