Efficacy of fingolimod in the clinical practice: results from a single-cohort observational study

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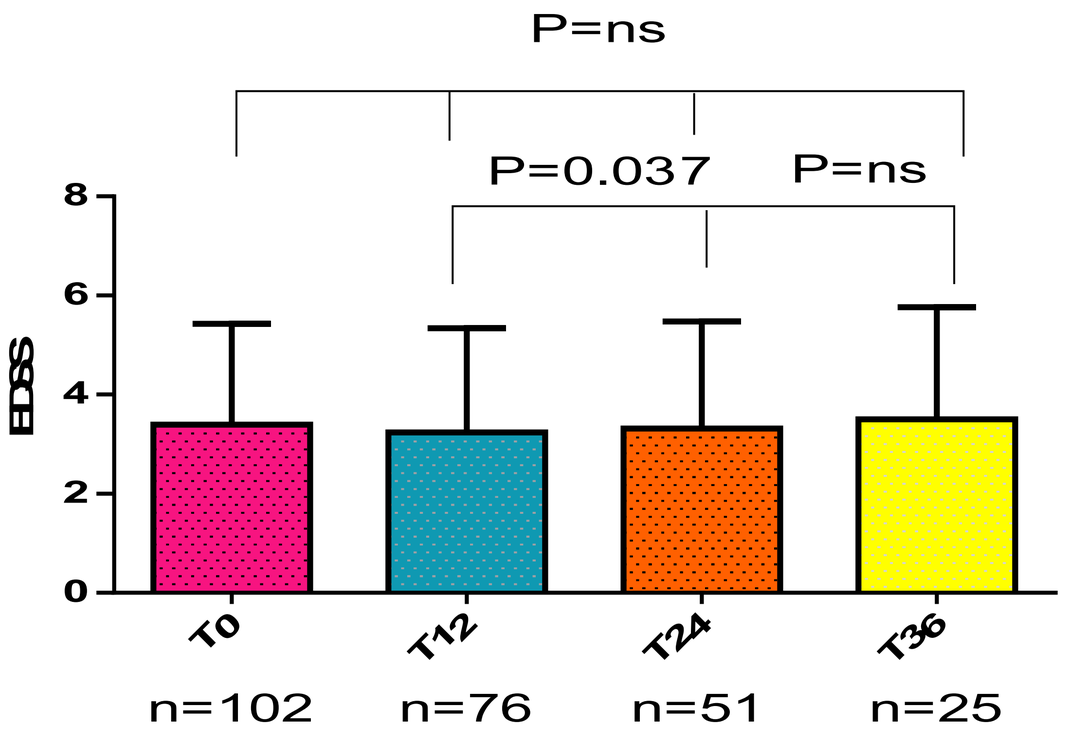
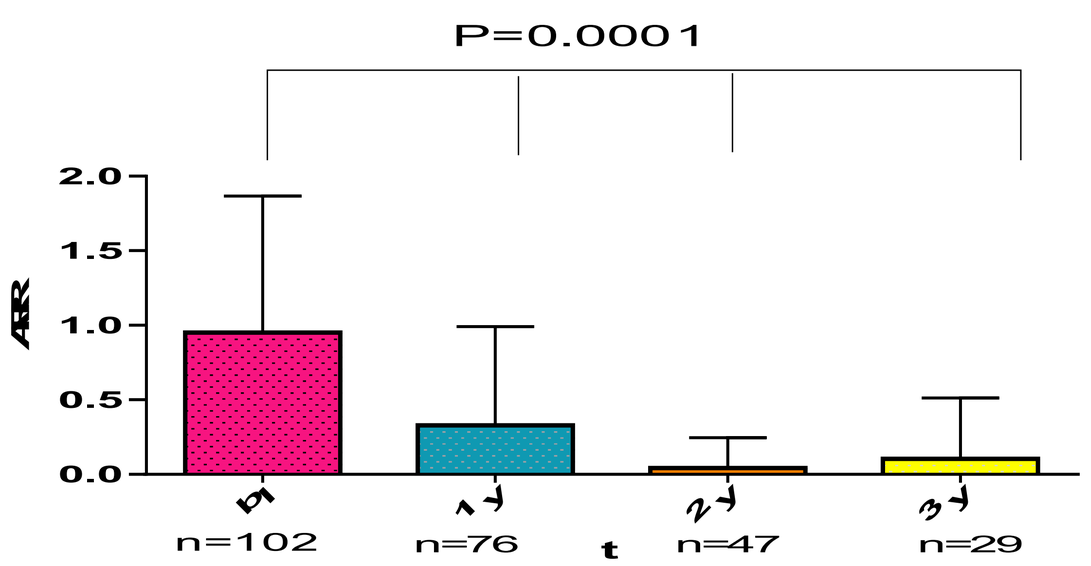
Introduction: Clinical trials have shown efficacy of fingolimod (FTY) for the treatment of relapsing-remitting multiple sclerosis (RRMS). However, there are conflicting data regarding efficacy, particularly in patients switching from natalizumab (NTZ) to FTY. Cardiac safety of fingolimod has been questioned after serious adverse events that occurred in the post marketing. The aim of this study was to evaluate safety and efficacy of FTY in a single-center cohort of 102 patients (pts) and to explore the possible role of previous treatment type.

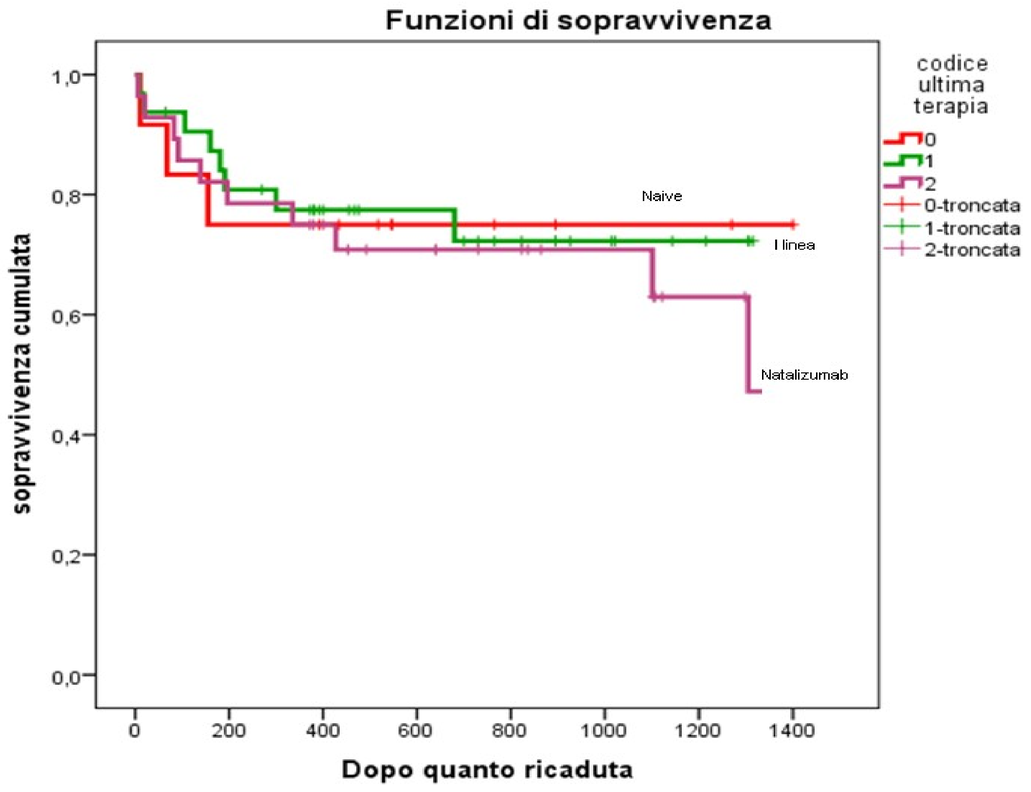
Methods: Data were collected prospectively. Expanded Disability Status Scale (EDSS), annual relapse rate (ARR) and data of safety were assessed in the whole population and in patient groups.

Results: Mean disability remained stable after one year (Y) of observation (3.38 ± 1.9 at baseline vs 3.44 ± 1.9 after 1 Y) while it was worsened after 2 Y and then stabilized after 3 Y. Mean ARR was significantly lower in the first Y of treatment (0.94 ± 2.12) compared to the previous Y (0.28 ± 0.5). We observed a significant efficacy in treatment-naïve pts. Disability was stable regardless of previous ARR; ARR decreased in pts with one relapse in previous Y as well as in those who had experienced two or more relapses. Mean ARR and EDSS did not increase significantly in pts who switched from NTZ. During the first dose administration we observed bradycardia (42.1%), second-degree atrioventricular block (1.9%) and prolonged QTc interval (1.9%). Most frequent AES was asymptomatic elevation of liver enzymes infection (18.6%), headache (15.6%) and increase in blood pressure (7.8%). Maximum decrease in lymphocyte counts in peripheral bloods occurred in the first semester of treatment. Eleven pts discontinued FTY due to inefficacy (N=9) and to mild AEs (N=2). None had severe reactivation after discontinuation.





Discussion and conclusions: We report safety and efficacy data in a "real-world" population, including a significant number of subjects who switched from NTZ. Stability in disability was associated with a marked decrease in mean ARR, regardless of previous disease activity. ARR decreased in patients who had treated with FTY as initial therapy, in pts switched from DMSs and did not increase in those who had been treated with NTZ. Asymptomatic elevation in liver enzymes was the most frequent AEs. In conclusion FTY is a safe and effective option for RRMS treatment-naïve patients and for who failed a first line treatment. Also it represents a good therapy after natalizumab discontinuation.



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