Adherence, Cognition and Behavioral Outcomes in Multiple Sclerosis (MS) Patients on Dimethyl Fumarate – 12-Month Results of a Longitudinal Registry Study in German MS Practice Centers (TREAT)

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Conclusions
- DMF is effective in stabilizing clinical, cognitive and behavioral parameters in early RRMS-patients.
- Behavioral factors, gender and pre-treatment issues emerged as putative predictors for non-adherence. Multiple regression analyses considering collinearity will be performed in the forthcoming final analysis.

Introduction
- NeuroTransData is a German network of currently 72 neurology practice centers using its MS database (n = 22,000 MS patients) to collect “real world” data about longitudinal evolution and treatment in MS.

Objectives
1. Assessment of adherence, disability, cognition and patient-reported outcomes (PRO) in relapsing-remitting MS (RRMS) patients on dimethyl fumarate (DMF) as first-line treatment or switching from other disease-modifying therapies.
2. Identification of relevant factors for non-adherence (discontinuation of study or DMF intake)

Methods
- 12 months interim analysis (T12) of a 2-year prospective, multicenter, open-label registry study with assessments at baseline (T0) and at T3, T6, T9, T12, T18 and T24 months.
- Demographic baseline characteristics of the study population (12 months analysis set) are shown in Table 1.

Results
- All clinical, behavioral and cognitive parameters remained stable during the first 12 months of DMF treatment (Table 2).
- By T12, 26.8% (193/721) of patients reported to be non-adherent. Women were more likely to be non-adherent (OR 1.19, HR 1.8). Among the non-adherents at T12, 41.9% (80/193) discontinued at T3. The primary reason for non-adherence by T12 was physical complaints (13.0%; 95/721), mainly of gastrointestinal origin (7.9%; 57/721). (Figures 2 and 3)
- Univariate (logistic/Cox) regression analyses (p<0.15) identified gender, premedication pause, pre-treatments (≥2), depression, QoL, life/treatment satisfaction, fatigue, anxiety and nonverbal memory as putative predictors of non-adherence. (Table 3)

Table 1. Development of clinical, behavioral and cognitive parameters during 12 months of DMF treatment

Table 2. Analysis of parameters probably affecting time to non-adherence (p<0.15) in RRMS-patients treated with DMF (T12 results)

Figure 1. Kaplan-Meier curve depicting gender-related non-adherence (male/female) in RRMS-patients treated with DMF (T12 patients)

Figure 3. Reasons for study discontinuation in RRMS-patients treated with DMF (12 results: 187 patients)

Main reasons for study discontinuation
- Physical side effects
- Psychological side effects
- Compliance, belief, efficacy
- Others

References

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