

Benefits of Budesonide/Glycopyrronium/Formoterol on Lung Function, Symptoms and Quality of Life Across Blood Eosinophil Ranges in Indian COPD patients: A post-hoc analysis from a Phase IV Clinical Trial.

Background: Triple therapy has been recommended as the preferred regimen by the GOLD 2024 strategy document for GOLD E COPD patients with a high eosinophil count and in patients with frequent exacerbations. In a Phase IV clinical trial a triple therapy FDC of Budesonide/Glycopyrronium/Formoterol (BGF) (400/25/12mcg) Dry Powder Inhaler (DPI) was found to be safe and improved the lung function, CAT score, SGRQ score and mMRC in Indian moderate-severe COPD patients. In this post-hoc analysis we evaluated treatment benefits based on baseline blood eosinophil count. Evidence is emerging with regards to benefits of triple therapy even in patients with a lower blood eosinophil count; however, it is limited and is not studied in Indian COPD patients.

Aims: To assess the impact of triple therapy on lung function, symptoms, and quality of life in patients with a high and a low blood eosinophil count.

Methods: The phase IV clinical trial was an open-label, prospective, non-comparative, multicenter, 24 weeks trial to evaluate the safety and efficacy of Glycopyrronium/Formoterol/Budesonide DPI twice daily in moderate-severe COPD patients. Patients between 40-75 years, current or ex-smokers, with a spirometry diagnosed COPD based on GOLD 2020 guidelines, CAT score > 10 and with the ability to use a DPI were included in the study. Efficacy outcomes evaluated in this post-hoc analysis were change from baseline till 24 weeks in FEV1, CAT score, SGRQ score & mMRC score in patients with a high (≥ 300) and low (<300) blood eosinophil count.

Results: Of the 179 patients in the per protocol population analyzed, 66% patients had a blood eosinophil count (BEC) < 300 . The change in FEV1 from baseline till the end of study was 0.082 ± 0.25 ml ($p < 0.005$) in patients with a high BEC. This significant change was observed as early as 12 weeks. A significant improvement of 0.061 ± 0.22 ml ($p < 0.001$) was also observed in patients with a low BEC by 24 weeks. A significant improvement ($p < 0.001$) of 7.14 ± 4.14 units and 7.096 ± 5.13 units was observed in the CAT score in patients with a high and low BEC respectively. Likewise, mMRC score showed an improvement ($p < 0.001$) of 0.313 ± 0.61 and 0.261 ± 0.61 in groups with a high and low BEC respectively. A statistically significant improvement in SGRQ was seen of 19.43 ± 19.11 and 18.89 ± 15.51 units in groups with a high and low BEC respectively.

Conclusion: Budesonide/Glycopyrronium/Formoterol significantly improved the lung function, CAT score, SGRQ score and mMRC in patients with a high and low blood eosinophil count. These findings confirm that the benefits of triple therapy are not restricted to patients with a high blood eosinophil count.