Differential diagnosis of adults with type 1 versus type 2 diabetes in administrative claims analysis: experience from the Biologics and Biosimilars Collective Intelligence Consortium

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INTRODUCTION

Presented at: AMCP Nexus 2018, Orlando, FL, October 21

METHODS

Data: This retrospective, observational study evaluated two datasets: 1) BBCIC DBN and 2) a sub-set of one BBCIC DBS Partner Enterprise Data Warehouse (DP EW). Both datasets examined patients with either Commercial or Medicare-Advantage health insurance and prevalent T1DM or T2DM.

BBCIC DBN identified adults and medical and drug health plan coverage from January 1, 2011 through December 31, 2013. The BBCIC insulin eligible study population criteria included health plan members 18 years or older, with at least one drug claim for long- or intermediate-acting insulin.

DP EW identified patients with any T1DM or T2DM diagnoses and medical and drug health plan coverage from January 1, 2016 through June 30, 2018. T1DM or T2DM diagnoses and oral anti-diabetic (OAD) drug dispensings were counted in the 30-month period. The DP EW allowed investigation of T1DM differentiation algorithms prior to use in the full BBCIC ORN.

Patients with diabetes was the unit of analysis. Insulin episodes were defined in the initial BBCIC analysis. The percentage of T1DM diagnoses in medical claims (T1DM, PC) was only calculated on patients with both T1DM/T2DM in the DP EW.

Descriptive analysis of diabetes type cohorts included counts, percentages, and means and the percentage of T1DM diagnoses for T1DM + T2DM patients. Data is presented by 3 diabetic types: 1) T1DM 2) T2DM 3) T1DM+T2DM.

Algorithms: Three peer-reviewed publications describing T1DM algorithms were analyzed. The algorithm variables were compared to the SCDM.

RESULTS

There were 3,871,266 eligible adults with diabetes in the BBCIC ORN. Of those, 56,682 (1%) had a T1DM diagnosis, 3,309,931 (85%) had a T2DM diagnosis, and 50,072 (1%) had both T1DM-T2DM diagnoses. The number and percentage of T1DM+T2DM adults with diabetes and new users decreased from 2011 through 2017, while the number of adults with only T1DM or T2DM claims increased. The age distribution and the average number of episodes of T1DM+T2DM and T2DM patients were similar. Over 35% of T1DM are over the age of 50.

T1DM identification algorithms from 3 publications were evaluated for variables within the BBCIC DRN. BBCIC DRN contains ample diagnoses and outpatient pharmacy dispensions, but not prescriptions, necessary lab values, or complete medical histories. The reasons for variable absence include people have multiple health plans in their lifetime; lab values and outpatient dispensings are not included on medical claims; and, health plans receipt of pharmacy dispensions, not prescriptions.

CONCLUSIONS

BBCIC analyzed prevalent insulin users to understand the populations expected to use biosimilars or follow-on biologics. The BBCIC insulin using population had 3% of people with T1DM-T2DM diagnosis codes observed during the study period which accounted for over 50% of insulin users who met the insulin study criteria (clinical exclusions applied). The initial BBCIC analysis excluded these patients; however, with an algorithm to differentiate T1DM and T2DM these patients could be included.

T1DM and T2DM algorithms include clinical elements not available or limited in the BBCIC ORN. With the large proportion of T1DM+T2DM insulin users, it was important to understand the differences between single and dual diagnosed diabetes, compare IC9 to IC10, and investigate T1DM algorithms to identify the appropriate diagnosis category for future insulin comparative studies.

Preliminary work to use a published T1DM differentiation algorithm within the BBCIC ORN is underway. There is need to assign a single diagnosis type due to real-world data paradoxes in future insulin originator biosimilar/follow-on biologic studies.