components of CP or treated as covariates. Because CP are active both on organizational (units) and individual (patients) level, a two-arm cluster Randomized Controlled Trial with hospitals and long-term rehabilitation facilities as randomization units was designed in phase II. Fourteen units were randomized either to arm 1 (CP) or to arm 2 (usual care) including 238 patients per group. The primary outcome measure was mortality, the CP were also analyzed with key quality indicators. The trial has been successfully performed (phase III) and in-hospital mortality has been reduced (OR = 0.10; $P = 0.04$). Because the adjusted results are not available yet, it was not possible to identify the active components of the CP and therefore phase IV has not been performed. **CONCLUSIONS:** Even if the results are still partial, it seems possible to apply this framework to the study of CP.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

CLINICAL OUTCOMES WITH DPP4 INHIBITORS IN SINGAPORE

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OBJECTIVES: 1) Compare efficacy and safety of sitagliptin and vildagliptin in type 2 diabetes; and 2) Examine prescription of concomitant oral hypoglycemic agents (OHAs) and insulin. **METHODS:** We conducted a retrospective database study, drawing information from all patients treated at Singapore Health Services cluster institutions over 1.5-year study period. Inclusion criteria: HbA1C >7%, naive to gliptins, and remained on gliptin for at least 90 days (from pharmacy records). Exclusion criteria: patients who switched gliptins, and HbA1c not tested within 10 days of exit timepoint. IRB approval was obtained. **RESULTS:** Sitagliptin (n = 340) and vildagliptin (n = 92) patients met inclusion and exclusion criteria. General demographics matched at baseline (all $P > 0.05$). Mean duration of gliptin treatment 242 days (sitagliptin) versus 220 days (vildagliptin) ($P = 0.944$). Mean baseline HbA1c matched at 8.95% (sitagliptin) versus 9.18% (vildagliptin) ($P = 0.15$). At exit, sitagliptin arm demonstrated absolute HbA1c reduction of –0.643% versus vildagliptin –0.728% ($P = 0.61$); percentage reduction in HbA1c was sitagliptin –6.55% versus vildagliptin –7.589% (p = 0.44). Subgroup analyses of a) patients with entry HbA1c >8%; b) stratification of outcome by dose of gliptin; and c) addition or discontinuation of OHA from baseline all did not demonstrate statistically significant difference. Majority of patients were not on maximal OHA doses at gliptin initiation, however total daily doses of OHAs was not significantly different at exit versus baseline for both arms. Almost 90% of patients in both groups received multiple OHAs for diabetes control. Change in creatinine clearance was comparable in both arms. Safety endpoints microalbuminuria/creatinine ratio, average % weight change and incidence of pancreatitis were not significantly different between both arms (all $P > 0.05$). Five sitagliptin patients required hospital admission for severe hypoglycemia vs 0 vildagliptin patients. **CONCLUSIONS:** We present our initial findings that vildagliptin is non-inferior to sitagliptin in HbA1c-lowering efficacy. Both products are well-tolerated without significant differences in safety endpoints save severe hypoglycemia in sitagliptin arm.

PDB2

LONG-TERM HEALTH OUTCOMES OF TREATMENT WITH LIRAGLUTIDE VERSUS GLIMEPRIRIDE IN TYPE 2 DIABETES PATIENTS IN ASIAN SETTING

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OBJECTIVES: To evaluate the long-term health outcomes associated with Liraglutide 1.2 and 1.8 mg versus Glimepiride 4 mg all combined with Metformin in Asian patients with type 2 diabetes (T2D). **METHODS:** A published and validated computer simulation model of diabetes (CORE Diabetes Model) was used to make the projection of long-term health outcomes (30 years). Simulated cohorts and treatment effects were derived from 928 T2D patients in the NCT00614120 trial held in China, South Korea and India. HbA1C was significantly reduced in Liraglutide 1.2 mg, Liraglutide 1.8 mg, and Glimepiride groups (–1.3%, –1.4%, and –1.3% respectively). Liraglutide treatments led to greater reduction in Body Mass Index and systolic blood pressure versus Glimepride. No major hypoglycemia was reported in Liraglutide groups, while the rate of major hypoglycemia for Glimepride was 0.029 per patient-year. The rate of minor hypoglycemia was lower in Liraglutide groups than Glimepiride. An annual discounting rate of 3% was used for health and cost outcomes. One-way sensitivity analysis was performed. **RESULTS:** The treatments of Liraglutide compared with Glimepiride were projected to reduce the cumulative incidences of diabetes complications and improve long term health outcomes for patients with T2D. For Liraglutide 1.2 mg, the cumulative incidences of background retinopathy, end stage renal disease, ulcer, and congestive heart failure event were reduced 0.20%, 0.086%, 0.020% and 0.53% respectively, discounted life expectancy was increased 0.058 year and quality adjusted life-years (QALY) was increased 0.11 QALY. For Liraglutide 1.8mg, the incidences reduction were 0.61%, 0.12%, 0.34% and 0.63% respectively, discounted life expectancy was improved 0.051 year, and 0.107 QALY. **CONCLUSIONS:** Liraglutide 1.2 mg and 1.8 mg therapy could delay the onset of diabetes complications and reduced related cumulative incidences over patient lifetimes compared with Glimepiride. It improved the life expectancy and quality adjusted life expectancy in Asian patients with T2D.

PDB3

EFFECTS OF EXTENDED-RELEASE VERSUS IMMEDIATE-RELEASE GLIPIZIDES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To address effects of extended-release versus immediate-release glipizide on glucose control, insulin secretion, and compliance. **METHODS:** We included parallel randomized trials and cohort studies (only for compliance assessment) comparing extended-release versus immediate-release glipizide for type 2 diabetes. We searched Medline, EMBASE, the Cochrane Library, and Chinese Biomedical database, screened reference lists, and contacted pharmaceutical company. We pooled data using random-effect model and explored heterogeneity by pre-specified hypotheses. **RESULTS:** Sixteen trials involving 1062 patients and two retrospective cohort studies of 13,452 patients were included. Trials are of inadequate quality. No trials reported patient-important outcomes. The reduction of fasting plasma glucose from the baseline appeared larger in extended-release than immediate-release glipizide (mean difference –0.30 mmol/L, 95% CI –0.57 to –0.03). The reduction was not significant different between two drugs in HbA_{1c} (–0.03%, –0.20% to 0.15%) and 2-hour postprandial plasma glucose (–0.28 mmol/L, –1.12 to 0.55). Extended-release glipizide appeared to reduce insulin secretion from the baseline, whereas immediate-release formulation increased the secretion (fasting insulin: –0.86 vs. 0.28 μIU/ml; 2-hour postprandial insulin: –2.94 vs. 0.24 μIU/ml). Patients administering extended-release glipizide had less hypoglycemia (Peto odds ratio 0.26, 95% CI 0.08 to 0.81) and lower missed dosing (Peto odds ratio 10.24, 95%CI 5.22 to 20.08). The cohort studies showed results in compliance consistent with trials. **CONCLUSIONS:** The two drugs may have comparable effects on glucose control. Extended-release glipizide might achieve glucose control with decreased insulin secretion, and fewer hypoglycemic episodes. The findings are inconclusive due to inadequate study quality, short follow-up, and unavailability of patient important outcomes.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB4

MEDICAL SERVICE COST ASSOCIATED WITH PIOGLITAZONE AND SULFONYLUREA TREATMENT AMONG TYPE 2 DIABETIC PATIENTS ENROLLED IN A US INTEGRATED HEALTH-CARE SYSTEM

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OBJECTIVES: To assess overall and diabetes-related medical service costs associated with pioglitazone (PIO) and sulfonylureas (SU) treatment among T2DM patients. **METHODS:** This is a retrospective cohort study based on electronic medical records (January 1, 2004–January 31, 2009) from the Geisinger Clinic in the Northeastern region of the United States. The date of the initial prescription for PIO or SU was denoted as the index date. Patients were required to be aged 18 years or older and prescribed an oral antidiabetic treatment in the 1 year prior to index. Patients with type 1 or gestational diabetes and prior insulin use were excluded, as were those who had prescriptions for the index drug in the 90 days prior. Propensity score 1:1 matching and a second stage of generalized linear regression were employed to assess overall and diabetes-related medical service costs (pharmacy costs were not available in the database) in the 2 years following the index date, adjusting for patient demographics, baseline comorbidities, medication use, and health-care resource utilization. **RESULTS:** A total of 2758 patients, 1379 each in the PIO and SU cohorts, were analyzed. For both cohorts, mean age was 62 years, 46% were male, and 96% were Caucasian. The two cohorts were similar in terms of current smoking status and diabetes-related comorbidities. The unadjusted total and diabetes-related medical costs were $1258 and $705 higher for SU versus PIO patients. After adjusting for covariates, the overall and diabetes-related medical service costs remained higher for patients receiving SU versus PIO ($8360 vs. $7400 for overall, and $5577 vs. $5238 for diabetes-related costs, $P < 0.05$ for both comparisons). **CONCLUSIONS:** Over a 2-year follow-up, patients with T2DM initiated on PIO therapy in an integrated system incurred lower overall and diabetes-related medical service costs than patients initiated on SU. Further studies describing clinical and humanistic aspects of PIO versus SU are warranted.

PDB5

TOTAL AND DIABETES-RELATED COSTS ASSOCIATED WITH HYPOGLYCEMIA IN TYPE 2 DIABETES MELLITUS PATIENTS INITIATED ON ORAL ANTIDIABETIC DRUGS FROM A LARGE US MANAGED CARE COHORT

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OBJECTIVES: To estimate annual health-care costs associated with hypoglycemia among T2DM patients initiated on oral antidiabetic drugs (OADs) in a large managed care cohort with managed care insurance benefits. **METHODS:** T2DM patients initiated on OADs were selected from the Ingenix Impact database (1999–2008). Patients aged 18 years or older with at least 1 year of continuous eligibility following the index date (the first OAD prescription fill date) who were diagnosed with moderate to severe