DISEASE-RELATED OUTCOMES – Clinical Outcomes Studies

PDB1

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

Liu L, Lin-goehr-Smith M, Novartis, Illinois, MN, USA

OBJECTIVES: 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 a 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 hypoglycaemia 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 hypoglycaemia was highly variable across the trials, ranging from 35%-96% with insulin glargine and 41%-77% with NPH insulin, as was nocturnal hypoglycaemia, which ranged from 8%-26% with insulin glargine and 10%-40% with NPH insulin. Two of the 7 trials reported that the frequency of symptomatic hypoglycaemia was significantly less among T2DM patients treated with insulin glargine vs. NPH insulin. Of the 5 trials reporting the frequency of nocturnal hypoglycaemia 4 reported it was significantly less among T2DM patients treated with insulin glargine vs. NPH insulin. Differences in the change in HbA1c during trial periods were reported as 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 glycomic 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

Curtis RJ, Shachaf A, Wu T, Fu H.

OBJECTIVES: Health care 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 hospitalized admissions among older patients with T2DM. 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 therapy prescription, which included an oral or insulin/injectable anti-diabetic therapy. The main outcomes assessed included hypoglycemia-related hospitalization and readmission, frequency of comorbidities, and clinical outcomes. RESULTS: Of more than 2.5 million T2DM hospitalization records (n=887,182), 52.3% were identified as medical claims. 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 hypoglycemia in patients ≥65 years of age was greater than in patients <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 glimepiride and glibenclamide 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 CATEGORIZED OBSTRUCTIVE PULMONARY DISEASE AND DIABETES MELLITUS

Uslan ID, Lee WJ, Lee TA, University of Illinois at Chicago, Chicago, IL, USA

OBJECTIVES: Tight control of 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 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 individuals that experienced a fracture between January 2006 and December 2011. Controls were matched with cases based on the following characteristics: gender, a geographic comparator, 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 2,672 cases matched with 5,344 controls. The crude OR for fractures compared with T2D was 1.14 (95% confidence interval [CI], 1.04-1.25). After adjustment for other antidiabetic drugs, comorbidities, and the OR was 1.28 (95% CI, 0.91-1.80). CONCLUSIONS: An association between use of insulin and fracture risk compared to T2Ds in patients with COPD and DM. Further research is needed, clinicians and policy makers should assure that screening guidelines consider this relative risk in patients with COPD and DM.