Safety and Efficacy of Dimethyl Fumarate in Patients with Relapsing Remitting MS (RRMS) in a Community Setting

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BACKGROUND

Dimethyl fumarate is a new oral disease modifying therapy approved in March 2013 to treat RRMS. It has demonstrated efficacy and safety in a number of large multicenter phase III clinical trials. However, its benefit in real world MS patients is still not well known.

OBJECTIVES

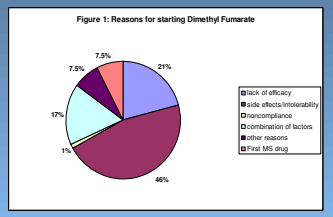
To report the safety and efficacy of dimethyl fumarate when used in MS patients followed in a community hospital MS center.

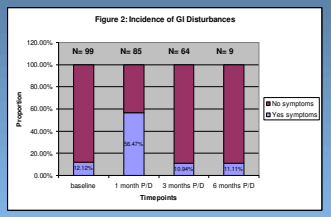
METHODS

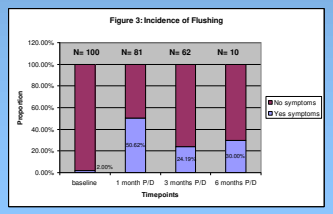
We retrospectively reviewed the charts of all our RRMS patients treated with dimethyl fumarate since its approval in March 2013. Number of clinical relapses and potential side effects were studied.

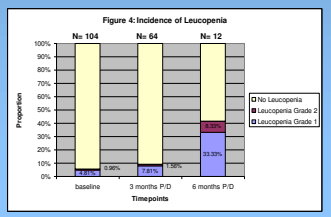
RESULTS

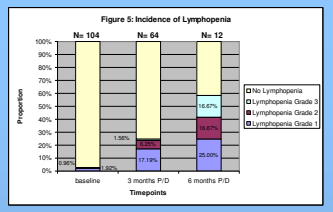
We had 104 patients, 73 women (70.2%) and 31 men (29.8%), with a mean age of 50.3 years. Patients were followed for a mean of 4.5 months.

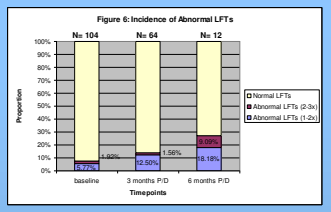












CONCLUSIONS

In our study, the side effects from dimethyl fumarate were similar to phase III trials, however, the incidence of flushing and severe leucopenia or lymphopenia at 6 months were higher than previously reported. During this short follow-up, clinical exacerbations have occurred in approximately 4% of the patients.

RESULTS (cont'd)

Side of effects from prior disease modifying agents (46%) was the most common cause for starting dimethyl fumarate followed by lack of efficacy (21%) to prior immunomodulators (Fig. 1). The most common side effects were gastrointestinal (GI) symptoms followed by flushing. GI side effects occurred in 56.5% of patients within the first month, but declined to 11% by the end of the third and sixth months. Twelve percent of those patients had history of prior GI symptoms (Fig. 2). The incidence of flushing was 50.6% in the first month, and decreased to 24.2 % and 30% by the end of the third and sixth months respectively (Fig. 3). Leucopenia grade 2 or lymphopenia grade 3 or higher occurred in 3.1% of patients at month 3 and 25% of patients at month 6 (Figs. 4 and 5). Two patients with grade 3 lymphopenia developed an infection, one patient had cellulitis and the other one developed herpes zoster. Mild elevation of LFTs (less than 3 x baseline) were seen in 14% of patients at month 3 and 27.3% of patients at month 6 (Fig. 6). Four patients had clinical exacerbations confirmed by imaging, half of the patients with multiple enhancing lesions. Treatment was discontinued in 13 patients (12.5%), the vast majority due to the GI side effects followed by clinical relapse in 3 patients.

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