

Brain atrophy by automated MRI reading in long-term natalizumab treated patients: Real world data suggests brain atrophy rates in range of healthy individuals

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**Background:** Natalizumab has been shown to be highly effective in improving clinical and MRI outcomes in RRMS. Long-term treatment effects including systematic follow-up with MRI in larger real-world cohorts have not been reported.

**Objective:** To investigate whether long-term (>2-year) treatment effects observed on clinical outcomes with natalizumab are similarly observed on MRI outcomes

**Methods:** Retrospective, longitudinal, multinational (Belgium, Czech Republic) and multicenter cohort of patients continuously treated with natalizumab of  $\geq 24$  months. Baseline MRI scan  $\leq 6$  month prior to natalizumab treatment acquired and  $\geq 1$  MRI scan of sufficient quality on natalizumab treatment. New/enlarging lesions and percentage of brain volume change (PBVC) were derived by an automated algorithm by Icometrix. We report the interim analysis of patients from the Czech cohort. The analysis including the Belgian cohort is ongoing and will be presented at the congress with further analysis on MRI (lesions and volumes) and clinical outcomes.

**Results:** 162 RRMS patients from the Czech cohort with mean EDSS prior to natalizumab treatment 3.4 (SD 1.17) and mean follow-up time on natalizumab treatment of 3.1 (SD 1.14) years. The majority of discontinuation occurred due to safety concerns in anti-JCV antibody positive patients, which decreases sample size over time. The proportion of patients with a new/enlarging FLAIR lesion decreased over time, with the most marked reduction after the first year of treatment. 14.9% (23 of 154 patients), experienced a new/enlarging FLAIR lesion in year 1 of treatment. Proportions of patients in the following years were 4.4% (6/137), 3.4% (4/119), 2.7% (2/73) and 2.7% (1/37) for year 2, 3, 4 and 5 respectively. Annualized brain volume loss (PBVC) occurred at a rate of -0.24% (95% CI -2.1, 1.61; N=145) in year 1 of treatment. In the following years PBVC was -0.26% (95% CI -1.78, 1.25; N=145), -0.22% (95% CI -1.84, 1.4; N=118), -0.18% (95% CI -1.65, 1.28; N=71), -0.26% (95% CI -1.29, 0.78; N=35) for year 2, 3, 4 and 5 respectively.

**Conclusion:** In line with previous results on treatment effects of natalizumab on clinical outcomes, this retrospective analysis with systematic long-term follow-up with MRI shows a marked reduction of occurrence of new/enlarging FLAIR lesions after 1 year of natalizumab treatment. Brain atrophy rates are in the range of the atrophy rate in healthy individuals, further supporting the long-term benefits of natalizumab treatment.

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