



Five by five: Nationwide Real-World Outcomes After ≥5 Years of Cladribine with an Age ≥50 Subanalysis

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OBJECTIVE

To assess long-term use of cladribine in people with multiple sclerosis (pwMS), including retreatment efficacy and observations in pwMS aged ≥50 years at baseline (first cladribine tablet) in real-world settings.

BACKGROUND

While cladribine shows sustained efficacy through 4 years in trials, real-world evidence beyond this timepoint remains limited, particularly retreatment strategies and age-specific outcomes.

METHODS

Data source: Czech national MS registry (ReMuS)

Inclusion criteria:

- pwMS who completed 2 courses of cladribine
- ≥5 years of follow-up by December 31, 2025

Methodology:

- Classification of treatment patterns

- N** (no further treatment),
- R** (retreatment with cladribine),
- S** (switch to another therapy).

- Assessment of clinical effectiveness
- Exploratory analysis in pwMS aged ≥50

ReMuS[®]
THE CZECH REPUBLIC
MULTIPLE SCLEROSIS
PATIENT REGISTRY

RESULTS

Of 1,938 pwMS initiating cladribine courses, 481 had 2 courses and ≥5-year follow-up (baseline characteristics below).

| | |
|--------------------------|-------------------------|
| Age, mean ± SD | 37.0 ± 9.5 years |
| at cladribine initiation | <50 years (n = 435) |
| | ≥50 years (n = 46) |
| Sex | 75% female |
| Previous DMT | |
| pre-treated | 92% |
| high-efficacy DMT | 13% |
| EDSS, mean ± SD | 2.6 ± 1.2 |

Table 1 Baseline characteristics, N = 481

Groups **N**/**R**/**S** comprised 49.5% / 26.0% / 24.5% of pwMS (see below and on the right), with majority of retreatments occurring in year 5.

Figure 2 Cumulative treatment pattern stratification by follow-up year

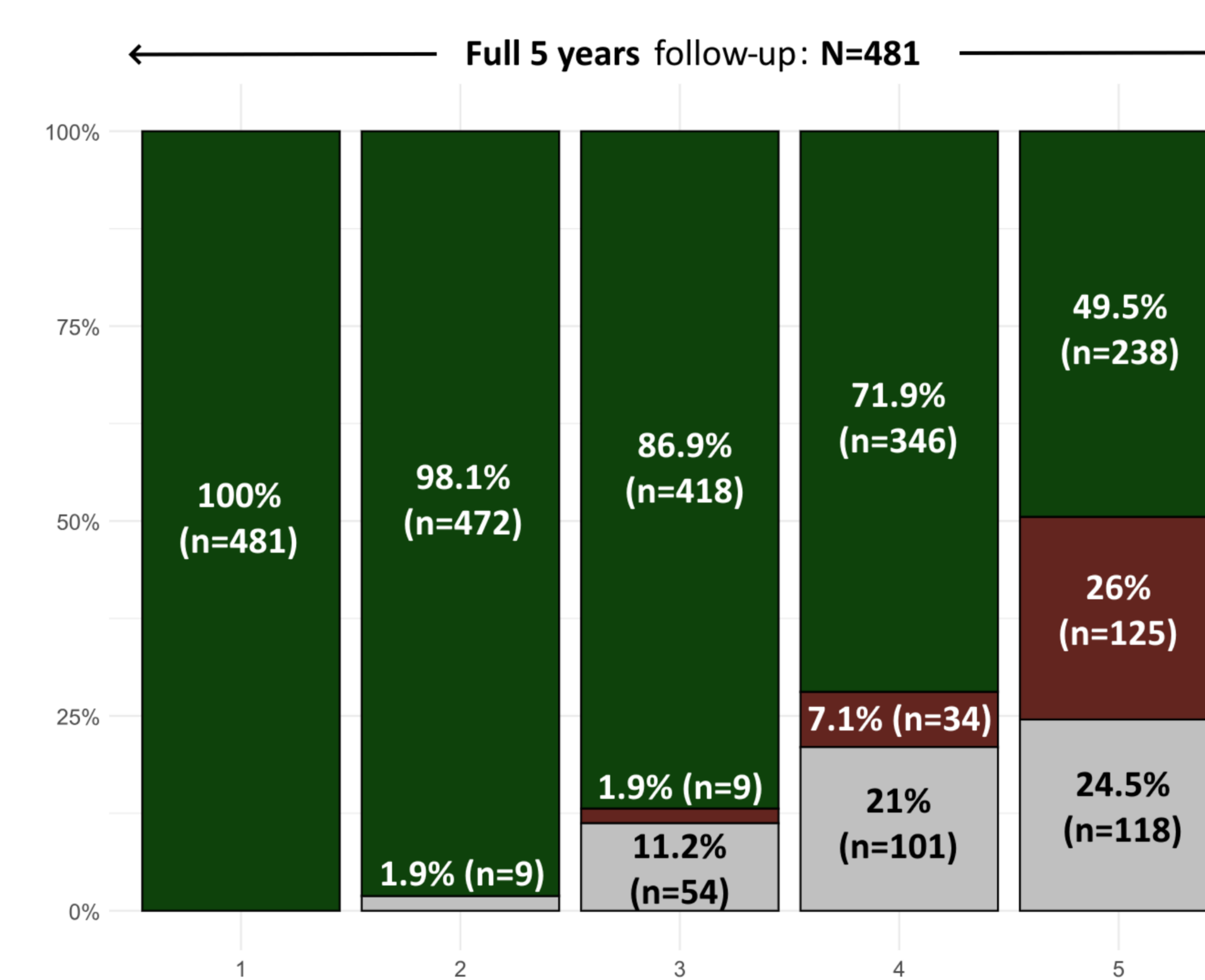
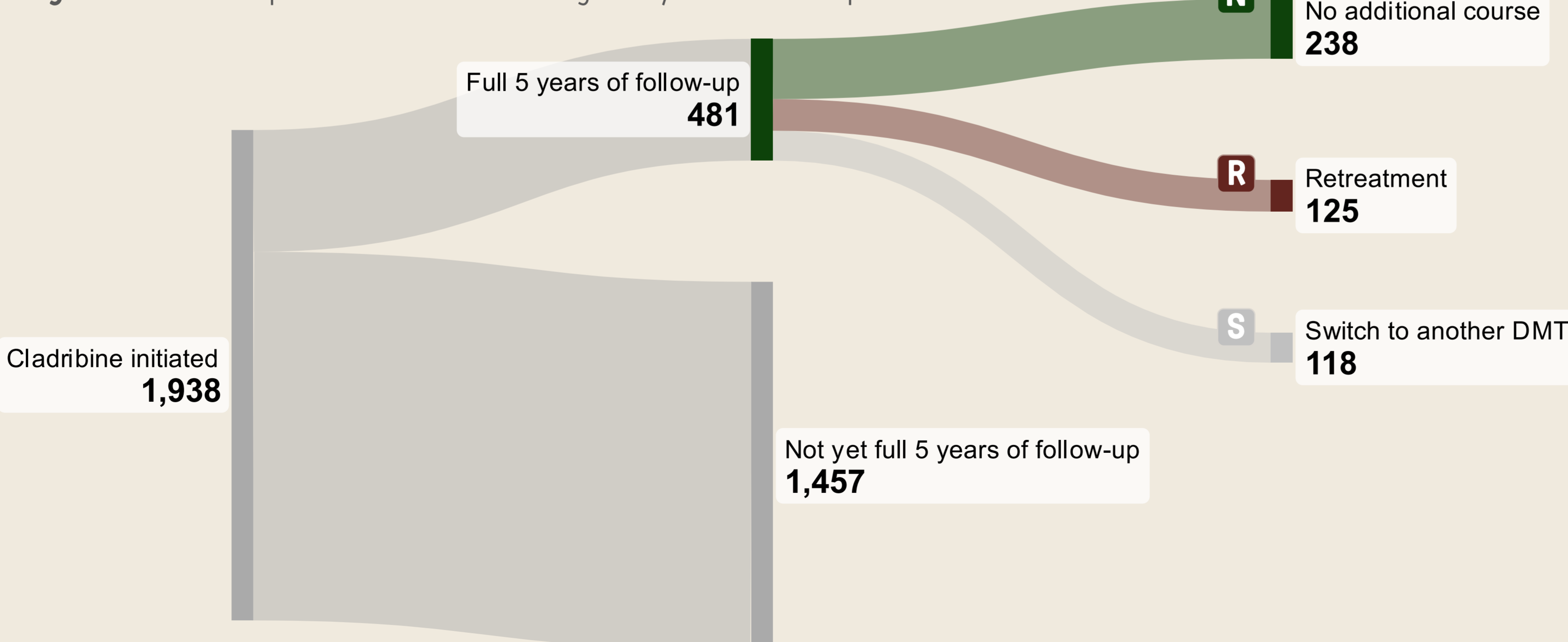


Figure 1 Treatment pattern stratification through five years of follow-up



N R S
Results through all 5 years and all patients
42% relapse-free
89% PIRA-free
72% 3m CDP free

R
Relapse-free improvement in the 1st year after retreatment with cladribine
41% → 83%
Among 109 retreated patients with ≥1-year follow-up after retreatment, relapse-free rates increased from 41% in a year pre-retreatment to 83% in a year post-retreatment.

N R S
AGE ≥50 SUBANALYSIS
In the age ≥50 subgroup (n=46), 65% received no further treatment (vs 48% in <50), only 13% switched (vs 26% in <50), and all retreated patients achieved relapse-free status in the year following retreatment. Other disease characteristics were comparable to pwMS aged <50 years, except for the baseline EDSS (median 3.5 in ≥50 subgroup vs. 2.5 in younger patients).

| | Age at cladribine initiation | <50 years (n = 435) | ≥50 years (n = 46) |
|---------------------------------|------------------------------|---------------------|--------------------|
| N No further treatment | | 48% | 65% |
| R Retreatment | | 26% | 22% |
| S Switch to another DMT | | 26% | 13% |
| Baseline EDSS, mean ± SD | | 2.6 ± 1.2 | 3.5 ± 1.2 |

Table 2 Subanalysis of cladribine persistence based on age groups

In radio communication, '5 by 5' means signal strength and clarity are both at maximum — we are glad, so is the message from the analyzed data.



CONCLUSIONS

Half of pwMS do not receive additional treatment 5 years after initiating cladribine tablets, despite not being treatment-naïve. Retreatment appears to be a beneficial strategy, effectively restoring disease control with relapse-free rates increasing from 42% to 83%. PwMS aged ≥50 years showed encouraging patterns consistent with suitability for an exit-strategy subgroup, albeit with interpretation limited by small sample size.

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