Effectiveness of Dimethylfumarate in multiple sclerosis, a French cohort within SNDS nationwide claims database

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Disclosure information

This study was carried out by the Bordeaux PharmacoEpi platform in collaboration with the Marketing authorisation holder of Dimethylfumarate that supported the study.

This work was supervised by an independent scientific committee.

Context

- Conflicting results remained on the effectiveness of the dimethyl fumarate (DMF) in comparison to the injectable immunomodulatory drugs (IMM), teriflunomide (TERI) and fingolimod (FTY)
- Comparative studies from real world practice carried out using large population-based healthcare databases and robust statistical methods to handle confounders are needed

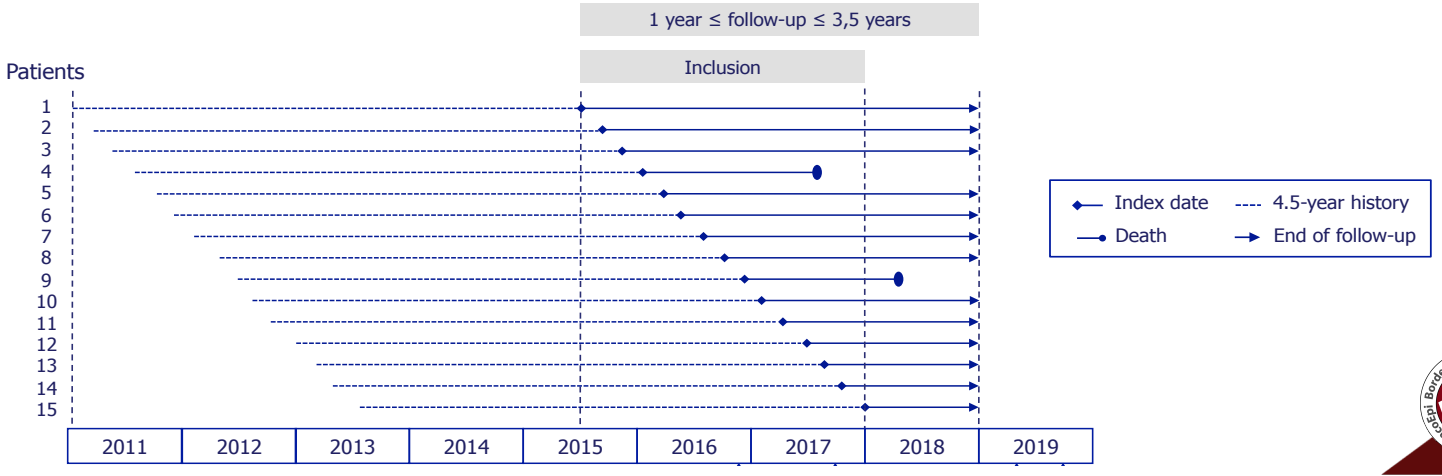
Objective

- Main objective
  - To assess the effectiveness of DMF on **annual rate of relapse (ARR)** in MS compared to IMM, TERI and FTY, in real life setting

- Secondary objective
  - To assess the effectiveness of DMF on **disability progression** in MS compared to IMM, TERI and FTY, in real life setting

Method

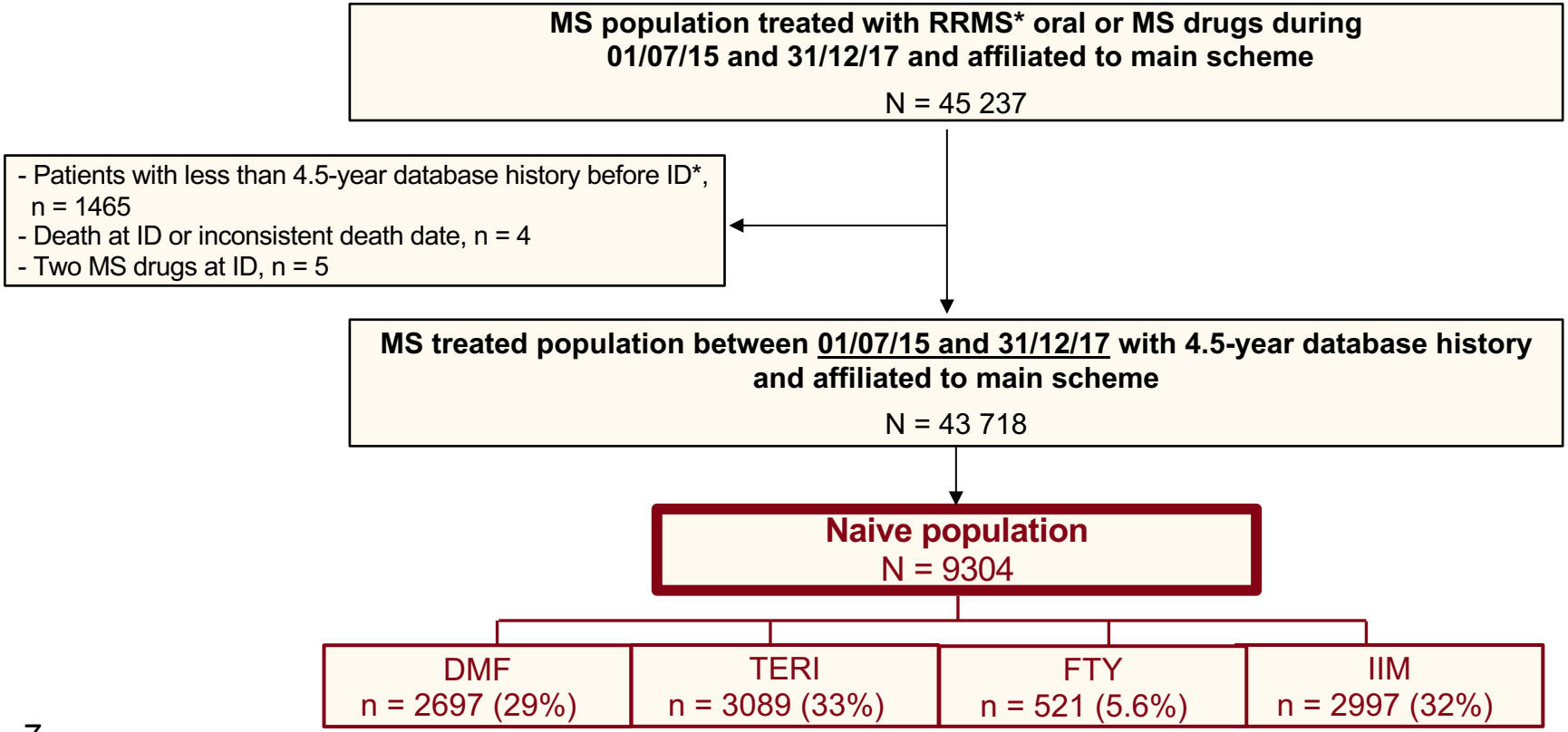
- Cohort study of patients initiating MS drug between 2015 and 2017, identified in the nationwide French claims database (Système National des Données de Santé, SNDS)
  - followed from 1 to 2.5 years after Index Date (ID)
  - with at least 4.5-year database history



Analysis

- Head-to-head comparisons
  - DMF *vs* IMMs
  - DMF *vs* TERI
  - DMF *vs* FTY
- High-dimensional propensity scores (hdPS) trimming and 1:1 matching
- Sensitivity analysis including hdPS adjustment and weighting
- Outcomes
  - ARR
    - identified using a validated algorithm based on corticosteroids prescription and MS hospitalization
  - Disability progression
    - identified using reimbursements related to the equipment for MS disability

Study population



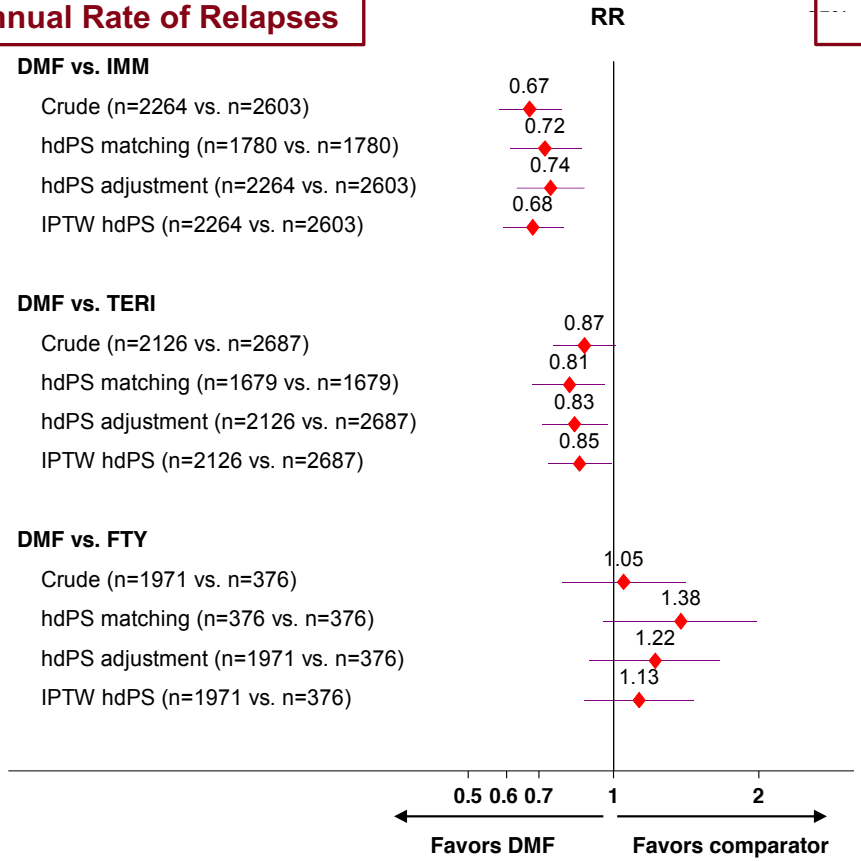
Baseline characteristics

	DMF n = 2697	TERI n = 3089	FTY n = 521	IMM n = 2997	Total N = 9304
Female, n (%)	1983 (73.5)	2111 (68.3)	342 (65.6)	2333 (77.8)	6769 (72.8)
Age (years), mean (SD)	39.4 (11.7)	43.1 (11.7)	38.2 (12.7)	37.5 (11.9)	39.9 (12.1)
CCI score, mean (SD)	0.52 (0.95)	0.65 (1.04)	0.61 (1.10)	0.54 (1.13)	0.58 (1.05)
Disability, n (%)	941 (34.9)	1088 (35.2)	201 (38.6)	1061 (35.4)	3291 (35.4)
Pre-index annual rate of relapse, mean (SD)	0.13 (0.27)	0.13 (0.26)	0.17 (0.31)	0.13 (0.26)	0.13 (0.26)
Pre-index MS-related hospitalizations (excluding relapse), n (%)	1120 (41.5)	1188 (38.5)	373 (71.6)	1239 (41.3)	3920 (42.1)
Pre-index medical visits to neurologist, n (%)	1570 (58.2)	1696 (54.9)	237 (45.5)	1529 (51.0)	5032 (54.1)
Pre-index cerebral or spinal cord MRI, n (%)	2536 (94.0)	2918 (94.5)	444 (85.2)	2775 (92.6)	8673 (93.2)

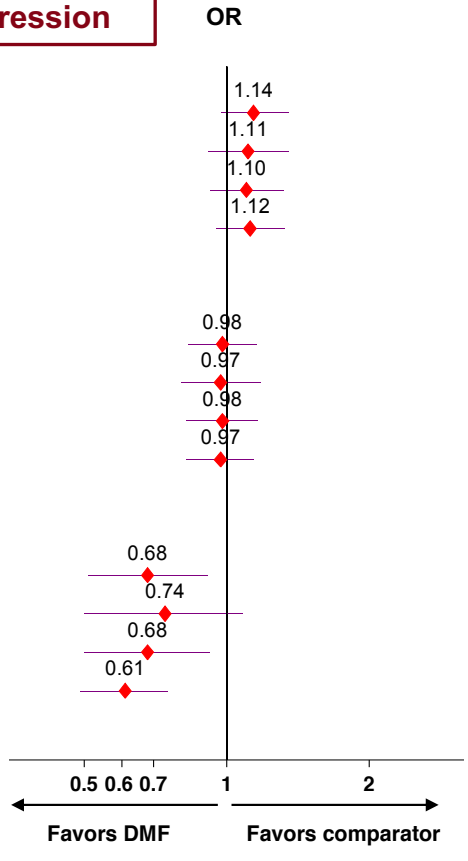
DMF: Dimethyl fumarate, TERI: Teriflunomide, FTY: Fingolimod, IMM: Injectable Immunomodulators, MS: Multiple Sclerosis, CCI: Charlson Comorbidity Index, MRI: Magnetic Resonance Imaging, ATC: Anatomical Therapeutic Classification, SD: Standard Deviation

Outcomes

Annual Rate of Relapses



Disability progression



Conclusion

- This study showed
  - higher clinical efficacy of DMT compared to TERI or IMM with lower rates of relapses.
  - Non difference was found between treatment groups for MS disability progression

- However FTY and DMF patients are difficult to compare
  - patients with very distinct profile
  - small number of DMF patients remaining after matching