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Real-world use of tirzepatide among individuals without evidence of type 2 diabetes: Results from the Veradigm® database

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Abstract

Aims: To understand real-world tirzepatide use among individuals without type 2 diabetes (T2D) diagnoses in a US electronic health record (EHR) database.

Materials and Methods: This retrospective, descriptive, cohort study used Veradigm's® Network EHR database linked with administrative claims. Adults (≥18 years) included had ≥1 tirzepatide prescription (index period: 13 May 2022–31 August 2023); continuous medical and pharmacy enrolment for ≥12 months pre-index; and no T2D diagnosis or baseline T2D medications except metformin (overall cohort). 'Anti-obesity medication (AOM)-eligible cohort' included individuals with body mass index (BMI) ≥30 or ≥27 kg/m^2 and ≥1 obesity-related complication (ORC) and ≥6 months of continuous post-index enrollment.

Results: The overall cohort included 10,193 individuals (mean age: 45.0 years; female: 77.1%). Among 6623 individuals with BMI data, 5931 were AOM-eligible. Of these, 3470 had 6-month follow-up data (AOM-eligible cohort; ≥1 ORC: 76.5%; ≥2 ORCs: 51.8%). Treatment patterns at 6 months were assessed among 755 individuals with complete claims data in the AOM-eligible cohort. Most individuals (95.6%) were initiated on a tirzepatide dose of ≤5 mg. At the fifth prescription refill ($n = 448$), 91.1% were receiving tirzepatide doses of ≤10 mg. At 6 months, tirzepatide adherence was 55.5% and persistence was 54.2%. Among discontinued individuals ($n = 346$), 10.1% switched to an alternate AOM.

Conclusions: Majority of individuals in the AOM-eligible cohort had ≥1 ORC, and half had ≥2 ORCs, indicating that in this study cohort tirzepatide was being used in people

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with multimorbidity. Tirzepatide dose escalation in this real-world cohort was slower than in clinical trials, which may have implications for its real-world effectiveness.

KEYWORDS
obesity, tirzepatide, treatment patterns

1 | INTRODUCTION

Obesity is a prevalent, relapsing, chronic medical condition, projected to affect nearly 50% of the US adult population by the year 2030.[1,2] Due to its strong link with numerous chronic diseases, including cardiovascular disease (CVD), hypertension, type 2 diabetes (T2D) and certain types of cancers, obesity is often associated with increased morbidity and mortality rates.[3,4] Overall, obesity led to a decrease of nearly 2.4 years in US life expectancy in 2016.[5] Additionally, the economic implications posed by obesity on individuals, society and the healthcare system are substantial, primarily due to increased healthcare expenditure and reduced workforce productivity.[6–8]

Weight reduction of 5%–10% is widely recognized as the threshold for achieving clinically meaningful health improvements.[9] Although lifestyle interventions (i.e., diet, physical activity and behavioural modifications) have traditionally been the cornerstone of obesity management, yielding an average weight reduction of 8%, long-term adherence is often low.[10–14] Current clinical guidelines recommend the use of pharmacotherapy in combination with lifestyle interventions in individuals with a body mass index (BMI) ≥30 or ≥27 kg/m^2 and ≥1 obesity-related complication (ORC).[15,16]

Tirzepatide is a once-weekly glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 (GLP-1) receptor agonist. It is approved in the United States for the treatment of T2D (May 2022), obesity (November 2023) and obstructive sleep apnea (December 2024).[17–19] Tirzepatide is also currently in development for heart failure with preserved ejection fraction and reduction in morbidity and mortality in adults with obesity.[20–22] In the phase 3 SURMOUNT clinical trials, tirzepatide use resulted in substantial weight reduction versus placebo in adults with obesity or overweight.[23–26] In people with obesity without T2D in the SURMOUNT-1 (NCT04184622), tirzepatide 15 mg demonstrated a mean weight reduction of 22.5% after 72 weeks, versus 2.4% with placebo (efficacy estimand).[23] In SURMOUNT-3 (NCT04657016), a 12-week intensive lifestyle intervention followed by a 72-week treatment period with tirzepatide maximum tolerated dose (MTD; 10 or 15 mg) led to a mean total weight reduction of 26.6% versus 3.8% with intensive lifestyle intervention followed by placebo (efficacy estimand).[25] The SURMOUNT-4 trial (NCT04660643) showed that continued treatment with tirzepatide MTD after a 36-week lead-in period resulted in an additional mean weight reduction of 6.7% over the next 52 weeks, while switching to placebo led to a mean weight regain of 14.8% (efficacy estimand).[26]

Although tirzepatide use has resulted in clinically meaningful weight reduction in the SURMOUNT studies, real-world data on tirzepatide utilization for chronic weight management are limited. The objective of this study was to understand the real-world use of tirzepatide among individuals without T2D diagnoses in the Veradigm® Network Electronic Health Record (EHR) database linked with claims and to describe patient characteristics and treatment patterns.

2 | METHODS

2.1 | Study design and population

This retrospective, observational cohort study used de-identified data from the Veradigm® Network EHR database linked with longitudinal administrative claims data. The study included adults (≥18 years) with ≥1 tirzepatide prescription (National Drug Codes [NDCs] listed in Table S1) in EHR or claims during the index period, 13 May 2022–31 August 2023. Individuals with a tirzepatide prescription in EHR or claims were included in the demographic and clinical characteristics analyses; however, for all treatment pattern analyses, only prescriptions from claims were utilized. The date of the earliest observed tirzepatide prescription was defined as the index date. During the index period, tirzepatide was only approved for the treatment of T2D; therefore, any use of tirzepatide by individuals without T2D during this time was off-label and solely at the discretion of their prescribing provider. Individuals with continuous medical and pharmacy enrollment for ≥12 months pre-index (baseline period) and no baseline use of antihyperglycaemic medications (except metformin) were included in the study. Use of metformin was allowed as it may have been prescribed for other conditions such as polycystic ovarian syndrome, metabolic dysfunction-associated steatotic liver disease and CVD. Individuals with a diagnosis of type 1 diabetes, T2D or any comorbid conditions associated with unintentional weight change during the baseline period were excluded (diagnosis codes listed in Table S1). Individuals meeting these criteria were categorized as the 'overall cohort'. Anti-obesity medication (AOM)-eligible individuals (i.e., BMI ≥30 or ≥27 kg/m^2 with at ≥1 ORC) who met the above inclusion criteria and had ≥6 months of continuous medical and pharmacy enrollment post-index (follow-up) comprised the 'AOM-eligible cohort'. Only individuals with complete 6-month follow-up data were included in the treatment pattern analyses.

2.2 | Data source

Veradigm is one of the largest providers of ambulatory EHR data in the United States, providing access to the records of over 185 million

unique patients. The Veradigm linked database integrates data from Veradigm's EHR platforms, which serve primary care and specialist physicians (including components from Allscripts, Practice Fusion and NextGen EHR), with closed pharmacy and medical claims data, capturing all of a patient's healthcare that is covered by insurance (including prescriptions).

Diagnoses were identified through the International Classification of Diseases, 9th and 10th Editions, Clinical Modification diagnosis codes (ICD-9-CM and ICD-10-CM) and Systematized Nomenclature of Medicine terms. Procedures were identified using Current Procedural Terminology and ICD-10 Procedure Coding System (ICD-10-PCS) codes. Medications were identified using NDCs (Table S1).

2.3 | Study outcomes

Demographic characteristics were assessed at the index date for both cohorts and comprised the following: age, sex, US census region, race, ethnicity and payer type. Clinical characteristics were measured during the 12-month pre-index period (inclusive of index date) and included the prevalence of common comorbid conditions, prevalence and number of ORCs, and most recent weight and EHR-based BMI. Baseline treatments assessed during the 12-month pre-index period (inclusive of index date) included prior use of AOMs and antihyperglycaemic medications (including metformin), bariatric surgery and lifestyle modification. The index tirzepatide prescription dose (2.5, 5 7.5, 10, 12.5 or 15 mg) was also assessed.

Additional analyses were conducted to evaluate the treatment patterns (dose distribution, adherence, persistence, discontinuation and switching) of tirzepatide during the 6-month follow-up period. The number of tirzepatide prescriptions (ranging from 1 to 5+) and the percentage of individuals filling a given tirzepatide dose (2.5, 5, 7.5, 10, 12.5 or 15 mg) from index to the fifth prescription were assessed. Adherence was measured using the proportion of days covered (PDC; sum of days of supply on all tirzepatide prescriptions filled during the 6-month follow-up period/180 days) and individuals were classified as adherent if the PDC was ≥80%. Persistence was defined as continuous treatment from tirzepatide initiation until the end of the follow-up period, allowing for a maximum fixed gap of 60 days between prescription refills. Stockpiling was permitted in the persistence analyses (i.e., if a patient had overlapping days of supply of a medication, it was assumed that the patient used all days of supply of the first prescription prior to starting the second). Treatment discontinuation was defined as failure to refill the index medication within 60 days after depletion of the previous supply. Discontinuation outcomes included the proportion of individuals discontinuing treatment, time to treatment discontinuation and tirzepatide dose at discontinuation. Among the individuals who discontinued tirzepatide, the proportion of individuals who switched to a different AOM was measured. A sensitivity analysis with a 45-day gap was also conducted for persistence, discontinuation and switching measures. It is to be noted that at the time of this study, claims data were available through August 2023, whereas EHR data were available through mid-October 2023. Due to pharmacy claims lag (i.e., the delay between prescription fill and the appearance of the claim in the dataset), the claims in the more recent months may have been incomplete. Therefore, treatment patterns were analysed among the subset of individuals who initiated tirzepatide between 1 May 2022, and 31 December 2022, to ensure that the pharmacy claims data were complete for the AOM-eligible cohort through the end of the 6-month follow-up period.

2.4 | Statistical analysis

Descriptive statistics to assess study outcomes were analysed using SAS software version 9.4. Continuous variables were summarised using means and standard deviations (SDs) and/or medians and interquartile ranges (IQRs), while categorical variables were summarised using frequency and percentage of individuals. Among demographic and clinical variables, missing values were captured as 'missing' or 'not reported'. No imputation of missing values was performed.

3 | RESULTS

Overall cohort

This cohort included 10,193 individuals who initiated tirzepatide without a T2D diagnosis and no use of antihyperglycaemic medications (except metformin) during the pre-index period (Figure S1).

AOM-eligible cohort

Of the 6623 individuals who initiated tirzepatide without a T2D diagnosis and had a BMI measurement, 5931 (89.6%) were AOM eligible. From these, 3470 individuals without baseline use of antihyperglycaemic medications (except metformin) and with a 6-month post-index follow-up were included in the 'AOM-eligible cohort' (Figure S1).

3.1 | Overall demographics and clinical measures

In the overall cohort, the mean (SD) age at index was 45.0 (11.5) years (Table 1). The majority of individuals were female (77.1%) and Caucasian (47.4%). Overall, 71.8% of individuals were commercially insured, and 26.5% of individuals had Medicaid coverage (Table 1). The most recent mean (SD) BMI (from EHR) was 34.4 (5.1) kg/m^2 ($n = 3558$). The majority of individuals (79.7%) had either class 1 (27.9%: BMI ≥30 to <35 kg/m^2), class 2 (23.8%: BMI ≥35 to <40 kg/m^2) or class 3 obesity (27.9%: BMI ≥40 kg/m^2). The mean (SD) weight at baseline was 220.5 (52.7) pounds ($n = 3679$) (Table 1). During the baseline period, 65.0% of individuals had ≥1 ORC, and the mean (SD) number of ORCs was 1.4 (1.4). A total of 19.5% of individuals had two ORCs, 12.0% had three ORCs, and 9.5% had ≥4 ORCs. Dyslipidaemia (33.9%), hypertension (33.2%) and prediabetes (22.8%) were the most prevalent ORCs (Table 2).

TABLE 1 Baseline demographics and clinical characteristics in tirzepatide initiators.

Variables	Overall cohort[a], N = 10 193	AOM-eligible cohort[b], N = 3470
Baseline demographics (index date)		
Age (years), mean (SD)	45.0 (11.5)	44.9 (11.5)
Age group (years), *n* (%)		
18–24	406 (4.0)	134 (3.9)
25–34	1636 (16.1)	569 (16.4)
35–44	2804 (27.5)	983 (28.3)
45–54	3064 (30.1)	1021 (29.4)
55–64	1998 (19.6)	659 (19.0)
65–80	278 (2.7)	100 (2.9)
81+	7 (0.1)	4 (0.1)
Sex, *n* (%)		
Female	7856 (77.1)	2640 (76.1)
Male	2328 (22.8)	826 (23.8)
Missing/not reported	9 (0.1)	4 (0.1)
Race, *n* (%)		
Caucasian	4829 (47.4)	1735 (50.0)
African American	711 (7.0)	310 (8.9)
Asian	350 (3.4)	94 (2.7)
Other	1313 (12.9)	456 (13.1)
Missing/not reported	2990 (29.3)	875 (25.2)
Ethnicity, *n* (%)		
Non-Hispanic	6731 (66.0)	2258 (65.1)
Hispanic	501 (4.9)	198 (5.7)
Missing/not reported	2961 (29.0)	1014 (29.2)
Geographic region, *n* (%)		
South	4653 (45.6)	1728 (49.8)
Northeast	2204 (21.6)	615 (17.7)
Midwest	1694 (16.6)	614 (17.7)
West	1239 (12.2)	396 (11.4)
Not reported	403 (4.0)	117 (3.4)
Payer type, *n* (%)		
Commercial	7321 (71.8)	2364 (68.1)
Medicaid	2703 (26.5)	1034 (29.8)
Medicare advantage	115 (1.1)	60 (1.7)
Other/unknown	54 (0.5)	12 (0.3)
Clinical measures (12-month pre-index period including index date)		
BMI measurement available[c]	3558 (34.9)	1955 (56.3)
BMI[c] (kg/m^2), mean, SD	34.4 (5.1)	35.8 (4.1)
BMI category[c] (kg/m^2), *n* (%)	*n* = 3558	*n* = 1955
<27	305 (8.6)	14 (0.7)
≥27 to <30 (overweight)	417 (11.7)	161 (8.2)
≥30 to <35 (class 1 obesity)	994 (27.9)	610 (31.2)
≥35 to <40 (class 2 obesity)	848 (23.8)	524 (26.8)
≥40 (class 3 obesity)	994 (27.9)	646 (33.0)
AOM eligible[d], *n* (%)		3470 (100.0)
BMI ≥30 kg/m^2		3235 (93.2)
BMI ≥27 to <30 kg/m^2 and ≥1 ORC		235 (6.8)
Weight measurement available, *n* (%)	3679 (36.1)	1985 (57.2)
Weight[e] (lbs), mean, SD	220.5 (52.7)	231.8 (50.2)

Abbreviations: AOM, anti-obesity medication; SD, standard deviation; T2D, type 2 diabetes.
[a]Overall cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) during the pre-index period.
[b]AOM-eligible cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) who met the AOM-eligibility criteria and had a 6-month post-index follow-up.
[c]Most recent BMI measurement recorded in the vitals table in the EHR during the 12-month pre-index period, including the index date.
[d]Most recent BMI measurement within 3 months before or on the index date from claims and EHR data. Obesity-related comorbidities were identified during the 12-month pre-index period, including the index date.
[e]Most recent weight measurement recorded in the vitals table in the EHR during the 12-month pre-index period, including the index date.

Prior to initiating tirzepatide, few individuals were prescribed long-term AOMs (10.4%; *n* = 1059; Table 3). Semaglutide (7.9%; *n* = 807) and liraglutide (2.4%; *n* = 241) were the most commonly prescribed long-term AOMs. Similarly, few individuals were prescribed short-term AOMs (8.4%; *n* = 857), most of whom received phentermine (8.3%; *n* = 851; Table 3). Very few individuals underwent lifestyle modification (4.9%; *n* = 501) or bariatric surgery (0.1%; *n* = 11).

3.2 | Tirzepatide utilization

The baseline characteristics of the 'AOM-eligible cohort' were largely consistent with the 'overall cohort' (mean [SD] age: 44.9 [11.5] years; female: 76.1%; Caucasian: 50.0%; Table 1). Few differences were noted in clinical characteristics between the two cohorts. The mean (SD) BMI (35.8 [4.1] kg/m^2; *n* = 1955) and weight (231.8 [50.2] pounds; *n* = 1985) were numerically higher in the AOM-eligible cohort than in the overall cohort. Most individuals (91.0%) in the AOM-eligible cohort had either class 1 (31.2%: BMI ≥30 to <35 kg/m^2), class 2 (26.8%: BMI ≥35 to <40 kg/m^2) or class 3 (33.0%: BMI ≥40 kg/m^2) obesity (Table 1). The mean (SD) number of ORCs was numerically higher (1.8 [1.5]) in the AOM-eligible cohort. Additionally,

TABLE 2 Presence of obesity-related complications during the pre-index period.

Variables	Overall cohort[a], N = 10 193	AOM-eligible cohort[b], N = 3470
Individuals with ≥1 obesity-related complication (ORC), *n* (%)	6625 (65.0)	2656 (76.5)
Number of ORCs, mean (SD)	1.4 (1.4)	1.8 (1.5)
Number of ORCs, *n* (%)		
0	3568 (35.0)	814 (23.5)
1	2438 (23.9)	857 (24.7)
2	1989 (19.5)	811 (23.4)
3	1228 (12.0)	531 (15.3)
4+	970 (9.5)	457 (13.2)
ORCs, *n* (%)		
Dyslipidaemia	3457 (33.9)	1402 (40.4)
Hypertension	3380 (33.2)	1428 (41.2)
Prediabetes (diagnosis)	2324 (22.8)	996 (28.7)
Obstructive sleep apnoea	1131 (11.1)	503 (14.5)
Asthma/reactive airway disease	884 (8.7)	392 (11.3)
Osteoarthritis (pelvis, hip, knee, lower leg)	745 (7.3)	336 (9.7)
Cardiovascular disease	523 (5.1)	224 (6.5)
Metabolic dysfunction-associated fatty liver disease/ metabolic dysfunction-associated steatohepatitis	500 (4.9)	210 (6.1)
Polycystic ovarian syndrome	432 (4.2)	186 (5.4)
Gastroesophageal reflux disease	335 (3.3)	147 (4.2)
Male hypogonadism	326 (3.2)	124 (3.6)
Urinary stress incontinence	191 (1.9)	81 (2.3)
Metabolic syndrome (diagnosis)	118 (1.2)	68 (2.0)
Female infertility	63 (0.6)	26 (0.7)
Comorbidities, *n* (%)		
Anxiety	2333 (22.9)	899 (25.9)
Knee osteoarthritis	626 (6.1)	281 (8.1)
Depression	382 (3.7)	168 (4.8)
Cardiovascular complication	263 (2.6)	106 (3.1)
Congestive heart failure	99 (1.0)	54 (1.6)
Heart failure with preserved ejection fraction (diagnosis)	35 (0.3)	24 (0.7)
Cerebrovascular complication	105 (1.0)	37 (1.1)
Obesity Hypoventilation Syndrome	26 (0.3)	13 (0.4)

Abbreviations: AOM, anti-obesity medication; SD, standard deviation; T2D, type 2 diabetes.
[a]Overall cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycemic medicatio (except metformin) during the pre-index period.
[b]AOM-eligible cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) who met the AOM-eligibility criteria and had a 6-month post-index follow-up.

TABLE 3 Baseline treatment utilization in tirzepatide initiators.

Variables	Overall cohort[a], N = 10 193	AOM-eligible cohort[b], N = 3470
Long-term AOMs[c], *n* (%)	1059 (10.4)	406 (11.7)
Semaglutide	807 (7.9)	298 (8.6)
Liraglutide	241 (2.4)	101 (2.9)
Naltrexone-bupropion	78 (0.8)	31 (0.9)
Phentermine-topiramate	50 (0.5)	16 (0.5)
Short-term AOMs[c], *n* (%)	857 (8.4)	337 (9.7)
Orlistat	7 (0.1)	2 (0.1)
Phentermine	851 (8.3)	335 (9.7)
Antihyperglycaemic medications, *n* (%)		
Any non-GLP-1 RA antihyperglycaemic medication	1144 (11.2)	376 (10.8)
Metformin	1134 (11.1)	373 (10.7)
Any non-AOM GLP-1 RA	190 (1.9)	64 (1.8)
Lifestyle modification[d], *n* (%)	501 (4.9)	256 (7.4)
Bariatric surgery, *n* (%)	11 (0.1)	3 (0.1)
Index tirzepatide dose, *n* (%)		
2.5 mg	7015 (68.8)	2569 (74.0)
5 mg	1989 (19.5)	627 (18.1)
7.5 mg	521 (5.1)	139 (4.0)
10 mg	337 (3.3)	75 (2.2)
12.5 mg	162 (1.6)	31 (0.9)
15 mg	169 (1.7)	29 (0.8)

Note: Baseline treatment utilization was assessed during the 12-month pre-index period, including the index date.
Abbreviations: AOM, anti-obesity medication; GLP-1, glucagon-like peptide-1; RA, receptor agonist; T2D: type 2 diabetes.
[a]Overall cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) during the pre-index period.
[b]AOM-eligible cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) who met the AOM-eligibility criteria and had a 6-month post-index follow-up.
[c]Long-term and short-term AOM use is not mutually exclusive. Individuals may have been prescribed multiple AOMs in the pre-index period, including the index date.
[d]Lifestyle modification included nutrition counselling, weight management classes and face-to-face behavioural counselling for obesity.

a higher number of individuals (76.5%) had ≥1 ORC (2 ORCs: 23.4%; three ORCs: 15.3%; and ≥4 ORCs: 13.2%). While dyslipidaemia (40.4%), hypertension (41.2%) and prediabetes (28.7%) were the most commonly reported ORCs in both cohorts, prevalence was numerically higher in the AOM-eligible cohort (Table 2). Baseline medication use was largely similar between the two cohorts, with semaglutide (11.7%) and liraglutide (8.6%) being the most frequently prescribed long-term AOMs (Table 3). The majority of individuals in the overall and AOM-eligible cohorts were initiated on a tirzepatide dose of ≤5 mg (88.3% and 92.1%, respectively).

Treatment patterns were assessed in 755 individuals in the 'AOM-eligible cohort' who initiated tirzepatide between May 1, 2022, and December 31, 2022 (Table 4 **and** Figure 1). More than half (59.3%; $n = 448$) had ≥5 tirzepatide prescription refills during the 6-month follow-up period (Table 4). The majority of individuals were initiated (index) on a tirzepatide dose of 2.5 mg (74.0%; $n = 559$) or 5 mg (21.6%; $n = 163$; Figure 1). By the fifth prescription refill (n = 448), most individuals (91.1%) were receiving tirzepatide doses of ≤10 mg (2.5 mg: 17.2%; 5 mg: 37.1%; 7.5 mg: 22.3%; 10 mg: 14.5%); and 7.1% and 1.8% were receiving doses of 12.5 mg and 15 mg, respectively (Figure 1). The mean (SD) PDC was 0.7 (0.3) and 55.5% of the AOM-eligible cohort ($n = 419$) were adherent (PDC ≥ 80%) to tirzepatide treatment (Table 4). Of the 755 individuals, 54.2% ($n = 409$) were persistent on tirzepatide when a 60-day gap was considered. A total of 45.8% of individuals ($n = 346$) discontinued tirzepatide, and the median (IQR) time to discontinuation was 61 (29–112) days. The majority of individuals discontinued tirzepatide at a dose of 2.5 mg (59.5%; $n = 206$) or 5 mg (24.6%; $n = 85$) (Table 4). Of the 346 individuals who discontinued, only 10.1% ($n = 35$) switched to an alternate AOM after the 60-day gap; 74.3% of these ($n = 26$) switched to semaglutide, 20% ($n = 7$) to liraglutide and 5.7% (n = 2) to phentermine/topiramate (Table 4). Using the 45-day gap, treatment persistence (52.6%), discontinuation (47.4%), time to discontinuation (median [IQR]: 61 [29–112] days) and dose at discontinuation (2.5 mg: 57.5%; 5 mg: 24.9%) were consistent with those observed using the 60-day gap (Table 4). Post-discontinuation, fewer individuals (10.3%; $n = 37$) switched to an alternate AOM after the 45-day gap; individuals switched to semaglutide (70.3%; $n = 26$), liraglutide (24.3%; $n = 9$) and phentermine/topiramate (5.4%; $n = 2$) (Table 4).

TABLE 4 Tirzepatide treatment patterns in AOM-eligible individuals (6-month follow-up period).

Variables		AOM-eligible cohort[a], N = 755
Number of tirzepatide prescriptions refills, *n* (%)		
Only 1		110 (14.6)
Only 2		81 (10.7)
Only 3		62 (8.2)
Only 4		54 (7.2)
5+		448 (59.3)
PDC[b], mean (SD)		0.72 (0.33)
PDC ≥ 80%[b], *n* (%)		419 (55.5)
Persistence[c] (60-day gap), *n* (%)		409 (54.2)
Discontinuation[d] (60-day gap), *n* (%)		346 (45.8)
Days to discontinuation (60-day gap)	Mean (SD)	78.3 (47.4)
	Median (IQR)	61 (29–112)
Dose at discontinuation (60-day gap), *n* (%)		
2.5 mg		206 (59.5)
5 mg		85 (24.6)
7.5 mg		32 (9.2)
10 mg		14 (4.0)
12.5 mg		6 (1.7)
15 mg		3 (0.9)
Switch to a different AOM post tirzepatide discontinuation (60-day gap), *n* (%)		35 (10.1)
Semaglutide		26 (74.3)
Liraglutide		7 (20.0)
Phentermine-topiramate		2 (5.7)
Persistence[c] (45-day gap), *n* (%)		397 (52.6)
Discontinuation[d] (45-day gap), *n* (%)		358 (47.4)
Days to discontinuation (45-day gap)	Mean (SD)	77.5 (46.6)
	Median (IQR)	61 (29–112)
Dose at discontinuation (45-day gap), *n* (%)		
2.5 mg		206 (57.5)
5 mg		89 (24.9)
7.5 mg		36 (10.1)
10 mg		18 (5.0)
12.5 mg		6 (1.7)
15 mg		3 (0.8)
Switch to a different AOM post tirzepatide discontinuation (45-day gap), *n* (%)		37 (10.3)
Semaglutide		26 (70.3)
Liraglutide		9 (24.3)
Phentermine/topiramate		2 (5.4)

Abbreviations: AOM, anti-obesity medication; PDC, proportion of days covered; SD, standard deviation; T2D: type 2 diabetes.
[a]AOM-eligible cohort: Individuals (≥18 years) without a T2D diagnosis and no use of antihyperglycaemic medications (except metformin) who met the AOM-eligibility criteria and had a 6-month post-index follow-up. This analysis was conducted in the subset of individuals who initiated tirzepatide between 1 May 2022, and 31 December 2022, to ensure that the pharmacy claims data were relatively complete for the AOM-eligible cohort through the end of the 6-month follow-up period.
[b]Adherence was measured using PDC (sum of days of supply on all tirzepatide prescriptions filled during the 6-month follow-up period ÷ 180 days) and individuals were classified as 'adherent' if the PDC was ≥80%.
[c]Persistence was defined as continuous treatment from tirzepatide initiation until the end of the follow-up period, allowing for a maximum fixed gap of 45 or 60 days between prescription refills. Stockpiling was permitted in the persistence analyses.
[d]Treatment discontinuation was defined as failure to refill the index medication within 45 or 60 days after depletion of the previous supply.

4 | DISCUSSION

This retrospective study used the Veradigm database to describe real-world utilization of tirzepatide among individuals without a T2D

diagnosis in the United States. The baseline demographics and clinical characteristics of individuals initiating tirzepatide in this real-world study were similar to those reported in the phase 3 SURMOUNT-1 trial.[23] The mean BMI of individuals initiating tirzepatide was in the upper end of class 1 obesity (overall cohort: 34.4 kg/m^2) or in class 2 obesity (AOM-eligible cohort: 35.8 kg/m^2). In the AOM-eligible cohort, more than half of the individuals were persistent on tirzepatide during the first 6 months of treatment. Switching to an alternate AOM was uncommon among the individuals who discontinued tirzepatide.

The risk of multimorbidity is higher in people with overweight (relative risk [RR]: 1.26; 95% CI: 1.12–1.40) and obesity (RR: 1.99; 95% CI: 1.45–2.72) compared with people with normal weight.[27] In a large real-world US cohort study, over 50% of individuals with obesity had one or more ORCs.[28] Congruent with these findings, our results showed that approximately three out of every four individuals had ≥1 ORC and more than half of the individuals (51.8%) had ≥2 ORCs in the AOM-eligible cohort. ORCs are driving the costs associated with obesity in the United States and direct healthcare costs escalate with an increase in the number of ORCs.[28] Moreover, the annual medical care costs in the United States for adults with obesity are twice as much as costs for adults with normal weight, while medical costs for people with class 3 obesity are 3.4 times higher than costs for those with class 1 obesity.[29] Thus, early and effective weight management strategies may prevent the onset or progression of ORCs and mitigate the increasing healthcare costs associated with obesity.[28]

Under-prescribing and low utilization of AOMs in eligible populations have been reported previously in the United States.[30–32] In this study, few individuals (11.7%) in the AOM-eligible cohort were prescribed AOMs during the 12-month baseline period, with semaglutide and liraglutide being the most commonly prescribed. Several factors, such as prescribers' preferences to prioritize lifestyle modification over medication, safety concerns, prescribers' lack of experience or familiarity with newer medications and low effectiveness of older AOMs, as well as US Food and Drug Administration restrictions on their long-term use, may impact AOM utilization in the eligible population.[33,34] While semaglutide was available during the study period, it had only been recently launched for obesity treatment (June 2021), likely explaining its low use in this study.[35] Additionally, there is significant variation in insurance coverage of AOMs across the United States. Most private healthcare insurance plans do not provide coverage for AOMs and require patients to pay out of pocket.[36,37]

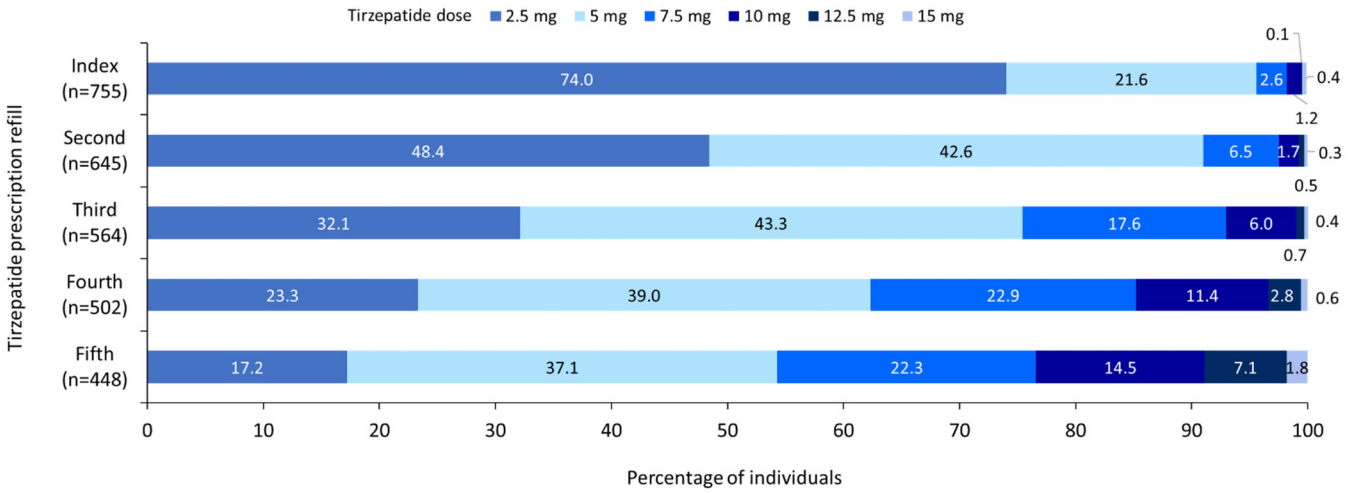
For chronic weight management, the recommended tirzepatide starting dose is 2.5 mg injected subcutaneously once weekly. It is recommended to increase the dosage in 2.5-mg increments after at least 4 weeks on the current dose, with the recommended maintenance dosages being 5 mg, 10 mg or 15 mg.[18] Consistent with these dosing recommendations, the majority of individuals in the 'AOM-eligible cohort' were receiving a tirzepatide dose of 2.5 mg (74.0%) at the index prescription. Although the 2.5-mg dose is used to initiate treatment,[18] 17.2% of individuals were receiving this dose at the fifth prescription refill. The majority of individuals were receiving a tirzepatide dose of <10 mg at the fifth prescription refill, with tirzepatide 5 mg being the most commonly prescribed dose. This suggests that in the real world, tirzepatide doses may not be escalated to the MTD (10 or 15 mg) used in the SURMOUNT clinical trial programme. Several factors, such as achieving the desired treatment response at low doses, tolerability, prescriber preferences, and access and supply issues, may contribute to real-world dose escalation strategies.[38–40] Moreover, tirzepatide was only approved for T2D during the study period and therefore, awareness regarding what constituted the tirzepatide MTD may have been low. Additionally, we did not assess longitudinal weight reduction for each tirzepatide dose, so we are unable to determine if there were dose-dependent differences in weight loss.

In this study, tirzepatide persistence (54.2%) at 6 months was higher than the overall GLP-1 persistence (46.3% at 6 months) previously reported in a real-world study in commercially insured individuals with obesity and without diabetes newly initiating GLP-1 therapy (January 2021–December 2021).[41] Similarly, in a real-world AOM persistence analysis ($N = 26\,522$; April 2015–March 2016), persistence to liraglutide was 41.8% at 6 months and much lower for non-GLP-1 weight reduction therapies (15.9%–27.3%).[42] These differences observed in treatment persistence could be due to supply chain challenges associated with semaglutide, lower efficacy of liraglutide compared with next-generation AOMs and the requirement of daily liraglutide dosing versus weekly dosing for next-generation AOMs.[41] In a different study we conducted with an index period (13 May 2022–30 June 2023) similar to the present study but using the Healthcare Integrated Research Database (HIRD®), the 6-month persistence to tirzepatide (73.7%) was numerically higher compared with that observed in the present study.[43] The relatively lower tirzepatide persistence in the current study could possibly be attributed to the higher number of individuals insured by Medicaid (26.5%–29.8%) versus no individuals with Medicaid insurance (∼95%: commercial; ∼5%: Medicare) in the HIRD study.

While the current study was designed to address the gap of limited real-world evidence on tirzepatide utilization, future studies should focus on long-term follow-up in people with obesity or overweight receiving tirzepatide. In addition, the investigation of reduction in weight and BMI and the associated improvement in cardiometabolic risk factors and T2D can enhance our understanding of the treatment effectiveness of tirzepatide in the real world. In the recent post hoc analyses of SURMOUNT-1, the 10-year predicted risk of developing T2D and atherosclerotic cardiovascular disease in people with obesity or overweight significantly decreased with tirzepatide.[44,45] Moreover, the ongoing SURMOUNT-MMO phase 3 trial and the extension phase of the SURMOUNT-1 trial that will finalize in 2027 and 2024, respectively, investigate the time to T2D onset and its progression among participants with obesity or overweight without T2D.[46,47]

5 | LIMITATIONS

The majority of individuals were commercially insured (68.1%–71.8%) and over a quarter had Medicaid coverage (26.5%–29.8%). Thus, the



Tirzepatide dose	Tirzepatide prescription refill, n (%)				
	Index (n=755)	Second (n=645)	Third (n=564)	Fourth (n=502)	Fifth (n=448)
2.5 mg	559 (74.0)	312 (48.4)	181 (32.1)	117 (23.3)	77 (17.2)
5 mg	163 (21.6)	275 (42.6)	244 (43.3)	196 (39.0)	166 (37.1)
7.5 mg	20 (2.6)	42 (6.5)	99 (17.6)	115 (22.9)	100 (22.3)
10 mg	9 (1.2)	11 (1.7)	34 (6.0)	57 (11.4)	65 (14.5)
12.5 mg	1 (0.1)	3 (0.5)	4 (0.7)	14 (2.8)	32 (7.1)
15 mg	3 (0.4)	2 (0.3)	2 (0.4)	3 (0.6)	8 (1.8)

FIGURE 1 Tirzepatide dose distribution in anti-obesity medication (AOM)-eligible individuals (6-month follow-up period). AOM-eligible cohort: Individuals (≥18 years) without T2D diagnosis and no use of antihyperglycaemic medications (except metformin) who met the AOM-eligibility criteria and had a 6-month post-index follow-up. This analysis was conducted in the subset of individuals who initiated tirzepatide between 1 May 2022 and 31 December 2022, to ensure that the pharmacy claims data were relatively complete for the AOM-eligible cohort through the end of the 6-month follow-up period.

study may not fully represent the US population, especially those uninsured or with other types of insurance. As demographic and clinical characteristics were assessed among individuals with filled (claims) and written (EHR) prescriptions, it is possible that not all individuals in the study filled a tirzepatide prescription; data suggest over 90% of patients do not fill new AOM prescriptions (primary nonadherence).[48] Since our list of prespecified ORCs may not include all ORCs that people with obesity or overweight experience, we may be underestimating the ORCs. Study definitions of AOM eligibility and payer access criteria may have influenced patient characteristics. Off-label use of tirzepatide could have affected treatment patterns in the AOM-eligible cohort. Tirzepatide supply shortages during the study period could have impacted dose escalation and persistence.[38] Tirzepatide samples (2.5 mg) are not captured in claims databases, so more people may have started on the lowest dose than recorded. The study used routinely collected EHR and claims data to assess real-world outcomes. Consequently, it may have limitations due to coding accuracy and completeness, possibly including individuals with T2D diagnosis. Coding errors may underestimate or overestimate outcomes like comorbidities and adherence. For example, individuals with recorded BMIs in the database may experience more health issues (i.e., have more ORCs) than people without recorded BMIs. Incomplete data, particularly for weight and BMI measurements available only for a subset of individuals, could affect the generalizability of these findings. Consistent with other claims/EHR database studies using structured data fields, the requirement of continuous 12-month pre-index and 6-month post-index enrollment to assess treatment patterns may exclude individuals who disenrolled after the index tirzepatide claim or had shorter follow-up. Patient numbers decreased with each prescription refill, which may be due to patient preference or limited tolerability. The reasons for treatment discontinuation and switching were not captured in the database used in this study. The potential impact of socioeconomic factors, healthcare access and patient preferences on treatment patterns was not evaluated in this descriptive study.

6 | CONCLUSION

Evidence from this real-world study suggests that most individuals in the AOM-eligible cohort had ≥1 ORC, and half had ≥2 ORCs, indicating tirzepatide was being used in people with multimorbidity. Individuals initiating tirzepatide showed a favourable adherence and persistence profile during the 6-month follow-up period, and we observed better persistence than previously reported for GLP-1 AOMs. However, in this real-world cohort, individuals were not

escalating doses consistent with clinical trials, which may have implications for the effectiveness observed in the real-world setting.

AUTHOR CONTRIBUTIONS

Design: Theresa Hunter Gibble, Chanadda Chinthammit, Jennifer M. Ward, Katherine Cappell, Robert Sedgley, Machaon Bonafede and Emily R. Hankosky. Conduct/data collection: Katherine Cappell and Machaon Bonafede. Analysis: all authors. Writing manuscript: all authors.

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CONFLICT OF INTEREST STATEMENT

Theresa Hunter Gibble, Chanadda Chinthammit, Jennifer M. Ward, Birong Liao, and Emily R. Hankosky: Employment and stockholder, Eli Lilly and Company. Katherine Cappell and Machaon Bonafede: Employment and stockholder, Veradigm. Robert Sedgley: Employment, Veradigm.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.16330.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analysed during the current study are not publicly available due to individual data privacy.

ETHICS STATEMENT

As this observational study used the de-identified Veradigm Network electronic health record (EHR) database linked with administrative claims, a formal Consent to Release Information form and Ethical Review Board approval or waiver were not required. This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Pharmacoepidemiology Practices and applicable laws and regulations of the country or countries where the study was conducted, as appropriate. Data accessed were compliant with the United States patient confidentiality requirements, including the Health Insurance Portability and Accountability Act of 1996 regulations.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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