Introduction

Delayed-release dimethyl fumarate (DMF) also known as gastro-resistant DMF has demonstrated favorable efficacy in Phase 3 clinical trials (DEFINE, NCT02012213; CONFIRM, NCT02440461). In patients with relapsing-remitting multiple sclerosis (RRMS), it leads to superior efficacy compared to fingolimod (FTY) in terms of annualized relapse rate (ARR), time to first relapse, and time to confirmed disability progression (TTPD). However, no head-to-head randomized controlled trial comparing the effectiveness of DMF with fingolimod (FTY) in patients with RRMS has been conducted.

The NeuroTransData (NTD) MS registry is a German practice network with RRMS patients registered with NTD since 2011. Regular 3-month follow-ups, which can support real-world comparisons of the effectiveness of DM treatments.

Methods

Patients

Inclusion criteria:
- Age ≥18 years at therapy initiation;
- Annualized relapse rate (ARR);
- 0.141
- 49.5
- .219
- 0.030
- 48.5
- 37.1 (9.6)
- 10.0
- .715
- 1 year
- 17.2
- 26.2
- 32.3
- .450
- P
- –0.065
- 2 (1, 3)
- 9.8
- –0.015
- 73.5
- 0.813 (0.775–0.853)
- Time to treatment discontinuation (TTD).

The proportions of relapse-free patients at Years 1 and 2 by treatment group are presented in Figure 2B. Similar results also were observed for time to confirmed disability progression (TTPD) (Figure 1A).

There was no evidence of difference in ARR between the DMF and FTY cohorts for each comparison. Nonpairwise censoring was applied as the primary analysis method with a predefined sensitivity analysis using pairwise censoring accounting for differential follow-up time.

Results

Patients and Matching

- The DMF cohort matched to the FTY-ALL cohort had similar baseline clinical characteristics and treatment history (Table). Similar occurs were seen for the DMF and FTY-EMA cohorts (Table).

Conclusions

- In pair-wise propensity-score matched populations from the NTD MS registry, no evidence of difference between FTY and DMF was observed across all clinical effectiveness outcomes assessed (TTPD, ARR, time to confirmed disability progression).
- Conclusion: Results were consistent within the cohort analyses and the study could not detect between-cohort differences.

Clinical Study

- NTD MS registry
- FTY-EMA patients meeting the European Medicines Agency label for fingolimod; FTY-ALL all fingolimod-treated patients with relapsing-remitting multiple sclerosis meeting the European Medicines Agency label for fingolimod.

Nonpairwise censoring was applied as the primary analysis method with a predefined sensitivity analysis using pairwise censoring accounting for differential follow-up time.

Table

<table>
<thead>
<tr>
<th>Table</th>
<th>Baseline characteristics in the DMF and FTY-ALL cohorts</th>
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<tbody>
<tr>
<td>Type</td>
<td>DMF vs. FTY-ALL</td>
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<tr>
<td>Female, %</td>
<td>52.3</td>
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<tr>
<td>Age (years), mean (SD)</td>
<td>51.9 (11.8)</td>
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<tr>
<td>EDSS at baseline, mean (SD)</td>
<td>2.8 (1.7)</td>
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<td>Time to 3- and 6-month EDSS confirmed disability progression</td>
<td>No evidence of difference.</td>
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<td>TTD (months), KM estimates (95% CI)</td>
<td>17.2 (16.3, 18.1)</td>
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Figures

1A. Time to first relapse hazard rates for the DMF vs. FTY-ALL and FTY-EMA cohorts

1B. Arranged relapse rate ratios for the DMF vs. FTY-ALL and FTY-EMA cohorts

2A. Time to 3- and 6-month EDSS confirmed disability progression for the DMF vs. FTY-ALL cohorts (nonpairwise)

2B. Time to 6-month EDSS confirmed disability progression for the DMF vs. FTY-ALL cohorts (nonpairwise)