Real life data of patients with multiple sclerosis treated with cladribine: serum neurofilament light chain dosage in clinical practice (p70)

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Introduction

Cladribine demonstrated sustained treatment benefits over a median follow-up period of 10.9 years (1). Revision of its safety profile confirmed data obtained from the clinical development programme (2). Careful monitoring has to be performed after treatment completion.

Objectives

To describe disease course in our cohort of patients treated with cladribine from August 2018 to March 2025

Methods : retrospective real world study

Patients

Total patients – N (F/M)	145 (86/59)
Lost at follow-up - N	11
Mean age at treatment start - (range)	37.5y (18-58)
Mean disease duration at treatment start (range)	7.5y (0-35)
Follow up duration (months)	26,6 (0-79)
Naive patients- N	54
Previously treated patients – N*	80
1 DMT - N	34
2 DMTs - N	25
3+ DMTs- N	21
Mean EDSS at treatment start (range)	1.4 (0-6.5)
Mean EDSS at the end of follow up (range)	1.3 (0-7)
Patients with disese activity before treatment start- N	102
Relapse only	22
MRI GD+ only	44
Both relapse and MRI GD+	36

*previous treatments were I line DMTs in 79 out of 80 patients

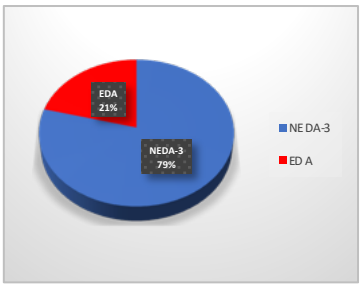
Contrast enhancing brain MRI was performed:
before treatment start, between the I and II course with cladribine, 6 months after the II course, than annually. Clinical evaluation occurred at the same time points.

Serum neurofilament light chain (sNFL) dosage:
in 22 out of 134 patients, longitudinal serum samples were available in our BioBank. In this group of patients, 73 serum samples were selected at:
-T0 (treatment start),
-T1 (at least 6m after T0)
-T2 (mean follow up of 36 months)
sNFL was measured with Simoa Quanterix (3).

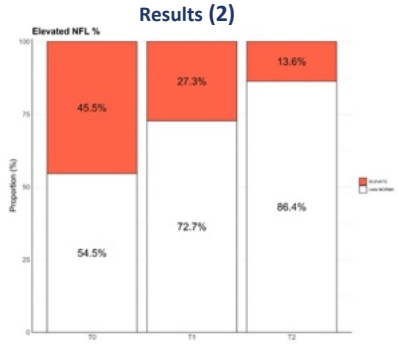
Results (1)

Patients with disease activity after treatment start	
N	**28**
Total N° pts with relapses (between I and II course)	6 (2)
Total N° pts with GD+ MRI (between I and II course)	11 (3)
Total N° pts with both relapses and GD+ MRI (between I and II course)	11 (4)
Switchers	
N	**12**
switch between I and II course N	2
Switch after II course - N	10
Reasons to switch	
Both Relapse and MRI GD+	8
Only MRI GD+	3
Progression	1
Mean time (months) from II course to switch (range)	17 (0-34)
Mean follow-up duration (months) from I course (range)	27 (0-79)
Mean follow-up duration (months) from II course (range)	15 (0 - 67)

NEDA-3 and EDA after Cladribine courses



Results (2)



sNFL value

Time	Normal	Elevated
T0	10/22 (54.5%)	10/22 (45.5%)
T1	16/22 (72.7%)	6/22 (27.3%)
T2	19/22 (86.4%)	3/22 (13.6%)

Prevalence of samples with elevated sNFL was significantly higher at T0 compared to T2 (p-value = 0.03887) and at T1 compared to T2 (p-value = 0.006)

Conclusions:

Cladribine treatment was efficacious and safe. Longitudinal dosage of NFLs is a useful tool in the management of patients.

References

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