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Title: Effectiveness of tiotropium in low-risk patients according to new GOLD severity grading

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Body: Background: GOLD recently updated their COPD severity classification to include risk of exacerbations. Increased risk is typically defined by a FEV_1 of <50% pred and/or ≥2 exacerbations in the previous year (C+D) and low risk by a FEV_1 ≥50% pred and 0-1 exacerbation in the previous year (A+B). Aims and objectives: To examine the effect of tiotropium 18 µg qd via Handihaler® in GOLD low risk patients (pts) using data from a 4-y, randomized, double-blind, placebo-controlled trial in COPD (UPLIFT®). Methods: Retrospective analysis of exacerbations, lung function and QoL (SGRQ) in low-risk pts (pts with a baseline postbronchodilator [BD] FEV_1 %pred ≥50% and ≤1 oral steroid/antibiotic course in the previous year). Pts with high risk (FEV_1 %pred <50% or more than 1 course of oral steroids/antibiotics) were also analyzed. Results: 2012 pts were analyzed (mean age 64.5±8.6 y, male 74%, mean (±SD) baseline postBD FEV_1 1.65 (0.37) L and FEV_1 %pred (±SD) 58.9 (5.8). The HR (tiotropium vs control) for time to first exacerbation was 0.76 (95% CI, 0.68; 0.86; P<0.0001); mean annual exacerbation rates were 0.43 (95% CI, 0.40; 0.48) vs 0.61 (0.56; 0.66), rate ratio 0.72 (0.63; 0.81; P<0.0001). The SGRQ total score after 4 y was significantly improved by tiotropium vs placebo: –3.63 (95% CI, –5.14; –2.12; P<0.0001) and the respective increase for trough FEV_1 was 110 mL (95% CI, 84; 136; P<0.0001). SGRQ and trough FEV_1 were significantly improved at all time points. The above-mentioned endpoints were also significantly improved in the high-risk population. Conclusion: Tiotropium qd was effective throughout 4 y in reducing exacerbations and improving lung function and QoL in low-risk pts with COPD (GOLD A+B).