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MSBase Neuro-Immunology Registry

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Real-world experience with Cladribine Tablets (Mavenclad) in the MSBase registry

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Introduction

We need to understand real-world long-term outcomes of cladribine tablets treatment (CladT) dosing in year one and two in multiple sclerosis (MS). Longer term treatment persistence and effectiveness in the real-world setting are currently unknown.

Aim

We describe the baseline characteristics, treatment persistence, re-treatment rate, relapse rate and 24 week confirmed disability progression (CDP) or improvement (CDI) of people with MS treated with CladT in MSBase centres.

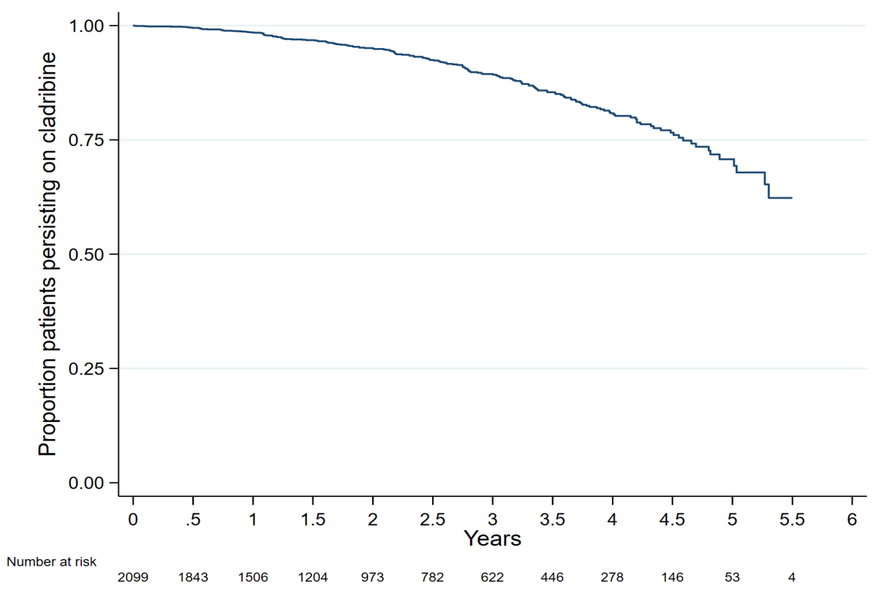
Methods

All patients in the MSBase registry with MS initiating CladT were included. Descriptive statistics were used to summarise demographic, clinical and treatment characteristics. Cox proportional hazard regression was used to compare clinical outcomes between treatment naïve and experienced groups.

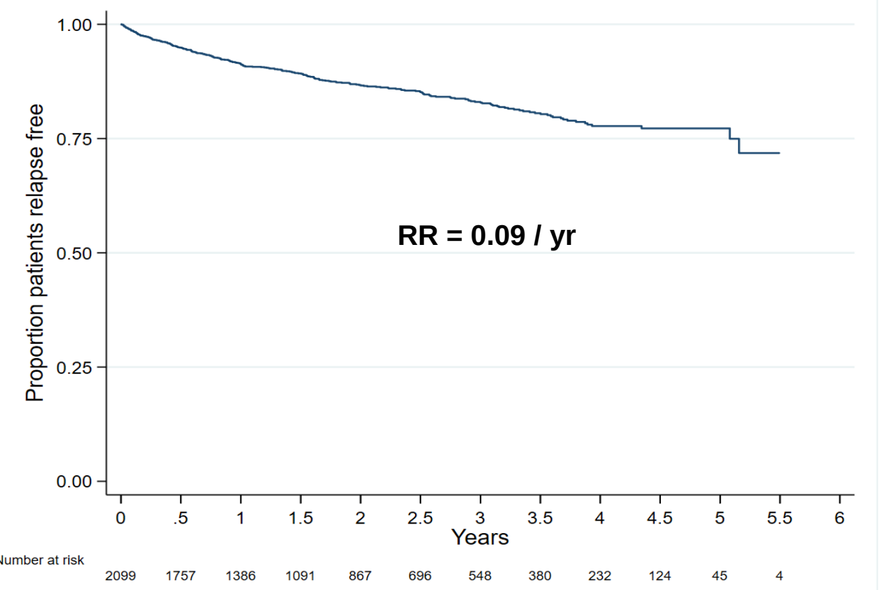
Results

A total of 2630 patients initiated CladT since 2017. Mean (SD) age at treatment start was 43.1 years (12.0) and 74.4% were female. 91% of patients starting CladT have relapsing remitting MS (RRMS), and 4.5% are secondary progressive. Mean (SD) time from diagnosis to first CladT exposure was 11.7 years (9.0). 18% were treatment-naïve. Mean (SD) observation time from first CladT dose was 1.9 years (1.5). 206 patients are followed for more than 4 years. Treatment switching from CladT occurred at a mean rate of 4.28% per year (95% CI 3.70, 4.94). In switchers, the median (IQR) time to switch was 2.2 years (1.2, 3.2). The annualised relapse rate on CladT was 0.09 (95% CI 0.08, 0.10). The rate of 24-week CDP was 0.035/year (IQR 0.03, 0.04) and the rate of 24-week CDI was 0.05 /year (IQR 0.05, 0.06).). In patients with a recorded follow-up duration of 3,4,5, or 6 years, 5.2 % (60/1152) reported re-treatment with CladT in year 3, 5.3% (42/786) reported re-treatment with CladT in year 4, 9.4% (37/392) reported re-treatment with CladT in year 5, and 3.4% (3/89) reported re-treatment with CladT in year 6. Among treatment-naïve patients there was no difference in time to first relapse (HR 0.94; 95% CI 0.71, 1.24), 24-week CDP (HR 0.84; 95% CI 0.57-1.25) or 24-week CDI (HR 1.31; 95% CI 0.87, 1.96) compared to patients who were treatment experienced at CladT start.

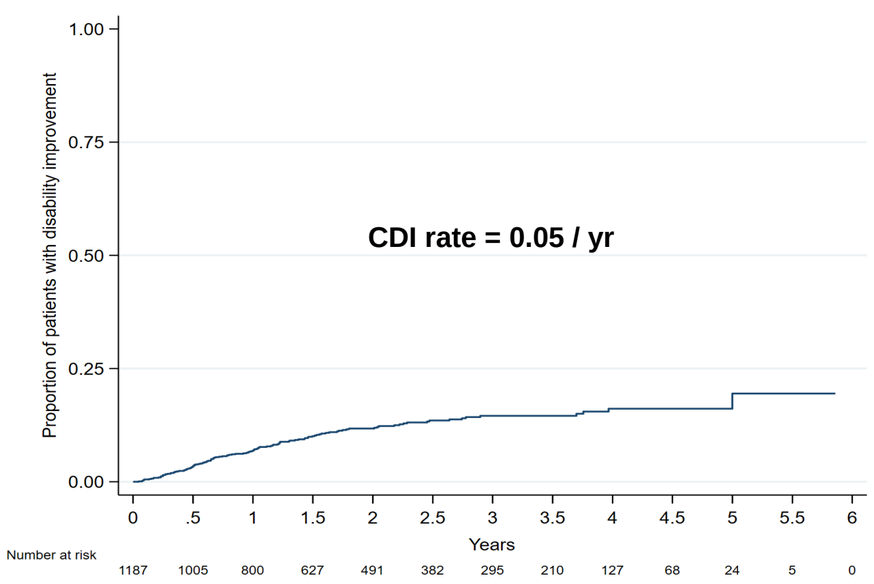
CladT persistence in RRMS – persistence over time



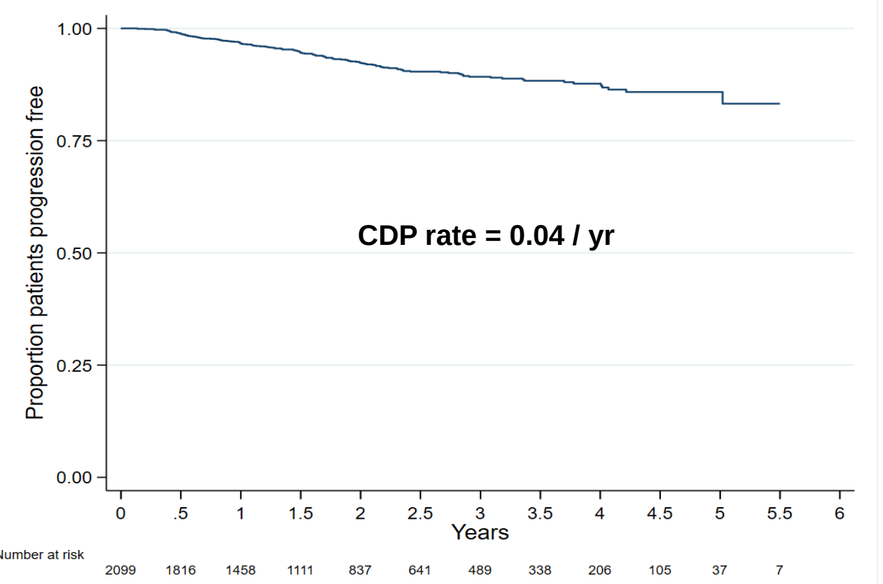
Freedom from relapse in RRMS



Confirmed Disability Improvement events in RRMS



Freedom from Confirmed Disability Progression Events in RRMS



Conclusion

In the MSBase cohort of 2630 relapse-onset CladT patients, treatment persistence was very high, with less than 5% of patients per year switching to other treatments. The annualised relapse rate was 0.09, and re-treatment with CladT occurred in year 3 in 5.2% of patients and in year 4 in 5.3% of patients. The Rate of CDP events was low, at 3.5%/year. CDI events were slightly more frequent, at 5%/year. In this real-world cohort, CladT is highly effective and has very high treatment persistence.

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