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Title: The effect of tiotropium on lung dynamic hyperinflation and treadmill exercise capacity in mild to moderate COPD

Dr. Richard 19746 Casaburi casaburi@ucla.edu MD ¹, Dr. Francois 19824 Maltais Francois.Maltais@fmed.ulaval.ca MD ², Dr. Janos 19825 Porszasz porszasz@ucla.edu MD ¹, Dr. Frank 19826 Albers frank.albers@boehringer-ingelheim.com ³, Dr. Qiqi 19827 Deng qiqi.deng@boehringer-ingelheim.com ³, Dr. Ahmar 19857 Iqbal ahmar.iqbal@pfizer.com ⁴, Heather 19876 Paden heather.bennett@boehringer-ingelheim.com ³ and Dr. Denis 19877 O'Donnell odonnell@queens.edu MD ⁵. ¹ Division of Respiratory and Critical Care Physiology and Medicine, Rehabilitation Clinical Trials Center, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, CA, United States, 90502 ; ² Centre de Recherche, Institut Universitaire de Cardiologie et de Pneumologie de Québec, Université Laval, Quebec, Canada, GV1-4G5 ; ³ Medical Affairs Respiratory, Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT, United States, 06877 ; ⁴ Respiratory Medical Affairs, Pfizer Inc, New York, NY, United States, 10017 and ⁵ Department of Medicine, Queen's University & Kingston General Hospital, Kingston, ON, Canada, K7L-2V6 .

Body: RATIONALE: In previous studies tiotropium improved cycle exercise duration in GOLD II-IV COPD patients. This double-blind crossover study (NCT01072396) compared tiotropium with placebo in GOLD I and II COPD using treadmill exercise testing. METHODS: Patients were current or ex-smokers aged ≥ 40 y with post-bronchodilator FEV₁/FVC <70%, FEV₁ $\geq 50\%$ predicted, and dynamic hyperinflation (≥ 100 mL inspiratory capacity [IC] decrease during incremental treadmill exercise). Patients received tiotropium 18 μ g qd and placebo for 6 weeks each (random order, 4-week washout). Patients performed constant work rate treadmill exercise at 80% of peak incremental test work rate before and after each treatment period. The primary endpoint was the difference in exercise isotime IC change from baseline to Week 6 between tiotropium and placebo. Secondary endpoints included change in exercise duration. RESULTS: Patients (n=126, 52% male) had mean age 61 y, post-bronchodilator FEV₁/FVC 59% and FEV₁ 77% predicted. Baseline IC was 2.27 L and exercise duration 447 s. The difference in change in isotime IC from baseline to Week 6 between tiotropium and placebo was statistically significant (65 mL, P=0.009). The difference in change from baseline in exercise duration between tiotropium and placebo was not significant in the combined GOLD I+II (29.3 s, P=0.109) and GOLD I (-23.5 s, P=0.415) groups, but was statistically significant for GOLD II (63.0 s, P=0.007). CONCLUSIONS: Tiotropium was associated with reduced lung hyperinflation at rest and during exercise in GOLD I and II COPD patients. Significantly improved exercise duration was observed in GOLD II patients but not the combined or GOLD I groups.