**PD1**  COMPARISON OF INSULIN GLARGINE VERSUS NPH INSULIN TREATMENT AMONG PATIENTS WITH TYPE 2 DIABETES BASED ON REVIEW OF CLINICAL TRIAL RESULTS

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**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 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 noc- turial hypoglycemia, which ranged from 13%-31% 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 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 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.

**PD2**  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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**RESULTS:** Older patients using both insulin and sulfonylurea were the most likely to experience a hypoglycemia-related hospitalization in this study. Age, 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 sulfonylurea 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 glycemic controls like peptide and diglyceride 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.

**PD3**  INSULIN OR THIAZOLIDINEDIONE USE AND FRUSTRIC RISK IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND DIABETES MELLITUS

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**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 result in fall and fracture risk.

**RESULTS:** Of the 672 patients, 47% were diabetic patients with COPD. The incidence of fractures which may result in fall and fracture risk was significantly higher in patients with COPD and DM.

**CONCLUSIONS:** The incidence of fractures which may result in fall and fracture risk was significantly higher in patients with COPD and DM.

**PD4**  CLINICAL EFFICACY AND SAFETY OF INSULIN ASPART COMPARED WITH REGULAR HUMAN INSULIN IN PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES TREATED WITH EXENATIDE RECEIVING FRANIDAL INSULIN REGIMEN - A SYSTEMATIC REVIEW AND META-ANALYSIS

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**OBJECTIVES:** 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 (IAsp) and regular human insulin (RHI).

**METHODS:** Randomized controlled trials (RCTs) directly comparing IAsp with RHI after ≥12 weeks of treatment in patients with either T1DM or T2DM receiving treatment within insulin-aspart regimens (35 RCTs, 46,500 participants, 32 RCTs were conducted in T1DM patients). The primary endpoint of the systematic review was the incidence of hypoglycemic events. Secondary endpoints included a comparison of the overall and severe hypoglycemic event rates in T1DM and T2DM patients.

**RESULTS:** The incidence of hypoglycemic events was significantly lower in T1DM patients treated with IAsp (4 RCTs; RR [95% CI], 0.69 [0.64, 0.74]), while no difference was observed for severe hypoglycemic events. In T2DM patients IAsp lead to a larger hypoglycemia reduction (5 RCTs; WMD [95% CI], -0.27 [-0.39, -0.05]) and provided superior postprandial blood glucose control. The risk of hypoglycemia, either overall or severe events was comparable between arms.

**CONCLUSIONS:** IAsp provided better glycemic control as compared with RHI in T1DM and T2DM in patients receiving prandial insulin regimen. T2DM patients treated with IAsp were less prone to develop nocturnal hypoglycemia, with both interventions presented comparable risk of severe hypoglycemic events.

**PD5**  A SYSTEMATIC LITERATURE REVIEW AND EVIDENCE SYNTHESIS OF ANTI-DIABETES TREATMENTS IN TYPE 2 DIABETES MELLITUS PATIENTS: INDIRECT COMPARISON OF EXENATIDE WITH METFORMIN + SU/LUPHONYLUREA


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**OBJECTIVES:** To support a German Federal Joint Committee (G-BA) submission, a systematic literature review and meta-analysis feasibility were conducted to assess the efficacy and safety of the GLP-1 receptor agonist exenatide vs. other comparators as required by the G-BA, for the management of patients with type 2 diabetes mellitus (T2DM). Both the short- (Byetta®) and long-acting (Byduerone®) 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+luphonylurea (SU) and Byetta®+metformin+SU vs insulin+metformin+SU. No head-to-head RCTs were identified that assessed Byduerone® vs Byetta® comparators. However, two RCTs were identified which permitted an indirect comparison of Byduerone®+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 5–7 years across treatment arms) and study duration (26-30 weeks) were comparable.

**CONCLUSIONS:** Indirect comparison results indicated that treatment with Byduerone®+metformin was associated with a significantly greater reduction in mean glycated haemoglobin difference compared to Byetta®+metformin across all assessed A1C (OR 1.22 [95% CI: 0.6, 5.70; p=0.800]) was similar. **CONCLUSIONS:** Indirect comparison results indicate that in patients with T2DM, treatment with Byduerone®+metformin is associated with significant efficacy benefits and a similar safety profile compared with metformin+SU.