Ocrelizumab in Multiple Sclerosis: Comparing Treatment-Naïve versus Non-Naïve Patients in Home Infusion

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Background

Multiple sclerosis (MS) is a chronic autoimmune disease that affects the central nervous system. According to the National Multiple Sclerosis Society, there are nearly one million people in the United States that have MS.[1] In MS, the body's immune system mistakenly attacks myelin, which is the protective coating around nerve fibers. This damage causes inflammation, scarring, and nerve damage.

There are four main types of MS which are classified according to the progression of symptoms over time: relapsing-remitting MS, secondary-progressive MS, primary-progressive MS, and progressive-relapsing MS. The most prevalent phenotype at diagnosis is relapsing-remitting MS (RRMS), in which patients experience symptoms in forms of attacks, while in between attacks, people recover or return to their usual level of disability. The periods in which no attacks occur are called remission. Over time, RRMS transitions to a more progressive disease (secondary progressive MS or SPMS) in most untreated patients. Primary progressive MS (PPMS) is less common and characterized by a steady worsening of symptoms from disease onset, with no phases of remission.[2-3]

In 2017, the FDA approved ocrelizumab for treatment of adult patients with relapsing or primary progressive forms of MS. Ocrelizumab is a monoclonal antibody that specifically targets CD20, a protein found on the surface of B cells. By binding to CD20, ocrelizumab depletes B cells, reducing the abnormal immune response that contributes to the damage of myelin in MS patients.[4] According to the American Academy of Neurology (AAN) practice guidelines for disease-modifying therapies (DMT) for adults with MS, ocrelizumab is the only starting DMT shown to alter disease progression in patients with PPMS who are ambulatory. When switching, none of the DMTs are completely effective against relapsing and MRI activity, and when a patient shows breakthrough disease activity, a different mechanism or efficacy profile may be beneficial. Current evidence supports higher efficacy of alemtuzumab, natalizumab, fingolimod, and ocrelizumab.

When considering switching DMTs in patients with relapsing MS, tolerability, likelihood of adherence, disease activity, adverse event profiles, and mechanism of action should be evaluated. While there are studies that evaluate safety and patient satisfaction for at home ocrelizumab administration for MS, there is less literature describing the tolerability (naïve versus non-naïve) of long-term treatment of ocrelizumab.[5-6]

Purpose

The primary objective of this study was to assess the tolerability of ocrelizumab for Multiple Sclerosis in home infusion patients by identifying adverse drug reactions reported by participants who are naïve versus non-naïve to MS treatment. This research focused on identifying factors behind discontinuation rates to provide evidence-based information for treatment decisions and optimizing patient care.

Methods

This was a retrospective, multi-center, chart review spanning a 2-year time period which was determined to be exempt by IRB. Data was collected from the electronic medical record and internal surveillance software. Patients aged 18 years or older with a confirmed diagnosis of Multiple Sclerosis who have received ocrelizumab were included. Patients were categorized as naïve versus non-naïve to therapy for Multiple Sclerosis. Baseline demographics, duration of therapy, and discontinuation rates with reasoning were reviewed.

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Wafa Daher; Christopher Roy; Maria Giannakos; Melissa Ostrander; Olivia Hanley: Nothing to disclose.

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Table 1: Patient Demographics and Disease Characteristics by Study Cohort

Characteristic, *n* (%)[a]	ADR home infusion cohort (*n*=106)
Age, mean (SD), years	39.9 (10.8)
Sex	
Female	74 (69.8)
Male	32 (30.2)
MS type	
RRMS	63 (80.8) [78][b]
PPMS	14 (17.9) [78][b]
SPMS	1 (1.3) [78][b]
Unspecified	28 (26.4)
Previous DMT therapy	
Non-Naïve	63 (63.6) [99][b]
Naïve	36 (36.4) [99][b]
Unspecified	7 (6.6)
Ocrelizumab duration [c], mean (SD), years	1.45 (1.06)

[a] data represented at n (%), unless otherwise stated
[b] denotes number of patients with available information
[c] includes 300 mg or 600 mg dose

Figure 1: Discontinuation Rates Post ADR

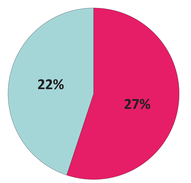
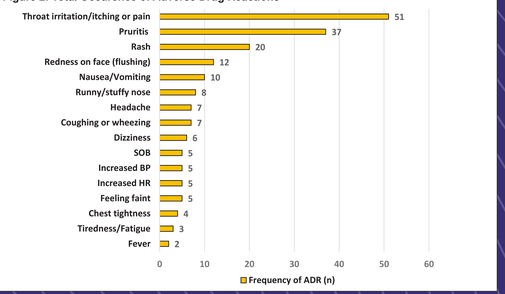


Figure 2: Total Occurence of Adverse Drug Reactions



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Results

In this retrospective analysis, a total of 4,059 patients met the inclusion criteria and were evaluated. Among these patients, 106 patients (2.6%) had reported an adverse drug reaction (ADR). The patient demographics for this subset of patients are highlighted in Table 1. This group (ADR home infusion cohort) consisted of 74 (69.8%) females and 32 (30.2%) males with an average age of 40 (19-72). Sixty-three patients were non-naive and 35 patients were naive to DMT therapy. The non-naïve patients had a history of prior DMT exposure, with medications including interferon beta-1a, interferon beta-1b, glatiramer acetate injection, ofatumumab, dimethyl fumarate, fingolimod, teriflunomide, diroximel fumarate, rituximab, alemtuxumab, daclizumab, mitoxantrone, and/or peginterferon beta-1a.

Discontinuation of these prior therapies was attributed to factors such as side effects, allergic reactions, disease progression, insurance limitations, pregnancy, and patient preference for alternative treatment options. After chart review, 63 patients had a confirmed diagnosis of RRMS, 14 had PPMS, 1 had SPMS, and 28 were diagnosed with unspecified MS. The average duration of ocrelizumab treatment (300 mg or 600 mg) in patients that experienced ADRs was 1.45 years.

Of the 106 patients that had ADRs (88 patients on 600 mg and 18 patients being on 300 mg), 51% of patients continued their infusion despite the reaction, while 49% discontinued after experiencing ADRs. As shown in Figure 1, among the group who discontinued future ocrelizumab infusions, 27% attributed the decision to the ADR. The remaining 22% discontinued due to reasons unrelated to the ADR, such as insurance, non-compliance with treatment, or relocation. All patients received pre-medications of methylprednisolone (100-125 mg orally or intravenously), diphenhydramine (25-50 mg orally or intravenously), and acetaminophen (500-1000 mg orally). Three patients required the administration of epinephrine.

Common ADRs shown in Figure 2 included throat irritation/itching or pain, itchy skin, rash, flushing, nausea/vomiting, runny/stuffy nose, and coughing or wheezing. A more detailed discussion of ADR management strategies can be found in the discussion section. These findings highlight the prevalence and characteristics of ADR observed in patients receiving ocrelizumab infusions. The following discussion will explore the clinical implications of these results.

Discussion

Ocrelizumab was administered intravenously according to the following regimen: initial doses consisted of two 300 mg infusions separated by two weeks. The infusion rate was gradually increased starting at 30 mL/hour and reaching a maximum of 180 mL/hour for a duration of 2.5 hours or longer. Subsequent doses where 600 mg administered every six months, with the infusion rate starting at 100 mL/hour and increasing in stages over 60 minutes to a maximum of 300 mL/hour with a duration of two hours or longer.

In patients experiencing ADRs, management often involved decreasing the infusion rate by half, and supportive medications administered as needed, including diphenhydramine, methylprednisolone, acetaminophen, hydration, and in some cases epinephrine. Despite experiencing ADRs, 98 out of 120 ADR reported, continued their infusions to completion, while 22 were discontinued. Five of those who initially discontinued their infusion later re-challenged ocrelizumab and tolerated it well. Three patients received epinephrine to manage severe ADRs.

In the subgroup of patients experiencing ADRs that necessitated epinephrine administration (n=3), the first patient tolerated the infusion after a rate reduction and continued ocrelizumab without further complications. The second patient developed hives and itchiness, leading to infusion interruption and transfer to higher level of care. Importantly, all patients who received doses of epinephrine due to an ADR were able to tolerate subsequent ocrelizumab infusions without further complications.

This study analyzed a large real-world dataset of 4,059 patients on ocrelizumab (300 mg or 600 mg). The study found that 106 patients (2.6%) experienced an adverse drug reaction. Twenty-eight patients (0.69%) permanently discontinued taking ocrelizumab due to these ADRs. These findings highlight the overall tolerability of ocrelizumab Notably, a significant proportion of patients had prior exposure to other DMT therapies, suggesting that ocrelizumab may be a suitable option even for patients who have not tolerated previous treatments. However, it is important to acknowledge the limitations of this retrospective study, such as reliance on clinical notes for data extraction and lack of patient-reported outcomes.

Conclusions

In conclusion, this study provides valuable insights into the tolerability of ocrelizumab in the home infusion setting. The low discontinuation rate due to ADRs, observed in a diverse patient population with multiples sclerosis, suggests that home infusion can be a feasible and effective treatment option for many patients. These findings, when considered alongside previous studies that evaluated patient-reported outcomes, safety, and efficacy, further support the conclusion that ocrelizumab is a promising treatment option for MS and may have important implications for clinical practice and future treatment decisions.

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