Multiple Sclerosis Patients Initiating Ofatumumab in the Real-World: Early 6 Months Data

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Introduction

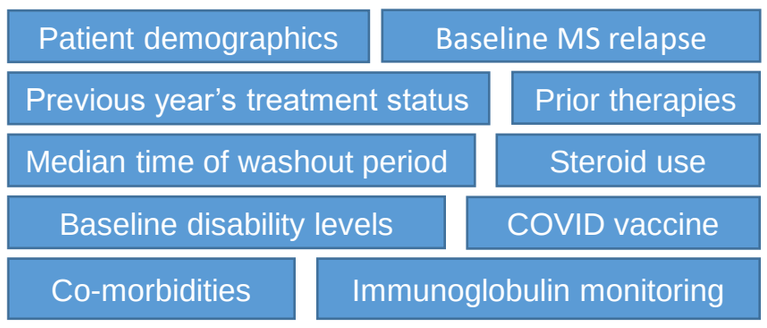
- The efficacy and safety of ofatumumab were demonstrated in two phase III ASCLEPIOS trials[1], which led to its approval by Food and Drug Administration (FDA) in August 2020 for the treatment of relapsing forms of multiple sclerosis (MS).

Objective

- To describe patient baseline demographics, treatment status, and disease characteristics for patients initiating ofatumumab in the first 6 months of availability after FDA approval in the United States (US).

Methods

- This was a retrospective cohort study of MS patients initiating ofatumumab in the US based on secondary data from IQVIA's open-source pharmacy claims database (IQVIA LRx Dx) between August 1, 2020 and February 28, 2021.
- Inclusion and Exclusion criteria: 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 diagnosis of MS within the 24-months prior to the index date or any time after index date. No exclusion criteria were applied to the study sample.
- Outcomes:



- 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.

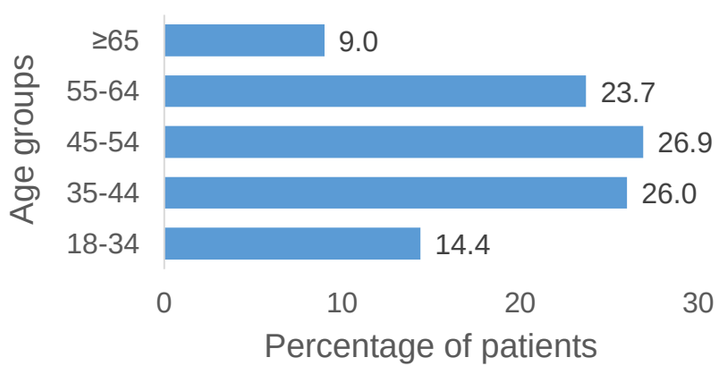
Results

- Among 1,778 patients identified from IQVIA LRx-Dx database, 1,015 newly initiating ofatumumab were included.

Baseline demographic characteristics

- Mean (SD) age of patients on ofatumumab was 48.2 (12.3) years, 33% of them were ≥55 years (**Figure 1**). The mean age of patients recruited in ASCLEPIOS I & II trials was 38-39 years.
- Most patients were female (72.5%) and from the southern region of the US (46.2%).

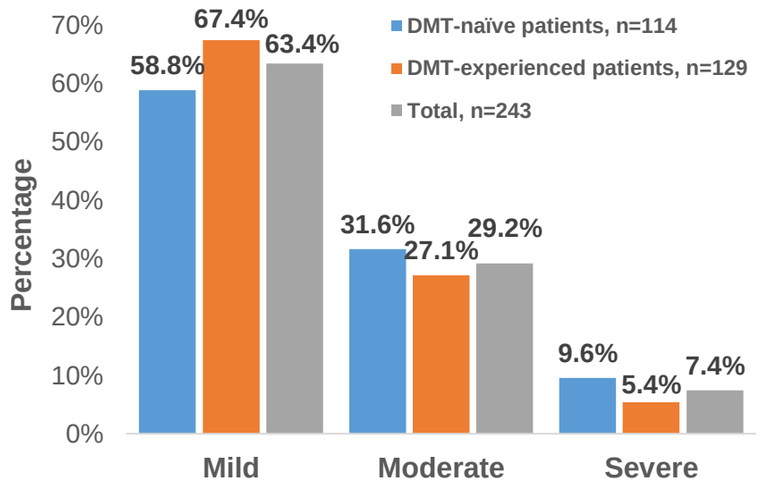
Figure 1. Age distribution of patients



Baseline Clinical Characteristics

- Relapse in the prior year was experienced by 19.2% of patients; the majority reported no relapse in the prior year (80.8%).
- Most patients initiating ofatumumab in the real world had mild level of disability (63.4%) (**Figure 2**).

Figure 2. MS disability level* at baseline



*measured by the occurrence of Expanded Disability Status Scale
DMT, Disease-modifying therapy

- Major comorbidities were osteoarthritis, hypertension and depression (**Table 1**).

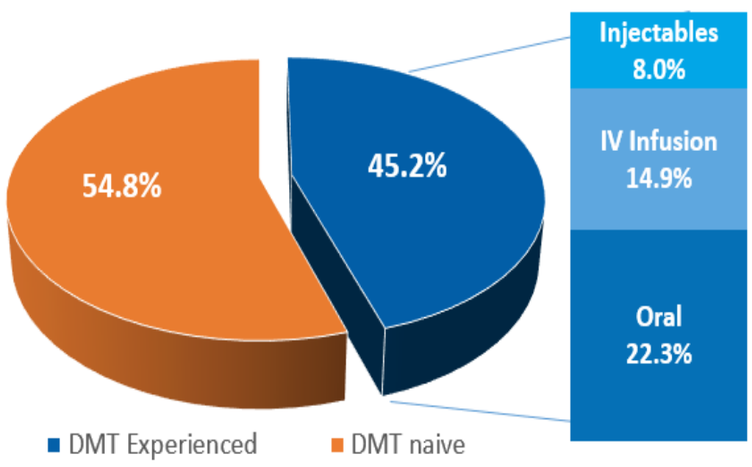
Table 1. Baseline clinical characteristics

	Total N=1,015	DMT-naïve n = 556	DMT-experienced n = 459
Charlson Comorbidity Index			
Mean (SD)	0.3 (0.8)	0.4 (0.9)	0.3 (0.7)
Comorbidities			
Chronic pain/ fibromyalgia	7.9%	9.4%	6.1%
Depression	12.2%	12.6%	11.8%
Diabetes	6.2%	6.7%	5.7%
Dyslipidemia	11.3%	10.3%	12.6%
Hypertension	16.7%	17.1%	16.3%
Migraine	8.0%	7.6%	8.5%
Osteoarthritis	31.3%	30.6%	32.2%
Sleep disorders	9.3%	9.4%	9.2%
Thyroid disease	5.9%	5.9%	5.9%
Pre-index or post-index COVID diagnosis			
n(%)	30 (3.0)	19 (3.4)	11 (2.4)
Pre-index or post-index COVID vaccine			
n(%)	17 (1.7)	7 (1.3)	10 (2.2)

Baseline Treatment Characteristics

- A total of 54.8% patients had no DMT treatment, while 45.2% patients were DMT exposed in prior year (**Figure 3**).
- Among the DMT experienced patients, most of them had exposure to oral DMTs (**Figure 3**).

Figure 3. Prior DMT exposure



- The median washout period for rituximab (191 days) was highest followed by ocrelizumab (174 days), cladribine (98 days), and siponimod (93 days) (**Table 2**).

Table 2. Pre-index DMTs and washout period

DMTs	n=459	Median wash out period*, days
Oral	226 (22.3%)	
Dimethyl fumarate	94 (9.3%)	62
Fingolimod	35 (3.4%)	38
Teriflunomide	62 (6.1%)	51
Cladribine	2 (0.2%)	98
Siponimod	22 (2.2%)	93
Ozanimod	2 (0.2%)	56
Diroximel fumarate	9 (0.9%)	26
Injectable (IV)	151 (14.9%)	
Natalizumab	37 (3.6%)	53
Ocrelizumab	110 (10.8%)	174
Rituximab	4 (0.4%)	191
Injectable (SC/IM)	82 (8%)	
Glatiramer acetate	47 (4.6%)	37
Any Interferon beta	35 (3.4%)	49

*defined as days from last claim of last DMT to initiation of ofatumumab
DMT, Disease-modifying therapy; IM, Intramuscular; IV, Intravenous; SC, Subcutaneous

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 pandemic environment, 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.

References

1. Hauser et al. *N Engl J Med.* 2020; 383: 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.

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