The INTREPID (Clinical Effectiveness of Once-Daily Single-Inhaler Fluticasone Furoate/Umeclidinium/Vilanterol Versus Multiple-Inhaler Triple Therapy in Usual Clinical Practice)

Introduction

- In patients with chronic obstructive pulmonary disease (COPD) who remain symptomatic or continue to experience exacerbations while receiving dual therapy, triple therapy with an inhaled corticosteroid (ICS), a long-acting β2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA) is recommended.
- Single-inhaler triple therapy is a recent development for the treatment of COPD and could provide a more practical option for patients, and improve treatment adherence and outcomes, compared with multiple-inhaler triple therapy (MITT).
- Recently, single-inhaler triple therapy with fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) delivered by the ELLIPTA inhaler has shown more sustained lung function benefit throughout the dosing interval compared with MITT, and similar health status improvements in the randomized controlled trial (RCT) environment. However, real-world effectiveness data on single-inhaler versus multiple-inhaler therapy is limited.
- The INTREPID (Investigation of Mitigating Effectiveness: Usual Practice Design) study evaluated the impact of usual-daily single-inhaler triple therapy with FF/UMEC/VI versus non-ELLIPTA MITT on health status in patients requiring triple therapy within the real-world clinical setting.

Methods

- Study design: Phase IV, open-label, randomized, controlled, parallel-group study.
- Patients: Adults ≥40 years of age with moderate COPD, as per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. Actual prior medication use strata were similar between the FF/UMEC/VI and MITT arms.
- Randomization: Single-inhaler FF/UMEC/VI (n=1545) versus multiple-inhaler MITT (n=1547). Randomization was based on the proportion of patients taking each medication in the prior year.
- Interventions: Once-daily FF/UMEC/VI (ICS+LAMA+LABA) versus twice-daily MITT (ICS+LABA, ICS+LAMA, or LAMA+LABA).
- Treatments were initiated based on current medication use in the prior year.

Results

- Table 1: Patient characteristics at screening
- Table 2: Serious AESIs
- Table 3: Treatment response at Week 24
- Table 4: Change in health status from baseline at Week 24

Figure 1: Proportion of CAT responders at Week 24

Figure 2: LS mean change from baseline in (A) FEV1, and (B) change in CAT score

Conclusions

- The INTREPID study broadens the understanding of the effectiveness of FF/UMEC/VI beyond the traditional RCT setting, with real-world clinical practice.

References


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