Acceptability of first-line Disease-Modifying Drugs in Relapsing-Remitting Multiple Sclerosis: a real-life multicenter study

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Introduction

Multiple sclerosis (MS) first-line disease-modifying drug (DMD) treatment options now include oral drugs in addition to injectable therapies. Primary aim of the present study was to compare the proportion of patients discontinuing first-line injectable DMDs for any reason during the first 12 months of treatment with the proportion of patients discontinuing oral DMDs.
Secondary aims were to compare the time to discontinuation and the reasons for discontinuation between the two groups and to explore the demographic and clinical factors associated with DMD discontinuation

Methods

In this prospective, multi-center, real-life observational study, 9 centres in Emilia-Romagna, Italy, enrolled Relapsing-Remitting (RR) MS patients commencing any of the following first-line DMDs: interferon beta 1a/1b, pegylated interferon, glatiramer acetate, dimethylfumarate and teriflunomide.
Patients were enrolled during routine clinical visits. Demographic and clinical data collected at baseline included age, disease duration, relapses/MRI activity in the preceding year, previous MS treatment, EDSS. Follow-up data, collected at least every six months, included data on treatment discontinuation (date, reason), on serious/adverse events and on disease activity (EDSS, relapses and MRI activity).

Results

Five-hundred and twenty patients were enrolled in the study. Patients' baseline characteristics are shown in Table 1.
An injectable drug was started in 262 patients (49.6%) and an oral one in 258 (50.4%). Patients were followed up for at least one year or until treatment was discontinued. Mean follow-up duration was 15 ± 4 months.
There was no difference in the proportion of patients on oral (nr=62, 24%) or injectable DMD (nr=60, 23%) discontinuing treatment, nor in the reasons for treatment discontinuation (Figure 1).
Time to treatment discontinuation was not different between the two groups at survival analysis (Figure 2) and was not influenced by the initiated DMD (oral versus injectable) at Cox analysis.
At multivariate logistic regression, only baseline EDSS scores (p=0.014, OR=1.23, 95%CI: 1.04-1.46) and age (p=0.011, OR=0.97, 95%CI: 0.95-0.99) were associated with treatment discontinuation, but not DMD type (oral versus injectable), gender, being treatment-naïve or having had relapses in the previous year.

Conclusion

There was no difference in the acceptability of injectable versus oral first-line DMD in MS patients, as measured by the proportion of patients discontinuing the drug for any reason during the first year of treatment.
Reasons for discontinuation (mostly adverse events or ongoing disease activity) were not significantly different in the two groups.
Higher baseline EDSS scores and younger age increased the odds of discontinuing treatment.

Table 1

Variable	
Age, years*	43 ± 11
Age at disease onset , years*	33 ± 10
EDSS*	1.8 ± 1.4
	nr/total (%)
Sex	
Male	155/520 (30)
Female	365/520 (70)
Relapses in the preceding year	
0	287/509 (57)
1	177/509 (35)
>1	45/509 (8)
Treatment-naive	
Yes	156/520 (30)
No	364/520 (70)
Basal brain MRI	
Active**	235/364 (65)
Not active	129/364 (35)
Treatment started at enrolment	
Dimethylfumarate	201/520 (38.7)
Teriflunomide	60/520 (11.5)
Glatiramer acetate	143/520 (27.5)
Interferon beta 1a/b	116/520 (22.3)

*mean ± standard deviation **new T2 lesions or gadolinium-enhancing lesions

Figure 1 Reasons for treatment discontinuation

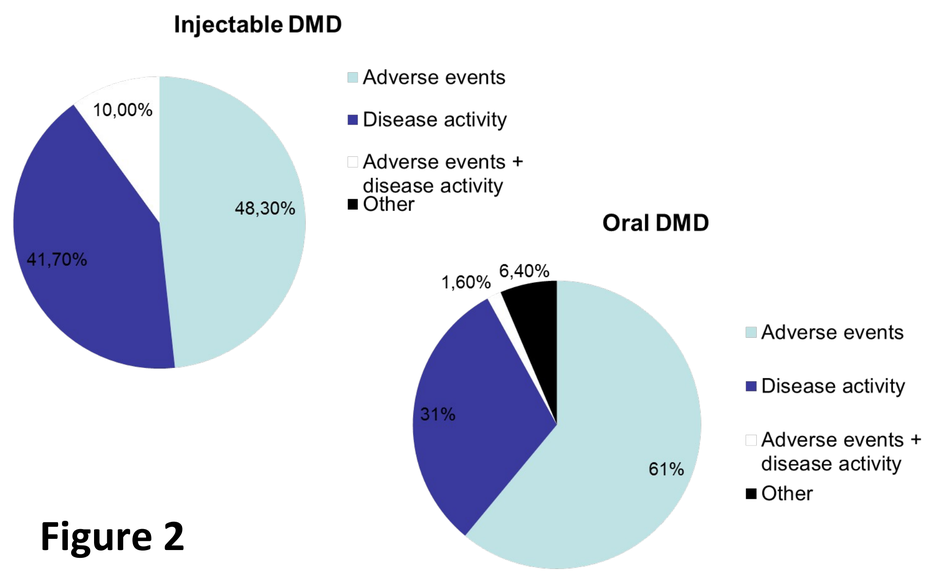
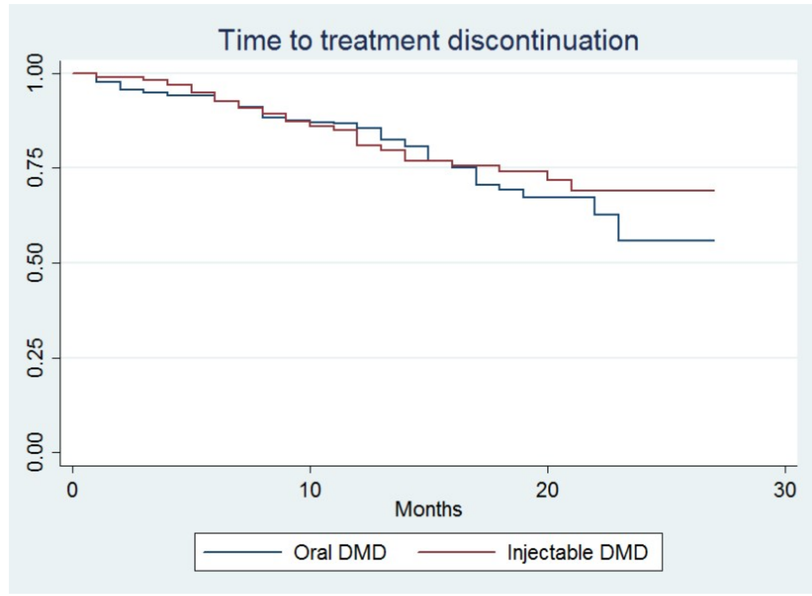


Figure 2



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