Reduced Asthma-Related HCRU in Omalizumab Treatment Responders, as Assessed by the GETE Questionnaire, From the PROSPERO Real-world Study

065

Allan T. Luskin,[1] Yamina Rajput,[2] Tmirah Haselkorn,[3] Ming Yang,[2] Joseph Dang,[2] Bradley E. Chipps[4]

[1]HealthyAirways, Madison, WI, USA; [2]Genentech, Inc., South San Francisco, CA, USA; [3]EpiMetrix, Inc., Los Altos, CA, USA; [4]Capital Allergy & Respiratory Disease Center, Sacramento, CA, USA

Background

- In 2016, asthma accounted for ~189,000 hospital admissions, 1.8 million emergency department (ED) visits, and 9.8 million physician office visits in the United States.[1]
- Omalizumab, an anti–immunoglobulin E monoclonal antibody, reduces asthma exacerbations and improves asthma control and health care resource utilization (HCRU) in patients with moderate-to-severe persistent allergic asthma.[2]
- The Global Evaluation of Treatment Effectiveness (GETE) is a validated tool used by physicians to evaluate omalizumab response in clinical trials and real-world studies of patients with moderate-to-severe asthma.[3-5]
  - Longer-term data exploring the relationship between the GETE and asthma exacerbations and asthma-related HCRU in a real-world setting are lacking.

Objective

- To examine asthma-related HCRU in omalizumab treatment responders, as assessed by the GETE questionnaire, from a real-world observational study.

Methods

- PROSPERO is a US-based, 48-week, single-arm, open-label, observational study in patients (≥12 years of age) initiating omalizumab for the treatment of allergic asthma based on physician-assessed need (ClinicalTrials.gov identifier NCT01922037).
- Patients were assessed at study end/early termination using the GETE, which measures the physician's overall impression of the effect of treatment on asthma symptoms.
  - Treatment response is assessed on a 5-point scale: 1=excellent (complete asthma control), 2=good (marked improvement), 3=moderate (discernible, but limited improvement), 4=poor (no appreciable change), or 5=worsening.
  - GETE responders were defined as those achieving a response of "excellent" or "good" in asthma control.
- Asthma exacerbations (worsening of asthma symptoms requiring oral corticosteroids, ED visit, or hospitalization) and asthma-related hospital admissions, ED visits, and unscheduled physician office visits were examined by GETE responder status at study end/early termination.

Statistical Analysis

- Summary statistics were used for baseline demographics and clinical characteristics, with continuous variables presented as mean (SD) and categorical variables presented as n (%).
- Means and SDs for asthma exacerbations and asthma-related HCRU were summarized at study end/early termination and stratified by GETE responder/nonresponder status.

Results

Patient Disposition and Baseline Characteristics

- All enrolled patients (N=806; **Table**).
  - Mean (SD) age was 47.3 (17.4) years, and 63.5% of patients were female.
  - Mean (SD) time on omalizumab was 9.7 (3.4) months (median, 11.2 months).
- Overall, 493/646 (76.3%) patients had a GETE result of "good" or "excellent," as rated by the investigator.
  - Mean time to GETE assessment was 49 weeks. The longer time frame was due to the last patient visit extending beyond 48 weeks for some patients.

Table. Baseline Demographic and Clinical Characteristics

Characteristic	Omalizumab N=806
Age, y, mean (SD)	47.3 (17.4)
Female, n (%)	512 (63.5)
Race, n (%)	
White	567 (70.3)
Black	132 (16.4)
Asian	34 (4.2)
Other/unknown	73 (9.1)
BMI, kg/m^2, mean (SD)	30.8 (8.3)
Serum total IgE, IU/mL, mean (SD)	580.7 (2,654.8)
Age at asthma diagnosis, y, mean (SD)	24.8 (20.7)
Physician-assessed asthma severity, n (%)*	
Mild	33 (4.1)
Moderate	387 (48.1)
Severe	385 (47.8)
Prebronchodilator % predicted FEV_1, mean (SD)	75.4 (20.6)
No. of asthma exacerbations in past year, mean (SD)	3.0 (3.3)

*n=805. BMI, body mass index; FEV_1, forced expiratory volume in 1 second; IgE, immunoglobulin E.

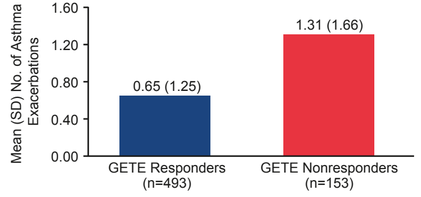
Asthma Exacerbation Rate Following Omalizumab Treatment by GETE Responder Status

- Mean (SD) number of asthma exacerbations was lower for GETE responders than nonresponders following omalizumab treatment (**Figure 1**).

Asthma-Related HCRU at Study End/Early Termination by GETE Responder Status

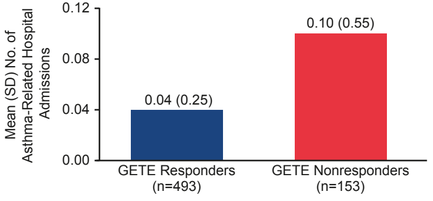
- GETE responders exhibited a lower mean (SD) number of asthma-related hospital admissions, ED visits, and unscheduled physician office visits than nonresponders following omalizumab treatment (**Figures 2–4**).

Figure 1. Mean (SD) Number of Asthma Exacerbations at Study End/Early Termination by GETE Responder Status



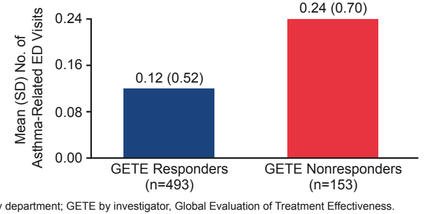
GETE by investigator, Global Evaluation of Treatment Effectiveness.

Figure 2. Mean (SD) Number of Asthma-Related Hospital Admissions at Study End/Early Termination by GETE Responder Status



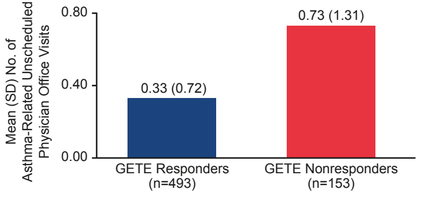
GETE by investigator, Global Evaluation of Treatment Effectiveness.

Figure 3. Mean (SD) Number of Asthma-Related ED Visits Following Omalizumab Treatment by GETE Responder Status



ED, emergency department; GETE by investigator, Global Evaluation of Treatment Effectiveness.

Figure 4. Mean (SD) Number of Asthma-Related Unscheduled Physician Office Visits Following Omalizumab Treatment by GETE Responder Status



GETE by investigator, Global Evaluation of Treatment Effectiveness.

Safety

- Safety results from the overall study population have been published in Casale et al (2019).[6] Safety for the subgroups presented has not been evaluated.
- The safety profile for the overall population in PROSPERO was consistent with the known safety profile of omalizumab.

Conclusions

- In this real-world analysis of patients with allergic asthma treated with omalizumab, the majority of patients were considered treatment responders based on the investigator's GETE assessment at ~49 weeks.
- Consistent with results of prior studies,[4,5] asthma exacerbations and asthma-related HCRU (hospitalizations, ED visits, and unscheduled physician office visits) were lower for GETE responders compared with GETE nonresponders.
- Limitations were inherent to the observational nature of the study.
- As this was an outcome-driven subgroup analysis and there was a substantial number of patients with missing GETE assessments, results may be biased.
- At present, a minimal clinically important difference for GETE has also not been defined.

References 1. Centers for Disease Control and Prevention. Most recent national asthma data. www.cdc.gov/asthma/most_recent_national_asthma_data.htm. Accessed January 20, 2020. 2. Normansell R, et al. *Cochrane Database Syst Rev*. 2014;(1):CD003559. 3. Lloyd A, et al. *J Med Econ*. 2007;10:285–96. 4. Bousquet J, et al. *Eur Respir J*. 2014;44(suppl 58):P3483. 5. Snelder SM, et al. *Allergy Asthma Clin Immunol*. 2017;13:34. 6. Casale TB, et al. *J Allergy Clin Immunol Pract*. 2019;7:156–64.e1.

Disclosures **ATL:** consultant and advisory board/speaker bureau member for Genentech, Inc. **YR, MY, JD:** employees of Genentech, Inc. **TH:** prior consultant for Genentech, Inc. and Novartis Pharmaceuticals Corporation. **BEC:** advisor, consultant, and speaker bureau member for AstraZeneca, Boehringer Ingelheim, Circassia, Genentech, Inc., Novartis, Regeneron, Sanofi, and Teva.

Acknowledgments This study (ClinicalTrials.gov identifier NCT01922037) was funded by Genentech, Inc., a member of the Roche Group, and Novartis Pharma AG. Third-party writing assistance was provided by Jordana Campbell, BSc, of Envision Pharma Inc., and funded by Genentech, Inc., a member of the Roche Group, and Novartis Pharmaceuticals Corporation.

Presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Annual Meeting, March 13–16, 2020, Philadelphia, PA