Real World Impact of Mepolizumab on Asthma Exacerbations: Adherence Matters

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Background and Objectives

- Mepolizumab has been shown to reduce asthma exacerbations by >50% in patients with severe eosinophilic asthma in clinical trials.[1,2]
- Understanding the effect of mepolizumab on rates of asthma exacerbations and adherence in a real-world setting is of critical importance to extend the findings from clinical trials to managed care settings.
- The objective of this study was to compare the asthma exacerbation rates and the impact of adherence among patients receiving mepolizumab in the year prior to administration to the year following using an insurance claims database.

Methods

- This study used a retrospective cohort design based on electronic medical records and pharmacy claims data from the IBM Watson Health MarketScan Commercial Database with claims between November 1, 2015 and September 30, 2016 indicating administration of mepolizumab (**Figure 1**)

Inclusion criteria:

- ≥12 years of age
- 12 months of continuous enrollment during both the year prior to index date (baseline period) and following the index date (follow-up period)
- ≥1 diagnosis for asthma during the baseline period
- ≥2 doses of mepolizumab in the first 180 days of the follow-up period

Exclusion criteria:

- Evidence of mepolizumab use during the baseline period
- Evidence of omalizumab, reslizumab, benralizumab, or dupilumab use during the baseline or follow-up periods

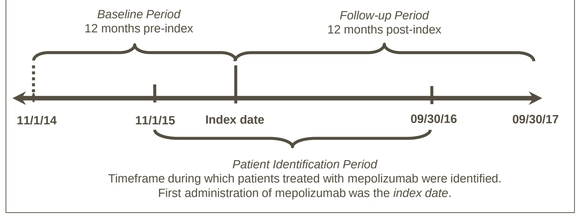
Adherence cohort:

- A separate cohort was created post-hoc to reflect previous clinical study design populations to examine the effect of adherence; the cohort required patients to have ≥2 baseline exacerbations and receive an optimized drug regimen (i.e. ≥10 administrations of mepolizumab) in the follow-up period

Statistics:

- Bivariate analyses were conducted to compare exacerbations between baseline and follow-up

Figure 1. Study design schematic



Results

Descriptive characteristics

- 138 patients met the inclusion criteria for the study. The mean age (SD) was 49.5 (11.7) years and slightly over half of patients were female (**Table 1**).
- As expected, the most common comorbidities were respiratory related (i.e. allergic rhinitis, sinusitis, and respiratory infections) followed by hypertension and GERD (**Table 2**).

Table 1. Baseline Demographics of Patients Treated with Mepolizumab

Demographic Characteristic	N=138
Age, Mean (SD)	49.5 (11.7)
Age Categories, n (%)	
12-17	5 (3.6%)
18-34	9 (6.5%)
35-44	21 (15.2%)
45-54	48 (34.8%)
55-64	55 (39.9%)
Gender, n (%)	
Male	60 (43.5%)
Female	78 (56.5%)
Geographic Region, n (%)	
Northeast	33 (23.9%)
North Central	29 (21.0%)
South	51 (37.0%)
West	25 (18.1%)
Insurance Plan Type, n (%)	
Comprehensive/indemnity	6 (4.3%)
EPO/PPO	81 (58.7%)
POS/POS with capitation	8 (5.8%)
HMO	9 (6.5%)
CDHP/HDHP	31 (22.5%)
Unknown	3 (2.2%)

CDHP=Consumer-directed health plan; EPO=Exclusive provider organization; HDHP=High-deductible health plan; HMO=Health maintenance organization; POS=Point of service; SD=Standard deviation

Table 2. Selected Comorbidities

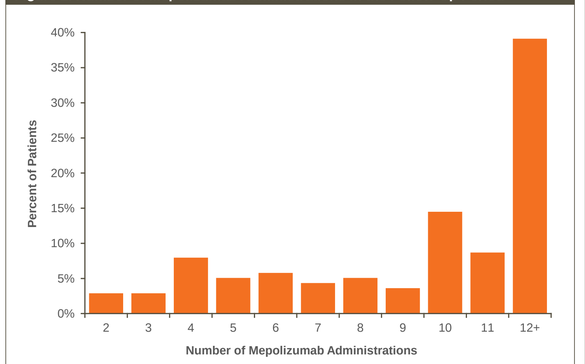
Selected Comorbid Conditions at Baseline	N=138 n (%)
Allergic rhinitis	96 (69.6%)
Sinusitis	87 (63.0%)
Acute	54 (39.1%)
Chronic	70 (50.7%)
Respiratory infections	62 (44.9%)
Hypertension	50 (36.2%)
Gastroesophageal reflux disease (GERD)	48 (34.8%)
Nasal polyps	38 (27.5%)
COPD	37 (26.8%)
Diabetes	16 (11.6%)
EGPA	4 (2.9%)
Chronic idiopathic urticaria	3 (2.2%)

COPD=Chronic obstructive pulmonary disease; EGPA=Eosinophilic granulomatosis with polyangiitis (approved dose of mepolizumab for EGPA is 300 mg/month subcutaneously)

Adherence

- Patients received a mean (SD) of 9.7 (3.8) injections of mepolizumab during follow-up, with 39.1% of patients completing ≥12 injections. Reasons for discontinuation could not be assessed from the database (**Figure 2**).
- By quarter, the average number of injections was relatively stable throughout the 12-month follow-up period with the mean (SD) per quarter ranging from 2.9 (1.0) to 2.2 (1.5) injections.

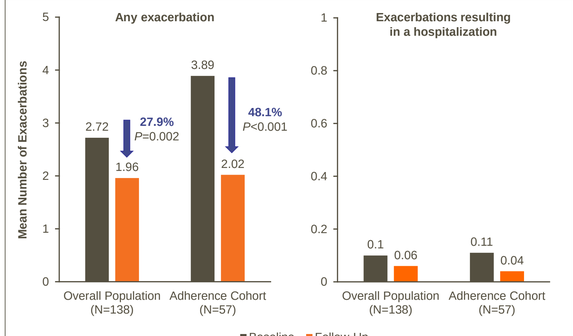
Figure 2. Number of Mepolizumab Administrations in the Follow-Up Period



Exacerbation rates

- Among the overall population, 87.0% (n=120) of patients experienced ≥1 exacerbations in the year prior to receiving mepolizumab. Compared with the year after, there was a 17.4% reduction in patients experiencing any exacerbation (69.6% in the follow-up period, p<0.001).
- With regard to exacerbation rate, there was a 27.9% reduction in the annual rate of exacerbations from baseline to follow-up (p=0.002). There was also a 40% reduction in exacerbations resulting in hospitalizations; however, the results were not significant (p=0.261) likely due to the small sample size (**Figure 3**).
- For the Adherence Cohort, which simulated the clinical trial population, there was a 24.6% (100.0% vs. 75.4%, p<0.001) reduction from baseline to follow-up in the proportion of patients with any exacerbation.
- The exacerbation rate for the Adherence Cohort decreased 48.1% (p<0.001) from baseline to follow-up. The reduction in rate of exacerbations resulting in hospitalization for the cohort was 63.6% (p=0.145) (**Figure 3**).
- Limitations of this study are rooted in the real world study design as unlike a clinical study, the data rely on claims data and are subject to data entry errors and coding limitations; moreover, the database is limited to patients with private commercial insurance and may not be generalizable all patients with asthma.

Figure 3. Exacerbation Rates During Baseline and Follow-Up Periods



The adherence cohort is defined as patients with ≥2 exacerbations in the baseline period and ≥10 mepolizumab administrations. Any exacerbation is identified as either of the following: outpatient or emergency room visit with a diagnosis of asthma and ≥1 dispensing of systemic corticosteroids within five days of the encounter; an exacerbation resulting in a hospitalization. Outpatient encounters with a Healthcare Common Procedure Coding System administration for mepolizumab and the first outpatient encounter with Current Procedural Terminology administration codes 96372 & 96401 in the 28 days following an National Drug Code (NDC) claim mepolizumab or prior to the next NDC claim were excluded from the definition of exacerbations. Exacerbations resulting in a hospitalization are defined as inpatient hospital admissions with a primary diagnosis of asthma.

Conclusions

- These findings provide the first examination of the impact of mepolizumab using insurance claims and demonstrate a significant reduction in exacerbation across a commercially insured population with varied adherence. When stratification consistent with an adherent dosing schedule was applied, the reduction in exacerbation rate further increased to 48%, resulting in a reduction consistent with that reported in the registrational clinical trials.

References

1. Pavord ID, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. *Lancet* 2012; 380(9842):651–9.
2. Ortega HG, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med* 2014;371(13):1198–207.

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