Persistence of Asthma Biologic Use in Clinical Practice

Maddux, Jacob T, MD1; Inselman, Jonathan, MS2; Jeffery, Molly M, PhD3; Shah, Nilay D, PhD2,3,4; Rank, Matthew A, MD2,5,6
1Department of Medicine, Mayo Clinic, Phoenix, AZ; 2Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, MN
3Division of Health Care Policy and Research, Department of Health Sciences Research, Mayo Clinic, Rochester, MN
4OptumLabs, Cambridge, MA; 5Division of Allergy, Asthma, and Clinical Immunology, Mayo Clinic, Scottsdale, AZ
6Division of Pulmonology, Phoenix Children’s Hospital, Phoenix, AZ

Rationale
Current guidelines suggest a trial of asthma biologics for at least 4 months
Limited evidence supports this suggestion
Describing persistence of asthma biologic use in clinical practice may provide evidence to inform length of asthma biologic trial

Data Source
• OptumLabs Data Warehouse (OLDW)
• US patients with Commercial and Medicare Advantage insurance
• The OptumLabs® Data Warehouse (OLDW) is a longitudinal, real-world data asset with de-identified administrative claims and electronic health record (EHR) data.
• Since this study involved analysis of pre-existing, de-identified data, it was exempt from Institutional Review Board approval.

Cohort
• Individuals with asthma defined by HEDIS
• Use of at least 1 asthma biologic from 2003-2018
• Excluded urticaria and atopic dermatitis
• Biologic use captured by claim for the biologic
  • Omalizumab
  • Mepolizumab
  • Reslizumab
  • Benralizumab
  • Dupilumab

Clinical Response to Asthma Biologics in The First 6 Months of use is Not Associated with Higher Persistence Of Use

Persistence of Asthma Biologic Use

<table>
<thead>
<tr>
<th>Months</th>
<th>Patients still on drug (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>6</td>
<td>60</td>
</tr>
<tr>
<td>12</td>
<td>30</td>
</tr>
<tr>
<td>18</td>
<td>20</td>
</tr>
<tr>
<td>24</td>
<td>10</td>
</tr>
<tr>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>36</td>
<td>0</td>
</tr>
</tbody>
</table>

* Assumes all patients who are lost to follow-up before the specified time point did not achieve a 50% reduction in asthma exacerbations

Time on Treatment by Clinical Response to Biologics

<table>
<thead>
<tr>
<th>Time on treatment</th>
<th>Clinical response</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 months</td>
<td>&lt;50%</td>
</tr>
<tr>
<td>6-12 months</td>
<td>50%</td>
</tr>
<tr>
<td>12-24 months</td>
<td>≥50%</td>
</tr>
</tbody>
</table>

Key Definitions
• Asthma exacerbation selected as this was the primary outcome for most asthma biologic trials
  - Hospitalization, emergency department, or urgent care visit with asthma in primary diagnosis or an any diagnostic position if associated with a primary respiratory diagnosis
  - Pharmacy claim for a systemic corticosteroid associated with a clinical visit for asthma within 30 days
• A clinical response to asthma biologic was defined as a 50% or greater reduction in asthma exacerbation; longer trial periods are less likely to find this reduction if it was not detected in the first 6 months

Summary of Conclusions
• Half of patients in our cohort did not have an asthma exacerbation in the 6 months before starting a biologic
  - Other outcomes such as quality of life, day-to-day symptoms, etc., may be driving use
  - Persistence of use for biologics, in this cohort, suggest that half of patients who start a biologic will have stopped using it within the first year
  - The reasons for stopping cannot be discerned in the current analysis
• A 6 month asthma biologic trial is long enough to show a reduction in asthma exacerbation; longer trial periods are less likely to find this reduction if it was not detected in the first 6 months
• A clinical response in the first 6 months of use is not associated with higher persistence of use compared to non-responders
  - Decisions to continue or stop asthma biologics appears to be unrelated to asthma exacerbation rates

Future Directions
• More research could help inform the best means of assessing clinical response after asthma biologic initiation
  - What are the best ways in clinical practice to determine response and how to best integrate other measures (quality of life, control, missing school/work, etc.)?
  - What are the effects of inconsistent use patterns (i.e. adherence levels) on asthma biologic outcomes?
  - Can we predict who will do well after stopping biologics?

Funding
• NHLBI HL140287
• Robert D. and Patricia E. Kern Center for the Science of Healthcare Delivery
• Mayo Clinic Foundation