

proportion of patients in categories A, B, C and D, respectively, when evaluated by CAT was 10, 49, 1 and 40%, and when evaluated by mMRC was 39, 20, 13 and 28%. By CAT evaluation in categories A, B, C, and D, patients were using a long-acting β_2 -agonist (LABA) alone (8, 6, 0 and 1%), long-acting muscarinic antagonist (LAMA) alone (37, 25, 8 and 5%), inhaled corticosteroid plus LABA (ICS/LABA) alone (22, 18, 8 and 8%), and ICS/LABA plus LAMA only (11, 20, 46, 43%).

Conclusion CAT assessment increased the number of patients in the more symptomatic categories (B and D), compared with mMRC. Contrary to the GOLD 2011 recommendations, by CAT assessment, a high proportion of low-risk patients (A and B) were using ICS/LABA.

P186 PERSPECTIVES OF PATIENT AND PROFESSIONAL PARTICIPANTS ON TELEHEALTHCARE AND THE IMPACT ON SELF-MANAGEMENT: QUALITATIVE STUDY NESTED IN THE TELESOT COPD TRIAL

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Background The TELESOT randomised control trial, is investigating the impact of a telemonitoring service for COPD with the primary aim of reducing hospitalisation.

Aim The nested qualitative study explored the views of patients and professionals on models of telemetric service delivery and the impact on self-management.

Method Semi-structured interviews with patient and professional participants at different time points in the TELESOT trial were transcribed, coded and analysed thematically. Interpretation was supported by multidisciplinary discussion.

Results 38 patients (47% male, mean age 67.5 years) and 32 healthcare professionals provided 70 interviews. Both patients and professionals considered that home telemonitoring had the potential to reduce the risk of hospital admission.

Patients generally appreciated being 'watched over' by the telemonitoring, which gave them confidence to manage their own condition. They used tele-data to improve their understanding of COPD, determine their current state of health and influence decisions about their daily activities. Numerical data (e.g. oxygen saturations) were particularly valued. Changes in readings validated their decisions to adjust treatment or seek timely professional advice, and eased access to clinical care.

Professionals emphasised the potential role of telemetry in encouraging prompt compliance with medically defined behaviours and attitudes, though there was concern that 'fixation' on monitoring physiological parameters (especially oxygen saturation levels), promoted a medical model of the disease and might increase dependence on services in some patients.

The GPs and community nursing or physiotherapy teams who provided home telemonitoring support services emphasised the importance of 'knowing the patient' and 'knowing what's normal for the individual' in using their clinical skills to interpret incoming telemonitoring data.

Conclusion Enthusiasm for telemonitoring as a means of facilitating self-management and thereby reducing admissions is tempered by concerns about increased medicalisation and dependence on support services. Tele-monitoring provides data which can be used to support self-management decisions and act as a channel for seeking professional support. The patient-practitioner relationship, personalisation and continuity of care were prioritised as important elements in delivering clinical support for telemonitoring services by patients and professionals.

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P187 TREATMENT OF STABLE COPD IN ALPHA 1 ANTITRYPSIN DEFICIENCY (AATD) PATIENTS USING THE 2011 GOLD TREATMENT ALGORITHM

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Background Previous versions of the GOLD strategy algorithm recommended treatment based on FEV1 which is now recognised as a poor descriptor of disease impact. The revised 2011 GOLD document has introduced individualised assessment of symptoms and future risk for initial management of stable COPD. Questionnaires such as COPD Assessment Test (CAT) and modified Medical Research Council (mMRC) are suggested to assess symptoms and risk depends on spirometric impairment or exacerbation frequency.

Aim To apply the current GOLD treatment algorithm to AATD patients and assess their current treatment against that recommended.

Methods 309 consecutive patients on the AATD registry (PiZZ) were grouped into the four categories (A, B, C, and D) as suggested by GOLD, on the basis of their CAT 10, 13 or mMRC scores and GOLD spirometric stage or Exacerbation frequency. We then documented the treatment combinations being used by the patients in the different groups.

Results Treatment for patients in the four groups differed widely from GOLD recommendations. Few patients in Group A (CAT 10 GOLD/MRC GOLD/CAT 13 GOLD: 6%/2%/2% and CAT 10 EXAC/MRC EXAC/CAT 13 EXAC: 6%/2%/3%) were on the GOLD recommended SABA/SAMA therapy. 40% were on none and 30% were on triple therapy. The majority of patients in group B and Group C (60% and 58% respectively) were on triple therapy with only 10% and 14% respectively being on the recommended regimen. Nearly 70% in group D were on recommended triple therapy with ICS, LABA and LAMA.

The proportion of patients in the groups A, B and C assessed by mMRC was significantly different using CAT 10 ($p < 0.02$) but not using CAT 13 ($p =$ not significant). The proportion of patients in group D was similar for all 3 symptom scores ($p =$ not significant).

Conclusions CAT 13 was most comparable to mMRC for patient distribution. Most of the AATD patients with low risk (low symptoms and high symptoms) were over treated with triple therapy. The majority in the high risk/high symptoms group were appropriately on triple therapy. It remains to be determined how this affects long term outcome.

P188 CAT SCORE THRESHOLD FOR SYMPTOM/RISK ASSESSMENT IN ALPHA-1-ANTITRYPSIN DEFICIENCY (AATD) USING THE 2011 GOLD ALGORITHM

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Background The revised COPD GOLD guidelines (2011) recommend that validated questionnaires like the CAT (COPD Assessment Test) or the modified MRC (Medical Research Council) breathlessness scale should be used to assess symptoms in COPD against "risk" as assessed by GOLD spirometric staging or exacerbation frequency. We have demonstrated that when either the MRC or CAT scores are used to determine symptoms, there is a significant difference in the proportion of patients being categorised into the risk categories which will affect risk assessment and may influence therapeutic choice.

Aim To determine the CAT threshold for risk assessment at which similar proportions of patients are categorised into the 4 risk categories.

Methods 309 consecutive patients on the AATD registry (PiZZ) were grouped into the four categories (A, B, C, and D) as suggested

by GOLD, on the basis of their CAT/mMRC scores and GOLD stage/Exacerbation frequency. Using CAT as the symptom grade, we compared patient distribution in the 4 categories using scores between 10 and 20 to determine the CAT threshold at which the distribution of patients in each group is proportional.

Results The proportion of patients in each of the 4 categories was consistent for each symptom score whether risk was assessed by FEV₁ or exacerbation number. However the proportions using CAT 10 and mMRC 0–1, ≥2 were significantly different in each category. When the CAT threshold was changed to 13, the proportions of patients in the four groups were no longer significantly different to those using mMRC.

Conclusion We have demonstrated that in patients with AATD, using CAT score of 13 as the threshold for assessing symptoms results in a similar proportion of patients being categorised into the risk categories. This affects risk assessment and therapeutic choice. Longitudinal follow up and monitoring will enable confirmation of this threshold for patient management.

P189 REDUCED COPD EXACERBATIONS ASSOCIATED WITH ACLIDINIUM BROMIDE VERSUS PLACEBO: A POOLED ANALYSIS OF PHASE III DATA

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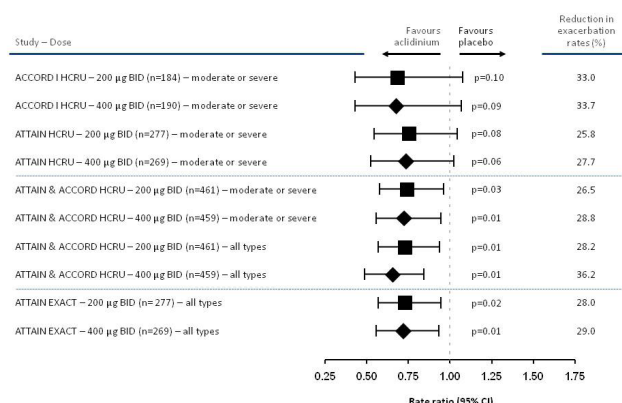
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Introduction and objective Acclidinium bromide is a novel, long-acting, inhaled muscarinic antagonist indicated for the treatment of chronic obstructive pulmonary disease (COPD). COPD is characterised by periodic worsening of symptoms (exacerbations) that are associated with increased morbidity and mortality. Here, we report the results of a pooled analysis of acclidinium on exacerbations.

Methods Data from two Phase III studies (3-month ACCORD COPD I and 6-month ATTAIN) were included in this analysis. Both were designed to evaluate the efficacy and safety of acclidinium 200 µg and 400 µg (metered dose) BID versus placebo (primary endpoint: change from baseline in FEV₁). Adults (aged ≥40 years) with moderate-to-severe COPD, who were current/former smokers with a smoking history ≥10 pack-years, were included. Exacerbations (additional endpoint) were assessed in both studies using healthcare resource utilisation (HCRU) criteria (increase in symptoms for ≥2 consecutive days that required increased medication use or other medical intervention) and, in ATTAIN only, with the Exacerbations of Chronic Pulmonary Disease Tool (EXACT [daily diary card data with exacerbations defined according to the developer's criteria]). Neither study was individually powered to assess treatment differences in exacerbation frequency. In this pooled analysis, exacerbation rate ratios (per patient/year for acclidinium versus placebo) were analyzed using a Poisson regression model corrected for over-dispersion; 95% confidence intervals and p-values were calculated.

Results Data for 1378 patients were included; the majority (62%) were male with a mean age of approximately 63 years. At baseline, >60% of patients were classed as GOLD stage II (moderate), and 31% reported ≥1 exacerbations in the previous 12 months. In both studies, there was a trend towards relative reduction (approximately 30%) in the rate of moderate or severe exacerbations (requiring antibiotic or corticosteroid treatment, or hospitalisation) with both acclidinium doses versus placebo (Figure). A significant reduction in moderate or severe exacerbation rate was observed with acclidinium 400 µg versus placebo when data from both studies were pooled (0.31 vs 0.44; rate ratio 0.71, p=0.01).

Conclusions This pooled analysis provides evidence to support a reduction in moderate or severe COPD exacerbations with acclidinium 200 µg and 400 µg BID compared with placebo.



Abstract P189 Figure 1

P190 QVA149 ONCE DAILY PROVIDES SIGNIFICANT IMPROVEMENTS IN LUNG FUNCTION OVER 1 YEAR IN PATIENTS WITH COPD: THE ENLIGHTEN STUDY

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Introduction QVA149 is a novel inhaled once-daily dual bronchodilator, containing a fixed-dose combination of the long-acting β₂-agonist indacaterol and the long-acting muscarinic antagonist NVA237 (glycopyrronium) in development for the treatment of COPD. This study evaluated the long-term effect of QVA149 on lung function in patients with COPD.

Methods This was a multicentre, double-blind, parallel group, placebo-controlled study in which patients with moderate-to-severe COPD were randomised (2:1) to receive QVA149 (110/50µg) or placebo once daily via the Breezhaler® device for 52 weeks. Treatment was taken in the morning at the same time of day. Lung function was measured as forced expiratory volume in 1 second (FEV₁) and forced vital capacity (FVC) at 30 and 60 minutes post-dose at clinic visits over 52 weeks.

Results 339 patients (77% male, mean age 63 years; mean post-salbutamol FEV₁ 57% predicted, FEV₁/FVC 54%) were randomised to receive QVA149 (n=226) or placebo (n=113); 86% and 79% of patients respectively completed treatment, respectively. QVA149 significantly increased FEV₁ and FVC versus placebo at all assessment points (table).

Conclusion QVA149 once daily provided rapid and clinically meaningful bronchodilation compared with placebo. No tachyphylaxis was observed and the bronchodilator effect was sustained over the 52 week treatment period.

Ronal Dahl: he participated in advisory boards for Novartis, AstraZeneca, Boehringer-Ingelheim, Pfizer, ALK-Abello, UCB, Nycomed, Daiippon and ONO.

Kenneth R Chapman: he holds the GSK-CIHR Research Chair in Respiratory Healthcare Delivery at the University Health Network, has served as a consultant to CSL Behring, GlaxoSmithKline, Novartis, Nycomed (Takeda), and Talecris (Grifols), and has received payment for lectures or service on speakers bureaus from Boehringer-Ingelheim, GlaxoSmithKline, Grifols, Nycomed (Takeda), Family Physicians Airways Group of Canada, Canadian Network for Respiratory Care, and Talecris.