Improving patient therapies in COPD

**P248** CURRENT COPD DISEASE BURDEN ASSOCIATED WITH MAINTENANCE MONOTHERAPY IN THE UK

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**Introduction** National Institute for Health and Care Excellence (NICE) recommends long-acting bronchodilators, including β2-agonists (LABAs) or muscarinic antagonists (LAMAs) as first-line maintenance treatment for patients with COPD. The aim of this descriptive study was to characterise a cohort of COPD patients who were on maintenance bronchodilator monotherapy for at least six months to establish their disease burden, measured by healthcare utilisation.

**Methods** Data were extracted from the UK Clinical Practice Research Datalink (CPRD) which also linked to Hospital Episode Statistics (HES). The monotherapy period spanned the first prescription of a LABA or LAMA until the end of the study period (31/12/2013) or until step-up to dual/triple therapy, for example the addition of another long acting bronchodilator, an ICS or ICS/LABA. A minimum of four consecutive prescriptions and six months on continuous monotherapy were required for study entry. Patients <50 years old at time of first COPD diagnosis or with another significant respiratory disease prior to the first COPD diagnosis were excluded. Disease burden was evaluated by measuring patients’ rate of consultations with a healthcare professional (HCP), COPD-related exacerbations, hospitalisations and referrals to key specialities.

**Results** A cohort of 8,811 COPD patients (94% GOLD stage A or B) on maintenance monotherapy was identified between 2002 and 2013; 45% (N=3,947) of these patients were still on monotherapy by the end of the study period. The median time from first COPD diagnosis to first monotherapy prescription was 56 days while the median time on maintenance bronchodilator monotherapy was 748 days. The median number of prescriptions during this period was 14. Patients had a median of 19 hospitalisations and referrals to key specialities, at a cost to the NHS.

**Conclusion** In summary, COPD patients who are on maintenance bronchodilator monotherapy for at least six months appear to remain on this therapy for over two years despite having a disease burden that requires healthcare resources, particularly HCP consultations, at a cost to the NHS.
Background Both tiotropium (T) and olodaterol (O) mono-therapies improve exercise endurance in patients with chronic obstructive pulmonary disease (COPD).

Objective To evaluate the effects of T+O fixed-dose combination on exercise endurance in patients with Global initiative for Chronic Obstructive Lung Disease (GOLD) 2–3 COPD after 12 weeks.

Methods TORRACTO (NCT01525615) was a 12-week, double-blind, parallel-group, placebo-controlled, Phase III study. Patients with GOLD 2–3 COPD received T+O 5/5 μg or placebo once daily via Respimat® Soft Mist™ inhaler. Primary end point was endurance time during constant work-rate cycle ergometry to symptom limitation after 12 weeks. Endurance time during exercise shuttle walking to symptom limitation after 12 weeks was also assessed in a subset of 165 patients. Other end points included pre-exercise inspiratory capacity.

Results 404 patients (269 men) were randomised (full analysis set n = 385). Mean post-bronchodilator forced expiratory volume in 1 second was 1.66 L (58.6% predicted). Endurance time during cycle ergometry was significantly increased by 14% with T+O 5/5 μg versus placebo at 12 weeks. Increases in endurance time during endurance shuttle walking were observed for both T+O doses versus placebo at 12 weeks (21% increase, nominal p = 0.06 for each dose). Both T+O doses increased pre-exercise inspiratory capacity versus placebo at 12 weeks (T+O 5/5 μg, 234 mL; T+O 2.5/5 μg, 207 mL; nominal p < 0.0001). No safety concerns were identified.

Conclusions T+O 5/5 μg improved endurance time during cycle ergometry versus placebo.