Magellan Rx MANAGEMENT

Real World Comparison of Patient Adherence and Persistence to Fingolimod vs. Dimethyl Fumarate in Multiple Sclerosis

Multiple Sclerosis

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Objective

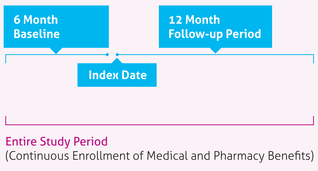
- Comparison of long-term adherence and persistence between patients receiving fingolimod (FTY) and dimethyl fumarate (DMF) for treatment of multiple sclerosis (MS) since the availability of DMF in March 2013.

Background

- Disease modifying therapies (DMTs) are the mainstay of treatment for patients with relapsing-remitting multiple sclerosis (RRMS).
- Clinicians report suboptimal adherence to DMTs lead to increased relapse rates and a decline in patient functional status.[1]
- Currently, there are limited data available comparing 1-year adherence and persistence between fingolimod (FTY) and dimethyl fumarate (DMF).
- DMF adherence data beyond 6 months are particularly limited as DMF has only been on the market since March 2013.
- FTY and DMF were selected for comparison since these two DMTs have the greatest market share among oral DMTs as of April 2015.[2]

Methodology

- This retrospective study was conducted using medical and pharmacy claims data from three regional health plans.
- Patients aged >18 years with a diagnosis of multiple sclerosis (ICD-9: 340) and at least 1 claim for FTY, GA, or IFN-β-1a during the identification period (1/1/2011-12/31/2011) and 1 additional claim during the follow-up period were included in this study.
- The index date was defined as the date of first claim for the specified drug of interest during the identification period.
- Patients were required to have continuous enrollment in medical and pharmacy benefits during the entire study period (18 months), which included baseline period prior to index date (6 months) and follow-up period post index date (12 months).
- Patient characteristic and demographic information were collected during the baseline period.
- Adherence measured by proportion of days covered (PDC) and persistence defined by no gap >60 days during the follow-up period were compared between FTY and DMF.



Results

- A total of 110 FTY and 123 DMF patients were included in the study.
- In this real-world setting, FTY patients had greater adherence and persistence to their treatment compared to patients on DMF within 12 month period.
- The most common comorbidities for both groups were dyslipidemia and hypertension.
- The most common MS-related symptoms for both groups were pain and issues affecting walking (balance, gait, and coordination).

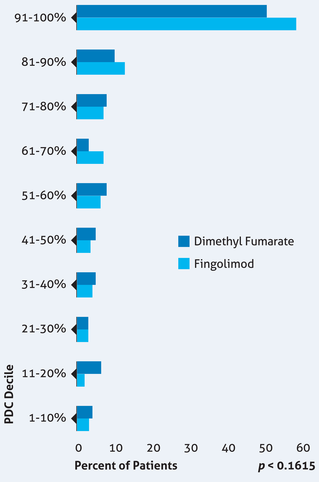
Patient Comorbidities

Comorbidity	Fingolimod # (%) n = 110	Dimethyl Fumarate # (%) n = 123
Cardiovascular Disease (other than IHD)	1 (2.56)	4 (8)
Dyslipidemia	10 (25.64)	13 (26)
Hypertension	12 (30.77)	15 (30)
Ischemic heart disease	1 (2.56)	2 (4)
Depression	6 (15.38)	6 (12)
Asthma	2 (5.13)	3 (6)
Diabetes Mellitus	2 (5.13)	4 (8)
Obesity	3 (7.69)	2 (4)

MS-Related Symptoms

Symptom	Fingolimod # (%) n = 110	Dimethyl Fumarate # (%) n = 123
Fatigue	21 (7.5)	37 (11.04)
Numbness	22 (7.86)	23 (6.87)
Walking (Balance, Gait, Coordination)	25 (8.93)	34 (10.15)
Bladder Dysfunction	13 (4.64)	27 (8.06)
Bowel Dysfunction	9 (3.21)	9 (2.69)
Visual Symptoms	8 (2.86)	16 (4.78)
Sexual Dysfunction	-	1 (0.3)
Dizziness and Vertigo	17 (6.07)	20 (5.97)
Pain	59 (21.07)	65 (19.4)
Muscle Weakness/Pain/Spasticity	19 (6.79)	20 (5.97)
Cognitive Function	10 (3.57)	12 (3.58)
Depression	6 (15.38)	6 (12)

Adherence



Adherence for Fingolimod and Dimethyl Fumarate Patients

FTY patients were more adherent to the treatment compared to DMF patients during the 12-month follow-up period (PDC 82% vs. 77%; $p = 0.0408$). The proportion of patients with PDC ≥80% was 77% for FTY and 64% for iDMT (p = 0.0361).

Adherence Over 12 months

Product	Average PDC	Difference Test
Fingolimod	0.822	$p = 0.0408$ (t-test)
Dimethyl Fumarate	0.769	

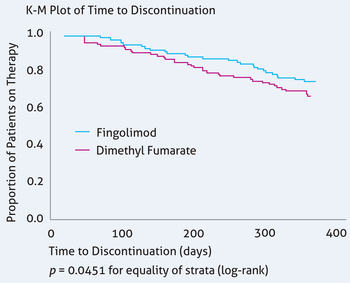
Proportion of Patients with PDC ≥ 80%

Product	Adherent # (%)	Non-Adherent # (%)	Difference Test
Fingolimod	82 (76.64)	25 (23.36)	$p = 0.0361$ (Fisher's Exact test)
Dimethyl Fumarate	88 (63.77)	50 (36.23)	

Persistence to the Index Drug

At the end of the 12-month study period, higher proportion of FTY patients (77%) remained on therapy compared to DMF patients (68%; $p = 0.0451$).

Unadjusted Probability of Patient Persistence on Medication



Quartiles: Days to Discontinuation for Fingolimod and Dimethyl Fumarate

Product	Percentile	Days
Fingolimod	25%	119
	50%	224
	75%	295
Dimethyl Fumarate	25%	99.5
	50%	190
	75%	286.5

Half of the DMF patients had discontinued therapy by day 190 of the study. This compares to 224 days for FTY.

Risk for Discontinuation

The risk of treatment discontinuation was four times greater for DMF patients than FTY patients (Hazard Ratio, 4.01; 95% CI, 2.65-6.08).

Conclusion

- In this real-world setting, FTY patients had greater adherence and persistence compared to DMF patients.
- Use of therapies demonstrating a favorable rate of adherence may result in improved clinical outcomes by reducing relapse rates and slowing disease progression.
- Before selecting a therapy for RRMS patients, treatment selection should incorporate the real-world patient experience of long-term adherence and persistence in order to maximize clinical benefit.

Limitations

- This study was limited to a continuously employed, insured population. This data largely represents commercial populations enrolled in regional health plans. This should be taken into account before generalizing the results to plans with potentially different populations and policies.
- The study was conducted based on medical/pharmacy claims data. Products and services not billed (including physician drug samples) cannot be captured in claims.

Disclosures

- This research was conducted by Magellan Rx Management, Newport, RI, with external funding by Novartis Pharmaceutical Corp.

References

[1]Tan H., Cai Q, et al. Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis. Adv Ther. 2011 Jan;28(1):51-61

[2]IMS Market Share April 2014