Multiple sclerosis (MS) is a chronic and debilitating disease that affects approximately 570,000 individuals in the USA, and affects 2.3 million worldwide.1,2 Therapeutic outcomes in routine clinical practice have the potential to be influenced by factors that are controlled for during clinical trials, including prior disease, treatment history, comorbidities, and disease duration and severity. Evaluation of real-world outcomes, using data provided by medical reimbursement claims, is therefore important for assessing therapeutic effectiveness.

Real-world data on the comparative effectiveness of DMTs for the management of MS in routine clinical practice are limited.3

INTRODUCTION

• Data were collected between January 2012 and September 2014.
• Therapeutic outcomes in routine clinical practice have the potential for assessing therapeutic effectiveness.
• Multiple sclerosis (MS) is a chronic and debilitating disease that affects approximately 570,000 individuals in the USA, and affects 2.3 million worldwide.1,2

OBJECTIVE

• To compare annualized relapse rates (ARR) and DMT adherence for patients with MS initiating dimethyl fumarate, interferon β, glatiramer acetate, teriflunomide or fingolimod in routine clinical practice.

METHODS

Data Source
• Truven MarketScan Commercial Claims Databases: Administrative claims and eligibility records of 80 million commercially-insured individuals from the USA.
• Medical services claims for inpatient and outpatient settings with associated procedures and diagnosis codes.
• Clinical data from US claims data, the real-world DMT effectiveness reported in large retrospective studies.

Patient Identification
• Adult patients with MS who initiated an injectable or oral DMT between January and September 2013 were included in the study.
• Index date was defined as the date of the first DMT initiation.

Study Measures
• Patient demographics included age at index date, sex, type of health plan and region of residence.
• Baseline clinical characteristics were assessed based on claims within the 1 year pre-index period and included chronic disease burden (measured by Charlson Comorbidity Index [CCI]) and MS-related symptoms.
• CCI is a composite score calculated based on the presence of 22 chronic conditions, such as diabetes, peptic ulcer, liver disease and cancer. It was initially developed to predict ten-year mortality and has been widely used to assess chronic disease burden in large retrospective studies.
• ARR, the primary outcome of interest, was calculated based on the number of MS-related relapses (identified from inpatient and outpatient claims) within one year after DMT initiation.

Statistical Analysis
• Annual relapse rates were compared pre- and post-DMT initiation for each cohort.
• To adjust for potential confounding, a Poisson regression model was used to estimate the adjusted incidence rate ratios (IRR) of relapses. As the largest patient group, the dimethyl fumarate cohort was used as the reference for the regression.

RESULTS

• Baseline differences between cohorts were observed in age, sex, prior DMT exposure and comorbidities (measured using the CCI) (Table 1).
• Significant decreases in unadjusted relapse rates were observed in the dimethyl fumarate and fingolimod cohorts, consistent with a previous claims database analysis.3 The largest decrease in unadjusted ARR was observed in the dimethyl fumarate cohort (0.14 [32.6%] decrease, Figure 2).

CONCLUSIONS

• In this retrospective study of real-world DMT comparative effectiveness in more than 5,000 patients with MS, the largest reduction in unadjusted relapse rates after DMT initiation was observed in the dimethyl fumarate cohort.
• Dimethyl fumarate is associated with significantly lower ARR than glatiramer acetate, interferon β and teriflunomide after DMT initiation. ARR during DMT initiation was comparable between the dimethyl fumarate and fingolimod cohorts.
• Despite differences in baseline patient demographics and comorbidities between DMT clinical trial populations and these US claims data, the real-world DMT effectiveness reported here is consistent with previous mixed and indirect treatment comparisons.6–8

References

Disclosures
This study is supported by Biogen (Cambridge, MA, USA). Aaron Boster has received research funding from Biogen, Novartis, and Genzyme and has received consulting and consulting honoraria from Biogen, Genzyme and Alexion. Jennifer Appling, Peng Zhang, David Tilles, Shu-Ru Chen, Ramesh Chari, and Ranganath Singh have received honoraria or travel expenses from Biogen, Genzyme, Teva, and Alexion. This study was done in collaboration with Biogen, which funds and provides clinical research support.

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Figure 1. Schematic figure of patient selection. Patients were required to have full enrollment 1 year before and 1 year after the index date.

Table 1. Baseline patient demographics and clinical characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DMT</th>
<th>Interferon β</th>
<th>Glatiramer acetate</th>
<th>Teriflunomide</th>
<th>Fingolimod</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median)</td>
<td>49.0</td>
<td>51.5</td>
<td>49.7</td>
<td>49.0</td>
<td>50.0</td>
</tr>
<tr>
<td>Sex, % females</td>
<td>76.2</td>
<td>68.2</td>
<td>76.2</td>
<td>70.9</td>
<td>70.9</td>
</tr>
<tr>
<td>Charlson Comorbidity Index (median)</td>
<td>5.1</td>
<td>5.9</td>
<td>5.1</td>
<td>5.9</td>
<td>5.9</td>
</tr>
</tbody>
</table>

Table 2. Adherence to index DMT in the year after DMT initiation

<table>
<thead>
<tr>
<th>DMT</th>
<th>Mean PDC</th>
<th>PDC 20%</th>
<th>Mean PDC</th>
<th>PDC 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>DMT</td>
<td>0.71</td>
<td>0.84</td>
<td>0.82</td>
<td>0.91</td>
</tr>
</tbody>
</table>

Table 3. Annualized relapse rates for 1 year before and 1 year after the index date

<table>
<thead>
<tr>
<th>Year</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
<th>IRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-index period</td>
<td>73.6</td>
<td>9.5</td>
<td>74.1</td>
<td>1.00</td>
</tr>
<tr>
<td>Post-index period</td>
<td>73.6</td>
<td>9.5</td>
<td>74.1</td>
<td>0.82</td>
</tr>
</tbody>
</table>