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Reduction in Emergency Department (ED) Visits in Patients With Chronic Obstructive Pulmonary Disease (COPD): Analysis of the IMPACT Trial

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Recording by Doug Mapel

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Objectives

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- ED visits and hospitalizations associated with COPD place a high burden on patients and healthcare systems and account for most COPD-related healthcare costs in the United States.[1–4]
- The IMPACT trial showed that once-daily single-inhaler FF/UMEC/VI triple therapy resulted in a lower rate of severe exacerbations (resulting in hospitalization or death) versus dual therapy with UMEC/VI, in patients with symptomatic COPD and a history of exacerbations.[5]
- The rate of ED visits in patients enrolled in IMPACT has not been published; this post hoc analysis of the IMPACT trial evaluated the annual rate of ED visits by treatment arm.

COPD, chronic obstructive pulmonary disease; ED, emergency department; FF, fluticasone furoate; UMEC, umeclidinium; VI, vilanterol

1. Kumbhare SD, et al. Chronic Obstr Pulm Dis. 2016;3:539–548; 2.Iheanacho I, et al. Int J Chron Obstruct Pulmon Dis. 2020;15:439-460; 3. Guarascio AJ, et al. Clinicoecon Outcomes Res. 2013;5:235-45; 4. Halpin DM, et al. Int J Chron Obstruct Pulmon Dis 2017;12:2891–908; 5. Lipson DA, et al. N Engl J Med 2018;378:1671–80.

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Methods

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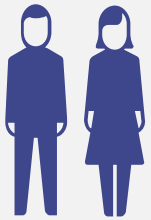
Study[1]

Randomized | Double-blind | Multicenter

Phase III

(CTT116855 [NCT02164513])

Patients[1]



≥40 years of age

Symptomatic COPD: CAT score ≥10 at screening

FEV_1 <50% predicted at screening and ≥1 moderate/severe* exacerbation in prior 12 months

OR

FEV_1 50–<80% at screening and ≥2 moderate or ≥1 severe exacerbation in prior 12 months

Treatments[1]

2 : 2 : 1 randomization
FF/UMEC/VI : FF/VI : UMEC/VI

FF/UMEC/VI Once daily	**Fluticasone furoate 100 mcg Umeclidinium 62.5 mcg Vilanterol 25 mcg**
FF/VI Once daily	**Fluticasone furoate 100 mcg Vilanterol 25 mcg**
UMEC/VI Once daily	**Umeclidinium 62.5 mcg Vilanterol 25 mcg**

52 weeks

Post hoc analysis

Quantification of on-treatment **ED visits** by treatment arm

- Unscheduled healthcare resource utilization, including ED visits, was recorded in patients' electronic case report forms
- Comparisons were made using a generalized linear model assuming a negative binomial distribution

FF/UMEC/VI

versus

FF/VI

or

UMEC/VI

PATIENTS

- The ITT population comprised 10,355 patients. Data on ED visits were available for 10,351 patients (FF/UMEC/VI, n=4148; FF/VI, n=4134; UMEC/VI, n=2069)

*Moderate exacerbation, any exacerbation requiring antibiotics and/or oral/systemic corticosteroids; severe exacerbation, any exacerbation leading to hospitalization or death. CAT, COPD assessment test; COPD, chronic obstructive pulmonary disease; ED, emergency department; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; ITT, intent-to-treat; UMEC, umeclidinium; VI, vilanterol

1. Lipson DA, et al. N Engl J Med 2018;378:1671–80.

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Baseline characteristics and demographics were similar between the treatment groups (ITT population)[1]

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Characteristic	FF/UMEC/VI (N=4151)	FF/VI (N=4134)	UMEC/VI (N=2070)
Age, mean (SD) years	65.3 (8.2)	65.3 (8.3)	65.2 (8.3)
Sex (male), n (%)	2766 (67)	2748 (66)	1356 (66)
BMI*, mean (SD) kg/m²	26.6 (6.2)	26.7 (6.1)	26.6 (5.9)
Smoking status history, n (%)			
Current	1436 (35)	1423 (34)	728 (35)
Former	2715 (65)	2711 (66)	1342 (65)
Exacerbation history in the prior 12 months, n (%)			
<2 moderate/severe exacerbation	1855 (45)	1912 (46)	933 (45)
≥2 moderate/severe exacerbations	2296 (55)	2222 (54)	1137 (55)
CAT score†, mean (SD)	20.1 (6.1)	20.1 (6.1)	20.2 (6.2)
Post-bronchodilator % predicted FEV_1‡, mean (SD)	45.7 (15.0)	45.5 (14.8)	45.4 (14.7)

*FF/UMEC/VI n=4148, FF/VI n=4134, UMEC/VI n=2070; †FF/UMEC/VI n=4142, FF/VI n=4124, UMEC/VI n=2061; ‡FF/UMEC/VI n=4145, FF/VI n=4133, UMEC/VI n=2069. BMI, body mass index; CAT, COPD assessment test; COPD, chronic obstructive pulmonary disease; ED, emergency department; FEV_1, forced expiratory volume in 1 second; ITT, intent-to-treat; FF, fluticasone furoate; SD, standard deviation; UMEC, umeclidinium; VI, vilanterol

1. Lipson DA, et al. N Engl J Med 2018;378:1671–80.
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The majority of patients had no on-treatment ED visits. Most patients with ED visits had 1 visit

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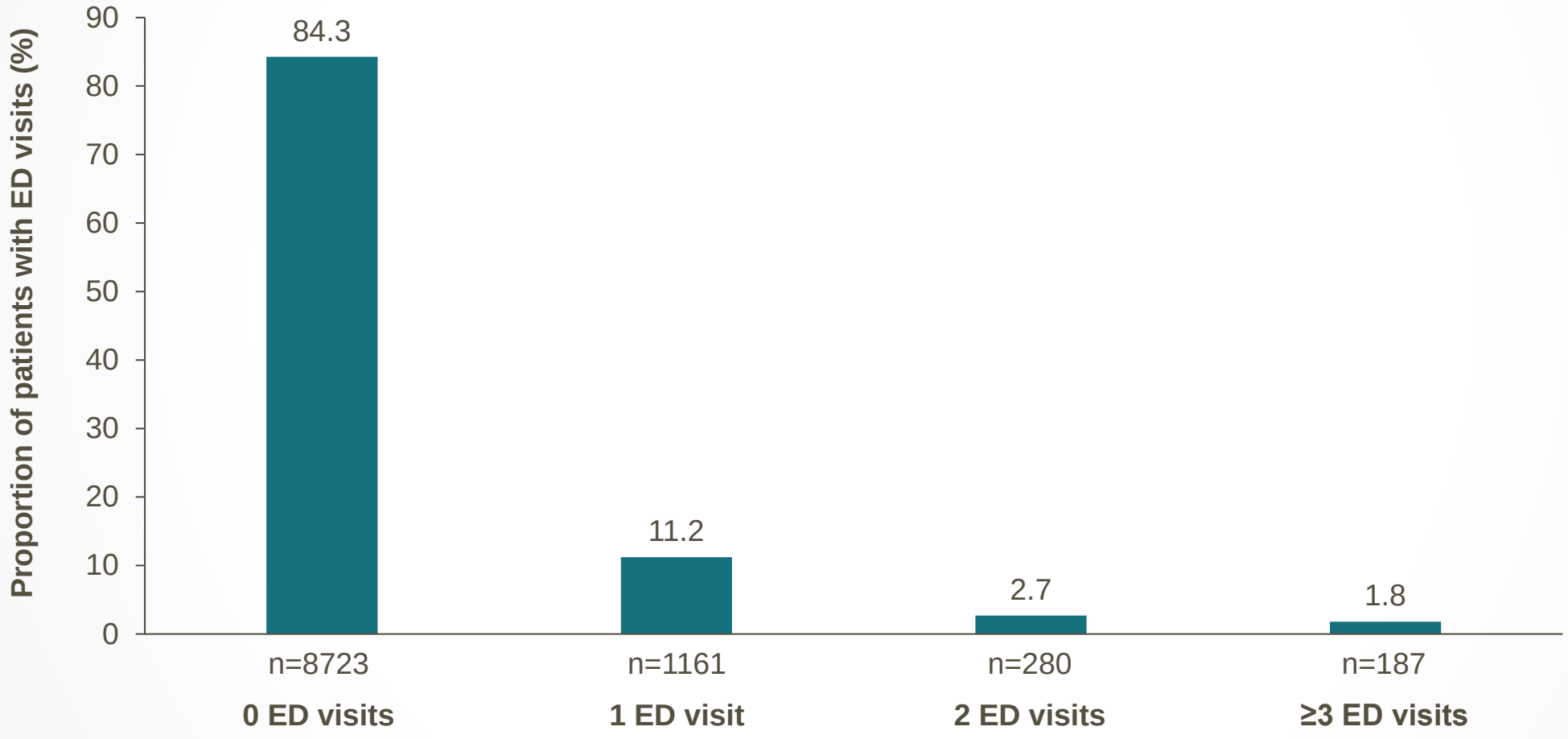

N=10,351. Patients were randomized 2:2:1 to FF/UMEC/VI:FF/VI:UMEC/VI.
ED, emergency department; FF, fluticasone furoate; N, number of patients in the analysis; n, number of patients with ED visits; UMEC, umeclidinium; VI, vilanterol
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The rate of ED visits was significantly lower with FF/UMEC/VI vs UMEC/VI, with no statistically significant difference vs FF/VI

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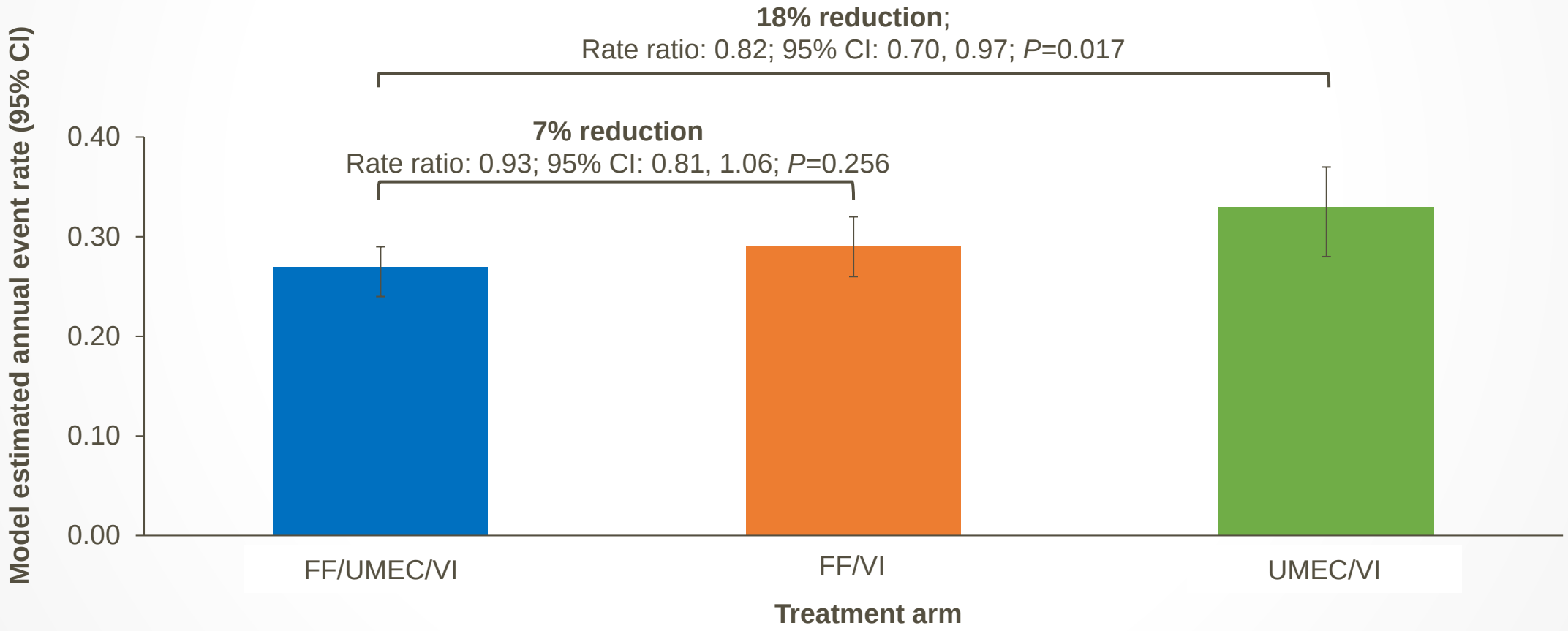
The model estimated annual event rates (95% CI) were 0.27 (0.24, 0.29) for FF/UMEC/VI, 0.29 (0.26, 0.32) for FF/VI, and 0.33 (0.28, 0.37) for UMEC/VI



Analysis covariates included treatment group, sex, exacerbation history (≤1, ≥2 moderate/severe), smoking status (screening), region and post-bronchodilator percent predicted FEV_1 (screening).
CI, confidence interval; ED, emergency department; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; UMEC, umeclidinium; VI, vilanterol
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Conclusions

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- The rate of ED visits was significantly lower for patients receiving FF/UMEC/VI compared with those receiving UMEC/VI.
- In addition to the reduction in severe exacerbation rates with FF/UMEC/VI versus UMEC/VI seen in the IMPACT trial, this reduction in ED visits highlights the benefits of single-inhaler FF/UMEC/VI triple therapy over UMEC/VI dual therapy in patients with symptomatic COPD and a history of exacerbations.

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CO-AUTHORS' DISCLOSURES

- GJ Criner reports personal fees from Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Broncus Medical, Chiesi, CSA Medical, Eolo, Gala Therapeutics, GSK, Helios Medical, Medtronic, Merck, Mereo BioPharma, NGM Pharmaceuticals, Novartis, Nuvaira, Olympus, Philips Respironics, Pulmonx, Respivant Sciences, The Implementation Group, and Verona; he also has ownership interest in HGE Technologies. M Bogart, R Jain, D Midwinter, and DA Lipson are employees of GSK and hold stocks/shares in GSK. MT Dransfield has received personal fees from AstraZeneca, Boehringer Ingelheim, PneumRx/BTG, Quark Pharmaceuticals, and GSK, grant support from the American Lung Association, Department of Defense, Department of Veterans Affairs, and NIH, and contracted clinical trial support from Boehringer Ingelheim, Novartis, AstraZeneca, Yungjin, PneumRx/BTG, Pulmonx, Boston Scientific, Gala, Nuvaira, and GSK. N Gaeckle, V Kaul and MJ Mammen have no conflict of interest to disclose. M Gotfried has received personal fees from GSK and the France Foundation, research support from Merck, Idorsia, Galapagos, Fibrogen, Avillion, and Takeda. DMG Halpin has received personal fees from AstraZeneca, Boehringer Ingelheim, Chiesi, GSK, Novartis, Pfizer, and Sanofi, and nonfinancial support from Boehringer Ingelheim, and Novartis. MK Han has received personal fees from AstraZeneca, GSK, Mylan, and Boehringer Ingelheim, and research support from Novartis and Sunovion. D Singh has received personal fees from GSK, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, Genentech, Glenmark, Menarini, Mundipharma, Novartis, Peptinnovate, Pfizer, Pulmatrix, Theravance, and Verona, and grant support from AstraZeneca, Boehringer Ingelheim, Chiesi, Glenmark, Menarini, Mundipharma, Novartis, Pfizer, Pulmatrix, Theravance, and Verona. R Wise reports financial and nonfinancial support from GSK, and financial support from AstraZeneca, Boehringer Ingelheim, Contrafect, Merck, Verona, Mylan/Theravance, Novartis, ChimRix, FSD Pharma, AbbVie, Bristol Myers Squibb, Puretech, Galderma, and Chiesi.