



NEW ORAL THERAPIES IN RELAPSING REMITTING MULTIPLE SCLEROSIS: SAFETY PROFILE EVALUATION

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Background

Teriflunomide and dimethyl-fumarate (DMF) are two new oral drugs for relapsing-remitting multiple sclerosis (RRMS). Due to the lack of experience in the management of these drugs, we realized a study to provide some knowledge.

Objectives

To evaluate the safety profile and the adherence to new oral treatment of RRMS in actual practice.

Key words: dimethyl fumarate, teriflunomide, security.

Methods

Observational, descriptive, cross-sectional study in a community hospital.

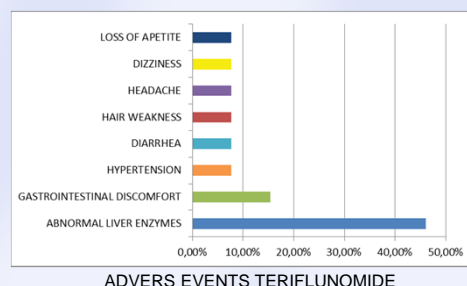
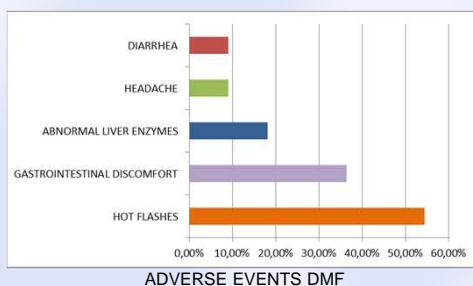
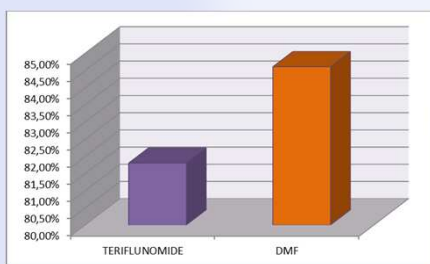
All patients with RRMS who started treatment with teriflunomide or DMF from January to May 2015. Data was obtained from blood test and information from pharmaceutical care visits.

We recorded demographic variables, line of treatment and adverse effects. Adherence was measured using Morisky-Green and Haynes-Sackett test.

Results

24 patients (13 teriflunomide, 11 DMF) were included, representing 30.4% of patients with multiple sclerosis treatment. In the group of teriflunomide (38.5% women, mean age 50.5 years, SD 7.8), 76.9% of patients were pretreated, half were prescribed in second line treatment and the other half in third. 84.6% were adherent. Most common adverse events recorded in pharmaceutical care visits were: abnormal liver enzymes in 46.1% of patients, gastrointestinal discomfort in 15.4% and hypertension, diarrhea, hair weakness, headache, dizziness and loss of appetite with 7.7% each one. 1 patient discontinued treatment because diarrhea and another one by abnormal liver enzymes three times the upper limit of normality.

Of all the patients treated with DMF (54.5% women, mean age 41 years SD 9.4) 10 were pretreated, 80% in second line. Adherence was correct in 81.8%. The most common side effects were hot flashes in 54.5% of patients, gastrointestinal discomfort in 36.4%, abnormal liver enzymes in 18.2%, headache and diarrhea with 9.1% each one. Not available data from 3 patients because they were in the first month of treatment. No patient discontinued treatment due to adverse effects.



Conclusions

The withdrawal rate due to adverse effects with teriflunomide was not negligible.

In the group of DMF was not evaluable because short follow-up time.

Adherence was lower in the group treated with DMF. This effect may be associated with worst dosage (BID) than teriflunomide (QD).

Monthly pharmaceutical care visits has allowed us to know the safety profile of new oral drugs for RRMS in actual clinical practice and intervene in enhancing adherence.