BACKGROUND

- Diabetes is one of the leading causes of death in the world, affecting 300 million individuals worldwide and accounting for 10% of deaths globally. Over 90% of Diabetes is Type 2 (T2DM) (∗). The number of patients with diabetes is expected to increase to 500 million by 2030.

- Despite significant recent innovation in diabetes drug development, less than half of the population with diabetes is medically or therapeutically controlled (∗).

- Non-adherence to therapy is recognized as a major cause of the lack of control of, and health care quality measures (e.g., HbA1c in the US).

- Better understanding of the causes and impact of non-adherence is needed to guide future strategies to improve glycemic control.

STUDY OBJECTIVES

- The objectives of the study were to:
  - Characterize the prevalence of non-adherence, and of "serial non-adherence" in particular, in a cohort of T2DM patients with diabetes.
  - Identify key predictors of non-adherence to anti-diabetic therapy.

- The analysis focused on patients receiving second-line anti-diabetic therapy (defined as patients who initiated another diabetes therapy following their first initiation of metformin or a patient with diabetes containing anti-diabetic medication). This research is a large scale population that is able to track patients with diabetes using large pharmaceutical data. Therefore it is able to evaluate adherence and it is not inherently prone to the case selection biases observed in prior adherence studies (i.e., a reporting confounding factor).

PATIENTS AND METHODS

Data Source

- "Feasibility Health Monitor" Commercial Claims and Encounters databases, one of the largest and most comprehensive electronic data sets in the U.S., were used to collect the study data. The data included individual-level medical and drug utilization information, demographics and employment data, and pharmacy claims data from U.S. employers.

- About 6 million T2DM patients in the U.S. are included in the data (2008Q1 – 2012Q4).

Study Design & Population

- The study used retrospective data from a cohort of treatment-naive patients who initiated their first-line anti-diabetic therapy containing metformin and subsequently initiated a second-line therapy as required by the treatment algorithm. Patients included in the study meet the criteria outlined in Figure 1 and Table 1. The cohort includes approximately 6 million U.S. patients with diabetes who are younger and likely healthier than the general U.S. T2DM population.

- The study data include a subset of U.S. patients with employer-sponsored health insurance who are younger and likely healthier than the general U.S. T2DM population.

- Administrative claims data does not reliably classify clinical characteristics that can impact treatment adherence and outcomes. In particular the absence of HbA1c values prevents controlling for potential important confounders such as non-diabetes medications.

- Medications adherence can be overestimated in claims, as claims only measure filled prescriptions regardless of all medications dispensed. This is likely by population. Notably our ICD-9 codes which is based on prescriptions filled (not claims data) is likely to underestimate the duration of medications taken as patients may delay in taking medications or discontinue their medication prior to use of the last prescription supply.

- The burden of non-adherence was measured during the first year after initiation of second-line therapy and thus likely underestimates the long-term impact of non-adherence.

CONCLUSIONS

- Based on real-world data, this study showed that more than half of patients initiating second-line anti-diabetic therapy are not adherent to therapy, and that serial non-adherence is present in a quarter of patients.

- Non-adherence to second-line therapy is associated with a 53% increase in the risk of observed severe hypoglycemia (0.5/1000 patient years) (∗∗). Non-adherence was further associated with a 53% increase in the risk of observed severe hypoglycemic events (0.5/1000 patient years) (∗∗). Non-adherence was further associated with a 53% increase in the risk of observed severe hypoglycemic events (0.5/1000 patient years) (∗∗). Non-adherence was further associated with a 53% increase in the risk of observed severe hypoglycemic events (0.5/1000 patient years) (∗∗).

- Prediction of non-adherence to second-line therapy is based on a new classification of severe hypoglycemia. This classification accounts for hypoglycemic events that are likely to be missed, including hypoglycemic events that are not severe, but are associated with a 53% increase in the risk of observed severe hypoglycemic events (0.5/1000 patient years) (∗∗).

- The burden of non-adherence was measured during the first year after initiation of second-line therapy and thus likely underestimates the long-term impact of non-adherence.

REFERENCES


