P208 IMPACT OF MORNING SYMPTOMS EXPERIENCED BY COPD PATIENTS ON EXACERBATION RISK, RESCUE INHALER USAGE AND NORMAL DAILY ACTIVITIES

doi:10.1136/thoraxjnl-2012-202678.269

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Impact of morning symptoms experienced by COPD patients on exacerbation risk, rescue inhaler usage and normal daily activities

Background Patients consider the impact of COPD on morning activities to be substantial. Evidence of the association of morning symptoms and the impact on the entire day with poor breathing control contributes to the understanding of their importance for managing COPD patients.

Objectives To quantify the impact of morning symptoms experienced by patients receiving inhaled corticosteroid plus long-acting β_2-agonist (ICS/LABA) by association with exacerbation frequency, rescue usage and impact on daily activities.

Methods Data were drawn from a real world study of consulting COPD patients in the USA and Europe in 2011. Results were tested for significance ($p<0.05$) using Mann-Whitney and negative binomial regressions. Confounders included age, gender, BMI, comorbidities, severity, smoking status and adherence.

Results Of the 3790 patients in the study, 593 were receiving ICS/LABA-only (+/– rescue). Of the 177 patients reported to experience morning symptoms, cough (65.5%) and excess sputum (53.1%) were the most common. Compared with patients without morning symptoms, these patients were associated with higher mean exacerbation frequency in the last 12 months (1.04 vs 0.63 $p<0.001$), rescue usage per day (0.58 vs 0.46 $p=0.025$) and daytime impact on a 7-point Likert scale where 7 represents a constant impact (3.61 vs 3.00 $p<0.001$).

Conclusion Morning symptoms were associated with significantly more impaired breathing control for patients treated with ICS/LABA-only therapy. The association implies morning symptoms are an important indicator when assessing the impact of COPD and their presence suggests that further therapeutic intervention may be necessary.

P209 IMPACT OF PATIENT SATISFACTION WITH THEIR MAINTENANCE INHALER ON TREATMENT COMPLIANCE AND HEALTH OUTCOMES IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: AN ANALYSIS OF REAL-WORLD CLINICAL PRACTISE IN EUROPE

doi:10.1136/thoraxjnl-2012-202678.270

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Introduction and objective Compliance with prescribed treatment is often suboptimal in patients with chronic obstructive pulmonary disease (COPD). This analysis examined the relationships between inhaler satisfaction, compliance and health outcomes.

Methods Data were analysed from a large, cross-sectional survey of real-world clinical practise conducted in five European countries. Respiratory specialists and primary care physicians provided information on six consecutive patients with COPD (aged ≥40 years with history of smoking). The same patients were then asked to voluntarily complete a self-assessment form. Physicians scored patient compliance with prescribing instructions (5-point Likert scale: 1='not at all compliant'; 5='fully compliant') and patients rated overall satisfaction with their maintenance inhaler (7-point Likert scale: 1='not at all satisfied'; 7='very satisfied'). Health outcomes assessments included exacerbations, the modified Medical Research Council dyspnoea scale, the EuroQoL (EQ-5D) instrument and the Jenkins Sleep Questionnaire. Sequential regression was used to analyze the relationship between inhaler attributes and overall satisfaction. Least-squares regression and additive models were used to analyze the relationships between inhaler satisfaction, compliance and health outcomes.

Results Data were included for 1443 patients for whom self-completed and matched physician-completed record forms were available. The majority of patients (71.8%) were male; mean age was 65.2 years. Very few patients (0.7%) were 'not at all compliant' with their physician's prescribing instructions, whilst 33.3% were 'fully compliant'. Most patients (75.1%) were more satisfied with their inhaler than not; 6.6% were 'very satisfied'. Key attributes influencing satisfaction related to durability, ergonomics and ease of use. There was a significant association between inhaler satisfaction and compliance (χ^2 – df=89.7; $p<0.001$). Other factors related to greater compliance, though to a lesser degree, were fewer maintenance drugs (χ^2 – df=17.7; $p<0.001$) and male gender (χ^2 – df=2.9; $p<0.05$). Severity of breathlessness, age and ethnicity were not significantly associated with compliance ($p>0.05$). Higher compliance scores were significantly associated with better health outcomes (Table). There was also a direct association between inhaler satisfaction and better health outcomes (exacerbations and EQ-5D, $p<0.001$).

Conclusions Inhaler satisfaction appears to be significantly associated with COPD treatment compliance, and patients with greater compliance experience better health outcomes, including less frequent exacerbations.

Abstract P209 Table 1

	Association with health outcomes		
	N	R^2	p-value
Relationship between health outcomes and increasing compliance score			
Fewer exacerbations in past 12 months[a]	1403	0.037	<0.001
Fewer exacerbations managed through hospitalisation in past 12 months[a]	1084	0.025	<0.001
Lower mMRC dyspnoea scale score[a]	1419	0.031	<0.0001
Higher EQ-5D score[b]	1422	0.035	<0.0001
Lower Jenkins Sleep Index[b]	1402	0.064	<0.0001
Relationship between health outcomes and increasing inhaler satisfaction			
Fewer exacerbations in past 12 months[a]	944	0.032	<0.001
Higher EQ-5D score[b]	959	0.030	<0.001

[a]Physician-reported; [b]patient-reported
Coefficient of determination (R^2) derived from generalised additive models
EQ-5D, EuroQoL-5 dimensions; mMRC, modified Medical Research Council

P210 ARE SPUTUM AND BLOOD BIOMARKERS OF INFLAMMATION REPEATABLE IN STABLE COPD?

doi:10.1136/thoraxjnl-2012-202678.271

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Background Spirometry is a commonly used end-point in COPD clinical trials and there is evidence that spirometric values are reproducible in COPD patients. COPD is heterogeneous and differences in biomarkers of pulmonary and systemic inflammation between patients can be identified. Currently limited short-term reproducibility is available in stable COPD.

Aims Assess repeatability of commonly used clinical measures in subjects with stable COPD over 3 and 6 months.

Methods Subjects with COPD were enrolled into an observational study and were reviewed at stable visits after 3 and 6 months. Spirometry, blood [peripheral blood total white cell and differential cell counts] and sputum [sputum differential cell counts (%)] markers of inflammation were repeated at each visit. Repeatability of

these measures was assessed using the intra-class correlation coefficient (Ri) and is expressed below as Ri (95%CI).

Results 145 subjects were recruited; 101 were male with a mean (SD) FEV1 (L) and FEV1/FVC ratio (%) of 1.34 L (0.57) and 53% (14.6) respectively.

Spirometry values showed excellent repeatability; FEV1 [0.93 (0.84 to 0.92) and 0.89 (0.83 to 0.92)] and FVC [0.80 (0.73 to 0.86) and 0.81 (0.72 to 0.87)] after 3 and 6 months respectively.

Sputum biomarkers of inflammation showed moderate repeatability at 3 and 6 months respectively; sputum neutrophils (%) [0.59 (0.43 to 0.71) and 0.50 (0.33 to 0.64)] and eosinophils (%) [0.62 (0.48 to 0.73) and 0.32 (0.13 to 0.49)].

The blood biomarkers peripheral blood white cell count (WCC), neutrophil and eosinophil counts demonstrated good repeatability after 3 and 6 month intervals respectively; WCC [0.68 (0.56 to 0.77) and 0.73 (0.62 to 0.81)], neutrophil count [0.66 (0.54 to 0.76) and 0.71 (0.59 to 0.79)] and eosinophil count [0.66 (0.54 to 0.76) and 0.73 (0.63 t o0.81)]. CRP showed fair repeatability [0.34 (0.16 to 0.5) and 0.30 (0.11 to 0.47) at both time intervals.

Discussions Sputum differential cell counts (%) and peripheral blood differential cell counts are repeatable after 3 and 6 month intervals. These findings may have clinical implications when targeting therapies to sub-groups of COPD patients.

P211 TIME-COURSE OF RHINOVIRUS AND BACTERIAL INFECTION DURING COPD EXACERBATION RECOVERY

doi:10.1136/thoraxjnl-2012-202678.272

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Introduction Airway bacteria and viruses are aetiological triggers of COPD exacerbations. Changes in prevalence of rhinovirus and typical airway bacteria together have not been examined during COPD exacerbation recovery. We compared the prevalence of the clinically relevant microorganisms (CRMs) human rhinovirus and typical pathogenic bacteria (*H. influenzae*, *M. catarrhalis* and *S. pneumoniae*) at five time points during COPD exacerbation recovery.

Methods London COPD cohort patients recorded any new or increased respiratory symptoms on daily diary cards and contacted the clinical team when symptoms worsened. Exacerbations were defined using our usual symptomatic criteria; an increase in respiratory symptoms for two consecutive days, with at least one symptom being major (dyspnoea, sputum purulence or volume) and the other a major or minor symptom (wheeze, cold, sore throat, cough). Reverse-transcription quantitative PCR was used to detect rhinovirus and real-time quantitative PCR was utilised to identify typical bacteria in sputum samples collected at exacerbation presentation (median 2 days after symptom onset), and at days 3, 7, 14 and 35 post-presentation.

Results Nineteen patients with moderate to severe COPD (mean age 68.8 years (SD±8.1); FEV_1 48.4% predicted (±19.2%); current smoker 37%; FEV_1/FVC 0.46 (SD±0.14); FEV_1 1.2L (SD±0.4); male gender 74%) provided 89 of 110 potential sputum samples at 5 time points during 22 exacerbations.

Rhinovirus prevalence progressively fell from 71.4% at exacerbation presentation to 0% at day 35 with significant decreases in prevalence between presentation and days 7, 14 and 35 (all $p<0.002$) (Figure 1). No exacerbation was negative for rhinovirus detection at presentation but positive at later time points. For typical bacteria, 64.7% of samples taken at presentation were positive. This proportion fell at days 3 and 7 but these falls were non-significant ($p=0.08$ and $p=0.09$, respectively) – all events were treated with antibiotics. Seven of the 22 exacerbations (31.8%) were positive for both CRMs at presentation.

Conclusion The prevalence of CRMs varies during recovery from a COPD exacerbation. Rhinovirus prevalence steadily decreases over 2 weeks whilst bacterial prevalence is more variable, presumably due to the background effects of lower airway bacterial colonisation. This emphasises the importance of rhinovirus as a major exacerbation trigger.

P212 ASSESSING THE REPEATABILITY OF BACTERIAL DETECTION IN STABLE COPD USING SEVERAL METHODS

doi:10.1136/thoraxjnl-2012-202678.273

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Background Stable COPD patients are colonised if potentially pathogenic organisms are identified on sputum culture. Associations between colonisation and clinical features such as exacerbation

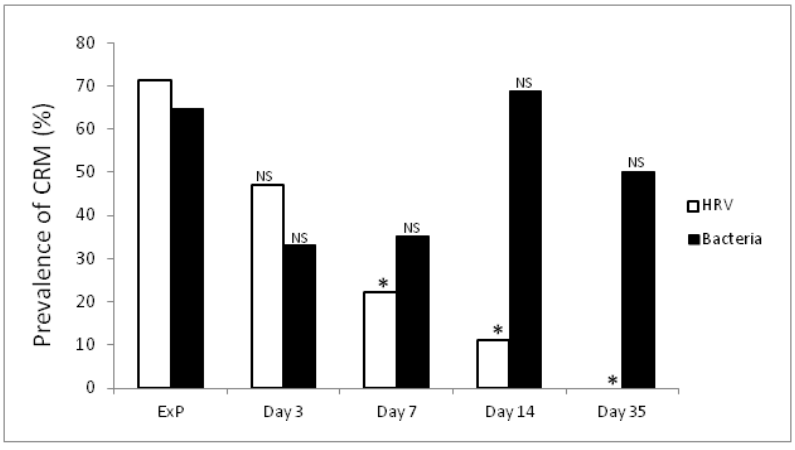

Figure 1. Changes in the prevalence of human rhinovirus (HRV) and typical bacteria at exacerbation and during recovery.

NS: No significant difference found between exacerbation presentation and each time point.

*: Significant decrease in prevalence between exacerbation presentation and each time point (all $p<0.002$).

Abstract P211 Figure 1