

Ocrelizumab and Rituximab in Multiple Sclerosis: A Single-Centre Retrospective Cohort

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Abstract

Objective: To describe the real-world outcomes and safety of anti-CD20 therapy—ocrelizumab (OCR) and rituximab (RTX)—in adults with multiple sclerosis (MS) treated at a single centre.

Methods: This was a retrospective, single-centre, observational cohort study of 75 patients who underwent therapy with OCR ($n = 37$) or RTX ($n = 38$). The primary outcome was the Expanded Disability Status Scale (EDSS) score at baseline and the last follow-up. Relapses and MRI activity were not systematically recorded and were therefore not analysed. Safety outcomes included any adverse event (AE), serious AE, infection-related AE, and death. Two-sided 95% confidence intervals (CIs) and exploratory standardised mean differences (Hedges' g) were recorded.

Results: The mean age was 34.1 ± 9.6 years, and 88% of patients had relapsing-remitting MS, while 12% had secondary progressive MS. EDSS decreased from 2.43 (95% CI 2.13–2.73) to 1.69 (95% CI 1.22–2.16; $P = 0.014$) overall, from 2.74 (95% CI 2.23–3.25) to 1.78 (95% CI 1.14–2.42; $P = 0.021$) in the OCR subgroup, and from 2.11 (95% CI 1.79–2.43) to 1.56 (95% CI 0.84–2.28; $P = 0.23$) in the RTX subgroup. Between-group differences were moderate at baseline (Hedges' $g \approx 0.48$) and trivial at follow-up (Hedges' $g \approx 0.11$). Relapses were reported descriptively: 4/75 (5.3%; 95% CI 2.1–12.9) overall; 0/37 (0.0%; 0.0–9.4) on OCR and 4/38 (10.5%; 4.2–24.1) on RTX. AEs occurred in 6/75 (8.0%; 3.7–16.4), and one death (meningitis) occurred in an RTX-treated patient.

Conclusion: In this retrospective, single-centre study, anti-CD20 therapy was associated with the stabilisation or improvement of disability and low overall AE rates. Considering the small sample size, baseline imbalances, and incomplete relapse/MRI capture, the superiority of OCR and RTX cannot be inferred. The findings are exploratory and underscore the need for larger, prospective, multicentre cohorts to determine comparative effectiveness and support value-conscious treatment selection.

Keywords: Expanded disability status scale (EDSS), multiple sclerosis, ocrelizumab, rituximab treatment naïve

Introduction

Multiple sclerosis (MS) is a chronic, immune-mediated disease of the central nervous system characterised by inflammatory demyelination and neurodegeneration. MS remains a leading cause of non-traumatic neurological disability in young adults. The disease substantially affects the quality of life and work productivity across the lifetime.^{1,2}

Advances in disease-modifying therapies (DMTs) have transformed MS care by reducing relapse rates and delaying disability progression. A decade of mechanistic and clinical evidence has established the central role of B cells in the pathogenesis of MS, leading to the development and widespread clinical adoption of anti-CD20 monoclonal antibodies. Currently available anti-CD20 agents used for MS include rituximab, ocrelizumab, ofatumumab, and ublituximab. Pivotal randomised trials have demonstrated that ocrelizumab reduces disease activity in relapsing MS (OPERA I/II) and slows disability progression in primary progressive MS (ORATORIO), whereas ofatumumab and ublituximab reduce relapses compared to teriflunomide (ASCLEPIOS I/II; ULTIMATE I/II).^{3–6}

Despite the central role of anti-CD20 therapy, direct head-to-head randomised comparisons between anti-CD20 agents are still lacking, and most comparative evidence comes from observational cohorts. For example, a nationwide registry study reported a higher relapse risk with rituximab than with ocrelizumab in routine practice, whereas randomised non-inferiority trials directly comparing rituximab and ocrelizumab are ongoing. Consequently, agent selection is individualised and is often shaped by regulatory status/availability (e.g., the

WHO added rituximab to the Essential Medicines List in 2023), cost/coverage considerations, administration/dosing, safety, and patient preferences through shared decision-making.^{7–9}

Monitoring treatment responses in MS typically integrates several domains: clinical relapses, MRI activity (new/enlarging T2 or gadolinium-enhancing lesions), and disability measures such as the Expanded Disability Status Scale (EDSS). International guidelines recommend routine magnetic resonance imaging (MRI) to monitor response and safety, along with clinical assessment. Composite targets such as NEDA-3 (no relapses, no MRI activity, and no confirmed worsening of the EDSS) reflect this multidomain approach. The EDSS remains the most widely used clinical metric for disability, and is routinely applied in real-world settings to benchmark outcomes.^{10–12}

This study aimed to describe a retrospective, single-centre, real-world experience with ocrelizumab and rituximab in adults with MS, focusing on EDSS as the primary outcome and summarising safety outcomes. Between-group comparisons were exploratory.

Materials and Methods

This was a retrospective, single-centre observational study conducted at King Abdulaziz University, Jeddah, which included 75 adults with MS who presented to the Neurology MS clinic and were receiving ocrelizumab or rituximab (RTX). All patients fulfilled the 2017 revised McDonald's criteria¹³ and did not have any other neurological disease. The study was approved by the ethics committee of

King Abdulaziz University and was conducted in accordance with the principles of the Declaration of Helsinki.

Data regarding baseline characteristics of the patients were collected, including the patients' age, disease duration, age at onset, sex, type of MS, and history of previous medications received before introducing ocrelizumab (OCR), RTX, as well as any side effects experienced. The EDSS was assessed.¹⁴ The scores range from 0 to 10, with higher scores indicating greater disability. The **primary outcome** was the EDSS scores at baseline and at the last follow-up. Relapse counts and MRI activity were not consistently recorded in the source charts; therefore, they were not analysed in this study. Safety outcomes included treatment-emergent adverse events (AE), serious AE, infection-related AE, and death.

Statistical Analysis

Statistical analyses were performed using SPSS v25 (IBM Corp.). Data were reported as *n* (%) or mean $\pm$ SD (with range/median where informative). The Mann-Whitney U test was used for independent non-normally distributed variables, and the Wilcoxon signed-rank test was used for paired baseline-follow-up comparisons. Spearman's correlation was used to assess associations. Two-sided 95% CIs were calculated for the mean (*t*-distribution) and proportions (Wilson's method). Reported exploratory standardised mean differences (Hedges' *g*) were also used for OCR–RTX EDSS comparisons. The analyses used the available data without imputation. Owing to the modest sample size and limited covariates, multivariable adjustment and paired change effect sizes were limited and are acknowledged as study limitations. Two-sided *P*-values < 0.05 were considered statistically significant.

Results

The mean age, disease duration, and age of disease onset were 34.1 ± 9.6 years, 6.2 ± 5.1 , and 28 ± 8.5 years, respectively. The female-to-male ratio was 1.3:1. The characteristics of treatment-naïve or previously treated patients receiving OCR or RTX are presented in Table 1.

Four patients in this study who underwent OCR therapy were above 50 years of age, and of those, only two (2.7%) had an onset at >50 years (Late-onset MS). Conversely, 2 patients (2.7%) who received RTX had paediatric-onset MS (aged 12 and 13 years). Relapse counts were not systematically captured across all visits and were descriptively reported. Relapse was observed after RTX in four cases: two once, one twice, and one thrice. One of these patients developed two new radiographic lesions after treatment. No relapse was observed in the OCR group. AEs occurred in 6/75 patients overall, with 4/37 (10.8%) patients in the OCR and 2/38 (5.3%) in the RTX group experiencing AEs. The patient who died was an RTX-treated patient, and the cause of death was meningitis. The AE types were as follows: in the OCR group, 3 patients had recurrent mild infections ($n = 3$), and one patient had neutropenia ($n = 1$). Conversely, in the RTX group, 1 patient had a urinary tract infection requiring intravenous antibiotics ($n = 1$), and 1 patient had meningitis with a fatal outcome ($n = 1$).

EDSS scores changed significantly after treatment with OCR and RTX ($P = 0.014$) compared to treatment with OCR alone ($P = 0.021$) (Figure 1). For all patients, baseline EDSS was 2.43 (95% CI 2.13–2.73) and follow-up EDSS was 1.69 (95% CI 1.22–2.16). In the OCR group ($n = 37$), baseline EDSS was 2.74 (95% CI 2.23–3.25) and follow-up EDSS was 1.78 (95% CI 1.14–2.42). In the RTX group ($n = 38$), baseline EDSS was 2.11 (95% CI 1.79–2.43) and follow-up EDSS was 1.56 (95% CI 0.84–2.28). The between-group difference in EDSS was moderate at baseline (Hedges' *g* ≈ 0.48) and trivial at follow-up (Hedges' *g* ≈ 0.11). The EDSS at baseline and after receiving OCR or RTX was comparable between the treatment-naïve patients and those previously exposed to other DMT ($P = 0.34$ and $P = 0.85$, respectively). The baseline EDSS score was similar across the various previous treatment options ($P = 0.74$).

The baseline ($P = 0.25$) and follow-up ($P = 0.53$) EDSS scores, age ($P = 0.28$), disease duration ($P = 0.59$), age at onset ($P = 0.74$), type of MS ($P = 0.14$), and duration of OCR or RTX treatment were similar between males and females. However, the treatment before receiving OCR or RTX was significantly different ($P = 0.003$), as more females were receiving interferon

Table 1. Characteristics of the multiple sclerosis patients receiving ocrelizumab or rituximab

Parameter mean $\pm$ SD or <i>n</i> (%)	MS cases (<i>n</i> = 75)			
	All (<i>n</i> = 75)	OCR (<i>n</i> = 37)	RTX (<i>n</i> = 38)	<i>P</i>
Age (years)	34.13 $\pm$ 9.63	37.59 $\pm$ 9.45	30.76 $\pm$ 8.66	0.002
Disease duration (years)	6.22 $\pm$ 5.09	6.71 $\pm$ 5.49	5.72 $\pm$ 4.66	0.41
Age at onset (years)	28.02 $\pm$ 8.47	30.86 $\pm$ 8.91	25.11 $\pm$ 6.97	0.003
Gender F:M	45:30 (1.5:1)	20:17 (1.2:1)	25:13 (1.9:1)	0.086
Type:				
RRMS	66 (88)	31 (83.8)	35 (92.1)	0.28
SPMS	9 (12)	6 (16.2)	3 (7.9)	
Treatment-naïve	37 (49.3)	16 (43.2)	21 (55.3)	0.3
Relapse	4 (5.3)	0 (0)	4 (10.5)	–
Side effects	6 (8)	4 (10.8)	2 (5.3)	0.39
Mortality	1 (1.3)	0 (0)	1 (2.6)	–

MS, multiple sclerosis; OCR, ocrelizumab; RTX, rituximab; RRMS, relapsing-remitting MS; SPMS, secondary progressive; EDSS, expanded disability status scale. Bold values were considered significant at $P < 0.05$.

(16.7% vs. 9.1%), OCR (4.8% vs. 0%), and teriflunomide (7.1% vs. 0%), while more males were receiving glatiramer acetate (9.1% vs. 2.4%) and natalizumab (6.1% vs. 0%), and 12.1% of males received unspecified treatment. The number of treatment-naïve patients was similar between females and males (50% vs. 48.5%, respectively).

When comparing the history of treatment based on the type of MS patients had, none of those with secondary progressive MS (SPMS) were treatment-naïve. Notably, the age (47.3 ± 10.9 years vs 32.3 ± 7.97 years, $P = 0.003$) and disease duration (13.88 ± 8.29 years vs 5.28 ± 3.66 years, $P = 0.02$) were significantly different from those with RRMS. Conversely, the age at onset was similar between the two groups ($P = 0.08$).

The correlations of EDSS scores before and after receiving OCR or RTX with age, disease duration, age at onset, and duration of treatment are presented in Table 2.

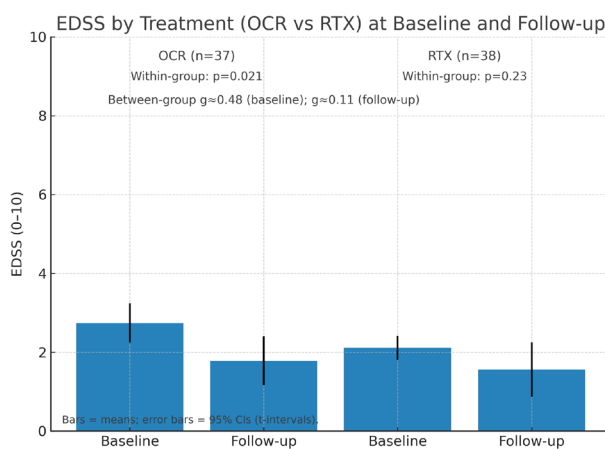


Fig. 1 EDSS by Treatment (OCR vs RTX) at Baseline and Follow-up. The bars in Figure 1 show the mean EDSS scores, and the error bars indicate 95% confidence intervals (*t*-intervals). The patients were divided into two groups: the ocrelizumab group (OCR; $n = 37$) and the rituximab group (RTX; $n = 38$), with Baseline and Follow-up data displayed for each treatment. Within-group changes were assessed using the Wilcoxon signed-rank test (OCR: $P = 0.021$; RTX: $P = 0.23$). Exploratory between-group standardised mean differences (Hedges' g) were ≈ 0.48 at baseline and ≈ 0.11 at follow-up. The EDSS scores ranged from 0–10.

Discussion

In this single-centre retrospective cohort, disability measured using the EDSS improved overall and within the ocrelizumab (OCR) subgroup, whereas the between-group difference at follow-up was small (Hedges' $g \approx 0.11$). OCR-treated patients were older and started with a moderately higher baseline EDSS score than those treated with rituximab (RTX); therefore, regression to the mean and baseline imbalances likely influenced the magnitude of the change. Relapses were not systematically captured; descriptively, none were recorded for OCR, whereas four were recorded for RTX. Adverse events (AE) were infrequent overall (any AE, 8.0%); OCR was associated with recurrent mild infections ($n = 3$) and neutropenia, whereas RTX was associated with one serious urinary tract infection and one meningitis-related death. Given the small sample size, variable follow-up period, and incomplete relapse/MRI capture, these observations were best interpreted as exploratory rather than comparative.

Our observations are consistent with broader evidence that suggests that anti-CD20 therapy is effective in MS. OCR reduced relapse and disability progression compared to interferon beta-1a in relapsing MS (OPERA I/II) and slowed progression in primary progressive MS (ORATORIO).^{5,15} RTX reduced inflammatory activity and relapse in a phase II RRMS trial (HERMES) and showed a signal in younger patients with active PPMS in OLYMPUS. However, the primary endpoint was not met in the overall PPMS cohort.^{16,17} Although direct head-to-head randomised comparisons between OCR and RTX have not been reported, an observational nationwide analysis suggested a higher relapse risk with RTX than with OCR, which is used in routine practice (no difference in disability accumulation), underscoring the impact of dosing heterogeneity and residual confounding in real-world data.^{5,15}

Safety in our cohort was dominated by infections, which mirrors the trial/post-marketing experience with anti-CD20 therapy; serious infections were uncommon in pivotal OCR trials but warrant vigilance with prolonged B-cell depletion.^{5,15} Given the small sample size, we cannot infer differential safety between agents. A single meningitis death in a patient receiving RTX emphasises standard infection risk mitigation and prompts careful and rapid evaluation of febrile illness.

Table 2. Correlation of the expanded disability status scale (EDSS) before and after receiving ocrelizumab or rituximab with the age, disease duration, age at onset, and duration of treatment in multiple sclerosis patients

Parameter <i>r</i> (<i>P</i>)	EDSS before and after treatment in MS cases ($n = 75$)					
	All ($n = 75$)		OCR ($n = 37$)		RTX ($n = 38$)	
	Before	After	Before	After	Before	After
Age (years)	0.28 (0.018)	0.3 (0.015)	0.35 (0.04)	0.43 (0.007)	0.14 (0.41)	0.17 (0.4)
Disease duration (years)	0.14 (0.23)	0.17 (0.18)	0.002 (0.99)	0.03 (0.86)	0.27 (0.12)	0.38 (0.049)
Age at onset (years)	0.2 (0.09)	0.22 (0.08)	0.22 (0.19)	0.3 (0.07)	0.1 (0.59)	0.06 (0.75)
Treatment duration (years)	0.19 (0.12)	0.17 (0.17)	−0.05 (0.78)	0.16 (0.33)	0.42 (0.013)	0.15 (0.48)

EDSS, expanded disability status scale; MS, multiple sclerosis; OCR, ocrelizumab; RTX, rituximab; RRMS, relapsing-remitting MS; SPMS, secondary progressive disease. Bold values were considered significant at $P < 0.05$.

Because OCR and RTX both share the CD20 target and deplete B cells, clinicians sometimes consider them substitutable; however, in the absence of head-to-head randomised data and given the observational signal favouring OCR for relapse outcomes, clinical interchangeability cannot be concluded from the current evidence. Treatment selection is best individualised using the clinical phenotype, age/comorbidity, prior therapies, administration preferences, local availability/coverage, and shared decision-making.

Cost and accessibility are crucial for many health systems. RTX, used off-label in MS, has a favourable cost/access profile, has been implemented successfully in resource-constrained settings, emphasises good effectiveness and generally low serious AE rates, and highlights feasibility where resources are limited. The World Health Organisation will add rituximab to the Essential Medicines List for MS in 2023, reflecting its role when access to labelled agents is restricted.¹⁸ In Saudi Arabia, a national clinical-economic evaluation found that rituximab was more effective and less costly than natalizumab for RRMS, with large average drug-cost differences favouring RTX. Although Ocrelizumab was also included in the evaluation framework, the key pairwise difference driving value was RTX vs. natalizumab.¹⁹ These data, along with the rising prevalence of MS in the Kingdom (≈ 40.4 per 100,000 overall; ≈ 61.9 per 100,000 Saudi nationals), emphasise the importance of affordable high-efficacy options.²⁰ Accordingly, where both agents are readily available, OCR's phase-3 evidence-based and labelled indications are advantageous. Conversely, in resource-limited settings, RTX is a reasonable alternative when OCR is unavailable or unaffordable, provided appropriate screening and monitoring are in place.²¹

The EDSS remains the most widely used clinical metric of disability in MS and is routinely applied in real-world settings; nonetheless, as an ordinal, non-linear scale weighted toward ambulation, it is less sensitive to cognition and upper-limb function, which may attenuate detectable treatment effects over short intervals.¹⁴

Limitations

This retrospective, single-centre observational study involved a relatively small cohort and, in many cases, a short follow-up period, limiting generalisability. This study was neither

designed nor powered to conclude the comparative efficacy of OCR and RTX. Treatment allocation was non-random and may have been affected by confounding indications and baseline imbalances (e.g., age and baseline EDSS). Analyses were performed on available data without imputation. Moreover, multivariable adjustment was limited by the sample size and covariate availability. We reported two-sided 95% confidence intervals to convey the precision of the estimates. Since outcomes focused primarily on the EDSS, relapse and MRI activity were not systematically captured, and adverse events were collected retrospectively. These constraints limit causal inference and underscore the need for larger prospective multicentre cohorts with standardised outcomes and adequate adjustments for confounders.

Conclusions

Both ocrelizumab and rituximab were associated with stabilisation or improvement in disability in this cohort, with low overall AE rates. In this small study, we found no clear safety or efficacy signals favouring a single agent. In settings with reliable access to either agent, OCR's labelled indications and randomised trial evidence base favour the choice of OCR for treatment. Conversely, RTX offers a pragmatic, cost-conscious alternative in settings where cost or availability constrains choices.

Conflict of Interest

The authors declare no conflicts of interest.

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Declaration of Generative AI in Scientific Writing

ChatGPT (OpenAI) was employed to improve word choice and sentence structure. The author assessed and edited the output as needed and assume full responsibility for the manuscript's content. ■

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