Patient characteristics, biomarkers and exacerbation risk in severe, uncontrolled asthma

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Shareable abstract (@ERSpublications)
A pooled analysis of placebo data from seven randomised controlled trials identified exacerbation risk factors in patients with severe, uncontrolled asthma and revealed a prognostic role for persistence of elevations in type 2 inflammation biomarkers https://bit.ly/3sWCKVd


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Abstract

Background Greater precision in asthma exacerbation risk prediction may improve outcomes. We sought to identify clinical characteristics and biomarkers associated with elevated exacerbation risk in patients with severe, uncontrolled asthma.

Methods Data were pooled from seven similarly designed phase II and III randomised controlled clinical trials of biologic therapies for the treatment of severe, uncontrolled asthma that enrolled comparable patient populations. Annualised asthma exacerbation rates (AAERs) for patients randomised to placebo were assessed by baseline clinical characteristics, and by biomarker concentrations at baseline and over the study duration.

Results The AAER for the 2016 patients in the combined placebo group was 0.91 (95% CI 0.84–0.98). Baseline characteristics associated with greater AAER were frequent or severe exacerbations within the prior 12 months, nasal polyposis, maintenance oral corticosteroid use, Asian race and Asian or Western European region. AAER increased with baseline blood eosinophil counts and exhaled nitric oxide fraction ($F_{ENO}$) concentration, with the greatest AAER occurring for patients with eosinophils $\geq 300$ cells·$\mu$L$^{-1}$ and $F_{ENO} \geq 50$ ppb. No relationship was observed between baseline serum IgE concentration and AAER. Combining type 2 inflammation criteria for eosinophils and $F_{ENO}$ had greater prognostic value than either biomarker alone. Persistent eosinophil and $F_{ENO}$ elevations throughout the study period were associated with greater AAER.

Conclusions Exacerbation history, maintenance corticosteroid use, nasal polyposis, Asian race, geographic region, and elevations in blood eosinophil counts and $F_{ENO}$ concentrations (particularly when combined and/or persistently achieving type 2 inflammation criteria) were associated with increased exacerbation risk in patients with severe, uncontrolled asthma.