Characterization of patient and treatment characteristics in SPMS and at risk for SPMS patients in clinical routine: The PANGAEA 2.0 EVOLUTION study

EP1198

C. Baufeld[1], V. E. Winkelmann[1], T. Ziemssen[2]

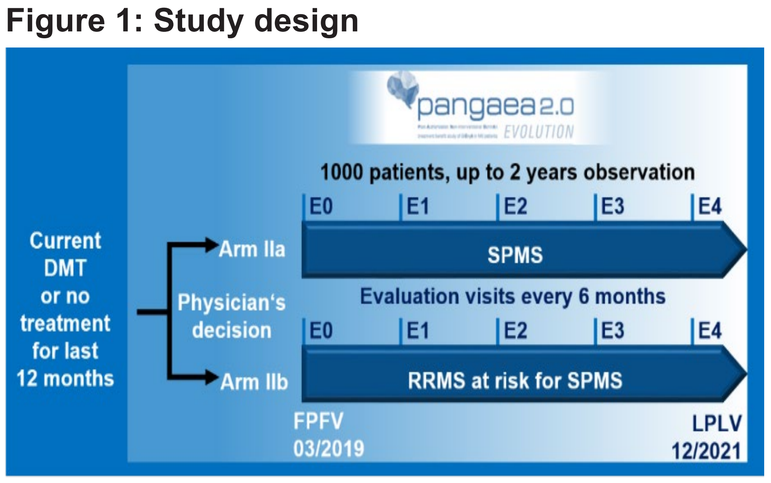
[1]Novartis Pharma GmbH, Nuremberg, Germany, [2]Zentrum für klinische Neurowissenschaften, Universitätsklinikum Carl Gustav Carus, Dresden, Germany

Introduction

Background

- 85% of MS patients are diagnosed with relapsing remitting multiple sclerosis (RRMS)[1] and 60% will convert to secondary progressive multiple sclerosis (SPMS) within 20 years due to evolvement of the disease over time[2,3].
- Inconsistent criteria to define the transition from RRMS to SPMS and previous lack of treatment options led to late and mostly retrospective diagnosis of SPMS[4,5].
- The PANGAEA 2.0 study is a post-authorization, non-interventional study in MS patients. The study aims to better understand the disease progression of MS and especially the conversion from RRMS to SPMS with the goal to develop new diagnostic tools. A new study arm was added to PANGAEA 2.0, termed PANGAEA 2.0 EVOLUTION focusing on RRMS-patients with high-risk for SPMS and SPMS patients (**Figure 1**).

Figure 1: Study design



Objective

- The aim of the PANGAEA 2.0 EVOLUTION study is to evaluate and compare clinical parameters and patient reported outcomes of patients with RRMS at high risk to develop SPMS with SPMS patients in order to characterize the transition between these two stages of MS.

Methods

- In the prospective non-interventional study PANGAEA 2.0 EVOLUTION approximately 600 patients with either SPMS or RRMS at high risk for SPMS are followed independently of treatment for up to 2 years.
- As there are no standard criteria for the transition state from RRMS to SPMS, physicians independently assign patients to the 'high risk for SPMS' cohort after a comprehensive evaluation of the patient's symptoms according to their daily practice.
- At 6-month intervals routine clinical measurements are documented.

Results

- 609 patients of PANGAEA 2.0 Evolution (187 SPMS, 422 at high risk for SPMS) satisfied all eligibility criteria and were included in this analysis.

Demography and baseline characteristics

- Demography and baseline characteristics are depicted in **Table 1**.

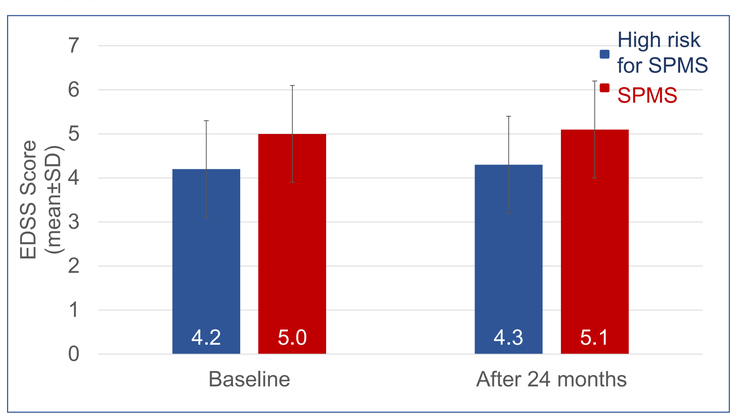
Table 1: Baseline characteristics

Variable	High-risk for SPMS	SPMS
Number of patients; n	422	187
Age; years [mean±SD]	49.5±9	53.7±7.1
Female[n (%)]	301 (71.3)	141 (75.4)
Disease and treatment history		
Time since MS diagnosis; years [mean±SD	14±8	17.2±9.5
Relapses within last 24 months prior to study inclusion; n [mean±SD]	0.46±0.89	0.3±0.69
Number of pretreatments; n [mean±SD]	2.4±1.4	2.2±1.5
Last treatment at inclusion; [%]	[%]	[%]
No treatment at inclusion (total)	**5.7**	**34.6**
Gilenya	22.0	9.0
Tecfidera	10.6	4.8
Ocrevus	6.6	8.5
Tysabri	6.6	3.7
Copaxone	6.6	3.2
Aubagio	6.6	1.1
Betaferon	2.4	4.3
IFNBeta1ASC	1.7	5.3
Lemtrada	3.8	0.0
Avonex	2.1	1.6
Cladribine	2.6	0.0
Rituximab	0.0	4.8
Extavia	0.9	2.1
Plegridy	1.4	0.5
Azathioprin	0.2	2.1
Mitoxandrom	0.5	0.5
IFNBeta1AIM	0.2	0.0
Cannot be identified / unknown / other	19.3	13.8

Disability

- At baseline, SPMS patients from PANGAEA 2.0 EVOLUTION showed an EDSS score higher than patients with high risk for SPMS. These difference remained unchanged after 24 month (**Figure 2**).

Figure 2: Assessment of disease burden by EDSS



Cognition and fatigue

- SPMS patients showed more pronounced fatigue (assessed by FSMC motor fatigue) and a stronger impairment of cognition (lower SDMT values) compared to patients with high risk for SPMS **(Figure 3 & Figure 4**).

Figure 3: Assessment of cognition by SDMT

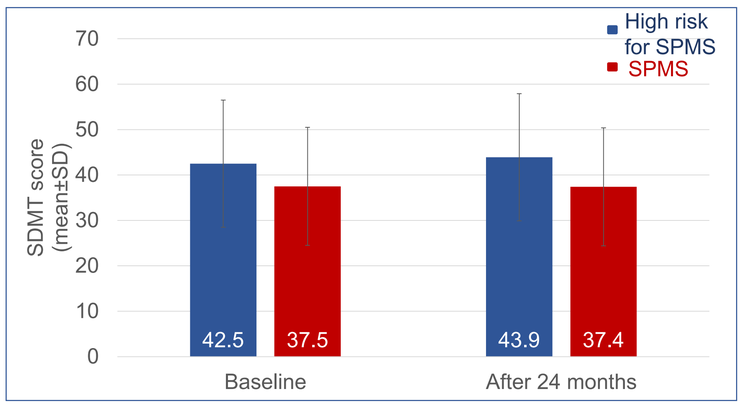
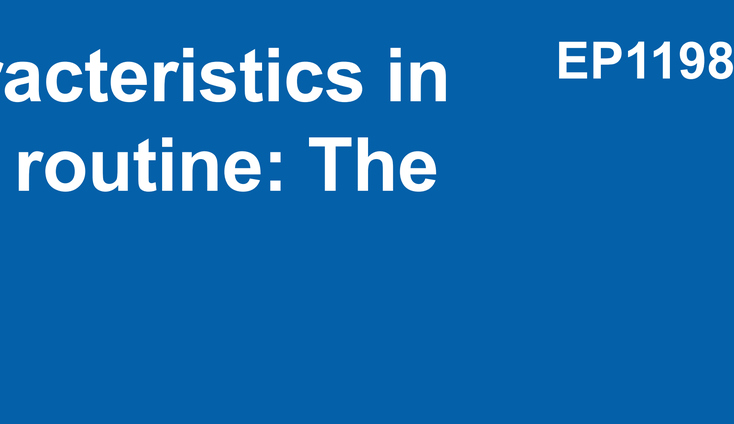


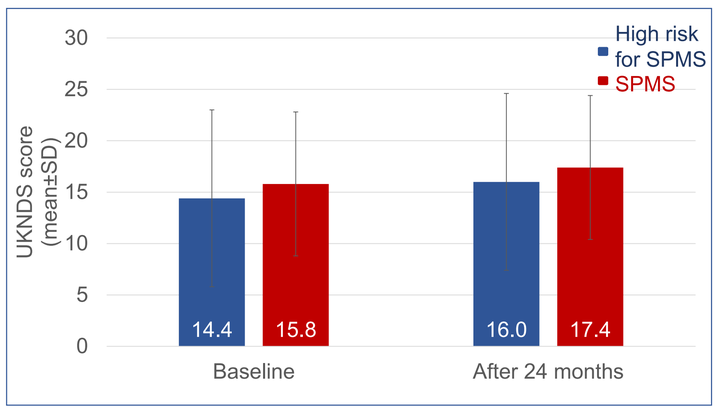
Figure 4: Assessment of MS-related fatigue by FSMC



Patients' disability assessment

- UKNDS indicates SPMS patients having higher disease burden (**Figure 5**).

Figure 5: Assessment of disability by UKNDS



Conclusion

- PANGAEA 2.0 EVOLUTION allows comparing SPMS patient profiles to RRMS patients at risk for SPMS in a real world, yet well-structured setting. Combining clinical and non-clinical parameters for a patient profile over 24 month may help to establish standard early diagnosis criteria and therapy of SPMS patients.
- The differences in disease burden, disability, cognition and MS-related fatigue remained stable between the two cohorts over 24 month.

References

1. Rio J, et el. 2011; Curr Opin Neurol. 24(3), 230-237. | 2. Tremlett H, et al. Mult Scler. 2008;14:314–24 | 3. Scalfari A, et al. J Neurol Neurosurg Psychiatry. 2014;85:67–75 | 4. Lublin FC, et al. Neurology. 2014 | 5. Shirani A, et al. Neurotherapeutics. 2016; 13(1): 58–69 | 6. Ziemssen T, et al. Poster P2.156 presented at AAN 2016 | 7. Simsek D, et al. Poster P241 presented at ECTRIMS 2015 | 8. Piani-Meier D, et al. Poster EP1401 presented at ECTRIMS 2017 | 9. Tolley C, et al. JMIR Med Inform. 2020;8(4):e17592 | 10. Ziemssen T, et al. J Med Internet Res. 2020;22(2):e16932 | 11. Ziemssen T, et al. Mult Scler Relat Disord. 2020;38:101861

Disclosures

V.E. Winkelmann and **C. Baufeld** are employees of the Novartis Pharma GmbH, Nuremberg, Germany.
T. Ziemssen has received personal compensation for participating on advisory boards, trial steering committees and data and safety monitoring committees, as well as for scientific talks and project support from: Almirall, Bayer, BAT, Biogen, Celgene, Sanofi Genzyme, Merck, Novartis, Roche, Vitaccess, and Teva.

This study is financed by Novartis Pharma GmbH, Nuremberg, Germany.

Poster presented at 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, October 26-29, 2022, Amsterdam (Netherlands).

Scan this QR code to download a copy Poster