Natalizumab Treatment for Multiple Sclerosis: a 10-years monocentric experience

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Background: Natalizumab (NAT) is a high effective treatment for relapsing-remitting multiple sclerosis (MS). Pivotal trials and post-marketing studies showed prolonged disease-free status for patients on treatment.**Objective:** To evaluate the long-term safety and efficacy of NAT in a monocentric real-world observational study. **Methods:** We collected data of patients who underwent at least one course of NAT since March 2007 at the MS Centre of San Raffaele Scientific Institute. We analysed clinical and radiological data during NAT therapy. We also reviewed medical charts for side effects. **Results:** Of the 555 included patients, 69% were female and mean age at inclusion was 33.5 years. Mean disease duration at time of inclusion was 8.6 years, with a mean number of 1.8 relapses in the year before NAT start. Median baseline EDSS was 3.0 and 88% of patients had an active baseline MRI. Mean follow-up on treatment was 3 years (range 1 month-10 years). During NAT treatment annualised relapse rate dropped to 0.26 and only 38% of patients presented at least one active MRI. The probability of disability worsening was 7% at 5 years, while 20% of patients presented a sustained reduction of disability. At 5-year follow-up the overall probability of "No Evidence of Disease Activity (NEDA 3)"was 47%. The most common adverse event was infection (45%) but less than 1% of the patients had to interrupt treatment due to the severity of infection. Seven percent of patients developed anti-NAT antibodies, which were linked to allergic reactions and poor response to treatment. Unfortunately 2 patients developed progressive multifocal leukoencephalopathy. **Conclusions:** Our data confirm that NAT is to date one of the most effective treatment available and that its benefits are persistent throughout long-term treatment. Our study demonstrated that the drug is well tolerated, improving patients' quality of life. These findings should be carefully pondered, together with information on PML risk stratification, in order to evaluate a personalized benefit-risk profile of NAT.