

Rituximab in Multiple Sclerosis: importance of the dosing regimen

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Introduction: Rituximab is a monoclonal antibody directed at CD20 positive B-lymphocytes used as an off-label treatment in Multiple Sclerosis (MS), with good efficacy and safety profile. The recommended dosing regimen and the role of lymphocyte population studies remain to be determined. We evaluated the effectiveness and safety of rituximab in MS patients and their relationship with the treatment regimen and the B lymphocyte population study.

Methods: Retrospective observational single-center study of MS patients treated with rituximab for ≥ 6 months. Demographics, dosing regimen, B lymphocyte population study (6 and 12 months after treatment start) and adverse events were analysed. Responders were defined by the absence of relapses, new lesions on follow-up brain imaging and disability progression.

Results: We included 64 patients with relapsing-remitting MS (42.2%), secondary progressive MS with (25%) and without (15.6%) activity, and primary progressive MS with (6.3%) and without (10.9%) activity. Most patients switched from another disease-modifying treatment, mainly natalizumab/fingolimod, due to disease activity/progression (70.3%). Mean treatment duration was 20.16 ± 7.60 months. Mean annual rituximab dose was 1305.47 ± 447.67 mg (400-3000mg) with infusion interval varying between 2-2 and 6-6 months. The responder rate was 65.4%, without differences between disease courses. The group of responders had a lower mean annual dose (1219.05mg vs. 1470.45mg, $p=0.032$) but no significant association with the B lymphocyte population study parameters. There were mild/moderate adverse events in 17 patients and severe infections in 3 patients. In total, 12 patients (7.8%) discontinued rituximab, due to adverse events (5 patients) or disease activity/progression (7 patients).

Discussion: In our clinical population, rituximab showed efficacy in stabilizing the disease. The lower mean annual dose in the responders group seems to support the need for a personalized treatment regimen. It is possible that the role of B lymphocyte study could be related with the inflammatory activity.

Abstract word count: 299