Healthcare Burden of Allergic Status in Patients with Severe Asthma: A Matched-Cohort Real-World Evidence Study

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RATIONALE

- More than 24 million (about 7.7%) people in the US have asthma,[1] and about 5-10% of them have severe asthma.[2]
- Allergic asthma, is a well-recognized asthma phenotype, that affects about half of patients with severe asthma.[3]
- There is limited understanding of the impact of allergic asthma in patients with severe asthma.

OBJECTIVE

- To quantify and compare asthma exacerbations, health service use, and healthcare expenditures associated with allergic and non-allergic severe asthma.

METHODS

Study Design

- This retrospective, propensity-score matched cohort study used the Truven MarketScan insurance claims database with the study identification period between 01/01/2012 and 12/31/2013.

Included Patients

- Patients ≥6 years old with severe asthma were defined by:
  - ≥1 claim on the first dispensing date (index date) for omalizumab, oral corticosteroids (OCS; ≥15 days supply), or high-dose inhaled corticosteroid (HD-ICS), AND
  - ≥1 inpatient or emergency department (ED) claim or ≥2 outpatient claims for an asthma diagnosis (ICD-9 code 493.xx) on the index date or 365 days prior (baseline), AND
  - 365 days of continuous insurance enrollment before and after the index date.

Excluded Patients

- We excluded patients with:
  - a claim for omalizumab, OCS, or HD-ICS in the baseline wash-out period (to minimize potential between-group misbalance on severe asthma duration and the effect of step 6 therapies on allergic status), OR
  - a diagnosis code for chronic obstructive pulmonary disease (COPD), emphysema, or cystic fibrosis during the baseline period or on the index date.

Allergic Asthma Cohort

- Among selected severe asthma patients, allergic asthma cohort included those with:
  - ≥1 diagnosis code for allergic asthma (ICD-9 code 493.0x), AND
  - any of the following allergic conditions: sinusitis, rhinitis, conjunctivitis, nasal polyposis, anaphylaxis, eczema or dermatitis, food allergy, urticaria or angioedema, and atopic dermatitis and related conditions during the baseline period or on the index date.

Non-Allergic Asthma Cohort

- Among selected patients, non-allergic asthma cohort included severe asthma patients without a diagnosis for extrinsic asthma and without any of the allergic conditions (listed above) during the baseline period or on the index date.

METHODS (continued…)

Study Outcomes

- Asthma exacerbations, defined as having:
  - an OCS burst (a pharmacy claim with days of supply ≤15), OR
  - an asthma-related hospitalization, OR
  - an asthma-related ED visit during the 1-year post index (follow-up)
- Health service use
  - Outpatient services: all services that occur in the outpatient setting
  - Evaluation and management (E&M): all office visits that involve patient history, physical examinations and medical decision making

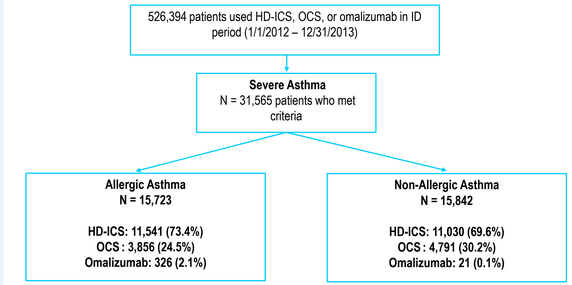
Statistical Analyses

- Before matching, sample size of allergic and non-allergic asthma patients was similar. To optimize patient matching, a 10% random sample of allergic asthma patients was selected, and non-allergic asthma patients were then matched to this group.
  - Matching was done in a 1:1 ratio based on a narrow difference in the estimated propensity scores (PS) and matched exactly on age, gender, region, provider specialty, and index year.
  - Propensity scores were estimated using baseline demographic characteristics (age, gender, and region), provider specialty, index year, Charlson comorbidity index, asthma medication ratio, and OCS prednisone-equivalent daily dose received on the index date.
- T-tests were used to compare the means.

RESULTS

- Before matching, allergic asthma patients (n=15,723) were younger, with fewer chronic conditions at baselines, had a higher percentage of allergists as usual healthcare providers than non-allergic asthma patients (n=15,842) (Fig. 1).

Figure 1. Selection of Study Population



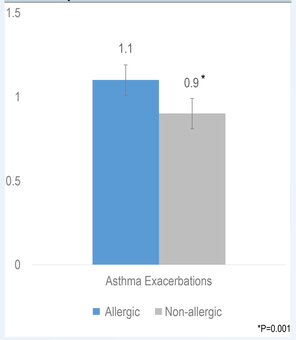
RESULTS (continued…)

Table 1. Selected Patient Characteristics at Baseline Before and After Matching

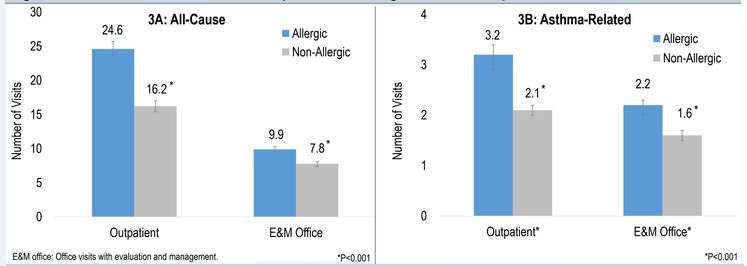
Patient Characteristics	Allergic Asthma	Non-Allergic Asthma	p-value
Before Matching			
Sample size, n (%)	15,723 (49.8)	15,842 (50.2)	
Age in years at index , mean (SD)	36.4 (21.1)	44.6 (20.6)	<.001
Female, n (%)	9,670 (61.5)	9,867 (62.3)	0.153
Charlson comorbidity index, mean (SD)	1.4 (1.1)	1.7 (1.5)	<.001
No. of chronic conditions, mean (SD)	3.2 (2.0)	3.4 (2.1)	<.001
After Matching			
Sample size, n (%)	1,523 (50.0)	1,523 (50.0)	
Age in years at index, mean (SD)	36.1 (20.9)	36.1 (20.9)	N/A
Female, n (%)	946 (62.1)	946 (62.1)	N/A
Charlson comorbidity index, mean (SD)	1.4 (1.0)	1.4 (1.1)	0.974
OCS prednisone-equivalent daily dose (mg) at index, mean (SD)	6.2 (18.9)	6.3 (22.1)	0.945
Baseline asthma medication ratio (range: 0 to 1), mean (SD)	0.5 (0.4)	0.5 (0.4)	0.509

- After matching, the 1,523 matched pairs were well-balanced at baseline (Table 1), except that more chronic conditions, cough, and upper respiratory infections appeared in the allergic cohort than in the non-allergic cohort (results not shown).
- During the 1-year post index period (follow-up), matched patients with evidence of allergic asthma experienced more exacerbations (Fig. 2), had more all-cause and asthma-related annual outpatient and E&M office visits (Fig. 3A & 3B) than non-allergic asthma patients.
- Inpatient and ED use and appeared similar between matched cohorts (Fig. 4A & 4B).

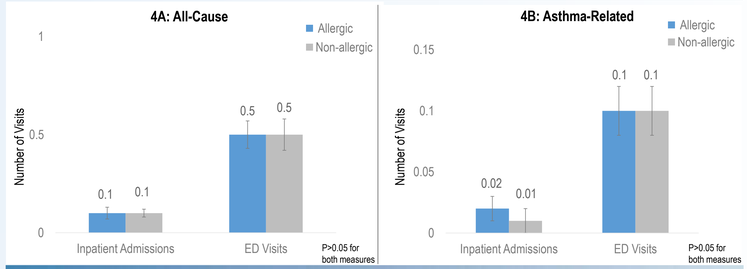
Figure 2. Mean Number of Asthma Exacerbations per Patient During 1-Year Follow-Up



Figures 3A and 3B: Mean Number of Visits per Patient During 1-Year Follow-Up



Figures 4A and 4B: Mean Number of Inpatient Admissions and ED Visits per Patient During 1-Year Follow-Up



LIMITATIONS

- We used ICD-9 code 493.0x and a number of allergic conditions to identify patients with allergic asthma. This approach may have resulted in misclassifications of patients.
- However, misclassification of allergic patients as non-allergic and vice versa would be likely to produce an underestimate of the true difference between groups.
- Commercial claims were used and the results may not be generalizable to the general population.
- Because the study cohort included patients with newly-obtained severe asthma status, the results might be not fully generalizable to patients who had severe asthma for longer than 1 year.

CONCLUSIONS

- Among severe asthma patients, those with evidence of allergic status experience more exacerbations and more outpatient and office visits (overall and asthma-related) than their counterparts without allergic status.

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