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Longitudinal analysis of real-world basal insulin utilization for type 1 and type 2 diabetes patients transferring to insulin glargine U-300 (Gla-300)

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INTRODUCTION

- Insulin therapy plays a critical role in the treatment of type 1 and type 2 diabetes mellitus (DM) (1).
- The ideal basal insulins should provide a slow, sustained release of insulin for up to 24 hours to help patients maintain stable glucose levels between meals.
- Gla-300 (insulin glargine 300 U/mL) is a long-acting insulin therapy approved for use in Canada in May 2015 for both type 1 and type 2 DM(2).
- Gla-300 is a new formulation of insulin glargine delivering the same amount of insulin [as Gla-100] in 1/3 volume, and both pharmacokinetic and pharmacodynamic profiles of Gla-300 have shown to be more stable and prolonged, with lesser intra-/inter-variability, which makes them more reproducible (3).
- Treat to target clinical trials tend to show a higher average daily dose (ADD) than typically seen in the real-world setting.
- Limited information exists on how these changes impact patient utilization in a real-world setting.

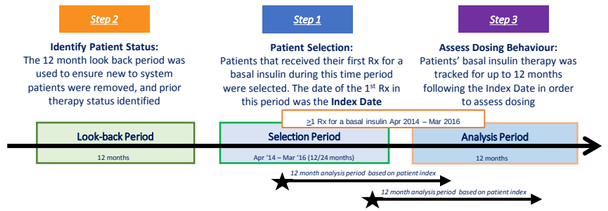
OBJECTIVES

1. **To examine how the ADD of insulin changed when patients transferred from a long or intermediate acting basal insulin, including i) Gla-100; ii) insulin detemir; or iii) neutral protamine Hagedorn (NPH) insulin, to Gla-300.**
2. **To examine basal insulin treatment persistence by insulin in private payer patients.**

METHODS

- **Study Design and Data Source:**
  - A retrospective cohort study was conducted using longitudinal prescription data from QuintilesIMS Private Drug Plan (PDP) claims database®, from April 2013 - March 2016 with a12-month lookback (**Figure 1**).
  - The QuintilesIMS PDP claims database contains patient-level data from over 12 million active claimants across Canada, comprising 70% of the private market nationally.
  - The data includes patient demographic characteristics, specific drug dispensed, dosage, quantity, number of days' supply, service date and place, cost, payer, and prescribing physician information.
- **Study Population:**
  - Patients with Type 1 diabetes mellitus (T1DM) and Type 2 diabetes mellitus (T2DM) treated with basal insulin who transferred to Gla-300 were selected from the QuintilesIMS PDP claims database®. Patients were indexed on first claim of Gla-300 between April 2014 and March 2016. A12-month look-back period was used to ensure new to system patients were removed, and prior therapy status identified. Patients' basal insulin therapy was tracked for up to 12 months following index date and calculated as ADD in international units (IUs) of insulin (**Figure 1**).
  - Patients who did not have continuous coverage and could not be followed in the longitudinal analysis, or who were inferred as suffering from gestational diabetes were excluded.
- **ADD Calculation:**
  - ADD was calculated by dividing the total amount of drug (units) prescribed by the number of days between two consecutive prescriptions. ADD was calculated for every patient between every prescription during the observation period.
  - The first three months post-transfer were excluded to remove the titration period.
- **Statistical Analyses:**
  - Differences in ADD of insulin were compared pre- and post-transfer to Gla-300 using the student's t-test.

Figure 1: Patients were indexed on their first claim of Gla-300 between April 2014 and March 2016. Patients' basal insulin therapy was tracked for up to 12 months following the index date and calculated as ADD in IUs of insulin.



RESULTS

- **T2DM Patients:**
  - 1,028 T2DM patients were identified.
  - In T2DM patients, the ADD was 111 IU in the 3 months prior to transfer and 98 IU following transfer to Gla-300 (p=0.010); the largest difference was observed in patients previously treated with determir, 144 IU to 97 IU (**Figure 2**).
  - Patient distribution by ADD histogram showed that 36% of T2DM patients were receiving more than 100 IU per day of other insulins before transferring to Gla-300; while post-transfer to Gla-300 this proportion dropped to 32% (**Figure 3**).
  - Gla-300 showed higher persistence than other basal insulins in the private payer market as Gla-300 is not yet reimbursed by public plans (**Figure 5**).
- **T1DM Patients:**
  - 231 T1DM patients were identified.
  - In T1DM patients, the ADD was 88 IU in the 3 months prior to transfer and 73 IU following transfer to Gla-300 (p=0.018); the largest difference was observed in patients previously treated with determir (**Figure 2**).
  - Patient distribution by ADD histogram showed that 22% of T1DM patients were receiving more than 100 IU per day of other insulins before transferring to Gla-300; while post transferring to Gla-300 this proportion dropped to 17% (**Figure 4**).
  - Gla-300 showed higher persistence than other basal insulins as Gla-300 is not yet reimbursed by public plans (**Figure 5**).

Figure 2: Insulin ADD pre and post transfer to Gla-300

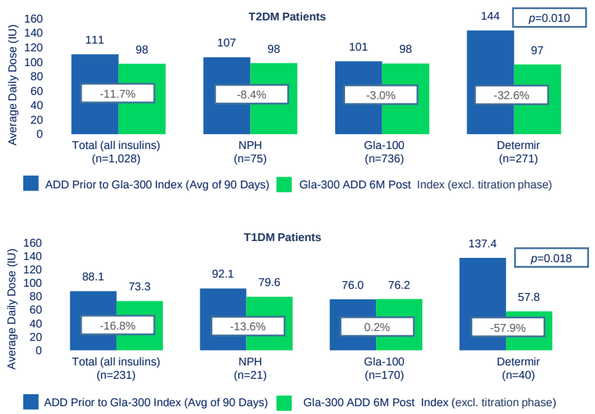
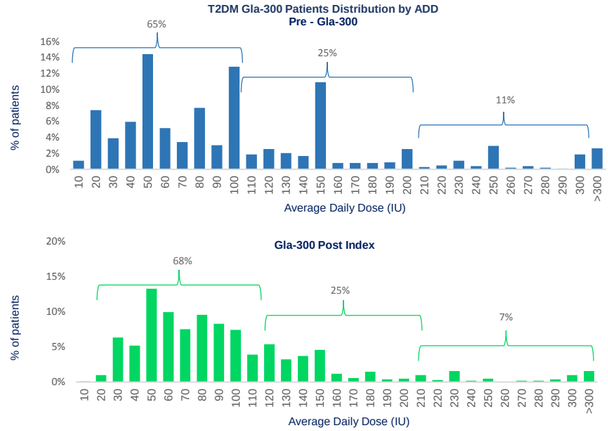
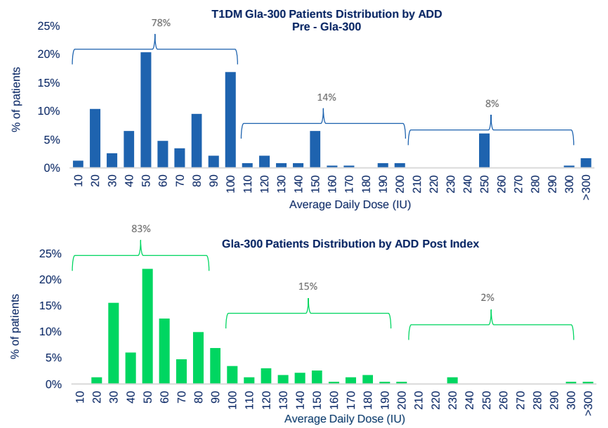


Figure 3: T2DM patients distribution according to ADD



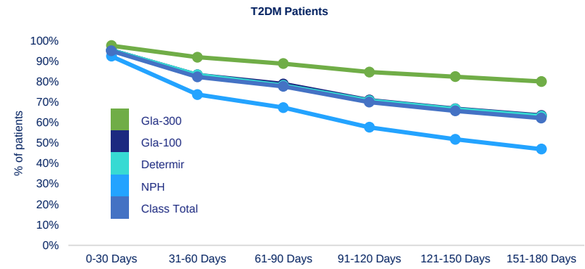
ADD Groups	≤100	100 - 200	>200
Pre-Gla-300 Patient (%)	65%	25%	11%
Gla-300 Post Index Patient (%)	68%	25%	7%

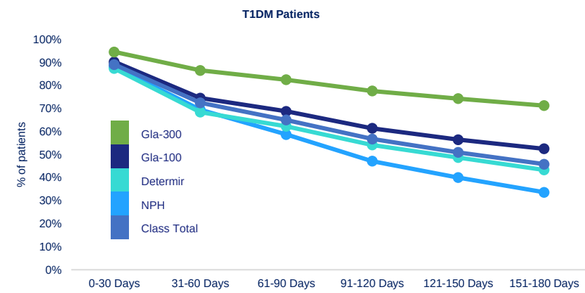
Figure 4: T1DM patients distribution according to ADD



ADD Groups	≤100	100 - 200	>200
Pre-Gla-300 Patients (%)	78%	14%	8%
Gla-300 Post Index Patients (%)	83%	15%	2%

Figure 5: 6-month basal insulin treatment persistence in T2DM and T1DM patients by insulin





SUMMARY

- Insulin therapy continues to play an important role in the management of DM.
- Gla-300 is a long-acting basal insulin analogue approved in Canada for the treatment of DM, and is an effective and generally well tolerated basal insulin therapy option for patients with T1DM or T2DM (4-7).
- The current study demonstrates that in the Canadian real-world practice, the overall basal insulin ADD was reduced once patients were transferred to Gla-300.
- The most significant decrease was observed in the group transferring from detemir to Gla-300.
- Patients on Gla-300 had better persistence than any other basal insulins, potentially requesting less medical visits and additional titration phase due to insulin change.

CONCLUSION

In Canadian real-world practice, the overall basal insulin ADD was reduced once patients were transferred (and titrated) to Gla-300. Further research and longer term data is needed to better understand the impact on patient persistence, overall patient outcomes, and safety.

Disclosures: Yvonne Zhang, Jennifer Glass, and Brad Millson are employees of QuintilesIMS and have collaborated on this study as consultants paid by Sanofi. Luc Sauriol is an employee of Sanofi-Aventis Canada
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