View metadata, citation and similar papers at core.ac.uk
brought to you by CORE
provided by Elsevier - Publisher Connector

PRS3

A COMPARISON OF EFFICACY OF FLUTICASONE WITH BUDESONIDE AND BECLOMETHASONE IN 1:1 DOSE RATIO IN THE TREATMENT OF BRONCHIAL ASTHMA

Pankiewicz O, Nadzieja-Koziol A, Kwaskowski A, Jaros P, Jagodzinska K, Lach K, Jarczewska D, Rys P, Wladysiuk M, Plisko R
HTA Consulting, Krakow, Poland

OBJECTIVES: This study compared efficacy of fluticasone (FL) with budesonide (BUD) and beclomethasone (BDP) in 1:1 dose ratio in the treatment of bronchial asthma. **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines and Agency for Technology Assessment in Poland. The most important medical databases (EMBASE, MEDLINE and CENTRAL) were searched. Two reviewers independently selected trials, assessed their quality and extracted data. Head-to-head comparisons were performed. **RESULTS:** The systematic search retrieved 11 and 10 RCTs for comparison FL vs. BUD and 10 for FL vs. BDP, respectively. Incidence of asthma exacerbations in FL and BUD was comparable. Significant improvement in favor of FL over BUD were found in respect to Forced Expiratory Volume in 1 second—FEV1 (% predicted) (WMD = 2.84 [0.80; 4.89]), morning (Peak Expiratory Flow PEF(% predicted) (WMD = 3.00 [1.59; 4.41]) and proportion of symptoms-free days (MD = 8.7; p = 0.02), while Asthma Symptoms Score (ASS) didn't differ between groups (MD = −0.06 [−0.18; 0.06]). FL in comparison with BDP was associated with lower risk of asthma exacerbations (RR = 0.74 [0.57; 0.96]), improvement in FEV1 (WMD = 0.07 liter [0.01; 0.13]) and in morning PEF (% predicted) (WMD = 1.57 [0,09; 3.06]). Moreover, efficacy analysis revealed higher proportion of symptoms-free nights (WMD = 8.30 [1.95; 14.65]) and greater reduction in ASS (MD = −0.21 [−0.37; −0.05]) in FL group. FL increased the risk of pharyngitis over BUD (RR = 1.66 [1.01; 2.73]) and the risk of hoarseness in comparison with BDP (RR = 2.21 [1.06; 4.60]), No other differences in safety outcomes were noted for both comparisons. **CONCLUSIONS:** Fluticasone in comparison with budesonide and beclomethasone in dose ratio 1:1 provides improvement in spirometric parameters and in comparison with beclomethasone but not budesonide reduces the risk of asthma exacerbations. Safety profile of fluticasone seems to be slightly worse than budesonide and beclomethasone.

PRS4

INDIRECT COMPARISON OF EFFICACY AND SAFETY OF FLUTICASONE AND BUDESONIDE IN THE TREATEMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Pankiewicz O, Jagodzinska K, Nadzieja-Koziol A, Jaros P, Lach K, Kwaskowski A, Jarczewska D, Rys P, Wladysiuk M, Plisko R
HTA Consulting, Krakow, Poland

OBJECTIVES: The main objective of this study is to evaluate efficacy and safety of fluticasone in comparison with budesonide in patients with chronic obstructive pulmonary disease (COPD). **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines and Agency for Technology Assessment in Poland. The most important medical databases (EMBASE, MEDLINE and CENTRAL) were searched. Two reviewers independently selected trials, assessed their quality and extracted data. Since no head-to-head comparisons between fluticasone and budesonide were found indirect comparison using placebo (PLC) as reference group was performed. **RESULTS:** The systematic search retrieved 34 RCTs which were included in the analysis (21 studies for FL compared with PLC and 13 for BUD vs. PLC. Indirect comparison showed that fluticasone (FL) is statistically significantly better than budesonide (BUD) in respect to Forced Expiratory Voume in 1 second (FEV1) before use of bronchodilator (WMD = 0.05 liter [0.01; 0.09]) and after use of bronchodilator (WMD = 0.06 liter [0.02; 0.10]), but those drugs didn't differ in respect to FEV1 expressed as percentage of predicted value. Moreover, morning Peak Expiratory Flow (PEF) was significantly better in favor of FL (WMD = 6.08 L/min [1.44; 10.72]). There were no statistically significant differences between FL and BUD in risk of death (RR = 1.24 [0.69; 2.22]), COPD exacerbations (RR = 1.11 [0.85; 1.45]) and quality of life measured with St George's Respiratory Questionnaire (WMD = 1.12 [−1.51; 3.75]). Risk of serious adverse events, candidosis, pneumonia and risk of withdrawals due to adverse events were similar in both groups. **CONCLUSIONS:** Treatment with fluticasone in comparison with budesonide is associated with better improvement in spirometric parameters. Fluticasone and budesonide have acceptable safety profiles.

PRS5

PRIMARY CARE OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS FROM GENERAL PRACTICE DATABASE

Citarella A, Menditto E, Cammarota S, de Portu S, Riegler S, Mantovani LG
University of Naples, Naples, Italy

OBJECTIVES: Describe patient with Chronic Obstructive Pulmonary Disease (COPD) primary care in an area of Campania, a region in the southwest of Italy. **METHODS:** A retrospective naturalistic longitudinal study was conducted using information from general practice database with 109 general practitioner (GP) clinical records whit a list of 151,884 subjects registered at the end of December 2008. The database contains patient demographic details, medical records (e.g. diagnoses, test, etc.), drug history and prevention information. Case of COPD were identified on the basis of the ICD-9 code (491, 496). All drugs prescribed were indentified according to the R03 therapeutic pharmacological subgroup (drugs for obstructive airway disease) of the Anatomical-Therapeutic-Chemical-Classification. **RESULTS: A total of 4856 (3.2%) patients** suffering from COPD were observed. Between 2006 and 2008, 32.5% of patient had at least one spirometry, 10.8% one hemogasanalysis and 9.3% both. In the same period, 45.6% had at least one influenza vaccination, 9.5% one pneumococci vaccination while 25.5% of COPD patients did not received any drug prescription for their disease. A total of 57.7% of COPD patients received at least one drug for their disease (R03), 24% had a mono-therapy and 76 % a poly-therapy. The most used drugs category in monotherapy were Inhaled corticosteroids (41.4%), β-agonists (24.6%), xanthine derivatives (19.2%), anticholinergics (14.0%). Among the poly-therapy cohort, there was an high variety of drug categories combination, in particular the most frequent were the pre-constituted formulation itself (19.4%). **CONCLUSIONS:** This study shows the high variability in the management of COPD in primary care, which does not seem to be always consistent to published guidelines.

PRS6

LESS THAN 20% OF COPD PATIENTS PERSIST WITH LONG-ACTING INHALED DRUGS FOR AT LEAST THREE YEARS

Penning-van Beest FJA[1], van Herk-Sukel MPP[2], Lammers JWJ[3], Gale R[4], Herings RMC[1]
[1]PHARMO Institute, Utrecht, The Netherlands, [2]PHARMO Institute, Utrecht, Utrecht, The Netherlands, [3]University Medical Center Utrecht, Utrecht, The Netherlands, [4]Novartis AG, Horsham, UK

OBJECTIVES: To determine persistence rates and treatment patterns of the following long-acting drugs used as inhaled maintenance therapies for COPD: long-acting muscarinic antagonists (LAMA), **long-acting** β2-agonists (LABA) and fixed dose combinations (FDC) of inhaled corticosteroids (ICS) and LABA. **METHODS:** From the PHARMO-database, all probable COPD patients were identified by new respiratory drug use (excluding ICS monotherapy) at age ≥55 years. New users of LAMA, LABA and FDC in the period 2002–2006 were included in the study. Persistence with the initial as well as any long-acting drug was determined up to three years after start and defined as time between start and stop of initial/any therapy, allowing a gap of ≤60 days between refills. For patients who failed to persist with initial therapy for one year, the first change in therapy was determined. **RESULTS:** The study included 4448 LAMA, 2019 LABA and 8341 FDC users. Persistence rates at 1, 2, and 3 years were 26%, 14%, 8% for LAMA, 23%, 10%, 6% for LABA and 27%, 14%, 8% for FDC. Of patients who did not persist with LABA alone for one year, 9% added therapy (mostly LAMA) and 31% switched therapy (mostly to FDC). Of patients not persisting with LAMA alone, 17% added and 12% switched therapy (both mostly relating to FDC). In patients not persisting with FDC, add-on and switch occurred with equal frequency (12%) and was mostly LAMA. Persistence rates with any long-acting drug at 1, 2 and 3 years were 37%, 23% and 17% respectively. **CONCLUSIONS:** Persistence with long-acting inhaled drugs in patients with COPD is low, with a substantial proportion of patients changing therapy. This indicates that current treatments are not adequate.

PRS7

IMPACT OF COUGH AND/OR SPUTUM SYMPTOMS ON THE BURDEN OF COPD IN EUROPE AND THE USA: A CROSS-SECTIONAL, OBSERVATIONAL STUDY

Müller TA[1], Wirén A[2], Small M[3], Cristino J[3], Pike J[3]
[1]Nycomed GmbH, Konstanz, Germany, [2]Nycomed, Taastrup, Denmark, [3]Adelphi Real World, Bollington, Cheshire, UK

OBJECTIVES: It is hypothesised that cough and/or sputum symptoms have a negative impact on disease burden in chronic obstructive pulmonary disease (COPD). This study assesses the impact of these symptoms in predicting the annual frequency of exacerbations in 1887 COPD patients. **METHODS:** Data were drawn from the Adelphi Respiratory Disease Specific Programme conducted in France, Germany, Italy, Spain, the UK and the USA in 2008. Information collected included physicians' perceptions of symptom severity and frequency of exacerbations in the previous 12 months. GLM regressions (using Gamma distributions with log link functions) were used to assess the impact of various factors on exacerbation frequency. Variables investigated included age, gender, body mass index, breathlessness, smoking status, co-morbidities (heart-related and anxiety/depression), compliance, most recent forced expiratory volume in 1 second (FEV_1, if available) and country of origin. Final models derived included statistically significant variables only ($p < 0.05$). **RESULTS:** Cough and/or sputum symptoms were associated with a significantly higher frequency of exacerbations (14% higher among patients with mild cough/sputum compared with those without, 18% higher among patients with moderate cough/sputum compared with mild, and 28% higher among patients with severe cough/sputum compared with moderate). A significantly higher frequency was also observed for exacerbations managed in the primary care setting (28%, 24% and 34% higher, respectively). Among 690 patients receiving secondary care, exacerbation frequency was 161% higher for patients with cough and/or sputum symptoms. In addition, exacerbation frequency was 173% higher among secondary care patients reported as poorly or non-compliant with their current medication (all $p < 0.05$). FEV_1 was only a significant predictor for exacerbations managed in secondary care. **CONCLUSIONS:** Presence and severity of cough and/or sputum in COPD symptoms has a marked association with increased frequency of exacerbations, even when considering FEV_1. These results indicate unmet therapeutic needs in this population.