Clinical outcomes in patients with severe asthma who had or had not initiated biologic therapy: results from the CLEAR study

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Purpose

Clinical guidelines recommend biologics as an add-on therapy for patients with severe, uncontrolled asthma. Although biologics have demonstrated efficacy in some patients with severe asthma, many patients do not initiate biologics, regardless of eligibility. This analysis compared real-world clinical outcomes in patients with severe asthma who had or had not initiated a biologic treatment (initiators or non-initiators).

Methods

CLEAR was a multicenter, observational study that included adults (≥ 18 years old) with severe asthma from 23 countries enrolled in the International Severe Asthma Registry (ISAR) between December 2015 and August 2021. Included patients had data for ≥ 12 months before and ≥ 6 months after the index date (ISAR enrollment date [for non-initiators] or biologic treatment initiation date). This analysis compared baseline characteristics and clinical outcomes over a 26-week follow-up period between initiators and non-initiators. Biologic eligibility was assessed based on clinical guidelines. Propensity score matching was used to ensure comparability between initiators and non-initiators. Further adjustment for residual confounders was made using multivariable models to assess the impact of biologic initiation. Adjusted incident rate ratios (aIRR) and adjusted β-coefficients (aβ) from a generalized linear model with 95% CIs were estimated to compare clinical outcomes between initiators and non-initiators.

Results

Overall, 1859 initiators and 1545 non-initiators were included. Of the non-initiators, 984 (64%) were biologic-eligible. At baseline, initiators had more exacerbations (88% vs 82%; mean, 4.5 vs 2.9), had less controlled asthma (well-controlled, 19% vs 55%) and were less likely to be current or ex-smokers compared with non-initiators. Most (76%) non-initiators were receiving long-term oral corticosteroids (OCS). Over the follow-up period matched initiators (n = 1114) had a lower incidence of exacerbations (aIRR: 0.75 [95% CI: 0.67–0.83])

than matched non-initiators (n = 501), after controlling for confounders. No differences were observed between the initiators and non-initiator subgroups in asthma control (aIRR: 0.84 [95% CI: 0.67, 1.06]) and long-term OCS use (aβ: −0.89 [95% CI: −2.37, 0.59]). Similar results were observed when initiators were compared with biologic-eligible non-initiators.

Conclusions

Over 60% of ISAR patients who had not initiated biologic treatment were eligible for biologics. These patients had a substantial exacerbation burden. Despite initiators having greater disease severity at baseline than non-initiators, initiation of biologic treatment was associated with a lower incidence of exacerbations.

Clinical implications

This analysis demonstrates the importance of initiating biologic therapy to reduce exacerbation rates in patients with severe asthma, particularly those who meet biologic eligibility criteria.

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Disclosures

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