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BRIEF REPORT

COVID-19 Vaccination Response in Patients with Multiple Sclerosis Treated with Ofatumumab in the United States: A Medical Record Review

Rahul H. Dave · Heidi Crayton · Augusto Miravalle · Ming-Hui Tai · Kerri Wyse · Katherine Houghton · Abby Hitchens · Regina Berkovich

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ABSTRACT

Introduction: Real-world data are required to provide a greater understanding of the impact of ofatumumab on the ability to mount an effective immune response following the receipt of approved COVID-19 vaccinations. This retrospective real-world analysis aimed to describe the humoral immune response to COVID-19 vaccination during ofatumumab treatment in patients with multiple sclerosis (MS).

Methods: Data from patients with MS treated with ofatumumab who were fully vaccinated against COVID-19 infection were abstracted from medical charts at four clinical sites in the USA. Patient characteristics and humoral response were summarized descriptively. Differences in humoral response were documented on the basis of vaccination status during ofatumumab treatment (i.e., after full vaccination and after booster vaccination) and prior disease-modifying treatment (DMT) exposure (i.e., DMT naïve, prior anti-CD20/sphingosine 1-phosphate [S1P] therapy, prior non-anti-CD20/S1P therapy). The sample size precluded formal statistical analysis.

Results: Thirty-eight patients were included. The mean (standard deviation) duration of ofatumumab treatment upon data collection was 20.4 (4.6) months (treatment ongoing for 35 [92%] patients). Definitive humoral response after full vaccination was documented for 34 patients, of whom 20 (60%) were seropositive. Definitive humoral response after booster vaccination was documented among five patients, of whom three (60%) were seropositive. Among patients who were DMT naïve prior to ofatumumab ($n=15$), 73% were seropositive; among patients exposed to prior anti-CD20/S1P therapy ($n=14$), 33% were seropositive; and among patients exposed to prior non-anti-CD20/S1P therapy ($n=9$), 56% were seropositive. Patients naïve to DMT had been living with an MS

R. H. Dave
Inova Medical Group–Neurology II, Fairfax, VA, USA

H. Crayton
Multiple Sclerosis Center of Greater Washington, Washington, VA, USA

A. Miravalle
Rush University Medical Center, Chicago, IL, USA

M.-H. Tai (✉) · K. Wyse
Novartis Pharmaceuticals Corporation, One Health Plaza East, Hanover, NJ 07936, USA
e-mail: mindy.tai@novartis.com

K. Houghton
RTI Health Solutions, Manchester, UK

A. Hitchens
RTI Health Solutions, Ann Arbor, USA

R. Berkovich
Los Angeles County General Hospital and Clinic, Los Angeles, CA, USA

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diagnosis for a shorter duration than those experienced with DMTs.
Conclusion: Patients with MS receiving ongoing treatment with ofatumumab can mount a positive humoral response to a COVID-19 vaccination. Prior treatment with anti-CD20 or S1P DMTs may be a risk factor for lower humoral response.

Keywords: Coronavirus 2 (SARS-CoV-2); Medical records; Multiple sclerosis; Ofatumumab; Real-world evidence; Vaccination

Key Summary Points

Reduced humoral immunity to SARS-CoV-2 has been demonstrated among patients with multiple sclerosis (MS) receiving treatment with anti-CD20 monoclonal antibodies such as ofatumumab.

This noninterventional retrospective study used real-world historic data to assess the ability of patients with MS receiving ongoing treatment with ofatumumab to mount a humoral immune response to a COVID-19 vaccination.

Patients with MS receiving ongoing treatment with ofatumumab may be able to mount a positive humoral response to a COVID-19 vaccination.

For patients treated with ofatumumab, their prior treatment with anti-CD20 or sphingosine 1-phosphate disease-modifying treatments and older age may be risk factors for a lower humoral response to a COVID-19 vaccination.

INTRODUCTION

Currently, 23 disease-modifying therapies (DMTs) are approved by the US Food and Drug Administration (FDA) for the treatment of multiple sclerosis (MS). Approved DMTs can be administered orally (e.g., fingolimod, teriflunomide), by injection (e.g., interferon beta, glatiramer acetate, ofatumumab), or by infusion (e.g., ocrelizumab, natalizumab) [1]. The effect of DMTs on B cell-mediated (humoral) and T cell-mediated (cell-mediated) immunity varies across DMTs.

Immunity to COVID-19 appears to depend on the combination of humoral and cell-mediated immune responses [2]. Reduced humoral immunity to SARS-CoV-2 vaccination has been demonstrated among patients with MS receiving treatment with anti-CD20 monoclonal antibodies and sphingosine 1-phosphate (S1P) modulators [3–7].

Treatment with anti-CD20s has been associated with severe COVID-19 in patients with relapsing–remitting MS (RRMS). In a retrospective cohort study conducted in France, treatment with anti-CD20 therapy was associated with development of severe COVID-19 in patients with RRMS ($n=51$; adjusted odds ratio, 5.32 [95% CI 2.78–9.71]) [8]. Of note, these patients were older, had more neurologic disability, had received a greater number of anti-CD20 infusions, and were more frequently treated with rituximab than anti-CD20-treated patients who did not experience severe COVID-19 ($n=350$); vaccination status was not shown to impact the association between anti-CD20 therapy and severe COVID-19. Further, ocrelizumab, compared with dimethyl fumarate, was associated with an increased risk of hospitalization and admission to an intensive care unit among patients with suspected or confirmed COVID-19 [9].

Humoral immune response to SARS-CoV-2 vaccines in patients with MS treated with DMTs, including anti-CD20 therapies, has also been assessed in recent years, with varying results dependent on both DMT type and vaccine type [5, 10–14]. These studies have shown an attenuated humoral immune response to SARS-CoV-2 vaccines in some patients treated with anti-CD20 therapies (e.g., ocrelizumab, fingolimod, ofatumumab) and support individualized patient guidance around prevention and control of COVID-19 infection.

Ofatumumab is the first self-injectable, fully human anti-CD20 monoclonal antibody.

Although other anti-CD20 therapies can reduce serum immunoglobulin level concentrations, sustained long-term reductions have not been seen with ofatumumab in clinical trials [15]. Reduced immunoglobulin levels are a risk factor for infections [16]. Recent analyses of data from the long-term extension study evaluating the safety of ofatumumab (ALITHIOS [NCT03650114]) identified 603 of 1703 patients who had laboratory-confirmed COVID-19 infection. Among these cases, 92% were characterized as nonserious, and 99% were either recovered, recovered with sequalae, or were recovering from COVID-19; five (0.8%) COVID-19-infected patients had a fatal outcome [17].

This noninterventional retrospective study used historic data already contained within patient medical records at four community practices in the USA. The aim was to generate real-world data describing the immune response to COVID-19 vaccination during ofatumumab treatment.

METHODS

This was a noninterventional, retrospective, observational cohort study involving the abstraction and review of pertinent data from medical records by participating physicians who completed a customized electronic case report form hosted on a secure electronic data capture system. Data were collected between August 5, 2022 and November 30, 2022. WCG Institutional review Board (IRB) approved a request for a waiver of authorization for use and disclosure of protected health information under 45 CFR 46 116(f) [2018 Requirements] 45 CFR 46.116(d) [Pre-2018 Requirements].

Eligible medical records were from patients diagnosed with MS who were aged 18 years or older upon receipt of their first COVID-19 vaccination, were fully vaccinated with any FDA-authorized COVID-19 vaccination (i.e., received two doses of a two-dose series [Pfizer, Moderna] or received one dose of a single-dose variant [Johnson & Johnson]), were receiving ofatumumab at the time of the full COVID-19 vaccination and/or first booster vaccination, and had a documented measure of humoral response at least 2 weeks after the full vaccination and/or first booster vaccination. Patients who received monoclonal antibodies to treat or prevent COVID-19 at any time between the first COVID-19 vaccination to within 6 months of the last COVID-19 vaccination (booster inclusive) were ineligible.

Data were collected on demographic characteristics, clinical characteristics, ofatumumab treatment, COVID-19 vaccination, and humoral response. Data were summarized descriptively among the total sample. Humoral response data were descriptively analyzed separately on the following basis: vaccination status while receiving ofatumumab (i.e., after full vaccination and after first booster vaccination) and prior DMT experience (i.e., DMT naïve, prior anti-CD20/S1P therapy, and prior non-anti-CD20/S1P therapy). As a result of the small sample size and exploratory nature of the study, no tests for statistical significance were conducted.

RESULTS

Data from a total of 38 patient medical records were included in the study, of whom 36 were receiving ofatumumab at full COVID-19 vaccination and 17 were receiving ofatumumab at first booster vaccination.

Demographic and clinical characteristics for the overall sample and by prior DMT history are shown in Table 1. Most patients (68%) had RRMS. Mean (SD) time from MS diagnosis to initiation of ofatumumab was 6.1 (8.6) years. Fifteen patients were DMT naïve, 14 patients had received anti-CD20/S1P therapy at any time prior to ofatumumab, and nine patients had received non-anti-CD20/S1P therapy at any time prior to ofatumumab. Patients who had not received prior DMT had a shorter duration of time from MS diagnosis to initiation of ofatumumab (0.5 [0.3] years) than patients who had received prior anti-CD20/S1P (11.1 [10.9] years) or non-anti-CD20/S1P (7.4 [6.8] years) therapy.

The mean (standard deviation [SD]) time from initiation of ofatumumab to data collection was 20.4 (4.6) months. Most patients

Table 1 Patient demographic and clinical characteristics

	Overall ($N=38$)	DMT naïve ($N=15$)	Prior anti-CD20/S1P therapy ($N=14$)	Prior non-anti-CD20/S1P therapy ($N=9$)
Age (years), mean (SD)	45.2 (10.9)	45.8 (11.9)	46.9 (9.3)	41.4 (11.9)
Sex, female, *n* (%)	29 (76.3)	11 (73.3)	12 (85.7)	6 (66.7)
MS diagnosis, *n* (%)				
Relapsing–remitting	26 (68.4)	9 (60.0)	9 (64.3)	8 (88.9)
Secondary progressive	4 (10.5)	2 (13.3)	1 (7.1)	1 (11.1)
Primary progressive	8 (21.1)	4 (26.7)	4 (28.6)	0
Time from MS diagnosis (years), mean (SD)	6.1 (8.6)	0.5 (0.3)	11.1 (10.9)	7.4 (6.8)
Number of comorbidities, mean (SD)	2.0 (1.4)	1.9 (1.3)	2.4 (1.5)	1.6 (1.3)
DMTs any time prior to ofatumumab initiation, *n* (%)*				
Ocrelizumab	8 (34.8)	0	8 (57.1)	0
Interferon beta-1b	7 (30.4)	0	5 (35.7)	2 (22.2)
Natalizumab	7 (30.4)	0	4 (28.6)	3 (33.3)
Glatiramer acetate	6 (26.1)	0	5 (35.7)	1 (11.1)
Teriflunomide	6 (26.1)	0	3 (21.4)	3 (33.3)
Dimethyl fumarate	5 (21.7)	0	4 (28.6)	1 (11.1)
Interferon beta-1a	5 (21.7)	0	3 (21.4)	2 (22.2)
Rituximab	5 (21.7)	0	5 (35.7)	0
Alemtuzumab	3 (13.0)	0	1 (7.1)	2 (22.2)
Fingolimod	3 (13.0)	0	3 (21.4)	0
Cyclophosphamide	2 (8.7)	0	0	2 (22.2)
Mitoxantrone	1 (4.3)	0	0	1 (11.1)
Ozanimod	1 (4.3)	0	1 (7.1)	0

DMT disease-modifying therapy, *MS* multiple sclerosis, *S1P* sphingosine 1-phosphate, *SD* standard deviation

*For the Overall column, percentage is calculated on the basis of the number of patients who had previously received a DMT ($N=23$)

($n=29$, 76%) were not receiving any concomitant immunomodulating medication (Table 2). The mean (SD) time from ofatumumab initiation to COVID-19 vaccination was 5.0 (2.9) months among patients receiving ofatumumab at full COVID-19 vaccination and 11.3 (3.2) months among patients receiving ofatumumab at first booster vaccination.

Most patients ($n=31$) were tested only once for antibody immune response following COVID-19 vaccination. Among patients receiving ofatumumab at the time of full COVID-19 vaccination ($n=36$), the mean (SD) time between

Table 2 Ofatumumab treatment and concomitant immunomodulating medications

	Overall ($N = 38$)	DMT naïve ($N = 15$)	Prior anti-CD20/S1P therapy ($N = 14$)	Prior non-anti-CD20/S1P therapy ($N = 9$)
Ofatumumab treatment duration (months), mean (SD)	20.4 (4.6)	21.7 (2.8)	18.6 (6.3)	20.9 (3.4)
Time from initiation of ofatumumab to receipt of last COVID-19 vaccination (months), mean (SD)	5.0 (2.9)	4.4 (1.8)	6.0 (4.1)	4.7 (1.5)
Concomitant immunomodulation medications, *n* (%)				
None	29 (76.3)	14 (93.3)	8 (57.1)	7 (77.8)
Immunomodulating drugs	5 (13.2)	0	5 (35.7)	0
Systemic steroids	2 (5.3)	0	1 (7.1)	1 (11.1)
Hydroxychloroquine	1 (2.6)	0	1 (7.1)	0
Immunosuppressive rheumatoid medications	1 (2.6)	0	1 (7.1)	0
Intravenous immunoglobulin	1 (2.6)	0	1 (7.1)	0
Not documented in the medical record	2 (5.3)	1 (6.7)	0	1 (11.1)

DMT disease-modifying therapy, *S1P* sphingosine 1-phosphate, *SD* standard deviation

the COVID-19 vaccination and the immune response assessment was 1.8 (1.5) months; 32 patients had a definitive humoral response (i.e., excluding patients with indeterminate results), of whom 18 (56.3%) were seropositive.

Among patients receiving ofatumumab at the time of first booster vaccination ($n = 17$), the mean (SD) time between the booster vaccination and the immune response assessment was 4.2 (2.7) months; five patients had a definitive humoral response, of whom three (60%) were seropositive. Among the three seropositive patients, the mean (SD) time between the booster and the assessment was 2.8 (2.1) months. Among the two seronegative patients, one patient was assessed 5 months after the booster and the other was assessed 8 months after the booster; thus, it is unclear whether the seronegative results were an effect of receiving ofatumumab or were due to waiting too long to reassess.

Humoral response by prior treatment experience is shown in Fig. 1. Among patients receiving ofatumumab at the time of full COVID-19 vaccination and who had an evaluable humoral response, 71% (10/14) of DMT-naïve patients were seropositive, 33% (4/12) of patients who had received prior anti-CD20/S1P therapy were seropositive, and 66% (4/6) of patients who had received prior non-anti-CD20/S1P therapy were seropositive. Among patients receiving ofatumumab at the time of first COVID-19 booster vaccination who had a definitive humoral response, 100% (1/1) of DMT-naïve patients were seropositive, no (0/2) patients who had received prior anti-CD20/S1P therapy were seropositive, and 100% (2/2) of patients who had received prior non-anti-CD20/S1P therapy were seropositive.

Following full vaccination among patients aged 40 years or younger who had a definitive humoral response ($n = 12$), 75% were seropositive; among patients older than 40 years with a definitive humoral response ($n = 22$), 50% were seropositive.

Four (11%) patients had documentation of breakthrough infection with COVID-19 following vaccination (at 3.4, 13.6, 12.0, and

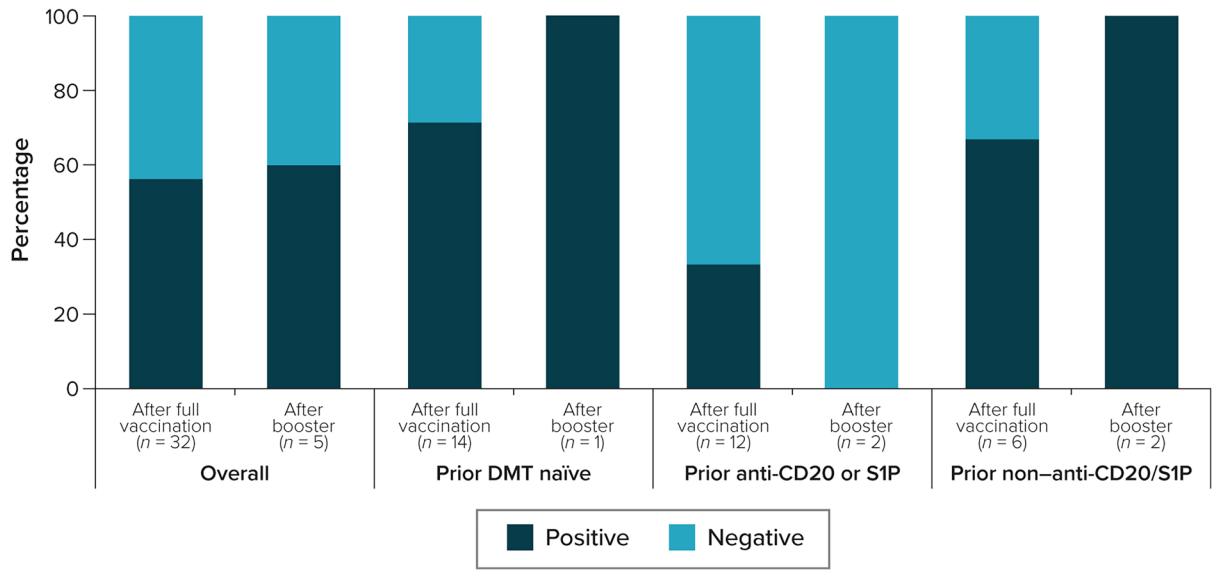

Fig. 1 Humoral response by prior treatment experience. *DMT* disease-modifying therapy, *S1P* sphingosine 1-phosphate

16.0 months, respectively, following full vaccination). Two patients were DMT naïve, one had received anti-CD20/S1P therapy prior to ofatumumab, and one had received non-anti-CD20/S1P therapy prior to ofatumumab. For two of these patients, humoral response was assessed following breakthrough infection: one patient was seropositive and the other had an indeterminate result. For three of the patients who had a breakthrough infection, the infection occurred in the spring/summer of 2022; for the remaining patient, the infection occurred during the summer of 2021.

DISCUSSION

Although existing literature [5] has raised concerns that patients on some B cell-depleting therapies cannot mount an immune response following receipt of FDA-approved vaccines against SARS-CoV-2, we found that 55% of patients in our real-world US sample receiving ofatumumab demonstrated a humoral response following receipt of a vaccine against SARS-CoV-2.

Impairment in postvaccination humoral response has been documented among patients treated with anti-CD20 and S1P therapies [5, 11]. However, studies formally investigating this impairment assessed antibodies at a specified timepoint following vaccination among all recruited patients. Our study was based on retrospective real-world data with no formal plan regarding humoral response assessment: 36 of 38 patients had an assessment following full vaccination, and the timeframe for the assessment was varied (ranging from 2 weeks to 6 months following vaccination).

The cohort of patients who received prior treatment with anti-CD20 or S1P had the lowest percentage of patients with a positive immune response (33%) while a positive immune response was most frequent among patients who had not received anti-CD20 or S1P DMT prior to ofatumumab initiation. Thus, the potential reduction of immunoglobulin levels from prior treatments such as anti-CD20 DMT before ofatumumab may impact humoral immune response. Similarly, a longer duration of DMT has been documented to be associated with lower spike antibody levels compared with healthy controls

[10]. Consistent with our results, a meta-analysis found that receipt of anti-CD20 therapy within 6 months of vaccination was associated with blunted humoral response [11]. However, our study sample size was small, and no statistical comparisons were planned among the subgroups.

This study recruited a sample from real-world practice settings in the USA, which allowed the capture of real clinical practice and effects of interventions among heterogeneous samples outside of controlled settings. However, this study was subject to certain limitations inherent in retrospective reviews of medical records. Patients selected for study inclusion were obtained from the clinical sites identified to participate in the study, which limits external generalizability. Unlike clinical trial settings, the assessment of response to COVID-19 vaccination in real-world clinical practice settings might not be performed consistently across patients and physicians, and data were limited to information available in the patients' medical records held by the clinical sites in the study. Additionally, humoral response may not completely capture vaccine effectiveness, as preclinical evidence suggests a potential role for memory $CD8^+$ T cells in mediating protection [15]. Finally, as a result of the small sample size and exploratory nature of the study, no tests for statistical significance were conducted. Given these limitations, this study should be considered hypothesis-generating, thus the results will require confirmation with larger, prospectively obtained datasets.

CONCLUSION

Patients with MS receiving ongoing treatment with ofatumumab may be able to mount a positive humoral response to COVID-19 vaccination. Prior treatment with anti-CD20 or S1P DMTs and older age may lead to poor humoral response, suggesting a further assessment is needed to explore these risk factors.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Rahul H. Dave has received honoraria for speaking engagements and consulting activities from Biogen, Bristol Myers Squibb, EMD Serono, Genentech, Novartis, Sanofi, and TG Therapeutics and has also received honoraria for the provision of clinical trial support to EMD Serono, Inova, and Novartis. Heidi Crayton has served as a consultant for Biogen, Bristol Myers Squibb,

EMD Serono, and Sanofi Genzyme; has received research support from Biogen, EMD Serono, Novartis, Roche/Genentech, and Sanofi Genzyme. Augusto Miravalle has received honoraria for consulting activities, research grants, and speaker fees from Alexion, Biogen, Bristol Myers Squibb, EMD Serono, Genentech, Novartis, Sanofi Genzyme, and TG Therapeutics. Ming-Hui Tai and Kerri Wyse are employees and stockholders of Novartis Pharmaceuticals Corporation. Katherine Houghton and Abby Hitchens are salaried employees of RTI Health Solutions, a research organization that provides consulting services to pharmaceutical companies; they did not receive compensation for participating in this work and do not have any other conflicts of interest. Regina Berkovich has received honoraria for speaking engagements, serving on scientific advisory boards, and consulting activities from Alexion, Amgen, ANI Pharmaceuticals, Biogen, EMD Serono, Mallinckrodt Pharmaceuticals, Novartis, Sanofi, and TG Therapeutics.

Ethical Approval. On November 2, 2021, WCG IRB approved a request for a waiver of authorization for use and disclosure of protected health information (PHI) under 45 CFR 46 116(f) [2018 Requirements] 45 CFR 46.116(d) [Pre-2018 Requirements]. This review was conducted through expedited review.

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