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Real World Analysis to Assess the Difference in Long-Term Medication Adherence and Persistence with Fingolimod Compared to Injectable Disease Modifying Therapies in Patients with Multiple Sclerosis

Multiple Sclerosis

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Objective

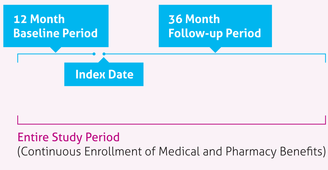
- Comparison of long-term adherence and persistence between patients receiving fingolimod (FTY) and injectable disease modifying treatments (iDMT), specifically glatiramer acetate (GA) and intramuscular interferon beta-1a (IFN-β-1a).

Background

- Disease modifying therapies (DMTs) are the mainstay of treatment for patients with relapsing-remitting multiple sclerosis (RRMS).
- Previous studies demonstrate that adhering to subcutaneous or intramuscular DMTs can be a challenge for patients.[1]
- Glatiramer acetate (GA) and intramuscular interferon beta-1a (IFN-β-1a) are commonly used injectable DMTs with a combined market share of over 50%.[2]
- Fingolimod is the first oral DMT approved by the FDA that provides a once-a-day dosing option for patients.
- Currently, there are limited data comparing long-term adherence and persistence between patients receiving injectable and oral DMTs.

Methodology

- This retrospective study was conducted using medical and pharmacy claims data from four 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.
- 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 (48 months), which included a baseline period prior to the index date (12 months) and a follow-up period post the index date (36 months).
- Patient characteristic and demographic information were collected during the baseline period.
- Adherence was measured by proportion of days covered (PDC), and persistence was defined as having no gap >60 days for the index drug during the follow-up period. Adherence and persistence were compared between FTY and iDMTs.



Results

- A total of 98 FTY and 978 iDMT patients were included in the study.
- Distribution of age and gender between the two groups were not statistically different.
- The most common comorbidities for both groups were dyslipidemia and hypertension.
- The most common MS-related symptoms for both groups were pain and fatigue.

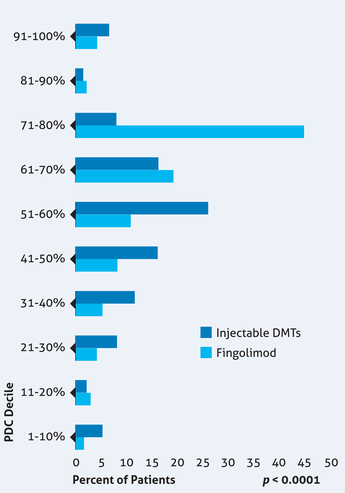
Patient Comorbidities

Comorbidities	Fingolimod # (%) n = 98	Injectable DMTs # (%) n = 978
Cardiovascular Disease (other than IHD)	2 (3.7)	28 (4.19)
Dyslipidemia	15 (27.78)	203 (30.34)
Hypertension	15 (27.78)	165 (24.66)
Ischemic heart disease	2 (3.7)	18 (2.69)
Depression	8 (14.81)	119 (17.79)
Asthma	3 (5.56)	38 (5.68)
Diabetes Mellitus	5 (9.26)	43 (6.43)
Obesity	2 (3.7)	27 (4.04)

MS-Related Symptoms

Symptom	Fingolimod # (%) n = 98	Injectable DMTs # (%) n = 978
Fatigue	34 (9.55)	329 (10.84)
Numbness	25 (7.02)	210 (6.92)
Walking (Balance, Gait, Coordination)	28 (7.87)	178 (5.86)
Bladder Dysfunction	25 (7.02)	138 (4.55)
Bowel Dysfunction	12 (3.37)	134 (4.41)
Visual Symptoms	26 (7.3)	148 (4.87)
Sexual Dysfunction	-	9 (0.3)
Dizziness and Vertigo	18 (5.06)	121 (3.99)
Pain	66 (18.54)	652 (21.48)
Muscle Weakness/Pain/Spasticity	24 (6.74)	140 (4.61)
Cognitive Function	5 (1.4)	64 (2.11)
Depression	23 (6.46)	212 (6.98)

Adherence



Adherence for Fingolimod and Injectable DMT Patients

FTY patients were more adherent compared to iDMT patients during the 36-month follow-up period (PDC 63% vs 52%; $p < 0.0001$). The proportion of patients with PDC ≥80% was 51% for FTY and 15% for iDMT ($p < 0.0001$).

Adherence Over 36 months

Product	Average PDC	Difference Test
Fingolimod	0.626	$p < 0.0001$ (t-test)
Injectable DMTs	0.515	

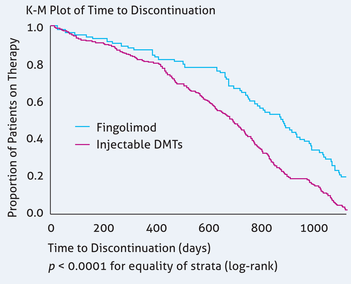
Proportion of Patients with PDC > 80%

Product	Adherent # (%)	Non-Adherent # (%)	Difference Test
Fingolimod	50 (51)	48 (49)	$p < 0.0001$ (Fisher's Exact test)
Injectable DMTs	150 (15.33)	828 (84.69)	

Persistence to the Index Drug

At the end of the 36-month study period, a higher proportion of FTY patients (19%) remained on therapy compared to iDMT patients (4%; $p < 0.0001$).

Unadjusted Probability of Patient Persistence on Medication



Quartiles: Days to Discontinuation for Fingolimod and Injectable DMTs

Product	Percentile	Days
Fingolimod	25%	494
	50%	748
	75%	934
Injectable DMTs	25%	342
	50%	616
	75%	817

Half of the iDMT patients had discontinued therapy by day 616 of the study. This compares to 748 days for FTY.

Risk for Discontinuation

The risk of treatment discontinuation was two times greater for iDMT patients compared to FTY patients (Hazard Ratio, 2.07; 95% CI, 1.54-2.79).

Conclusion

- In this real-world setting, FTY patients had greater long-term adherence and persistence to treatment compared to iDMT 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]Wingerchuk, DM., Carter, JL. Multiple Sclerosis: Current and Emerging Disease-Modifying Therapy and Treatment Strategies. Mayo Clin. Proc. 2014; 89(2): 225-240.

[2]IMS Market Share April 2014