Asthma Control in Patients With Severe Eosinophilic Asthma Treated With Mepolizumab in Real-Life Settings: The Prospective, REALITI-A Study

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Aims

The aims of patient management in asthma are to improve asthma control and associated symptoms.

Mepolizumab is approved as an add-on therapy for patients with severe eosinophilic asthma and eosinophilic granulomatosis with polyangiitis in the USA.[1]

Improvements in asthma control have been demonstrated with mepolizumab in clinical trials of severe eosinophil asthma compared with placebo, as assessed by the Asthma Control Questionnaire-5 (ACQ-5).[2–4] However, data from a real-world setting are limited.

Here, we present data from the global REALITI-A study on the impact of mepolizumab on asthma control in a large number of early treatment initiators who received mepolizumab in real-world clinical practice.

Methods

REALITI-A (GSK ID: 204710)
Study design

- Real-world
- Observational
- Prospective
- Global
- Single-arm

Clinical diagnosis of asthma:
≥18 years of age
Newly prescribed mepolizumab
12 months of relevant medical records prior to enrollment

Standard of care therapy, plus:
Mepolizumab 100 mg SC Every 4 weeks
Initiation of mepolizumab was at the **physician's discretion**

Follow-up period: 24 months **Endpoint:*** **Asthma control assessed via ACQ-5**

Analysis of data from early initiators at 12 months†

Subgroup analysis Baseline blood eosinophil count‡: <150 cells/μL; ≥150–300 cells/μL; ≥300 cells/μL

Study enrollment period: **Dec 2016 to Oct 2019**
Initial analysis enrollment period: **Dec 2016 to Feb 2018**
368 patients from 51 centers in 7 countries

A treatment policy estimand for treatment discontinuation approach was used. The analysis used mixed model repeated measures. *The primary endpoint of the REALITI-A study is the rate of exacerbations; here, we present data on one of the secondary endpoints, ACQ-5. Since no visits were scheduled specifically for this observational study, and data were collected at usual asthma healthcare visits (routine or unscheduled), data may not be available for all patients at all time points; †this 12-month analysis of early initiators of mepolizumab from the REALITI-A study included all patients enrolled with 1 year post-exposure data by the cutoff date of February 28, 2019 (n=368); ‡baseline blood eosinophil count in this study refers to the value available on the treatment index date (first administration of mepolizumab), or nearest historic or highest historic value (if nearest historic value was missing). SC, subcutaneous

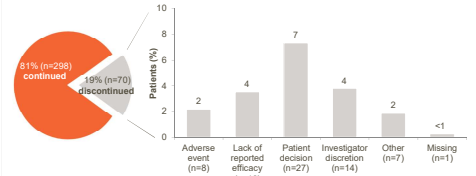
Results

Demographics and baseline characteristics* (N=368)

- Mean (SD) age: **53 (14) years**
- Female: **62%**
- Mean (SD) BMI: **28.7 (7.3) kg/m²**
- Never smoked: **61%** Current smoker: **3%** Former smoker: **37%**
- Mean (SD) asthma duration: **20 (15) years**
- Mean # exacerbations in the previous year: **4.7**
- On maintenance OCS: **48%**
- Geo. mean (SD log) IgE: **174.5 (1.5) KU/L**
- Mean (SD) ACQ-5 score: **3.0 (1.4)**
- Mean (SD) pre-bronchodilator % pred. FEV_1: **64.4 (20.3)%**
- Geo. mean (SD log) BEC: **370 (1.3) cells/μL**

*Data collected at enrollment visit; presented data refer to the early initiators of mepolizumab (N=368). Percentages may not add up to 100% owing to rounding.
BEC, blood eosinophil count; BMI, body mass index; FEV_1, forced expiratory volume in 1 second; geo, geometric; IgE, immunoglobulin E; OCS, oral corticosteroids; pred., predicted; SD, standard deviation

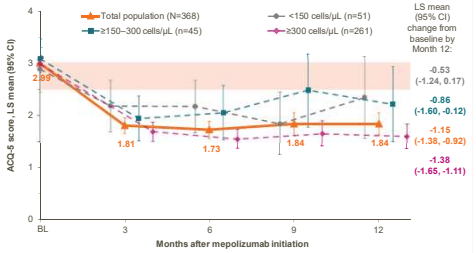
Overall, 19% of patients discontinued mepolizumab within the first year of treatment; the most common reason was patient decision



Conclusions

- In total, 19% of patients discontinued mepolizumab in the first year of treatment during this study.
- Significant improvements in asthma control were noted after mepolizumab initiation in patients with asthma who were treated in the real world; improvements were sustained throughout the study (12 months).
- Improvements in asthma control were observed regardless of baseline blood eosinophil count.
- The results of this analysis indicate that the efficacy of mepolizumab demonstrated in clinical trials, in terms of asthma control, translates to patients in a real-world setting. These data also support an early and meaningful benefit in asthma control with mepolizumab.

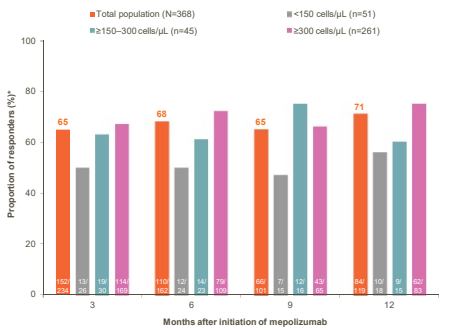
Within 3 months of initiating mepolizumab treatment, an improvement in asthma control from baseline was observed, regardless of blood eosinophil count



N=	347	239	165	104	123
N=	47	26	24	15	18
N=	45	30	23	16	15
N=	244	174	112	68	87

The baseline value for ACQ-5 was that at the first administration of mepolizumab (index date) or the most recent value available prior to this date. Data collection was at the discretion of the investigator; therefore, data were not available for all patients at all time points. Numbers of patients with analyzable ACQ-5 data at the given time point are shown at the bottom of the graph; the analysis included all data from a patient, even if they had discontinued mepolizumab. Decreases in ACQ-5 scores indicate an improvement in asthma control. The MCID for ACQ-5 score is 0.5 units; the shaded area indicates the change from baseline needed to achieve the MCID (assuming an ACQ-5 score of 3 at baseline).
BL, baseline; CI, confidence interval; LS, least squares; MCID, minimal clinically important difference

Within 3 months, the majority of patients in most subgroups had a minimally important difference in ACQ-5 compared with baseline; by 12 months the majority of patients in all subgroups had achieved this



*Responders were patients who had a MCID in the ACQ-5 score of ≥0.5 units. Numbers of patients with analyzable ACQ-5 data at baseline and at the given time point are shown at the bottom of the graph.

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