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People with multiple sclerosis in their 5th year of treatment with cladribine: Long-term observation of the German MS Register

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Background

Treating people with MS (PwMS) who suffer from a highly active disease course with cladribine (CLAD) is an established strategy described in guidelines. However, real-world data regarding the clinical outcome of long-term therapy with CLAD are scarce.

Objective

We aimed to characterize the 5th (& 6th) year of CLAD treatment in PwMS from Germany regarding disease activity and disability level.

Methods

PwMS in the German MS Registry treated with CLAD without switching to another therapy for a period of ≥4 years of follow-up (FU) were analysed regarding relapse activity (annualized relapse rate [ARR]), disability level (expanded disability status scale [EDSS]) and MRI activity (gd+/new T2 lesions) within their 5th and 6th year, i.e. in the 1st quarter [Y4Q1] and subsequent quarters [Y4Q2/3/4, Y5Q1/2/3].

Results

In GMSR, a group of 90 PwMS were observed in their 5th year after CLAD initiation out of a total of 586 patients who have started CLAD. Of these, 76.7% were female and median age at CLAD start was 43.1 years. The ARR in the 5th year of CLAD therapy was 0.19 (11 relapses in 57.4 person-years of observation time).
MRI coverage and if done MRI activity was low with 12.8% (2/39) active MRIs.

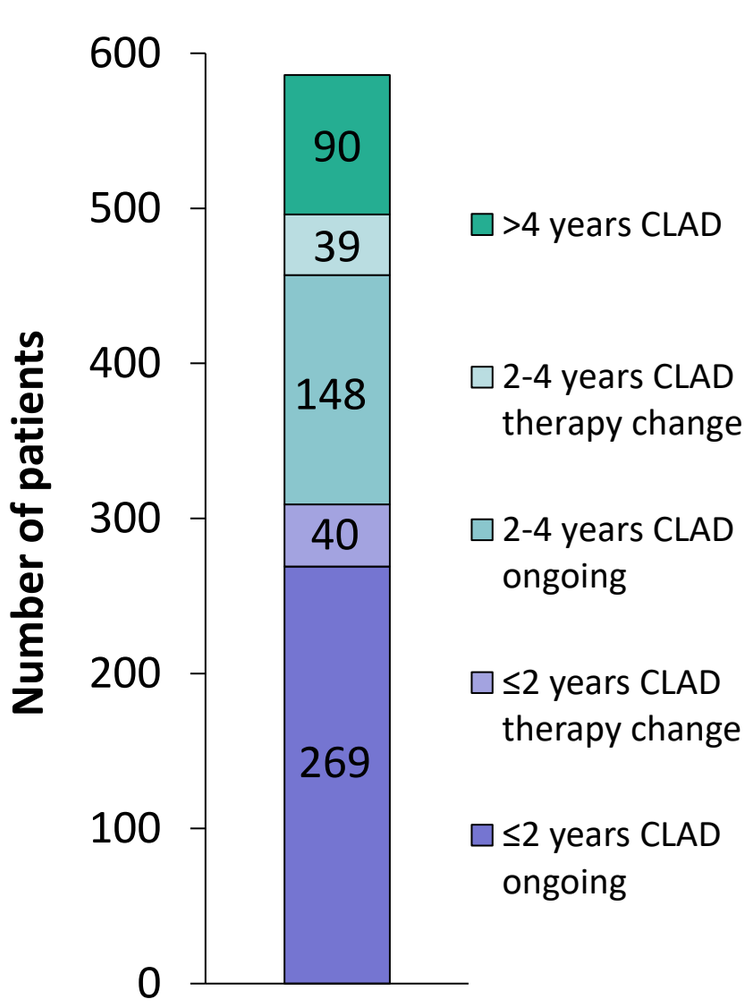

Figure 1. Overview of follow-up of patient treated with cladribine in GMSR (N=586). CLAD – cladribine

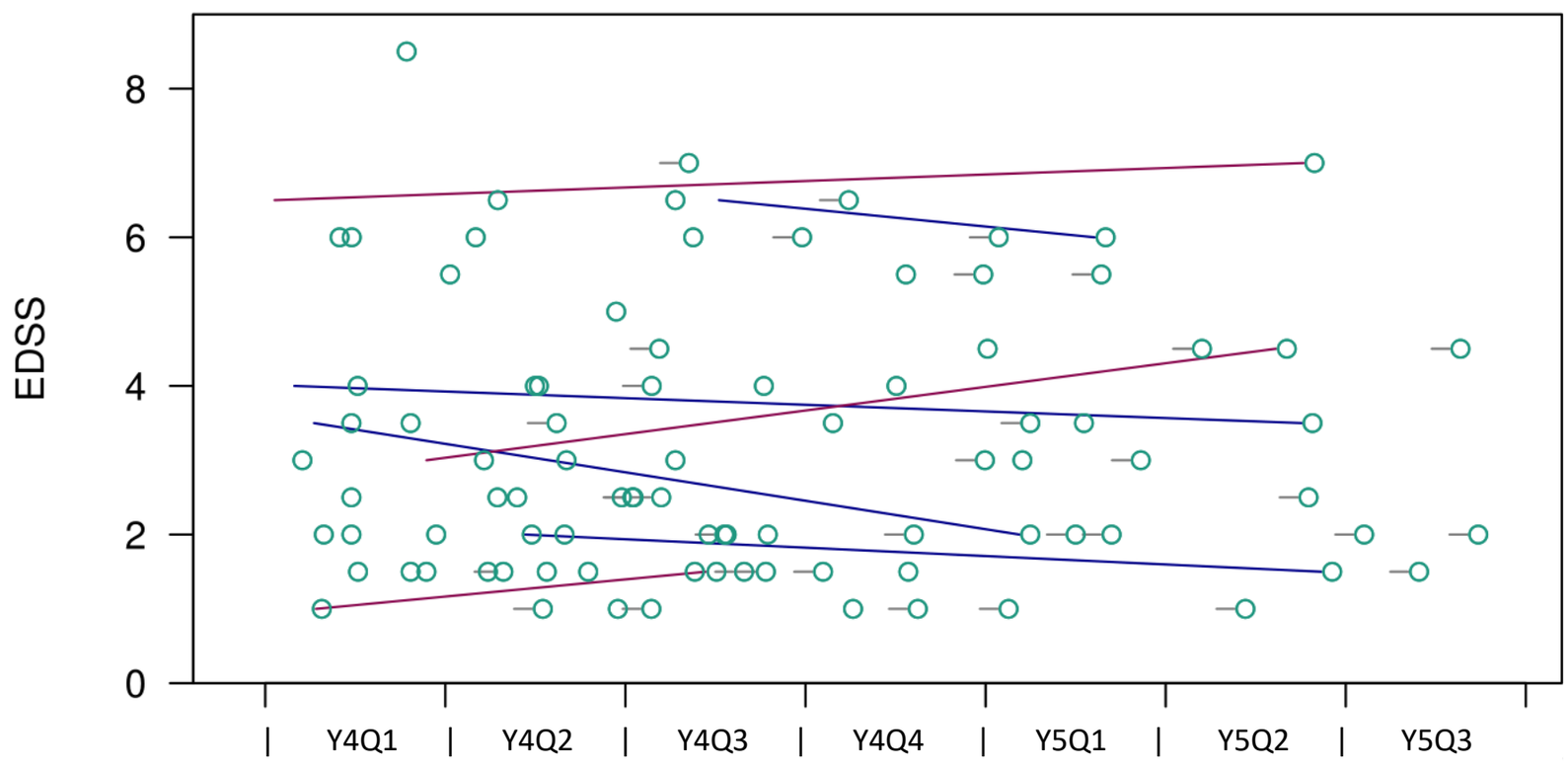

Figure 2. EDSS trajectories of patients treated with cladribine after >4 years of treatment in GMSR (N=90). EDSS assessments at the last visit are given. Changes in EDSS occurring >4 years after CLAD start are given as colored lines (from the first EDSS in Y4 towards last EDSS; increase in purple, decrease in blue; stable EDSS marked by short grey line; singe EDSS as points without trajectories);
1 patient without EDSS assessment; CLAD - cladribine

The median EDSS scores stayed stable over the whole treatment episodes, with 2.5 [N=86] after ≥4 years of CLAD treatment and 2.5 [N=52] at CLAD start.

For patients in whom both EDSS values are recorded, the median change in EDSS was 0.0 [1st,3rd quantiles: -0.5, 0.5]. Within the 5th year, median EDSS scores were stable with 2.5 [N=41] in Y4Q1 and subsequent 2.5 [N=57] in Y4Q2/3.

Table 1. Demographics of CLAD treated patients in GMSR.

	CLAD >4 years (N = 90)	CLAD ≤4 years (N=496)
sex [female, %]	69 (76.7%)	362 (73.0%)
age at CLAD start (y) median/mean(SD)	43.1 / 43.8 (±11.0)	38.8 / 40.8 (±11.9)
age at last visit (y)	47.7 / 48.5 (±11.0)	41.1 / 42.8 (±11.9)
disease duration at last visit (years)	15.5 / 15.8 (±7.0)	10.5 / 12.6 (±9.0)

Declaration of interest: David Ellenberger, Firas Fneish and Melanie Peters had no personal financial interests to disclose other than being employees of the German MS Registry. Niklas Frahm is an employee of the MSFP. Moreover, he is an employee of Rostock's University Medical Center and received travel funds for research meetings from Novartis. None resulted in a conflict of interest. Alexander Stahmann has no personal financial interests to disclose, other than being the leader of the German MS Registry, which receives (project) funding from a range of public and corporate sponsors, recently including G-BA, The German Retirement Insurance, The German MS Trust, German MS Society, Biogen, Bristol Myers Squibb, Merck, Novartis and Roche. None resulted in a conflict of interest. Peter Flachenecker has received speaker's fees and honoraria for advisory boards from Almirall, Bayer, Biogen Idec, BMS-Celgene, Coloplast, Genzyme, GW Pharma, Hexal, Janssen-Cilag, Novartis, Merck, Roche, Sanofi, Stadapharm and Teva. None resulted in a conflict of interest. Tim Friede has received personal fees for consultancies (including data monitoring committees) in the past three years from Bayer, BiosenseWebster, Boehringer Ingelheim, Cardialysis, CSL Behring, DaiichiSankyo, Enanta, Feldmann Patent Attorneys, Fresenius Kabi, Galapagos, IQVIA, Janssen, Mediconomics, Novartis, Penumbra, Roche, SGS, Vifor. None resulted in a conflict of interest. Friedemann Paul has received speaking fees, travel support, honoraria from advisory boards and/or financial support for research activities from Bayer, Novartis, Biogen, Bristol Myers Squibb, Teva, Sanofi-Aventis/Genzyme, Merck Serono, Alexion, Chugai, MedImmune, Shire, German Research Council, Werth Stiftung of the City of Cologne, German Ministry of Education and Research, EU FP7 Framework Program, Arthur Arnstein Foundation Berlin, Guthy Jackson Charitable Foundation and National Multiple Sclerosis of the USA. He serves as academic editor for PLoS ONE and associate editor for Neurology, Neuroimmunology and Neuroinflammation. None resulted in a conflict of interest. Clemens Warnke has received institutional support from Novartis, Alexion, Sanofi Genzyme, Biogen, Merck and Roche. None resulted in a conflict of interest. Uwe K. Zettl has received speaking fees, travel support and /or financial support for research activities from Alexion, Almirall, Bayer, Biogen, Bristol Myers Squibb, Janssen, Merck Serono, Novartis, Octapharma, Roche, Sanofi Genzyme, Teva as well as EU, BMBF, BMWi and DFG. None resulted in a conflict of interest.

Conclusions

- PwMS who are in their 5th and 6th year after CLAD initiation (without any DMD treatment switch <4 years) seem to be stable in regard to EDSS, MRI and relapses.
- Additional data on therapy management in CLAD patients can be found in ePoster **P1565**

References

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