

REAL-WORLD EVALUATION OF OCRELIZUMAB: EFFICACY AND SAFETY IN PATIENTS WITH MULTIPLE SCLEROSIS

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BACKGROUND AND IMPORTANCE

Multiple sclerosis (MS) is a chronic autoimmune disease causing inflammation and neurodegeneration in the central nervous system, resulting in physical and cognitive disability. Despite available treatments, there remains a need for therapies that effectively slow disease progression while maintaining a favorable safety profile. Ocrelizumab, a monoclonal antibody targeting CD20-positive B cells, is used, but real-world evidence on its efficacy and safety is still limited.

AIM AND OBJETIVES

To evaluate the real-world efficacy and safety of ocrelizumab in patients with multiple sclerosis. The study aims to assess its impact on disability progression, measured by confirmed disability progression (CDP), as well as on relapse rates and the incidence of adverse events over at least 12 months of therapy.

MATERIAL AND METHODS

Retrospective observational study  January 2018 – March 2025
At least 2 doses

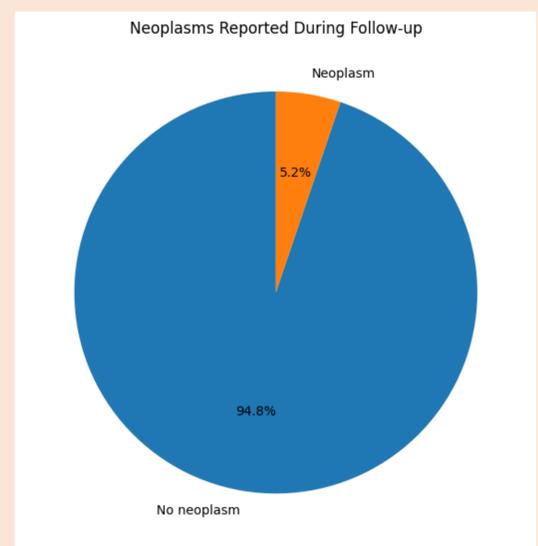
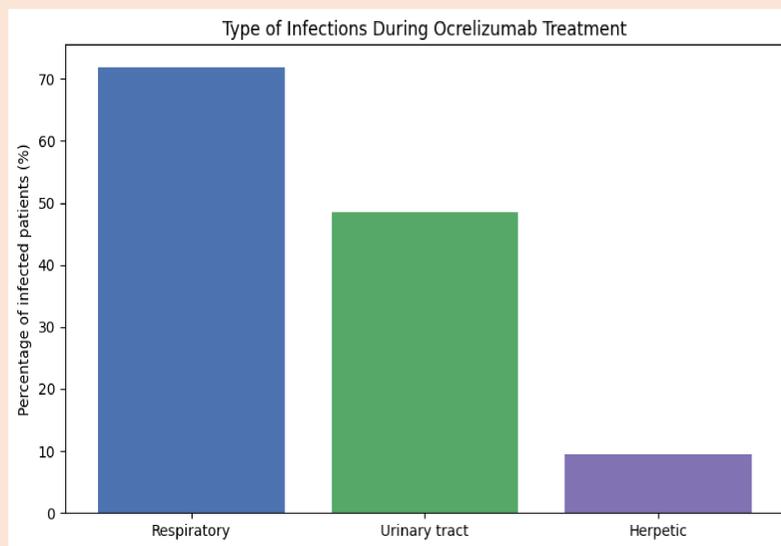
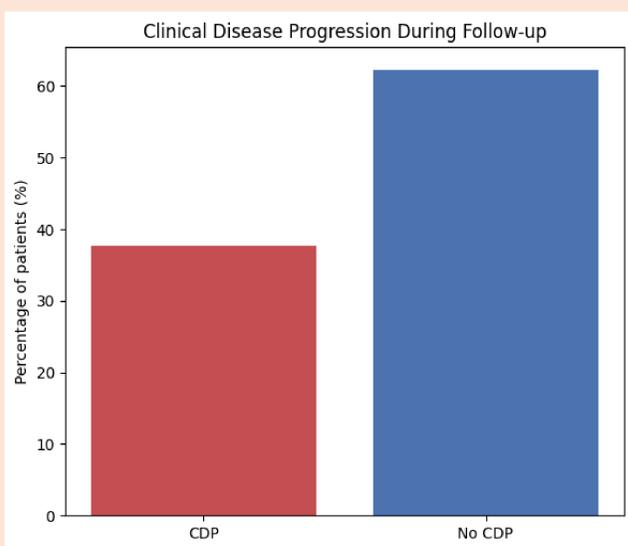
Variables collected



1. Age and sex
2. Efficacy assessments
 - Relapse rates
 - Disability outcomes using EDSS and confirmed disability progression (CDP)
 - CDP defined by EMA criteria: increase of ≥ 1.0 point from baseline if ≤ 5.5 , or ≥ 0.5 if > 5.5
3. Safety assessments:
 - Laboratory parameters
 - Infections
 - Neoplasms
 - Severe lymphopenia (< 200 cells/ μ L)

RESULTS

n=77 patients 63,2% women Age: 43 ± 8.8 years



No elevated liver enzymes or severe lymphopenia ($< 200/\mu$ L) were observed. However, lymphocyte counts significantly decreased at 12 months (mean $-284.1 \pm 871.7/\mu$ L, $p = 0.024$)

CONCLUSION AND RELEVANCE

- ✓ Ocrelizumab demonstrated clinical stability in MS patients, with low relapse rates and moderate disability progression.
- ✓ Infections were frequent but generally manageable, with no severe hepatic or hematologic toxicity observed.
- ✓ The incidence of neoplasms underscores the importance of continued long-term safety monitoring in real-world clinical practice.

