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Effect of Ofatumumab on Lymphocytes and Neutrophils in Patients with Relapsing Multiple Sclerosis over 4 Years

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Abstract Text:

Background:

Ofatumumab, a fully human anti-CD20 monoclonal antibody, is approved for the treatment of relapsing multiple sclerosis (RMS) in adults. Anti-CD20 therapies have been associated with neutropenia and an increased risk of infections.

Objectives:

To assess the effect of ofatumumab on lymphocyte and neutrophil levels over 4 years and its association with the risk of serious infections (SIs) during the core and open-label extension studies in RMS patients.

Methods:

Mean absolute lymphocyte/neutrophil levels from baseline (BL) up to Week (W) 216 were analyzed for the overall (N=1969), continuous (ofatumumab in core+extension; N=1292) and switch (teriflunomide core/ofatumumab extension; N=677) groups (cut-off, 25 Sep 2021). The proportions of patients with levels below lower limit of normal [LLN ($10^9/L$): lymphocytes, 0.91; neutrophils, 1.96] at least once or twice consecutively post-BL and their association with the incidence rate (IR, per 100 patient-years) of SIs were assessed. Incidence, severity and outcomes of lymphopenia/neutropenia were reported.

Results:

A transient mean decline in lymphocytes was observed up to W4 (%change: continuous, -11.9%; switch, -8.2%) followed by a reversal and increasing trend close to BL in both groups up to W216. Mean neutrophil levels remained stable and above BL for all visits up to W216 (%change: continuous, 17.8%; post-switch, 18.0%) with rapid increase in levels after switching to ofatumumab (%change at W72: pre-switch, -6.8%; W120: post-switch, 18.7%). Over 4 years, the overall proportion of patients with levels below LLN at least once or twice consecutively were 17.9% (352/1966) and 5.9% (116/1966) for lymphocytes, and 13.6% (267/1966) and 3.1% (60/1966) for neutrophils. The IR of lymphopenia and neutropenia remained low [0.31 (0.19, 0.51)

for both]; most events [lymphopenia (15/16), neutropenia (12/16)] were of Grade 1 or 2 in severity. All patients with Grade 3 events recovered while on ofatumumab; no Grade 4 events were reported. The overall IR of SIs was 1.53 (95% CI: 1.23, 1.91). Only 5/352 (vs 57/1614 \geq LLN) and 1/267 (vs 64/1699 \geq LLN) patients had SIs occurring up to 1 month prior to 1 month after any drop in lymphocytes or neutrophils $<$ LLN, respectively.

Conclusions:

Over 4 years of ofatumumab treatment, mean lymphocyte and neutrophil levels remained stable, levels below LLN were transient for the majority of patients. Few cases of neutropenia and lymphopenia were reported without serious adverse events. Overall incidence of SIs was low with no apparent association with decreased lymphocytes/neutrophils.

Title:

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Preferred Presentation Format:

Poster

Category:

Disease-modifying therapy

Has this abstract been presented/published elsewhere prior to this meeting?:

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No

Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:

No

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| Consortium of MS Centers; 3 University Plaza Dr, Ste 116, Hackensack NJ 07601 | Gave CME at Orlando meeting |
| Consortium of MS Centers; 3 University Plaza Dr, Ste 116, Hackensack NJ 07601 | Secretary of Board of Councilors of CMSC |
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