REal-World Impact of Once-Weekly Injectable Semaglutide on G**L**ycemic Control and Weight Outcomes Based on Highest Dose Received and Persistence With Treatment in Type 2 Di**A**be**TE**s (**RELATE** – OW Injectable Semaglutide)

https://sciencehub.novonordisk.com/adces2023/Amamoo1.html?cid=qr-p8ayr3512d

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Aim

The aim of this real-world database study was to assess the impact of the once-weekly injectable formulation of semaglutide type 2 diabetes mellitus (sema OW T2D) on glycated hemoglobin (HbA_{1c}) and weight outcomes from baseline to the end of a 12-month follow-up period, based on highest dose received and persistence with treatment over the follow-up period.

Introduction

- Sema OW T2D is indicated as an adjunct to exercise and diet to improve glycemic control in adult patients with T2D.[1]
- Real-world data are needed to further evaluate the clinical effectiveness of sema OW T2D in patients with T2D.

Methods

Study design

- This retrospective, real-world study identified new initiators of sema OW T2D in patients with T2D utilizing a linked patient population from IQVIA's Longitudinal Prescription Claims (LRx), Professional Fee Claims (Dx), and Ambulatory Electronic Medical Records (AEMR) databases in the US.
- Selection window was between January 1, 2018 and September 30, 2021, and study period was between January 1, 2017 and September 30, 2022. The date of the first observed claim was termed the index date.
- Demographic data and clinical characteristics were collected at baseline (i.e. over the 12 months before the index date). AEMR were used to assess HbA_{1c} and weight outcomes at baseline and at the end of the 12-month follow-up period.

Outcomes

- Changes in HbA_{1c}, weight, and body mass index (BMI) over the 12-month post-index period had been assessed for the main population and presented at the American Diabetes Association (ADA) 83rd Scientific Sessions, San Diego, CA, June 23–26, 2023.
- In the present analysis, changes in HbA_{1c}, weight, and BMI were assessed for subgroups of patients over the 12-month post-index period: **1)** patients initiating sema OW T2D and up-titrating to a dose of ≥1 mg; **2)** patients persistent with treatment with sema OW T2D; **3)** patients initiating sema OW T2D and up-titrating to a dose of ≥1 mg and persistent with treatment. Persistent with treatment were those who did not have a gap of more than 60 days in days' supply during the 12-month follow-up period.
- Post-index values for HbA_{1c} and weight were measured at 12 months post-index (360 days post-index ± 90 days, taking the value closest [absolute] to day 360).

Data analysis

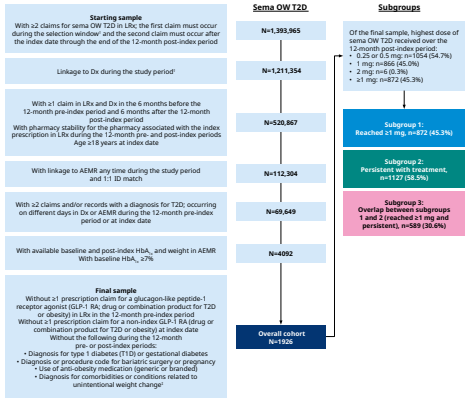
- Within-group comparisons of baseline and post-index measurements were conducted using descriptive statistics for all study measures. Changes in HbA_{1c}, weight, and BMI were compared between baseline and the 12-month post-index period for all patient subgroups.
- Paired t-tests were conducted on the mean and Wilcoxon signed-rank tests on the median for continuous variables, and McNemar's tests for categorical variables.

Results

Study population

- The final sample consisted of 1926 patients with sample sizes for subgroups ranging from 589 to 1127 patients. Patient selection and subgroups are shown in **Figure 1**.
- Of all patients, 49.3% were male; mean (SD) age was 59.2 (11.2) years. Demographic characteristics for the overall patient sample and subgroups are presented in **Table 1**.

Figure 1. Patient selection



[a]Cohorts are not mutually exclusive.
[b]Including cancer (except non-melanoma skin cancer), human immunodeficiency virus, acute/chronic pancreatitis, feeding difficulties, eating disorders, liver cirrhosis, stage 5 chronic kidney disease/dialysis/renal failure; procedure codes also used for dialysis.

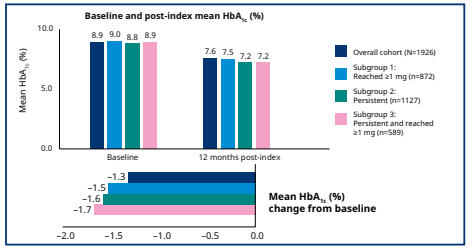
Table 1. Demographic characteristics

	Overall cohort N=1926	Subgroup 1 Reached ≥1 mg n=872	Subgroup 2 Persistent n=1127	Subgroup 3 Persistent and reached ≥1 mg n=589
Age (years)				
Mean (SD)	59.2 (11.2)	58.4 (11.3)	58.6 (10.9)	58.0 (11.1)
Age group (years) (n, %)				
18–44	192 (10.0)	99 (11.4)	112 (9.9)	68 (11.5)
45–54	423 (22.0)	193 (22.1)	254 (22.5)	130 (22.1)
55–64	690 (35.8)	314 (36.0)	441 (39.1)	230 (39.0)
65+	621 (32.2)	266 (30.5)	320 (28.4)	161 (27.3)
Sex (n, %)				
Male	949 (49.3)	418 (47.9)	565 (50.1)	290 (49.2)
Female	977 (50.7)	454 (52.1)	562 (49.9)	299 (50.8)

Change in HbA_{1c}

- At the end of the 12-month post-index period, patients initiating sema OW T2D had a statistically significant decrease in mean HbA_{1c} compared with baseline (for overall cohort and all subgroups, p<0.001). The decrease was numerically greater for subgroup 3 as compared with the overall cohort and the other subgroups **(Figure 2)**.

Figure 2. Change in HbA_{1c} from baseline to the end of the 12-month post-index period



Change in weight

- At the end of the 12-month post-index period, patients initiating sema OW T2D had a statistically significant decrease in mean weight compared with baseline (for overall cohort and all subgroups, p<0.001). The decrease was numerically greater in subgroup 3 as compared with the overall cohort and all other subgroups **(Figure 3)**.
- Approximately 38–45% of patients in the sema OW T2D overall cohort and its subgroups had a ≥5% decrease in weight from baseline to post-index. A numerically greater decrease in weight was seen in subgroup 3 as compared with the overall cohort and other subgroups **(Figure 4)**.

Figure 3. Change in weight from baseline to the end of the 12-month post-index period

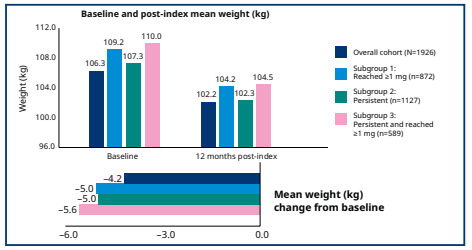
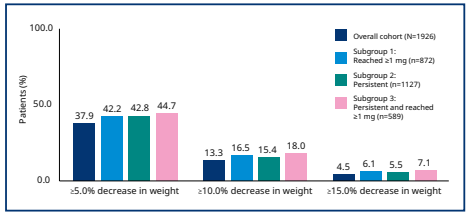


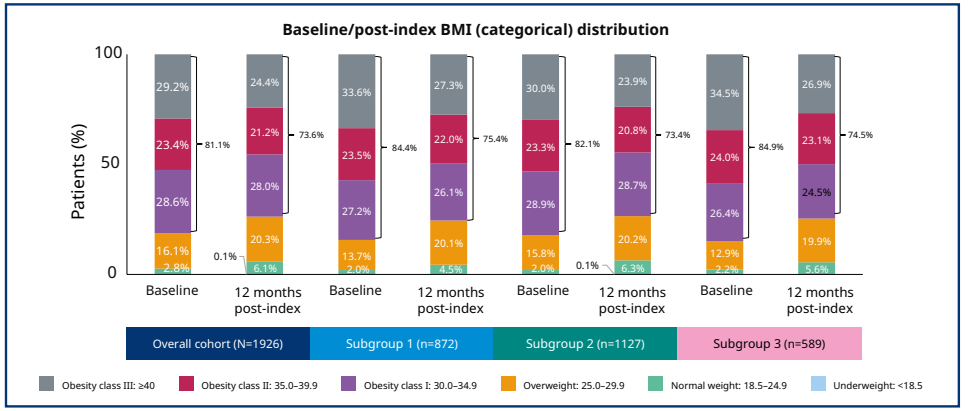
Figure 4. Percent of patients with weight decrease at the end of the 12-month post-index period



Change in BMI

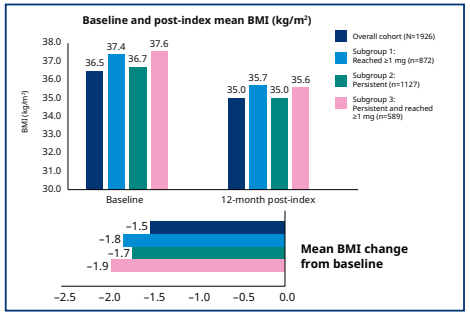
- At the end of the 12-month post-index period, the overall sema OW T2D cohort and its subgroups had a lower percent of patients with class II/III obesity, and a higher percent of patients with normal weight as compared with baseline **(Figure 5)**.
- In all subgroups, the proportion of patients with obesity (BMI ≥30.0 kg/m²) decreased from 81–85% at baseline to 73–75% at 12 months post-index (all p<0.001). Subgroup 3 showed a numerically greater difference (10.4%) between baseline and 12 months post-index, as compared with the overall cohort and other subgroups **(Figure 5)**.

Figure 5. Percent of patients in each BMI category at baseline and at the end of the 12-month post-index period



- At the end of the 12-month post-index period, patients initiating sema OW T2D had a statistically significant decrease in mean BMI as compared with baseline (for overall cohort and all subgroups, p<0.001). Patients in subgroup 3 had the greatest numerical decrease in mean and median BMI compared with the overall cohort and other subgroups **(Figure 6)**.

Figure 6. Change in BMI from baseline to the end of the 12-month post-index period



Study limitations

- These descriptive pre-post study findings establish associations, not cause-and-effect relationships.
- There is a potential for miscoding or misclassification in claims data.
- The use of an open-source claims database meant that there was no cost-comparison cohort for this study.
- Our sample may be biased towards capturing patients who more frequently touch the healthcare system and have available values for HbA_{1c} and weight.

Conclusions

- This real-world database study found that patients who were initiating sema OW T2D had significant decreases in HbA_{1c} levels, body weight, and BMI from baseline to the end of the 12-month follow-up period.
- These findings indicate that treatment adherence and dose escalation, when available and appropriate as part of treatment planning, may play an important role in clinical outcomes.
- There is a need for future studies to compare these effects with other anti-diabetic medications and further describe these correlations.

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Reference

(1) Ozempic® (semaglutide injection) Prescribing Information. Available at: https://www.ozempic.com/prescribing-information.html. Accessed April 25, 2023.