A CONTROLLED, PROSPECTIVE LONGITUDINAL, INTERVENTIONAL, NATURALISTIC STUDY TO EVALUATE THE UNIQUE HEALTH CARE PROGRAM “CONVERSATION MAP®” FOR TURKISH PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) WHO FAILED METFORMIN MONOTHERAPY

Qi Y1, Fu AZ2, Radican L3

1MRC London Institute of Cardiovascular Sciences, London, UK; 2Lilly Deutschland GmbH, Bad Homburg, Germany; 3Lilly Deutschland GmbH, Mainz, Germany; 4Novo Nordisk A/S, Soeborg, Denmark

OBJECTIVES: To evaluate the prescribed daily dose of liraglutide for patients in monotherapy failure in clinical practice.

METHODS: Data from the SUGAR study (PDB32) were analyzed. Patients with T2DM who failed metformin monotherapy were included. Data were collected from the German statutory health insurances (SHI) was provided by Insight Health (patient tracking data) for the period from July 2009 to March 2010 (9 months) covering about 11% of all patients in German SHI. All patients with prescriptions of liraglutide were identified (n = 4,284). Patients with only one prescription and less than 4 weeks between first and last date of prescription were excluded to avoid overrepresented influence of low dosage therapy starters (remaining patients: n = 2,118). Total number of prescribed pens was determined from first to second last provision and total consumption in mg was calculated. Number of days between first and last prescription was determined and mean average consumption in mg per day was calculated. RESULTS: The mean PDD of liraglutide in 2118 patients was 1.28 mg. Sensitivity analyses including only patients with longer periods in Glowered decreasing average consumption; patients with at least 10 weeks duration of treatment showed a mean daily dose of 1.25 mg. Stocking effects (prescription before package is empty) could have driven the increase in average use in the starting period and at the end of the calendar year. CONCLUSIONS: The longer patients use liraglutide the lower the observed PDDs. The DDD of 1.2 mg is a valid estimate for real life usage of liraglutide.

TIME TO TREATMENT MODIFICATION AMONG PATIENTS WITH TYPE 2 DIABETES WHO INITIATED EXENATIDE OR INSULIN GLARGINE

Pawasaki M1,2, Bonafele M3, Johnson BH4, Fowler R5, Hoogwerf B6

1Lilly USA, Indianapolis, IN, USA; 2Thomson Reuters Research Data Base, Philadelphia, PA, USA; 3Novo Nordisk A/S, Soeborg, Denmark; 4Lilly Germany, Hanover, Germany; 5Lilly Deutschland GmbH, Bad Homburg, Germany; 6Korolewa V, Clouth J, Freidrich-Alexander-Universität Erlangen-Nürnberg, Nuremberg, Germany

OBJECTIVES: To examine time to treatment modification for patients with type 2 diabetes (T2D) initiating treatment with exenatide BID or insulin glargine. METHODS: A retrospective analysis was conducted using the Thomson Reuters Research Database. Data were extracted from 9197 adult patients with T2D who initiated exenatide (N = 9197) or glargine (N = 2449) between October 1, 2006 and September 30, 2007 with 12 months pre- and 18 months post-index continuous enrollment included. Treatment modification was defined as the first event of change in the treatment and was classified further into two: intensification, switch or discontinuation of the particular treatment. The 1:2 cohorts were 1:1 propensity score matched on baseline demographics, clinical characteristics, and prior health care utilization. Survival analysis was used to examine time to treatment modification. RESULTS: Propensity score matching resulted in 4499 pairs of 3774 exenatide and 14 glargine patients with baseline characteristics comparable. The duration of time to treatment modification was 13.5 and 10.0 months for exenatide and glargine respectively. CONCLUSIONS: This analysis showed that exenatide-treated patients were less likely to modify their treatment suggesting potential long-term durability with exenatide therapy. Furthermore, exenatide-treated patients were less likely to discontinue or intensify but more likely to switch their treatment than glargine-treated patients.
A substantial number of new pharmaceutical treatment strategies have been introduced for the treatment of diabetes mellitus type II. The availability of these new antidiabetic drugs along the regulatory process by EMA (Europe) and FDA (USA) for the assessment of efficacy and safety as well as for reimbursement decisions by NICE (England) and IQWIG (Germany) and to compare their consistency, with a special focus on IQWIG’s procedures. METHODS: A review of relevant current method documents and reports on evaluations of antidiabetic drugs published by IQWIG was conducted. These were compared with guidance documents issued by FDA, EMA and NICE with respect to endpoints considered in diabetes and their definition, criteria for the type of evidence, and potential comparators. RESULTS: Consistently, across all agencies severe and non-severe hypoglycemia were considered highly relevant. There was, however, a substantial heterogeneity in the definition of hypoglycemia. The surrogate parameter HbA1c, as primary endpoint was accepted by all agencies investigated apart from IQWIG. In its assessments, evidence from randomized as well as from observational studies was accepted by NICE. For safety evaluations publications and studies that were taken into consideration by EMA and FDA in addition to randomized controlled trials. IQWIG on the other hand focused exclusively on randomized controlled trials for the assessment of effectiveness as well as safety. CONCLUSIONS: There is a substantial variation of criteria applied and evidence considered relevant within the assessment process of IQWIG compared to other agencies. This might lead to regional variations in the availability of drugs. It is important to be aware of the different requirements of agencies, when designing trials and planning market access.

LEARNING FROM DISEASE MANAGEMENT PROGRAMMES: HOW MEDICAL TREATMENTS AND QUALITY OF DIABETIC CARE (TYPE II) IN GERMANY ARE DIRECTLY AND INDIRECTLY IMPROVED BY DMPs


OBJECTIVES: To examine the rate and predictors of diabetes monitoring in the US. METHODS: This cross-sectional retrospective study was conducted on a representative, non-institutionalized sample of the US population, using the self-reported information from the 2007 Household Component (HC) of the MEPS. According to the American Diabetes Association (ADA) 2007 practice guidelines, proper monitoring is defined as at least two A1c tests, one eye and one foot examination annually. Health status was measured by SF-12Version2. A logistic regression model was used to examine the predictors of proper monitoring. Differences in health status and medical expenditures between patients with and without proper monitoring were examined using t-tests. Estimates were weighted to the total population (WTP).

RESULTS: Among 1,747 (WTP: 19,320,394) patients with diabetes, 80.64% had at least two A1c tests; 63.29% had an eye examination; and 67.51% had a foot examination. Older patients (OR:1.021, 95% confidence interval [CI]: 1.012–1.030), non-Hispanic Caucasians compared with African American patients (OR: 1.236, 95% CI: 0.933–1.636), patients with a higher education level (OR:1.211, 95% CI: 1.056–1.390), insurance coverage (OR:2.216, 95% CI: 1.408–3.461), use of oral anti-diabetic drugs (OR:2.935, 95% CI: 2.131–4.042) and insulin (OR:3.453, 95% CI: 2.477–4.814) were more likely to undergo the proper monitoring. Well monitored patients had a higher Mental Component Summary score (30.09 ± 0.37 vs. 48.31 ± 0.43, P < 0.05), but a lower Physical Component Summary score (39.95 ± 0.34 vs. 42.28 ± 0.47, P < 0.05).