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Immune Response to Influenza Vaccine in Patients With Relapsing Multiple Sclerosis Treated With Ofatumumab: Results From an Open-Label, Multicenter, Phase 4 Study

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Abstract:
Background: Vaccinations comprise an important component of multiple sclerosis (MS) management. There is currently a need for data regarding whether treatment with ofatumumab (OMB) impacts humoral immune response (HIR) to vaccines, including the influenza vaccine, in patients with relapsing MS (RMS).
Objectives: To report the final results of a prospective phase 4 study (NCT04667117) assessing whether patients with RMS treated with OMB 20 mg every 4 weeks can mount an HIR to the 2020-2021, 2021-2022, or 2022-2023 inactivated influenza vaccine compared with patients treated with interferon or glatiramer acetate (IFN/GA).
Methods: Patients (aged 18-55 years) with RMS were grouped into 3 cohorts: Cohort (C)1 received the influenza vaccine ≥2 weeks before starting OMB; C2 received it ≥4 weeks after starting OMB; and C3 were currently being treated with IFN/GA and received the influenza vaccine ≥4 weeks after enrollment. Patients with recent major infections were excluded. All groups underwent a hemagglutination inhibition (HI) titer before and 4 weeks after vaccination. The primary endpoint was achieving seroprotection to influenza at week 4 (post-vaccination antibody titer ≥40). Secondary endpoints included achieving seroconversion (post-vaccination HI titers ≥4-fold increase or ≥40 in those with pre-vaccination titers ≥10 or <10, respectively) and adverse events (AEs). Only patients who had pre- and post-vaccination antibody titers were included in this analysis.
Results: Sixty-three patients (mean [SD] age, 41.1 [8.5] years; 76.2% female; 85.7% White) were included. The proportions of patients with seroprotection/seroconversion at wk4 among commonly tested strains were as follows: influenza A Cambodia (C1: n=13, 100%/84.6%; C2: n=5, 80%/20%; C3: n=7, 85.7%/42.9%), influenza A Victoria (C1: n=13, 100%/92.3%; C2: n=5, 100%/20%; C3: n=7, 100%/42.9%), influenza A Wisconsin (C1: n=13, 61.5%/46.2%; C2: n=20, 40%/10%; C3: n=16, 68.8%/37.5%), influenza B Phuket (C1: n=18, 77.8%/50%; C2: n=22, 68.2%/18.2%; C3: n=17, 76.5%/41.2%), and influenza B Washington (C1: n=13, 76.9%/38.5%; C2: n=5, 20%/0%; C3: n=7, 71.4%/42.9%). Further information about less commonly assessed strains will be presented. Over the entire study, 16 (72.7%) patients from C1, 6 (27.3%) patients from C2, and 2 (10.5%) patients from C3 experienced ≥1 AE. No AEs resulting in discontinuation were reported and 1 patient from C2 experienced a serious AE (MS pseudo relapse).
Conclusions: Findings from this study suggest that OMB-treated patients with RMS are able to mount an immune response following inactivated influenza vaccination. These results will help to inform the coordination of vaccination and OMB treatment in patients with RMS.

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