Patient Perspectives on Factors Related to Medication Persistence in MS Patients Experiencing DMF-Associated Gastrointestinal Events

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Introduction
- As of January 31, 2018, ~311,000 patients have chosen delayed-release dimethyl fumarate (DMF) treatment worldwide, representing >544,000 patient-years of exposure. Of these, ~2520 patients (~14% of total patient-years) were from clinical trials.
- Gastrointestinal (GI) symptoms, mostly mild or moderate in severity, affect >10% of patients, with adverse events (AEs) associated with DMF.
- The incidence of GI AEs is more frequent during the first month of treatment and usually decreases over time.
- Successful strategies for managing common side effects of therapies for relapsing-remitting multiple sclerosis (RRMS) are important to optimize clinical outcomes.
- Health care providers (HCPs) employ different strategies in an attempt to mitigate GI symptoms, including taking DMF with food, gradual dose increase, and a variety of symptomatic therapies. Patients' expectations about the nature of GI symptoms at therapy initiation also has been found to be helpful.
- There are limited patient-reported data on the effectiveness of and adherence to different GI management recommendations.

Objective
- The primary objective of the study was to identify patient-reported approaches to improve persistence on DMF among patients with DMF-associated GI AEs.

Methods
- An online survey using Health Union's proprietary platform MultipleSclerosis.net was conducted June 30, 2017–August 25, 2017 with 3 groups of adult patients with RRMS: DMF users without GI AEs who were treated with DMF for ≥3 months, n=1351; DMF users with GI AEs who were treated with DMF for ≥3 months, n=468; and Previous DMF users who discontinued DMF due to GI symptoms, n=468.
- This online survey platform was selected to reach an extensive MS population across the United States, enabling the inclusion of 2 distinct groups of DMF-treated patients, and minimizing the risk of included self-reports of MS diagnoses.
- The questionnaire was pretested with patients with MS before study initiation. Because strategies for mitigation of GI symptoms have evolved since the launch of DMF in the United States, and to minimize recall bias, only patients who initiated DMF after January 1, 2015 were included in the survey.
- Participants reported on concurrent chronic inflammatory bowel syndrome (IBS), Crohn's disease (CD), or ulcerative colitis (UC) were excluded.
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Results
- Patient Demographics and MS History
  - There were no significant differences among study groups in gender, ethnicity, body mass index, prior treatment status, and time since MS diagnosis or DMF initiation (Table).
  - Overall, DMF-treated patients with GI AEs (both those who persisted and those who discontinued) tended to be younger than those without GI AEs (mean 46.5 vs. 49.3 years, respectively).
  - Patient groups were similar in their type of health insurance, type of prescribing HCP, and type of health care facility where they receive MS care (not shown).
- Patients who persisted on DMF despite GI AEs were more likely to be employed than those who discontinued therapy (P=0.05).
- Most patients were exposed to other MS therapies before DMF.

Conclusions
- Persistence on DMF when experiencing DMF-associated GI AEs can be improved by effective communication between patients and HCPs, identifying a rationale for therapy selection, expectation setting on the timeline and duration of GI events, iterative instructions that include food recommendations, and appropriate symptomatic management.