spirometry to predict exacerbations and to indicate subsequent worsening of lung function resulting from a previous COPD exacerbation.

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Please refer to page A273 for declarations of interest in relation to abstract P297.

REFERENCE

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TIOTROPIUM/OLODATEROL THERAPY PROVIDES SYMPTOMATIC BENEFITS IRRESPECTIVE OF PRIOR MAINTENANCE TREATMENT: POST HOC ANALYSES OF THE OTEMTO® STUDIES

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Rationale The combination of tiotropium (T), a long-acting muscarinic antagonist (LAMA), plus olodaterol (O), a long-acting β_2 -agonist (LABA), is approved for once-daily maintenance treatment of COPD. The randomised, double-blind, Phase IIb OTEMTO® 1 and 2 studies (NCT01431274; NCT01431287) showed improvements in quality of life and lung function after 12 weeks' treatment with T/O compared to T alone or placebo in patients with moderate to severe COPD. This *post hoc* analysis investigated whether previous maintenance treatment with a long-acting bronchodilator or inhaled corticosteroid (ICS) influenced symptomatic benefits of T/O.

Methods Patients aged ≥ 40 years received T/O 2.5/5 μ g, T/O 5/5 μ g, T 5 μ g or placebo once daily for 12 weeks via Respimat® inhaler. St George's Respiratory Questionnaire (SGRQ) total score was a primary end point, alongside lung function (FEV₁ area under the curve from 0–3 hours and trough FEV₁ responses). Secondary end points included Mahler Transition Dyspnoea Index (TDI) focal score. Salbutamol/albuterol was provided as rescue medication and use was recorded in an e-diary. We report comparisons between T/O 5/5 μ g, T 5 μ g and placebo. **Results** Of the 1621 patients evaluated, 943 had received prior maintenance treatment (66.7% LABA; 59.4% LAMA; 64.5% ICS) and 678 had not. Similar improvements in mean SGRQ total score were observed with T/O compared to T and placebo, respectively, in patients receiving prior maintenance treatment (–2.02 and –4.59 units) and those without (–2.20 and –4.78 units) (Table). TDI focal scores improved with T/O compared to T and placebo, respectively, in patients receiving prior maintenance treatment (0.60 and 1.87 units) and those without (0.60 and 1.33 units) (Table). Patients with and without prior maintenance treatment demonstrated similar improvements in daytime and night-time rescue medication use and lung-function improvements with T/O compared to T and placebo.

Conclusions T/O provides symptomatic benefits as demonstrated by improvements in SGRQ score, TDI focal score and decreased rescue medication use compared to placebo and T, independent of previous maintenance treatment. These findings suggest T/O is beneficial over monotherapy when used as first COPD maintenance treatment.

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Abstract P298 Table 1

Treatment comparison	Prior maintenance treatment	No prior maintenance treatment
SGRQ total score		
T/O 5/5 μ g – placebo	–4.59 (–10.23, 1.06)	–4.78** (–6.93, –2.63)
T/O 5/5 μ g – T	–2.02 (–5.42, 1.37)	–2.20* (–4.34, –0.07)
Mahler TDI focal score		
T/O 5/5 μ g – placebo	1.87** (1.36, 2.39)	1.33** (0.76, 1.90)
T/O 5/5 μ g – T	0.60* (0.09, 1.10)	0.60* (0.04, 1.17)

Adjusted mean (95% confidence interval) **p<0.001, *p<0.05

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EFFECTS OF SYMPTOM SEVERITY AT BASELINE ON LUNG-FUNCTION AND SGRQ RESPONSES IN THE OTEMTO® STUDIES

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Rationale In the randomised, double-blind, Phase IIb OTEMTO® 1 and 2 studies (NCT01431274; NCT01431287), the combination of tiotropium (T), a long-acting muscarinic antagonist, plus olodaterol (O), a long-acting β_2 -agonist, showed meaningful improvements in quality of life (St George's Respiratory Questionnaire [SGRQ]) and lung function in patients with moderate to severe COPD after 12 weeks' treatment compared to T alone or placebo. This *post hoc* analysis investigated whether symptomatic status at inclusion, as measured by the modified Medical Research Council (mMRC) dyspnoea scale and the Baseline Dyspnoea Index (BDI), influenced lung-function and SGRQ responses.

Methods Patients aged ≥ 40 years received T/O 2.5/5 μ g, T/O 5/5 μ g, T 5 μ g or placebo once daily for 12 weeks via Respimat® inhaler. SGRQ total score and lung function (FEV₁ area under the curve from 0–3 hours [AUC_{0–3}] and trough FEV₁ responses) were primary end points. Patients completed the mMRC and BDI scales at baseline. We report comparisons between T/O 5/5 μ g, T 5 μ g and placebo.