care and office based chest medicine clinics. A convenience sample of 500 was selected.

**Results** We report the characteristics of the first 250 COPD patients from our ongoing 500 patient survey.

**Basic demographics** 55% Male, 45% Female. Mean age patients 68 ± 12 yrs, all patients were previous smokers with 56 ± 10 pkt/yr smoking history. 34% remain current smokers.

Mean FEV1 48% ± 10%, Mean FEV1/FVC ratio 49% ± 10. Median mMRC dyspnea score 2. Mean CAT score 18 ± 10 (Range 0–38).

**GOLD Stage Classification** 13% GOLD Stage A, 67% GOLD Stage B, 1% GOLD Stage C and 19% GOLD Stage D.

**Current treatment** LAMA (long-acting muscarinic antagonist) was prescribed to over 90% of all patients in groups B, C and D whereas monotherapy with LABA (long acting beta-agonist) or dual bronchodilator with LABA/LAMA therapy was prescribed to less than 5%.

There was significant overtreatment with ICS/LABA in all categories with high dose ICS (inhaled corticosteroid) being preferred. 20% of patients in GOLD Stage A where receiving Triple therapy (LAMA + ICS/LABA) and a further 20% where receiving monotherapy with ICS/LABA, yet had no history of exacerbations. 30% of patients in GOLD Stage B where receiving Triple therapy (LAMA + ICS/LABA) yet had no history of exacerbations.

**Conclusion** Current Canadian Guidelines and the GOLD strategy focus on symptom relief and striving to prevent exacerbations with step-wise prescription of short and long-acting bronchodilators with individual or combinations of LAMA, LABA, LAMA/LABA or ICS/LABA inhalers. Patients in GOLD Group C are rare. Current prescription choices in our survey does not reflect current evidence or guidelines. We report a heavy reliance on ICS/LABA along with over prescription of triple therapy at all stages of disease.

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**P253** META – ANALYSIS ON STATINS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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10.1136/thoraxjnl-2014-206260.381

**Background** Chronic obstructive pulmonary disease (COPD) is an inflammatory lung disease characterised by progressive airflow limitation. Statins have anti-inflammatory and immunomodulating properties that could alter inflammation of the airways. The objective of this study is to systematically evaluate the effectiveness of adjunct statin therapy in improving exercise tolerance and pulmonary function indices in patients with chronic obstructive pulmonary disease.

**Search strategy and inclusion criteria** A thorough search was done using Medline and PubMed, with limits set on studies involving humans in a randomised control trial in English that examined the effect of statins in COPD.

**Study manoeuvres** All the articles retrieved were appraised separately and independently by two reviewers for its applicability, validity and the methodological quality of the randomised control trials by assessing allocation, blinding, and if follow up rate was adequate. Disagreements between the reviewers were resolved by consensus.

**Statistical analysis** Data collected were analysed using Review Manager Version 5.2.

**Results** A total of two articles met the end criteria. Outcome shows improvement in exercise time (treadmill test) at 95% CI, with statistically significant benefit with mean difference of 335.18 [253.93, 416.43] favouring Pravastatin group. The studies show inconclusive results for Pravastatin in improving FEV1 (%) with 95% CI with mean difference of 0.05 [-4.61, 4.7]. The outcome in total lung capacity shows inconclusive results but shows a trend toward benefit with 95% CI with mean difference of -0.08 [-0.46, 0.30]. Inspiratory capacity results at 95% CI with mean difference of 0.13 [-0.06, 0.32] showed an inconclusive outcome but has a trend toward benefit. Improvement in the Borg dyspnea score at 95% CI, showing statistically significant benefit with mean difference of -2.91 [-3.19, -2.63] favouring the Pravastatin group.

**Conclusions** Statins already have an established role in treating cardiovascular patients because of their cholesterol-lowering ability, but also have anti-inflammatory and immunomodulatory effects that are beneficial in airway inflammation in COPD. Statin administration to COPD patients showed amelioration in exercise tolerance, improvement in dyspnea scores and augmentation in pulmonary function indices. Thus, statins may be useful as adjucent to currently available therapies as well as improvement in lipid status.

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**P254** ONCE-DAILY TIOTROPIUM AND OLODATEROL FIXED-DOSE COMBINATION VIA THE RESPIMAT® IMPROVES OUTCOMES VERSUS MONO-COMPONENTS IN COPD IN TWO 1-YEAR STUDIES

8B Buhl, 1E Derom, 1G Ferguson, 1E Pizzichini, 1L Reid, 1H Watz, 1L Grönke, 1A Hamilton, 1K Tetzlaff, 1R Korducki, 1H Husman, 1S Waite-Wijker, 1F Malais. Pulmonary Department, Mainz University Hospital, Mainz, Germany; 2Ghent University Hospital, Ghent, Belgium; 3Pulmonary Research Institute of Southeast Michigan, Livonia, Michigan, USA; 4UPAIVA (Asthma Research Centre), Universidade Federal de Santa Catarina, Santa Catarina, Brazil; 5Dundee School of Medicine, University of Dundee, Dundee, New Zealand; 6Pulmonary Research Institute at Lung Clinic Grosshansdorf, Airway Research Center North, Member of the German Center for Lung Research, Grosshansdorf, Germany; 7Boehringer Ingelheim Pharma GmbH & Co KG, Ingelheim, Germany; 8Boehringer Ingelheim, Burlington, Ontario, Canada; 9Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, Connecticut, USA; 10Boehringer Ingelheim B. V., Aalmaar, The Netherlands; 11Centre de Recherche, Institut Universitaire de Cardiologie Et de Pneumologie de Quebec, Quebec, Canada

10.1136/thoraxjnl-2014-206260.382

**Introduction** Tiotropium (T), a once-daily long-acting muscarinic antagonist, is a well-established first-line maintenance treatment in chronic obstructive pulmonary disease (COPD); olopatadine (O) is a once-daily long-acting β2-agonist that has recently gained approval in several countries. Two Phase III replicate pivotal studies assessed the efficacy and safety of fixed-dose combinations of T and O (T+O) delivered via Respimat® Soft Mist™ inhaler in patients with GOLD 2–4 COPD.

**Methods** Two 52-week, double-blind, parallel-group studies randomised 5162 patients to T 5 μg, T 2.5 μg, T 5 μg, T+O 2.5/5 μg or T+O 5/5 μg. Primary efficacy end points were trough forced expiratory volume in 1 second (FEV1) response (ie change from baseline), FEV1 area under the curve from 0–3 h and St George’s Respiratory Questionnaire (SGRQ) total score after 24 weeks. Pooled data from the two studies are presented here; lung function from the individual studies will subsequently be provided.

**Results** All treatments resulted in clinically relevant improvements in lung function, with significant increases with both T+O doses over the individual components (p1 responses were 0.055 L (O 5 μg), 0.073 L (T 2.5 μg), 0.080 L (T 5 μg), 0.118 L (T+O 2.5/5 μg) and 0.123 L (T+O 5/5 μg) vs baseline).
L (T+O 2.5/5 μg) and 0.140 L (T+O 5/5 μg). SGRQ total scores improved by 5.1 (O 5 μg), 5.7 (T 2.5 μg), 5.6 (T 5 μg), 6.2 (T+O 2.5/5 μg) and 6.8 points (T+O 5/5 μg); differences between T+O 5/5 μg and O 5 μg and T 5 μg were statistically significant (p).

Conclusions T+O 5/5 μg significantly improved lung function and provided symptomatic benefit over O 5 μg and T 5 μg.

P255
ONCE-DAILY TIOTROPium RESPIMAT® ADD-ON TO AT LEAST ICS MAINTENANCE THERAPY REDUCES EXACERBATION RISK IN PATIENTS WITH UNCONTROLLED SYMPTOMATIC ASTHMA

Background A reduction in asthma exacerbation risk may provide improvements in clinical burden, patient experience and healthcare costs. In Phase III trials, once-daily tiotropium (delivered via the Respimat® SoftMist™ inhaler) added on to at least inhaled corticosteroids (ICS) improved lung function in patients with symptomatic asthma. We investigated exacerbation risk in each trial.

Methods Five Phase III, double-blind, placebo-controlled, parallel-group trials in patients with symptomatic asthma. Patients received tiotropium Respimat® 5 μg or placebo as add-on to at least ICS maintenance therapy (Table). Pre-planned co-primary or secondary end points were time to first severe exacerbation and time to any asthma worsening.

Results Mean baseline% of predicted forced expiratory volume in 1 second, seven-question Asthma Control Questionnaire score and time to any asthma worsening.

Conclusion Once-daily tiotropium Respimat® 5 μg add-on to at least ICS maintenance therapy consistently reduced exacerbations across asthma severities and so may be a beneficial add-on option to reduce current and future exacerbation risk.

Abstract P255 Table 1

<table>
<thead>
<tr>
<th>Trial</th>
<th>Background medication</th>
<th>Tiotropium Respimat® 5 μg Placebo</th>
<th>HR* (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICS + LABA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PrimoTinA-asthma*</td>
<td>(800 μg budesonide or equivalent)</td>
<td>122/453 (26.9)</td>
<td>149/454 (32.8)</td>
<td>0.79 (0.62, 1.00) 0.034</td>
</tr>
<tr>
<td>MezzoTinA-asthma*</td>
<td>(400-800 μg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS 400-800 μg</td>
<td></td>
<td>31/513 (6.0)</td>
<td>43/518 (8.3)</td>
<td>0.72 (0.45, 1.14) 0.164</td>
</tr>
<tr>
<td>GraziaTinA-asthma*</td>
<td>(200-400 μg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICS 200-400 μg</td>
<td></td>
<td>1/151 (0.7)</td>
<td>4/151 (2.6)</td>
<td>0.25 (0.03, 2.24) 0.216</td>
</tr>
</tbody>
</table>

*Hazard ratio; time to first severe exacerbation (versus placebo, <1 favours tiotropium Respimat®); 95% CI: 95% confidence interval; HR: hazard ratio; SD: standard deviation.

Abstract P256 Table 1

<table>
<thead>
<tr>
<th>Pts with AE, %</th>
<th>ICS</th>
<th>LABA</th>
</tr>
</thead>
<tbody>
<tr>
<td>T+O 0 μg</td>
<td>5 μg</td>
<td>2.5 μg</td>
</tr>
<tr>
<td>T 2.5 μg</td>
<td>5 μg</td>
<td>5 μg</td>
</tr>
<tr>
<td>T+O 5/5 μg</td>
<td>5 μg</td>
<td>5 μg</td>
</tr>
<tr>
<td>Total</td>
<td>1038</td>
<td>1032</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>17.4</td>
<td>15.1</td>
</tr>
<tr>
<td>Fatal AEs</td>
<td>1.3</td>
<td>1.2</td>
</tr>
<tr>
<td>Cardiac disorders*</td>
<td>5.7</td>
<td>5.8</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders*</td>
<td>45.3</td>
<td>43.9</td>
</tr>
</tbody>
</table>

*MedDRA SOC
P254 Once-daily Tiotropium And Olodaterol Fixed-dose Combination Via The Respimat® Improves Outcomes Versus Mono-components In Copd In Two 1-year Studies


Thorax 2014 69: A188-A189
doi: 10.1136/thoraxjnl-2014-206260.382

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