Impact of Umeclidinium/Vilanterol (UMEC/VI) Versus Tiotropium (TIO), Fluticasone Propionate/Salmeterol (FP/SAL), and Budesonide/Formoterol (B/F) on Time-to-first Severe Exacerbation Among Patients with Chronic Obstructive Pulmonary Disease with High Comorbidities and High Costs

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Aims

- The most costly and vulnerable patients with COPD are those with a high number of comorbidities and, consequently, high healthcare costs.[1-3] Disease control is particularly important in this group to reduce burden on patients, as well as the healthcare system.
- Controlling severe exacerbations resulting in hospitalization, due to the impact on cost and disease burden,[4] for this group is key.
- This study examined the time-to-first (TTF) and rate of severe exacerbations among patients with high comorbidities and costs in three identical studies comparing UMEC/VI with TIO (Study #1), FP/SAL (Study #2), and B/F (Study #3).

Methods

Study Design

A retrospective cohort study was conducted identifying patients from Optum's de-identified Clinformatics Data Mart Database initiating UMEC/VI, TIO, FP/SAL, or B/F from January 1, 2014 to December 31, 2018, with the earliest fill defined as the index date. Propensity score matching was used to balance cohorts.

Key Inclusion Criteria

- ≥40 years of age as of index
- ≥12 months continuous enrolment prior to the index date (i.e., pre-index period) or on the index date
- ≥1 primary or secondary diagnosis of COPD during 1-year pre-index or on the index date
- Defined as **high-comorbidity** (Quan-Charlson Comorbidity Index ≥3) and **high-cost** (pre-index medical costs ≥80th percentile of the cost distribution of COPD treated patients)

Key Exclusion Criteria

- ≥1 pharmacy claim for a non-index controller medication on index date
- ≥1 pharmacy claim for ICS-, LABA-, or LAMA-containing controller during the 1-year pre-index or on the index date
- ≥1 diagnosis of asthma in any position during the study period

Outcome: Severe Exacerbation defined as a hospitalization with a COPD-related exacerbation diagnosis code in the primary position

- **Time-to-First Severe Exacerbation**
  - Assessed with Kaplan-Meier survival analysis; risk was compared using hazard ratios (HR) from Cox regression models
- **Rate of Severe Exacerbations**
  - Rates were compared using rate ratios from Poisson regression models; p-values were calculated using bootstrap procedures

Results

Table 1. Matched Cohorts' Demographic and Clinical Baseline Data

Demographics	On-treatment follow-up (days)	Age	Female	Commercial Insurance	Medicare	COPD-related Medical Costs	COPD Severe Exacerbations
UMEC/VI vs. TIO	Mean (SD)	Mean (SD)	%	%	%	Mean (SD)	Mean (SD)
UMEC/VI (N=1,277)	143.2 (183.3)	72.1 (9.4)	44.6	15.8	84.2	$43,911 (55,865)	0.52 (0.73)
TIO (N=1,277)	130.3 (167.5)	72.1 (9.3)	43.9	15.2	84.8	$45,124 (52,941)	0.53 (0.68)
Std. Dif. (%)	**7.3**	**0.9**	**1.4**	**1.7**	**1.7**	**2.2**	**0.2**
UMEC/VI vs. FP/SAL							
UMEC/VI (N=1,194)	144.9 (185.3)	72.2 (9.4)	46.2	13.6	86.4	$43,731 (55,663)	0.55 (0.75)
FP/SAL (N=1,194)	107.5 (153.0)	72.1 (10.0)	46.3	14.6	85.4	$43,498 (49,066)	0.54 (0.72)
Std. Dif. (%)	**22.0**	**1.3**	**0.2**	**2.9**	**2.9**	**0.4**	**1.1**
UMEC/VI vs. B/F							
UMEC/VI (N=1,441)	139.5 (176.9)	72.0 (9.4)	45.5	16.1	83.9	$42,350 (54,206)	0.51 (0.72)
B/F (N=1,441)	102.5 (139.9)	71.9 (9.9)	44.1	16.3	83.7	$42,733 (54,732)	0.50 (0.68)
Std. Dif. (%)	**23.2**	**0.9**	**2.8**	**0.6**	**0.6**	**0.7**	**1.2**

*For continuous variables, the standardized difference is calculated by dividing the absolute difference in means of the control and the case by the pooled standard deviation of both groups. The pooled standard deviation is the square root of the average of the squared standard deviations. For dichotomous variables, the standardized difference is calculated using the following equation where P is the respective proportion of participants in each group: $|(P_{case}-P_{control})| / \sqrt{((P_{case}(1-P_{case})+P_{control}(1-P_{control}))/2}$

Figure 1. Time-to-First Severe Exacerbation Resulting in Hospitalization

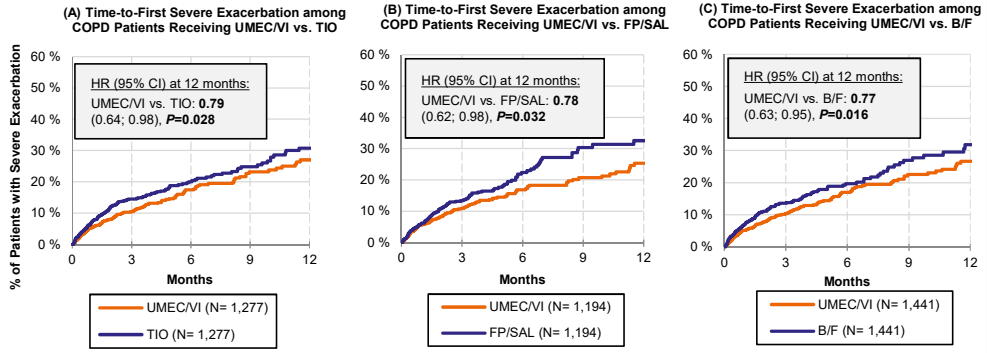
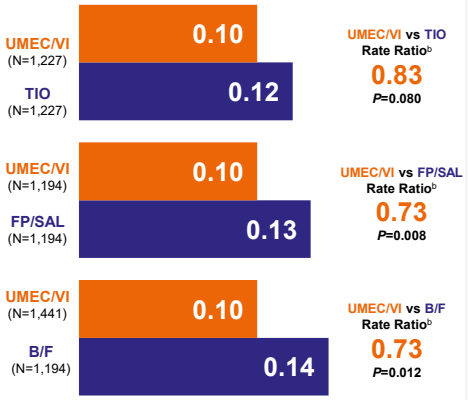


Figure 2. Rates of Severe Exacerbations[a] Resulting in Hospitalization



[a]Severe COPD-related exacerbations were defined as a hospitalization with a COPD-related exacerbation diagnosis code in the primary position. [b]Rate ratios were calculated from Poisson regression models.

Conclusions

- Patients initiated on UMEC/VI had significantly lower risk of severe exacerbation resulting in hospitalization compared with those initiated on TIO, FP/SAL, or B/F.
- These findings suggest that use of UMEC/VI in patients with COPD with high disease burden can reduce risk of future severe exacerbations.

Disclosures

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