Abstract

Background: Patients with severe asthma not meeting the strict trial eligibility criteria for mepolizumab are now routinely treated with this biological in clinical practice, but it remains unclear whether these ineligible patients respond differently to mepolizumab treatment.

Objective: This study investigated the extent and reasons for trial ineligibility of real-life, mepolizumab-treated patients with severe asthma and compared the characteristics of these patients with trial populations. Subsequently, therapeutic response in ineligible patients was assessed on the basis of oral corticosteroid (OCS) reduction.

Methods: Trial eligibility, population differences, and therapeutic response were assessed using the baseline characteristics of mepolizumab-receiving patients with severe asthma treated in the Amsterdam University Medical Centres and OCS dose at 6 months for OCS-dependent patients extracted from patients' electronic health records. Eligibility criteria and population characteristics from trials investigating mepolizumab were extracted from their original publications.

Results: A total of 82.4% of 119 mepolizumab-receiving, real-life patients with severe asthma were ineligible for trial inclusion, wherein 42.9% and 39.5% were excluded on the basis of inclusion and exclusion criteria, respectively. The clinical care population was older, more often male and demonstrating a better lung function under lower OCS maintenance dosages in comparison with trial populations. A total of 50% of 66 ineligible, OCS-dependent mepolizumab-treated patients were able to reduce their maintenance OCS dosage to ≤5 mg prednisone/day.

Conclusions: A large proportion of the real-life, mepolizumab-treated population with severe asthma would be excluded from trial participation, and significant differences in population characteristics exist. Regardless, a large fraction of ineligible patients in clinical care can reduce maintenance OCS dosage under mepolizumab therapy.

Keywords: Anti-IL-5; Asthma; Biologicals; Real-life evidence; Type 2 asthma.