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Real-World Effectiveness of Ofatumumab in Relapsing-Remitting Multiple Sclerosis

PIRA/PIRMA and Clinical Outcomes

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INTRODUCTION

Progression independent of relapse and magnetic resonance imaging activity (PIRA/PIRMA) is increasingly recognized as a key contributor to disability accumulation in multiple sclerosis (MS). Real-world evidence (RWE) is essential to evaluate whether high-efficacy therapies, such as ofatumumab, effectively limit both inflammatory activity and progression.

OBJECTIVES

To assess the real-world effectiveness of ofatumumab in reducing disease activity and PIRA/PIRMA in treatment-naïve and previously treated patients with relapsing-remitting MS (RRMS) over three years.

METHODS

This multicenter RWE study enrolled patients with RRMS treated with ofatumumab across six MS centers in Poland. Demographic and clinical data were collected, including annualized relapse rate (ARR), Expanded Disability Status Scale (EDSS), and MRI activity (new T2 and gadolinium-enhancing [Gd+] lesions). PIRA and PIRMA were assessed over a three-year follow-up. Statistical significance was assessed using Mann-Whitney U and Wilcoxon signed-rank tests, with p< 0.05 considered significant.

RESULTS

In the analysis 438 patients with RRMS treated with OFA across six Polish MS centers were included. Women accounted for 68.7% of the cohort, the mean age at disease onset was 30.47 ± 8.74 years, and the median time from disease onset to ofatumumab initiation was 2.67 years (IQR, 0.34–8.35). At baseline, de novo-treated patients had lower disability but greater inflammatory activity than switchers: EDSS 1.59 vs 1.96, ARR 0.75 vs 0.35, Gd+ lesions 1.16 vs 0.38, and T2 lesions 1.20 vs 1.20. The annual number of relapses decreased from 0.50 before OFA initiation to 0.09 in year 1, 0.06 in year 2, and 0.10 in year 3 (p<0.0001). New T2 lesions decreased from 1.20 at baseline to 0.17, 0.12, and 0.00, while Gd+ lesions decreased from 0.64 to 0.01, 0.04, and 0.00, respectively. Mean EDSS changed from 1.83 at baseline to 1.91 at year 3 (p=0.0043). PIRA decreased from 10.82% in year 1 to 8.68% in year 2 and 7.37% in year 3; PIRMA was 10.05%, 7.94%, and 8.90%, respectively. Relapse activity remained suppressed in both treatment-naive patients and switchers, and new Gd+ and T2 lesion counts were 0.00 in both treatment-history groups. Lymphocyte counts remained comparable to baseline at month 36. Among patients with treatment-status data, 93.3% continued OFA, and no safety signals were identified.

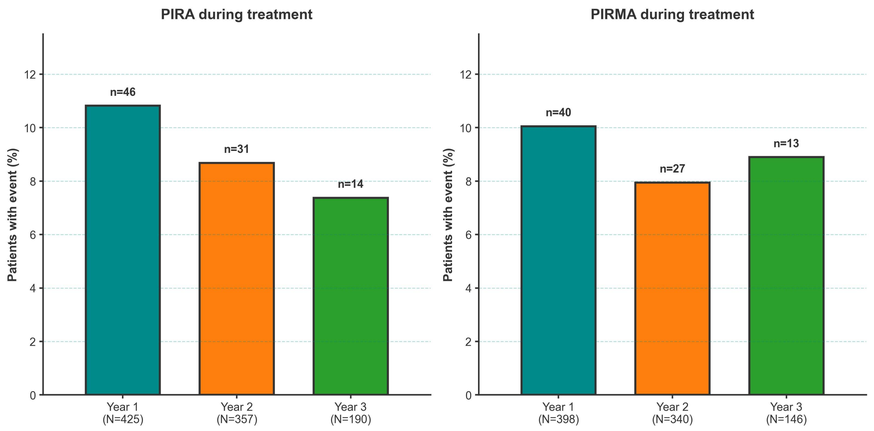

Figure 3. Proportions of patients with progression independent of relapse activity (PIRA; left) and progression independent of relapse and MRI activity (PIRMA; right) at years 1, 2, and 3. Counts above bars indicate events (n); denominators below the x-axis indicate patients with available data (N). PIRA occurred in 46/425 (10.8%), 31/357 (8.7%), and 14/190 (7.4%) patients; PIRMA occurred in 40/398 (10.1%), 27/340 (7.9%), and 13/146 (8.9%), respectively. Denominators vary across years; therefore, percentages should not be interpreted as longitudinal within-cohort trends.

CONCLUSION

Ofatumumab demonstrates high real-world effectiveness in reducing inflammatory disease activity and is associated with a decrease in PIRA and PIRMA over three years. These findings support its role in limiting both relapse-related and relapse-independent disease progression in RRMS. RWE data complement clinical trial findings and provide important insights into treatment performance in routine clinical practice.

CONTACT INFORMATION

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RESULTS

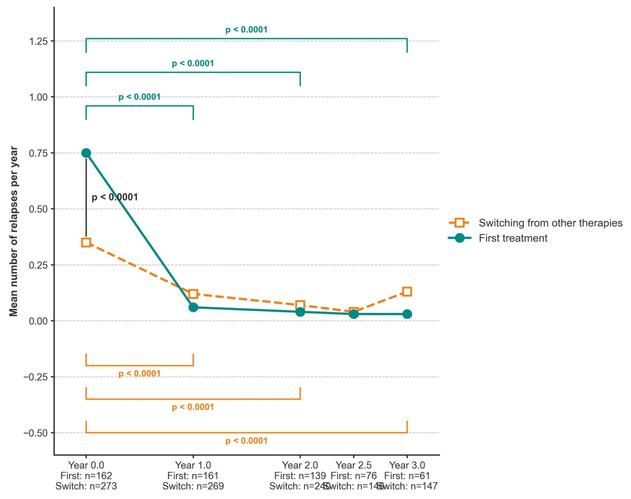

Figure 1. Mean annualized relapse rate (ARR) at baseline and years 1, 2, 2.5, and 3 in treatment-naïve patients ("First treatment") and patients switching from other therapies. Sample sizes at each time point are shown below the x-axis. Baseline ARR was higher in the first-treatment group than in switchers (p < 0.0001). Compared with baseline, ARR decreased significantly at years 1, 2, and 3 in both groups (all p < 0.0001).

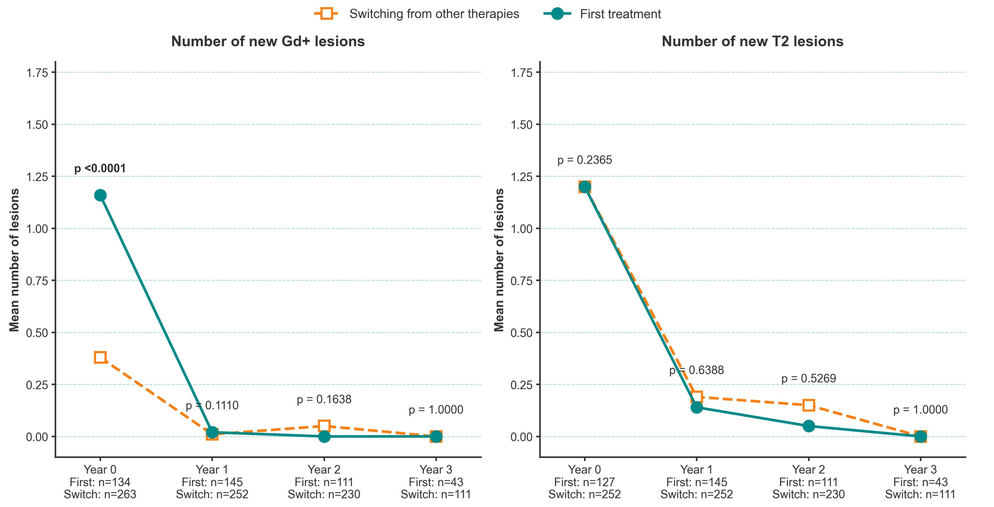

Figure 2. Mean numbers of new gadolinium-enhancing (Gd+) and new T2 lesions at baseline and years 1, 2, and 3 in treatment-naïve patients ("First treatment") and patients switching from other therapies. Sample sizes are shown below each time point. *P* values indicate between-group comparisons. Baseline Gd+ lesion counts were higher in treatment-naïve patients (p < 0.0001); no significant between-group differences were observed at follow-up.

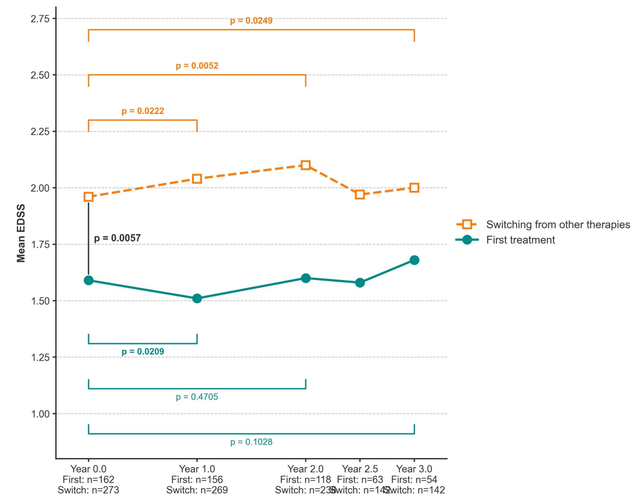

Figure 4. Mean Expanded Disability Status Scale (EDSS) scores at baseline and years 1, 2, 2.5, and 3 in treatment-naïve patients ("First treatment") and patients switching from other therapies. Sample sizes at each time point are shown below the x-axis. Brackets indicate comparisons with baseline; p values are color-coded by treatment group. The baseline between-group comparison was p = 0.0057.

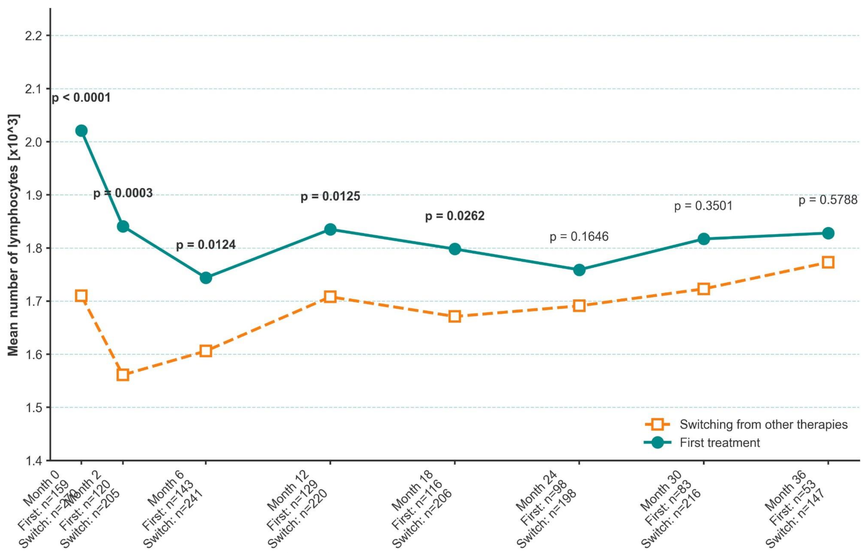

Figure 5. Mean absolute lymphocyte counts (×10³/μL) at baseline and months 2, 6, 12, 18, 24, 30, and 36 in patients receiving ofatumumab as their first treatment and those switching from other therapies. Sample sizes are shown at each time point. *P* values indicate between-group comparisons; differences were significant through month 18, but not at months 24, 30, or 36.