PERSISTENCE, SAFETY AND ASSOCIATED LYMPHOPEANIA OF DIMETHYL FUMARATE IN RELAPSING REMITTING MULTIPLE SCLEROSIS, REAL WORLD DATA

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Dimethyl fumarate (DMF) is a hospital dispensing drug indicated for the treatment of relapsing remitting multiple sclerosis (RRMS).

Lymphopenia is a frequent adverse event (AE), eventhough it is not an extensive discontinuation cause.

Background and importance

Aim and objectives

To analyze the persistence of dimethyl fumarate and the reason for discontinuations.
To describe the toxicity of the treatment, focusing on lymphopenia.

Material and methods

- Observational, retrospective study.
- Followed up from the start until August-2022
- Follow-up of lymphopenia: 22 months.

Variables collected

- Sex
- Age
- Previous treatments
- Type of dose-escalation
- Date and reason for discontinuation
- AE and quarterly (±2 month)
- Lymphocyte levels

Results

94 patients

<table>
<thead>
<tr>
<th>Difference in discontinuation</th>
<th>64</th>
<th>30</th>
<th>♀</th>
<th>68.1% female</th>
<th>Mean age: 40.3 years SD=10.1</th>
<th>Mean EDSS: 2 0-6.5</th>
</tr>
</thead>
</table>
| No (p=0.385)                 | No (p=0.761) | No (p=0.828) 

Less discontinuations in naive patients (p=0.028) but no difference in persistence (p=0.178).

Previously treated with disease modifying therapies

<table>
<thead>
<tr>
<th>Discontinuation</th>
<th>25%</th>
<th>52.7%</th>
<th>25%</th>
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</thead>
<tbody>
<tr>
<td>Naive</td>
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<tr>
<td>Pretreated</td>
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13.8% patients required slower than our standard dose-escalation.

Adverse events

- Gastrointestinal: 85.1%
- Vascular (flushing, heat, hypersensitivity, reddening): 62.5%
- Pruritus: 52.2%
- Other EA: 28.8%

Lymphopenia

36.2%

Conclusion and relevance

- In a real-world setting, the largest number of DMF discontinuations are due to intolerance; gastrointestinal toxicities mostly observed.
- Despite the higher discontinuation in no-naive patient, persistence is not different.
- Lymphopenia appears in similar percentage to observed in clinical trials. Real-life data on lymphocyte levels may decrease during the first year of treatment as described in clinical trials, but stabilize after a few months recovering normal levels most of patients.