Although NTZ is usually well-tolerated, infusion-related reactions (IRRs) may occur, and the patients have to be monitored during the infusion and for one hour afterwards” Sacco et al (2019).

Abstract:

BACKGROUND: Natalizumab (NTZ) is a humanized monoclonal antibody used in the treatment of relapsing remitting multiple sclerosis. Although NTZ is usually well-tolerated, infusion-related reactions (IRRs) may occur, and the patients have to be monitored during the infusion and for one hour afterwards.

OBJECTIVE: To identify frequency and severity of IRRs during NTZ infusions and one-hour post-infusion observation period in a clinical practice setting.

METHODS: Multicenter, observational study involving three Swiss (Lugano, St. Gallen and Luzern) and two Italian (Milano and Napoli) tertiary MS centers. Predisposing factors to IRRs were investigated using multivariate Cox regression models.

RESULTS: A total of 11’133 infusions received by 302 MS patients were analyzed (68.9% females, median age 33.6 years, median EDSS 2.5). IRRs occurred in 24 (8%) patients during NTZ infusions and in 7 (2%) during one-hour post-infusion. Only 8 patients needed pharmacological treatment, of whom 7 during NTZ infusion. Age, sex and history of allergies were not associated with risks for IRR. The frequency of post infusion IRRs after the fifth cycle was low compared to that during the first four infusions (0.83% vs 0.06%).

CONCLUSION: In our cohort, NTZ associated IRR mainly occurred during the infusion period compared to the one-hour observational period. Also, the first IRR exclusively occurred within the first 4 NTZ administrations. However, further multi-center studies with a larger sample size are needed to capture rare and serious events that could emerge during the observational period and to make clinical recommendations.

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