Real-World Effectiveness of Ofatumumab in Relapsing Multiple Sclerosis: Single-Center Experience From a Large Italian MS Cohort

Mangialardi V[1], Iaffaldano A[1], Teofilo A[1], Vitobello R[1], Oggiano F[1], Bianco A[1], Guerra T[1], Caputo F[1], Iaffaldano P[1], Manni A[1], Paolicelli D[1]

1 Department of Translational Biomedicine and Neurosciences-DiBraiN, University of Bari "Aldo Moro", Bari, Italy, Bari, Italy

Introduction

Ofatumumab (OFA), a fully human anti-CD20 monoclonal antibody administered subcutaneously, is approved for the treatment of relapsing multiple sclerosis (RMS). While randomized controlled trials have established the efficacy of OFA, complementary real-world data are needed to support its use in routine clinical practice

Objective

To evaluate the effectiveness and predictors of response to OFA in a real-world cohort of RMS patients

Methods

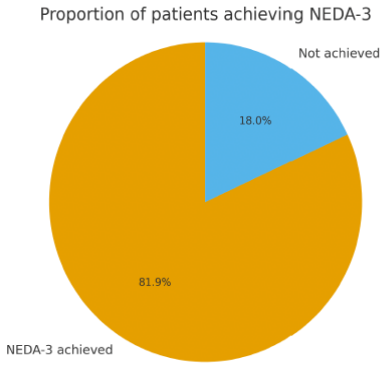
We performed a longitudinal, retrospective analysis of 248 RMS patients treated with OFA at the MS Center of Bari, Italy, between 13 March 2022 and 23 March 2025. Effectiveness endpoints included annualized relapse rate (ARR), confirmed disability progression (CDP), MRI activity, and achievement of No Evidence of Disease Activity-3 (NEDA-3). A multivariate analysis was conducted to identify baseline predictors of clinical and radiological outcomes.

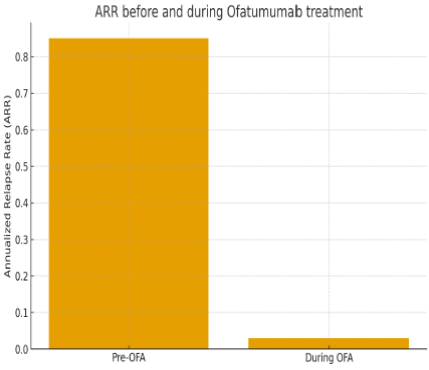
Results

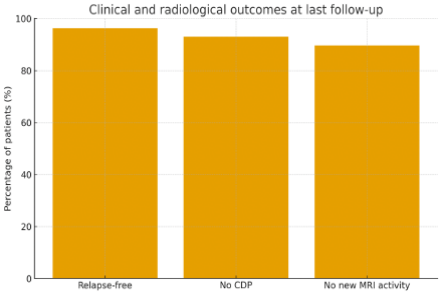
Mean follow-up was 1.46 years (± 0.86). At OFA initiation, mean age was 37.31 years (± 10.83), 32.4% were treatment-naïve, mean EDSS was 2.91 (± 1.32), and disease duration was 8.73 years (± 8.44).

Treatment with OFA resulted in a 96% reduction in ARR, decreasing from 0.83 pre-treatment to 0.03 during therapy ($p < 0.01$). At last follow-up, 96.31% of patients were relapse-free, 93.04% showed no CDP, and 89.66% had no new MRI activity. Overall, 81.95% of patients achieved NEDA-3.

Shorter disease duration at baseline was independently associated with a reduced risk of gadolinium-enhancing lesions during OFA treatment ($p < 0.001$).







Conclusion

This large real-world cohort confirms the high effectiveness of OFA in controlling disease activity in RMS. Earlier treatment initiation appears to be associated with a lower risk of MRI activity.

1. Hauser SL, Bar-Or A, Cohen JA, Comi G, Correale J, Coyle PK, Cross AH, de Seze J, Leppert D, Montalban X, Selmaj K, Wiendl H, Kerloeguen C, Willi R, Li B, Kakarieka A, Tomic D, Goodyear A, Pingili R, Häring DA, Ramanathan K, Merschhemke M, Kappos L; ASCLEPIOS I and ASCLEPIOS II Trial Groups. Ofatumumab versus Teriflunomide in Multiple Sclerosis. N Engl J Med. 2020 Aug 6;383(6):546-557. doi: 10.1056/NEJMoa1917246. PMID: 32757523.

2. Hauser SL, Zielman R, Das Gupta A, Xi J, Stoneman D, Karlsson G, Robertson D, Cohen JA, Kappos L. Efficacy and safety of four-year ofatumumab treatment in relapsing multiple sclerosis: The ALITHIOS open-label extension. Mult Scler. 2023 Oct;29(11-12):1452-1464. doi: 10.1177/13524585231195346. Epub 2023 Sep 11. PMID: 37691530; PMCID: PMC10580679.