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Effectiveness and Safety of Dimethyl Fumurate Treatment in Relapsing Multiple Sclerosis Patients: A Real-World Evidence

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Background: Dimethyl fumarate (DMF) has been recently approved as a disease-modifying therapy for the treatment of mul-tiple sclerosis (MS). Post-marketing studies are important to con-firm what was established in clinical trials.

Methods: Using the national MS registry, we prospectively assessed relapsing patients with MS who had been prescribed DMF for at least 6 months. Primary outcome measure was the proportion of relapse-free patients at last follow-up visit. Secondary outcome measures were the mean change in Expanded Disability Status Scale (EDSS) and the proportion of patients with radiological activity (gadolinium-enhancing or new T2 lesions) at the last follow-up visit. Absolute lymphocyte count (ALC) was assessed at baseline (within 6 months prior to DMF initiation) and at one or more times during DMF treatment 3 months post-initiation.

Results: Of 134 patients identified, 119 were eligible and included in the analysis. Women represented 59.7% of the studied cohort. Mean age and mean disease duration were 33.5 ± 11.1 and 8.3 ± 7 years, respectively. A total of 75.6% of the patients received prior disease-modifying therapies. Mean duration of DMF exposure was 20.5 ± 9.5 months. The proportion of relapse-free patients increased significantly from 51.2% to 89.9% ($p < 0.0001$), while the mean EDSS score decreased from 2.8 ± 1.8 at baseline to 2.3 ± 1.7 ($p = 0.058$) at last follow-up visit. The proportion of patients with magnetic resonance imaging (MRI) activity decreased significantly from 61.1% to 15.1% ($p < 0.0001$). The mean ALCs decreased from 2170 to 1430 cells/μL (34% decrease). Lymphopenia was seen in 13 (10.9%) patients, of whom 3 (2.5%) patients had grade 3 lymphopenia necessitating discontinuation of DMF. Although no serious adverse events were reported, 19.3% of patients discontinued DMF.

Conclusion: In clinical practice, DMF appeared to be effective in reducing disease activity and progression of disability throughout the observational period. DMF was well tolerated with no serious adverse events. ALC profiles in DMF-treated patients were gener-ally stable throughout the observational period. The proportion of patients who developed severe lymphopenia was similar to fig-ures in clinical trials.