Title

Treatment Failure in patients with multiple sclerosis initiating frequently used first line therapies

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Authors (order TBD)

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Abstract

Background: Despite an array of disease modifying therapies (DMTs), interferons/glatiramer acetate (IFN/GA) and dimethyl fumarate (DMF) are still the most frequently used to treat multiple sclerosis (MS) in United States.

Objective: Our objective was to evaluate treatment patterns and disease breakthrough for patients initiating IFN/GA/DMF as first-line therapies to determine if there is an unmet need for more effective agents to be used first-line.

Methods: Adult MS patients (age \geq 18) with \geq 1-DMT claims of IFN/GA/DMF from January 2016-March 2018 were identified using a large US administrative claims database (IBM® MarketScan® Database). The date of the first MS DMT claim was defined as the index date and patients were followed for one year. Treatment switch was defined as changing from initial therapy to another DMT (within 60 days) and discontinuation was defined as no DMT use for at least 60 days after stopping the initial DMT. Breakthrough-disease was defined as occurrence of relapse (characterized via a validated claims algorithm) during the treatment period. Outcomes were evaluated as a combined DMT group and by individual DMTs. **Results:** We identified 1,096 patients initiating IFN/GA and 565 patients initiating DMF. Of these, 43.4% experienced treatment failure (29.3% discontinued or 14.1% switched DMTs) within one year of initiation (results for individual DMTs were similar). The median time to discontinuation was 4.8 months, and the median time to switch was 5.6 months. Approximately, 28.2% of patients experienced at least 1 relapse over the 1-year observation period. The median time to relapse was 4.6 months. There was no reduction in annualized relapse rate (ARR) after initiation of IFN/GA/DMF therapy [ARR for 1-year prior to initiation = (0.41) and 1 year post-initiation = (0.42)].

Conclusions: There is an unmet need for early use of high efficacy DMT, as the most frequently used first-line DMTs show treatment failure (discontinuation/switching/disease-breakthrough) and lack of treatment benefit at high rates in a real-world setting.

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Disclosures

- Chinmay Deshpande and Fei Yang are employees of Novartis Pharmaceuticals
 Corporation
- **Wang Mengru** is an employee of KMK Consulting, Inc. and works as a consultant to Novartis Pharmaceutical Corporation
- **Dr.Devon Conway** has received research support paid to his institution by the National Multiple Sclerosis Society and Novartis Pharmaceuticals. He has received speaking fees from Biogen.
- **Dr.Carrie Hersh** has received speaking and consulting fees from Novartis, Biogen, EMD Serono, Genzyme, and Genentech. She has received research support paid to her institution from Biogen, Genzyme, Novartis, Genentech, and PCORI.

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Disease-modifying therapy

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