

≥40 years diagnosed with COPD who newly initiated roflumilast from March 2011 to September 2015, were identified from the Truven MarketScan database. We measured demographic and clinical characteristics in the 12-month period prior to first date of use, the index date. Adherence was measured using prescription days covered (PDC) ≥ 80% threshold over a 6-month period. We calculated persistence as the proportion of patients that did not discontinue roflumilast, defined as a gap of >30 days. **Results:** A total of 9919 patients were included with a mean age of 67.7 years (± 10.1) and 4972 (50.1%) were female. Inhaled corticosteroids (ICS) and long-acting beta agonists (LABA), single inhaler use or in combination, were frequently used, 7300 (73.6%) and 7073 (71.3%) respectively, in the baseline period. We also captured multiple COPD medication use prior to the index date. Accordingly, LABA and ICS 6903 (69.6%) were commonly prescribed followed by long acting muscarinic antagonists (LAMA) and ICS (5112, 51.5%). The overall PDC over a 6-month period was 69% with only 3104 (48.8%) patients being adherent (PDC ≥ 80%). Over the same 6-month period, only 2581 (26.0%) were persistent. We also measured PDC over 3-month (81%) and 12-month (56%). In addition, persistence to roflumilast was 4899 (49.4%) and 1196 (12.1%) over a 3- and 12-month period respectively. **Conclusions:** A substantial number of adult patients with COPD have sub-optimal adherence and persistence to roflumilast. Reasons for low adherence or discontinuation such as prevalence of treatment-related adverse effects deserve further investigation.

PRS66

PSYCHOMETRIC EVALUATION OF THE C-PATH PRO CONSORTIUM'S ASTHMA DAYTIME AND NIGHTTIME SYMPTOM DIARIES (ADSD AND ANSD) IN THE 54-WEEK, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLINDED PHASE IIB STUDY OF MSTT1041A IN PATIENTS WITH UNCONTROLLED, SEVERE ASTHMA (NCT02918019)

Le Scouiller S,¹ Devine J,² Yang X,² Chen M,² Cheung D,² Greene A²

¹Roche, Welwyn, CA, UK, ²Genentech, South San Francisco, CA, USA

Objectives: Provide evidence to support the Asthma Daytime Symptom Diary (ADSD) and the Asthma Nighttime Symptom Diary (ANSD) to measure change in asthma symptom severity in clinical trials. **Methods:** The study was used to assess item performance, factor structure, reliability, construct validity, and sensitivity to change. ADSD was completed each evening; ANSD was completed seven consecutive days at beginning, middle and end of trial. Meaningful change estimates were derived using anchor- and distribution-based approaches. **Results:** ADSD (n=428) and ANSD (n=309) study populations were mean ages 52.1 and 51.4 years; predominantly female (n=321, 66.6% and n=201, 65.05%); and white (n=405, 84.02% and n=247, 79.94%). Both six-item measures showed high internal consistency (Cronbach's alpha coefficients = 0.95 and 0.96); ADSD score reproducibility was observed among subjects stable on PGI-2 between baseline and week 26 (ICC = 0.89). Similar ANSD data were insufficient to present ICC. Factor analyses produced high factor loadings (>0.78) for all constituent items supporting overall latent traits of daytime and nighttime symptom severity. As hypothesized, correlations (Spearman's) of greater magnitude were observed with disease-proximal measures, ACQ-5 and AQLQ symptoms (0.50 and -0.47 and 0.48 and -0.49), than distal measures, AQLQ activity limitations and EQ-5D-5L VAS (-0.39 and -0.36 and -0.43 and -0.39). ADSD and ANSD scores were significantly lower (all p<0.0001) among subgroups categorized on an external anchor as healthier (lower PGIS-PM global symptom severity, better ACQ-5 asthma control, and higher HRQOL based on EQ-5D-5L VAS). Triangulation of anchor- and distribution-based methods supports a 2-point threshold for interpreting meaningful change for ADSD and ANSD. **Conclusions:** Evidence supporting psychometric properties and meaningful change scores are presented for ANSD and ADSD, although additional data to confirm ANSD reliability are warranted.

PRS67

BARRIERS TO AND COMPETENCY WITH THE USE OF METERED DOSE INHALER AMONG ADULT ASTHMATIC PATIENTS IN ETHIOPIA

Abegaz TM

University of Gondar, Gondar, Ethiopia

Objectives: The aim of this study was to assess the barriers to and competency with the use of Metered Dose Inhaler (MDI) and its impact on disease control among adult asthmatic patients. **Methods:** A prospective cross-sectional study was conducted in University of Gondar comprehensive specialized hospital outpatient department (OPD) chronic follow up from 12-March-2018 to 15-May-2018. Patients were interviewed face to face with questions which determined their competency, asthma control level and barriers for inhaler use. **Results:** Overall, 307 asthmatic patients were included in the study. More than half of participants were females, 170 (55.4%) and lived in urban area 185 (60.3%). The mean age of the respondents was 51.77 with a standard deviation of ± 15.40. The cost of medication, 282 (91.9%) and the perception that medication should be used in response to symptoms but not on a regular basis 277 (90.2%) were the most identified barriers. Only 56 (18.2%) were competent for Metered Dose Inhaler use (MDIU) and 17 (5.5%) patients had well controlled asthma. Being not competent AOR 0.168[0.41-0.687] was one of the factors decreasing asthma control. **Conclusions:** Generally from this study, cost of the medication and the perception that medication should be used only for symptoms were the major identified barriers that affect the MDI use among asthmatic patients. Patients show very poor competence to their MDI which in turn led to poor asthma control. So, patients need to be taught the correct inhaler technique in the hospital and pharmacy while they came for follow up every time.

Respiratory-Related Disorders - Real World Data & Information Systems

PRS68

HEALTHCARE RESOURCE USE IN PATIENTS WITH SEVERE EOSINOPHILIC ASTHMA AFTER THE INITIATION OF MEPOLIZUMAB IN REAL-LIFE SETTINGS - REALITI-A STUDY

Yang S,¹ Maxwell A,² Joksaite S,³ Chaudhuri R,⁴ Pastorello EA,⁵ Lee J,⁶ Köhler TC,⁷ Ramos-Barbón D,⁸ Schleif F,⁹ Steven G,¹⁰ Alfonso R¹
¹GlaxoSmithKline, Collegeville, PA, USA, ²GlaxoSmithKline, Stevenage, UK, ³GlaxoSmithKline, Uxbridge, UK, ⁴Gartnavel General Hospital, Glasgow, UK, ⁵University of Milano and ASST GOM NIGUARDA, Milan, Italy, ⁶Toronto Asthma and Asthma Clinic, Toronto, ON, Canada, ⁷Universitätsklinikum Freiburg, Freiburg, Germany, ⁸Hospital Santa Creu i Sant Pau, Barcelona, Spain, ⁹University of Liège, Liège, Belgium, ¹⁰Allergy, Asthma and Sinus Center, Greenfield, WI, USA

Objectives: Patients with Severe Eosinophilic Asthma (SEA) represent only 5-10% of the population with asthma but their healthcare resource use (HRU) represents the largest proportion of asthma expenditures. Understanding the patterns of HRU after initiation of mepolizumab, in real-life settings, is very relevant to inform healthcare systems resource allocation. **Methods:** REALITI-A, a multicenter, international, prospective study, enrolled patients with SEA, who initiated mepolizumab. These preliminary analyses include subjects from 51 centers in 7 countries. 12-month of relevant historical data was required before enrolment for all participants to allow for a standardized period of history to describe participant's demographics, disease burden and previous medication use. Specific HRU was compared with a 12-month prospective observation period for each patient. Changes in annual rates from baseline in each health resource category were evaluated. Changes in medication use is reported elsewhere. **Results:** Preliminary data were available for 368 treated subjects who completed 12 months of follow-up. 19% of subjects discontinued mepolizumab within 1-year. Annualized rates of asthma-related hospitalizations, emergency room visits, planned and unplanned office or clinic visits, and home visits were reduced after the initiation of mepolizumab. On average, rates of asthma-related hospitalizations were reduced by 55.8% (0.52, 95% CI [0.41, 0.67] vs. 0.23, 95% CI [0.16, 0.33]) emergency visits by 55.7% (0.61 [0.45, 0.81] vs. 0.27 [0.20, 0.36]); planned and unplanned office visits by 52.2% (4.92 [4.46, 5.44] vs. 2.35 [1.97, 2.79]). The annual rate on the use of telephone calls to providers (0.90, [0.71, 1.14] vs. 1.13, [0.54, 2.34]) or home visits (0.12, [0.06, 0.25] vs 0.10, [0.02, 0.44]) was similar before and after mepolizumab. **Conclusions:** The use of mepolizumab in patients with severe eosinophilic asthma, in real-world settings, resulted in substantial reductions in healthcare resource use, particularly hospitalizations, emergency and office visits. Funding: GSK (204710)

PRS69

DIRECT MEDICAL COSTS OF SEVERE ASTHMA IN TWO COLOMBIAN REFERENCE CENTERS

Alvis-Zakzuk NJ,¹ Carrasquilla Sotomayor M,² Zakzuk Sierra J,³ Gutierrez-Clavijo J,⁴ García E,⁵ Ocampo J,⁶ Sanchez J,⁷ García Núncira CY⁸

¹Universidad de la Costa-CUC, Barranquilla, Colombia, ²ALZAK Foundation, BOGOTA, CUN, Colombia, ³ALZAK Group, Cartagena, Colombia, ⁴ALZAK Foundation, Cartagena, Colombia, ⁵Universidad de los Andes, Bogota, Colombia, ⁶Unimeq ORL SAS, Bogota, Colombia, ⁷Universidad de Antioquia, Medellin, Colombia, ⁸GlaxoSmithKline, Bogota, Colombia

Objectives: Severe asthma, although infrequent, generates an important clinical and economic burden in both patients and healthcare system. We aimed to describe demographic and clinical characteristics, exacerbations, healthcare resource utilization (HRU), and annual direct medical costs in a severe asthma patient cohort in Colombia. **Methods:** Cost of illness study from payer perspective. Patients with clinician-confirmed severe asthma diagnosis (GINA criteria) from two specialized reference centers between January 2014 and August 2018 were included. The last year within this period under GINA step 4/5 therapy was observed for each patient. Clinical information was extracted from medical records, and HRU from hospital invoices and public price lists. **Results:** 147 patients were included, 59% female. Mean (±SD) age and time with asthma diagnosis was 46±15 and 21±17 years, respectively. Most frequent comorbidities were allergic rhinitis (70%), conjunctivitis (27%) and hypertension (19%). Most common sensitization cause was house dust mite (61%). Median baseline blood eosinophil count was 260 cells/μl (range 10-4,040), mean total IgE serum level was 697±1,893 IU/ml. The mean annual frequency of HRU was 5.0±4.0 for laboratory tests, 4.1±1.2 for medical visits, 1.0±1.5 for emergency visits, 0.3±0.7 for hospitalizations, and 0.1±0.3 for ICU. Omalizumab was prescribed in 42.2% of patients, with a mean among users of 30.2±20.3 vials per year. Mean annual direct cost for outpatient care was 4,743.6±6,331.1 USD (range 256.7-31,286.1) (1 USD=2,956.4 COP); medications were responsible for 98% of costs. Data from 55 hospitalizations was obtained, 4 in ICU. Mean stay and cost per episode were 6.5±4.9 days and 1,010.5±1,379.9 USD in general ward, and 14.1±4.1 days and 3768.9±3748.2 USD in ICU. **Conclusions:** Severe asthma is a costly disease for the Colombian health system. Most of the direct outpatient medical costs in this cohort were caused by pharmacological therapy, particularly omalizumab. Funding: GSK (PRJ2813).