RESEARCH POSTER PRESENTATIONS – SESSION V

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

COMPARISON OF INSULIN GLARGINE VERSUS NPH INSULIN TREATMENT AMONG T2DM PATIENTS WITH TYPE 2 DIABETES BASED ON REVIEW OF CLINICAL TRIAL RESULTS

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OBJECTIVE: Basal insulin therapy is commonly initiated in type 2 diabetes (T2DM) patients with a long-acting insulin, such as insulin glargine or the intermediate-acting insulin, NPH. In this study we evaluated the frequency of hypoglycemia associated with insulin glargine vs. NPH insulin treatment based on clinical trial results.

METHODS: A systematic search was conducted in PubMed to identify clinical trials (2000-2013) in which the efficacy and safety of insulin glargine and NPH insulin treatments were evaluated among patients with T2DM. The primary outcome was the response to review of clinical trial results were the frequencies of symptomatic and nocturnal hypoglycemia during trial periods. Of the 366 abstracts reviewed, 7 were of clinical trials with insulin glargine and NPH insulin treatment arms in which hypoglycemia frequency was reported.

RESULTS: A total of 1,389 T2DM patients were treated with insulin glargine and 1,132 with NPH insulin. The frequency of symptomatic hypoglycemia was highly variable across the trials, ranging from 35%–96% with insulin glargine and 41%–77% with NPH insulin, as was nocturnal hypoglycemia, which ranged from 0%–14% with insulin glargine and 10%-40% with NPH insulin. Two of the 7 trials reported that the frequency of symptomatic hypoglycemia was significantly less among T2DM patients treated with insulin glargine vs. NPH insulin. Of the 5 trials reporting the frequency of nocturnal hypoglycemia 4 reported it was significantly less among T2DM patients treated with insulin glargine vs. NPH insulin. Differences in the change in HbA1c with insulin glargine vs. NPH insulin. Of the 5 trials reporting the frequency of nocturnal hypoglycemia were non-significant in all studies, except for 2 with morning insulin glargine arms. CONCLUSIONS: Based on clinical trial results insulin glargine and NPH insulin appear similar in glycemic efficacy, but treatment with insulin glargine may be associated with less symptomatic and nocturnal hypoglycemia than treatment with NPH insulin. Additional studies are needed to confirm these findings.

PDB2

IDENTIFYING FACTORS ASSOCIATED WITH HYPOGLYCEMIA-RELATED HOSPITALIZATION AMONG ELDERLY PATIENTS WITH T2DM IN THE UNITED STATES: A Novel Approach Using Influential Variable Analysis

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OBJECTIVE: The providers managing older patients with type 2 diabetes mellitus (T2DM) face a complex milieu of medical conditions and comorbidities, which increase the risk of unintended treatment consequences. The objective of this study was to understand major factors associated with hypoglycemia-related hospitalization in T2DM among older adults (≥ 65 years of age) with T2DM with or without complications.

Methods: A large claims-based retrospective cohort study in the United States was undertaken on actively registered patients with a diagnosis of T2DM and at least one diabetes treatment prescription during 2010, which included all oral or insulin/insulin-antidiabetic therapy. The main outcomes assessed included hypoglycemia-related hospitalization and readmission, frequency of comorbidities, and clinical outcomes. RESULTS: Of patients ≥ 65 years of age with T2DM in hospitalization records (n=887,182), 52.3% were women, 30.7% were aged ≥65 years. At baseline, the proportion of patients taking metformin was 52.4%, insulin 7.3%, and sulfonylurea 26.4%. Among those who experienced a diabetes-related hospitalization, the incidence of hospitalization-related hypoglycemic events was 26.2% among patients ≥65 years of age compared to <65 years of age (0.59 compared to 0.16 per 1000 person years). Using boosted regression tree modeling, age (older vs. younger), sulfonylurea use, insulin use and renal disease were the variables most associated with predicting a hospitalization associated with hypoglycemia. Elderly patients prescribed both insulin and sulfonylurea were most likely to have hypoglycemia-related hospitalizations (odds ratio=4.7, 95% CI 3.7-6.1). CONCLUSIONS: Older patients using both insulin and sulfonylureas were the most likely to experience a hypoglycemia-related hospitalization in this study. Age, sulfonylurea use, insulin use, and renal disease were the top four influential variables to be associated with hypoglycemia-related hospitalization, while glucagon-like peptide and dipeptidyl peptidase 4 were less likely to be associated with these events. More research is required to quantify the burden of these events given sulfonylurea and insulin are presently seen as a very effective and low cost treatment alternatives.

PDB3

INSULIN OR THIAZOLIDINEDIONE USE AND FRUCTOSE RISK IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND DIABETES MELLITUS

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OBJECTIVE: Tight control diabetes mellitus (DM) with insulin has the potential to increase hypoglycemic episodes which may result in fall and fracture risk. Moreover, patients with chronic obstructive pulmonary disease (COPD) are at high risk of fractures which may put patients with combination COPD and diabetes are at particular risk. Our goal was to compare the risk of fractures associated with insulin use compared to T2Ds in patients with COPD and DM. METHODS: We conducted a nested case-control study using the IMS LifeLink® Health Plan Claims database, including patients at least 45 years old with a diagnosis of COPD and DM that were new users of either a T2D or insulin. Cases were identified that experienced a fracture between January 2006 and December 2011. Controls were matched with cases based on the following characteristics: gender, a geography, an insurance type, and date of first dispensing of a T2D or insulin prescription. We conducted conditional logistic regression analyses to estimate the odds ratios (ORs) of having a fracture associated with the use of insulin compared to T2D while controlling for other covariates. RESULTS: There were 2,861 cases matched with 8,256 controls. The mean (standard deviation) age of the study subjects was 46.5 years (0.9) and 57.6% were women. Among cases, 32.8% used insulin and 67.2% used T2Ds, and for controls 40.3% used insulin and 59.7% used T2Ds. The crude OR for getting a fracture compared with T2D was 1.14 (95% confidence interval [CI], 1.04-1.25). After adjustment for other antidepressant drugs, comorbidities, and comorbidities, the OR was 1.28 (95% CI, 1.09-1.49). CONCLUSIONS: We found an association between use of insulin and fractures compared to T2Ds in patients with COPD and DM. While further research is needed, clinicians and policy makers should assure that screening guidelines consider this relative risk in patients with COPD and DM.

PDB4

CLINICAL EFFICACY AND SAFETY OF INSULIN ASPART COMPARED WITH REGULAR HUMAN INSULIN IN PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES

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OBJECTIVE: Prandial insulins are a key component in insulin treatment in type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) patients. The evidence supporting a choice between available insulin preparations is still limited. We performed a systematic review of clinical data comparing efficacy and safety of insulin aspart (Asp) and regular human insulin (RHI). RESULTS: METHODS: Randomized controlled trials (RCTs) directly comparing Asp with RHI after >12 weeks of treatment in patients with either T1DM or T2DM receiving treatment within similar background (data from clinical trials analysed). RESULTS: Of patients with T2DM, 1,132 with insulin glargine and 1,132 with NPH insulin. The difference in the change in HbA1c with insulin glargine vs. NPH insulin. Of the 5 trials reporting the frequency of nocturnal hypoglycemia 4 reported it was significantly less among T2DM patients treated with insulin glargine vs. NPH insulin. Differences in the change in HbA1c with insulin glargine vs. NPH insulin. Of the 5 trials reporting the frequency of nocturnal hypoglycemia were non-significant in all studies, except for 2 with morning insulin glargine arms. CONCLUSIONS: Based on clinical trial results insulin glargine and NPH insulin appear similar in glycemic efficacy, but treatment with insulin glargine may be associated with less symptomatic and nocturnal hypoglycemia than treatment with NPH insulin. Additional studies are needed to confirm these findings.

PDB5

A SYSTEMATIC LITERATURE REVIEW AND EVIDENCE SYNTHESIS OF ANTI-DIABETES TREATMENTS IN TYPE 2 DIABETES MELLITUS PATIENTS: INDIRECT COMPARISON OF EXENATIDE WITH METFORMIN + SULPHONYLUREA


OBJECTIVES: To support a German Federal Joint Committee (G-BA) submission, a systematic review and meta-analysis feasibility were conducted to assess the efficacy and safety of the GLP-1 receptor agonist exenatide as compared to metformin required by the G-BA, for the management of patients with Type 2 diabetes mellitus (T2DM). Both the short- (Byetta®) and long-acting (Bydureon®) exenatide formulations were eligible for inclusion. METHODS: Database searches (accessed September 2013) were conducted to identify eligible randomised controlled trials (RCTs) that evaluated Byetta®/Bydureon® in one of the G-BA approved indications. In the absence of appropriate head-to-head studies, the feasibility of conducting a robust meta-analysis was assessed for outcomes of interest. RESULTS: With regard to Byetta®, single head-to-head RCTs were identified for two G-BA required comparisons: Byetta®+metformin vs metformin+glibenclamide (SU) and Byetta®+metformin+SU vs insulin+metformin. No head-to-head RCTs were identified that assessed Bydureon® vs G-BA comparators. However, two RCTs were identified which permitted an indirect comparison of Bydureon®+metformin vs metformin+SU via a common treatment (sitagliptin+metformin). Baseline patient characteristics (body weight 81-89 kg; HbA1c 7.5-8.6%; duration of diabetes ≥7 years) were comparable across these studies and were compa-