Symptom Burden in Medicare Advantage Patients with COPD Initiating Umeclidinium/Vilanterol or Fluticasone Propionate/Salmeterol Therapy

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Background

- The Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy report 2020[1] categorizes patients with COPD for pharmacologic management into groups A, B, C, or D using scores from patient-reported outcome measures and exacerbation history.
- ICS/LABA remains the most widely used therapy for COPD, despite GOLD's recommendation that long-acting bronchodilators (LAMA and/or LABA) be used for patients initiating therapy without risk of exacerbations (groups A and B), reserving ICS/LABA use for patients with increased symptoms and risk of exacerbations (group D).
- We compared disease burden and GOLD classification in a group of Medicare beneficiaries initiating therapy with umeclidinium/vilanterol (UMEC/VI), a LAMA/LABA, with those patients initiating therapy with fluticasone propionate/salmeterol (FP/SAL), an ICS/LABA.

Methods

Study Design: This study was a claims-linked, cross-sectional survey linked to 12 months of pre-survey (baseline) claims among Medicare Advantage enrollees from June 1, 2016 to January 11, 2019. Sample identification occurred in 4 waves between June 1, 2017 and September 30, 2018.

Key inclusion criteria

- Patients with ≥1 pharmacy claim for UMEC/VI OR FP/SAL 250mg during the 6 months closest to sample identification
- Age ≥65 as of calendar year 2017
- Continuous Medicare Advantage enrolment during the 12-month baseline period
- ≥2 ICD-10-CM COPD diagnosis codes at least 30 days apart during the 12-month baseline period

Key exclusion criteria

- Patients with evidence of UMEC/VI AND/OR FP/SAL during 6 months prior to the study criteria period
- Patients with evidence of triple therapy during the 12-month baseline period
- Patients with ≥1 asthma ICD-10 diagnosis codes during the 12-month baseline period
- Diagnosis or treatment for lung cancer
- Missing or invalid demographic or insurance information

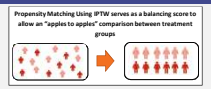
Symptom burden measures

- **COPD Assessment Test (CAT)** captured from the patient reported survey
- **Modified Medical Research Council (mMRC) Dyspnea Scale** captured from the patient reported survey
- **Exacerbation history** obtained from medical/pharmacy claims

Methods (cont.)

Statistical Analysis

Inverse Probability of Treatment Weighting (IPTW)



Observed covariates were balanced using IPTW for:
- Demographics
- Socioeconomic Characteristics
- Baseline Healthcare Use

Descriptive Analysis

GOLD ABCD Classification
Using CAT, mMRC, and history of exacerbations

C D
A B

Results

3335 invited to participate

891 completed survey

789 final sample post IPTW

Table 1. Post-IPTW Clinical and Demographic Characteristics

	UMEC/VI N = 392	FP/SAL N = 397	ASD %*
Age Category, %			
65 – 69	15.6	15.0	1.6
70 – 74	31.3	33.2	-4.0
75 – 79	28.4	27.9	1.2
80 +	24.7	23.9	1.8
Gender (female), %	53.3	54.0	-1.4
Race (white), %**	89.3	89.2	0.4
Smoking History (pack years), mean(SD)**	45.1 (28.9)	45.7 (34.7)	-1.9
Time since COPD Diagnosis, %**			
<1 year	14.1	14.6	-1.5
1 to 5 years	40.4	40.1	0.7
6 to 10 years	23.5	24.3	-1.9
11 to 19 years	14.1	13.4	2.1
≥20 years	8.0	7.7	1.0
Baseline Exacerbation Count, mean(SD)	0.8 (1.2)	0.7 (1.0)	5.1
COPD-related Total Costs, $US mean(SD)	$4,361 (10,005)	$4,019 (7,691)	3.8

Abbreviations: ASD: absolute standardized difference; COPD: Chronic Obstructive Pulmonary Disease; FP/SAL: fluticasone propionate/salmeterol; SD: standard deviation; UMEC/VI: umeclidinium/vilanterol; $US: United States Dollar; *ASD < 10% indicates treatment groups were similar on measured confounders.**Patient self-reported.

Results (cont.)

Figure 1. Pre-IPTW Percent of Patients by CAT categories

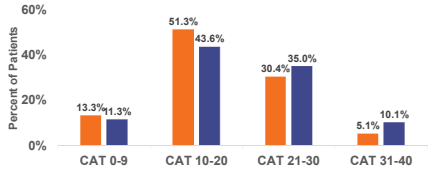


Figure 2. Pre-IPTW Percent of Patients by mMRC categories

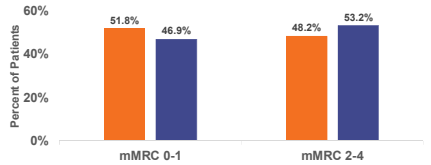


Figure 3. GOLD Grades by mMRC and CAT

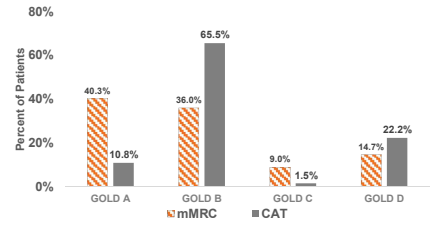
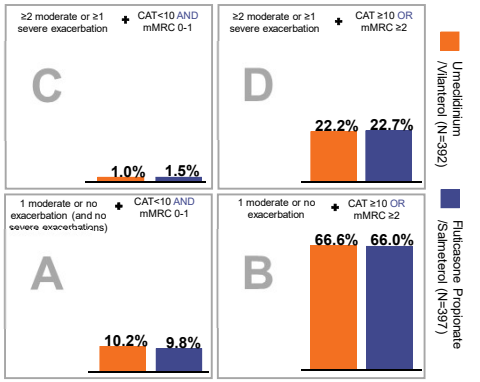


Figure 4. UMEC/VI and FP/SAL GOLD ABCD Grades using CAT/mMRC



Conclusions

- After controlling for confounding variables, including exacerbations, symptom burden as measured by the CAT and mMRC was similar in patients treated with UMEC/VI compared with those treated with FP/SAL.
- GOLD classification did vary by patient reported measure. Using only the mMRC appears to produce more conservative results, potentially underestimating symptom burden as compared to the CAT.
- Using both the mMRC and the CAT, the majority of patients on UMEC/VI and FP/SAL were categorized as GOLD B despite the GOLD recommendation that initial therapy for patients at low risk of exacerbation should be started on a non-ICS containing therapy.
- These findings support the need for routine assessment of symptoms in patients with COPD.

References

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD); Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2020.

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Disclosures

- This study was funded by GlaxoSmithKline (GSK ID HO-18-18992/208782).
- BH and RR are employees of GSK and hold stocks/shares in GSK. CM is a former GSK employee. JW, AH, BE, CE are current employees of Optum, a consulting company that has received research funds from GSK.

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