FACTORS ASSOCIATED WITH PRESCRIBING OF TERIFLUNOMIDE AND DIMETHYL FUMARATE VERSUS FINGOLIMOD IN MULTIPLE SCLEROSIS

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UNIVERSITY of HOUSTON
COLLEGE OF PHARMACY

Contact Information:
Jagadeswara Rao Earla
University of Houston
Phone: (832)-212-8168
Email: Jagadesh.e.rao@gmail.com

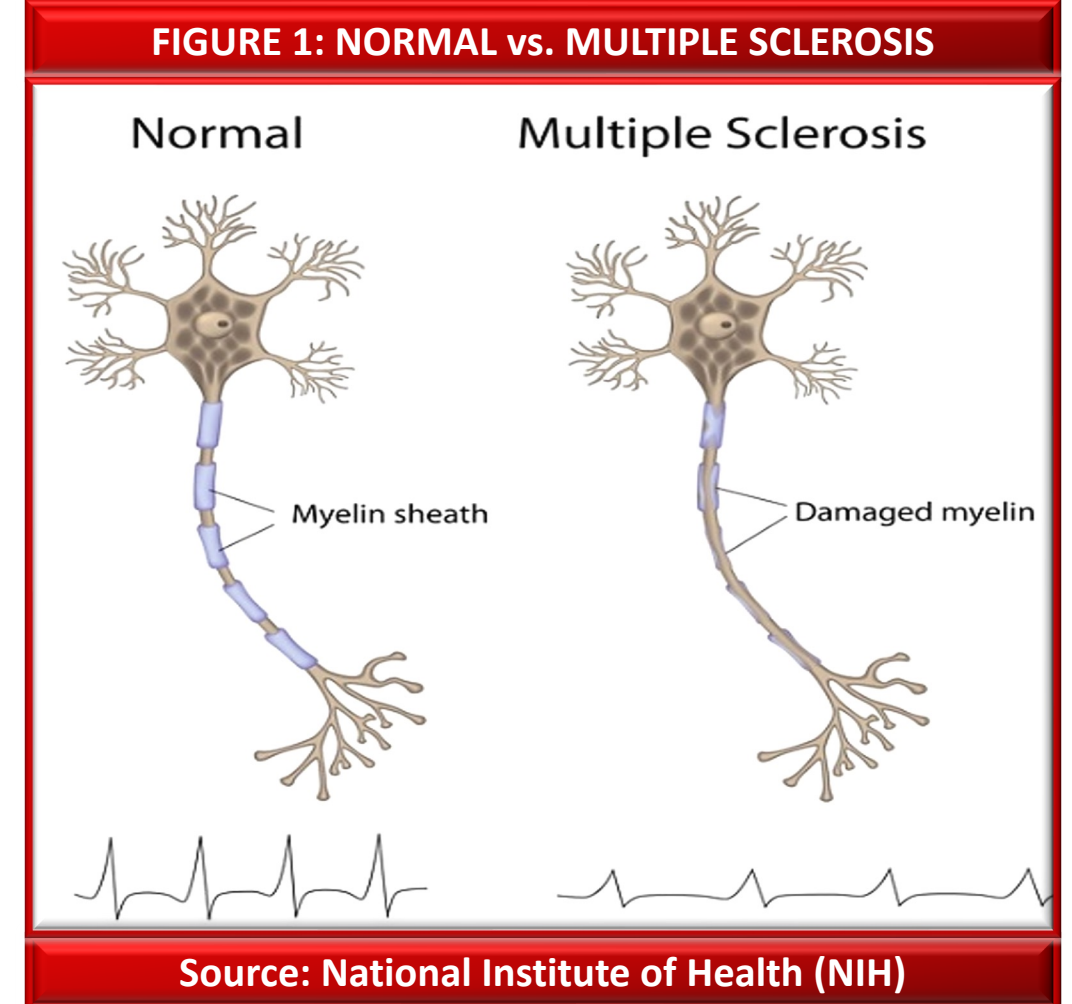**Jagadeswara Rao Earla[1], George J Hutton[2], Rajender R Aparasu[1]**
[1]Pharmaceutical Health Outcomes and Policy, University of Houston College of Pharmacy, Houston, TX;
[2]Baylor College of Medicine Medical Center, Houston, TX, USA

BACKGROUND

❖ Multiple sclerosis (MS) is a chronic, autoimmune, inflammatory neurological disease characterized by the demyelination & irreversible damage to the nerve fibers (Recent prevalence in the US - 1 million)

❖ MS treatment involves the three-pronged approach -

1. **Disease Modifying Agents (DMA)** - To reduce relapses and to delay the disability progression
2. **Corticosteroids -** To treat inflammation during acute relapse attack
3. **Symptomatic Treatment** - To treat pain, fatigue, spasticity, bladder problems & walking difficulty, etc.

❖ In the last decade, the treatment paradigm of MS has changed significantly with the introduction of several new DMAs, importantly several oral DMAs were approved since 2010

❖ Oral DMAs are additional options to neurologists beyond existing DMAs for MS, but little is known about the factors associated with prescribing of specific oral DMA
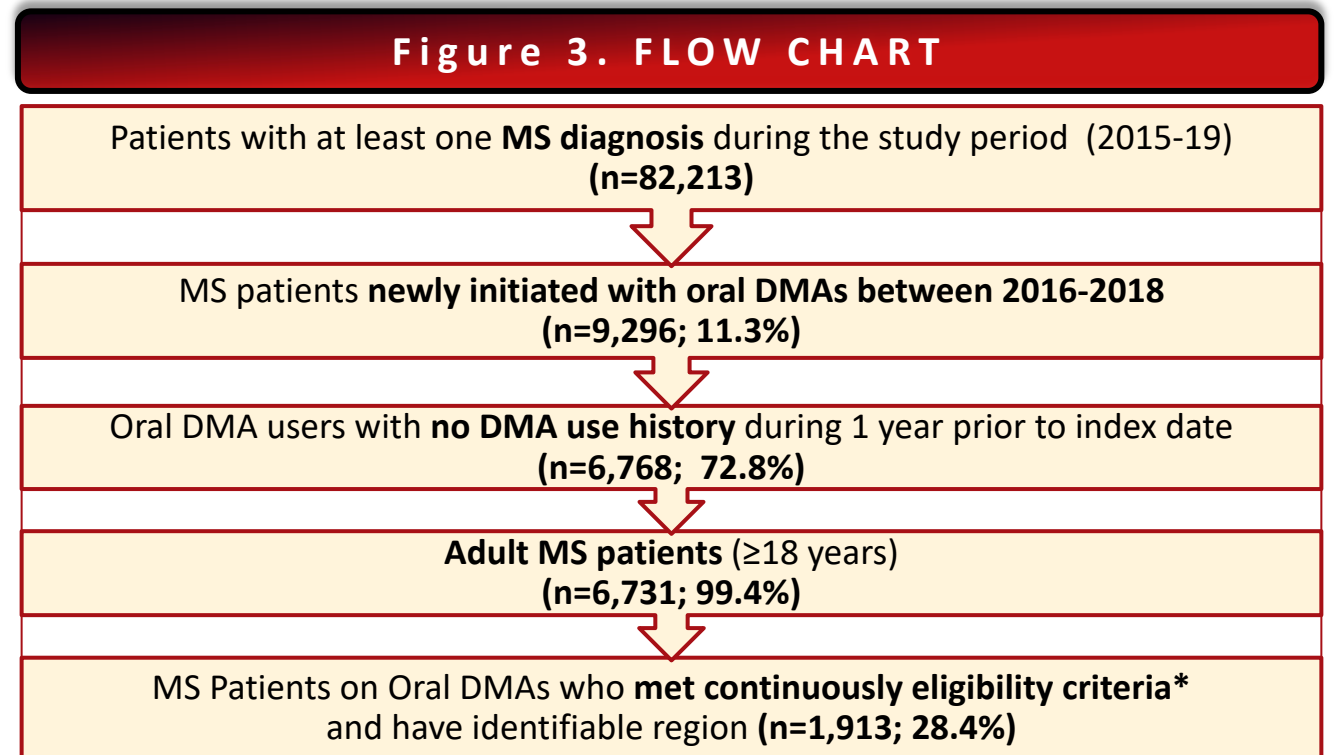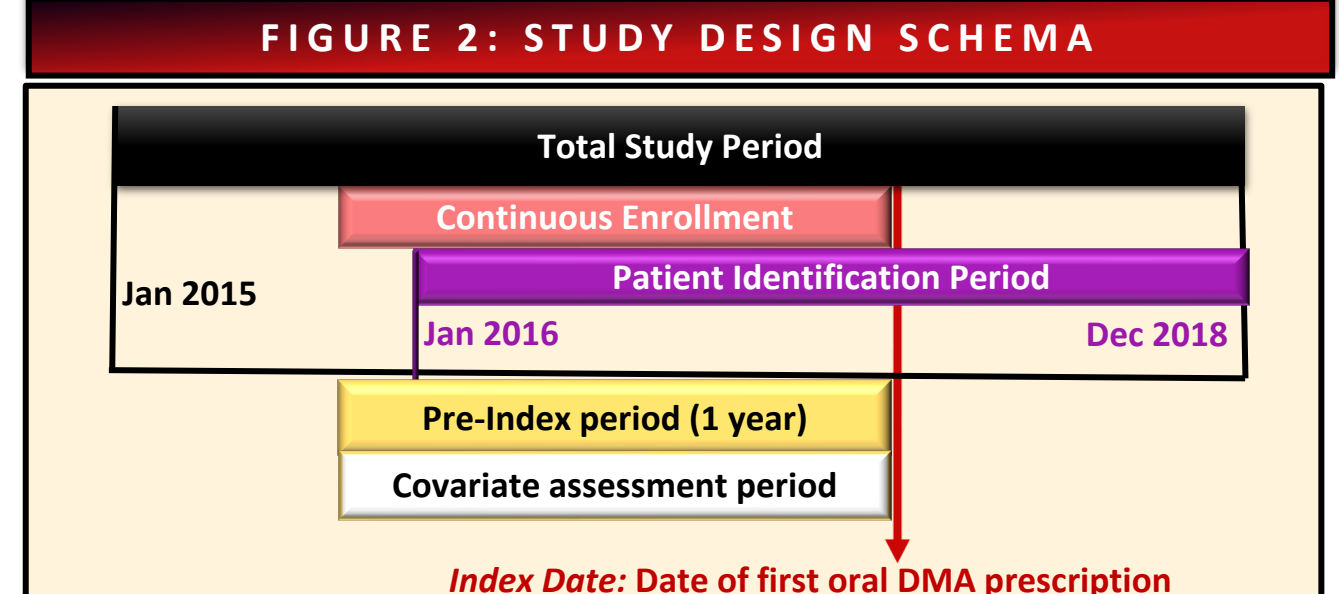

FIGURE 1: NORMAL vs. MULTIPLE SCLEROSIS

Normal — Myelin sheath

Multiple Sclerosis — Damaged myelin

Source: National Institute of Health (NIH)

OBJECTIVES

❖ The primary objective of the study to examine the factors associated with prescribing of oral DMA, specifically teriflunomide (TER) and dimethyl fumarate (DMF) compared to fingolimod (FIN) in patients with MS

METHODS

❖ **Study Design:** Retrospective observational cohort study

❖ **Data Source:** 2015-2019 IBM MarketScan Commerical Claims Database -Inpatient, Outpatient, Facility, Prescription, and Annual Enrollment files

❖ **Study Sample**

➢ **Inclusion Criteria:** Adult (≥18 years) patients diagnosed with MS (ICD-9/10-CM – 340/G35) and newly prescribed with an oral DMA (Fingolimod, Teriflunomide and Dimethyl fumarate) with no previous DMA use

➢ **Exclusion Criteria:** Patients on combination DMA users or injectable/infusible DMA users were excluded

❖ **Statistical Analysis**

➢ **Descriptive Analyses:** To compare the characteristics of three different oral DMA users

➢ **Multinomial Logistic Regression:** To determine the factors associated with prescribing of a specific DMA

  ▪ **Dependent variable:** Dimethyl fumarate, Teriflunomide vs Fingolimod

  ▪ **Independent variables:** Covariates were selected based on Andersen Behavior Model (ABM) of health service utilization

➢ SAS 9.4 at a level of significance (α value of 0.05) were used for analyses

FIGURE 2: STUDY DESIGN SCHEMA

Total Study Period
Continuous Enrollment
Patient Identification Period
Jan 2015
Jan 2016 — Dec 2018
Pre-Index period (1 year)
Covariate assessment period
Index Date: Date of first oral DMA prescription

Figure 3. FLOW CHART

Patients with at least one **MS diagnosis** during the study period (2015-19) **(n=82,213)**

MS patients **newly initiated with oral DMAs** between 2016-2018 **(n=9,296; 11.3%)**

Oral DMA users with **no DMA use history** during 1 year prior to index date **(n=6,768; 72.8%)**

Adult MS patients (≥18 years) **(n=6,731; 99.4%)**

MS Patients on Oral DMAs who **met continuously eligibility criteria*** and have identifiable region (n=1,913; 28.4%)

RESULTS

▪ The cohort consisted of 2,556 MS patients; 51.53% initiated with DMF, followed by teriflunomide (24.26%) and fingolimod (24.22%).

▪ The characteristics of study cohort and comparison between three different oral DMA users were presented in **Table 1**

Table 1: Characteristics of Adult patients with MS and non-MS

Characteristic	Dimethyl Fumarate	Fingolimod	Teriflunomide
Predisposing Factors			
Age: Mean (SD)	43 (11)	41 (11)	48 (10)
Gender: Females	72%	76%	79%
Enabling Factors			
Health plan: PPO	53%	56%	55%
Need Factors (during baseline)			
Comorbidities	Musculo skeletal disorders Mood disorders	Heart Diseases Eye disorders Nutritional deficiencies	Heart Diseases Eye disorders Nutritional deficiencies Mood disorders Musculo skeletal disorders
MS Symptoms	No differences in symptomatic burden		
Medication Use (≥30%)	Analgesics & Spasticity drugs	-	Analgesics & Spasticity drugs
Healthcare Utilization			
Relapse	35%	33%	32%
Neurologist visit	64%	70%	62%

▪ Multinomial logistic regression findings **(Table 2)** revealed that compared to young adults (18-34 years), older adults (≥35 years) had a 2–9 fold higher likelihood to be prescribing with TER and DMF than FIN

▪ Patients from the West had lesser odds of prescribing TER, whereas those from the Northeast had higher odds of prescribing DMF compared to FIN.

▪ Patients with HMO insurance had lesser odds of prescribing TER than FIN. Mood disorders were associated with higher odds, and eye disorders had lesser odds of prescribing TER and DMF relative to FIN.

▪ Cancer, heart diseases, and nutritional deficiencies had lesser odds, and other neurological disorders had higher odds of prescribing DMF than FIN. Baseline neurologist visit was associated with reduced odds of prescribing TER and DMF compared to FIN.

Table 2: Findings of Multinomial Logistic Regression on Factors Associated with specific oral DMA

Characteristic	Dimethyl Fumarate AOR (95% CI)	Teriflunomide AOR (95% CI)
Predisposing Factors		
Age Group (in years)		
18-34	*Reference*	
35-44	1.06 (0.81-1.39)	1.88 (1.29-2.76)
45-54	1.40 (1.04-1.90)	3.45 (2.32-5.15)
55-64	2.08 (1.40-3.11)	8.21 (5.08-13.25)
Region		
South	*Reference*	
Northeast	1.36 (1.02-1.82)	1.08 (0.76-1.51)
North Central	0.99 (0.75-1.30)	1.10 (0.80-1.50)
West	1.16 (0.87-1.56)	0.61 (0.42-0.89)
Enabling Factors		
Health Insurance Plan		
PPO	*Reference*	
HMO	0.97 (0.70-1.33)	0.59 (0.39-0.89)
POS	1.17 (0.81-1.67)	1.07 (0.70-1.65)
Others (EPO, POS with capitation, CDHP, HDHP)	1.39 (1.07-1.81)	1.48 (1.09-2.00)
Clinical Factors		
AHRQ CCS comorbidities		
Cancer	0.74 (0.57-0.96)	0.79 (0.59-1.07)
Nutritional Deficiencies	0.76 (0.61-0.96)	1.11 (0.85-1.45)
Mood Disorders	1.49 (1.09-2.05)	1.50 (1.04-2.15)
Eye Disorders	0.54 (0.44-0.67)	0.56 (0.43-0.71)
Other Neurological Disorders	1.36 (1.05-1.76)	1.07 (0.79-1.45)
Healthcare Utilization	-	-
Any Neurologist Consultation	0.70 (0.55-0.89)	0.69 (0.52-0.91)

AOR – Adjusted Odds Ratio, CI - Confidence Interval; Only significant variables in the model are shown.

CONCLUSIONS

▪ The study found that DMF is the most prescribed oral DMA for MS.

▪ Patients' predisposing (age group and region), enabling (insurance), and need factors (comorbidities and neurologist consultation) influenced the selection of specific oral DMA.

▪ More research is needed to address adherence and clinical outcomes of these different oral DMAs introduced in the past decade.

Thanks for your interest in this poster.
For additional information/questions on this topic, please email
Jagadesh.e.rao@gmail.com.