Poster R270

Improved Outcomes, Emergency Visits, and Quality of Life for Patients With Food Allergy on Omalizumab Monotherapy

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Introduction

Omalizumab, a monoclonal anti–immunoglobulin E (IgE) antibody, is approved for the reduction of allergic reactions in adults and children with IgE-mediated food allergy.[1] The phase 3 OUtMATCH trial (NCT03881696) showed that, compared with placebo, omalizumab substantially increased reactivity threshold for common food allergens in patients aged ≥1 year with food allergy[2]; however, omalizumab has not been assessed in the real-world setting. In this real-world study, we assessed physician-reported outcomes for patients with food allergy who were treated with omalizumab in the first year post US Food and Drug Administration (FDA) approval.

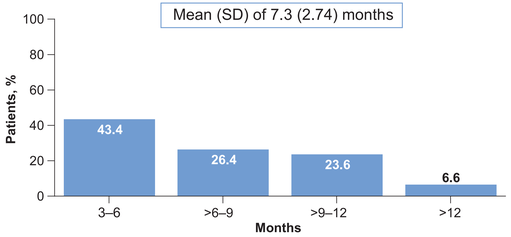
Overall, 49 physicians participated in the survey and reported on a total of 123 patients. The majority of patients were aged <18 years, were female, and had a peanut allergy. Over 40% of patients had multiple food allergies, and hives was a common symptom of any allergic reaction.

Table. Demographics and Clinical Characteristics of Patients With Food Allergy Receiving Omalizumab Monotherapy

	Patients (n=123)
Age, y, mean (SD)	22.3 (13.91)
<18 y, n (%)	66 (53.7)
≥18 y, n (%)	57 (46.3)
Female, n (%)	65 (52.8)
Age at diagnosis,* y, mean (SD)	13.5 (13.49)
Multiple food allergies, n (%)	54 (43.9)
Current food allergy in ≥10% of patients, n (%)	
Peanut	71 (57.7)
Cow's milk	29 (23.6)
Tree nut	30 (24.4)
Egg	23 (18.7)
Shellfish†	23 (18.7)
Symptoms experienced by ≥50% of patients during any allergic reaction,‡ n (%)	
Hives	87 (70.7)
Flushing	68 (55.3)

SD, standard deviation.
*n=64. †Includes shrimp, crab, oysters, and clams. ‡Excluding anaphylaxis.

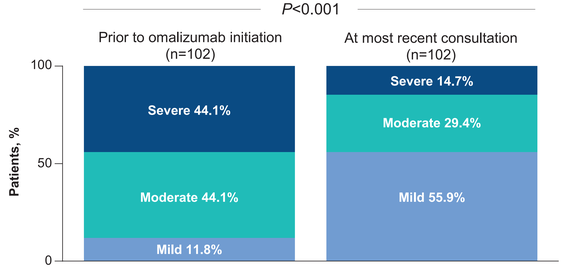
Duration of Omalizumab Monotherapy* (n=106)



SD, standard deviation.
*In patients with known data.

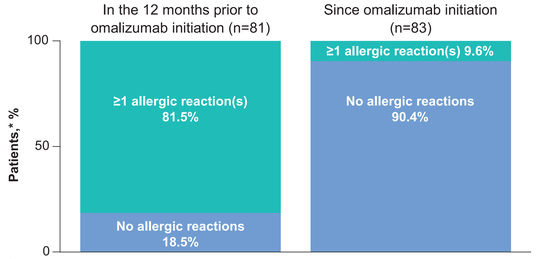
Physician-assessed food allergy severity improved over time with omalizumab monotherapy; significantly fewer patients were considered by their physicians as having "severe" food allergy at their most recent consultation post omalizumab initiation compared with before omalizumab initiation (P<0.001).

Food Allergy Severity Based on Physician's Own Definition of Mild/Moderate/Severe Food Allergy



More than 90% of patients with food allergy experienced no allergic reactions and no ED visits following initiation of omalizumab monotherapy. In addition, most patients (99.0%) with food allergy experienced no events of anaphylaxis.

Allergic Reactions in Patients With Food Allergy*



ED, emergency department.
*In patients with known data. †As a symptom of an allergic reaction to food.

Since Omalizumab Initiation*:

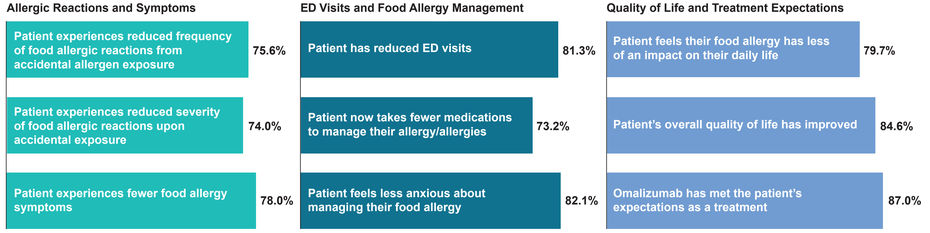
Patients had a mean (SD) of 0.1 (0.22) ED visits
- **94.8%** (73/77) had no ED visits

- **99.0%** (96/97) of patients experienced no anaphylaxis†

The majority of physicians "agreed" or "completely agreed" that their patient(s) experienced improved clinical outcomes, quality of life, and treatment satisfaction since initiating omalizumab monotherapy for food allergy.

Physician Agreement ("Agree" or "Completely Agree"*) With Statements

% of Patients With Food Allergy Experiencing Improved Outcomes and Quality of Life



ED, emergency department.
*Five-point scale from 1 (completely disagree) to 5 (completely agree).

Conclusion

Omalizumab was recently approved by the FDA for the reduction of allergic reactions in adults and children with IgE-mediated food allergy.[1] In this first real-world assessment, the majority of physicians "agreed" or "completely agreed" that omalizumab is meeting treatment expectations and led to a decrease in disease burden and an improvement in quality of life for patients with food allergy. These findings highlight the potential of omalizumab to benefit patients with food allergy in the real-world setting.

Methods

- Data were drawn from the Adelphi Real World Food Allergy Disease Specific Programme (DSP)™, a cross-sectional survey with elements of retrospective data collection from physicians in the United States, from January to April 2025.
  - Adelphi Real World DSP methodology has previously been published.[3-6]
  - Allergists, pediatricians, and primary care physicians were included in the survey and reported data on their patients with IgE-mediated food allergy receiving omalizumab monotherapy for ≥3 months.
    - Physicians had access to patient charts while responding to the survey.
    - Analyses were descriptive, and Wilcoxon signed rank tests were performed to compare clinical outcomes (α=0.05)

Key Findings

In this real-world study, physicians reported that patients with IgE-mediated food allergy on ≥3 months of omalizumab monotherapy experienced a reduction in symptom severity and number of allergic reactions compared with pre omalizumab initiation. In addition, most patients experienced no emergency department visits or anaphylaxis events.

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Disclosures
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Acknowledgments
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References
1. Xolair. Prescribing information. South San Francisco, CA: Genentech, Inc.; 2024.
2. Wood RA, et al. *N Engl J Med.* 2024;390:889–99.
3. Anderson P, et al. *Curr Med Res Opin.* 2008;24:3063–72.
4. Babineaux SM, et al. *BMJ Open.* 2016;6:e010352.
5. Higgins V, et al. *Diabetes Metab Syndr Obes.* 2016;9:371–80.
6. Anderson P, et al. *Curr Med Res Opin.* 2023;39:1707–15.