Introduction

• More than 6 million children under 18 years of age in the United States suffer from asthma.

• Oral glucocorticoids (OGC) are recommended in short courses for severely uncontrolled asthma and acute exacerbations.

• Although a majority of asthma therapy, chronic use of OGC may increase risk of morbidity, specifically potential long-term related adverse events (AEs), in children.

• There is lack of contemporary research evaluating the impact of chronic OGC (C-OGC) exposure in children with asthma and those who did not have C-OGC exposure.

Methods

• Data Source

  • This retrospective, observational cohort study used the Truven Health MarketScan® Commercial Research Database (2009–2014).

  • This nationally representative, de-identified US administrative database contains inpatient and outpatient medical claims and prescription prescription drug claims for individuals with private insurance.

• Patient Selection

  • Patients aged 2–19 years of age with evidence of asthma (ICD-9-CM diagnosis code 493.xx) in any position (International Classification of Diseases, Ninth Revision, “Clinical Modification” (ICD-9-CM)), oral glucocorticoids (OGC) and inhaled corticosteroid (ICS) claims from 2009-2014 were identified (Figure 1).

  • Patients were stratified into cohorts of C-OGC initiators and C-OGC non-initiators.

  • C-OGC was defined as at least 15 consecutive days with OGC “on hand” based on the service dates and days’ supply fields on outpatient pharmacy claims for OGC.

• Outcomes and Covariates

  • The following AEs were evaluated during the follow-up period on a monthly basis. For OGC users, the date of C-OGC initiation was the index date. For participants without C-OGC exposure, the index date was randomly assigned.

  • Selection criteria used in this Figure.

Table 1. Patient Demographic Characteristics for Chronic OGC Initiators and Non-initiators

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>C-OGC Initiators (n=929)</th>
<th>C-OGC Non-initiators (n=970)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, %</td>
<td>Male</td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>54.6%</td>
<td>45.4%</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Race, %</td>
<td>White</td>
<td>Black</td>
<td></td>
</tr>
<tr>
<td>74.5%</td>
<td>25.5%</td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Median (IQR) age, y</td>
<td>12.1 (3.4)</td>
<td>10.5 (3.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Presence of asthma exacerbation, n (%)*</td>
<td>245 (3.2)</td>
<td>349 (4.6)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

• Other potential AEs that were studied, but did not demonstrate statistical significance, were as follows:

  • Asthma-related conditions: adrenal insufficiency, recurrent pneumonitis, osteoporosis, persistent cough, behavioral problems, and sleep disorders.

  • Skin conditions: acne, eczema, molluscum contagiosum.

Conclusions

• This study was funded by Genentech, Inc., a member of the Roche Group. The authors would like to acknowledge Shaswati Khan, employees of Truven Health Analytics, an IBM Company.

• Outcomes of C-OGC initiation was associated with increased risk for experiencing any potential AEs among children and adolescents with asthma (relative risk, 1.22; 95% CI, 1.20–1.25; P=0.0001).

• This is consistent with other research studies with smaller AEs being associated with C-OGC initiation.

• Despite evidence from other studies that C-OGC was associated with future asthma-related conditions, including adrenal suppression, recurrent pneumonitis, and behavioral problems, compared with children with asthma who did not initiate C-OGC.

• Among C-OGC initiators, higher doses of OGC were associated with increased risk for adrenal insufficiency (hazard ratio, 1.37; 95% CI, 1.16–1.61; P=0.0005).