Conclusions The increase in time to first severe exacerbation and first episode of asthma worsening found with the addition of tiotropium was not limited to specific subgroups of patients, including some characteristics that are usually found in patients with chronic obstructive pulmonary disease, such as former smoking, non-allergic status or minimal reversibility. Tiotropium seems effective across a broad spectrum of patients with severe persistent asthma who remain symptomatic and experience exacerbations despite the combination use of moderate- to high-dose inhaled corticosteroids plus long-acting beta agonists.

**P164** USE OF BETA-AGONISTS PRIOR TO HOSPITAL ATTENDANCE FOR SEVERE EXACERBATIONS OF ASTHMA: INSIGHTS FROM A RANDOMISED CONTROLLED TRIAL USING ELECTRONIC MONITORING OF INHALER USE

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Introduction Observational studies have reported that the overuse of inhaled beta-agonists during severe asthma is a common feature associated with a fatal outcome. However, patterns of actual use of beta-agonists prior to hospital attendance for severe exacerbations are poorly understood.

Objectives We have recently reported that in 303 adult asthma patients randomised to receive either combination budesonide/formoterol metered dose inhaler (MDI) as part of a single maintenance and reliever therapy regimen (‘SMART’) or as fixed-dose maintenance treatment with salbutamol MDI for relief (‘Standard’), overuse of beta-agonists without subsequent medical review occurred commonly in both groups. We now report on the use of beta-agonists by patients who attended hospital with a severe exacerbation of asthma. Our hypothesis was that extremely high beta-agonist doses would be used by patients in both groups and that inhaled corticosteroid (ICS) non-adherence may occur in the Standard group during severe asthma.

Methods Data on MDI use, as measured by electronic monitoring, were extracted for each patient for the 14 24-hour periods before the attendance time at hospital for a severe exacerbation.

Results Electronic data were available for 7/7 and 9/11 hospital attendances in the SMART and Standard groups respectively. The median (range) daily number of actuations 14 days before hospital attendance was 4 (2 to 12) budesonide/formoterol in SMART and 4 (0 to 26) salbutamol and 2 (0 to 8) budesonide/formoterol in Standard. This increased to 11 (6 to 39) budesonide/formoterol in SMART and 23 (3 to 86) salbutamol and 4 (0 to 39) budesonide/formoterol in Standard, in the 24-hours before attendance. The median (range) maximum daily number of actuations was 14 (9 to 63) budesonide/formoterol in SMART and 46 (6 to 95) salbutamol in Standard. Repeated days of no ICS use occurred in 3/9 patients in the Standard group, despite concomitant salbutamol use.

Conclusions Very high doses of beta-agonists are commonly self-administered by patients for prolonged periods prior to hospital presentation with severe asthma. The opportunity exists for clinical review and appropriate medical intervention during this period, which may reduce the risk of a life-threatening attack.

**P166** EFFECTS OF LOW-VS HIGH-DOSE FLUTICASONE/FORMOTEROL COMBINATION THERAPY ON AMP CHALLENGE IN ASTHMATIC PATIENTS

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Background The ICS fluticasone propionate (FP) and the LABA formoterol fumarate (FORM) have now been combined in a single aerosol inhaler (FP/FORM; flutiform). The effect of low- (2 puffs 50/5 µg bid) vs high-dose (2 puffs 250/10 µg bid) FP/FORM on airway responsiveness to AMP was compared in an
Efficacy and Safety of Omalizumab in Real-world Clinical Practice in Indian Patients with Allergic (IgE-mediated) Asthma: Analysis by Baseline Severity of Asthma

Omalizumab (OMA) is a humanised anti-immunoglobulin E (IgE) monoclonal antibody, indicated as add-on therapy for moderate-to-severe persistent allergic (IgE-mediated) asthma. Here, we report the interim results of a 52-week observational study of OMA in patients in India, stratified by baseline severity of asthma.

In this open-label, non-comparative, non-interventional study, patients (age = 12 years) with moderate-to-severe persistent allergic asthma, inadequately controlled despite ICS + LABA (GINA step 4) treatment, were recruited. All patients were receiving OMA at baseline. Outcomes were assessed every 4 weeks, and mean change (D) in FEV1, ACQ5 score, ACT score from baseline to end of study was analysed using a logistic regression model.

Conclusions A significant dose-response was found between low- and high-dose FP/FORm with the higher dose demonstrating a greater reduction in airway responsiveness to AMP.

Introduction

AQLQ data from four phase III studies were pooled to assess how AQLQ scores are affected by treatment with fluticasone propionate (FP)/formoterol fumarate (FORM) in a single MDI (FP/FORM; flutiform) compared with other combination treatments.

Method

AQLQ data from a pooled analysis of two phase III open-label studies in patients with mild-moderate/severe asthma [pool 1; FP/FORM 50/5 or 125/5 (n = 206) vs. FP 50 + FORM 12 given together in separate inhalers and FP/salmeterol 50/25 or 125/25 (n = 206)], and a pooled analysis of two phase III double-blind studies in patients with moderate/severe asthma [pool 2; FP/FORM 250/10 (n = 294) vs. FP 250 + FORM 12 given together in separate inhalers and budesonide/Form 200/6 (n = 295)] were analysed. AQLQ scores range from 1–7; a low score indicates the most severe impairment. Change in AQLQ from baseline to end of study was analysed using an ANCOVA.

Results

In pool 1, both groups had a similar increase in overall AQLQ score from baseline to end of study (0.635 in the FP/FORM group and 0.771 in the combination group) and the percentage of patients with a clinically relevant change in overall AQLQ score was 56% and 59%, respectively. In pool 2, the mean increase in overall AQLQ score from baseline to end of study was 0.837 in the FP/