MSBase
Neuro-Immunology Registry

Real-world Experience with Cladribine Tablets in Older Age Groups in the MSBase Registry

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Introduction

Older patients with Multiple Sclerosis (MS) are underrepresented in clinical trials and real-world studies. Cladribine tablets are safe and effective treatment for relapsing MS. However, there are limited real-world data on the outcomes of cladribine tablets treatment (CladT) in people with MS (PwMS) over 50 years old.

Aim

We aimed to describe the baseline characteristics, treatment persistence, relapse rate, and 24-week confirmed disability progression (CDP) or improvement (CDI) in older PwMS treated with CladT, stratified by age sub-groups: 50-54, 55-59, and ≥60 years, using real-world data from the MSBase registry.

Methods

We included all PwMS aged ≥50 years recorded in MSBase as of 1 February 2025, with a confirmed diagnosis of MS and who had initiated CladT. We used descriptive statistics to summarise demographic, clinical, and treatment characteristics, including switch patterns, treatment persistence, and effectiveness. Treatment persistence was defined as follow-up time without switch to another DMT. For persistence analysis, patients were censored if they switched to another DMT or reach the end of recorded follow-up.

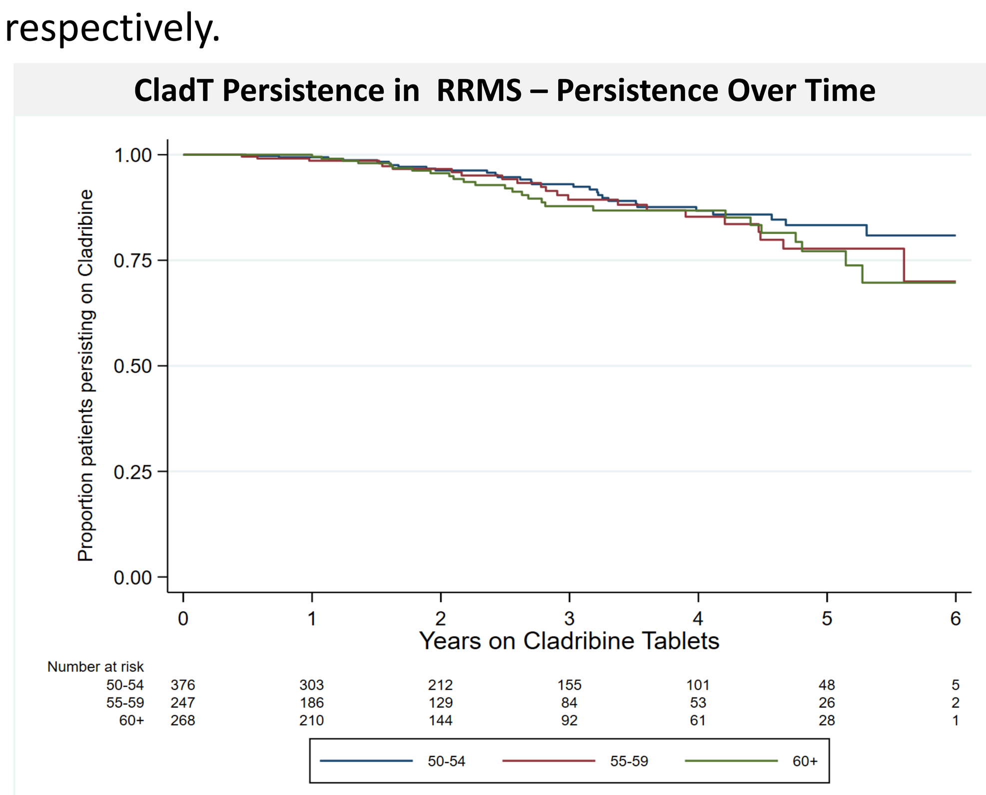
Results

Patient Demographics

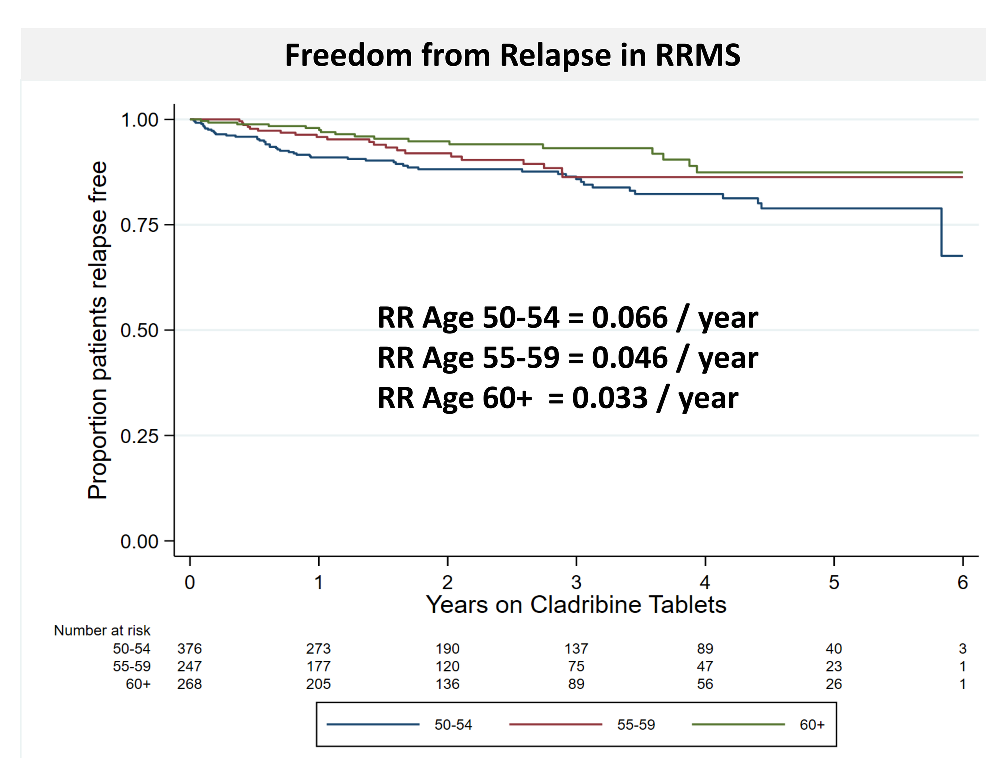
Since 2017, a total of 993 PwMS aged ≥ 50 years initiated CladT. We included 414, 286, and 293 patients aged 50-54, 55-59, or ≥60 years, respectively. Main contributing countries for each age group, respectively, were Australia (*n* = 175, *n* = 137, *n* = 190), Czech Republic (*n* = 54, *n* = 29, *n* = 16), Spain (*n* = 33, *n* = 18, *n* = 12), Türkiye (*n* = 27, *n* = 31, *n* = 18), Italy (*n* = 19, *n* = 0, *n* = 5), Netherlands (*n* = 15, *n* = 6, *n* = 1) and Croatia (*n* = 10, *n* = 10, *n* = 11). Mean (standard deviation [SD]) ages at CladT initiation were 52.37 (1.44), 57.39 (1.41) and 65.35 (4.32) years, respectively. Mean (SD) time from diagnosis to first CladT exposure was 11.77 (8.04), 14.36 (8.73), and 16.12 (9.92) years. Mean baseline (SD) EDSS scores were 3.25 (2.01), 3.45 (2.10) and 4.17 (2.01), respectively. The included patients typically had relapsing MS (94.4%), mean (SD) relapses in the 12-month pre-baseline were 0.41(0.68), 0.29 (0.62), and 0.24 (0.52); and in the 24-month pre-baseline, 0.58 (0.91), 0.41 (0.76), and 0.32 (0.66), respectively. The most common immediate prior DMTs for each age group, respectively, were fingolimod (15.7%, 21.7%, 17.1%), teriflunomide (12.8%, 10.1%, 8.5%), natalizumab (10.4%, 8.4%, 11.3%), dimethyl fumarate (10.6%, 7.0%, 7.5%), glatiramer acetate (9.9%, 9.1%, 7.9%), interferons (8.5%, 9.8%, 6.9%), and ocrelizumab (5.8%, 5.6%, 9.6%).

Outcomes

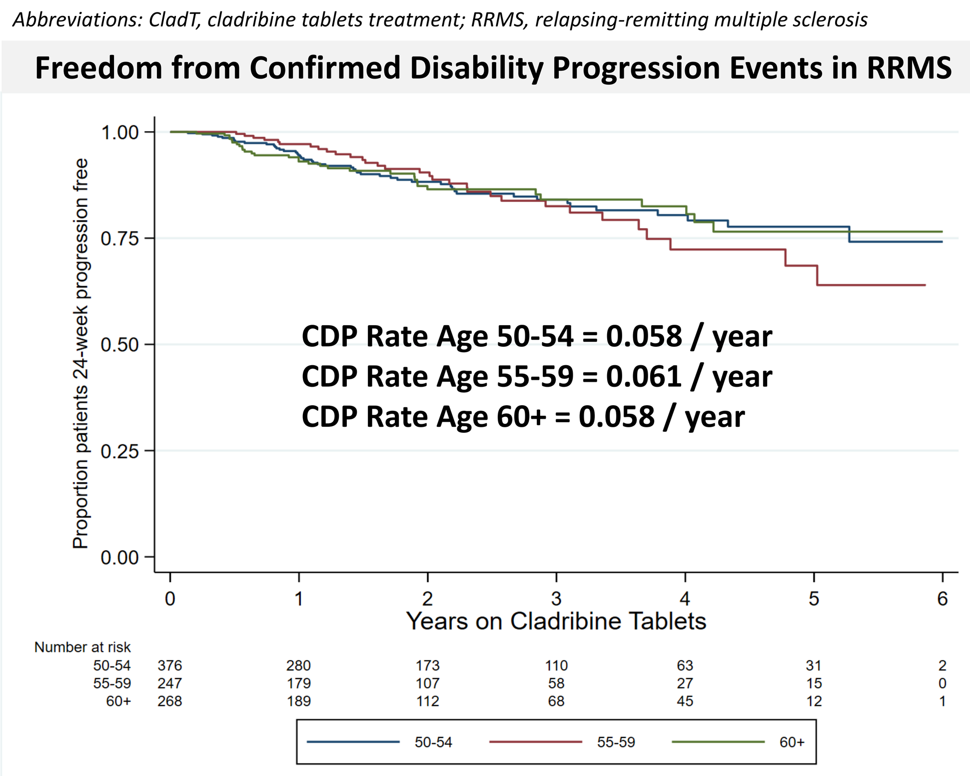
Mean follow-up durations on CladT for patients aged 50-54, 55-59, and ≥ 60 years were 2.41, 2.12, and 2.27 years, respectively. Mean switching rates from CladT were 3.00, 3.64, and 3.92 switches per 100 person-years, respectively. In switchers, the median (interquartile range) time to switching were 2.70 (1.67, 3.52), 2.80 (1.63, 3.90), and 2.53 (1.78, 4.21) years, respectively. Annualised relapse rates (ARR) were 0.07 (95% CI 0.05, 0.08), 0.05 (95% CI 0.03, 0.07), and 0.03 (95% CI 0.02, 0.05). Rates of 24-week CDP were 0.06 (95% CI 0.04, 0.08), 0.06 (95% CI 0.04, 0.09), and 0.06 (95% CI 0.04, 0.08); and for 24-week CDI in the baseline EDSS 2+ subgroup, 0.04 (95% CI 0.03, 0.07), 0.01(95% CI 0.01, 0.03) and 0.01 (95% CI 0.005, 0.02) per year, respectively.



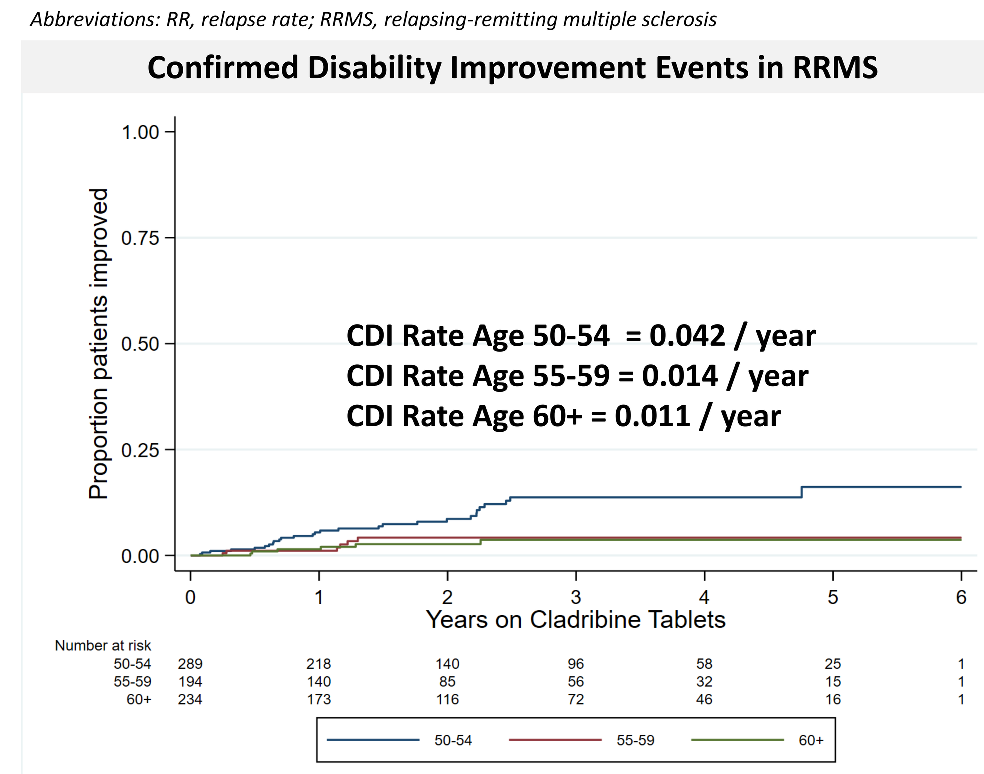
Abbreviations: CladT, cladribine tablets treatment; RRMS, relapsing-remitting multiple sclerosis



Abbreviations: RR, relapse rate; RRMS, relapsing-remitting multiple sclerosis



Abbreviations: CDP, confirmed disability progression; RRMS, relapsing-remitting multiple sclerosis



Abbreviations: CDI confirmed disability improvement; RRMS, relapsing-remitting multiple sclerosis

Conclusion

In the MSBase cohort of 993 PwMS over the age of 50 treated with CladT, treatment persistence was notably high, with fewer than 4% of PwMS per year switching to other treatments. ARR was very low (0.03-0.07). Only 6% of the cohort experienced a CDP event every year. CDI events were also rare (between 1-4% year). This analysis demonstrates CladT treatment is highly effective and has very high treatment persistence in older PwMS who still experience relapses.

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