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**Title:** Effect of roflumilast on quality of life in frequent and infrequent exacerbators

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**Body:** Background COPD exacerbations deteriorate quality of life (QoL) in COPD patients. This single-arm, non-interventional study investigated the effects of add-on roflumilast 500µg o.d. on QoL, assessed using the COPD Clinical Questionnaire (CCQ) and the COPD Assessment Test™ (CAT). Primary results were reported elsewhere. Here we report results on subgroups stratified by exacerbation frequency. Methods Patients with severe COPD (65% male; mean age: 65.5±9.9 years; mean BMI 27.3±5.7 kg/m<sup>2</sup>) were treated with roflumilast under real-life conditions for 6 months (intention-to-treat, ITT). Frequent exacerbators (FE) (n=1,841) were defined as patients with ≥2 moderate/severe exacerbations, and infrequent exacerbators (IFE) (n=1,736) as having <2 in the 12 months prior to study start (V1). CCQ and CAT scores were measured at V1, 3 months (V2) and 6 months (V3). Results There was significant improvement from V1 in total CCQ scores (±SD) at V3 in both FE (−1.0±1.1; n=999) and IFE (−0.7±1.0; n=848) (p<0.001). Improvements from V1 in each CCQ domain at V2 and V3 were also reported in both subgroups (p<0.001). Changes were larger in FE versus IFE at V3 (between-group comparison: p<0.001). These results were confirmed in the per-protocol analysis. Mean changes in total CAT scores between V1 and V3 were −6.6±7.3 (N=962) in FE and −4.9±7.3 (N=809) in IFE (both p<0.001). Changes were also larger in FE compared with IFE (between-group comparison: p<0.001). Conclusions Roflumilast significantly improved health status, as measured by both CCQ and CAT in frequent exacerbators and infrequent exacerbators, respectively. Improvements were clinically meaningful and more pronounced in frequent exacerbators.