

Clinical Remission in Oral Corticosteroid (OCS)-dependent Patients with Severe Asthma: An Analysis of the ANDHI-IP and PONENTE Trials

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Introduction: The ANDHI-In Practice (AIP) and PONENTE trials evaluated benralizumab, a monoclonal antibody directed at the interleukin-5 receptor α , in patients with severe eosinophilic asthma (SEA). We evaluated data from these trials to describe the characteristics of oral corticosteroid (OCS)-dependent (defined as a daily OCS dose ≥ 5 mg for ≥ 3 months) patients with uncontrolled SEA receiving benralizumab who met a proposed composite definition of clinical remission (CR).

Methods: We analyzed data from ANDHI and PONENTE to characterize patients who met CR outcomes of interest. AIP was a 56-week open-label extension of ANDHI (NCT03170271) during which OCS and other asthma therapies were tapered in patients who achieved asthma control on benralizumab. PONENTE (NCT03557307) was a phase 3b, open-label, multicenter trial designed to evaluate rapid OCS tapering in patients with SEA on benralizumab. Eligible patients were ≥ 18 years of age with blood eosinophil (bEOS) counts ≥ 150 cells/ μ L or a historical bEOS counts ≥ 300 cells/ μ L in the last 12 months who were receiving high-dose inhaled corticosteroids and long-term OCS at baseline. Patients who received placebo in ANDHI were excluded. Components of CR for this analysis were zero exacerbations, zero OCS, and ACQ-6 score < 1.5 ; patients who achieved all three components at 12 months (PONENTE)/18 months (AIP) were defined as in CR. We compared baseline patient

characteristics (ANDHI and PONENTE) for patients who achieved CR with patients who did not achieve remission (non-remission).

Results: Among 66 patients from AIP, 28.8% achieved CR; among 312 patients from PONENTE, 26.0% achieved CR. Patients who achieved CR had a shorter mean [SD] time since diagnosis (AIP, 17.2 [11.42] years; PONENTE, 17.6 [13.97] years) than non-remission patients (AIP, 25.5 [20.93] years; PONENTE, 23.1 [15.92] years) (**Table**). Mean [SD] age at asthma onset was higher for CR patients (AIP, 40.7 [15.26] years; PONENTE, 35.2 [18.59] years) than for non-remission patients (AIP, 28.3 [18.07] years; PONENTE, 28.6 [18.93] years). Median OCS dosages were similar between groups. Mean [SD] baseline ACQ-6 scores were lower for CR patients (AIP, 2.8 [0.70]; PONENTE, 1.6 [1.19]) than for non-remission patients (AIP, 3.2 [0.86]; PONENTE, 2.3 [1.21]).

Conclusions: Our analysis of OCS-dependent patients in AIP and PONENTE showed that those who achieved CR had a shorter time since asthma diagnosis, an older age at asthma diagnosis, and a lower ACQ-6 score, highlighting a need to diagnose and appropriately treat SEA as early as possible.

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