

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

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Background and importance

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.

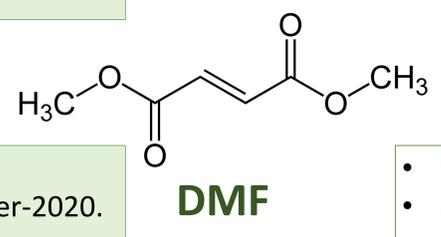
Aim and objectives

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.
- RRMS patients who started DMF treatment: August-2015→October-2020.
- 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

Statistics: **SPSS**

Results

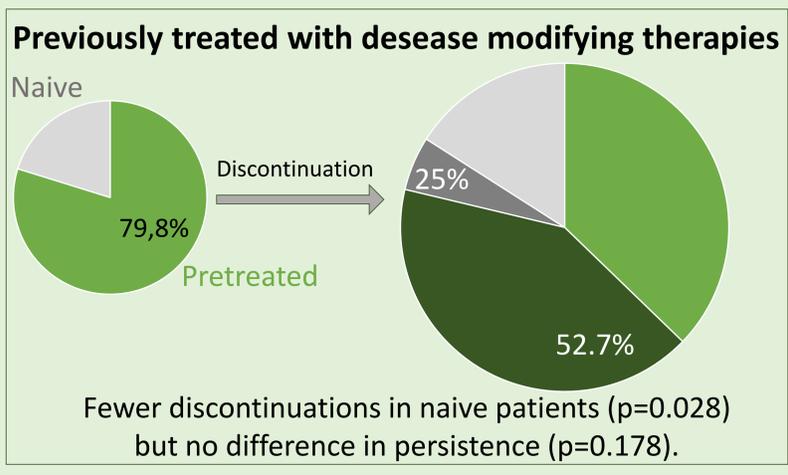
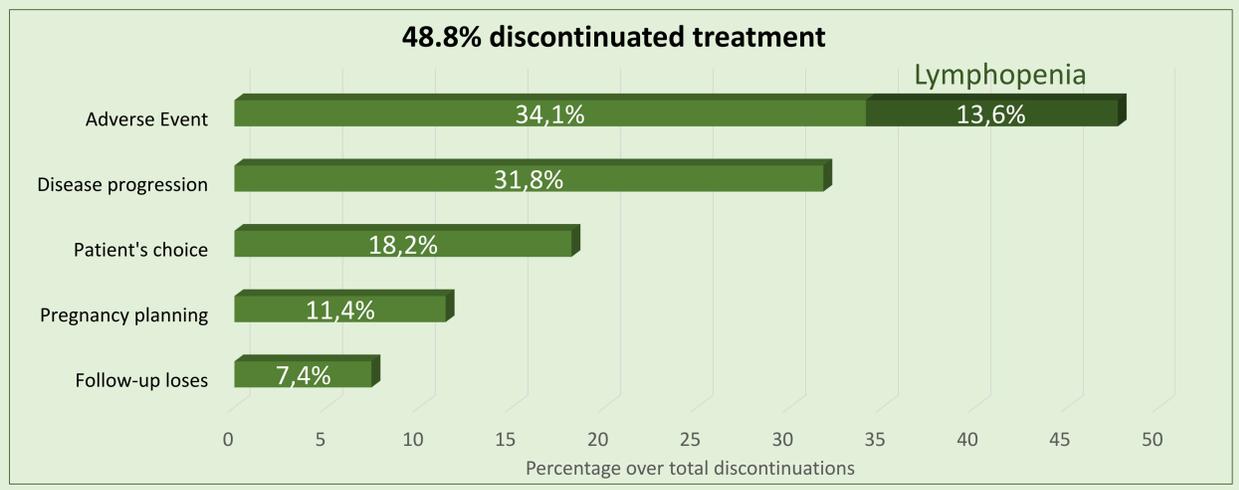
94 patients

♂ 30 ♀ 64
68.1% female

Mean age: 40.3 years SD=10.1

Mean EDSS: 2.0-6.5

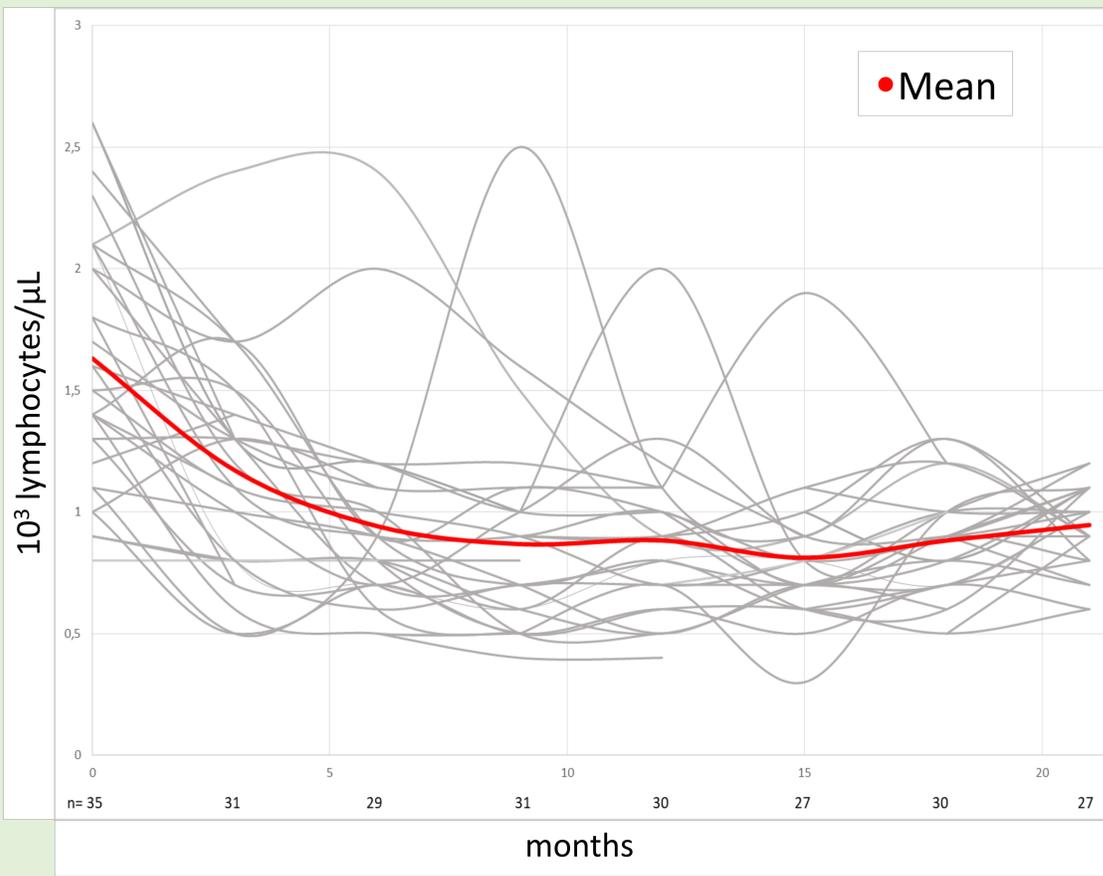
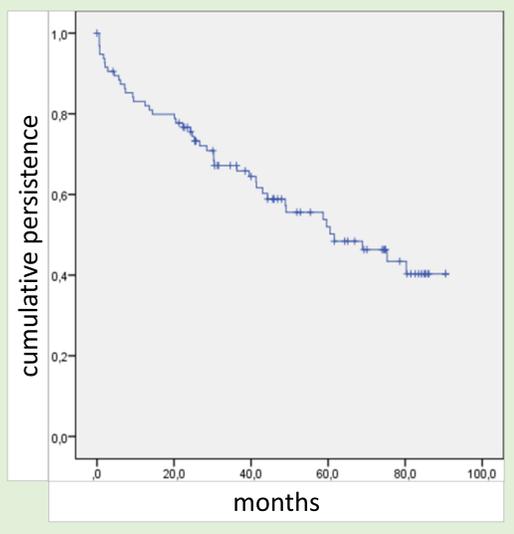
Difference in discontinuation	No (p=)
Sex	0.385
Age	0.761
EDSS	0.828



Median time to discontinuation 61.6 months
IC95%: 36.9-86.2

Persistence			
6 months	1 year	2 years	5 years
93.6%	88.3%	76.4%	56.3%

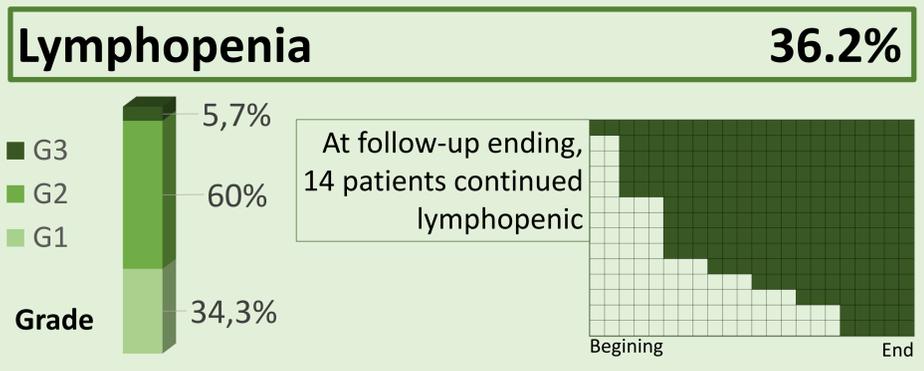
10.6% restarts



13.8% patients required slower than our standard dose-escalation.

Adverse events 85.1%

Gastrointestinal	62.5%
Vascular (flushing, heat, hypersensitivity, reddening)	52.2%
Pruritus	28.8%
Other EA	48.8%



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.

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