Administrative claims analysis of patients with type-2 diabetes initiating SGLT1 inhibitor therapy

To evaluate the diabetes control and medication adherence of patients initiating SGLT1 inhibitor therapy (SGLT1i) at a single specialty pharmacy, we reviewed claims of 10,448 adult patients with type-2 diabetes who initiated SGLT1i therapy for the first time between January 1, 2017, and December 31, 2018. Patients were stratified into two groups: those who claimed SGLT1i within 30 days of initiating a first-generation diabetes agent (metformin or sulfonylurea) and those who initiated SGLT1i without such a concomitant diabetes drug within 30 days. We compared the diabetes control, adherence, and medication costs of these two groups. Patients who initiated SGLT1i with a first-generation diabetes drug experienced a greater improvement in HbA1c compared to patients initiating SGLT1i without a concomitant diabetes agent. In addition, patients initiating SGLT1i with a first-generation diabetes agent were more likely to be adherent to their therapy. These findings suggest that patients initiating SGLT1i with a first-generation diabetes drug may experience better diabetes control and medication adherence compared to patients initiating SGLT1i without a concomitant diabetes agent.

PBDB8

Comparing dosing patterns of duloxetine and pregabalin among patients with diabetic peripheral neuropathy (DPN)

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OBJECTIVES: To compare dosing patterns between duloxetine and pregabalin among patients with diabetic peripheral neuropathy (DPN). METHODS: Using a retrospective administrative claims database in the United States, we examined commercially insured individuals aged 18-90 who dispensed duloxetine or pregabalin in 2016. The study period was from January 1, 2016, to December 31, 2016. We identified patients with a primary diagnosis of diabetes using ICD-9 codes. We then identified patients with a diagnosis of diabetic peripheral neuropathy using ICD-10 codes. We excluded patients who had a history of diabetes mellitus type 1. We then included patients who were continuously insured for at least 6 months and had a minimum of 30 days of follow-up. We included patients who received duloxetine or pregabalin for at least 30 days and had a minimum of 7 days of follow-up. We excluded patients who were enrolled in a clinical trial or were enrolled in a rebate program. We analyzed the data using descriptive statistics. RESULTS: A total of 303 duloxetine patients and 1,751 pregabalin patients were identified. The average daily dose of duloxetine was 25 mg, and the average daily dose of pregabalin was 174 mg. The average dose intensity was 1.5 mg/kg/day for duloxetine and 1.1 mg/kg/day for pregabalin. The median duration of therapy was 120 days, with a range of 30-365 days. The average daily dose of duloxetine was 25 mg, and the average daily dose of pregabalin was 174 mg. The average dose intensity was 1.5 mg/kg/day for duloxetine and 1.1 mg/kg/day for pregabalin. The median duration of therapy was 120 days, with a range of 30-365 days. The average daily dose of duloxetine was 25 mg, and the average daily dose of pregabalin was 174 mg. The average dose intensity was 1.5 mg/kg/day for duloxetine and 1.1 mg/kg/day for pregabalin. The median duration of therapy was 120 days, with a range of 30-365 days. The average daily dose of duloxetine was 25 mg, and the average daily dose of pregabalin was 174 mg. The average dose intensity was 1.5 mg/kg/day for duloxetine and 1.1 mg/kg/day for pregabalin. The median duration of therapy was 120 days, with a range of 30-365 days. The average daily dose of duloxetine was 25 mg, and the average daily dose of pregabalin was 174 mg. The average dose intensity was 1.5 mg/kg/day for duloxetine and 1.1 mg/kg/day for pregabalin. The median duration of therapy was 120 days, with a range of 30-365 days.
Results must be interpreted with caution, and further studies are needed to carefully address limitations and improve upon these initial results.

**PD12**

**RISK FACTORS FOR DEMENTIA IN ELDERLY PATIENTS WITH DIABETES MELLITUS**


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OBJECTIVES: Various factors may interact with Diabetes Mellitus (DM) to increase the risk of dementia. This study examined socio-demographic factors, the use of diabetes-specific drugs and the duration of DM as risk factors for dementia in elderly DM patients who are eligible to receive care at Veterans Health Administration.

METHODS: This was a retrospective study on a national cohort of US veterans. Incident DM elderly (265 years) identified between October 1, 1996 and December 31, 2000 in the VA records or between January 1, 1999 and December 31, 2000 in the VA-Medicaid merged claims files were included for the final analysis. The period prevalence of diabetes-specific drugs was determined in Calendar Year (CY) 2000. The time to the incidence of dementia was assessed from CY2001 to CY2002. A multivariable Cox regression model was used to estimate the adjusted relative risk of dementia for various predictors. RESULTS: A total of 377,838 patients were included in the final analysis. Age was a major risk factor for dementia: patients 75–85 years of age, HR 2.09, 95% CI 2.02–2.17; patients 85 years and older, HR 3.47, 95% CI 3.27–3.67. Compared to white Americans, African Americans had a higher risk of dementia (1.22; 1.16–1.27). People from the southern region of the US had a higher risk of dementia compared to other regions. Oral hypoglycemic agent use was associated with a higher risk of dementia (1.34, 1.29–1.39). The use of HMG-CoA reductase inhibitors was associated with a reduced risk of dementia (0.88, 0.85–0.91). Insulin was not associated with dementia [1.02, 0.98–1.07]. The duration of diabetes was an important risk factor for dementia. CONCLUSIONS: This exploratory study provides an important insight into the risk factors for dementia in a large population of DM patients. Additional studies should examine the process and outcomes for patients with these important chronic disease conditions.

**PD13**

**PATTERNS AND POTENTIAL RISKS OF CO-PRESCRIBING ANTHYPERGLYCEMICS AND SILYMARIN: A TAIWANESE POPULATION-BASED STUDY**

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OBJECTIVES: The aim of this study was to analyze trends and potential risks of combined use of silymarin and hypoglycemic drugs in a Taiwanese population.

METHODS: Data for this retrospective and descriptive population-based study were retrieved from the Taiwanese National Health Insurance Research Database representing 200,000 sampling beneficiaries enrolled in the program in the year 2000. The prescription details of ambulatory care orders were retrieved for 2000 to 2006. The extent of co-prescription of silymarin and hypoglycemic drugs and associations with patient characteristics, hospital type, and co-morbid chronic diseases were assessed, including an analysis using the many-faceted Rasch model. RESULTS: Silymarin prescriptions increased from 0.17% (860/515765) in 2000 to 0.76% (2315/309053) in 2006. Silymarin combined with hypoglycemic drugs was mostly prescribed to patients 60 years or older. In this group, the percentage of prescriptions with silymarin alone increased about four-fold, from 245 in 2000 to 1022 in 2006. The number of co-prescriptions in the same age group also increased in the same period from 11 (15.49%) to 206 (38.8%). Most prescriptions were prescribed for 28 days. Of the combined prescriptions, 42% were prescribed at the same ambulatory care visit. Co-prescriptions of silymarin and hypoglycemic drugs correlated with patient characteristics, physician specialty, antidiabetic type, and other confounders. CONCLUSIONS: There was a trend to increase of co-prescription of silymarin and hypoglycemic drugs in Taiwan’s elderly population from 2000 to 2006. Physicians should take particular care in adjusting the dose of hypoglycemic drugs when prescribing these drugs and silymarin concurrently in this age group.

**PD14**

**FORECASTING THE NUMBER OF DIABETIC PATIENTS IN THE UNITED STATES THROUGH 2025**

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OBJECTIVES: To project the number of people with diagnosed diabetes in the United States through 2025, accounting for changing demography and diabetes prevalence rates. METHODS: We combined age, sex, and race specific diabetes prevalence rates – predicted from the 1980–1998 trends in prevalence data from the National Health Interview Survey – with the population projections derived from MEPS. Sensitivity analysis was performed by varying both population projections and prevalence rates. RESULTS: Populations of the number of people with diabetes will rise to almost 118 million in 2025. The largest increases in the number of people with diabetes are likely to occur in the oldest age category. The highest growth will be among black males whereas the lowest increase will be in the white females category. Twenty percent of the overall projected growth will be due to population growth, 35% to an increase in prevalence rate, and 45% to changes in demographic compositions. CONCLUSIONS: This paper shows the projection of dramatic increase of the diabetic population in the United States by 2025. Worldwide surveillance of diabetes is a necessary first step toward its prevention and control.

**PD15**

**UTILIZATION PATTERNS AND HYPOGLYCEMIA IN PATIENTS WITH TYPE-2 DIABETES ON CONCOMITANT EXENATIDE AND LONG-ACTING INSULIN THERAPY**

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OBJECTIVES: To examine utilization patterns and hypoglycemia in patients with type-2 diabetes mellitus (T2DM) receiving concomitant exenatide and long-acting insulin therapy over 6 months. METHODS: A retrospective analysis was performed using claims data (January 1, 2004 to March 31, 2008) from a large US prescription database. Adult patients with T2DM and no claim for exenatide (index drug) in the previous 12 months were included. At least 12 months pre-index and 26 months post-index continuous eligibility were required. Concomitant long-acting insulin use was defined as a claim for NPH, insulin glargine or insulin detemir 10 days pre-index to 15 days post-index. Therapy discontinuation was defined as a ≥30-day gap between prescription claims. Hypoglycemic events were identified by ICD-9 codes 250.8, 251.0, 251.1, and 251.2. Hypoglycemia generating a claim using these codes is generally severe. RESULTS: Concomitant exenatide and long-acting insulin use was identified in 2082 patients. Of these, 38% discontinued both therapies, 15% discontinued exenatide but remained on long-acting insulin, 24% discontinued long-acting insulin but remained on exenatide and 23% continued both therapies. There were no differences in age, gender or Deyo-Charlson comorbidity index score among cohorts. Patients who discontinued exenatide and remained on long-acting insulin had a higher rate of hypoglycemia (0.95 ± 0.101) than patients who discontinued long-acting insulin but remained on exenatide (0.02 ± 0.20), discontinued both therapies (0.04 ± 0.37) or continued both therapies (0.03 ± 0.26; p < 0.0001 across groups). Insufficient pre- and post-AIC values were available for an analysis of this endpoint. CONCLUSIONS: Patients remaining on concomitant exenatide and long-acting insulin did not experience more hypoglycemic events than patients who remained on either drug alone. However, patients discontinuing exenatide but remaining on long-acting insulin experienced significantly more hypoglycemic events. The increase in hypoglycemic events may have been due to an increase in basal insulin dose and/or the addition of other insulin therapy.

**PD16**

**REPLICATION AND VALIDATION OF THE QUANTIFICATION OF THE RELATIONSHIP BETWEEN PHARMACOLOGIC INTERVENTION, REDUCTIONS IN HBA1C AND REDUCTIONS IN COMPLICATIONS: ITS APPLICATION IN QUANTIFYING THE BENEFITS OF ADDING COLESEVELAM HYDROCHLORIDE TO METFORMIN IN TYPE-2 DIABETICS**

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OBJECTIVES: Quantify the reductions in diabetic related complications associated with the addition of colesevelam hydrochloride to metformin in patients with type-2 diabetes who have not achieved optimal control. METHODS: The quantification of the effect of pharmacologic intervention on glycosylated control in type-2 diabetes and the quantification that improved glycosylated control reduces the risk of diabetic-related complications was measured in the UK, Germany and the USA using Generalized Estimating Equations (GEE) on longitudinal data. The three models quantified that pharmacologic intervention reduced HbA1c by 0.99%, 0.92% and 0.89%, respectively, (P < 0.01). The second set of models quantified that a 1% reduction in HbA1c reduced the rate of complications by 0.38%, 0.414% and 0.436% (P < 0.01). Using these validated equations, the efficacy data from a clinical trial comparing the addition of colesevelam hydrochloride to metformin versus metformin alone in type 2 diabetic patients who lack optimal control despite treatment was converted into reductions in the onset new diabetic-related complications. 5000 bootstrap samples of 100 patients from each treatment group were replicated to measure and minimize bias. RESULTS: In the first year, the addition of colesevelam to metformin reduces the number of diabetic related complications by 10.75% in 100,000 type-2 diabetes who lack glycemic control despite treatment. The most prevalent of those complications are manifestations of neurological dysfunction (0.0166), disorders of the peripheral circulation (0.0170) and ischemic heart disease (0.0178). Treatment with colesevelam in these patients who had not achieved optimal control reduced overall complications by 1790 neurological disorders, 1829 peripheral circulatory disorders and 1917 new cases of ischemic heart disease. The number of events avoided by year two and three accrued to 18,173 and 27,405 per 100,000 patients. CONCLUSIONS: Effective treatment by adding colesevelam to metformin quantitatively reduces HbA1c and complications in patients who have not achieved control.