switch (OR = 1.6, 1.2–2.1) and discontinuation (OR = 1.8, 1.5–2.1). Heart failure was associated with augmentation (OR = 1.6, 1.0–2.5) and discontinuation (OR = 1.7, 1.2–2.4). Age was inversely associated with augmentation and discontinuation and time since diabetes diagnosis was also inversely associated with augmentation. CONCLUSIONS: HbA1c is a clear driver of treatment regimen changes although there are other factors also independently related to change such as age, heart failure and baseline OAD.

PSDB/7

TREATMENT PATTERNS OF ORAL ANTI-DIABETIC DRUGS IN THE UK

Magura A1, Mitchell R2

1United BioSource Corporation, London, UK; 2Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: In the UK, Oral Anti-Diabetic drugs (OAD) are administered to control hyperglycemia in type 2 diabetes when HbA1c exceeds 48mmol/mol (6.5%). Treatment guidelines determine initial OAD and subsequent changes in regimen depend on HbA1c response. Hence, the aim of this study is to quantify OAD treatment patterns. METHODS: All patients who initiated an OAD (except rosiglitazone) with first visit to GP OAD dataset (1/1/2016) were included. Periods of continuous and overlapping prescribing (Rx) were used to define discontinuation, switching, and augmentation; a gap of 60 days since expiry of Rx defined discontinuation. RESULTS: Of 63,600 patients commencing OAD, 88% started on metformin and 8% on glitazone both as monotherapy. Hence, all other OAD regimens comprised only 4% of all patients. Compared to metformin, the glitazone patient group was older (mean age 67 vs. 61 years) and had higher median baseline HbA1c (70 (IQR 60-95) vs. 64 (IQR 56-74) mmol/mol). The rate of discontinuation of baseline OAD at one year was 32% whilst the discontinuation of all OAD was 26%. It was rare for discontinuation of OAD to be permanent; only 3.3% of patients who discontinued in the first 12 months did not restart during 4 years. The rate of switching was 6.4% and the rate of augmentation was 15% over the first year. These rates differed according to baseline OAD. Compared to metformin the discontinuation rate remained high for gliclazide (61%); as was switching (41%), and augmentation (23% vs. 14%). Lastly, insulin uptake was just 2% by one year since OAD initiation; again this was higher in the glitazone group compared to metformin (7% vs. 1.4%). CONCLUSIONS: Most patients initiated on metformin, whilst for those initiating on glitazone, discontinuation, switching, augmentation, and insulin initiation were all higher. Most patients who discontinued OAD subsequently restarted.

SYSTEMIC DISORDERS/CONDITIONS - Clinical Outcomes Studies

PSY1

CARDIOVASCULAR AND CONGENITAL SAFETY EVALUATION OF ANTIOBESITY AGENTS, INCLUDING TOPIRAMATE: A PHARMACOVIGILANCE ANALYSIS OF THE ADVERSE EVENT REPORTING SYSTEM

Ali AK1

1University of Florida, Gainesville, FL, USA

OBJECTIVES: To review the development and properties of systemic lupus erythematosus (SLE) disease activity indices (DAIs) used in clinical trials, observational studies, and case studies. METHODS: A structured search was conducted to identify published articles in 2005-2011 through key literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from targeted rheumatology outcomes research and quality-of-life scientific meetings in 2009-2011 were included. SLE therapeutic trials within the past five years were identified through the ClinicalTrials.gov database. RESULTS: The search resulted in more than 15 different DAIs, with the most frequently used being the British Isles Lupus Assessment Group Scale (BILAG), European Consensus Lupus Activity Measure (ECLAM), Systemic Lupus Erythematosus Activity Measure (SLAM), and Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI), SLEDAI-2K-50 (SRI-50). The number of items (24-97), time to complete (5-20 mins; >20 mins for some tools in case of less physician training/familiarity), scoring (no global score or 0-100), organ/systems assessments to complete these tools, further investigation is needed to assess their feasibility for use outside of the research arena in routine clinical practice for optimal SLE management.

PSY2

PRELIMINARY VALIDATION OF COLLECT SCALE: A CO-MORBIDITY ASSESSMENT TOOL FOR PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA

Giraldo F1, Lopez A2, Ros E2, Gonzalez-Granda I1, Roset M3, Castro-Gomez A1, De La Serna J1, Carbonell I2

1Hospital Universitario de Canarias, Santa Cruz, Spain; 2Hospital Universitario de Canarias, Santa Cruz, Spain; 3Hospital Universitario del Sureste, Badajoz, Spain

OBJECTIVES: To develop, validate, and evaluate the feasibility of a co-morbidity scale to support clinical decision making for patients with Chronic Lymphocytic Leukaemia (CLL) in 5 steps: 1. Literature review, 2. -Focus Group, 3. -Pilot study to evaluate scale feasibility, 4. -Scale design, 5. -Scale validation in an observational, prospective phase IV study (evaluating safety profile of rituximab in CLL). The preliminary validation presents the preliminary validation of the COLLECT scale. METHODS: A total of 219 patients were included. The scale is to be fulfilled before initiating CLL treatment and it collates and rates the presence of 11 relevant comorbidities. The range of the score goes from 0 to 57 points. Four scoring clusters were predefined: 0-3 points (low comorbidity), 3-6 (moderate comorbidity), 7-10 (moderate comorbidity) and >10 (high comorbidity). RESULTS: Data from 218 patients of 47 hospitals were analyzed. Most frequent therapeutic scheme was rituximab-Fludarabine-Cyclophosphamide (R-FC) (61.3%), followed by Rituximab- Bendamustine (R-B) (20.9%) and Rituximab-Chlorambucil (R-C) (14.1%). COLLECT median score (SD) was 4 (0-21) with a mean of 4.8 (3.1) points. 39.2% of patients scored between 4-6 and 33% between 0-3. Statistically significant differences were observed in COLLECT score according to age (p=0.01) and ECOG (p=0.03). The greater the age and ECOG, the higher the score. The score of immunochemotherapy treatment differed depending on the score cluster: the higher the score, the higher the likelihood of SLE. CONCLUSIONS: COLLECT scale allows defining 4 levels of comorbidities, with a very good correlation to age and ECOG status. Although the aim of the scale is not to drive treatment decision, the study shows the association of comorbidity score with intensity of treatment.

PSY3

DISEASE ACTIVITY INDICES (DAIS) IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

Wyrwich K1, Winnette R2, Oglesby A1, Narayanam S3

1United BioSource Corporation, Bethesda, MD, USA; 2United BioSource Corporation, London, UK; 3GlaxoSmithKline, Research Triangle Park, NC, USA

OBJECTIVES: Assess the development and properties of systemic lupus erythematosus (SLE) disease activity indices (DAIs) used in clinical trials, observational studies, and case studies. METHODS: A structured search was conducted to identify published articles in 2005-2011 through key literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from targeted rheumatology outcomes research and quality-of-life scientific meetings in 2009-2011 were included. SLE therapeutic trials within the past five years were identified through the ClinicalTrials.gov database. RESULTS: The search resulted in more than 15 different DAIs, with the most frequently used being the British Isles Lupus Assessment Group Scale (BILAG), European Consensus Lupus Activity Measure (ECLAM), Systemic Lupus Erythematosus Activity Measure (SLAM), and Systemic Lupus Erythematosus Disease Activity Index (SLEDAI), SLEDAI-2K-50 (SRI-50). The number of items (24-97), time to complete (5-20 mins; >20 mins for some tools in case of less physician training/familiarity), scoring (no global score or 0-100), organ/systems assessments to complete these tools, further investigation is needed to assess their feasibility for use outside of the research arena in routine clinical practice for optimal SLE management.

PSY4

LENALIDOMIDE OR BORZOMIB FOR THE TREATMENT OF RELAPSED OR REFRACtORY MULTIPLE MYELOGENOUS LEUKAEMIA: A COMPARATIVE EFFECTIVENESS ANALYSIS USING INDIRECT STATISTICAL TECHNIQUES

Kaur S1, Drantisar C2

1Celgene Corporation, Summit, NJ, USA; 2Augmentum Pharma Consulting, Toronto, ON, Canada

OBJECTIVES: Lenalidomide (LEN) and bortezomib (BORT) are both effective for the treatment of relapsed/refractory MM. The former is administered 25 mg/day orally on days 1-21 of repeated 28-day cycles. The latter as a 1.3 mg/m2 intravenous dose on days 1, 8 and 15 for three weeks cycles. Currently, there are no data from head-to-head randomized trials comparing LEN and BORT. In the absence of such data, an indirect comparison between LEN and BORT was performed in the relapsed/refractory MM setting. Such an analysis was feasible because comparable controls were used in the pivotal randomized trials and patients had similar baseline characteristics. METHODS: Three pivotal randomized trials with LEN (n = 201) and BORT (n = 202) in the relapsed/refractory setting were identified. Patients within each trial had similar disease characteristics. Data in terms of response rate (RR), time to progression (TTP) and overall survival (OS) were extracted from the pivotal trials. An indirect statistical comparison between LEN and BORT was then performed using the methods of Bucher et al. (1997), which partly maintains the benefits of randomization on the magnitude of benefit. RESULTS: The analysis identified significant differences in efficacy between these drugs. Patients treated with LEN were significantly more likely to achieve a disease response (OR = 1.50; 95%CI: 1.15 - 2.05) and to have a prolongation in TTP (HR = 0.64; 95%CI: 0.44 - 0.91). The analysis also identified a trend for an OS benefit in patients receiving treatment with LEN over BORT (HR = 0.71; 95%CI: 0.46 - 1.11). CONCLUSIONS: