Utilization, user characteristics, and adverse outcomes of insulin glargine originators and follow-on drug in patients with diabetes in the US

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BACKGROUND

Insulin glargine is a long-acting insulin used in patients with type 1 diabetes mellitus [T1DM] or type 2 diabetes mellitus[T2DM]. The first follow-on insulin glargine was approved in 2015 in the US, and information on its utilization and health outcomes in real-world settings is limited.

OBJECTIVE

To describe utilization, user characteristics, and adverse outcomes of the follow-on insulin glargine [follow-on drug] and insulin glargine originators to inform future comparative investigations

METHODS

Study design: A retrospective observational study using the FDA Sentinel analytic tools[1]

Data source: Healthcare claims data representing >90 million individuals from five commercial health plan partners in the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) Distributed Research Network[2]

Eligible individuals for analyses: Diabetes patients (age ≥18 years) with prevalent use of the originator (Lantus®, Toujeo®, Soliqua®) and follow-on (Basaglar®) insulin glargine between 01 January 2011 – 28 February 2021 (some health plan partners' data were not available through 28 February 2021) with continuous enrollment for ≥183 days prior to the first observed dispensing date of insulin glargine ("baseline period") and no evidence of diabetes ketoacidosis, hypoglycemia, or pre-specified cardiac events in the inpatient or emergency department setting during the baseline period

Main measurements and statistical analyses: Descriptive analyses on the utilization, patient characteristics, and adverse health outcomes (Major Adverse Cardiac Events (MACE), diabetic ketoacidosis, hyperglycemia, and hypoglycemia) for insulin glargine, (a) overall and (b) among the TIDM group and the T2DM group

RESULTS

- We identified 508,438 users (5,544,116 episodes) of OG and 63,199 users (341,618 episodes) of FO.
- The proportions of the follow-on drug users among total insulin glargine users were 9.1% (n=7,070) in the T1DM group and 11.4% (n=56,129) in the T2DM group

Figure 1. Proportion of follow-on drug users among total insulin glargine users by year, 2017-2020

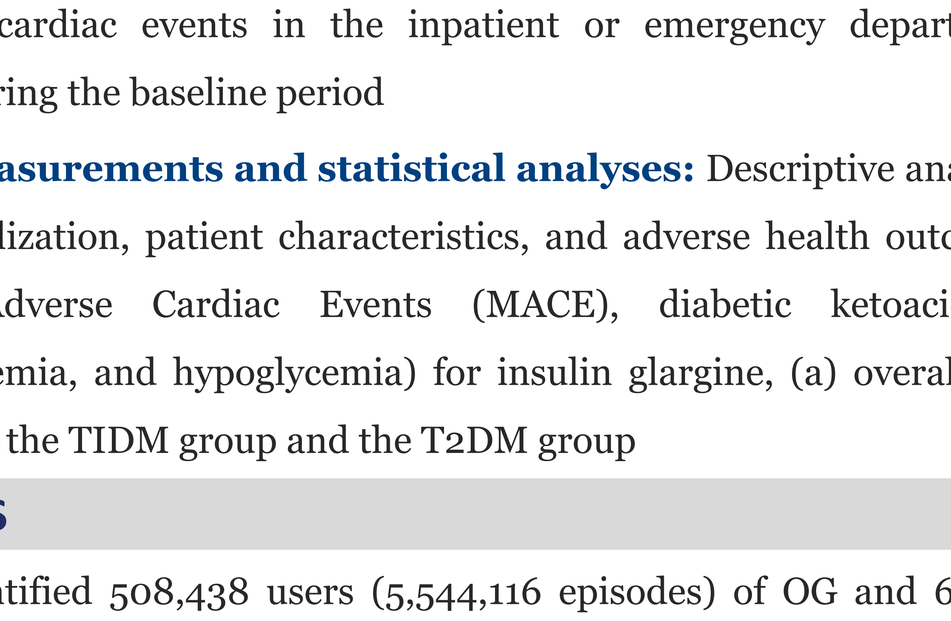

Figure 2. Selected baseline characteristics of the users of the originator and the follow-on insulin glargine among the T1DM and T2DM groups

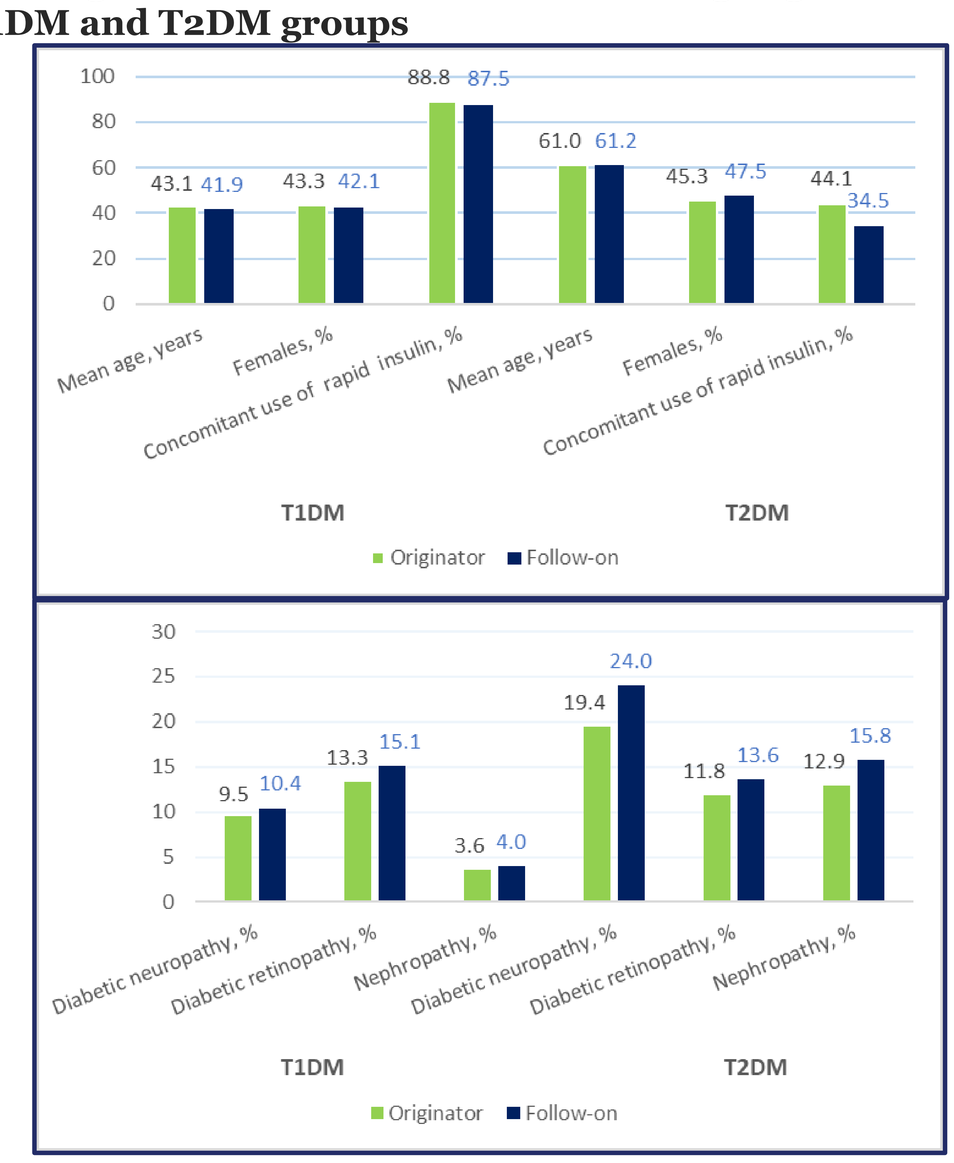

Table 1. Combined baseline comorbidity score (standard deviation)

	T1DM	T2DM
Originator	0.5 (1.1)	1.0 (1.8)
Follow on	0.8 (1.2)	1.4 (2.0)

Table 2. Proportion of patients with adverse health outcomes within 183 days following the index dispensing (%)

	T1DM		T2DM	
	Originator	Follow-on	Originator	Follow-on
Diabetic ketoacidosis	2.5	3.9	2.3	3.9
Hyperglycemia	1.7	3.3	2.4	3.9
Hypoglycemia	1.2	1.5	0.7	0.8
MACE	1.9	1.6	7.2	6.3

CONCLUSION

- Increasing trend in the use of follow-on drug since 2016
- Decreasing trend in the use of originators in most recent years, possibly related to the increasing use of the follow-on drug
- Higher percentage of diabetic neuropathy at baseline among follow-on drug users than originator users in the T2DM group
- Higher mean baseline comorbidity score among users of follow-on drug than among the originator drug users
- Hyperglycemia, hypoglycemia and diabetic ketoacidosis higher among the insulin glargine follow-on drug users than originator users

LIMITATIONS

- Statistical examinations on the comparability across different insulin users in the patients' baseline characteristics were not performed
- Potential confounders were not controlled for in the assessment of percentages of episodes with adverse health outcomes

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