examine the effectiveness of sequential vs. initial combination therapy. Selected patients had HbA1C ≥ 7 at initiation of combination therapy (baseline) and no prior insulin use. A1C reduction was calculated from baseline within 30 days of each other; sequential combination was defined as havingPIO monotherapy for ≥ 2 months and initiation of DP4P4 within 1 year of the initiation of PIO. Baseline characteristics were compared between cohorts using Wilcoxon rank-sum and chi-square tests. HbA1c reduction at months 4, 8, 12, and 16 from baseline was compared using linear models adjusting for demographic variables, baseline HbA1c, diabetes duration, comorbidities, and medications. RESULTS: Patients starting initial (n = 255) and sequential (n = 211) combination with PIO and DP4P were eligible for this study. Patients in the two cohorts were similar in demographics, disease duration, and most comorbidities; however, patients receiving initial combination therapy had a higher average baseline HbA1C (8.6 vs. 8.0; P = 0.001), a higher proportion with coronary artery disease (11.6% vs. 6.2%, P = 0.006), and lower weight (79.7 kg vs. 81.8 kg, P = 0.012) and hypertension (62.4% vs. 72.0%; P = 0.029). In adjusted analyses, initial combination therapy was associated with greater reduction in HbA1c at months 12 (0.98 vs. 0.82, P = 0.034) and 16 (1.45 vs. 1.24, P = 0.048) than sequential combination therapy.

CONCLUSIONS: Initial combination therapy with PIO stratified a significantly greater reduction in HbA1c than sequential combination among patients with poorly controlled blood glucose.

PDB5 REAL-WORLD TREATMENT PATTERNS AND OUTCOMES WHEN INITIATING ONCE-DAILY INJECTABLE PEN THERAPY WITH INSULIN GLARGINE OR LIRAGLU'TIDE – PILOT DATA FROM THE INITIATOR STUDY

Grabner M1, Wei W2, Meyers J3, Wang GC4, Dalal MR5, Bromberger LA6, Levin P6
1MEDICAL Clinical Research, Baltimore, MD, USA; 2Sanofi-Aventis U.S., Bridgewater, NJ, USA; 3RTI Health Solutions, Research Triangle Park, NC, USA; 4MEDICAL Health Solutions, RTP, NC, USA; 5Sanofi-Aventis U.S., BRIDgewater, NJ, USA; 6Bay West Endocrinology Associates, Baltimore, MD, USA

OBJECTIVES: Injectable pen therapy with insulin glargine (GLA-P) or the glucagon-like peptide 1 (GLP-1) analog liraglutide (LIRA) may be initiated by type 2 diabetes mellitus (T2DM) patients failing oral antidiabetic therapy. Real-world treatment patterns among T2DM patients initiating these drugs were assessed using electronic medical record (EMR) data in this retrospective study. METHODS: The study included adult T2DM patients who initiated GLA-P or LIRA at seven US endocrinology practices. EMR data for ≥4 months before treatment initiation (baseline), baseline A1C and weight data, and ≥1 additional A1C measurement were available; patients had ≥2 visits during a minimum of six months follow-up. Baseline characteristics of these patients were assessed descriptively at the end of 1-year follow-up. Patients were stratified by whether they were injectable-naïve (IN) or injectable-experienced (IE) at initiation. RESULTS: The study included 440 patients. At baseline, GLA-P patients (n = 117), compared with LIRA patients (n = 323), were older, had higher baseline A1C, and lower weight; more were male, fewer IE (60.7% vs. 65.3%). Insulin/GlP1 were the only injectables in 49.3% 31.3% of LIRA vs. 62.0% to 26.8% of GLA-P patients at baseline. Through follow-up, 88% of GLA-P and 91.6% of LIRA patients remained on study treatment. A1C was significantly reduced in all four treatment groups (range – 0.42% for LIRA IE to – 1.38% for GLA-P IN). Weight loss occurred in 74.2% of LIRA vs. 43.3% of GLA-P patients. Mean change in weight/BMI = 2.25kg/0.86kg/m2 for LIRA vs. 2.4kg/0.85 kg/m2 for GLA-P patients. No severe hypoglycemic events were reported. CONCLUSIONS: Our study identifies a trend in the real-world prescribing of LIRA and GLA-P to T2DM patients in our study. This introduces a future study when performing real-world comparative effectiveness studies. Due to the small sample size and descriptive nature of this study, these data should be confirmed by future large scale studies.

PDB6 REAL-WORLD COMPARE EFFICACY ANALYSIS OF PATIENTS INITIATING INJECTABLE TREATMENTS FOR TYPE 2 DIABETES MELLITUS (T2DM): PILOT DATA FROM THE INITIATOR STUDY

Grabner M1, Wei W2, Rapala S2, Quimbo RA3, Cziraky MJ4, Thayer SW5, Brekke L6
1MEDICAL Clinical Research, Baltimore, MD, USA; 2Sanofi-Aventis U.S., Bridgewater, NJ, USA; 3RTI Health Solutions, Research Triangle Park, NC, USA; 4MEDICAL Health Solutions, RTP, NC, USA; 5Bay West Endocrinology Associates, Baltimore, MD, USA; 6Bay West Endocrinology Associates, Baltimore, MD, USA

OBJECTIVES: Injectable pen therapy with insulin glargine (GLA-P) or the glucagon-like peptide 1 (GLP-1) analog liraglutide (LIRA) may be initiated by type 2 diabetes mellitus (T2DM) patients failing oral antidiabetic therapy. Real-world treatment patterns among T2DM patients initiating these drugs were assessed using electronic medical record (EMR) data in this retrospective study. METHODS: The study included adult T2DM patients who initiated GLA-P or LIRA at seven US endocrinology practices. EMR data for ≥4 months before treatment initiation (baseline), baseline A1C and weight data, and ≥1 additional A1C measurement were available; patients had ≥2 visits during a minimum of six months follow-up. Baseline characteristics of these patients were assessed descriptively at the end of 1-year follow-up. Patients were stratified by whether they were injectable-naïve (IN) or injectable-experienced (IE) at initiation. RESULTS: The study included 440 patients. At baseline, GLA-P patients (n = 117), compared with LIRA patients (n = 323), were older, had higher baseline A1C, and lower weight; more were male, fewer IE (60.7% vs. 65.3%). Insulin/GlP1 were the only injectables in 49.3% 31.3% of LIRA vs. 62.0% to 26.8% of GLA-P patients at baseline. Through follow-up, 88% of GLA-P and 91.6% of LIRA patients remained on study treatment. A1C was significantly reduced in all four treatment groups (range – 0.42% for LIRA IE to – 1.38% for GLA-P IN). Weight loss occurred in 74.2% of LIRA vs. 43.3% of GLA-P patients. Mean change in weight/BMI = 2.25kg/0.86kg/m2 for LIRA vs. 2.4kg/0.85 kg/m2 for GLA-P patients. No severe hypoglycemic events were reported. CONCLUSIONS: Our study identifies a trend in the real-world prescribing of LIRA and GLA-P to T2DM patients in our study. This introduces a future study when performing real-world comparative effectiveness studies. Due to the small sample size and descriptive nature of this study, these data should be confirmed by future large scale studies.

PDB8 WEIGHT LOSS OF ≤3% OF BODY WEIGHT AFTER INITIATING NEW ANTI-DIABETIC THERAPY IS ASSOCIATED WITH GLYCEMIC CONTROL AT 6 MONTHS IN PATIENTS WITH TYPE 2 DIABETES

McClam-marx C1, Reowers R2, Vigny GP3, Mukherjee J, Eniojukan JF1
1University of Utah, Salt Lake City, UT, USA; 2Eli Lilly and Company, Indianapolis, IN, USA; 3Eli Lilly and Company, Bridgewater, CT, USA

OBJECTIVES: We previously identified a correlation between weight loss and glycemic control in patients with type 2 diabetes (T2DM) newly treated with oral or GLP-1 inhibitor therapy in the real-world setting. This study expands on those findings including prescribing patterns of T2DM patients who received insulin. METHODS: This cohort study included T2DM patients aged ≥18 years in an electronic medical record database from 2008-2011 prescribed a class of anti-diabetic not previously used (index date), and with a baseline HbA1c ≥7.0%. Weight and HbA1c data were collected from baseline to 6-month follow-up among patients who lost ≥3% of body weight and attained HbA1c goal (<7.0%) were identified. Logistic regression was used to describe the association between weight loss and glycemic control for confounding factors, including initiation of insulin or other therapies. RESULTS: The study included 861 patients. Mean (SD) age was 58.7 (12.3) years; 54.8% were male. Most patients (85.9%) were prescribed a non-insulin agent. Baseline HbA1c was 8.7% (1.6); weight was 103.6 kg (23.6). At 6 months, mean weight change was -1.6 (5.3) kg (p = 0.13) and 31.8% lost weight. Mean change in HbA1c was -1.2% (1.8) (p = 0.003). Overall, 42.9% attained HbA1c goal while 64.2% of patients who lost weight and 32.9% of those who did not lose weight. These data are consistent with T2DM treatment guidelines that emphasize the importance of weight loss and prioritization of anti-diabetes agents that are not associated with weight gain.

PDB9 OUTCOME OF FIXED DOSE RADIOACTIVE IODINE FOR THE TREATMENT OF HYPERTHYROIDISM

Obidiya SO1, Ogunjobi K2, Eniojukan JF1
1University College Hospital, Ibadan, Nigeria; 2Obafemi Awolowo University, Ile-Ipese, Nigeria

OBJECTIVES: To determine: 1) the response or cure rate of hyperthyroidism to fixed dose of 370MBq (10mCi) radioactive iodine (RAI) therapy, and 2) the incidence of hypothyroidism at 6 months post RAI therapy. METHODS: A retrospective review of the records of 20 hypothyroid patients treated with radioactive iodine to determine response rate of hyperthyroidism to two fixed dose regimens of RAI therapy was carried out. Twelve (12) and 8 patients received 370MBq (10mCi)
and 555Mbq (15mCi) fixed dose regimens respectively. The data on demographic (age, gender), clinical (presence of eye disease, the size/type of goiter) and biochemical variables (fasting/two-hour glucose, HbA1c) were collected. The entry criterion to be included in this study was having T2DM patients inadequately controlled by monotherapy under real life conditions. Here we demonstrate effectiveness results for patients receiving vildagliptin or sulfonylureas (SU) add-on to metformin in Germany. METHODS: T2DM patients inadequately controlled with monotherapy were randomized to vildagliptin or SU. Patients were grouped into tertiles of sites treated. RESULTS: A total 8887 patients were enrolled in Germany, 5779 patients received metformin + vildagliptin (4960) or metformin + SU (819). Mean age was 62.1 ± 11.1 years, mean BMI duration was 5.8 ± 4.9 years. Average BMI was 30.8 ± 5.5 kg/m2. Mean baseline HbA1c was comparable (vildagliptin 7.8%, SU 7.7%). After 12 months of treatment, HbA1c decreased in both cohorts (vildagliptin: -0.69%, SU: -0.46%) but the drop was significantly greater with vildagliptin compared to SU (p < 0.001). The overall recorded number of hypoglycemic events was low (vildagliptin:0.11%, SU:0.41%) but almost 4-fold higher in the SU cohort when compared to the vildagliptin cohort. CONCLUSIONS: In real life clinical practice in Germany, vildagliptin is associated with a low incidence of hypoglycemic events and a higher percentage of patients reaching target HbA1c without hypoglycemia and weight gain compared to SU.

PDB11 EFFECTIVENESS OF VILDAGLIPTIN COMPARED TO SUFONYLUREAS IN TYPE 2 DIABETES PATIENTS IN GERMANY: RESULTS FROM A LARGE REAL-LIFE COHORT STUDY

Depeña M1, Gruenberger RF2, Rader G3, Novartis Pharma GmbH, Germany, 4Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: Metformin is an established first line treatment for type 2 diabetes mellitus (T2DM) patients but intensification of oral antidiabetic therapy is usually required over time. The Effectiveness of Diabetes control with vildagliptin and vildagliptin/metformin (EDGE) study compared effectiveness and safety of vildagliptin alone or in combination with SU (combinations) in German general practice and throughout the world. Aim of the study was to investigate inadequately controlled by monotherapy under real life conditions. Here we demonstrate effectiveness results for patients receiving vildagliptin or sulfonylureas (SU) add-on to metformin in Germany. METHODS: T2DM patients inadequately controlled with monotherapy were randomized to vildagliptin or SU. Patients were grouped into tertiles of sites treated. RESULTS: A total 8887 patients were enrolled in Germany, 5779 patients received metformin + vildagliptin (4960) or metformin + SU (819). Mean age was 62.1 ± 11.1 years, mean BMI duration was 5.8 ± 4.9 years. Average BMI was 30.8 ± 5.5 kg/m2. Mean baseline HbA1c was comparable (vildagliptin 7.8%, SU 7.7%). After 12 months of treatment, HbA1c decreased in both cohorts (vildagliptin: -0.69%, SU: -0.46%) but the drop was significantly greater with vildagliptin compared to SU (p < 0.001). The overall recorded number of hypoglycemic events was low (vildagliptin:0.11%, SU:0.41%) but almost 4-fold higher in the SU cohort when compared to the vildagliptin cohort. CONCLUSIONS: In real life clinical practice in Germany, vildagliptin is associated with a low incidence of hypoglycemic events and a higher percentage of patients reaching target HbA1c without hypoglycemia and weight gain compared to SU.