Multiple Sclerosis Patients Initiating Ofatumumab in the Real-World: Early 3-Months Data

7302

Patricia K. Coyle,[1*] Magdaliz Gorritz,[2] Rolin L. Wade,[2] Zifan Zhou,[2] Yao Cao,[2] Chinmay Deshpande[3]

[1]Department of Neurology, Stony Brook University, Stony Brook, NY, USA; [2]IQVIA, Plymouth Meeting, PA, USA; [3]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, *Presenting author

Background

- The efficacy and safety of ofatumumab were demonstrated in two phase III ASCLEPIOS trials[1], which led to it's approval by Food and Drug Administration (FDA) in August 2020 for the treatment of relapsing forms of multiple sclerosis (MS).
- It is important to have an understanding of the early patient demographic and clinical characteristics, map early patient and prescribers, as well as examine the pre-and post-index treatment patterns for patients receiving ofatumumab. This analysis aims to provide an account of real-world patients initiating ofatumumab in the first 3 months of availability after FDA approval in the United States (US).

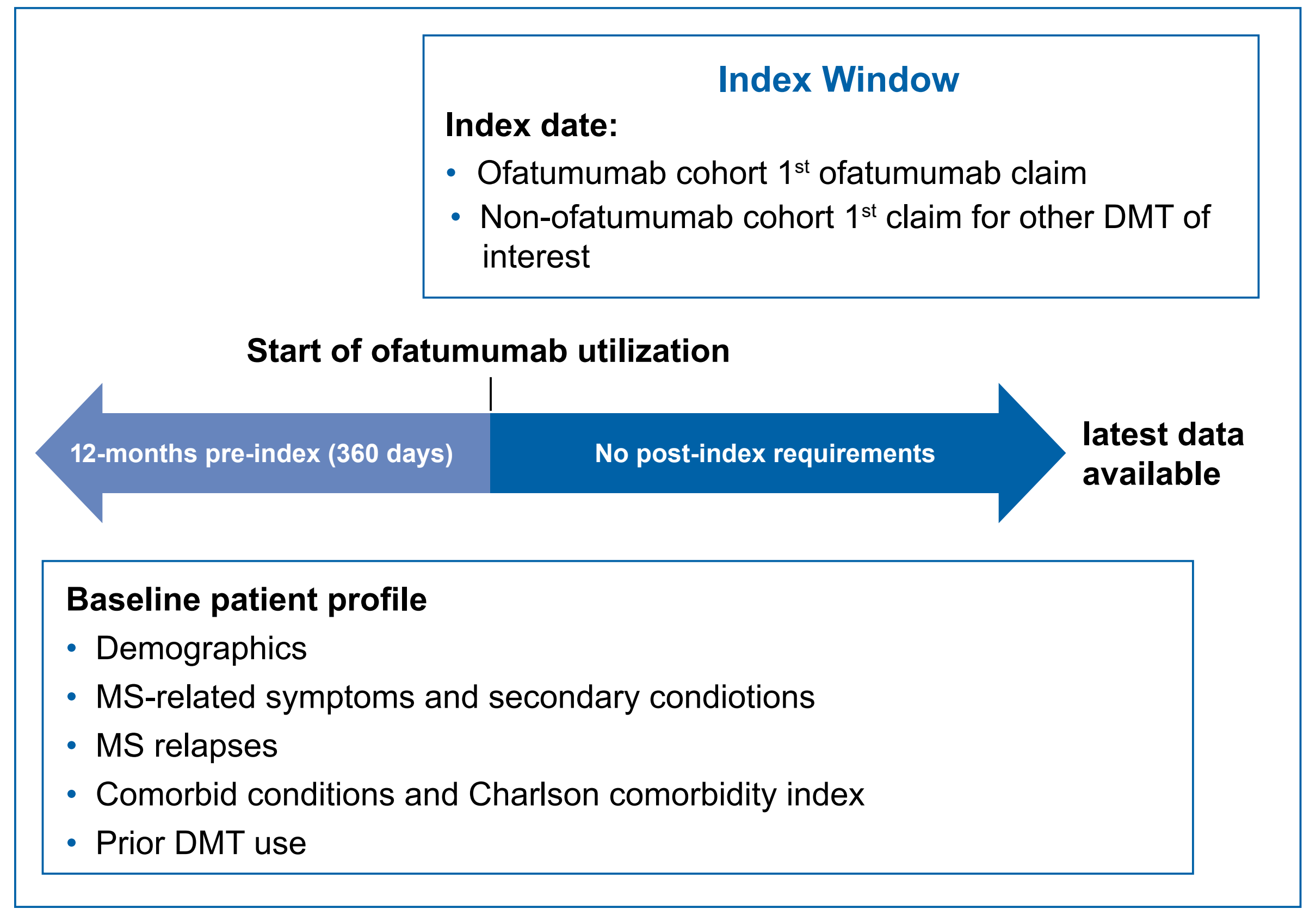
Objectives

- To describe patient baseline demographic characteristics, prior disease-modifying therapy (DMT) use, and disease indicators in patients with MS initiating ofatumumab using a nationally representative US claims database.

Methods

- This was a retrospective cohort study of MS patients initiating ofatumumab in the US. The study used secondary data from IQVIA's open-source pharmacy claims database (IQVIA LRx-Dx) to select patients with prescription claims for ofatumumab between August 1, 2020 and October 31, 2020.
- The index date was defined based on the first prescription fill for ofatumumab, and the baseline period was 1-year prior to the index date. The overall study design has been illustrated in **Figure 1.**

Figure 1. Study design scheme



Index Window

Index date:

- Ofatumumab cohort 1st ofatumumab claim
- Non-ofatumumab cohort 1st claim for other DMT of interest

Start of ofatumumab utilization

12-months pre-index (360 days) | No post-index requirements | **latest data available**

Baseline patient profile

- Demographics
- MS-related symptoms and secondary condiotions
- MS relapses
- Comorbid conditions and Charlson comorbidity index
- Prior DMT use

- Patients aged ≥ 18 years at the time of the index date, with ≥1 prescription for ofatumumab in the IQVIA LRx-Dx database, linkage to IQVIA Dx data, with ≥1 medical claim with a MS diagnosis in IQVIA LRx-Dx within the 24-months prior to the index date or any time after index date. No exclusion criteria were applied to the study sample.
- Patient demographics, treatment status (naive prior-year vs experienced), geographical distribution, claims-based baseline disability levels, prior DMT use, and corresponding median time of washout period (treatment gap) were assessed in the study.
- All study data were accessed using techniques compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and no identifiable or protected health information was extracted for the study.

Results

- Among 418 patients identified from IQVIA LRx-Dx database, 243 patients newly initiating ofatumumab were included in the analysis. Details pertaining to patient selection are presented in **Table 1.**

Table 1. Patient's selection as per the inclusion and exclusion criteria

Criteria	Patient count
1. Patients with ≥1 claims for ofatumumab in IQVIA LRx between Aug 1, 2020 and Oct 31, 2020 (the date of the first observed prescription within served as the index date)	418
2. Patients aged ≥ 18 years at index date	418
3. Pharmacy stability in the 12-month baseline using the most frequent pharmacy, defined as consistent reporting of data from the pharmacy most frequently visited by the subject in the 12-month baseline for that pharmacy in each month of the 12-month pre-index period	373
4. Linkage to the Dx database	293
5. Patients with ≥1 medical claims with a diagnosis of MS in IQVIA LRx-Dx within 24-months pre-index or any time after index date	243
Final ofatumumab cohort	**243**

Baseline demographic characteristics

- Among the 243 patients newly initiating ofatumumab in the real world, mean (SD) age of patients was 47.6 (12.2) years, 30% of them were ≥55 years. The mean age of patients recruited in ASCLEPIOS I & II trials was 38-39 years.
- Nearly three-fourth of the patients initiating ofatumumab in the real world were females.
- The majority of patients were from the Southern (51.9%) and Western (20.6%) regions of the US.
- The majority of patients had commercial insurance (69.1%), while less than 1% of patients had Medicare Part D insurance. **Table 2** summarises the key demographics for patients newly initiating ofatumumab in the real world.

Table 2. Patient baseline demographics

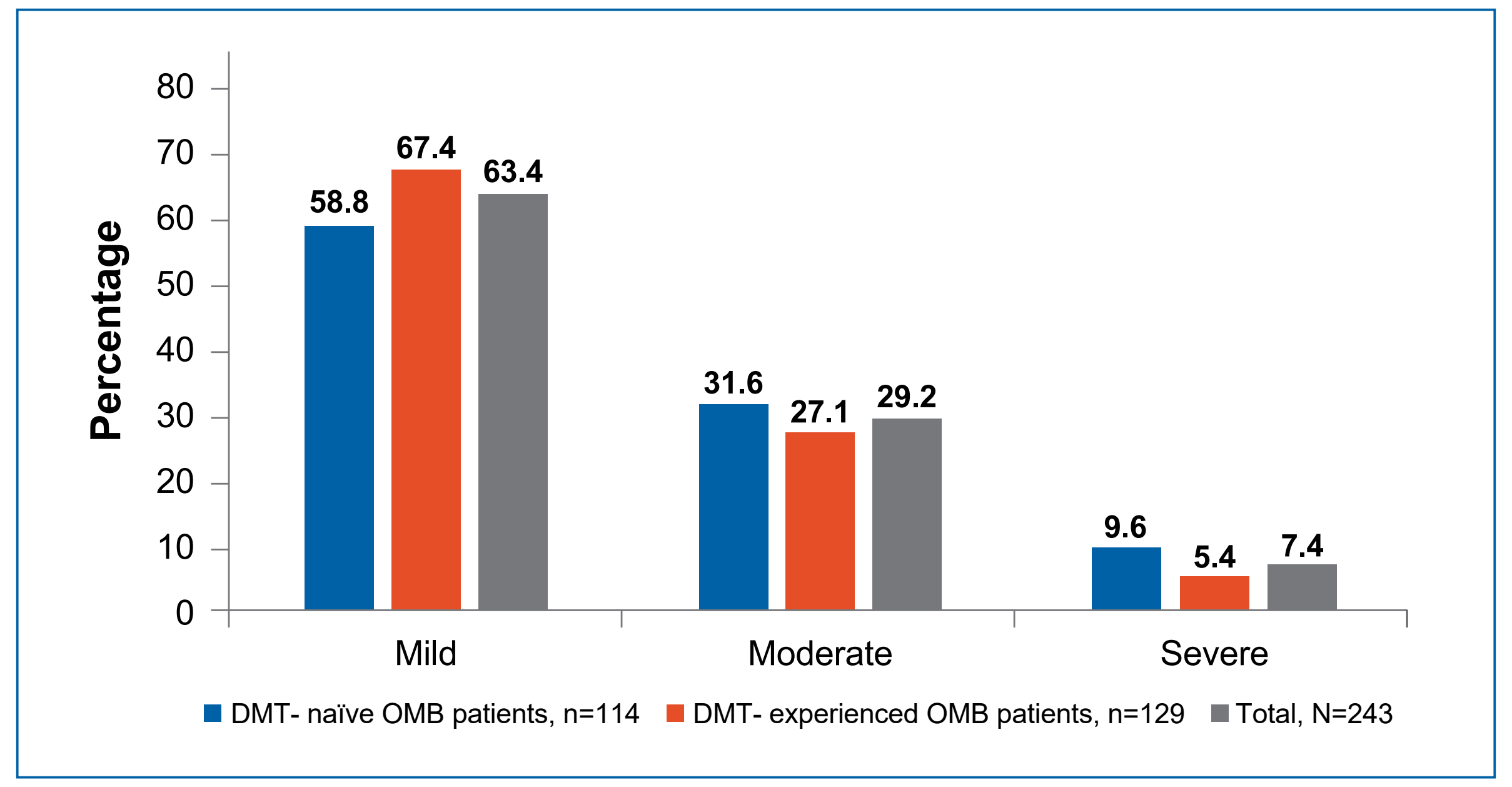
Baseline Demographic Characteristics	Total, N=243
Age (years), mean (SD)	47.6 (12.2)
Age group (years), n (%)	
18-34	34 (14.0)
35-44	67 (27.6)
45-54	69 (28.4)
55-64	52 (21.4)
≥65	21 (8.6)
Female, n (%)	181 (74.5)
Geographic Region, n (%)	
Northeast	26 (10.7)
Midwest	31 (12.8)
South	126 (51.9)
West	50 (20.6)
Unknown Region	10 (4.1)
Insurance type on index claim, n (%)	
Commercial	168 (69.1)
Others	75 (30.86)

SD, standard deviation

Baseline clinical characteristics

- The majority of patients initiating ofatumumab in the real world had mild level of disability (63.4%) measured by the occurrence of Expanded Disability Status Scale (EDSS) - related symptoms and DMT use **(Figure 2).**

Figure 2. MS disability level at baseline



DMT, disease-modifying therapy; **OMB**, ofatumumab; Disability level was measured by the occurrence of EDSS-related symptoms

- Relapse in the prior year was experienced by 27.6% of the patients newly initiating ofatumumab in the real world. The majority of patients newly initiating ofatumumab reported no relapse in the prior year (72.4%) **(Table 3).**

Table 3. Baseline clinical characteristics

Baseline clinical characteristics	All OMB patients N = 243	DMT-naïve OMB patients n = 114	DMT-experienced OMB patients n = 129
MS relapses in the prior year			
Patients with a relapse, n (%)	67 (27.6%)	28 (24.6%)	39 (30.2%)
Number of relapses in all patients			
Mean (SD)	0.5 (1.0)	0.4 (1.2)	0.5 (0.9)
0	176 (72.4%)	86 (75.4%)	90 (69.8%)
1	44 (18.1%)	19 (16.7%)	25 (19.4%)
2	14 (5.8%)	7 (6.1%)	7 (5.4%)
3+	9 (3.7%)	2 (1.8%)	7 (5.4%)
Number of relapses in patients with at least 1 relapse, n (%)			
Mean (SD)	1.6 (1.4)	1.8 (1.9)	1.6 (0.9)
1	44 (65.7%)	19 (67.9%)	25 (64.1%)
2	14 (20.9%)	7 (25.0%)	7 (17.9%)
3+	9 (13.4%)	2 (7.1%)	7 (17.9%)

DMT, disease modifying therapies; **OMB,** ofatumumab; **SD,** standard deviation
Relapse defined as inpatient hospitalization with primary diagnosis of MS (ICD-9-CM code of 340 or ICD-10-CM code of G35) or a claim for an oral or intravenous corticosteroid use on with within 7 days after a MS-related outpatient visit. Corticosteroid used on the same date as DMT IV was not flagged as a relapse

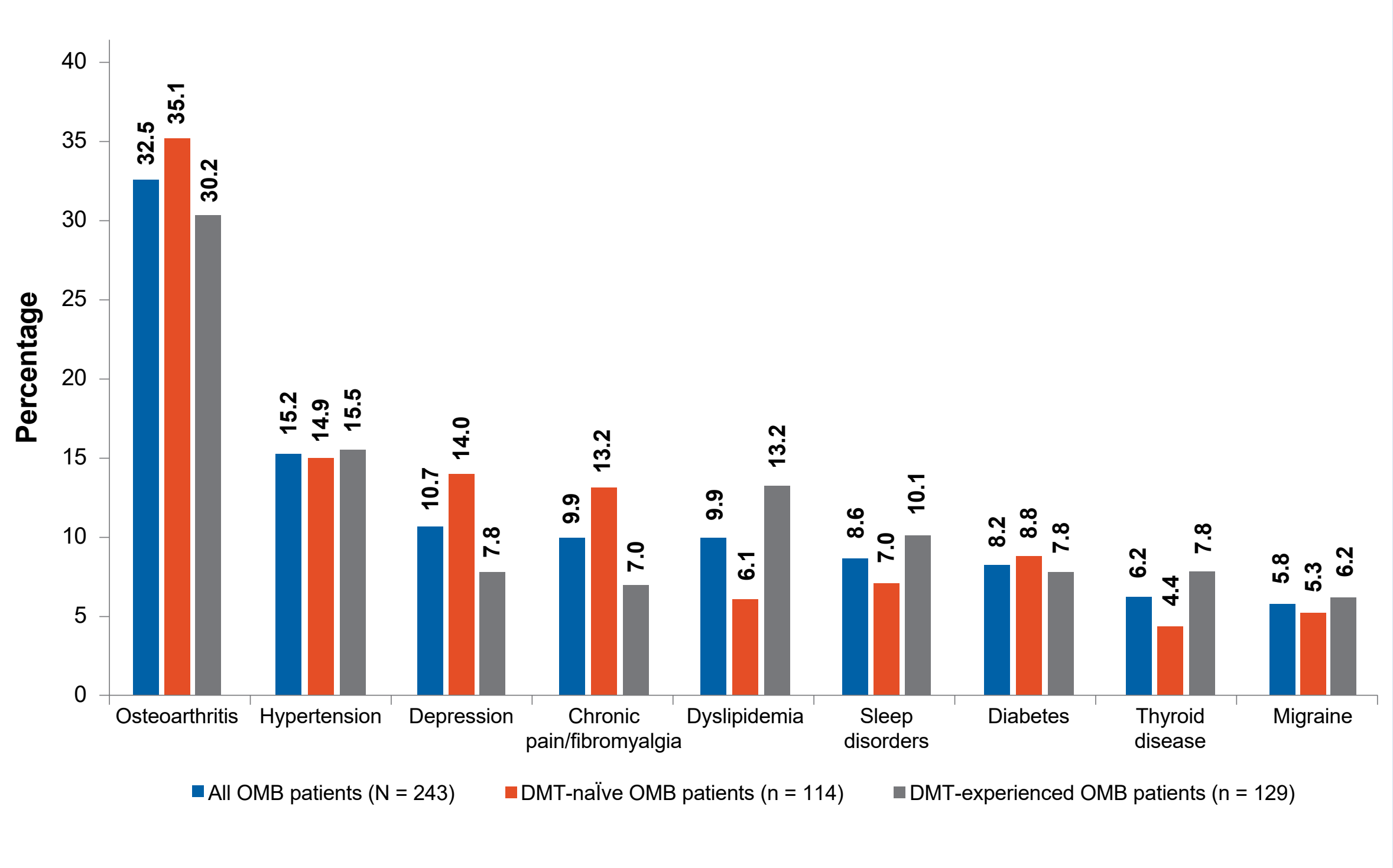
- Major comorbidities among patients newly initiating ofatumumab in the real world were osteoarthritis (32.5%), hypertension (15.2%) and depression (10.7%) **(Figure 3)**. The mean Charlson Comorbidity Index score was 0.4 and most of patients had no comorbidities at baseline **(Table 4).**

Table 4. Baseline comorbidities

	All OMB patients N = 243	DMT-naïve OMB patients n = 114	DMT-experienced OMB patients n = 129
Charlson Comorbidity Index (CCI)			
Mean (SD)	0.4 (0.8)	0.4 (1.0)	0.3 (0.7)
CCI categories, n (%)			
0	192 (79%)	90 (78.9%)	102 (79.1%)
1	23 (9.5%)	8 (7%)	15 (11.6%)
2	20 (8.2%)	9 (7.9%)	11 (8.5%)
3+	8 (3.3%)	7 (6.1%)	1 (0.8%)

DMT, disease modifying therapies; **OMB,** ofatumumab; **SD,** standard deviation

Figure 3. Key comorbidities experienced by patients before initiating ofatumumab



DMT, disease modifying therapies; **OMB,** ofatumumab

- The HBV screening (9.9%) and serum immunoglobulins screening (10.3%) rates were low among patients newly initiating ofatumumab in the real world. The proportion of patients with pre-index flu vaccine was also low (0.4%) **(Table 4).**

Table 4. Other clinical characteristics at baseline

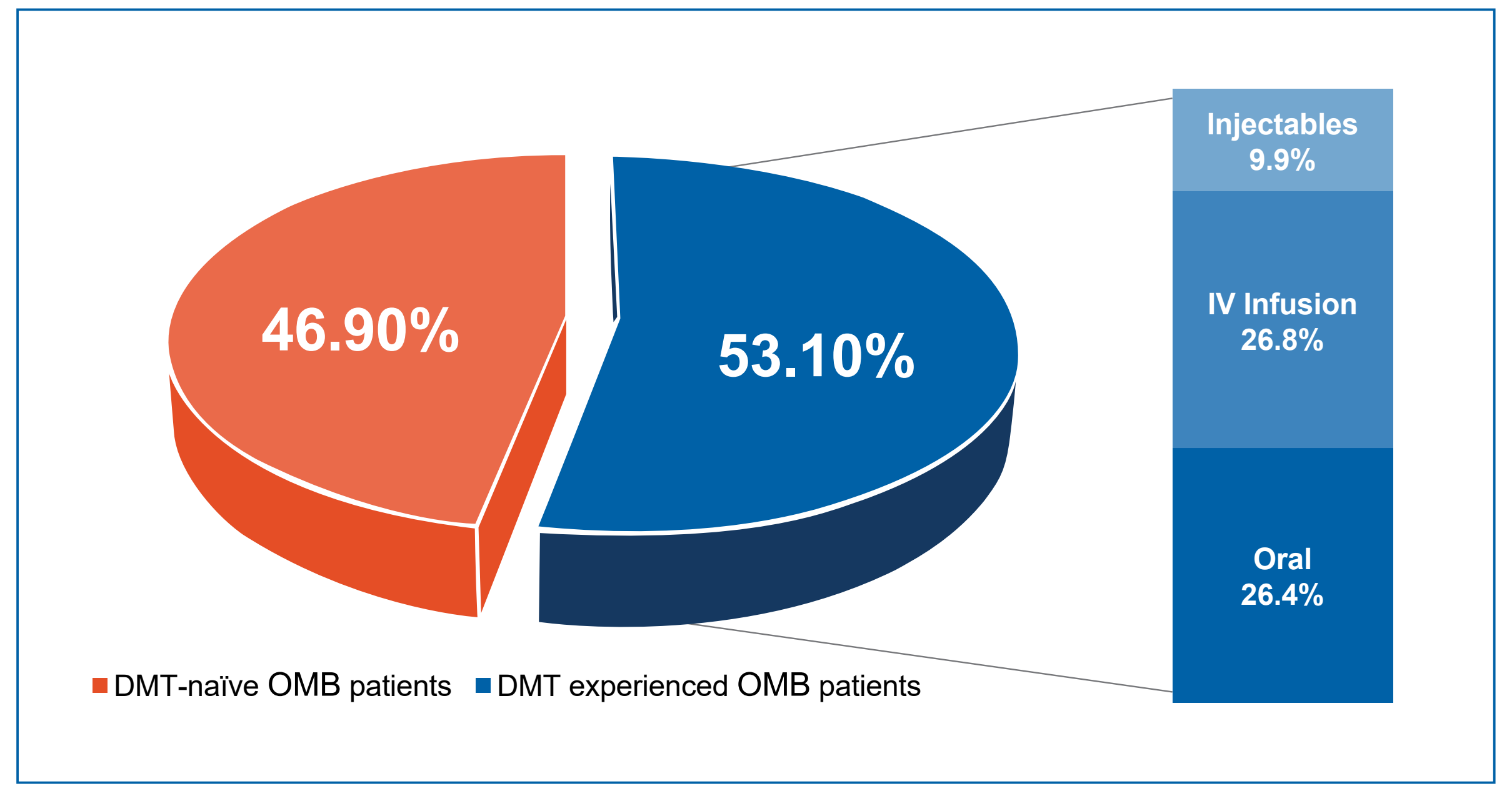
Other clinical characteristics at baseline	All OMB patients N = 243	DMT-naïve OMB patients n = 114	DMT-experienced OMB patients n = 129
Patients with HBV screening, n(%)	24 (9.9%)	10 (8.8%)	14 (10.9%)
Patients with quantitative serum immunoglobulins screening, n(%)	25 (10.3%)	11 (9.6%)	14 (10.9%)
Patients with pre-index COVID diagnosis, n(%)	1 (0.4%)	0 (0%)	1 (0.8%)
Patients with pre-index flu shot, n(%)	27 (11.1%)	12 (10.5%)	15 (11.6%)

DMT, disease modifying therapies; **HBV,** hepatitis B virus; **OMB,** ofatumumab

Baseline treatment characteristics

- Of the 243 patients newly initiating ofatumumab in the real world, 47% of the patients had no DMT treatment in the prior year, while 53% of the patients were DMT exposed. Type of DMTs administered in the prior year are presented in **Figure 4.**

Figure 4. Prior DMT exposure of patients initiating ofatumumab



DMT, disease modifying therapies; **IV,** intravenous

- Ocrelizumab (20.2%), dimethyl fumarate (18.6%), teriflunomide (19.4%) were the most commonly used DMTs prior to starting ofatumumab in the real world **(Table 5).**
- The median washout period (defined as days from last claim of last DMT to initiation of ofatumumab), for ocrelizumab, dimethyl fumarate, and teriflunomide was 185 days, 119 days, and 98 days, respectively.

Table 5. Treatment Characteristics – use of pre-index MS-related medication in DMT experienced patients newly initiating ofatumumab

Pre-index MS-related medication use (all use during 12-month pre-index period), n (%)	DMT-experienced OMB patients, n = 129
Patients with any disease modifying therapy (DMT)	129 (100%)
Oral	
Dimethyl fumarate (Tecfidera)	24 (18.6%)
Fingolimod (Gilenya)	9 (7%)
Teriflunomide (Aubagio)	25 (19.4%)
Cladribine (Mavenclad)[1]	0 (0%)
Siponimod (Mayzent)	9 (7%)
Injectable (IV infusion)	
Natalizumab (Tysabri)	15 (11.6%)
Alemtuzumab (Lemtrada)	0 (0%)
Ocrelizumab (Ocrevus)	26 (20.2%)
Rituximab (Rituxan)[2]	1 (0.8%)
Injectable (Subcutaneous/Intramuscular)	
Glatiramer acetate (Copaxone, Glatopa)	15 (11.6%)
Any Interferon beta (Avonex, Rebif, Betaseron, Extavia, Plegridy)	10 (7.8%)
Patients with no DMT within 12-months prior to index	0 (0%)

DMT, disease modifying therapies; **OMB,** ofatumumab
[1]Approved for MS March 29, 2019 [2]Includes biosimilars (Ruxience; Truxima)

- In the real world, ofatumumab was mostly prescribed by neurologists (86%). The details related to outpatient physician prescriber specialty are presented in **Table 6.**

Table 6. Ofatumumab outpatient physician prescriber specialty

Outpatient physician prescriber specialty, n (%)	All OMB patients N = 243	DMT-naïve OMB patients, n = 114	DMT-experienced OMB patients, n = 129
Neurologist	211 (86.8%)	96 (84.2%)	115 (89.1%)
PCP[1]	1 (0.4%)	1 (0.9%)	0 (0%)
PA/Nurse[2]	29 (11.9%)	15 (13.2%)	14 (10.9%)
Other specialty	2 (0.8%)	2 (1.8%)	0 (0%)

DMT, disease modifying therapies; **IV,** intravenous; **OMB,** ofatumumab; **PA,** physician assistant; **PCP,** primary care physician
[1]family medicine; general practice; internal medicine; geriatric medicine (internal medicine); internal medicine (pediatrics)
[2]clinical nurse specialist; nurse practitioner; physician assistant

Limitations

- This analysis was conducted using administrative claims data, hence is limited by coding errors or omission.
- The study results are from a very short observational period, so should not be generalized.

Conclusions

- In the real-world, ofatumumab is being prescribed in MS patients above 55 years of age, which is beyond the trial population. A large proportion of patients newly initiated ofatumumab with no treatment in the prior year. Understanding the patient profile, prior DMT use, and corresponding washout periods in the real-world may help stakeholders guide treatment decisions. Future data refreshes are planned upon data availability.

Reference

1. Hauser et al 2020; N Engl J Med, 383(6): 546-557.

Disclosures

- **Chinmay Deshpande** is an employee of Novartis Pharmaceuticals Corporation.
- **Magdaliz Gorritz, Rolin L. Wade, Zifan Zhou and Yao Cao** are employees of IQVIA Inc. and worked as a consultant to Novartis Pharmaceuticals Corporation.
- **Dr. Patricia Coyle** has received consulting fees from Accordant, Biogen, Bristol Myers Squibb, Celgene, Genentech/Roche, GlaxoSmithKline, Janssen, Novartis, Sanofi Genzyme, Viela Bio and grant funding from Actelion, Alkermes, Corrona LLD, Genentech/Roche, MedDay, NINDS, and Novartis.

Acknowledgements

Authors would thank Mrs. Vijayalakshmi Vasanthaprasad (Novartis healthcare pvt ltd, India) for writing support and Mool Tatvam Consulting LLP for designing the poster layout.

Funding

This study was funded by Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA.

Poster presented at 2021 Consortium of Multiple Sclerosis Annual Meeting in Orlando, Florida, USA. October 25-28.