A Real-World Analysis of Apremilast and Cardiometabolic Comorbidities in Psoriasis and Psoriatic Arthritis, Including Impact on Weight Loss by Diabetic Status

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BACKGROUND

- Patients with psoriasis (PsO) and psoriatic arthritis (PsA) have a higher prevalence of cardiometabolic diseases including obesity, diabetes and dyslipidemia compared to the general population.[1]
- Treatment with apremilast has been associated with weight loss in clinical trial populations,[2,3] and emerging research suggests PDE4 has a role in fat and glucose metabolism.
- We examined weight loss among apremilast initiators in a real-world population over a 12-month follow-up period.

OBJECTIVES

- Describe the demographic, clinical characteristics, and treatment history of patients with psoriasis and/or psoriatic arthritis who initiated apremilast.
- Describe changes in weight by diabetes and obesity status over a 12-month follow-up period among patients on apremilast.

STUDY DESIGN AND METHODS

Data Source

- The US OM1 real-world data includes linked, de-identified specialty electronic medical records, claims, and laboratory values.

Study Population

- Patients with PsO or PsA that initiated apremilast (index date) between March 2014 and November 2021.
- Had a 365-day baseline period with a weight measure within 3 months prior to index and at 12 months (± 3 months).
- Persistent on apremilast for 12 months (allowable gap of 60 days).

Statistical Analysis

- Described baseline characteristics by diabetes status (no diabetes vs pre-diabetes (two diagnosis codes at least 30 days apart during baseline, HbA1c: 5.7%-6.4%, or fasting glucose: 100-125 mg/dL)/ type 2 diabetes mellitus (T2DM) (two diagnosis codes at least 30 days apart or antidiabetic medication during baseline) and obesity status (no obesity: BMI < 30, obese: 30 ≤ BMI < 34.9, severe obesity: BMI ≥ 35).
- Percent weight change at 12 months follow-up was calculated, frequencies and percentages were reported by cutoff points and cumulative proportional weight change was presented.

Patient Population Initiating Apremilast

Pre-diabetes/ T2DM	Obesity
N = 8,487 with PsO or PsA, 23.6% (n = 2004 with T2DM)	N = 8,250 with PsO or PsA (26.9% were obese and 33.5% severely obese)
37.2% Male, Mean age = 55.2 y	36.9% Male, Mean age = 55.2 y
Patients with diabetes were older, weighed more and higher proportions had hypertension, dyslipidemia.	Obese and severely obese patients were more likely to have hypertension, dyslipidemia, diabetes and depression.

RESULTS

Table 1: Baseline Characteristics by Diabetes Status

Patients	No Diabetes	Pre-diabetes/ T2DM	Overall	p-Value
Characteristics	6,483 (76.4%)	2,004 (23.6%)	8,487	
Age (y), Mean (SD)	54.0 (12.8)	59.0 (10.8)	55.2 (12.5)	< 0.001
Sex, Female (%)	4,092 (63.1%)	1,242 (62.0%)	5,334 (62.8%)	0.355
Race (%)				< 0.001
Black	148 (2.3%)	83 (4.1%)	231 (2.7%)	
White	5,047 (77.8%)	1,538 (76.7%)	6,585 (77.6%)	
Other	121 (1.9%)	65 (3.2%)	186 (2.2%)	
Unknown	1,167 (18.0%)	318 (15.9%)	1,485 (17.5%)	
BMI (kg/m^2), Mean (SD)	31.8 (7.1)	35.5 (7.4)	32.7 (7.4)	< 0.001
Weight (lbs), Mean (SD)	199.05 (49.70)	221.02 (52.76)	204.36 (51.32)	< 0.001
CCI[1] , Mean (SD)	0.4 (1.2)	1.2 (2.0)	0.6 (1.4)	< 0.001
PsO only[2] (%)	1,950 (30.1%)	755 (37.7%)	2,705 (31.9%)	< 0.001
PsA only[2] (%)	1,657 (25.6%)	394 (19.7%)	2,051 (24.2%)	< 0.001
PsO and PsA[2] (%)	2,876 (44.4%)	855 (42.7%)	3,731 (44.0%)	0.181
Hypertension (%)	1,961 (30.2%)	1,302 (65.0%)	3,263 (38.4%)	< 0.001
Dyslipidemia (%)	1,519 (23.4%)	1,143 (57.0%)	2,662 (31.4%)	< 0.001
Cardiovascular disease[3] (%)	632 (9.7%)	503 (25.1%)	1,135 (13.4%)	< 0.001
Anti-diabetics (%)	0 (0.0%)	1,375 (68.6%)	1,375 (16.2%)	< 0.001
Anti-hypertensives (%)	2,084 (32.1%)	1,316 (65.7%)	3,400 (40.1%)	< 0.001
Lipid-lowering therapies (%)	1,193 (18.4%)	1,044 (52.1%)	2,237 (26.4%)	< 0.001

[1]Charlson comorbidity index
[2]Dentified during the 12 months on or before the index date
[3]Includes coronary artery disease, peripheral vascular disease, stroke, and congestive heart failure

Table 2: Baseline Characteristics by Obesity Status

Patients	No Obesity	Obese	Severe Obesity	Overall	p-value
Characteristics	3,263 (39.6%)	2,222 (26.9%)	2,765 (33.5%)	8,250	
Age (y), Mean (SD)	55.5 (13.4)	56.0 (12.1)	54.3 (11.7)	55.2 (12.5)	< 0.001
Sex, Female (%)	2,033 (62.3%)	1,316 (59.2%)	1,857 (67.2%)	5,206 (63.1%)	< 0.001
Race (%)					< 0.001
Black	67 (2.1%)	59 (2.7%)	97 (3.5%)	223 (2.7%)	
White	2,479 (76.0%)	1,772 (79.7%)	2,154 (77.9%)	6,405 (77.6%)	
Other	119 (3.6%)	31 (1.4%)	31 (1.1%)	181 (2.2%)	
Unknown	598 (18.3%)	360 (16.2%)	483 (17.5%)	1,441 (17.5%)	
BMI (kg/m^2), Mean (SD)	25.8 (2.8)	32.4 (1.4)	41.0 (5.0)	32.7 (7.4)	< 0.001
Weight (lb), Mean (SD)	162.4 (26.6)	203.6 (24.7)	255.4 (43.1)	204.3 (51.3)	< 0.001
CCI[1], Mean (SD)	0.5 (1.4)	0.6 (1.4)	0.7 (1.6)	0.6 (1.4)	< 0.001
PsO only[2] (%)	1,068 (32.7%)	686 (30.9%)	849 (30.7%)	2,603 (31.6%)	0.175
PsA only[2] (%)	856 (26.2%)	528 (23.8%)	611 (22.1%)	1,995 (24.2%)	< 0.001
PsO and PsA[2] (%)	1,339 (41.0%)	1,008 (45.4%)	1,305 (47.2%)	3,652 (44.3%)	< 0.001
Hypertension (%)	957 (29.3%)	903 (40.6%)	1,349 (48.8%)	3,209 (38.9%)	< 0.001
Dyslipidemia (%)	921 (28.2%)	720 (32.4%)	972 (35.2%)	2,613 (31.7%)	< 0.001
Cardiovascular disease[3] (%)	480 (14.7%)	534 (24.0%)	956 (34.6%)	1,970 (23.9%)	< 0.001
Anti-diabetics (%)	311 (9.5%)	365 (16.4%)	671 (24.3%)	1,347 (16.3%)	< 0.001
Anti-hypertensives (%)	1,023 (31.4%)	926 (41.7%)	1,382 (50.0%)	3,331 (40.4%)	< 0.001
Lipid-lowering therapies (%)	702 (21.5%)	646 (29.1%)	839 (30.3%)	2,187 (26.5%)	< 0.001

[1]Charlson comorbidity index
[2]Identified during the 12 months on or before the index date
[3]Includes coronary artery disease, peripheral vascular disease, stroke, and congestive heart

RESULTS / FOLLOW-UP

- Weight loss was observed consistently at 12 months. Overall, 50% of patients lost ≥ 1% of body weight, 31% gained ≥ 1% of weight, and 19% had no change. Nearly one quarter of patients lost at least 5% of their body weight.
- Among those with diabetes, 28.1% of patients lost at least 5% of weight compared to 21.6% of those without diabetes at 12 months (**Figure 1**).
- 26.7% of severely obese patients, 25.4% of obese patients and 19.0% of non-obese patients lost at least 5% of weight at 12 months. (**Figure 2**).

Figure 1: Cumulative Proportional Weight Change at 12 months by Diabetes Status

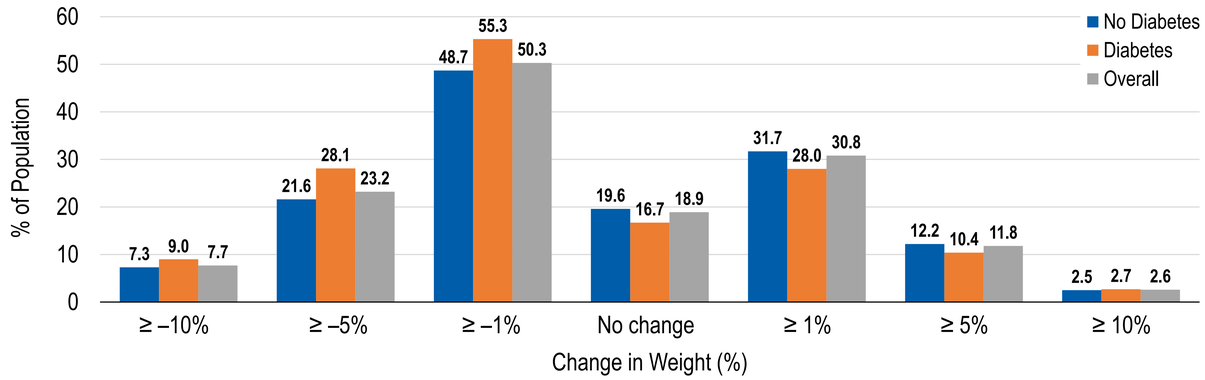
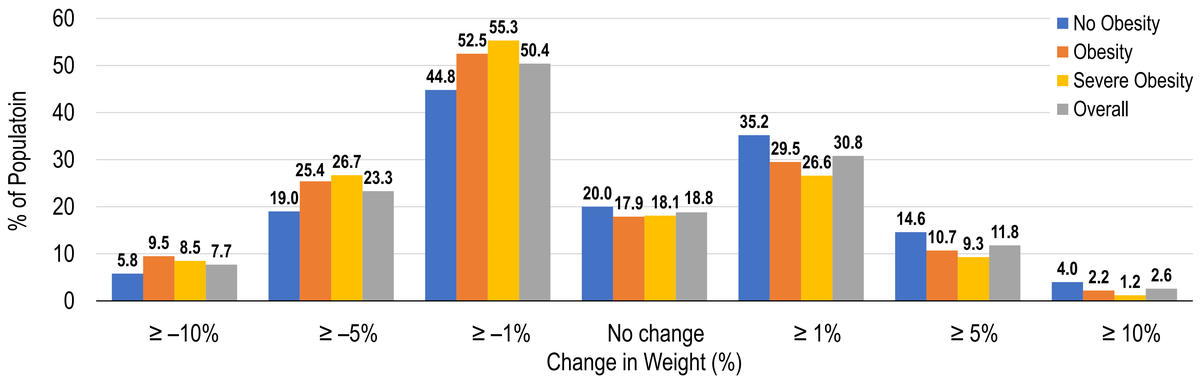


Figure 2: Cumulative Proportional Weight Change at 12 months by Obesity Status



CONCLUSIONS

- Half of the patients experienced weight loss and a quarter of obese patients lost ≥ 5% of weight consistent with pooled trial data showing a mean proportional weight loss of 1.3% among those treated with apremilast.[4]
- Diabetes and obesity were associated with increased weight loss in patients who initiated apremilast.
- Metabolic syndrome is a common systemic comorbidity of psoriatic disease, weight loss has been shown to improve this condition. Further research into the impact of apremilast treatment on weight loss and cardiometabolic parameters is needed.

REFERENCES

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4. See P2346, EADV 2023

DISCLOSURES

This study was funded by Amgen, Inc. CK, PM were contracted by Amgen, Inc. to conduct the study. KO, MC, YK, SC, CD are employees and own stock in Amgen, Inc. NNM has no relevant disclosures.

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