Real-World Safety and Effectiveness of Ofatumumab in Relapsing-Remitting Multiple Sclerosis: A Multicenter Observational Study

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Introduction

Ofatumumab is a fully human monoclonal antibody that targets **CD20**-positive B lymphocytes. It was first approved by the FDA in 2009 for chronic lymphocytic leukemia (CLL) and later, in 2020, for relapsing forms of multiple sclerosis (**RMS**) in adults. With its expanding use across different clinical settings, careful evaluation of its safety and effectiveness in real-world practice is increasingly important.

Aim

To evaluate **safety, efficacy, and tolerability** of ofatumumab in patients with relapsing-remitting multiple sclerosis (RR-MS) in real-world clinical practice.

Method

This multicenter, observational, retrospective-prospective study includes approximately **285 patients** recruited from 11 centers located in Trentino-Alto Adige, Veneto, and Friuli Venezia Giulia, with enrollment continuing as new patients are identified. Data—including clinical history, laboratory results, MRI findings, and ofatumumab treatment details—were collected from medical records and routine follow-up visits. Outcomes assessed include safety, tolerability (adverse events, laboratory abnormalities) and effectiveness (relapse rate, EDSS progression, and MRI activity).

Results

Characteristic	Total (n=285)
Age, mean (SD), years	39.8 (10.8)
Women, n (%)	196 (68.8%)
Desease duration, mean (SD), months	98.7 (100.7)
EDSS score at baseline, mean (SD)	2.12 (1.55)

Fig 1 – Baseline characteristics of the study population

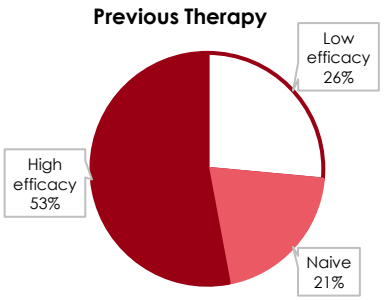

Fig 2 – Previous treatment prior to initiation of Ofatumumab

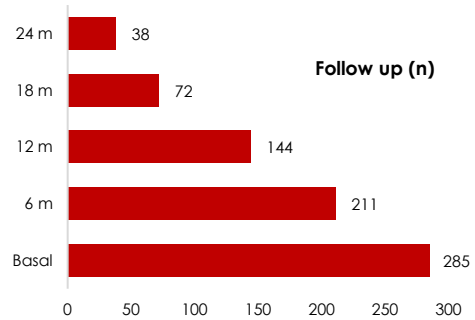

Fig 3 – Patient follow-up since initiation of Ofatumumab therapy

During follow-up, **no clinical relapses** were observed in the study population. At the 6-month MRI, only 3% (n=8) of subjects showed **new lesions**, and an additional 5 patients developed new lesions at later follow-up. Specifically, there was no significant change in EDSS scores between baseline and 12 months (Wilcoxon test: p = 0.614). **Adverse events** were reported in 20.1% of patients, most commonly following the first injection; these events were generally mild, and only two patients discontinued treatment due to adverse effects.

Conclusions

Ofatumumab demonstrated a good safety and effectiveness profile in patients with RR-MS, with stable disability scores and low rates of mild adverse events. These findings support its use as a therapeutic option in real-world clinical practice.