EFFICACY OF NATALIZUMAB AND FINGOLIMOD IN RELAPSING-REMITTING MULTIPLE SCLEROSIS IN REAL WORLD CLINICAL PRACTICE

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Objective: The aim of our study was to assess the efficacy at the 1-year follow-up in a cohort of patients treated with either fingolimod or natalizumab in the real world clinical practice.

Methods: We enrolled 391 patients starting either natalizumab or fingolimod for RRMS, referred to four multiple sclerosis centers throughout Central and Southern Italy between March 2007 and July 2013. The main end point was the cumulative proportion of patients free from any disease activity, as defined by freedom from relapse, Expanded Disability Status Scale progression, new or newly enlarging T2 lesions and gadolinium enhancing lesions at magnetic resonance imaging (MRI) assessed at 12-month follow-up. As additional end-points, we also considered each single disease activity measure independently.

Results: Out of 391 patients, 197 were treated with natalizumab and 194 with fingolimod. In the fingolimod group 52 patients were previously treated with natalizumab.

The cumulative proportion of patients free from any disease activity was 72.0% in the natalizumab and 59.1% in the fingolimod group (P=0.014) (Table 1). This proportion was lower in fingolimod patients with prior natalizumab exposure compared to those without (51.7% vs. 61.8%; P=0.008). Moreover, the cumulative proportion of patients free from new MRI lesions was 87.5% in the natalizumab vs. 70.0% in the fingolimod group (P<0.001); the cumulative proportion of patients free from clinical relapse was 82.5% in the natalizumab vs. 81.3% in the fingolimod group (P=0.739); 93.5% of patients on natalizumab were free from Expanded Disability Status Scale progression compared to 89.6% of patients on fingolimod (P=0.186).

Conclusions: Results from the present prospective observational study suggest greater efficacy of natalizumab over fingolimod in the real-world setting.

Table 1: Cumulative proportion of patients free from disease activity at 1-year follow-up.

	Natalizumab	Fingolimod	P*	Fingolimod		P**
				without prior natalizumab exposure	with prior natalizumab exposure	
Proportion of patients free from any disease activity	72.0%	59.1%	0.014	61.8%	51.7%	0.008
Proportion of patients free from MRI lesions	87.5%	70.0%	<0.001	74.5%	68.3%	<0.001
Proportion of patients free from relapse	82.5%	81.3%	0.739	86.3%	68.2%	0.01
Proportion of patients free from EDSS progression	93.5%	89.6%	0.186	92.2%	82.5%	0.06

*Comparison between natalizumab and fingolimod groups
**Comparison between natalizumab, fingolimod without prior natalizumab exposure, and fingolimod with prior natalizumab exposure,

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