Real-world efficacy and safety of Ofatumumab for the treatment of highly active Multiple Sclerosis: the San Raffaele Hospital single-centre experience

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Introduction and Aims: Ofatumumab (OFA) is an anti-CD20 monoclonal antibody approved to treat Relapsing Multiple Sclerosis (RMS). Clinical trials demonstrated its efficacy, safety, and tolerability, but post- marketing data remain limited.

Our aims:

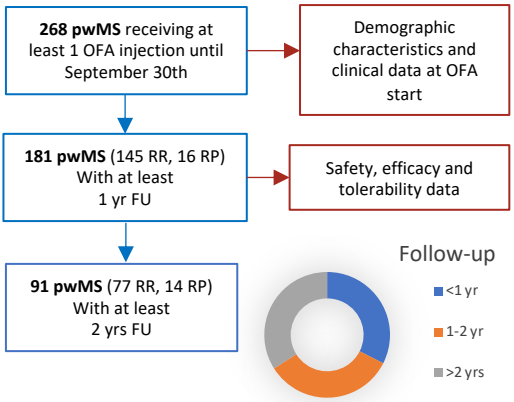
to present our real-world experience in terms of:

- characteristics of patients treated with OFA;
- efficacy, safety and tolerability in patients with at least 1 year follow-up (FU).

Methods:

268 pwMS starting OFA at our centre were enrolled and prospectively followed up. Demographic characteristics and clinical data at OFA initiation, were collected.

181 pwMS had received OFA for at least 1 year: of this subgroup, efficacy and safety data were obtained.

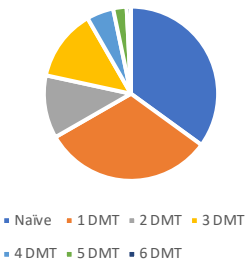


Results

Demographic and clinical baseline characteristics of the whole population	
Age - mean (SD)	38.1 (±9.6)
Female sex - n° (%)	190 (70.9)
EDSS - median (range)	2.0 (0.0-8.0)
Disease Duration – median (range)	7.0 (0.4-40.8)

Discontinuation of OFA: 3/268 pwMS

- 2/268 severe neutropenias
- 1/268 drug-induced liver injury



94 pwMS were **treatment naïve (35%),** while the remaining 174 pwMS (65%) had been treated with at least another disease modifying therapy (DMT), with a prevalence of '**early switchers**' (pwMS treated with just 1 previous DMT) (**29,3%**). (see Graph.)

Motivations of switch were:

efficacy (122–70,1%), safety (25–14,4%) and positivity to test Stratify (27–15,5%).

Efficacy and safety on the 1-yr FU population:

A total of **181 pwMS had at least 1 year FU** (mean follow up 1,75±0,67 yr).

Efficacy at 1 year FU:

Clinical relapses: 0/181 pwMS
6-mo MRI activity: 15/181 pwMS (no Gd+ lesions)
12-mo MRI activity: 3/181 pwMS (no Gd+ lesions)

- Efficacy persisted in 91 patients with at least 2 yrs FU
- CD19+ lymphocyte count was available at 3/6 and 12 months in 105/181 patients: all showed B-cells depletion (mean 0.06%±0.001), persisting at 1 year.

Safety: No premedication was administered. Treatment was well tolerated. (see Tab.)

In the entire population only 3 patients discontinued OFA: 2 for severe neutropenia, 1 for drug-induced liver injury.

Adverse events on the 1 yr FU population	
Injection-related Reactions	
Fever, n (%)	
• After first injection	63 (34.8)
• After titration	8 (4.4)
Allergic Reactions, n (%)	0
Hypogammaglobulinemia, n (%)	1 (0.6)
Infections	
Mild-to-moderate Infections, n (%)	21 (11.6)
Severe/opportunistic Infections, n (%)	0

Discussion and conclusions: According to our experience, Ofatumumab is mainly prescribed to young, naïve or early switchers patients, with short disease duration and low disability. Our real-world data suggest that it is effective, safe and well tolerated. Longer FU is needed for confirmation.

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References:

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2.Hauser, S. L. et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. N Engl J Med 383, 546–557 (2020).