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Late-breaking abstract: Sildenafil for chronic obstructive pulmonary disease: A randomized crossover trial

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Background: Pulmonary hypertension with exercise is common in chronic obstructive pulmonary disease (COPD) and may contribute to exercise limitation in this disease. We aimed to determine the effects of treatment with sildenafil on exercise capacity in patients with COPD and emphysema.

Methods: We performed a randomized, double-blind, placebo-controlled two-period crossover trial of sildenafil thrice daily in ten adults with COPD and emphysema on CT scan. We randomized study participants to four weeks of sildenafil (or placebo) followed by a one-week washout and then four weeks of placebo (or sildenafil). The two primary outcomes were the six-minute walk distance and oxygen consumption at peak exercise.

Results: The study subjects had a mean age of 66 years, and 80% were male. The mean \pm standard deviation FEV1 was 38 \pm 17% predicted. Sildenafil had no effect on six minute walk distance (placebo-corrected difference = -7.8 m, 95% confidence interval, -23.2 to 7.5 m, p = 0.35) or oxygen consumption at peak exercise (placebo-corrected difference = -0.1 ml/kg/min, 95% confidence interval -2.1 to 1.8 ml/kg/min, p=0.89). Sildenafil increased the alveolar-arterial oxygen gradient (p=0.02), worsened symptoms (p=0.04), and decreased quality-of-life (p=0.03). Adverse events were more frequent while receiving sildenafil (p=0.005).

Conclusions: Routine sildenafil administration did not have a beneficial effect on exercise capacity in patients with COPD and emphysema. Sildenafil significantly worsened gas exchange at rest and quality of life.

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Assessing the impact of a chronic obstructive pulmonary disease (COPD) discharge care bundle piloted on the respiratory ward on readmission rates

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COPD is the 4th leading cause of death worldwide, and accounts for 1 in 8 of all hospital admissions in the UK. A National UK audit (2008) showed that 33% of COPD patients were readmitted within 3 months.

Objective: The aim was to implement a COPD discharge care bundle on the respiratory ward in order to improve quality of patient care, ensure early follow up, and reduce readmissions.

Methods: Using improvement methodology and regular education for healthcare professionals, a discharge care bundle was piloted for 6 months on the respiratory ward at West Middlesex Hospital. A multi-disciplinary team used a bespoke reporting tool to record weekly measures of bundle compliance. Regular project team meetings were held to assess progress.

Results: A baseline audit of 50 patients admitted to all general medical wards was compared to 50 patients discharged from the respiratory ward using the care bundle. Results showed that referrals to the smoking cessation service in current smokers increased from 25% to 100%, written information on COPD given to patients increased from 4% to 100%, inhaler technique demonstration increased from 10% to 100%. The number of patients who were given a 4 week out patient appointment increased from 30% to 95%. All patients using the bundle received a 3 day post discharge phone call. Regional CQINN data shows a 39% reduction in 14 and 28 day readmissions, since introduction of the bundle.

Conclusion: Implementation of a COPD discharge bundle can improve patient experience and reduce readmission rates with COPD. The project was funded and supported by NIHR CLARHC for NW London.

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Adherence with inhaled respiratory therapeutics is associated with reduced acute exacerbations of chronic obstructive pulmonary disease

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Background: Adherence to inhaled chronic obstructive pulmonary disease (COPD) medications is variable and generally low. We examined the association of medication adherence with subsequent acute exacerbations (AE) among adult members of a large health maintenance organization.

Methods: We used data from electronic medical records to identify individuals with COPD defined by ICD-9 coded encounters during the period 2000-2008 and computed modified medication possession ratio (mMPR) to measure adherence to three classes of inhaled COPD medications. Using Cox regression, we evaluated the association between six-month adherence score (calculated forward from index date) and subsequent risk of first AE-COPD within 12 months, adjusting for age, race, sex, baseline smoking status, body habitus, and co-morbidities. AE-COPD was defined by outpatient/emergency encounters with steroid use or hospitalization.

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Late-breaking abstract: HR-lowering efficacy and respiratory safety of ivabradine in patients with obstructive airway disease

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Aim: There is substantial evidence that heart rate (HR) is a powerful predictor of mortality in both normal individuals and in patients with cardiovascular disease. β -blockers confirmed importance of lowering elevated HR for patients prognosis. However, due to risk of bronchoconstriction, are contraindicated in obstructive airway diseases. Ivabradine, a new I_f inhibitor which acts specifically on the sino-atrial node, is a pure HR-lowering agent. The objective of this study was to assess efficacy and respiratory safety of ivabradine in patients with asthma and chronic obstructive pulmonary disease (COPD).

Methods: In this double blind, placebo-controlled, crossover study, 20 asthmatics and 20 COPD patients received ivabradine 7,5 mg b.i.d. and placebo b.i.d. for 5 days in crossover manner. HR in ECG holter monitoring, peak expiratory flow rate (PEFR), symptoms, rescue medication consumption and adverse events (AEs) were evaluated.

Results: Ivabradine produced significantly lower mean HR than placebo in all patients: asthma 67,4 \pm 8,38 vs 82,85 \pm 11,19 (P=0,000016) and COPD 69,75 \pm 8,9 vs 81,05 \pm 9,75 (P=0,000470). No significant difference was found between ivabradine and placebo in morning and evening PEFr, PEF diurnal variability, symptom scores and rescue medication usage (all P>0,05). The incidence of AEs was low and generally similar in both treatments, except for visual symptoms during ivabradine treatment reported by 5% of patients.

Conclusions: Our study demonstrates that selective HR reduction with ivabradine is effective and safe in patients with asthma and COPD. Ivabradine offers an interesting alternative in patients with respiratory disease and contraindications to β -blockers.

Results: We identified 26,516 individuals with COPD (59% female, mean age 61±13 years) of whom 80% contributed adherence data. Adherence rates (mMPR±S.D, number contributing) were 0.62±0.34, n=11317 for anticholinergics (Ach), 0.61±0.32, n=17018 for inhaled corticosteroids (ICS), and 0.66±0.29, n=5336 for long-acting beta-agonists (LABA). The relative risk for subsequent AE based on a 0.20 difference in mMPR at the start of follow-up was 0.86 (95% CI=0.84, 0.93) for ICS, 0.91 (0.84, 1.00) for LABA, and 0.89 (0.84, 0.93) for Ach. **Conclusions:** Better adherence to any of the major classes of inhaled controller therapeutics reduced the risk of subsequent AE-COPD. **Funding:** Investigator Initiated Grant, Novartis Pharmaceuticals Corporation.

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Provision of nonpharmacological treatment options for COPD patients in 13 European countries: Results from the European COPD audit

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Background: Evidence from the literature suggests that nonpharmacological treatment for COPD patients improve the outcome of this disease. To explore the provision of non invasive ventilation (NIV), early supported discharge programs, and access to pulmonary rehabilitation, data from the European COPD Audit study was evaluated in 258 hospitals from 13 European countries

Study design: In an observational study, all participating hospitals collected data on the organisation of care for COPD admissions. Preliminary results of 258 (132 general/153 teaching/university) hospitals out of 450 participating centres of the ongoing study will be presented.

Results: Although the majority of centers offer noninvasive (ICU and/or HDCU-High dependency care units- available) for decompensated COPD patients, the capacity for eligible patients is only close to 60%. In addition, supported discharge as well as pulmonary rehabilitation programs are provided in less than 50% of cases.

	Teaching/university hospital % mean	General hospital % mean
Offer NIV?	93,5%	87,1%
Capacity for all eligible patients?	62,7%	56,8%
Access to rehabilitation program after discharge?	49%	47,7%
Early supported discharge program?	32,7%	30,3%

Conclusion: Contrary to international recommendations, participating European centers in the COPD audit lack sufficient availability for non invasive ventilation; in addition, neither rehabilitation, nor early supported discharge programs are sufficiently available. University hospitals are not superior to general hospitals.

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Integrated care intervention prevents hospitalisations for exacerbations and reduces the disease costs in COPD patients

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Introduction: Efficacy of interventions aimed at preventing hospitalisations due to exacerbations in clinically stable COPD patients is controversial.

Objectives: To evaluate usefulness of integrated care intervention (ICI) on hospital admission for exacerbations and disease costs in COPD patients.

Methods: This prospective study was carried out in 208 COPD patients recruited by

general practitioners between January 2009 and December 2009 in Massa-Carrara sanitary district.

The interventions included individually tailored care plan following GOLD guidelines shared among the chest physician, nurse team and general practitioner, educational program on self-management of the disease, treatment supervision during scheduled visits, home visits by specialised nurses.

Results: 105 patients completed 12 months of follow-up, stratified in stage 1 (n.11), stage 2 (n.47), stage 3 (n.34), stage 4 (n.13) using the GOLD classification. Twelve months of ICI decreased the mean number of hospitalisations (0.54±1.1 versus 0.82±1.1 p<0.05), reduced the percentage of hospitalised patients (27% versus 51% respectively) compared to the previous year. Gold 3 and 4 stages showed the highest reduction in hospitalisation rate. Drug-acquisition costs significantly increased (average difference in means + 256 €) while the mean total disease cost per patients decreased (-201 €) after ICI.

Conclusions: The study demonstrates that a standardised ICI based on share-care intervention between primary care team and hospital team effectively prevents hospitalisations for exacerbations and decreases the total disease cost in COPD patients.

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Establishment of an integrated clinical network and comprehensive data warehouse for the conduct of comparative effectiveness research in COPD

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Background: Chronic obstructive pulmonary disease (COPD) affects many millions worldwide and is increasing in incidence, morbidity, and mortality. Efficacy trials can guide COPD care, but an infrastructure for comparative effectiveness research (CER) across diverse settings are needed to more fully evaluate commonly used therapies in clinical practice.

Methods: We created an inter-disciplinary and multi-institutional network for CER named COPD Outcomes-based Network for Clinical Effectiveness and Research Translation (CONCERT). We developed a platform for comprehensive interoperable clinical data upload and synthesis across diverse outpatient and hospital practice settings to create a comprehensive COPD data warehouse (COPD DataHub) and have begun populating it thru inclusion pathways designed to maximize identification of COPD patients from 2006 through 2008.

Results: The COPD DataHub was designed to be flexible to incorporate data from seven varied health care settings including university-affiliated medical centers, a community medical center, a health maintenance organization and a government-operated veteran medical center. It includes a total of 146,240 unique patients, 58.3% female at non-veteran sites, whites 68.4%, blacks 14.3% and other races 17.3%, average patient age 61.8 years (S.D. 13.5).

Conclusions: We demonstrated the feasibility of developing a rich CER data repository by linking COPD patients across diverse health care settings. CONCERT has successfully created a multi-institutional platform to pursue observational CER studies and identify patients with COPD for enrollment into prospective pragmatic clinical trials.

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Lack of oximeters in primary care risks increasing the mortality from COPD

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The ERS and ATS (2005), GOLD (2010), NICE (2010) guidelines for COPD recommend long term oxygen therapy (LTOT) in hypoxic patients. LTOT improves the mortality of these patients. NICE recommends that patients with oxygen saturations which are ≤ 92% on breathing air should be assessed for LTOT. In order to do this these patients must be identified with pulse oximetry.

Aims and methods: This study undertaken in 2010 examines the availability of pulse oximetry in GP surgeries and the views of GPs to pulse oximetry by post or questionnaire in all 67 practices who serve this hospital.

Results: 60 practices (89.6%) responded to the questionnaire. Of these 40 (66%) had ≥ 1 pulse oximeters. 24 (40%) had only one oximeter, usually shared between doctors and nurses. 20 (33%) had no oximeter. 64 (23%) stated they would like an oximeter whilst 4 (6.6%) thought an oximeter was not necessary. The main reason given for not having an oximeter was financial.

Conclusions: 33% of GP practices do not have a pulse oximeter. 40% have only one oximeter, which was usually shared between doctors and nurses. Lack of oximeters could lead to referral into secondary care just to have pulse oximetry measured. Lack of finance was the major reason given for not having an oximeter

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but oximeters are now cheap and one referral into secondary care is approximately equivalent to the cost of an oximeter. This study suggests that hypoxia patients with COPD will not be identified early and therefore not treated with LTOT. This will mean that their life expectancy will be reduced. The identification of hypoxia patients in primary care must be urgently addressed by increasing the number of oximeters.