Real-world Experience with Cladribine in the MSBase Registry

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Introduction

Cladribine tablets are approved for relapsing multiple sclerosis (RMS) treatment in many jurisdictions. MSBase investigators are committed to characterising real-world longitudinal treatment outcomes using this registry data.

Aim

To describe cladribine treatment outcomes in the MSBase cohort. These include baseline characteristics at cladribine start, treatment pathways, discontinuation rate, and relapse outcomes.

Methods

We extracted from the MSBase registry data for all patients with a confirmed diagnosis of MS who were newly treated with cladribine tablets since 1/1/2018.

Descriptive statistics were used to analyse baseline patient characteristics recorded within 3 months of cladribine tablets initiation, including demographics, disease course and duration, prior disease modifying treatments (DMT), and EDSS. Relapse outcomes were described in patients with a minimum 6-month observation period, and discontinuation rates in all patients with at least one recorded follow-up visit.

Results

MSBase included a total of 782 patients treated with Cladribine, and 7 countries contributed at least 8 patients. . Patients with relapsing-remitting MS (RRMS) accounted for 89% of the study population. The median age of cladribine tablet start was 43.8 years and median disease duration was 11.8 years. Median EDSS at cladribine initiation was 2 (IQR 1.5,4). 13.3% of all RRMS patients initiated cladribine as first line therapy.

Table 1. Demographics for Cladribine patients in the MSBase Registry.

Characteristic	RRMS (n=696)	SPMS (n=59)	PPMS (n=4)
Age (years), mean SD	43.76 (11.78)	57.4 (8.98)	64.16 (12.48)
Sex, n (%)			
Female	520 (74.7)	43 (72.9)	1 (25.0)
Male	176 (25.3)	16 (27.1)	3 (75.0)
Country, n (%)			
Australia	380 (54.6)	45 (10.2)	4 (100.00)
Belgium	35 (5.0)	1 (1.7)	0 (0.0)
Canada	99 (12.2)	10 (17.0)	0 (0.0)
Spain	95 (13.7)	2 (0.3)	0 (0.0)
Italy	8 (1.2)	0 (0.0)	0 (0.0)
Kuwait	15 (2.2)	0 (0.0)	0 (0.0)
Turkey	35 (5.0)	1 (1.7)	0 (0.0)
Other	29 (4.2)	0 (0.0)	0 (0.0)

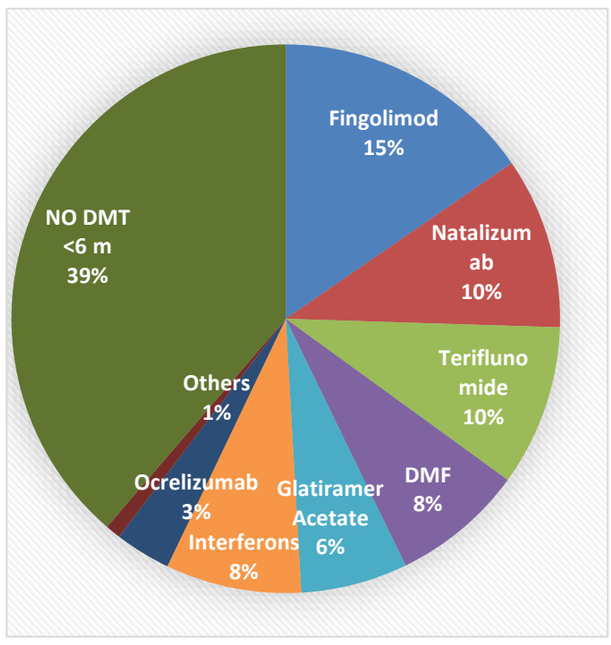


Figure 1: Immediate prior DMT in RRMS cohort with switch gap <6 months

Table 2. Disease characteristics and treatment history of Cladribine patients in the MSBase Registry.

Characteristic	RRMS (n=696)	SPMS (n=59)	PPMS (n=4)
Disease duration from 1st symptoms, mean (SD), years	11.82 (5.96)	24.70 (8.55)	25.18 (14.38)
Disease duration from diagnosis, mean (SD), years	9.11 (5.11)	19.59 (6.72)	12.39 (2.37)
Baseline EDSS score, median (IQR)	2 (1.5,4)	6.5 (5.5,7)	6.25 (5,7.75)
Relapse rate, mean (SD)			
Past 12 months	0.41 (0.64)	0.34 (0.86)	0.00 (0.00)
Past 24 months	0.61 (0.85)	0.51 (1.25)	0.00 (0.00)

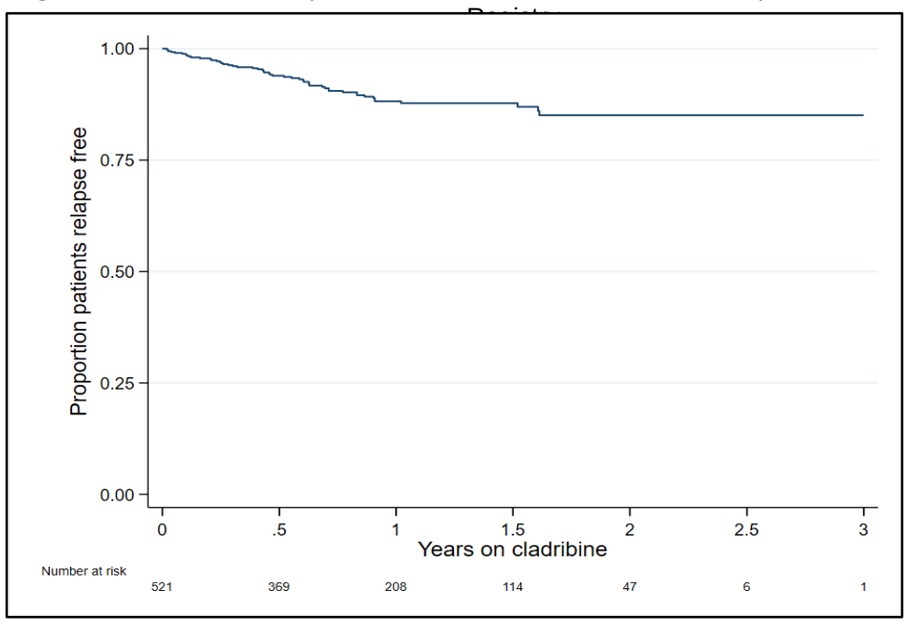
Table 4. Kaplan-Meier estimates for overall MSBase Cladribine-treated patient cohort.

Kaplan-Meier estimates (overall cohort)	Proportion free from discontinuation or relapse (95% CI)	
Cohort duration (person-years)	**12 months (453)**	**24 months (612)**
Cladribine persistence	0.97 (0.94, 0.98)	0.91 (0.86, 0.94)
Freedom from first relapse	0.89 (0.86, 0.92)	0.85 (0.80, 0.89)

Total n of recorded relapses	ARR	95% Confidence interval
72	0.11	(0.09, 0.14)

Table 3. Annualised relapse rate for Cladribine-treated RRMS patients.

Figure 2. Time to first relapse event for RRMS Cladribine-treated patients in the MSBase



Conclusion

The growing MSBase real-world cohort increasingly informs cladribine treatment outcomes in the real world. The most common switches to cladribine are from other high-efficacy DMTs such as Fingolimod or Natalizumab. The annualised relapse rate on treatment is 0.11, consistent with and extending clinical trial data. The observed discontinuation rate over 24months is 9%, which is consistent with low treatment failure rates. Future analyses will address relapse freedom over longer time periods and describe rates of disability worsening and improvement.

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