Changes in Weight Across the Life Span in Patients with Bipolar Disorder I Treated with Second **Generation Antipsychotics**



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Disclosures

This study was initiated and internally funded by OM1, Inc. All authors are employees of OM1, Inc. Dr. Marci is also affiliated with Massachusetts General Hospital and Harvard Medical School.

Background

Antipsychotics are indicated for symptom relief and relapse prevention in bipolar disorder I (BD-1). Many second-generation antipsychotics (SGAs) are associated with weight gain. Systematic reviews of clinical trial data report that younger patients are more susceptible to SGA-induced weight gain^{1,2}, but additional real-world evidence is needed.

Objective

To describe changes in weight across the life span in a US realworld cohort of patients with BD-1 treated with SGAs.

Methods

Study Design

	Female (N = 23,445)	Male (N = 9,283)	Overall (N = 32,728)
Age, mean (SD)	46.4 (15.7)	46.6 (16.3)	46.4 (15.8)
Age group, n (%)			
12-14	143 (0.6%)	114 (1.2%)	257 (0.8%)
15-17	450 (1.9%)	247 (2.7%)	697 (2.1%)
18-24	1,766 (7.5%)	744 (8.0%)	2,510 (7.7%)
35-44	3,521 (15.0%)	1,247 (13.4%)	4,768 (14.6%)
45-54	4,507 (19.2%)	1,580 (17.0%)	6,087 (18.6%)
55-64	5,285 (22.5%)	2,080 (22.4%)	7,365 (22.5%)
65+	4,777 (20.4%)	2,038 (22.0%)	6,815 (20.8%)
Race, n (%)			
Black	2,182 (11.3%)	663 (8.6%)	2,845 (10.6%)
White	16,961 (88.0%)	6,951 (90.6%)	23,912 (88.7%)
Other	140 (0.7%)	59 (0.8%)	199 (0.7%)
Unknown	4,162	1,610	5,772
Insurance status, n (%)			
Commercial	5,727 (24.4%)	2,333 (25.1%)	8,060 (24.6%)
Medicare	3,637 (15.5%)	1,419 (15.3%)	5,056 (15.4%)
Medicaid	1,520 (6.5%)	563 (6.1%)	2,083 (6.4%)
Other	7,013 (29.9%)	2,824 (30.4%)	9,837 (30.1%)
Multiple	5,548 (23.7%)	2,144 (23.1%)	7,692 (23.5%)
Type 2 diabetes, n (%)	3,671 (15.7%)	1,648 (17.8%)	5,319 (16.3%)
Hypertension, n (%)	7,177 (30.6%)	3,402 (36.6%)	10,579 (32.3%)
Dyslipidemia, n (%)	5,721 (24.4%)	2,735 (29.5%)	8,456 (25.8%)

Table 1. Baseline Patient Characteristics

Retrospective observational cohort study during the study period of January 2013 – November 2020

Data Source

OM1 Real-World Data Cloud (RWDC, OM1, Inc., Boston, MA, USA), a US real-world data network with linked healthcare claims and electronic medical records (EMR) data from multiple specialty providers, including OM1's Mental Health Network of 2.5+ million patients seen in 2,000+ communitybased practices.

Inclusion Criteria

- At least one prescription or dispensing date for a SGA indicated for BD-1 treatment with no use of any SGA in the prior 12 months (SGA initiation)
- ≥ 12 years of age on the date of SGA initiation
- At least one diagnosis code for BD-1 in the 12 months before through 30 days after the date of SGA initiation
- Linked EMR and claims data 12 months before and 12 months • after the date of SGA initiation
- At least one weight measurement in the 3 months before SGA initiation and in the 12 months after SGA initiation

Exclusion Criteria

- At least one diagnosis code for schizophrenia in the 12 months before through 30 days after the date of SGA initiation
- At least one prescription or dispensing date for a firstulletgeneration antipsychotic (FGA) in the 12 months prior to or on the date of SGA initiation

Study Outcomes

- Changes in body weight in pounds (lbs) and body mass index ٠ (BMI) in kg/m^2 from baseline to follow-up
 - Baseline measurement: most recent measurement within 3 months prior to SGA initiation

0, 121(27.770)

Figure 1. Mean Percent Change in Weight from Baseline to Follow-up

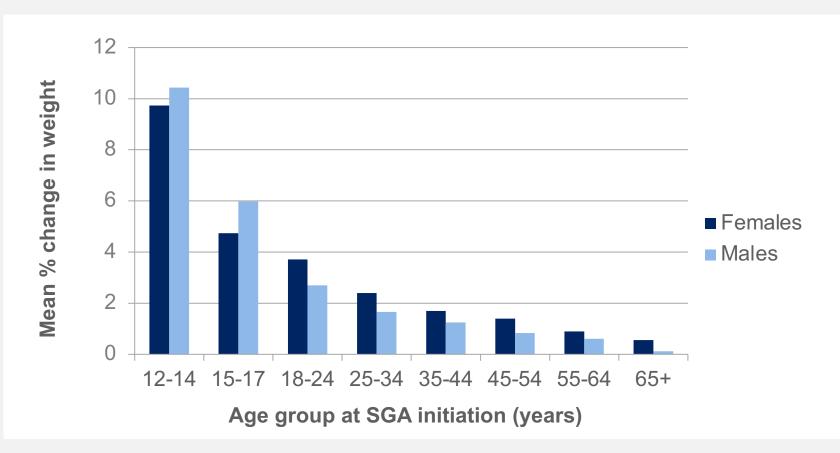


Table 2a. Mean Baseline and Follow-up Weights in Females

Age Group	N	Baseline weight mean (SD)	Follow-up weight mean (SD)
12-14	143	144.2 (42.1)	157.5 (45.6)
15-17	450	155.7 (46.0)	162.9 (49.5)
18-24	1,766	174.0 (54.6)	179.1 (54.7)
25-34	3,521	189.3 (57.8)	192.5 (57.5)
35-44	4,507	197.9 (54.9)	200.0 (54.7)
45-54	5,285	194.0 (51.7)	195.8 (52.1)
55-64	4,777	186.1 (47.3)	186.9 (47.6)
65+	2,996	173.5 (42.2)	173.7 (42.2)
Overall	23,445	187.3 (52.4)	189.3 (52.4)

Table 2b. Mean Baseline and Follow-up Weights in Males

Age Group	N	Baseline weight mean (SD)	Follow-up weight mean (SD)
12-14	114	133.3 (44.0)	147.2 (50.7)
15-17	247	174.0 (49.7)	183.6 (53.7)
18-24	744	194.4 (54.1)	198.9 (54.7)
25-34	1,247	212.8 (56.5)	215.3 (55.9)
35-44	1,580	224.1 (56.2)	226.0 (56.6)
45-54	2,080	221.9 (51.9)	222.9 (51.6)
55-64	2,038	214.8 (47.1)	215.4 (47.3)
65+	1,233	203.2 (40.5)	202.7 (40.4)
Overall	9,283	212.5 (52.9)	214.2 (52.7)

Follow-up measurement: measurement closest to the 12 months after SGA initiation

Analytic Methods

Mean annual percent changes in BMI (in kg/m²) and body ٠ weight (in pounds) from baseline to follow-up were calculated by sex and age group.

Results

- A total of 32,728 patients met inclusion criteria (71.6% female; 28.4% male). Baseline characteristics are displayed in **Table 1**.
- Overall, the mean % change in body weight was 1.7% in females and 1.3% in males. In both sexes, the mean % change was highest during adolescence (9.7% in females and 10.4% in males aged 12-14 years) and steadily decreased through adulthood (0.6% in females and 0.1% in males aged 65+ years) (Figure 1). Mean baseline and follow-up body weights are presented in Table 2a (females) and Table 2b (males).
- Overall, the mean % change in BMI was 1.7% in females and 1.2% in males. Similar to the findings for body weight, the mean % change steadily decreased from adolescence (7.6% in females and 5.2% in males aged 12-14 years) through adulthood (0.7% in females and 0.2% in males aged 65+ years) (Figure 2). Mean baseline and follow-up BMIs in Table **3a** (females) and **Table 3b** (males).

Conclusions

The magnitude of weight gain and increase in BMI in this preliminary analysis of a real-world population of SGA initiators with BD-1 was highest in adolescent patients and decreased with increasing age across the adult life span in

Figure 2. Mean Percent Change in BMI from Baseline to Follow-up

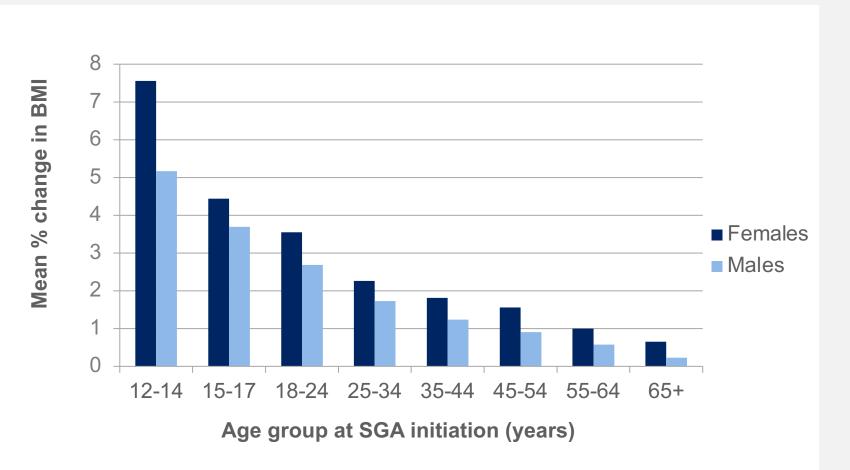


Table 3a. Mean Baseline and Follow-up BMIs in Females

Age Group	Ν	Baseline BMI mean (SD)	Follow-up BMI mean (SD)
12-14	138	26.1 (6.9)	27.9 (7.1)
15-17	435	26.7 (7.3)	27.8 (7.9)
18-24	1,723	29.4 (8.4)	30.3 (8.5)
25-34	3,446	31.8 (8.9)	32.3 (8.8)
35-44	4,414	33.1 (8.4)	33.5 (8.3)
45-54	5,218	32.6 (8.1)	33.0 (8.1)
55-64	4,711	31.8 (7.6)	31.9 (7.7)
65+	2,942	30.3 (7.0)	30.3 (7.0)
Overall	23,027	31.7 (8.2)	32.1 (8.2)

both females and males.

- The percent weight gain observed in adults in this study is consistent with the average weight gain of 1-2 pounds per year reported in the general adult US population.³
- Additional research is needed to identify patient subgroups at higher risk for SGA-induced weight gain to implement strategies to prevent or ameliorate weight gain and improve medication adherence and quality of life.
- Future research should consider comparisons of weight changes in adult SGA users with the general population to determine the extent of weight gain associated with SGA use versus expected changes in weight associated with age.

Table 3b. Mean Baseline and Follow-up BMIs in Males

Age Group	N	Baseline BMI mean (SD)	Follow-up BMI mean (SD)
12-14	106	23.5 (6.0)	24.6 (6.7)
15-17	239	26.3 (6.6)	27.2 (7.1)
18-24	723	28.2 (7.4)	28.8 (7.5)
25-34	1,206	30.6 (7.6)	30.9 (7.6)
35-44	1,548	32.1 (7.4)	32.4 (7.5)
45-54	2,037	32.0 (6.8)	32.2 (6.8)
55-64	2,007	31.1 (6.5)	31.2 (6.5)
65+	1,211	29.9 (5.6)	29.9 (5.6)
Overall	9,077	30.8 (7.0)	31.0 (7.0)

Conference

Presented at the 38th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. August 24-28, 2022. Copenhagen, Denmark.

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