

and $\geq 9\%$, respectively. Compared with placebo, more patients achieved HbA1c $< 7\%$ (39.4% vs 24.4%) and $< 8\%$ (79.5% vs 60.6%) and fewer patients remained at or worsened to HbA1c $> 9\%$ (4.2% vs 13.9%) with dapagliflozin. **CONCLUSIONS:** Dapagliflozin 10 mg/day reduced HbA1c across all baseline HbA1c categories; greater reductions were seen in patients with higher baseline HbA1c. Substantially more patients attained HEDIS HbA1c categories of $< 7\%$ and $< 8\%$ and substantially fewer patients remained at or worsened to HbA1c $> 9\%$ with dapagliflozin, compared with placebo. Collectively, dapagliflozin provided better glycemic control than placebo over a range of HbA1c levels.

PDB9

COST-EFFECTIVENESS ANALYSIS OF SAXAGLIPTIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN RUSSIA

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OBJECTIVES: To evaluate the long-term clinical and economic consequences of saxagliptin in comparison with sulphonylurea available in the Russian market. **METHODS:** The analysis is based on the Cardiff Long Term Model (Clarke et al. 2004). Three scenarios were developed and tested. Scenario 1 "trial based scenario" (S1) the active treatment is saxagliptin (Onglyza®) added to metformin (MET), which is compared to MET plus sulphonylurea (SU); input data are derived from study D1680C00001 (Goke et al. 2010). Scenario 2 "real world scenario" (S2). Efficacy and safety data taken from study D1680C00001, the cohort was taken from the Russian Federal Diabetes Patient Register, time horizon was set to 40 years, HbA1c threshold of 9.0% was assumed. Scenario 3 "MET monotherapy scenario" (S3). Efficacy and safety data taken from a study of DeFronzo et al. 2009. Patient demographic characteristics were the same as in Scenario 2; time horizon - nine years as in the base case scenario 1. The cost-effectiveness analysis was performed from the government health care system's perspective. The costs applied were based on prices listed in the essential drug list (MoH 2010) and official standards of treatment developed by expert groups at the Ministry of Health level (Russian Federation). **RESULTS:** In S1 - MET plus saxagliptin was associated with an incremental cost-effectiveness ratio (ICER) of Russian Roubles (RUB) 38,840 per QALY gained, and RUB 7,142,690 per life year gained (LYG) versus SU. In S2 - ICER of RUB 104,153 per QALY gained and RUB 9,884,121 per life year. In S3 - ICER resulted in RUB 20,353,081 per QALY and RUB 29,044,346 per life year gained. **CONCLUSIONS:** In both scenarios (1 and 2), assuming a willingness to pay threshold of RUB 800'000, saxagliptin would be considered cost-effective in the Russian setting.

PDB10

A META-ANALYSIS OF EFFICACY AND SAFETY OF DIPEPTIDYL PEPTIDASE-4 [DPP-4] INHIBITORS IN TYPE 2 DIABETES

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OBJECTIVES: To assess the efficacy and safety of DPP-4 inhibitors, including sitagliptin, saxagliptin, vildagliptin and linagliptin, in type 2 diabetic patients. **METHODS:** Both published and unpublished randomized controlled trials (RCTs) for type 2 diabetic patients were selected if they: 1) compared DPP-4 inhibitors with either placebo or another hypoglycemic; 2) had study duration of ≥ 12 weeks; and 3) had at least one baseline and post-treatment efficacy and/or safety outcome. **RESULTS:** A total of 62 articles met the inclusion criteria. Seven of these trials involved Japanese patients, but inclusion resulted in significant heterogeneity ($I^2 = 82\%$). Exclusion of these 7 trials resulted in a reduction of heterogeneity ($I^2 = 59\%$) with a more stable pooled effect size. Analyses of the non-Japanese studies ($n = 55$ RCTs) indicated that, compared to placebo, DPP-4 inhibitors were associated with a reduction in hemoglobin (Hb) A1c (weighted mean difference (WMD) = -0.65%; 95% CI, -0.71 to -0.60) but a higher risk of hypoglycemia (Odds ratio (OR) = 1.30; 95% CI, 1.01 to 1.68). A separate analysis of the 7 Japanese studies showed that, compared to placebo, DPP-4 inhibitors were associated with a greater reduction in HbA1c than non-Japanese patients (WMD = -1.67%; 95% CI, -1.89 to -1.44; $P < 0.05$) and a non-significant increase in risk of hypoglycemia (OR, 1.41; 95% CI, 0.51 to 3.88). When comparing DPP-4 inhibitors to active comparators, the I^2 was still high after separating out Japanese studies. In the 17 active comparator trials, there was no significant difference in HbA1c reduction (WMD = 0.04%; 95% CI, -0.09 to 0.16) or risk of hypoglycemia (OR = 0.60; 95% CI, 0.22 to 1.61) for DPP-4 inhibitors compared to other anti-diabetic medications. **CONCLUSIONS:** Differences in efficacy and safety were observed between Japanese and non-Japanese patients. The extent of HbA1c reduction was more than doubled in trials including Japanese populations compared to non-Japanese populations.

PDB11

HEALTH OUTCOMES OF INITIATING BASAL ANALOG INSULIN VIA DISPOSABLE PENS AMONG PATIENTS WITH TYPE-2 DIABETES IN A NATIONAL MANAGED CARE PLAN IN THE UNITED STATES

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OBJECTIVES: To evaluate, in a US managed care setting, health outcomes among patients with type 2 diabetes mellitus (T2DM) initiating basal insulin therapy via disposable pen with insulin glargine (GLA-P) or insulin detemir (DET-P). **METHODS:** Using the claim database from a US health plan (InVision™), T2DM patients initiating GLA-P or DET-P were included if they were ≥ 18 years, had continuous health plan coverage for 6 months before (baseline) and 1-year after initiation (follow-up), with ≥ 1 prescription for oral antidiabetic drugs (OADs) and/or exenatide, but no

insulin use, during baseline. To minimize selection bias, stringent 1:1 propensity score matching was used to balance baseline characteristics of the two cohorts. Outcomes measures included 1-year treatment persistence and adherence, hemoglobin A1c (A1C), hypoglycemia-related events, healthcare utilization and costs. **RESULTS:** A total of 5828 matched patients were included ($n = 2914$ in each cohort; female 44.4%, baseline mean age 54.4 years; Charlson comorbidity index 0.55; number of OADs 2.60). During 1-year follow-up, patients initiating GLA-P, compared with DET-P, were more persistent (58.8 vs. 44.1%, $P < 0.001$) and adherent (adjusted medication possession ratio 0.68 vs. 0.66, $P = 0.002$) with treatment, had lower daily insulin doses (DAICON) (29.2 vs. 32.5 units/day, $P = 0.012$), similar rates of hypoglycemia-related events (5.9 vs. 6.6%, $P = 0.281$), lower diabetes prescription costs (mean \$3,142 vs. \$3,372, $P = 0.043$) and marginally lower total health care costs (mean \$30,364 vs. \$33,109, $P = 0.086$). Among patients with A1C data available (GLA-P $n = 356$, DET-P $n = 332$), A1C at 1-year follow-up was 8.14% in GLA-P vs. 8.50% in DET-P ($P = 0.007$), reflecting A1C reduction from baseline of -1.03 vs. -0.86% ($P = 0.260$). **CONCLUSIONS:** This real-world comparative study suggested that among T2DM patients initiating basal analog insulins using disposable pen, compared with DET-P, GLA-P might be associated with increased treatment persistence and adherence, similar rates of hypoglycemia, lower DAICON and healthcare costs during 1-year follow-up. This, however, should be confirmed in future pragmatic randomized clinical trials.

PDB12

COMPARATIVE EFFECTIVENESS STUDY OF ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND ANGIOTENSIN RECEPTOR BLOCKERS IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: Angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) are recommended to reduce albuminuria, a risk factor for nephropathy and all-cause mortality. The objective of the study was to compare ACEIs and ARBs for development of end-stage renal disease (ESRD) development and all-cause mortality in veteran patients with type 2 diabetes. **METHODS:** This was a retrospective cohort study utilizing data in years 2002-2007 from the national Department of Veterans Affairs (VA) databases. To be included in the sample patients had to be newly-diagnosed, new users of ACEIs or ARBs, and have a baseline measure of albuminuria. Multivariate logistic regression models that assessed effect of ACEIs and ARBs on ESRD and all-cause mortality were estimated with controls for risk factors of ESRD and all-cause mortality, Elixhauser comorbidities, and location of care. Propensity scores were used to adjust for differences in baseline characteristics between ACEI and ARB patients. **RESULTS:** A total of 20,876 patients using ACEIs ($n = 18,947$) or ARBs ($n = 1929$) met inclusion criteria. Mean follow-up was two years. No significant differences were found between ACEIs and ARBs for ESRD (1.12 [95% CI=0.19-6.72]) and all-cause mortality (0.86 [95% CI=0.24-3.07]). Some comorbidities, however, had higher adjusted odds for ESRD (liver disease odds ratio 7.40 [95% CI=2.91-18.87]; fluid and electrolyte disorders odds ratio 7.71 [95% CI=3.46-17.17]; deficiency anemias odds ratio 5.81 [95% CI=2.40-14.09]) or all-cause mortality (history of myocardial infarction odds ratio 2.85 [95% CI=1.26-6.46]), underlining the importance of prevention of these conditions. **CONCLUSIONS:** There were no significant differences in ESRD and all-cause mortality between ACEIs and ARBs in this study that included patients from every state in the United States, the District of Columbia, and Puerto Rico. Additionally, this study shows that clinicians should focus educational efforts on disease prevention due to downstream effects of certain conditions in patients with type 2 diabetes.

PDB13

SHORT STATURE IN TURNER SYNDROME: BASAL CHARACTERISTICS AND FOLLOW-UP OF A COLOMBIAN COHORT

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OBJECTIVES: Turner syndrome (TS) is a chromosomal disorder that has total or partial absence of chromosome X and haploinsufficiency of the SHOX gene. Furthermore, it is associated with short stature with particular phenotype and hypogonadism. Several studies have shown that the use of recombinant human growth hormone (GH) in girls with TS raises final height. The aim of this study was to describe the characteristics of a cohort of girls with TS diagnosed and treated with GH in Colombia. **METHODS:** A cohort of 22 girls with TS, who entered to the drug-international epidemiological record (KIGS) between 2004 and 2010 were tracked in Colombia. Girls were diagnosed with short stature and treated with GH therapy and followed-up for 2 years. Tracking measures were: the time of starting therapy, treatment regimens and clinical outcomes were estimated in terms of height measured by standard deviation units (SDS) and velocity growth in cm per year. Cohort data was compared against literature findings published for girls treated on GH with TS (Ranke MB et al 1988) and girls without GH treatment and TS (Tanner JM et al 1976). **RESULTS:** Girls started GH therapy at a mean age of 7.03 years with a dose