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Real-world experience with ocrelizumab in patients with primary progressive multiple sclerosis: Insights from the German NeuroTransData registry

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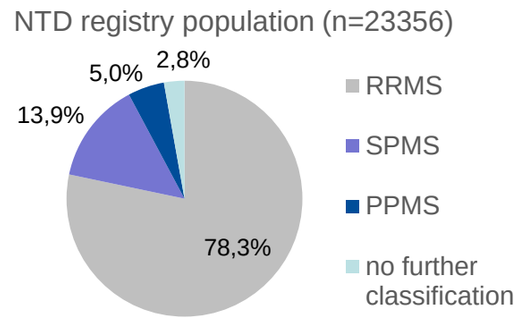
BACKGROUND

- Ocrelizumab (OCR), a monoclonal antibody that selectively targets CD20-expressing B cells, is currently the only approved treatment for patients with primary progressive multiple sclerosis (PPMS).
- To date, real-world data on contemporary German cohorts of patients living with PPMS as well as those receiving OCR for the treatment of PPMS remain limited.
- The NeuroTransData (NTD) MS registry is a database capturing demographic, clinical history, and clinical variables from MS patients in Germany in a real-world setting.



METHODS

- Cross-sectional analysis (MA30143) of German outpatients diagnosed with PPMS according to clinical practice and captured by the NTD MS registry between 01/2016 and 12/2020.
- Patients were divided into two cohorts and baseline characteristics were recorded from the most recent visit prior to index date 01/01/2021 (cohort 1) or within 6 months prior to OCR initiation (cohort 2).
- OCR treatment persistence was estimated for all PPMS patients treated with OCR with at least the initial OCR dose (2x 300mg) and one assessment or discontinuation date after first dosing.

Cohort 1:
PPMS patients not treated with OCR

- ✓ Patients with PPMS diagnosis, and not treated with OCR
- ✓ Visit within two years prior to index date (01/01/2021)
- ✗ Patients ever (any time) treated with OCR

Cohort 2:
PPMS patients treated with OCR

- ✓ Patients with PPMS diagnosis and treated with OCR*
- ✓ Visit within two years prior to initiation of OCR treatment
- ✗ PPMS patients untreated or treated with any DMT other than OCR at data cut-off

*received at least the initial dosing

RESULTS

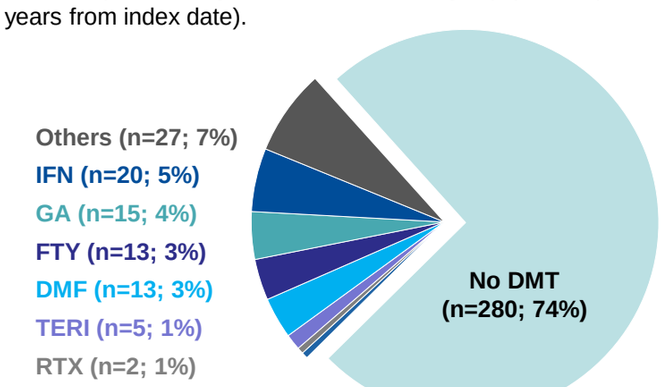
Baseline characteristics of PPMS patients

Characteristics	Cohort 1 Not treated with OCR N=378	Cohort 2 Treated with OCR N=82
Gender, n (%)		
Female	235 (62.2)	43 (52.4)
Age, mean (SD), years		
At MS disease onset	43.6 (12.0)	42.8 (10.6)
At PPMS diagnosis	55.0 (11.0)	49.3 (9.6)
At index date*	**62.3 (11.4)**	**51.5 (10.0)**
Disease duration up to index date*, mean (SD), years		
Since symptom onset	**18.7 (11.0)**	**8.7 (7.8)**
Since diagnosis	7.3 (5.0)	2.2 (3.7)
EDSS score (last assessment ≤2yrs index date*), mean (SD)	**5.0 (2.1)**	**4.4 (1.8)**
Time from last EDSS assessment to index date, mean (SD), months	**9.4 (6.8)**	**2.2 (4.1)**
MRI Lesion count >8, n (%)	48/61 (78.7)	34/46 (73.9)
Mean time from last MRI to index date (months)	13.79 (6.9)	5.47 (5.7)
Prior MS subtype diagnosis during course of documentation, n (%)		
RRMS	49 (13.0)	11 (13.4)
SPMS	5 (1.3)	1 (1.2)
History of previous DMTs any time prior to index date*, n (%)		
Treatment naive	280 (74.1)	58 (70.7)
1	60 (15.9)	17 (20.7)
≥2	38 (10.0)	7 (8.5)

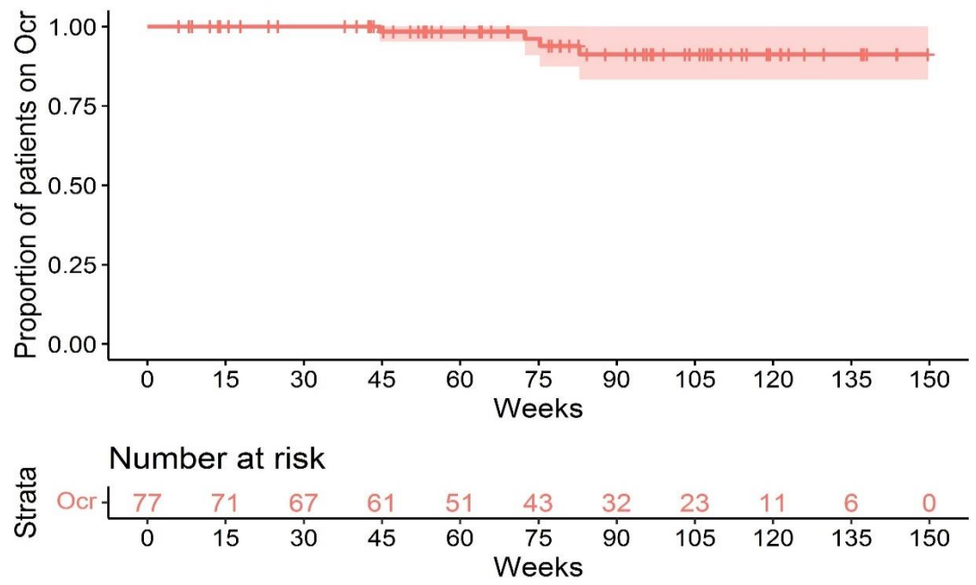
*Index date: cut-off date January 2021 (cohort 1) or initiation date of OCR therapy (cohort 2). Patient numbers for analysis (n=460) were comparatively low vs the number of PPMS patients registered in the NTD registry (n=1168) due to inclusion criteria for analysis (last patient visit within 2 years from index date).

Cohort 1: Disease modifying therapy in patients not treated with OCR (n=378)

DMF, dimethyl fumarate; DMT, disease modifying therapy; FTY, fingolimod; GA, glatiramer acetate; IFN, interferon; TERI, teriflunomide; NAT, natalizumab; RTX, rituximab



Cohort 2: Persistence rate* in PPMS patients treated with OCR



*Persistence was examined as a function of time free from event (discontinuation).

- In cohort 2, the mean exposure time to OCR was 1.50 years (SD 0.73, minimum 0.1, maximum 2.9).
- Mean EDSS in the 2nd year of OCR treatment was 4.3 (median 4, SD 1.9).
  - 80.4% of patients showed unchanged, 13.0% deteriorated and 6.5% improved EDSS vs their baseline
- The KM estimate of OCR treatment persistence at 12 and 24 months was 98.4% and 91.2%, respectively.
- According to the recommended administration schedule the median time interval between single doses ranged between 5.8 - 6.3 months.

KEY FINDINGS / CONCLUSIONS

This study provides first insights into the German NTD real-world cohort of PPMS patients and clinical experience with OCR treatment.

- The unmet medical need remains high in PPMS patients as most are largely untreated.
- Diagnosis of PPMS seems to be established at higher age and with longer disease duration than in RRMS.[1]
- PPMS patients treated with OCR vs PPMS patients not treated with OCR showed younger age, shorter time from first PPMS symptoms and similar EDSS levels.
- The majority of patients showed an unchanged EDSS in the second year of treatment.
- Critical factors for achieving therapeutic goals were met with low discontinuation rate over the first 24 months of OCR treatment and drug administration adherent to recommended interval.
- To further expand real-world experience of OCR therapy on disability outcomes longer observation times are needed.

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Reference: 1. Weih et al. Fortschr Neurol Psychiatr 2020; 88:379-385.