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SAFETY PROFILE OF FINGOLIMOD IN REAL WORLD CLINICAL PRACTICE: A PRELIMINARY STUDY

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INTRODUCTION

- Fingolimod is an approved drug for Relapsing–Remitting Multiple Sclerosis (RRMS). Oral treatments allow a better quality of life than injectable drugs, but are not harmless.

PURPOSE

- To assess fingolimod safety in patients with RRMS in clinical practice.

MATERIAL AND METHODS

Cross-sectional, retrospective and observational study of a cohort of patients diagnosed of RRMS from a referral hospital in this pathology. A random sample was taken from the total of treated patients during 2016-2017 years in order to study long-term safety profile.
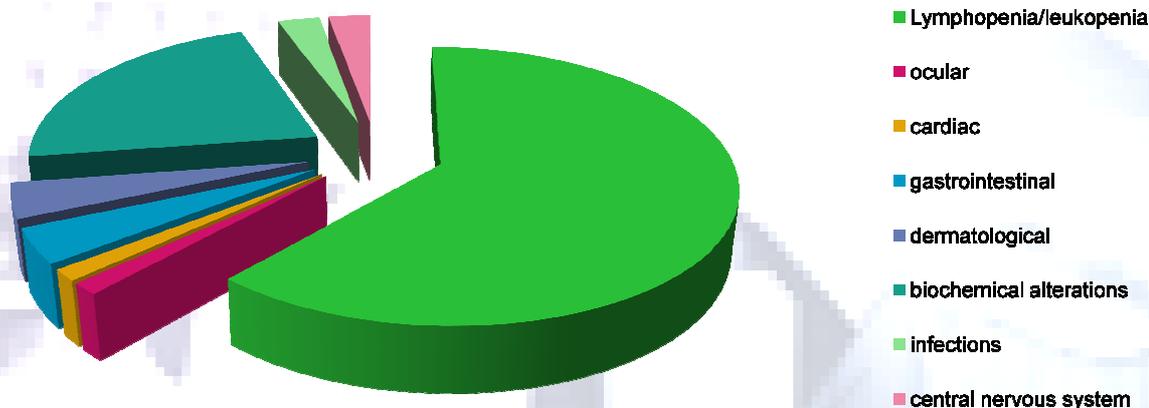
The following variables were collected: demographic, clinical and therapeutic (treatment duration, adverse events (AE), and causes of treatment discontinuation and dosing reduction by extension of administration interval to 48 hours).

RESULTS

50 patients were included (mean age: 41,6±9 years, 64% females). Mean duration of therapy: 3,4±2,5 years.

AE reported during treatment were: Lymphopenia/leukopenia: 90% (grade 4: 2%, grade 3: 58%, grade 2: 28% and grade 1: 2%), ocular (2% maculopathy), cardiac (2% first-degree atrioventricular block during first dose), gastrointestinal (6%), dermatological (6%: 2% alopecia, 2% dermographism and 2% skin rash), biochemical alterations (22% elevation of transaminases, 10% hypercholesterolemia and/or hypertriglyceridemia), infections (4% recurrent urinary infections), central nervous system (4% headaches/migraines).

Definitive interruption of therapy had to be performed in 10% of patients. Most patients in our sample are still in treatment nowadays. Causes were: maculopathy, dermographism, atrio-ventricular block, elevated transaminase levels and oncological lesion. On the other hand, in 4% of patients a temporal discontinuation of therapy was carried out until resolution or improvement of the AE (2% grade 4 lymphopenia and 2% severe hypertransaminemia). In 24% of patients an extension of drug interval to 48 hours was performed to minimize drug exposure and to reduce the intensity of the AE (22% grade 3 lymphopenia and 2% hypertansaminemia).

- Lymphopenia/leukopenia
- ocular
- cardiac
- gastrointestinal
- dermatological
- biochemical alterations
- infections
- central nervous system

CONCLUSIONS

The most common undesirable effect in our study population is lymphopenia/leukopenia, followed by transient elevation of liver enzymes, as described in the drug's summary of product characteristics.

The extension of drug interval to 48 hours is an efficient alternative in those patients with good response to the drug but who develop AE that may compromise the success of therapy. Prospective studies with a larger sample size are needed to confirm these preliminary results.