Background and importance  Fingolimod is an approved drug for relapsing–remitting multiple sclerosis (RRMS). Oral treatments allow better quality of life than injectable drugs but are not harmless.

Aim and objectives To assess fingolimod safety in patients with RRMS in clinical practice.

Material and methods A cross sectional, retrospective, observational study was conducted in a cohort of patients diagnosed with RRMS from a referral hospital in this pathology. A random sample was taken from the total number of treated patients during 2016–2017. The following variables were collected: demographics, and clinical and therapeutic variables (treatment duration, adverse events (AE), and causes of treatment discontinuation and dosing reduction by extension of administration interval to 48 hours).

Results Fifty patients were included (mean age 41.6±9 years, 64% women) and mean duration of therapy was 3.4±2.5 years.

AE reported during treatment were: lymphopenia/leucopenia 90% (grade 4, 2%; grade 3, 58%; grade 2, 28%; and grade 1, 2%); ocular (2% maculopathy); cardiac (2% first degree atrioventricular block during the first dose); gastrointestinal (6%); dermatological (6%); alopecia, 2% dermatomusculoskeletal and skin rash); biochemical alterations (22% elevation of transaminases, 10% hypercholesterolaemia and/or hypertriglyceridaemia); infections (4% recurrent urinary infections); and CNS (4% headaches/migraines).

Definitive interruption of therapy was performed in 10% of patients. Causes were: maculopathy, dermatomusculoskeletal, atrioventricular block, elevated transaminase levels and oncological lesion. In 4% of patients, temporary discontinuation of therapy was carried out until resolution or improvement in AE (2% grade 4 lymphopenia and 2% severe hypertransaminasemia). In 24% of patients, an extension of the drug interval to 48 hours was performed to minimise drug exposure and to reduce the intensity of AE (22% grade 3 lymphopenia and 2% hypertransaminasemia).

Conclusion and relevance The most common undesirable effect in our study population was lymphopenia/leucopenia, followed by transient elevation in liver enzymes, as described in the drug’s summary of product characteristics. The extension of the 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.