Lung function normalisation with indacaterol/glycopyrronium/mometasone furoate in patients with asthma

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Introduction

The combination of an inhaled corticosteroid (ICS) plus a long-acting β2-agonist (LABA) is considered the cornerstone of long-term asthma treatment. Patients who have uncontrolled symptomatology or maintenance corticosteroid use despite a moderate- to high-dose ICS are candidates for treatment with LABA plus ICS.

Methods

Study design

• Both B2208 and B2209 studies had a randomized, double-blind, 3-period, crossover design. B2208

B2208

• This was an active-comparator-controlled study with 21 treatment days per treatment period (AM/PM, 8:00 and 17.00 hours) in 357 patients with asthma treated with indacaterol/glycopyrronium/mometasone furoate (IND/GLY/MF) with high-dose ICS and medium-dose ICS and placebo (SFC 50/500 μg).

B2209

• This was a placebo-controlled study with 3 treatment periods of 14 days each (AM, 8:00 hours; PM, 17.00 hours) in 201 patients with asthma treated with IND/GLY/MF with high-dose ICS and medium-dose ICS and placebo (SFC 50/500 μg).

Assessments (B2208 and B2209)

• Spirometry measurements followed the American Thoracic Society/European Respiratory Society guidelines4 and were performed at screening and at the end of each treatment period, at home, and at specific time points: 2 hours post-dose in the morning, at the end of the treatment period and at the end of each period in the evening, and 1 hour before bedtime in the evening.

Results

Demographics and clinical characteristics

In B2208, 101 patients were randomized of whom 107 completed the study with IND/GLY/MF. In B2209, 20 patients were randomized of whom 21 completed the study with IND/GLY/MF.

• Patients with asthma were more likely to be rescue-medication free with IND/GLY/MF (high-dose ICS) compared with placebo (N = 101) (P = 0.0175). This was observed when patients were treated with IND/GLY/MF versus high-dose ICS salmeterol/fluticasone (45% vs 7%) (P = 0.0280).

Safety

• In B2208, all study treatments were well tolerated and there were no relevant differences in tolerability between IND/GLY/MF and placebo.

Conclusions

High-dose IND/GLY/MF is associated with statistically significant and similar improvements in lung function and concomitant use of rescue medication when patients were treated with IND/GLY/MF versus high-dose ICS salmeterol/fluticasone.

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References
