Assessing the Expanded Disability Status Scale in Secondary Progressive Multiple Sclerosis Patients Treated with Disease-Modifying Therapies within a Large, Representative Real-World Multiple Sclerosis Registry

OM1

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Background

- Until recently, most of the evidence for the use of DMTs in MS has been concentrated in the management of relapsing-remitting forms of the disease
- Treating progressive MS is complicated by the lack of consensus on the definition of treatment failure, whether it is continuing active disease in the form of relapses, or worsening relapse-independent disability, or both
- With the more recent approvals of novel therapies for SPMS, longer term clinical data are needed to better understand the treatment decisions and longitudinal effects of therapy on individual SPMS patients
- The Expanded Disability Status Scale (EDSS) is not routinely captured in clinical visits, however EDSS is commonly used to assess the effectiveness of disease-modifying therapies (DMTs) in clinical trials. This analysis looks to describe EDSS and patient characteristics in a real-world cohort of patients with secondary progressive multiple sclerosis (SPMS).

Objective

To compare EDSS scores among patients with SPMS who were treated with DMTs and those who were not.

Methods

- Data were derived from the OM1 MS Registry (OM1, Boston, MA). Registry patients are followed longitudinally by neurologists with demographic, disease and medical history, medication data, medical and pharmacy claims, laboratory and imaging data, and clinical notes available to better understand the management of patients with MS (2013-2021).
- Patients were included in a cross-sectional analysis if they had clinician-documented SPMS and had an observed or estimated (by machine-learning algorithm) EDSS score within 6 months prior to and including the first documentation of SPMS (index).
- Patients were categorized as being treated with DMTs, if they had a record for a DMT within 6 months prior to and including index. Patient characteristics were assessed at index.
- EDSS scores were categorized as no disability (0-1.5), minimal disability (2-2.5), moderate disability (3-4.5), and severe disability (5-9.5).

Results

- Of 19,455 patients with MS, 764 patients (3.9%) had clinician-documented SPMS and a qualifying EDSS score. Of the 764 patients, 202 patients (26.4%) were treated with a DMT within the 6 months prior to and including index.
- Patients treated with DMTs were on average 59.2 years old (standard deviation [SD]: 9.7), 72.3% female, and 85.4% White. Patients not treated with DMTs had similar characteristics with an average age of 60.6 years (SD: 10.5), were 74.2% female, but a lower proportion were White (79.4%, p=0.03).
- Mean (SD) EDSS was not statistically significantly different between patients who were treated with DMTs and those who were not (5.0 [1.7] vs 5.2 [1.8], p=0.13).
- SPMS population was widely distributed across the U.S. (Figure 1). Disability by EDSS in both the DMT-treated and non-DMT-treated populations were characterized as moderate or severe in majority of patients (88.7% and 90.0%, respectively) (Figure 2).

Conclusions

- Patient characteristics (except race) were similar among SPMS patients treated vs not treated with DMTs.
- White patients were slightly more likely to be treated with DMTs.
- EDSS scores were similar among those treated vs not treated.

		Treated with any DMT (N=202)	Not treated with DMT (N=562)	Total (N=764)	P-Value
Sex	Female	146 (72.3%)	417 (74.2%)	563 (73.7%)	0.595*
	Male	56 (27.7%)	145 (25.8%)	201 (26.3%)	
Race	Black	10 (5.8%)	18 (3.9%)	28 (4.4%)	0.028*
	White	146 (85.4%)	369 (79.4%)	515 (81.0%)	
	Other	15 (8.8%)	78 (16.8%)	93 (14.6%)	
	Unknown	31	97	128	
Geographic location	East North Central	30 (14.9%)	57 (10.2%)	87 (11.4%)	0.213*
	East South Central	2 (1.0%)	10 (1.8%)	12 (1.6%)	
	Middle Atlantic	40 (19.9%)	108 (19.3%)	148 (19.5%)	
	Mountain	51 (25.4%)	130 (23.3%)	181 (23.8%)	
	New England	13 (6.5%)	48 (8.6%)	61 (8.0%)	
	Pacific	15 (7.5%)	67 (12.0%)	82 (10.8%)	
	South Atlantic	38 (18.9%)	121 (21.6%)	159 (20.9%)	
	West North Central	5 (2.5%)	7 (1.3%)	12 (1.6%)	
	West South Central	7 (3.5%)	11 (2.0%)	18 (2.4%)	
	Unknown	1	3	4	
Age	Mean (s.d.)	59.2 (9.7)	60.6 (10.5)	60.3 (10.3)	0.084**
	Median (Q1-Q3)	59 (53-66)	61 (54-67)	61 (54-67)	
EDSS	Mean (s.d.)	5.0 (1.7)	5.2 (1.8)	5.2 (1.8)	0.132**
	Median (Q1-Q3)	5.0 (3.5-6.5)	6.0 (3.5-6.5)	6.0 (3.5-6.5)	

*Chi-Square Test   **Analysis of Variance

Figure 1. Distribution of Study Population in the U.S. (n=764): dots on the map represent the 3-digit zip codes
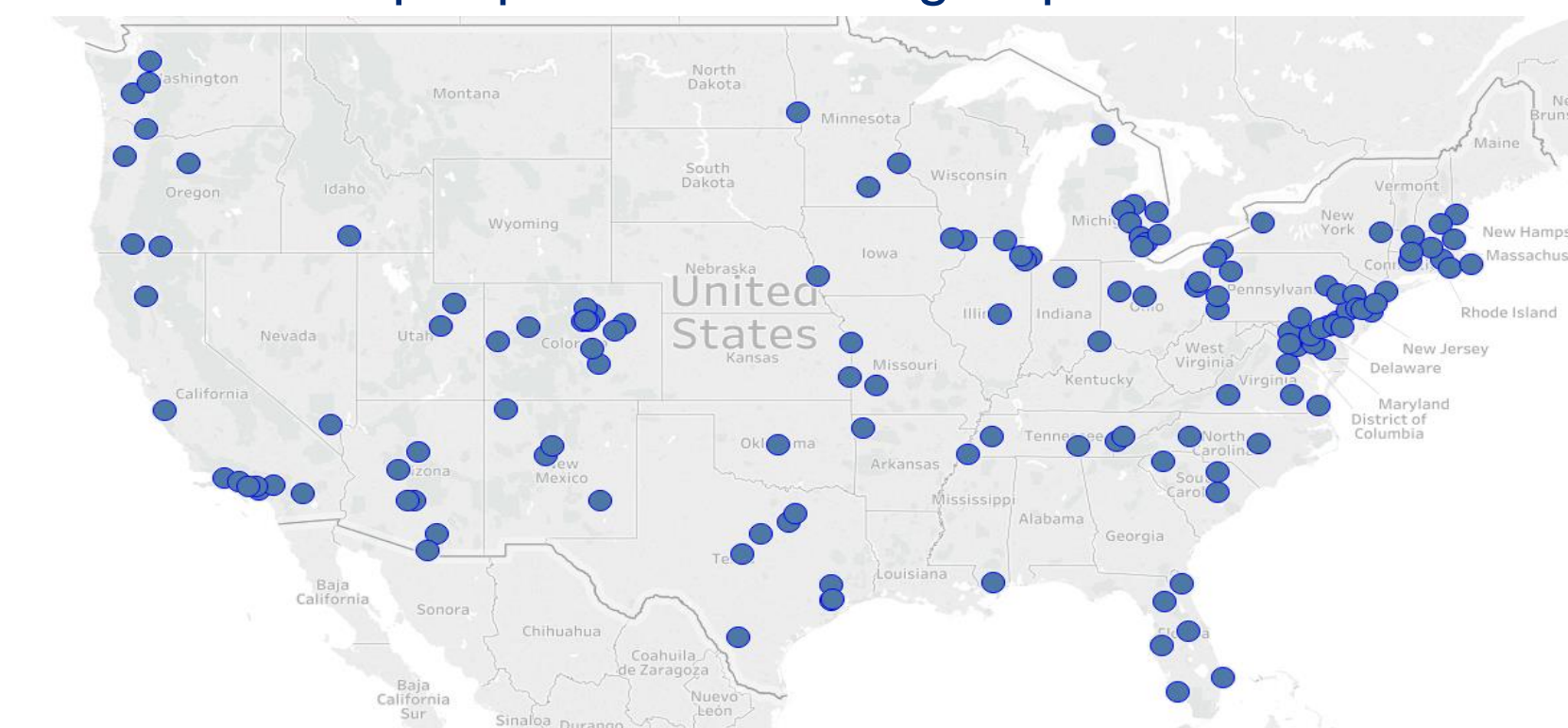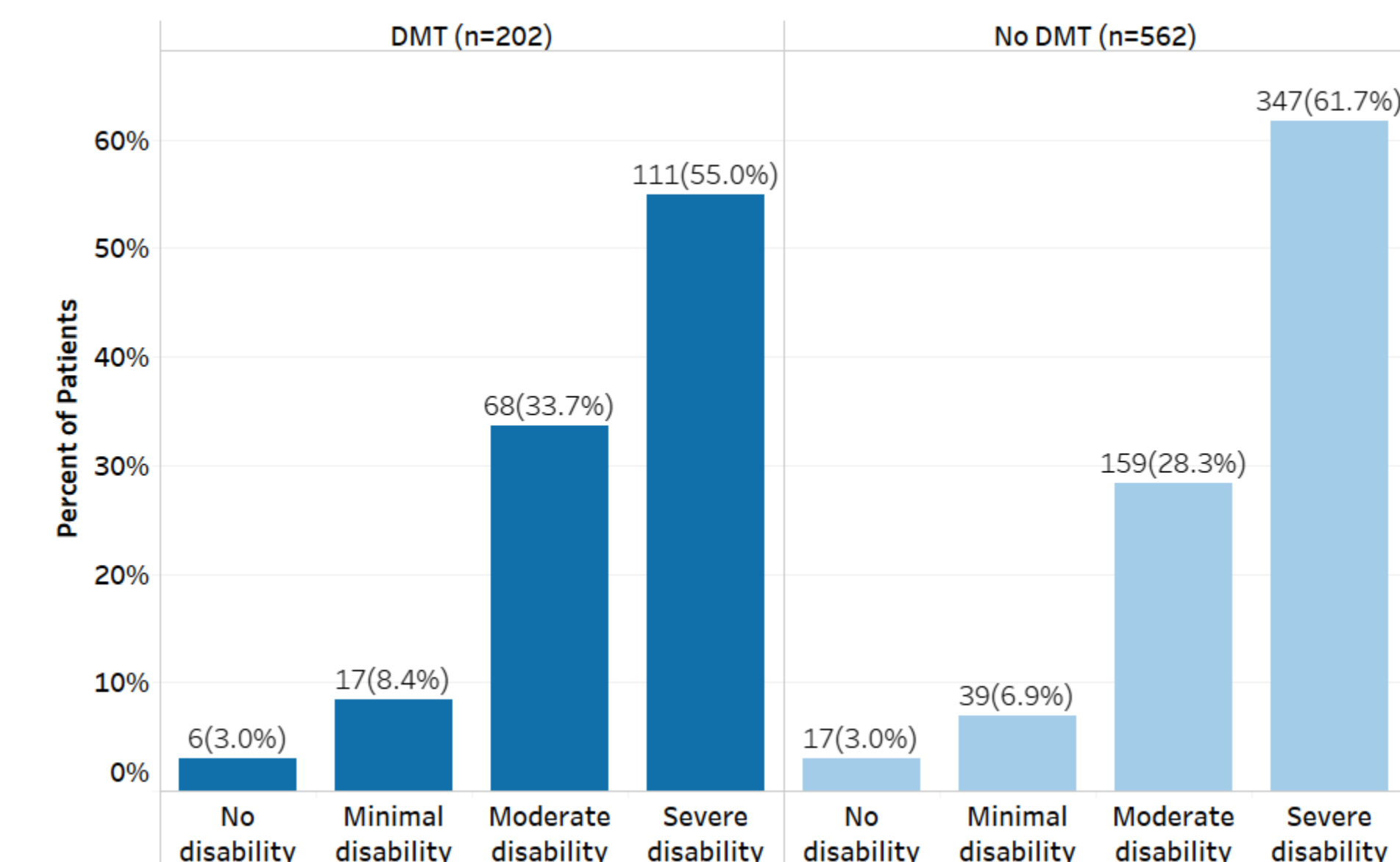

Figure 2. Distribution of Index EDSS Scores

DMT (n=202): No disability 6(3.0%), Minimal disability 17(8.4%), Moderate disability 68(33.7%), Severe disability 111(55.0%)

No DMT (n=562): No disability 17(3.0%), Minimal disability 39(6.9%), Moderate disability 159(28.3%), Severe disability 347(61.7%)

Limitations and References

Limitation: in the absence of consistent documentation of progressive disease in patients with MS, and lack of consensus on how to define the transition from RRMS to SPMS, this may not represent the complete SPMS population.

References: the manuscript on EDSS score is under review.