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

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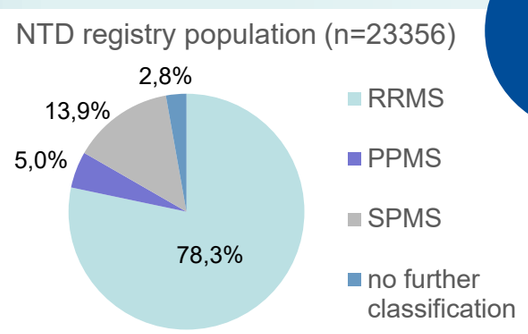
BACKGROUND

- 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 and PATIENTS

- Cross-sectional data analysis of real world data of German outpatients with PPMS captured by the NTD MS registry between 18/01/2016 and 01/01/2021 as diagnosed by a neurologist following clinical practices and guidelines. According to the protocol, patients with a visit within two years prior to 01/01/2021 (cohort 1) or OCR initiation (cohort 2) were included.
- Baseline characteristics were recorded from the most recent visit prior to 01/01/2021 (cohort 1) or OCR initiation (cohort 2).
- Analysis of OCR experience in patients on OCR therapy in their second year of therapy

Cohort 1:
PPMS patients not treated with OCR

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

Cohort 2:
OCR-treated PPMS patients

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

*received at least the initial dosing

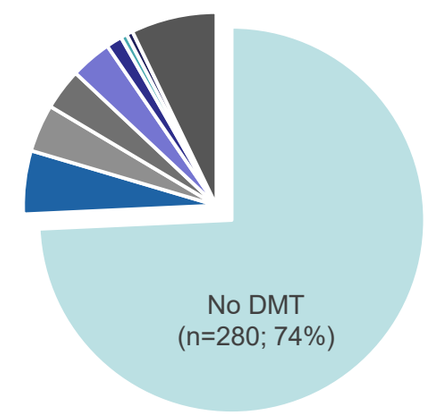
RESULTS

NTD registry: Baseline characteristics of 460 PPMS patients

Characteristics	Cohort 1 Not treated with OCR N=378	Cohort 2 OCR-treated 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)

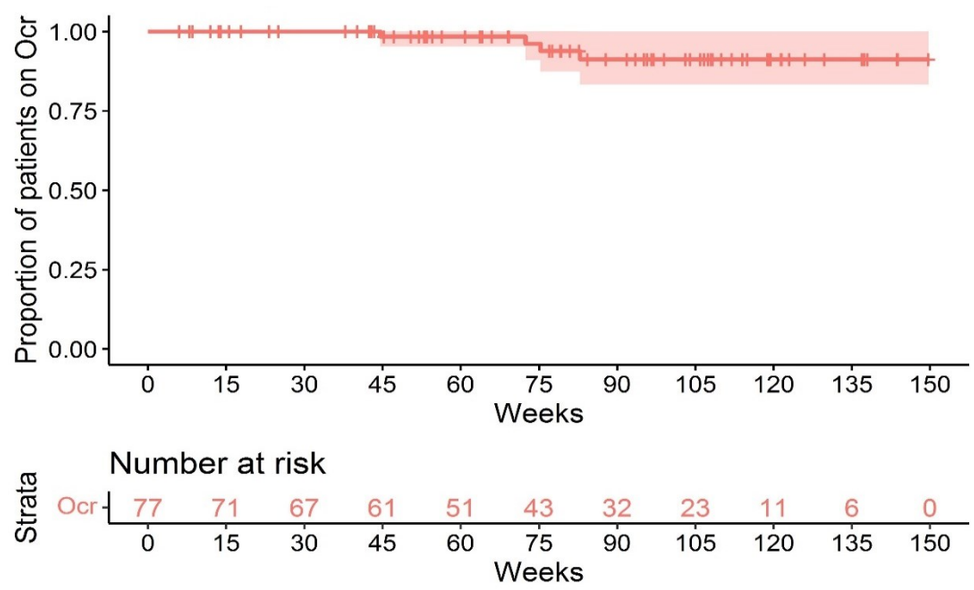
*Index date: cut-off date January 2021 (cohort 1) or initiation date of OCR therapy (cohort 2). Patient numbers for analysis (n=460) were comparatively low vs the number of PPMS patients registered in the NTD registry (n=1168) due to inclusion criteria for analysis (last patient visit within 2 years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

Ongoing therapy at index date in PPMS 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

Persistence rate* in OCR-treated PPMS patients



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

- The mean exposure time to OCR captured was 1.50 years (SD 0.73, minimum 0.1, maximum 2.9) for the overall OCR population.
- Mean EDSS in the 2nd year of OCR treatment was 4.3 (median 4, SD 1.9). 80.4% of patients showed unchanged EDSS in the 2nd year of treatment (with a mean observation time of 1.5 years), 13.0% deteriorated and 6.5% improved vs their baseline (baseline collected between 6 months before and time of treatment initiation).
- Persistence rate at 12 and 24 months was calculated to be 98.7% (76/77) and 94.8% (73/77), respectively.
- Median time interval between infusions 2 to 8 ranged between 5.8 and 6.3 months, adherent to recommended administration schedule.

KEY FINDINGS / CONCLUSIONS

We provide first insights into a German real-world cohort of PPMS patients and clinical OCR experience

Baseline characteristics of PPMS patients

- Diagnosis of PPMS seems to be established at higher age and with longer disease duration than in RRMS
- Younger age, shorter time from first PPMS symptoms and similar EDSS levels in PPMS patients treated with OCR vs those not receiving OCR
- Very similar mean EDSS at initiation of OCR therapy (4.4 +/- 1.8) compared to the population of the ocrelizumab phase III trial ORATORIO (4.7 +/- 1.2)

OCR treatment: Real-world experience

- 80.4% of patients showed unchanged EDSS in the second year of treatment (with a mean observation time of 1.5 years), 13.0% deteriorated and 6.5% improved vs baseline.
- High persistence rate and adherence over the first 24 months of OCR treatment as critical factors for achieving therapeutic goals
- Need for longer observation times to further expand real-world experience of OCR therapy on disability outcomes.

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