A descriptive analysis of time to first treatment with disease-modifying drugs in newly diagnosed patients with multiple sclerosis

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Introduction

- The clinical manifestations of multiple sclerosis (MS) often follow an intermittent course, as the disease typically advances in a series of exacerbations, also called relapses, or attacks.
- After each attack, there may be complete or partial recovery, but in general, each subsequent attack reduces the amount of recovery that can occur.
- Evidence suggests that early treatment with disease-modifying drugs (DMDs) following a diagnosis of relapsing multiple sclerosis (MS) is recommended for most patients with MS.[1,2]
- As there is no cure for MS, treatment aims to reduce the burden of illness by slowing/altering the disease process and alleviating symptoms.[2,3]
  - Treat acute relapses as they occur
  - Treat with DMDs which have been proven to reduce the number of relapses and, in some cases, delay the progression of disability
  - Provide therapy to improve or alleviate symptoms
- A greater degree of disability is reached earlier in patients who have a greater number of relapses compared to patients with fewer relapses.[1,4]
- A significant proportion of patients with MS may remain untreated:
  - A study of newly-diagnosed MS patients in a commercial managed care population found that nearly 60% remained untreated despite the risk of disease progression.[5]
  - Another recent study in a commercial managed care population found the proportion of untreated patients decreased from 58% in 2006 to 49% in 2012.[6]
  - A better understanding of DMD utilization could help in the optimization of therapeutic benefit from DMD treatment.
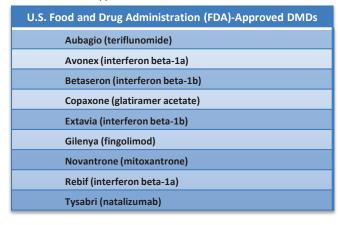
Objective

- The objective of this study was to examine the time to first DMD prescription in newly diagnosed patients with MS.

Methods

Study Population

- This retrospective database analysis of newly diagnosed patients with MS was conducted using a national managed care database.
  - Third party payer coverage from the IMS Life Link Health Plans Database; an anonymous patient-centric, HIPAA compliant, national managed care database that represents approximately 70 million enrollees from more than 65 health plans.
    - A subset of data that contains all enrollment, demographic, and medical and pharmacy claims information for all patients with MS or a DMD claim was utilized.
- Patients aged 18–64 years, with a first MS claim (ICD-9-CM: 340.xx) between 1/1/2008 and 10/31/2012 (index date), with continuous eligibility for 6 months pre- and 24 months post-index, and who had at least one DMD claim during the 24-month post-index period were included in the analysis (Table 1).

Table 1. US FDA-approved DMDs included in the evaluation.

U.S. Food and Drug Administration (FDA)-Approved DMDs
Aubagio (teriflunomide)
Avonex (interferon beta-1a)
Betaseron (interferon beta-1b)
Copaxone (glatiramer acetate)
Extavia (interferon beta-1b)
Gilenya (fingolimod)
Novantrone (mitoxantrone)
Rebif (interferon beta-1a)
Tysabri (natalizumab)

Exclusion Criteria

- Patients who had evidence of DMD use prior to first MS claim were excluded from the analysis.
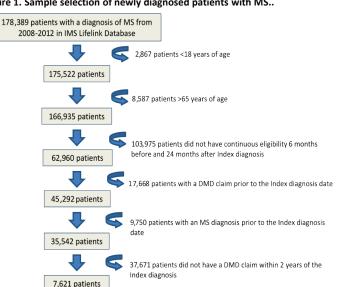
Data Analysis

- Data were accessed and analyses were conducted using the Instant Health Data (IHD) platform developed by Boston Health Economics (BHE).
- Categorical and binary variables were summarized using frequencies and percentages. Continuous variables were summarized using means, SDs and medians.
- A secondary analysis examined time to first DMD claim for newly diagnosed MS patients who received a DMD claim any time following the index date (i.e., patients could have received a DMD after 2 years of the index date).

Results

Patient Selection

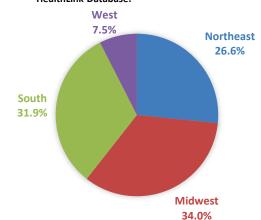- Figure 1 outlines the sample selection using the inclusion/exclusion criteria.

Figure 1. Sample selection of newly diagnosed patients with MS..

178,389 patients with a diagnosis of MS from 2008-2012 in IMS Lifelink Database

2,867 patients <18 years of age

175,522 patients

8,587 patients >65 years of age

166,935 patients

103,975 patients did not have continuous eligibility 6 months before and 24 months after Index diagnosis

62,960 patients

17,668 patients with a DMD claim prior to the Index diagnosis date

45,292 patients

9,750 patients with an MS diagnosis prior to the Index diagnosis date

35,542 patients

37,671 patients did not have a DMD claim within 2 years of the Index diagnosis
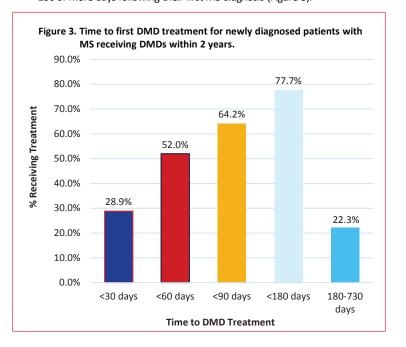
7,621 patients

Baseline Characteristics

- 7,621 patients with MS met the study inclusion criteria:
  - Mean age was 41.6 years (SD=10.4)
  - 74.5% were female
  - Patients were most likely to be from the Midwest (34.0%) or South (31.9%) regions, which reflects sampling for the national database used in this study (Figure 2).

Figure 2. Baseline region of newly diagnosed patients with MS in the IMS HealthLink Database.
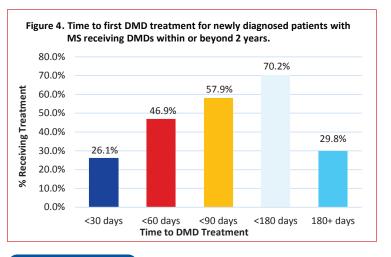

West 7.5%
Northeast 26.6%
South 31.9%
Midwest 34.0%

- The average time from first MS diagnosis to first DMD claim was 128.3 days (SD=164.3), with median time of 56 days.
  - 28.9% received their first DMD in less than 30 days
  - 52.0% in less than 60 days
  - 64.2% in less than 90 days and
  - 77.7% in less than 180 days.
- Over one-fifth of patients (22.3%) did not have their first DMD claim for 180 or more days following their first MS diagnosis (Figure 3).

Figure 3. Time to first DMD treatment for newly diagnosed patients with MS receiving DMDs within 2 years.

Time to DMD Treatment	% Receiving Treatment
<30 days	28.9%
<60 days	52.0%
<90 days	64.2%
<180 days	77.7%
180-730 days	22.3%

Secondary Analysis

- The secondary analysis of newly diagnosed MS patients who received a DMD any time during the post-index period (n=8,441) showed that the mean and median time to DMD treatment for this broader population was 227.1 (SD=355.9) and 66 days, respectively.
  - Mean age was 41.7 years (SD=10.3); 74.9% were female; and patients were most likely to be from the Midwest (34.4%) or South (31.3%) regions.
- More than a quarter of patients (29.8%) did not have their first DMD claim for ≥180 days following first MS diagnosis (Figure 4).

Figure 4. Time to first DMD treatment for newly diagnosed patients with MS receiving DMDs within or beyond 2 years.

Time to DMD Treatment	% Receiving Treatment
<30 days	26.1%
<60 days	46.9%
<90 days	57.9%
<180 days	70.2%
180+ days	29.8%

Conclusions

- This study demonstrates that many patients with newly diagnosed MS have a delay before having their first DMD claim, with 22.3% waiting to start therapy for at least 6 months.
- Data suggest that early initiation of DMD therapy following a diagnosis of relapsing MS is important for optimizing MS management.
- Further research is needed to better understand why patients experience delays in initiating DMD therapy.

References

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Acknowledgements

Disclosures