Cognition, patient reported behavioral outcomes (PRO) and adherence in MS patients on dimethyl fumarate – a 12-month observational study in German MS practice centers

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Background: The long-term stability of cognitive and psycho-behavioral factors is an eminent treatment goal in MS patients, since they have a significant impact on their quality of life (QoL).

Objectives: (1) to longitudinally document cognition, clinical evolution and patient-reported behavioural outcomes (PRO) in patients with relapsing-remitting multiple sclerosis (RRMS) treated with Tecfidera® as first-line treatment or changing from other baseline therapies (2) to identify factors exerting significant influence on adherence.

Methods: Interim analysis of a prospective, multi-center, open-label registry study of 24 months with assessments at baseline/BL and after 3, 6, 9,12, 18 and 24 months follow-up (T3, T6, T9, T12, T18, T24). At T12 follow-up, 609 RRMS patients (Mc Donald) on Tecfidera[R] (mean age: 41.1 yr, 73% female, median EDSS 2.0) entered analysis. Outcomes: adherence rate, clinical/mobility (EDSS, ambulation index,2-minute walk test/TMWT), cognition battery (BICAMS) indexing processing

speed/SDMT, verbal/CVLT and visual/spatial memory/BVMTR), and PROs representing treatment satisfaction (TSQM-9), depression (BDI), anxiety (STAI X1/2), fatigue (FSMC), QoL (EQ-5D), disease coping (FKV), personality (NEO-FFI) and life-satisfaction (FLZ).

Results: At T12 months follow-up, all cognitive parameters (sum scores of SDMT, CVLT and BVMT-R) had remained stable within normal ranges. In BL vs. T12, increased QoL (EQ-5D: 73,3 vs. 75,2) and treatment satisfaction (TSQM 9: : 46,0 vs. 48,8), as well as slightly decreased scores of state anxiety (STAI X1: 39,5 vs. 38,8) and depression (BDI: 2,49 vs. 2,41) were observed with dimethyl fumarate. Only fatigue distinctly aggravated over time (FSMC: 53,8 vs. 57,6). We found non-adherence in 24,5 % of patients, and significantly more frequent in women than in men (OR 3,0). The major reason for non-adherence was gastrointestinal (GI) side effects (26,9%). Univariate logistic regression analysis (cut-off: 0,25) identified gender, fatigue, state anxiety, depression, QoL, treatment satisfaction, number of premedications and life-satisfaction as significant determinates of influence.

Conclusion: (1) Except for fatigue, dimethyl fumarate is effective stabilizing cognitive and behavioral variables in early RRMS (2) Non-adherences in women is there show a three times higher non-adherence rate than men which may be due to more susceptibility to GI side effects. (3) Behavioral factors are emerging as determinates of adherence