**Title:** Pneumonia in COPD patients treated with fixed ICS/LABA combinations

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**Body:** Background Inhaled corticosteroids (ICS) in combination with long-acting β₂-agonists (LABA) improve quality of life and reduce exacerbations in chronic obstructive pulmonary disease (COPD). Increased prevalence of pneumonia has been indicated during treatment with fluticasone but not with budesonide, but no direct comparisons have been performed. Objectives To investigate occurrence of pneumonia in a COPD population treated with fixed ICS/LABA combination; budesonide/formoterol (B/F) or fluticasone/salmeterol (F/S) (NCT01146392). Methods Medical records' data from primary care patients ≥ 18 years was linked to Swedish hospital and drug register data for 1999 – 2009. Index date was first prescription of a fixed ICS/LABA combination post COPD diagnosis. Propensity score matching was done at index date. Results The total sample covered 9,893 patients. Matching gave two equivalent populations (2,734 patients/group) using either B/F or F/S at index. Mean prescribed daily steroid dose was 562 µg budesonide and 786 µg fluticasone. In all, 15,353 pneumonia diagnoses were seen. 44% of all patients had experienced pneumonia within 8 years post COPD diagnosis. Yearly rate of pneumonia for B/F was significantly lower, 0.062 compared to 0.11 for F/S; 44% difference (p<0.0001). Yearly rate of hospitalisations due to pneumonia was 0.041 vs 0.074 (-45%); days at hospital/year 0.34 vs 0.63 (-46%) for B/F vs F/S, respectively. Time to first diagnosis of pneumonia showed a hazard ratio of 0.794 (95% CI 0.706, 0.892) in favor of B/F. Conclusion In this observational register study, COPD patients treated with budesonide/formoterol experienced fewer pneumonias than patients treated with fluticasone/salmeterol. Study sponsor; AstraZeneca.