The IMPACT Trial: Single Inhaler Triple Therapy Fluticasone Furoate/Umeclidinium/Vilanterol Versus Fluticasone Furoate/Vilanterol and Umeclidinium/Vilanterol in Patients With COPD: Results on Rescue Use and Nighttime Awakenings

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Introduction

COPD is a chronic, progressive and disabling disease, and it is the fourth leading cause of death.1-3 The symptoms and exacerbations of COPD negatively impact patients’ quality of life and increase hospitalization and mortality.4,5 Moreover, patients frequently experience nighttime awakenings, which could be due to respiratory symptoms or non-respiratory events.6 Reducing nighttime awakenings is associated with improved quality of life, reduced healthcare resource use, and survival.7-9 Therefore, the development of effective therapies to reduce nighttime awakenings is warranted.

COPD rescue medication use is an indicator of symptomatic benefits in patients with COPD and is associated with improved clinical outcomes such as lung function, breathlessness, and health status, and reduced hospitalization and healthcare cost.10-12 Recent evidence suggests that nighttime awakenings are better regarded as a number of disease control (as in Asthma) and not the frequency of these events may be important for respiratory health outcomes.9

The current study evaluated the nighttime rescue use during nighttime awakenings in the IMPACT trial. The IMPACT trial demonstrated that twice-daily single inhaler triple therapy (SIT) containing Fluticasone Furoate/Umclidinium/Vilanterol (FF/VI) resulted in a lower rate of nighttime awakenings compared with the long-term use of LAMA/LABA (45 mcg FF/VI) compared with dual therapy with FF/UMEC (100 mcg FF/UMEC) in patients with moderate-severe COPD.13 The current study aimed to evaluate the rescue medication use at nighttime awakenings and the impact of nighttime awakenings due to COPD.

Methods

IMPACT was a phase III, double-blind, placebo-controlled, parallel-group, 28-week study (NCT02793066) with a 12-week run-in and 26-week active treatment phase. Eligible patients were men or women ≥ 40 years of age with moderate-severe COPD (GOLD II–IV) as defined by the GOLD guidelines.14 The primary endpoint was the annual rate of nighttime awakenings. Secondary endpoints included the number of nighttime awakenings per year, the number of rescue medications used per year, the number of nighttime awakenings per month, the use of rescue medications at nighttime awakenings, the number of rescue medications used per month, and the use of rescue medications at nighttime awakenings per month.

Results

The IMPACT trial demonstrated that twice-daily single inhaler triple therapy containing Fluticasone Furoate/Umclidinium/Vilanterol (FF/VI) resulted in a lower rate of nighttime awakenings and number of rescue medications used at nighttime awakenings compared with the long-term use of LAMA/LABA (45 mcg FF/VI) compared with dual therapy with FF/UMEC (100 mcg FF/UMEC) in patients with moderate-severe COPD.13 The current study aimed to evaluate the rescue medication use at nighttime awakenings and the impact of nighttime awakenings due to COPD.

Conclusions

The findings are in line with previous studies showing that twice-daily single inhaler triple therapy containing Fluticasone Furoate/Umclidinium/Vilanterol and/or LAMA/LABA resulted in a lower rate of nighttime awakenings and number of rescue medications used per year, week, month, and day compared with the long-term use of LAMA/LABA alone.2,3 This study adds to the evidence that twice-daily single inhaler triple therapy containing Fluticasone Furoate/Umclidinium/Vilanterol and/or LAMA/LABA resulted in a lower rate of nighttime awakenings and number of rescue medications used at nighttime awakenings compared with the long-term use of LAMA/LABA alone.2,3 The findings included a consistent efficacy profile with once-daily Fluticasone Furoate/Umclidinium/Vilanterol compared with FF/VI and UMEC/VI across a range of COPD subgroups.

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References


