

9-2019

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## Recommended Citation

Smoot, Kyle, "The Impact of Ocrelizumab on Immunoglobulin Levels and the Risk of Infection." (2019). *Articles, Abstracts, and Reports*. 1404.

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## The Impact of Ocrelizumab on Immunoglobulin Levels and the Risk of Infection.

**Background:** Ocrelizumab (OCR), a CD20 antibody, was approved in the US in 2017 for the treatment of relapsing MS (RMS) and primary progressive MS (PPMS). In clinical trials, infection rates are higher in patients receiving OCR. Rituximab, which is very similar to OCR, has been reported to be associated with higher risk of infection particularly in patients with low levels of IgM or IgG. **Objective:** To determine if low levels of IgM or IgG increase the risk of infection in patients treated with OCR. **Methods:** MS patients in the OCR registry with at least one IgM/IgG value at doses 2, 3 or 4 of OCR were included. Levels are obtained within a month of the next dose of OCR. Wilcoxon rank sum and chi-squared tests and linear mixed models and generalized estimating equations were used to examine the relationships between IgM/IgG and infections. **Results:** Of 205 patients included in the analysis, 73.5% were female; mean (SD) age was 52.3 (12.1) years with a mean (SD) disease duration of 13.8 (7.94) years. 72.6% had RMS and 27.4% had PMS. 27.9% of patients were treatment naïve. Infections were seen in 51.2% (n=110) of patients. Mean (SD) age of patients who did and did not have an infection was 51.3 (12.4) and 53.4 (11.8), respectively. Prior exposure to glatiramer acetate was associated with lower rate of infection, 5 of 15 (33%), while prior fingolimod treatment was associated with higher rate of infection, 19 of 34 (56%). Mean (SD) IgM levels were 70.0 (45.4) mg/dL for patients who had an infection and 71.8 (41.0) mg/dL for patients who did not have an infection (p=0.193). Infections were more common in patients who had an IgM level < 45 mg/dL, 41.0% versus 29.1% (p=0.037). Male sex and disease duration were predictors of lower IgM levels. Patients who had infection were 1.85 times more likely to have a below normal IgM level, after adjusting for other factors (95% CI: 1.02, 3.37; p=0.044). Mean (SD) IgG levels were significantly lower for patients with an infection (796 (203) versus 876 (251) mg/dL; p<.001). Longer disease duration was also a predictor of lower levels of IgG, but elevated levels were seen in patients with PMS.

**Discussion:** Reduced levels of serum IgM and IgG predicted increased risk of infection in OCR treated patients. Age did not affect immunoglobulin levels, but disease duration did, possibly due to previous exposure to DMTs. In addition, PMS patients, who are more likely to be treatment naïve, had higher levels of IgG.