

FORM group and 0.756 in the combination group, with 58% and 56% of patients experiencing a clinically relevant change in overall AQLQ score, respectively. The difference between the groups in each analysis was not statistically significant.

**Conclusion** FP/FORM has a similar effect on the quality of life of asthma patients as other combination treatments, with a similar improvement shown in each treatment group for both pools. Over 50% of patients in both treatment groups showed a clinically relevant change in AQLQ from baseline to end of study.

## REFERENCES

1. Juniper EF, et al. *Am J Respir Med* 2002;1(6):435–40.

## P169 TIOTROPIUM IS EFFECTIVE IN PATIENTS WITH SEVERE ASTHMA WITHOUT EVIDENCE OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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**Rationale** Given the known effectiveness of tiotropium in chronic obstructive pulmonary disease (COPD) and the significant benefit observed in COPD patients with concomitant features of asthma, it is relevant to investigate whether patients included in the recent large trials of tiotropium in asthma can be confidently considered to have asthma alone.

**Methods** Baseline characteristics were analysed for patients enrolled in two replicate Phase III, randomised, double-blind, placebo-controlled, parallel-group studies of tiotropium in asthma patients symptomatic despite treatment with inhaled corticosteroids plus long-acting beta agonists (Kerstjens *et al.* NEJM 2012). The entry criteria were: age 18–75 years; asthma diagnosed before the age of 40 years; ≥5-year history of asthma; score of ≥1.5 in the Asthma Control Questionnaire (ACQ) 7; and life-long non-smokers or ex-smokers (<10 pack-years). Patients were also required to have persistent airflow limitation. Asthma diagnosis was confirmed in line with current Global Initiative for Asthma guidelines. Patients with a diagnosis of COPD or other lung disease were excluded from the studies.

**Results** 912 patients were enrolled: 456 received add-on treatment with tiotropium and 456 received placebo. Mean age of the study population was 53.0 years; 37.6% of patients were aged ≥50 years. Mean age at diagnosis of asthma was 22.7 (range 0–44) years. Median duration of asthma was 28.0 (range 5–72) years, with 76.5% of patients having asthma for ≥20 years before enrolment. The majority of patients (75.9%) were life-long non-smokers; 24.1% were ex-smokers with a median number of pack-years of only 5.0. Mean ACQ score was 2.6 (range 1–5). Mean immunoglobulin E was 1210 mol/L. The mean (± SD) bronchodilator response to salbutamol was 217 ± 217 mL.

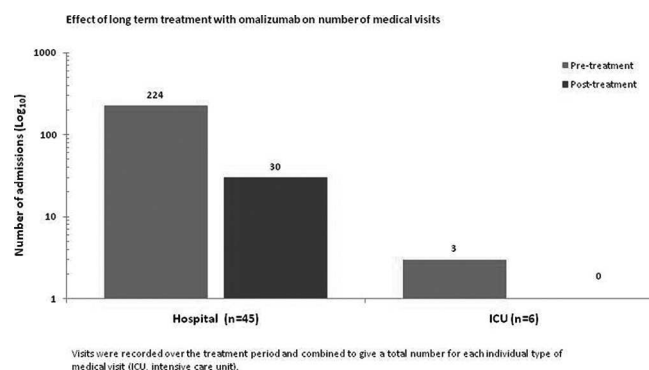
**Conclusions** The age of onset, duration of symptoms, lack of smoking, allergic status and bronchodilator response provide reasonable certainty that the patients enrolled in these studies had asthma and not COPD. Features compatible with COPD were thus more likely to reflect the effects of long-standing severe persistent asthma than the alternative diagnosis, and the efficacy demonstrated by tiotropium to represent improvement of asthma.

## P170 LONG-TERM EFFECTIVENESS OF OMALIZUMAB IN PATIENTS WITH SEVERE PERSISTENT ALLERGIC (IGE-MEDIATED) ASTHMA: UK CENTRE REAL-LIFE EXPERIENCE

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Omalizumab has been shown to be an effective add-on therapy for patients with uncontrolled severe persistent allergic (IgE-mediated) asthma. There has been a steady accumulation of evidence on long-term effectiveness of omalizumab; however, data on real-life outcomes beyond one year of treatment in a UK clinical setting is limited. In this analysis, data were compared for a number of patients from the Heartlands Hospital (Birmingham, UK), to determine if improvements were sustained with longer-term treatment. Patients (n = 45, mean age 44.9 years, range: 19–69) received omalizumab for a mean duration of 49.3 months (range: 23–96). All patients with available data (n = 18/45) showed a clinically relevant improvement in asthma control questionnaire (ACQ) scores post-omalizumab (mean ΔACQ: 2.27, range: 0.5–4.1; mean baseline ACQ: 4.1, range: 3.7–4.7). In patients on oral corticosteroids (OCS) *vs* patients not on OCS (at baseline), improvements were greater: ACQ of patients on OCS at baseline was 4.1 and 1.6 post treatment *vs* 4.0 at baseline and 2.7 post treatment. Mean OCS dose reduced pre- to post-omalizumab: 30.5 to 7 mg/day. Reductions in hospital admissions/bed days were seen post-treatment (figure). There were also reductions in work/school days missed in 17/19 patients; the other 2 patients showing no change. Overall mean FEV<sub>1</sub> was improved in the majority of patients with available data (17/20). Results from this real-life follow-up study demonstrate that improved outcomes in patients with severe allergic asthma are sustained with longer-term omalizumab therapy.



Abstract P170 Figure 1.

## P171 EFFICACY AND SAFETY OF BRONCHIAL THERMOPLASTY IN CLINICAL PRACTICE: EARLY RESULTS FROM A NATIONAL REGISTRY

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