Eosinophilic Gastritis and Eosinophilic Enteritis Patients Endure a Lengthy Path to Diagnosis and Experience Persistent Symptoms After Diagnosis

Mirna Chehade1, Lauren T. Gehman2, Amol P. Kamboj2, Henrik S. Rasmussen2
1Icahn School of Medicine at Mount Sinai, New York, NY, United States; 2Allakos, Inc., Redwood City, CA, United States

Background
- Eosinophilic esophagitis (EoE), eosinophilic gastritis (EG), and eosinophilic enteritis (EEn) are chronic inflammatory diseases characterized by persistent gastrointestinal (GI) symptoms, esophageal eosinophilia in the esophagus, and small intestine, respectively.1,2
- Patients with EG and/or EEn (EG/EEn) often complain of allergic conditions such as asthma and atopic dermatitis.3,4
- Approximately 40% of EG/EEn patients also have eosinophilic gastroenteritis.5
- There are no FDA-approved treatments for EG/EEn; current disease management often includes diet modification or restriction, and/or topical or systemic corticosteroids1,2

Aim: To characterize the real-world experience of patients after EG/EEn diagnosis, including utilization of pharmacologic treatments

Methods
- Retrospective observational study of Symphony Health’s PatientSource® claims data (2008–18)
- Age groups defined as 28 years of age (y) of adults, 11 to 17 y (adolescents), and 0 to 10 y (children), based on age at initial symptom presentation
- Statistical significance tested using Wilcoxon Rank Sum test (continuous variables) or Pearson’s chi-squared test (categorical variables)

Patient selection criteria
- ≥1 claim with ICD diagnosis code for EG/EEn
- ≥1 claim with code for relevant GI symptom, ≥1 claim with code for endoscopy procedure and ≥1 claim for histopathology procedure prior to EG/EEn diagnosis date
- Evidence of continuous claims coverage for ≥2 years prior to and ≥1 year after 1st EG/EEn claim

Results
- A total of 4,097 patients (62% adults, 11% adolescents, 27% children) met study inclusion criteria (Table 1).

Table 1. Patient baseline characteristics

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N=4,097</th>
<th>N=2,531</th>
<th>N=1,644</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>2,453</td>
<td>1,527</td>
<td>926</td>
</tr>
<tr>
<td>Adolescents</td>
<td>842</td>
<td>537</td>
<td>315</td>
</tr>
<tr>
<td>Children</td>
<td>702</td>
<td>468</td>
<td>403</td>
</tr>
</tbody>
</table>

Demographics
- Number of patients: 4,097
- Age range: 18–2018 y
- Female: 56%
- Insurance coverage, n (%):
  - Commercial/managed care: 3,017 (74%) (64%)
  - Medicaid: 584 (14%) (11%)
  - Other: 496 (12%) (25%)

Diagnosis
- Median (IQR) time from presentation to diagnosis: 40.4 (17.6–78.3) months
- Median (IQR) annual systemic steroid volume (grams): 1,285 (625–2,835)

Allergic comorbidities (asthma, rhinitis, conjunctivitis, atopic dermatitis, urticaria, food allergy) were common, affecting 77% of patients
- Systemic steroids included oral and i.v. prednisone, prednisolone, dexamethasone and hydrocortisone

- Proportion of patients with GI symptom(s) and visited healthcare providers for their GI symptoms an average of 3.4 times per year after diagnosis
- Among patients with persistent EG/EEn symptoms, their use may be driven by anecdotal evidence from published case reports.5,6

Conclusions
- Patients with EG/EEn endured a substantial delay across multiple steps in the diagnostic process, highlighting the need for heightened disease awareness and standardized diagnostic criteria
- Most EG/EEn patients received pharmacologic treatment following diagnosis; while these treatments were not necessarily prescribed for EG/EEn, their use may be driven by anecdotal evidence from published case reports and the lack of FDA-approved treatment options
- The use of pharmacologic treatments even in patients without allergic comorbidities suggests that many of these treatments were prescribed in an attempt to manage EG/EEn symptoms
- Following diagnosis, most patients with EG/EEn remained symptomatic and visited healthcare providers for their GI symptoms an average of 3.4 times per year, underscoring the need for improved approaches to disease management
- Patients with GI symptoms persisting after EG/EEn diagnosis were more likely to receive systemic steroids, and at higher volumes, than patients without persistent symptoms, suggesting that healthcare providers often resort to systemic steroids to manage EG/EEn symptoms
- Frequent systemic steroid exposure in patients with EG/EEn despite the well-established risks emphasizes the unmet need for targeted therapies that are efficacious and safe for long-term use

Table 2. Reported frequency of GI symptoms in 12 months after EG/EEn diagnosis

<table>
<thead>
<tr>
<th>Symptom</th>
<th>All Patients</th>
<th>Adults (≥18 y)</th>
<th>Adolescents (11-17 y)</th>
<th>Children (&lt;11 y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>78%</td>
<td>75%</td>
<td>78%</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>35%</td>
<td>30%</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>38%</td>
<td>36%</td>
<td>40%</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>34%</td>
<td>31%</td>
<td>37%</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Systemic steroids dispensed to patients with and without GI symptoms in the 12 months following EG/EEn diagnosis

<table>
<thead>
<tr>
<th>Symptom</th>
<th>All Patients (N=4,097)</th>
<th>Patients with persistent GI symptoms (N=2,453)</th>
<th>Patients without persistent GI symptoms (N=1,644)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPI</td>
<td>2,453 (60%)</td>
<td>1,425 (57%)</td>
<td>1,028 (67%)</td>
</tr>
<tr>
<td>Enteric</td>
<td>743 (18%)</td>
<td>375 (15%)</td>
<td>368 (23%)</td>
</tr>
<tr>
<td>Montelukast</td>
<td>583 (14%)</td>
<td>303 (12%)</td>
<td>280 (17%)</td>
</tr>
</tbody>
</table>

2. Pesek et al., Am J Gastroenterol. 2019 Jun;114(6):984
4. Eosinophilic Gastritis and Eosinophilic Enteritis Patients Endure a Lengthy Path to Diagnosis and Experience Persistent Symptoms After Diagnosis. Mirna Chehade et al. Presented at ACG Congress October 2019, San Antonio, Texas
5. Systemic steroids included oral and i.v. prednisone, prednisolone, dexamethasone and hydrocortisone
6. Approved treatment options for EG/EEn are efficacious and safe for long-term use

Figure 1. Mean time between diagnostic milestones

Figure 2. Frequency of drug treatments used in 53% of patients