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**

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


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10.1136/thoraxjnl-2013-204457.320

**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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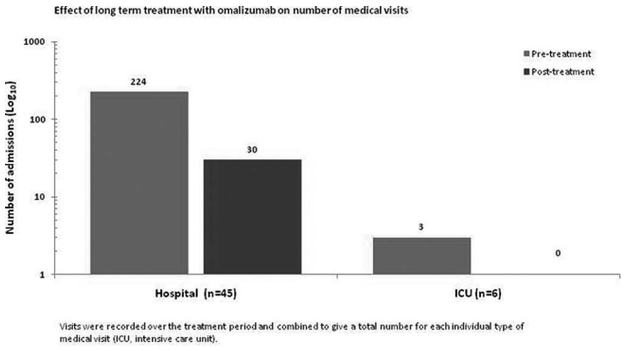
10.1136/thoraxjnl-2013-204457.321

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 ?ACQ: 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 $FEV_1$ 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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10.1136/thoraxjnl-2013-204457.322

**Introduction and Objectives** NICE Guidance for bronchial thermoplasty (BT) recommended the collection of safety and efficacy outcomes through the BTS Difficult Asthma Registry. This study summarises the data collected to June 2013, with objectives of describing the demographic and baseline characteristics of patients undergoing BT and early consideration of safety and efficacy, which will be updated for presentation at the December 2013 meeting.

**Methods** Records for 21 patients from 5 UK centres were studied. Age, gender, lung function and quality of life were compared to those reported in two previous clinical trials. Potential safety issues were examined and efficacy outcomes compared to baseline.

**Results** Data:20 baseline records, 62 BT procedure records, 9 patients followed up to 6 months, 7 followed up to 12 months. At follow-up, 12 patients had data at 6 and/or 12 months for pre bronchodilator $FEV_1$ and AQLQ to enable comparison with baseline. Baseline demographics and characteristics are presented in Table 1.

Outcomes: one patient was re-admitted to hospital for 3 days with an exacerbation after the second of three routine BT procedures, but recovered to complete the final procedure. 17 patients were admitted post-procedure (max 8 days) but no adverse outcomes were reported. Mean AQLQ score at 6 months was 4.61 ± 1.80 (n = 10). 6/10 patients had improved AQLQ (> 0.5 above baseline) at 6 months and 2/3 at 12 months. 1/10 patients had worse AQLQ (> than 0.5 below baseline) at 6 months and 0/3 at 12 months. Mean pre-bronchodilator $FEV_1$ (% of predicted) at 6 months was 64.88 ± 26.57 (n = 8) and at 12 months 75.20 ± 13.77 (n = 5).

**Conclusions** Early indications are that this cohort are marginally older and have worse mean lung function and AQLQ scores at baseline than patients in two previous clinical trials.No serious issues relating to equipment or adverse outcomes were observed. Patients were often admitted post-procedure - this may have been precautionary, as there were no reports of unanticipated procedural morbidity. To date, efficacy outcomes appear consistent with those observed in previous clinical trials, with a suggestion of smaller improvement in AQLQ score.

**Abstract P171 Table 1. Baseline demographics and characteristics.**

| | *BT registry* | *AIR2 trial* | *AIR trial* |
|---|---|---|---|
| Mean age (years) | 44.3 ± 11.5 (n=21) | 40.7 ± 11.9 (BT) | 40.0 ± 11.2 (BT) |
| | Range 23-69 | 40.6 ± 11.9 (C) | 40.8 ± 12.1 (C) |
| % female | 57 | 59 | 57 |
| Pre-bronchodilator $FEV_1$ | 70.25 ± 23.5 (n=16) | 77.8 ± 15.7 (BT) | 72.5 ± 10.9 (BT) |
| (% of predicted) | range: 22-105 | 79.7 ± 15.1 (C) | 74.9 ± 8.9 (C) |
| AQLQ score | 4.17 ± 1.2 (n=14) | 4.30 ± 1.17 (BT) | 5.6 ± 0.9 (BT) |
| | range 2.44 - 6.31 | 4.32 ± 1.21 (C) | 5.6 ± 0.9 (C) |

# Monitoring and management of sleep disordered breathing and respiratory failure

## P172 ACUTE NIV AND MORTALITY - FAILURE OF DELIVERY OR PATIENT SELECTION?

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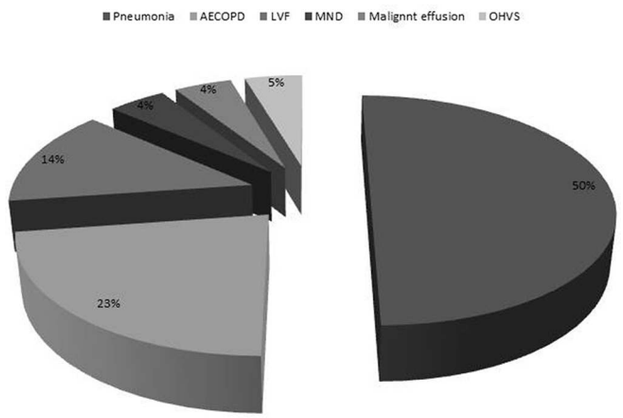
10.1136/thoraxjnl-2013-204457.323

**Background** Non-invasive ventilation (NIV) is an established treatment for patients with acute ventilatory failure. It can be successfully provided on a specialist ward, rather than intensive care (ICU) when certain criteria are met. It is frequently delivered outside ICU when a patient is deemed not suitable for invasive ventilation.

**Methods** Deaths in 2012 on our dedicated ventilation unit were analysed as part of ongoing clinical governance. Information on demographics, admission diagnosis, respiratory and metabolic acidosis, consolidation or pulmonary oedema on chest radiograph reports, Glasgow Coma Score (GCS), serum creatinine and hospital length of stay prior to NIV were recorded. Escalation of care and resuscitation decisions were noted.

**Results** There were 228 admissions for acute NIV, with 31 recorded deaths (13.6%), 22 case notes were available for review. Mean age was 79 years, 77.3% had known COPD, admission median MRC score of 4, and 18.2% had been in hospital for >7 days before NIV. All had acute hypercapnic respiratory failure. Not for resuscitation decisions had been made for 95.5% prior to NIV, and 100% had NIV as a 'ceiling of care'. Mean pH was 7.25 (SD 0.06), similar to previous reports of admissions to our unit[1], 22% had mixed acidosis (BE <-2.0 mmol/l). GCS was <8 in 9% and 36.4% had serum creatinine >100 mol/l, all triggering alerts for acute kidney injury. Admission diagnoses are shown in figure 1. Radiographic consolidation was reported in 59.1% and pulmonary oedema in 18.2%.




**Abstract P172 Figure 1. Admitting diagnoses based on initial clinician assessment.**

**Conclusion** The mortality of patients receiving acute NIV is low[2]. Most deaths had an underlying diagnosis of COPD, they were an elderly frail group, deemed inappropriate for escalation to critical care. There were multiple risk factors for NIV failure on initiation of therapy. Whilst a trial of NIV may have been appropriate based purely on blood gases, it was at high risk of failure and discussion about end of life care may have offered an alternative approach.

### REFERENCES

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