

Occurrence of Exacerbations and Mortality in High-Risk Chronic Obstructive Pulmonary Disease Patients While on Treatment With Dual or Triple Inhaled Therapy: Results From the SIRIUS I Observational Study in the US

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Why did we perform this research?

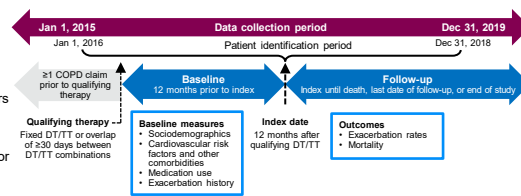
- Many patients with chronic obstructive pulmonary disease (COPD) remain at high risk of exacerbations and mortality despite receiving dual or triple inhaled therapy (DT/TT).
- Evaluation of the long-term outcomes for this patient population is needed to inform clinical care and guide future research.
- This study evaluates the 3-year occurrence of exacerbations and mortality among high-risk patients with COPD who are receiving DT/TT.

How did we perform this research?

Study design and participants

- This was a retrospective cohort study of people aged ≥40 years with a COPD diagnosis using Optum's deidentified Market Clarity Data in the US (2015-2019).
- Index date was the date on which the following criteria were met (**Figure 1**):
 - Patients had a continuous 12-month baseline period of treatment with DT/TT maintenance inhalers (either open or fixed DT/TT covering both start and end of baseline) between 2016 and 2018.
 - Patients had evidence of either ≥2 moderate exacerbations or ≥1 severe exacerbation during baseline period of DT/TT exposure. Moderate exacerbations required an emergency department or outpatient visit with a primary COPD diagnosis and corticosteroid or antibiotic prescription within ±7 days; severe exacerbations involved an overnight hospital admission.
- Exacerbations and all-cause mortality during follow-up were analyzed using the Kaplan-Meier method for the overall cohort and subgroups stratified by exacerbations experienced during baseline (≥2 moderate exacerbations or ≥1 severe exacerbation).

Figure 1. Study cohort and observation period



What did we find?

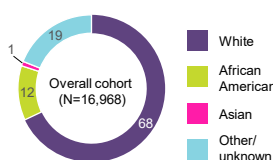
Overall cohort: N=16,968

Mean (SD) age
62.6 (10.2) years

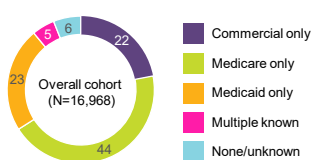
37% 63%

Mean (SD) follow-up
20.4 (12.2) months

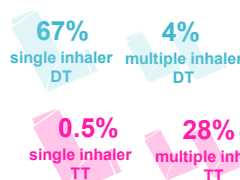
Race, %



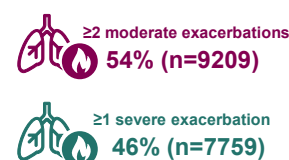
Insurance type, %



Maintenance therapy received



Exacerbations (baseline)

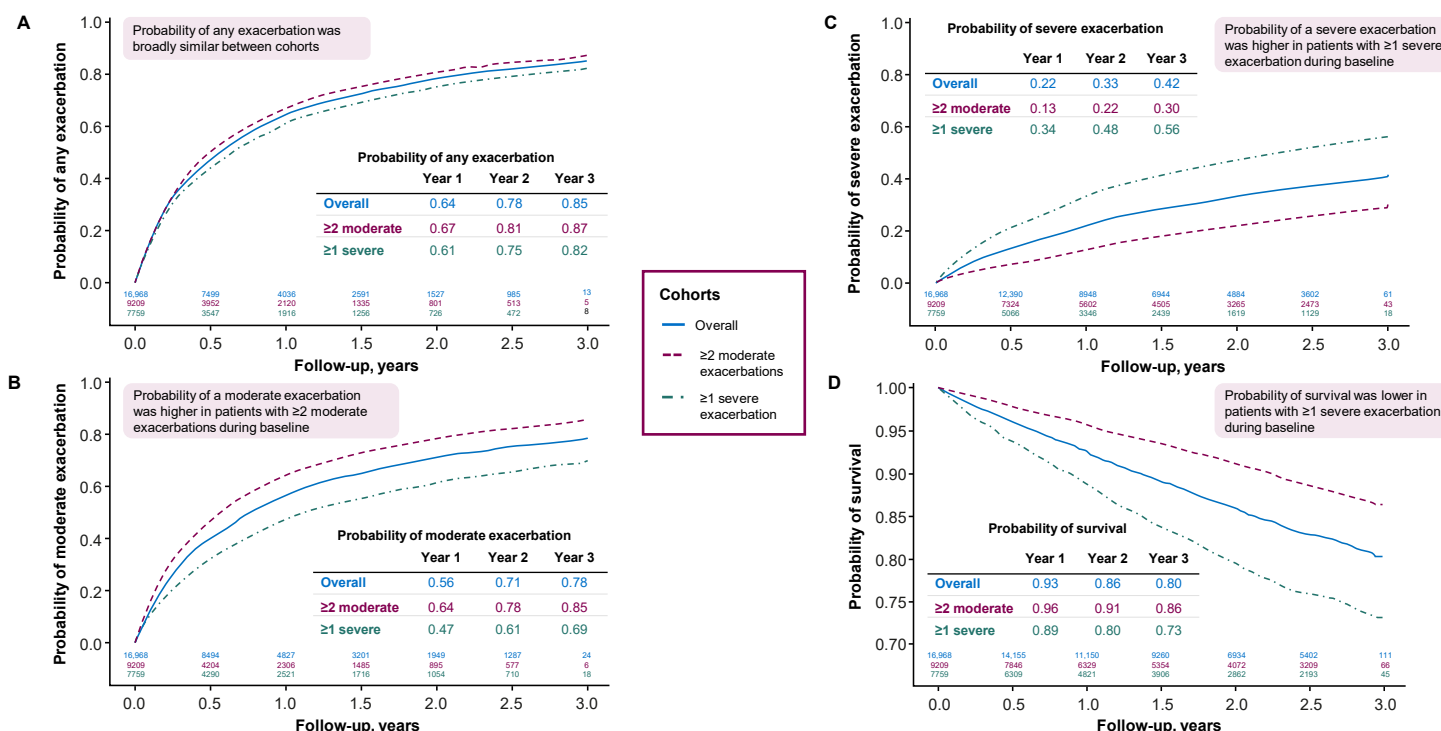


Reason for end of follow-up



See **Supplementary Table 1** via the QR code for additional sociodemographics, comorbidities, prescriber type, and baseline medications received among the overall cohort.

Figure 2. Cumulative probabilities of (A) any exacerbation, (B) moderate exacerbations, (C) severe exacerbations, and (D) survival during follow-up



- In the overall cohort (N=16,968), mean age was 63 years; 63% of patients were female, 68% were White, 44% had Medicare coverage, and 71% and 29%, respectively, were on dual and triple inhaled therapy.
- In patients with ≥2 moderate exacerbations during baseline (n=9209), the probabilities of moderate exacerbations (in Years 1, 2, and 3) were 0.64, 0.78, and 0.85, respectively; probabilities of severe exacerbations were 0.13, 0.22, and 0.30, respectively.
- In patients with ≥1 severe exacerbation during baseline (n=7759), the probabilities of moderate exacerbations (in Years 1, 2, and 3) were 0.47, 0.61, and 0.69, respectively; probabilities of severe exacerbations were 0.34, 0.48, and 0.56, respectively.
- 3-year mortality was higher among patients with severe exacerbations (27%) than moderate exacerbations (14%).

How might this impact current clinical practice?

- Patients who experienced exacerbations while receiving dual or triple inhaled therapy for COPD remain at significant risk of future exacerbations and mortality.
- Innovative therapeutic approaches and targeted interventions are needed to reduce events and improve outcomes for this patient population, thereby alleviating the overall burden associated with COPD.



E-poster



Supplementary material

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Abbreviations

COPD, chronic obstructive pulmonary disease; DT, dual inhaled therapy; TT, triple inhaled therapy.

Acknowledgements

This study was sponsored by AstraZeneca. Medical writing was provided by Magdalene Michael, PhD, of Envision Value & Access, a part of Envision Medical Communications, funding for which was provided by AstraZeneca.

Disclosures

JP, MP, HDM, and MF are employees of AstraZeneca and may hold stocks/shares. TLB is an employee of Optum Life Sciences. MCM reports NIH funding; royalties or licenses from UpToDate for authorship and editorial work for pulmonary function testing; consulting fees from Andis, Boehringer Ingelheim, GSK, MCG Diagnostics, and NDD Medical Technologies; and payment or honoraria from Talem Health for medical education for asthma and COPD.