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A real-world single-centre analysis of the safety and efficacy of cladribine tablets for relapsing multiple sclerosis

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Introduction: Cladribine tablets (CT) are a highly effective immune reconstitution therapy for Relapsing Multiple Sclerosis (RMS). However, real-world data (RWD) on its safety and efficacy, certainly beyond 2 years, remains scarce.
Objectives: To evaluate safety and efficacy outcomes (no evidence of disease activity (NEDA) and its components) from our cohort of Cladribine treated RMS patients at the Rehabilitation and MS Centre (RMSC), Pelt, Belgium.
Aims: To provide novel insights into the use of CT in a diversified real-world setting.
Methods: All RMS patients who received CT between August 2018 and November 2021 were included for retrospective chart review. Patients with data for all three NEDA components (relapse, MRI, and Expanded Disability Status Scale (EDSS)), were incorporated into the efficacy analysis during follow-up. Efficacy endpoints were re-baselined at 3 months. Safety endpoints included grade of lymphopenia, liver transaminases, and adverse events. Descriptive statistics, logistic regression, and time-to-event analysis were performed, including subgroup analysis.
Results: Data from 84 eligible patients, with a mean follow-up of 22.6 ±11.5 (range: 4-43) months was analysed. Eight (9.5%) patients were treatment-naive, while 29 patients (34.5%) received at least one highly active treatment prior to CT. Most patients switched from dimethyl fumarate (21.4%) and fingolimod (19.0%), while disease activity was the most common reason for CT initiation (61.8%). Mild and serious adverse events were reported by 62 (73.8%) and 3 (3.6%) patients. Fatigue and mild infections were the most frequent (61.3% and 46.8%). Concerning the NEDA constituents, 14 (16.7%) patients experienced a relapse during follow-up, while disability progression and brain MRI activity occurred in merely 8.5% (6/71) and 6.3% (5/79) of the patients. This resulted in a cumulative NEDA-status of 86.4%, 72.4%, and 55.6% for patients reaching the 1 year- (n=59), 2 year- (n=29), and 3 year-mark (n=9). Analysis of factors predictive for disease activity after CT treatment initiation is ongoing and will be reported at the ECTRIMS Conference.
Conclusions: In our cohort of RMS patients treated with Cladribine, we observed retainment of NEDA status over 3 years in more than half of the patients following treatment initiation. Treatment with Cladribine was well tolerated and no new safety signals were seen.

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A real-world study of four-year follow up study of patients treated with oral cladribine from 2018-2022

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Background: The administration of oral cladribine reduces relapses and slows accumulation of disability, however it is currently unknown how previous treatment with high efficacy disease modifying therapies (DMTs) may affect expanded disability status scale (EDSS).Real-world outcomes data for cladribine is limited. Real-world data provides safety and effectiveness data that is not provided through randomised controlled trials.
Objective: To explore two-year EDSS change after initiation of oral cladribine and characterise lymphocyte profile and immunoglobulin levels, to evaluate short term safety profiles and the number that need to be retreated in years 3 and 4.
Methods: In a cohort of 180 patients with MS from a single centre in Australia, lymphocyte subsets and IgG levels were measured at baseline, 12,18, 24-month time points after starting therapy with cladribine. EDSS change, and number of patients with relapse and lesion count were also captured at these time intervals. Safety data was reviewed. Patients were clinically reviewed each 6 months and if retreated further laboratory tests were conducted. The impact of COVID19 affected some clinical assessment timing.
Results: Of the total cohort treated with cladribine, 46 patients were naïve to therapy, 12 patients switched to cladribine with a treatment gap of >2 years, and the most common immediate prior DMTs were fingolimod (n=33), B cell therapy (n=38, natalizumab (n=30), and others (n=21). Mean Baseline EDSS was 4, Year 1, 3.9 and year 2 was 4.1. 85% were stable or improved and 15% had a higher EDSS. From baseline to year 2, 79% were stable or improved and 21% had worsened. CD4 cell count fell slightly, while CD8 and CD19 cell counts and IgG count remained stable from baseline, 12-month and 24-month intervals. Relapse rate fell over the 2 years to 11%. Grade 4 lymphopenia occurred in 1% of patients at the 24-month interval. 9 of 131 patients completing year 3 were given a third dose in their third year and 4 of 54 received a third dose in their 4th year.