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Title: Inflammatory biomarkers and exacerbations in chronic obstructive pulmonary disease

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Body: Background: We tested the hypothesis that elevated levels of inflammatory biomarkers in patients with stable chronic obstructive pulmonary disease (COPD) are associated with an increased risk of having exacerbations. Methods: We measured baseline C-reactive protein (CRP), fibrinogen, and leukocyte count in 6,574 COPD patients from the Danish general population. During a median four years follow-up, we recorded 3,083 exacerbations defined as short course treatment with oral corticosteroids and/or hospital admission due to COPD. CRP, fibrinogen, and leukocyte count were defined as high or low according to cut-points of 3 mg per liter, 14 µmol per liter, and 9 x10⁹ per liter, respectively. Results: In the first year of follow-up, multivariable adjusted odds ratios for having frequent exacerbations were 1.3(95% confidence interval, 0.7 to 2.4) in individuals with one high biomarker, 2.0(1.8 to 3.6) in individuals with two high, and 4.2(2.1 to 8.2) in individuals with three high biomarkers compared to individuals with no elevated biomarkers. Corresponding hazard ratios using maximum follow-up time were 1.5(1.1 to 1.9), 1.8(1.4 to 2.3), and 2.8(2.0 to 3.7), respectively. Relative risks were consistent across grades of COPD and history of frequent exacerbations. The highest 1-year, 3-year, and 5-year absolute risk of frequent exacerbations in individuals with three high biomarkers were found in those with the most severe COPD and/or history of frequent exacerbations. Conclusions: Simultaneously elevated levels of CRP, fibrinogen, and leukocyte count in patients with COPD are associated with increased risk of having exacerbations independent of degree of airflow limitation and previous exacerbations.