

Results Between June 2013 and December 2015, 246 patients with advanced COPD underwent a CRA: 61.0% male, mean (SD) age 66.0 (9.1) yrs, FEV₁/predicted 31.1% (10.4%). 98.4% of participants were in GOLD combined assessment group D. The prevalence of the 13 comorbidities ranged from 68.8% (muscle wasting) to 7.7% (renal impairment). 93.9% of participants had at least two of the assessed comorbidities. Cluster analysis was applied to a subsample of 203 participants with sufficient data: five multimorbid clusters were identified according to a significantly higher prevalence of certain comorbidities: Cluster 1 – psychological disease, Cluster 2 – left ventricular systolic dysfunction and anaemia, Cluster 3 – features of cachexia, Cluster 5 – features of metabolic syndrome and vitamin D deficiency. Cluster 4 had a significantly lower prevalence of comorbidities. Table 1 shows the differences between the five clusters in demographics, airflow limitation, health status, hospital admissions, use of antibiotics and steroids, and future cardiovascular risk.

Conclusions In this cohort of patients with advanced COPD, five multi-morbid phenotypes were identified. The phenotypes differed significantly in comorbidity prevalence, airflow limitation, health status and future coronary heart disease risk, however the number of hospital admissions in the past year was similar.

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P55

BENEFITS OF TIOTROPIUM/OLODATEROL ON SYMPTOMS AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH MODERATE TO SEVERE COPD WITH CHRONIC BRONCHITIS AND/OR EMPHYSEMA

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Rationale Chronic bronchitis and emphysema are common features of chronic obstructive pulmonary disease (COPD), and are associated with adverse symptoms and poor health-related quality of life. The efficacy and safety of the combination of tiotropium (T), a long-acting muscarinic antagonist, and olodaterol (O), a long-acting β_2 -agonist, has previously been established in COPD. This *post hoc* analysis of data from two Phase III studies was conducted to assess the effects of this combination on lung function, symptoms and health-related quality of life in patients with COPD with chronic bronchitis and/or emphysema.

Methods In two replicate, double-blind, parallel-group, placebo-controlled trials (OTEMTO[®] 1 and 2), patients with COPD (GOLD 2–3) were randomised to receive T/O 5/5 μ g, T/O 2.5/5 μ g, T 5 μ g or placebo (P) for 12 weeks via Respimat[®] inhaler. 1 Patients were classified as having chronic bronchitis, emphysema or both based on the investigator's clinical judgement. Lung-function testing was performed during the studies and forced expiratory volume in 1 second (FEV₁) area under the curve from 0–3 hours (AUC_{0–3}) and trough FEV₁ responses (i.e., change from baseline) calculated. Patients also completed the St George's

Respiratory Questionnaire (SGRQ) and the Mahler Transition Dyspnoea Index (TDI). Comparisons between T/O 5/5 μ g, T 5 μ g and P at Week 12 are reported here.

Results The numbers of patients included in the analysis were as follows: bronchitis, 506; emphysema, 476; both bronchitis and emphysema, 206. The baseline characteristics of these three groups were generally comparable. After 12 weeks of treatment, there were significant improvements in FEV₁ AUC_{0–3} and trough FEV₁ in all groups, with similar improvements across the groups. Significant improvements in SGRQ and TDI occurred in all groups at Week 12 and, again, these seemed to be similar (Table).

Conclusions T/O 5/5 μ g resulted in significant improvements in lung function, dyspnoea and health-related quality of life in patients with moderate to severe COPD with bronchitis, emphysema or both bronchitis and emphysema.

Abstract P55 Table 1

Comparison at		Bronchitis	Emphysema	Both
Week 12				
FEV ₁ AUC _{0–3} response	T/O – P	0.306 (0.264, 0.347) ^b	0.321 (0.277, 0.366) ^b	0.285 (0.203, 0.366) ^b
	T/O – T	0.097 (0.055, 0.138) ^b	0.121 (0.079, 0.162) ^b	0.086 (0.008, 0.165) ^a
Trough FEV ₁ response	T/O – P	0.157 (0.115, 0.199) ^b	0.178 (0.137, 0.220) ^b	0.147 (0.081, 0.212) ^b
	T/O – T	0.024 (–0.018, 0.066)	0.044 (0.004, 0.085) ^a	0.021 (–0.044, 0.087)
SGRQ	T/O – P	–6.16 (–8.19, –4.13) ^b	–6.76 (–8.87, –4.65) ^b	–6.76 (–10.06, –3.47) ^b
	T/O – T	–2.63 (–4.66, –0.61) ^a	–2.24 (–4.33, –0.16) ^a	–3.10 (–6.40, 0.20)
TDI	T/O – P	2.11 (1.52, 2.69) ^b	2.22 (1.63, 2.81) ^b	2.43 (1.47, 3.38) ^b
	T/O – T	0.61 (0.02, 1.19) ^a	0.74 (0.16, 1.32) ^a	0.53 (–0.43, 1.49)

Adjusted mean (95% confidence interval) differences
^ap<0.05; ^bp<0.001

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Please refer to page A271 for declarations of interest in relation to abstract P55.

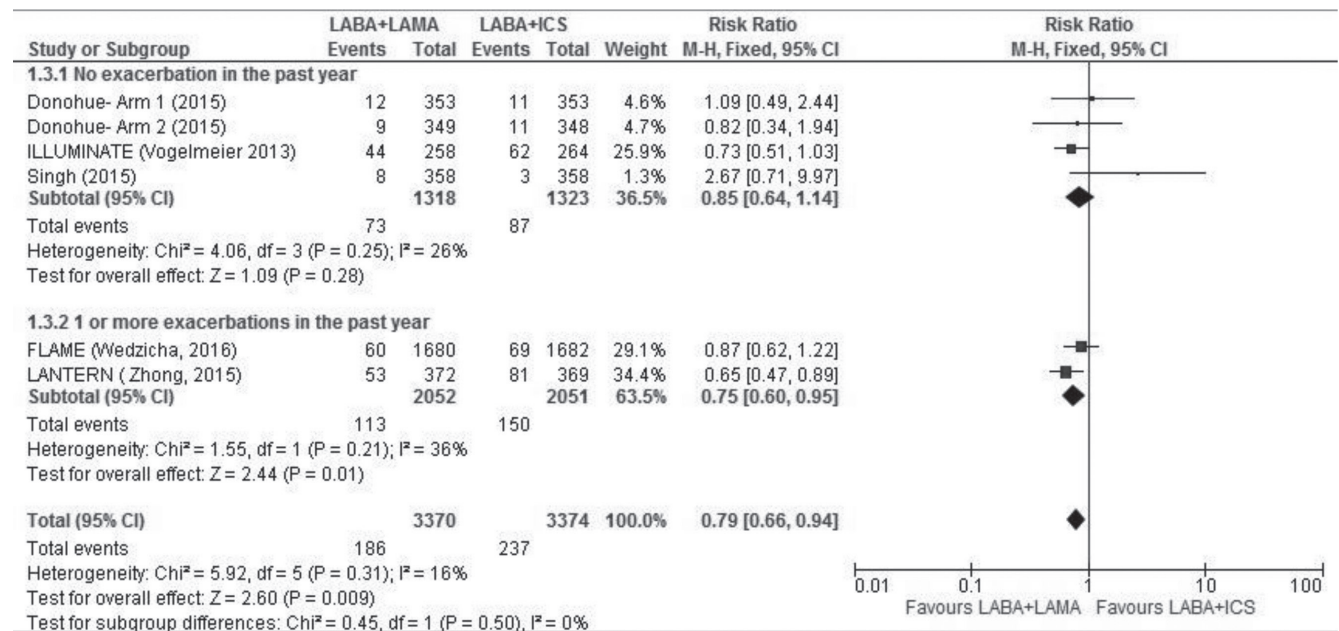
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EFFICACY AND SAFETY OF LONG-ACTING BETA AGONISTS + LONG ACTING MUSCARINIC ANTAGONISTS VS. LONG-ACTING BETA AGONISTS + INHALED CORTICOSTEROIDS IN COPD: A META-ANALYSIS

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Background and significance Current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend the use of long-acting beta agonists (LABA) plus inhaled corticosteroids (ICS), or long-acting muscarinic antagonists (LAMA) for the treatment of patients with moderate to severe



Abstract P56 Figure 1

COPD. The combination of LABA+LAMA is recently indicated for COPD patients with severe symptoms; however, its role in reducing exacerbations is less clear.

Methods We performed a meta-analysis of randomised controlled trials that compared efficacy and safety of LABA+LAMA versus LABA+ICS in moderate to severe COPD patients. The primary outcome is the rate of COPD exacerbations. Other outcome measures include improvement in trough FEV₁, St. George Respiratory Questionnaire for COPD (SGRQ-C) scores, transition dyspnea index (TDI) scores, rescue medication use and pneumonia risk. Analysis was performed in accordance with the Quality of Reporting of Meta-Analyses (QUORUM) guidelines.

Results A total of 6 RCTs with 3370 patients were included. Over-all exacerbation rates were 21% lower in those treated with LABA+LAMA versus LABA+ICS (RR 0.79, [95% CI: 0.66–0.94]). This effect is more pronounced in patients who had >1 exacerbation per year, showing 25% lower exacerbation rates (RR 0.75 [0.60–0.95]) compared to those with no history of prior exacerbations (RR 0.85 [0.61–1.14]). Patients given Indacaterol+Glycopyrronium also experienced lower rates exacerbation versus LABA+ICS (RR 0.71 [0.57–0.59]) compared to those given Umeclidinium+Vilanterol (RR 1.16 [0.68–2.00]).

There were also statistically significant improvements in FEV₁ (mean difference 70 mL [95% CI: 0.07–0.07 Liters]), improvement in SGRQ-C (mean difference –0.92 points [–0.95, –0.90]), improvement in TDI scores (mean difference 0.24 [0.23–0.25]) and decrease in use of rescue medications (mean difference –0.20 puffs/day[–0.21, –0.20]). Pneumonia risk was 41% lower in patients given LABA+LAMA compared LABA+ICS (RR 0.59 [0.43 – 0.80]).

Conclusions The combination of LABA+LAMA is safer and more effective in reducing exacerbations and improving clinical outcomes compared with LABA+ICS in patients with moderate to severe COPD.

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THE COST-CONSEQUENCE OF FLUTICASONE FUROATE/ VILANTEROL 100/25 MCG IN THE UK USING THE RESULTS FROM THE COPD SALFORD LUNG STUDY

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Introduction To support clinicians and healthcare organisations in their decision making on Chronic Obstructive Pulmonary Disease (COPD) related care, there is a need for studies conducted in patient populations which are representative of everyday clinical practice. The Salford Lung Study (SLS) is an open label prospective randomised controlled effectiveness trial (RCT). The study was conducted between 2012 and 2015. SLS investigated the effectiveness and safety of initiating treatment with once daily fluticasone furoate/vilanterol 100/25 microgram (FF/VI) compared with continuing with usual COPD maintenance treatment (usual care) in patients with COPD in an everyday clinical setting. Compared with usual care, FF/VI statistically significantly reduced the annual rate of moderate and severe exacerbations by 8.41% (NNT = 7) in the intention to treat population (≥1 exacerbation in previous 3 y; n = 2799), and in patients with ≥1 exacerbation in previous 1 y; n = 2269). The current study estimates the potential economic impact of these results in a typical local UK payer environment.

Methods A total of 1000 patients with COPD were included in an Excel based cost-consequence model. The model has a 1-year time-horizon. It was assumed that within one year the use of FF/VI would increase from 5% to 20%. Mean annual rates of moderate/severe exacerbations after twelve months for the ITT population were directly obtained from the RCT and included in the model (1.50 FF/VI and 1.64 usual care). Serious adverse events (SAEs) were excluded from the analysis. Costs were obtained