

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

from UK public sources and encompassed annual drug costs (£268 FF/VI; £491 usual care), and COPD exacerbation management costs (moderate £114; severe £2,053).

**Results** Substituting usual care with FF/VI is likely to be associated with reduced COPD medication and exacerbation management costs. Total annual savings of £34,000 were obtained for a population of 1000 patients with COPD.

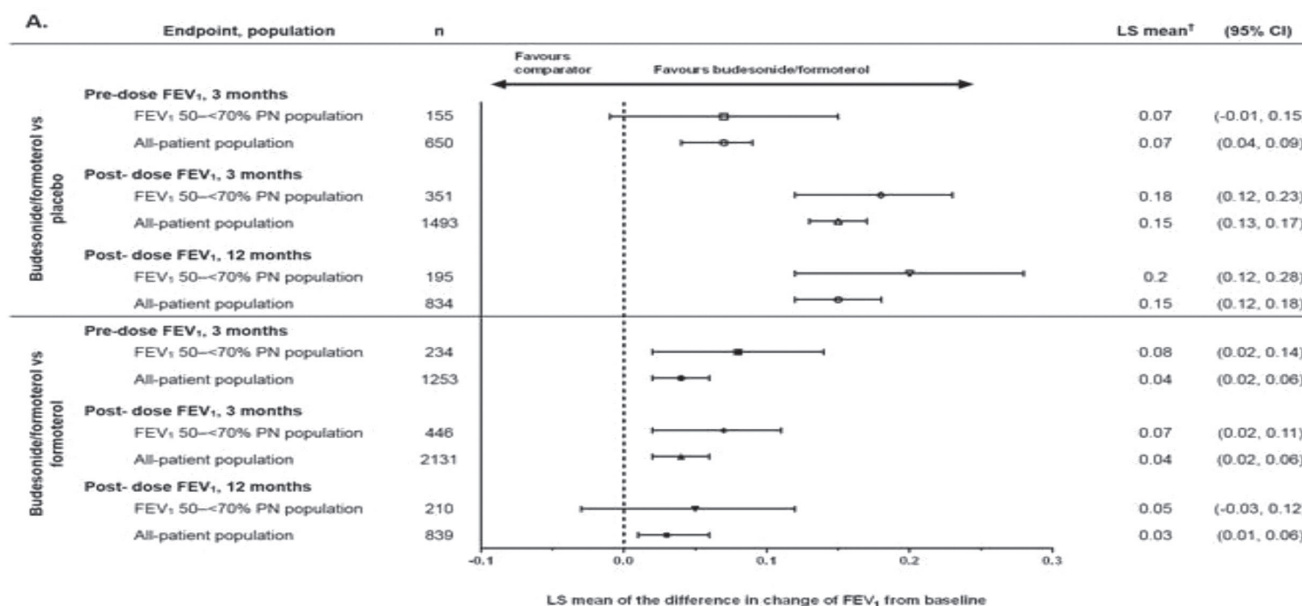
**Conclusion** In an everyday UK clinical setting, substituting usual care with FF/VI in patients with COPD can result in substantial annual cost savings. These results are relevant for clinicians and health care organisations.

**P58 EFFICACY OF BUDESONIDE/FORMOTEROL IN COPD PATIENTS WITH A POST-BRONCHODILATOR FEV<sub>1</sub> 50 TO <70% OF PREDICTED NORMAL: POOLED ANALYSIS ACROSS FOUR PHASE III/IV STUDIES**

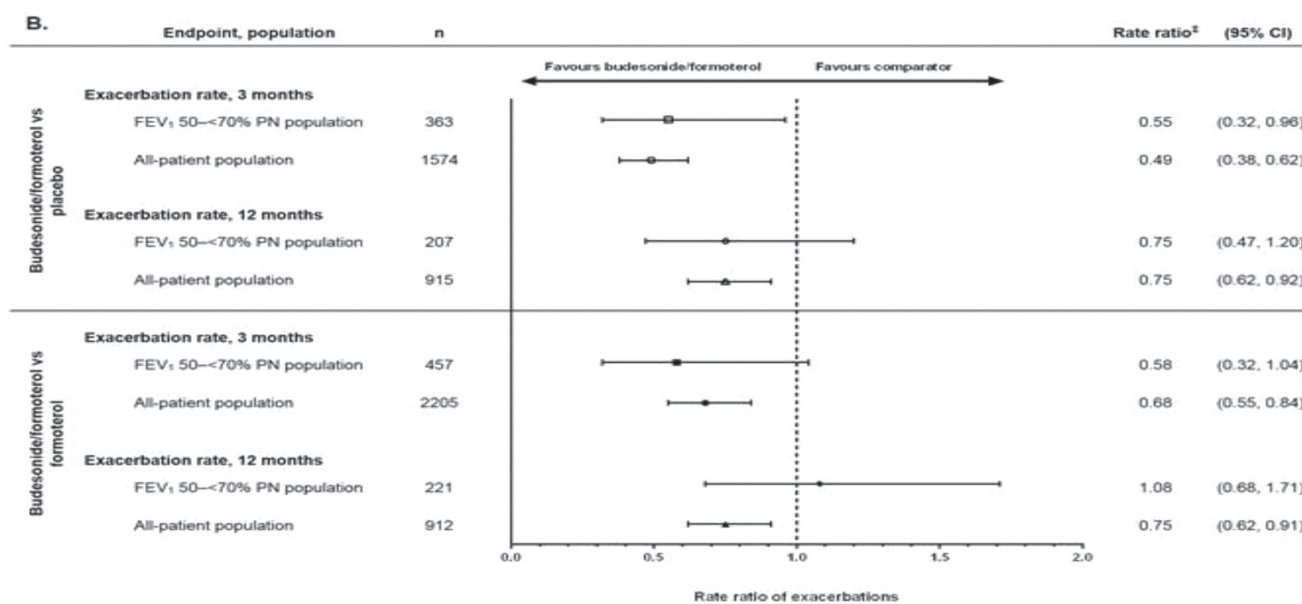
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**Background** GOLD guidelines have changed from classifying COPD severity using pre-bronchodilator FEV<sub>1</sub> to classifying severity based on post-bronchodilator FEV<sub>1</sub>. We therefore conducted a pooled *post-hoc* analysis of four budesonide/formoterol (Symbicort®) Turbuhaler® trials in COPD (which included patients based on pre-bronchodilator FEV<sub>1</sub>), assessing efficacy and safety



<sup>†</sup>The LS mean is the difference between budesonide/formoterol and the comparison treatment in mean change from baseline FEV<sub>1</sub>, determined by ANCOVA



<sup>‡</sup>The rate ratio is the exacerbation rate ratio between budesonide/formoterol and the comparison treatment, determined by a negative binomial model

ANCOVA, analysis of covariance; CI, confidence interval; FEV<sub>1</sub>, forced expiratory volume in one second; LS, least squares; n, number of evaluable patients; PN, predicted normal

**Abstract P58 Figure 1** Comparison of FEV<sub>1</sub> (A) and exacerbation rates (B) with budesonide/formoterol treatment vs placebo and vs formoterol for the FEV<sub>1</sub> 50-<70% PN subpopulation and the all-patient population. Pooled data across four phase III/IV studies